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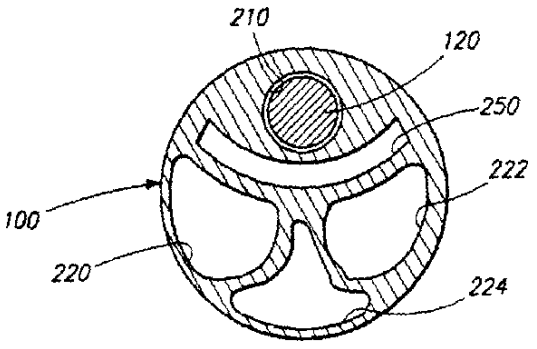
(54)【発明の名称】患者の体温を測定するためのデバイスおよび方法

(57)【要約】
カテーテルもしくは導入器のようなアクセスデバイス、または上記の任意の組み合わせが提供される。アクセスデバイスの内部は、注入流体のような、熱的に活性な塊を輸送するかまたはそれ自体である、少なくとも１つの管腔、チャネルまたは器具、制御ワイヤーなどである。サーミスタのような温度センサーは、患者の温度媒体（代表的には、血液）の温度を測定するために、アクセスデバイスに確保される。種々の断熱管腔、断熱部材ならびに取りつけおよび押出しの構成は、温度センサーを熱塊から熱的に断熱するように、本発明によって提供され、さもなければ、温度測定の精度を低下し得る。本発明はまた、温度センサーが、患者の温度表示のための外部モニターに接続される、配置を提供する。



【特許請求の範囲】
【請求項１】
患者の温度媒体の温度を測定するためのデバイスであって、該デバイスは、以下：
該温度媒体の位置において該患者内に挿入可能なアクセスデバイスであって、該アクセスデバイスは、該温度媒体以外に熱塊を有する、少なくとも１つの熱管腔を備える複数の管腔を有する、アクセスデバイス；
該アクセスデバイスによって支持される温度センサー；および、
該温度センサーの近くであり、かつ該温度センサーと該複数の管腔との間の位置に延び、該熱塊から該温度センサーを熱的に隔離する、少なくとも１つの断熱ギャップ、
を備える、デバイス。
【請求項２】
前記温度センサーが、前記アクセスデバイスの外壁におけるくぼみ内に位置する、請求項１に記載のデバイス。
【請求項３】
前記温度センサーが、前記アクセスデバイスの外表面に外面的に位置する、請求項１に記載のデバイス。
【請求項４】
前記温度センサーが、前記アクセスデバイスのセンサー管腔内に位置する、請求項１に記載のデバイス。
【請求項５】
前記温度センサーが、キャリアに取り付けられる、請求項１に記載のデバイス。
【請求項６】
請求項５に記載のデバイスであって、該デバイス内において、前記断熱ギャップは前記キャリア内の障壁として形成され、そして該キャリアは、前記温度センサーと前記熱管腔との間に該障壁を延ばして、前記アクセスデバイスの管腔のうちの１つに保有される、デバイス。
【請求項７】
前記キャリアが、前記アクセスデバイスの管腔に取り外し可能に挿入できる、請求項６に記載のデバイス。
【請求項８】
前記キャリアが、前記アクセスデバイスの管腔に取り外し可能に挿入できる、請求項５に記載のデバイス。
【請求項９】
前記断熱ギャップが、前記アクセスデバイス長の少なくとも一部分に沿って延びる、一般的に細長いスリットを備える、請求項１に記載のデバイス。
【請求項１０】
請求項１に記載のデバイスであって、該デバイスが、以下：
前記アクセスデバイスの外壁に形成される１対のポート；
該アクセスデバイス内に形成され、そして該１対のポートの間に延びる流動チャネルであって、ここで、前記温度媒体が、該流動チャネルを占有する流動チャネルをさらに備え；
そして、
該流動チャネルが、前記温度センサーと前記熱管腔との間に位置し、それによって、該流動チャネルが、該温度センサーと該温度媒体との間の熱的接触を増加して、そしてまた、該温度センサーをさらに該熱管腔から熱的に単離する、デバイス。
【請求項１１】
前記流動チャネルが、前記断熱ギャップである、請求項１０に記載のデバイス。
【請求項１２】
前記流動チャネルが、前記断熱ギャップと前記熱管腔との間に位置する、請求項１０に記載のデバイス。
【請求項１３】

請求項１に記載のデバイスであって、該デバイスにおいて：
前記アクセスデバイスが、外壁において開口部を有し；そして、
展開された位置における場合、前記温度センサーが、該開口部内に延び、それによって、該温度センサーと前記温度媒体との間の熱的接触を増加し、そして、該温度センサーを前記熱塊からさらに断熱する、デバイス。
【請求項１４】
請求項１３に記載のデバイスであって、該デバイスにおいて：
前記温度センサーが、キャリアに取り付けられ；
該キャリアの端が、前記アクセスデバイス内部に固定され；そして、
該キャリアが、該温度センサーと各熱管腔との間に位置し、それによって、前記断熱ギャップを形成する、デバイス。
【請求項１５】
前記温度センサーが、前記アクセスデバイスの中心軸に対して主に垂直な開口部から延びるように取りつけられた直角サーミスタである、請求項１３に記載のデバイス。
【請求項１６】
前記温度センサーが、ポッティング化合物によって前記アクセスデバイスに装着される、請求項１に記載のデバイス。
【請求項１７】
請求項１に記載のデバイスであって、該デバイスにおいて、前記温度センサーは粘着して装着され、そしてこの粘着剤は体温で溶解し、それによって、前記患者内の適切な位置における場合、該温度センサーは前記温度媒体との接触を増加させる、デバイス。
【請求項１８】
前記断熱ギャップが、前記アクセスデバイス内に形成され、そして前記温度センサーと前記熱塊との間に延びる、少なくとも１つの内部断熱管腔を備える、請求項１６に記載のデバイス。
【請求項１９】
請求項１３に記載のデバイスであって、ここで：
前記温度センサーは、前記アクセスデバイスの外壁において、前記開口部を通って出る環として突出するキャリア内に取り付けられ、そして該キャリアの端部は、該アクセスデバイス内部に固定され；
前記断熱ギャップは、該開口部の位置において、該キャリアと該アクセスデバイスとの間、従って、該温度センサーと該熱塊との間に形成される前記温度媒体のための流動チャネルを備え；そして、
該温度センサーは、該キャリアのみを介して、該温度センサーの実質的に全外周を越えて該温度媒体に露出される、デバイス。
【請求項２０】
請求項１に記載のデバイスであって、ここで：
前記温度センサーは、断熱部材における凹部に取り付けられ；そして、
該断熱部材は、該温度センサーと共に、前記アクセスデバイスの１つの管腔内に取り付けられ、その結果、該断熱部材は、該温度センサーと前記熱管腔との間に延びる、デバイス。
【請求項２１】
前記断熱ギャップが、前記アクセスデバイスと共押出しされ、そして各熱管腔の少なくとも一部分を取り囲む、断熱物質を備える、請求項１に記載のデバイス。
【請求項２２】
前記断熱ギャップが、前記アクセスデバイスと共押出しされ、そして前記温度センサーを取り囲む、断熱物質を備える、請求項１に記載のデバイス。
【請求項２３】
請求項１に記載のデバイスであって、ここで：
前記アクセスデバイスは、管腔およびセンサーポートを有し；そして、

前記温度センサーは、該アクセスデバイスの管腔内に挿入可能なプローブの遠位先端部に取り付けられ、その結果、該温度センサーは該センサーポートを介して延びる、デバイス。

【請求項２４】

請求項１に記載のデバイスであって、ここで：

前記断熱ギャップは、分離部材として断熱物質から形成された前記アクセスデバイスの遠位先端部を備え；そして、

前記温度センサーは、該遠位先端部の内部に取り付けられる、デバイス。

【請求項２５】

請求項１に記載のデバイスであって、ここで：

前記アクセスデバイスは、長さ方向に延びるスリットを有する遠位先端部を有し；

前記温度センサーは、該遠位先端部の第一側面に取り付けられ；

前記熱塊を運ぶ少なくとも１つの熱管腔は、該遠位先端部の第二側面を介して延び；そして、

一旦配置された位置において、該遠位先端部は、該スリットに沿って分離され、ここで該先端部の第一および第二側面は、該スリットのいずれかの側面に配置されている、デバイス。

【請求項２６】

請求項１に記載のデバイスであって、ここで：

前記アクセスデバイスは、複数の管腔を含む中心静脈カテーテルであり；

前記温度媒体は、血液であり；

前記熱塊は、該管腔の１つの内部を運ばれる注入流体であり；そして、

前記温度センサーは、サーミスタである、デバイス。

【請求項２７】

前記断熱ギャップが、該温度センサーと該熱塊との間の距離を増加するように拡張可能である、請求項１に記載のデバイス。

【請求項２８】

前記断熱ギャップが、前記温度センサーを取り囲むように形成される、請求項１に記載のデバイス。

【請求項２９】

２つの断熱ギャップを備える、請求項２に記載のデバイス。

【請求項３０】

前記アクセスデバイスが、外壁を有し、該外壁が開口部を有し、かつ前記温度センサーが該開口部に位置している、請求項１に記載のデバイス。

【請求項３１】

前記外壁の開口部内に温度センサーを固定するポッティング化合物をさらに備える、請求項３０に記載のデバイス。

【請求項３２】

患者の温度媒体の温度を測定するデバイスであって、該デバイスは、以下：

該温度媒体の位置において、該患者内に挿入可能なアクセスデバイスであって、該アクセスデバイスは、該温度媒体以外に、少なくとも１つの熱塊を備え、このような少なくとも１つの熱塊は、該アクセスデバイスの熱管腔内に配置される、アクセスデバイス；

該アクセスデバイスの外壁において形成される１対のポート；

該アクセスデバイスによって支持される温度センサー；および、

該熱塊から温度センサーを断熱する断熱構造体、

を備えるデバイスであって、

ここで、該断熱構造体は、該アクセスデバイス内に形成され、かつ該１対ポートの間に延びる流動チャネルを備え、この結果、該温度媒体は、該流動チャネルを占有し、該流動チャネルは、該温度センサーと該熱管腔との間に位置し、それによって該流動チャネルは、該温度センサーと該温度媒体との間の熱的接触を増加し、そしてまた該温度センサーをさ

らに該熱管腔から熱的に単離する、デバイス。
【請求項３３】
患者の温度媒体の温度を測定するデバイスであって、該デバイスは、以下：
本体容器内に適合するようなサイズに作られた、押し出された細長アクセスデバイス本体であって、該アクセスデバイス本体は、近位端および遠位端、外壁ならびに該近位端と該遠位端との間の該デバイス本体において予め決定された位置に熱塊を備える、アクセスデバイス本体；
該デバイス本体の予め決定された位置に配置された温度センサー；および、
該デバイス本体とは異なる物質の断熱構造体であって、かつ該温度センサーと該熱塊との間に延びる該デバイス本体と共押出しされる、断熱構造体、
を備える、デバイス。
【請求項３４】
前記断熱構造体が、前記温度センサーを取り囲む、請求項３３に記載のデバイス。
【請求項３５】
前記断熱構造体が、前記デバイス本体の少なくとも一部分に沿った前記温度センサーを取り囲む管を形成する、請求項３４に記載のデバイス。
【請求項３６】
前記熱塊が、前記デバイス本体において形成された管腔内に流体を含み、ここで、前記断熱構造体が、該管腔を取り囲む、請求項３３に記載のデバイス。
【発明の詳細な説明】
【０００１】
（発明の分野）
本発明は、患者内におけるアクセスデバイス（例えば、カテーテルまたは導入器）の位置に関連して、患者の体温を測定するための方法およびデバイスに関する。
【０００２】
（関連分野の概要）
患者を適切に処置し、かつ患者の生理学的状態についてできる限りたくさんの情報を得る必要は、しばしば、できる限り患者の不快感を減らす要望に相反する。例えば、頻繁に必要なことは、種々の薬剤を患者に送達し、そしてまた患者の体温をモニターすることである。従って、カテーテルをしばしば患者の血管系に挿入して、種々の薬剤、水和した流体などの送達を可能にし、そして血圧を測定する。しかし、患者の体温は、別々に挿入される分離デバイスでモニターされる。
【０００３】
温度を測定する慣習的なデバイスとしては、周知の腔体温計、直腸体温計、腋窩（ａｘｉｌｌａｒｙ）（ａｒｍｐｉｔ）温度計および鼓膜（耳）体温計およびプローブ、ならびにフォーリーカテーテル（膀胱温度）および鼻咽頭プローブ（食道）プローブが挙げられる。これらのデバイスの各々は、１つ以上の欠陥を有する。第一に不都合なことは、患者になったことがある人になら誰にでも明らかである：直腸、膀胱、耳もしくは鼻の内部に、または喉に沿って分離デバイスもまた挿入されなければならないことを除いても、静脈または動脈にカテーテルが挿入されていることはあまり心地よくはない。
【０００４】
第二に不都合なことは、精度に関係する。わきの下または口内に体温計を入れることで患者の温度を測ることは、患者にほとんど不快感を与えないが、これが与えるこの温度値は、通常は正確さが低く、そして主要な血中の血液の温度測定よりも、位置により依存する。
【０００５】
これらの不都合を克服する１つの方法としては、挿入されるカテーテルそれ自体の内部での温度センサーのいくつかの形態が挙げられる。これによって血液温度の測定は可能となり、この血液温度は、ほとんどの場合において、患者の実際の身体芯の温度に近い。次いで、問題は、このカテーテルシステムの他の要素が、それら自体がセンサーの検出する温

度に影響を与える熱的特性を有し得ることに起因する。この問題は、心臓の流量を測定するための熱希釈システムに関連して生じる。例えば、米国特許第４，８１７，６２４号（Ｎｅｗｂｏｗｅｒ、１９８９年４月４日）、米国特許第５，１７６，１４４号（Ｙｏｓｈｉｋｏｓｈｉ、１９９３年１月５日）および公開欧州特許出願０３５７３３４Ｂ１（発明者：Ｗｉｌｌｉａｍｓら、１９９０年３月７日）は、このようなシステムを記載する。周知なように、このような熱希釈システムにおいて、心臓の血流温度は、通常は相対的により冷たい流体か、または温かい流体のいずれかの一連のボーラスである指示薬の注射によって引き起こされる、予め決定された形態によって調節される。温度調節に対する下流の応答は、サーミスタによって検出され、そして血流を算出し、かつ評価するために使用される。

【０００６】

Ｎｅｗｂｏｗｅｒのようなシステムにおいて、温度調節は、血液よりも冷たい熱的によく制御された流体の正確な用量のボーラスを介して、血液を冷却することによって達成される。Ｗｉｌｌｉａｍｓにおいて、調節された血液の冷却は、血流中へのいかなるボーラスの実際の注射をも必要としない、熱交換機構を用いて達成される。Ｙｏｓｈｉｋｏｓｈｉのようなシステムにおいて、血液は、代わりに心臓カテーテルの遠位（ｆａｒ（ｄｉｓｔａｌ））端の近くに取り付けられた加熱要素を用いて、局所的に温められる。以前のように、サーミスタが下流応答プロフィールを検出し、それらの特性は心臓の流量を算出するために使用される。

【０００７】

このような熱希釈システムは、これらのシステムが本出願の特異的ないくつかの問題を処理しなければならないので、特定の臨床的な制限を有する。１つ目は、逆流の問題である：このサーミスタが、加熱器またはボーラス注射ポートの近位に位置する場合、加熱／冷却血液はカテーテル先端部から逆流する。この時、このカテーテル（種々の他の管腔、注射器、制御ワイヤーなどを含み得る）自体の温度は、熱的に調節された血液の温度プロフィールに影響を与え得、そして流量計算の程度を下げ得る。

【０００８】

この影響を克服するために、この注射は、新たな定常状態ベースラインを得るために、指示薬の連続的な注入によって交換されるが、これは患者にロードする容量に起因する望ましくない臨床的制限である。このサーミスタが、相対的に加熱器／ボーラスポートの遠位に位置する場合でさえ、この問題はなお生じ得る。

【０００９】

これらの熱希釈システムのカテーテルは、通常は、サーミスタまたは温度センサーの下を通過し、かつカテーテルの先端部において出る、遠位注入管腔を有する。このような注入管腔における流量が、温度センサー測定正確さの程度をひどく下げるので、この流量は、血流測定がなお正確であるために最大値まで制限される。もちろん、このような注入管腔流量に対する制限はまた、臨床的展望からは望まれていない。

【００１０】

断熱の類似した問題は、米国特許第５，６８８，２６６号（Ｅｄｗａｒｄｓら、１９９７年１１月１８日）に記載されるカテーテルに基づく心臓剥離システムのような、他の心臓デバイスにおいて同様に生じる。Ｅｄｗａｒｄｓのシステムにおいて、熱を用いて局所的に組織を殺すために剥離電極が使用され、そして１つ以上の温度を感知する要素は、剥離されるべき組織の温度を感知するために使用され、そして剥離温度および時間の正確な制御を可能にする。従って、物理的分離によって主に提供される単離は、電極と温度センサーとの間で要求される；さもなければ、このセンサーは高すぎる読み込みを与える傾向がある。

【００１１】

少なくとも１つの因子は、患者の体温を測定するための一般的な使用において、これらの公知なシステムの使用を制限する：これらのシステムは、患者の実際の、自然な体温を測定するようには全く準備されておらず、システム自体が故意に変化させる血液または何ら

かの体組織の温度をむしろ測定する。
【００１２】
中心静脈カテーテル（ＣＶＣ）、末梢性カテーテルおよび他のカテーテル様器具（例えば、導入器）のような他のデバイスが存在する。これらの名称が意味するように、このようなカテーテルは、心臓内での位置を必要とせず、従って、病院の種々の分野において、より頻繁に使用される。心臓カテーテル（これらはしばしば１００ｃｍを越える長さであり、そして挿入のために導入器を必要する）とは異なり、これらのデバイスは、約２０～３０ｃｍより長いことはめったになく、そしてセルディンガー法によって挿入され得る。例えば、ＣＶＣは、しばしば患者の頸静脈に配置され、そしてデバイス内部の多数の管腔を通して、種々の注入のため、血圧をモニターするためなどに使用される。
【００１３】
ＣＶＣのような器具は、ある種の流体（例えば、薬剤および他の浸剤）を運び得るいくつかの種々の管腔、および器具（例えば、圧力変換器）をしばしば含む。これらの流体および器具の各々は、異なる温度においてであり得るか、もしくは異なる熱的特性を有し得るか、またはその両方であり得る。従って、このようなカテーテルを用いた温度の任意の測定は、カテーテルの他の部分からの重大な熱的影響の危険性がある。
【００１４】
血液温度を正確に測定するために配置を組み入れるＣＶＣ、末梢性カテーテルまたは導入器のようなデバイスは、現在公知でない。従って、カテーテルおよび導入器のようなアクセスデバイスと共に温度を正確に測定することが可能であり、一方で、現在の慣習のように温度を測定するために、患者に二次デバイスを挿入する必要性をなくすことは有利である。このようなデバイスはまた、非侵襲性デバイスまたは侵襲性の低いデバイスより正確で、かつ消費時間が短い体温測定を提供する。本発明は、このような配置を提供する。
【００１５】
ＣＶＣまたは類似のカテーテルを標準患者モニターに接続し得ることもまた有利である。これは、患者の温度が、他のモニターパラメーターと共に一瞥され得る明らかな利点をもたらすだけでなく、要求されれば、他の工程のために利用可能な温度値を与えることである。しかし、多数の患者モニターは、大きなサーミスタまたは温度センサーと両立され得、肺動脈カテーテルに使用される小型温度センサーの出力とは両立し得ないシグナル基準を使用する。小型サーミスタの使用は、カテーテルサイズを相対的に小さくし得るので望ましい。もちろんモニターを再プログラムし得るが、この問題に対するこのような解決手段は、コストがかかり、かつ複雑であり、現存のモニターにおいて不可能であるか、または実際的ではないかもしれない。本発明は、カテーテルに基づく温度センサーを、現存のモニターに接続させる配置を提供する。
【００１６】
さらなる問題点は、多数の患者は自分の状況の改善に伴って、温度の継続したモニタリングを要求せず、従ってカテーテルとモニターとの間の専用の接続を要求しないことである。現在、専用の接続は、システムがモニターし得る患者の数、および必要とされるケーブルおよびコネクターの増加数を限定する。このシステムが、１人より多くの患者をモニターすることが自由であるということは有利である。これは例えば、看護婦または内科医が患者の温度をすばやく見ることを可能にし、あるいは、それを患者のカルテにつけて、次いで他の仕事または患者に移るのを可能にする。従って、この融通性および単純性を提供する配置を有することは有益である。本発明は同様に、これを行う。
【００１７】
（発明の要旨）
一般的に、本発明は、アクセスデバイス（カテーテル、導入器またはカテーテル、導入器、プローブなどの組み合わせなど）を提供し、このアクセスデバイスは、例えば、熱塊（例えば、アクセスデバイスの一部分に導入される注入流体または器具）によって引き起こされる熱的影響から温度センサーを断熱することによって、血液のような温度媒体の体温のさらに正確な感知を可能にする。本発明の好ましい実施形態において、このアクセスデ

バイスは、サーミスタ、熱電対などのような温度センサーを備える、中心静脈デバイスである。

【００１８】

このアクセスデバイスは、温度媒体の位置において患者内に挿入可能であり、そしてこのアクセスデバイスは、この温度媒体の他に少なくとも１つの熱塊を備える。このアクセスデバイスは、温度センサーを支持し、そして熱塊からこの温度センサーを断熱する、少なくとも１つの断熱構造体を備える。

【００１９】

本発明の特定の実施形態において、各熱塊は、アクセスデバイス内部の熱管腔内に配置される。温度センサーは、このアクセスデバイスの外表面に外面的に、またはアクセスデバイスのセンサー管腔内に取り付けられる。断熱構造体は、好ましくは温度センサーと各熱管腔との間に延びる。

【００２０】

この温度センサーはまた、キャリア内またはキャリア上に取り付けられ得る。次いで、この断熱構造体は、好ましくはキャリア内の障壁として形成され、そしてこのキャリアは、温度センサーと熱管腔との間に障壁を延ばして、アクセスデバイスの管腔のうちの１つに保有される。このキャリアは、アクセスデバイスの管腔において取り外し可能に挿入され得る。

【００２１】

本発明の他の実施形態において、１対のポートはアクセスデバイスの外壁に形成され、そして流動チャネルはアクセスデバイス内に形成され、かつ１対のポートの間に延びる。次いで、血液のような温度媒体は、この流動チャネルを占有する。この流動チャネルは、温度センサーと熱管腔との間か、または断熱構造体と熱管腔との間に位置し、それによって、温度センサーと温度媒体との間の熱的接触を増加するだけでなく、温度センサーをさらに該熱管腔から熱的に単離する。従って、この流動チャネルは、それ自体が断熱構造体を形成し得る。

【００２２】

本発明の別の実施形態において、アクセスデバイスは、外壁において開口部を有し、そして温度センサーは、展開された位置における場合、開口部内に延びる。これは、温度センサーと温度媒体との間の熱的接触を増加し、そして、温度センサーを熱塊からさらに断熱する。温度センサーがキャリアに取り付けられる場合、キャリアの端部はアクセスデバイス内部に固定され得る。次いで、キャリアは、温度センサーと各熱管腔との間に位置し、それによって、断熱構造体を形成する。

【００２３】

この温度センサーは、あるいはキャリア内に取り付けられ得、次いでアクセスデバイスの外壁において開口部を通って出る環として突出する。次いで、このキャリアの端部は、好ましくはアクセスデバイス内部に固定される。この実施形態において、断熱構造体は、開口部の位置において、キャリアとアクセスデバイスとの間、従って、温度センサーと熱塊との間に形成される温度媒体のための流動チャネルを備える。この実施形態の１つの利点は、温度センサーがキャリアのみを介して、温度センサーの実質的に全外周を越えて該温度媒体に露出されることである。

【００２４】

あるいは、この温度センサーは、アクセスデバイスの中心軸に対して主に垂直に、開口部から外に延びるように取り付けられた直角サーミスタであり得る。

【００２５】

本発明の別の実施形態において、温度センサーは、アクセスデバイスに粘着して装着される。この粘着剤は体温で溶解し得、それによって、患者内の適切な位置における場合、この温度センサーはアクセスデバイスとの接触から分離する。

【００２６】

このアクセスデバイスは、複数の管腔を備え得、それによって温度センサーは、断熱部材

における凹部に取り付けられる。次いで、この断熱部材は、温度センサーと共に、アクセスデバイスの１つの管腔内に取り付けられ、その結果、断熱部材は、温度センサーと熱管腔との間に延びる。

【００２７】

本発明の別の実施形態において、この断熱構造体は、アクセスデバイスと共押出しされ、そして各熱管腔の少なくとも一部分か、または温度センサーそれ自体かのいずれかを取り囲む、断熱物質を備える。

【００２８】

本発明のなお別の実施形態において、このアクセスデバイスは、管腔およびセンサーポートを有し、そして、温度センサーは、分離デバイス（例えば、プローブ）の遠位先端部に取り付けられる。このプローブは、アクセスデバイスの管腔内に挿入可能であり、それによって、この温度センサーはセンサーポートを介して延びる。

【００２９】

この断熱構造体はまた、アクセスデバイスそれ自体の遠位先端部を備え得る。次いでこの先端部は、好ましくは分離部材として断熱物質から形成され、そして温度センサーは、遠位先端部内に取り付けられる。あるいは、アクセスデバイスの遠位先端部は、長さ方向に延びるスリットを提供され得る。次いで、この温度センサーは、遠位先端部の第一側面に取り付けられ、そして熱塊を運ぶ少なくとも１つの熱管腔は、遠位先端部の第二側面を介して延びる。次いで、展開された位置において、遠位先端部は、スリットに沿って分離され、ここで先端部の第一側面および第二側面は、スリットのいずれかの側面に配置されている。

【００３０】

本発明の別の実施形態において、この断熱構造体は、温度センサーと熱塊との間の距離を増加するように拡張可能であるアクセスデバイスにおける管腔またはチャンバーである。

【００３１】

本発明によるアクセスデバイスは、好ましくは患者の体温をモニターするためのより一般的なシステムにおける感知部材として備えられる。このシステムにおいて、アクセスデバイスは、患者内に挿入可能であり、そしてアクセスデバイスのセンサー出力シグナルを、患者の温度シグナルに変換し、そして患者の温度シグナルを表示するための温度モニターに接続される。次いで、コネクターは、この温度センサーを温度モニターと接続するために提供される。

【００３２】

本発明によるシステムは、好ましくは温度モニターにおけるアダプターをさらに備える。このアダプターは、センサー出力シグナルを予め決定した表示形式に変換する。この温度モニターはまた、表示装置および電力源を備え得、この場合において、全モニタリングシステムは、種々の患者の間で携帯可能な手動の独立式として実行され得る。

【００３３】

本発明はまた、患者の体温を測定する方法を含む。本発明に従う方法の主要な工程は、アクセスデバイス上で温度センサーを支持する工程；血管内にアクセスデバイスを挿入する工程；少なくとも１つの熱塊をアクセスデバイス内に導入する工程；および、熱塊から温度センサーを断熱する工程、を包含する。本発明による好ましい方法において、熱塊は、アクセスデバイス内に配置される熱管腔を通して導入される。次いで、アクセスデバイス内のセンサー管腔において温度センサーを取り付け、そして温度センサーと熱管腔との間に少なくとも１つの熱的に断熱な構造体を形成する。いくつかの実施形態において、熱的に断熱な構造体を提供するために、熱的に断熱な物質をアクセスデバイス内部の管腔に導入し得る。

【００３４】

本発明はまた、アクセスデバイスを製造する方法を含む。好ましい実施形態において、この方法は、アクセスデバイスを押出す工程、熱塊が導入される熱管腔を形成する工程、温度センサーが導入されるセンサー管腔を形成する工程、およびセンサー管腔を熱塊から分

離する断熱構造体を形成する工程を包含する。アクセスデバイスの製造において、温度センサーは、このアクセスデバイスの遠位端において、センサー管腔に取り付けられ得る。次いで単一ワイヤーは、温度センサーから外部患者モニターまで牽引される。

【００３５】

（詳細な説明）

もっとも広範な場合において、本発明は、温度センサーが、患者の体内に挿入するためのアクセスデバイス（好ましくは血管アクセスデバイス）を用いて使用される、配置またはデバイスを提供する。本発明はまた、アクセスデバイス内部の他の部分からの温度センサーの熱的影響を減らす種々の断熱構造体を提供する。この温度センサーは、患者の体内における何らかの温度媒体（例えば、血液）を感知するように設計される。

【００３６】

本発明の好ましいアクセスデバイスの１つの例は、中心静脈カテーテル（ＣＶＣ）であるが、これは、温度センサーにおいて温度に影響を与え得る流体または他のデバイス（漸増的に「熱塊」）を輸送するまたは備える、何らかの他の器具であり得る。他のアクセスデバイスの例としては、末梢性カテーテル、導入器、閉塞具およびプローブが挙げられる。実際には、「アクセスデバイス」はまた、これらのデバイスの任意の組み合わせ（例えば、１つ以上の導入器、カテーテルおよびプローブの組み合わせ）を考慮する。例えば、カテーテルは導入器内部にしばしば挿入され、そしていずれか、または両方が、本発明の適した実施例に従って、温度測定の精度を向上するように配置され得る。

【００３７】

本発明の状況において、熱塊は、この塊に流入するかまたはこの塊から流出する熱が、感知される温度に有意に影響を与え得る、温度および熱容量を有するかまたは有し得る、アクセスデバイス内に運ばれる任意の物質または構造体である。ここで、「有意に」とは、温度測定が、臨床的使用のために受容可能に正確でないことを単に意味する。

【００３８】

本発明において使用される場合、「断熱構造体」は、温度センサーを熱塊から断熱する、任意の構造体である。以下に記載および図示されるように、本発明において使用される断熱構造体としては、デバイス管腔またはデバイス管腔の任意の一部分、チャネル、ギャップ、チャンバーまたは温度センサーのすぐ周囲に提供される、まさにその領域が挙げられるそれに限定されない。断熱構造体としてはまた、例えば、セラミックのような断熱物質または分離デバイス（例えば、アクセスデバイス内部にまたはアクセスデバイスを介して挿入されるプローブ）が挙げられ得る。

【００３９】

以下に記載される、適したアクセスデバイスの例は、好ましくは、生体適合性ポリマー製物質から作製される。なぜなら、ほとんどの場合においてこれらは、少なくとも部分的に患者内に挿入されるからである。ポリウレタンは、患者における場合、熱的および機械的な安定性についての全ての規定要求を満たすため、最も一般的な物質である；ＰＶＣおよびテフロン（登録商標）はまた、他の従来の物質と同様に受容可能である。本発明の使用のためのアクセスデバイスは、さらに、抗菌物質から作製され得るか、あるいは抗菌または凝塊抵抗特性を有する物質またはコーティングで被覆され得る。

【００４０】

本発明において使用される温度センサーは、任意の従来のデバイスであり得る。最も簡単に実施されるセンサーは、小さく、広範に利用可能で、かつ検定するのが比較的簡単なサーミスタである。しかし、他の温度センサーもまた、使用され得る。代替物は、従来の熱電対および光ファイバーの温度センサーを含む。このセンサーが、測定可能な物理的特性（例えば、その電気抵抗または光学スペクト）を温度変化に対して予測可能に変化させるべきであり、そしてこの変化が、電気コンダクターまたは光学コンダクターを介して、温度が電気シグナルに変換され得るような様式において外面的に検出可能であるべきことは、唯一の必要条件である。これらのデバイス、およびさらなるプロセシングのためにそのシグナルが調整される方法は、周知である。

【００４１】
本発明の種々の例示的な実施形態の以下の議論において、単に例として、そのアクセスデバイスがＣＶＣであること、温度センサーはサーミスタであること、カテーテルは、静脈のような体管内に挿入されること、および温度が決定されるべき温度媒体は血液であることが想定される。本発明は、当業者に明らかなように、他のアクセスデバイスおよびセンサー、挿入点、ならびに温度媒体を用いてと全く同様に作用する。
【００４２】
図１は本発明の一般的な構造体を図示する。カテーテル１００は、従来の様式において患者の静脈１１０に挿入される。この静脈１１０内の矢印は、流動している血液を示す。サーミスタ１２０はカテーテルの遠位端に位置しており、このカテーテルは、管腔、チャネルまたはチューブを備える、これを通して、流体が患者内に導入され得るか、あるいは他の器具を保持する。２つの従来の注入コネクター１３０、１３２は、カテーテルにおけるそれぞれの管腔に挿入されて示される。管腔およびコネクターの数は、もちろん、用いられる特定のカテーテルおよび適用に依存する。本発明は、任意の数のカテーテルの管腔または内部チャネルを用いて作用する。
【００４３】
シグナルワイヤーを形成するコンダクター（破線１２５として示す）は、サーミスタを電気的に（または用いられる温度センサーの型によっては光学的に）外部の調整、プロセシングおよび表示回路構成１５０と接続する。図１において、この例示的な回路構成は、外部の回路構成１５０にサーミスタのシグナルワイヤー１２５を接続している従来の電気カプラー１８０およびガイドチューブ１８５を有する、シグナルアダプター１６０および患者モニター１７０を備えるように示される。従来の電源１７２はまた、別個の表示デバイスまたは現存するモニター表示の単に一部分のいずれかであり得る、温度表示１７４と同じように備えられる。そのいくつかは必要に応じてか、またはその実施形態に依存して変化し得るこれらの特徴は、より詳細に以下に記載される。任意の従来のデバイスおよび回路はまた、サーミスタ１２０の出力シグナルを外部のモニターまたは表示装置に伝達するために使用され得る。
【００４４】
図１はまた、断面線Ａ－Ａを示す。本発明によるカテーテルの種々の実施形態の記載は、断面図によって図示される。線Ａ－Ａは、これらの断面図のための参照線である。
【００４５】
図２は、本発明の１つの例示的な実施形態を図示する。この実施形態において、サーミスタ１２０は、カテーテル１００内の専用の開口部または管腔２１０の内部に配置される。この図において、サーミスタの管腔２１０は主に環状であるように示される。これは必ずしも必要ではない；任意の適切でかつ所望な管腔の形状が使用され得る。しかし、標準サーミスタは、しばしば主に丸い断面を有するガラスに包まれたビーズとして提供されるので、ほとんどの場合において、環状または少なくとも丸い管腔の断面が好ましい。３つの他の管腔２２０、２２２、２２４もまた図示される（しかし、任意の数の管腔が含まれ得る）。
【００４６】
ここで、管腔２２０、２２２、２２４の１つ以上が、サーミスタ１２０によって測定される温度に影響を与え得る熱塊および温度を有する、何らかの流体を輸送する（または何らかの器具を含む）と仮定する。例えば、注入流体は、管腔２２０を介して投与され得る。その流体の温度が、患者の血液の温度よりも高いまたは低い場合、サーミスタと流体との間のカテーテル材料の熱伝導性に起因して、温度の測定に影響を及ぼし得る。従って、管腔またはギャップ２５０のような、さらなる断熱構造体は、例えば、サーミスタと他の管腔２２０、２２２、２２４の全てとの間に側方に延びるように、カテーテルにおいて好ましくは押し出される。
【００４７】
断熱管腔（ギャップ）２５０は、カテーテルおよび管腔の安定性ならびにデバイスの最大

外径を維持するために必要とされる、最小の許容可能な物質の厚みを考慮して、サーミスタの熱的な断熱の程度を最大限にするように、好ましくはできる限り広くかつ厚い。しかし、このサーミスタ管腔２１０とカテーテル１００の外表面との間の最小距離は、サーミスタと周囲の血液との間の最も良い熱的接触を確保するように、好ましくはできる限り小さい。

【００４８】

図２の管腔またはギャップ２５０のような断熱構造体は、好ましくは空気で満たされるか、または何らかの他の従来のガス、セラミックペレット、従来の高インピーダンスゲルなどで満たされ、その熱的インピーダンスをさらに増加する。この断熱物質はまた、管腔２５０内に挿入される断熱物質の小片または層または同様な分離片であり得る。この断熱物質はまた、任意の公知な方法において、カテーテルに必要に応じて接合され得る。この断熱管腔の最も遠位端は、血液の流入および熱的に断熱なガスまたは他の断熱物質の流出を防ぐように、好ましくはシールされる。

【００４９】

図２において、１つの断熱管腔のみが示される。これは例としてのみが目的である。空間に余裕がある場合、１つより多くのギャップが、サーミスタと他の管腔との間に延びるように作製され、このサーミスタの熱的単離をさらに増加し得る。また、この断熱管腔は、任意の長さの管腔であり得、これはアクセスデバイスの全長またはその長さの任意の適切な一部分を介して延び得る。例えば、管腔２５０の一部分は、薬剤またはガイドワイヤーの導入のための注入管腔またはデバイス管腔として使用され得る。プラグは、このような管腔の長さに沿ったどこかに位置し得、注入／デバイス管腔の残りを閉鎖し、その結果、この残った一部分は断熱構造体として作用する。このプラグの位置は、注入／デバイス管腔の閉鎖部分が、温度センサーの位置に隣接するように選択されなければならない。この注入／デバイスをアクセスデバイスから退去できるように、プラグの配置前に側面ポートを提供することが必要である。

【００５０】

管腔２５０はまた、図２に示されるように、一般的に側方に延びるスリットとして形成される必要はないが、これは代表的に、他の管腔からのサーミスタの単離を最大にする。代わりに、管腔２５０は、半月形として形成され得るか、またはサーミスタの管腔と同心であり得るか、またはさもなければ、サーミスタ管腔２４０を取り囲むように押出され得る。また、ギャップは、サーミスタと他の管腔２２０、２２２、２２４との間に展開する、いくつかの主として円柱状または他の曲線状の管腔によって作製され得る。

【００５１】

断熱管腔２５０のなお別の構造において、この断熱管腔（つまり、その周囲のおよびそれを形成する、カテーテル物質）は、カテーテルが患者内に挿入される後に、管腔２５０が膨張可能であるために十分に弾性にされる。例えば、管腔２５０は、可撓性のウェブを有するように形成され得る。一旦カテーテルが挿入されれば、任意の加圧するのに適した物質（例えば、空気、不活性ガス、フォームまたは何れかの他の熱抵抗物質）は、管腔２５０内にポンピングされ、これによってその断面積は拡大され、そしてサーミスタと熱塊との間のギャップまたは距離を増加させる。断熱管腔または構造体は、デバイスが適所にきた後にのみ膨張されるので、この実施形態は、その外径を小さく保つことによって、デバイスの簡単な挿入を容易にする。

【００５２】

管腔２２０、２２２、２２４はまた、任意の従来の目的のために使用され得る。例えば、それらのいずれかまたは全ては、流体を輸送し得るか、または他の器具（例えば、プローブ、変圧器など）を先導するためのチャネルとして作用し得る。もちろん、これらの全てが同じ機能を有する必要はない（１つの管腔は注入流体を輸送しているかもしれないが、別の管腔は器具のためのチャネルである）。

【００５３】

図３ａおよび３ｂは、サーミスタ１２０および熱的に断熱な管腔／ギャップ３５０が、現

存する管腔３１０に挿入され得る別個の主として管状の部材３００においてか、またはカテーテル１００内のチャネルにおいて提供される、本発明の実施形態を図示する。この管状部材３００は、カテーテルそれ自体と同じか、または少なくとも同じ型の物質（つまり、ポリウレタンのような熱的に安定で、生体適合性のポリマー）から好ましくは作製される。しかし、この管状部材カテーテル内に取り付けられるので、この物質要求は、カテーテル自体に対するほど厳密ではない。次いで、管腔２５０について上記のようにさらなる断熱物質で満たされ得るギャップ３５０は、サーミスタとカテーテル内の他の管腔３２０、３２２、３２４、３２６との間に延びるように、管腔３１０内で方向付けられる。必要な場合、管腔３１０内において管状部材の適した配向を提供するために、ギャップ３５０に一致するように形成される杆状体のようなキー（示さない）が提供され得る。次いで、ユーザはまず、サーミスタと共に管腔３１０内に部材３００を挿入し得、次いでギャップ３５０の近位端内にキーを挿入して、そして部材３５０を適した配置に回転させ得る。

【００５４】

図４および図５は、血液自体が、サーミスタ１２０と１つ以上の他の管腔４２４との間に導かれ、この管腔は注入流体のような熱的「ノイズ」の供給源を輸送しているかもしれない、本発明の実施形態を図示する。これらの実施形態において、ポート４１０、４１２は、カテーテル１００の外壁の主に正反対に対向している部分において形成され、そしてチャネルが（２つのポートの間の通常の押出しの部分として）形成される。このポート４１０、４１２は、温度センサーと熱塊との間に血液が流動し得る限り、カテーテル壁の周囲に沿ったいずこかに配置され得るが、まさに正反対に対向しない。図４において、チャネルは３つのチャンバー（２つの外部チャンバー４４０、４４４および１つの中間チャンバー）を有し、これらを介して血液は流れ得る（チャネルを通り越す矢印によって示される）。ポート４１０、４１２は、サーミスタ１２０の領域においてのみ形成されることが必要であり、従って、カテーテル壁において刻まれる単純なホールまたはスリットであり得ることに注意のこと。このチャネルは、小さなチャンバーとして形成され得るか、または押出しを単純化するのに必要とされる結果として、任意の長さのカテーテルにわたって伸長し得る。心臓カテーテルとは異なり、ＣＶＣまたは末梢性カテーテルは、代表的には約３０ｃｍ長にすぎず、そのため、チャネルを他の管腔４２４の距離まで伸長することは、一般的に問題ではない。

【００５５】

図４で示される本発明の実施形態について、血液は、サーミスタ１２０にすぐ隣接した（つまり、真下に伸長する、図４に示す）領域（中間チャンバー４４２）に向かい；その温度が上下両方で測定されるべき血液からサーミスタを分離する最大距離は、カテーテル物質の構造的に許容される最小の厚さと同じくらい小さく作製され得る。従って、血液は、サーミスタを管腔４２４から単離するのを手助けするだけでなく、熱的にサーミスタにより接触する。なぜなら、これは片側のみからでなく、両側から接触するからである。サーミスタを通り越えて流入血液を方向づけるためだけでなく、血液の断熱層をサーミスタと管腔４２４との間に依然として流動させながら、カテーテル内の血液量を減らすために中心隆線またはタブ４７０は、２つの外部チャンバー４４０、４４４の間および管腔４２４からサーミスタの方へ伸長するように押出され得る。しかし、この隆線は、本発明のこの実施形態において必要ではない。

【００５６】

図５に図示される本発明の実施形態において、チャンバー４４０、４４４および４４２ならびに隆線４７０（図４）は除去された。代わりに、中間チャンバー４４２は血流から封鎖され、従って、図２における管腔／ギャップ２５０と類似の断熱ギャップまたは管腔５５０を形成する。この実施形態において、単一チャネル５４０を通る血流は、サーミスタを管腔４２４から熱的に単離するように、主に働く。特に、チャネルを通る血流が、熱塊（チャネルは、この熱塊からサーミスタを分離する）に対するまたは熱塊からの有意な熱伝達を防ぐのに十分速い場合、この管腔／ギャップ５５０は、さらなる断熱障壁を提供するが、これは必要とはされない。図５に示される実施形態の別の利点は、チャネル５４０

の中の血液がまた、ギャップ５５０内の温度を血液温度にする傾向があり、従って熱塊をさらに断熱すること、に注意のこと。

【００５７】

図４および図５の両方に示される本発明の実施形態において、チャネル５４０は、サーミスタ自体の近位に配置される制限されたチャンバーであり得るか、またはアクセスデバイスの長さの任意の一部分を通り越す管腔であり得る。いずれの場合においても、チャネル５４０自体（通り越す血液を有する）は、断熱構造体として働く。

【００５８】

図６ａおよび６ｂは、本発明の他の実施形態のそれぞれ部分的に切り取られた側面図および端面図であり、ここでサーミスタ１２０はキャリア６００に取り付けられ、このキャリアは、好ましくは生体適合性物質から作製され、そしてまた、向上された熱的断熱を提供する。例えば、これはプラスチック、金属またはセラミックから作製され得る。このサーミスタは、任意の従来の物質（例えば、ポッティング化合物または非毒性、防湿、熱的に安定な接着剤のような標準粘着剤）を用いて、キャリア上へしっかりと取り付けられ得る。

【００５９】

この実施形態において、ポートは、カテーテル１００の外壁において切り取られた開口部６０５として形成される。次いで、このサーミスタは、カテーテルにおける開口部内に位置するように配置され、従って、間にカテーテルのどんな一部分をも介さずに、その表面積の大部分にわたって血液に対して直接的に露出される。このサーミスタの単一ワイヤー１２５はまた、図６ａに示される。

【００６０】

サーミスタ１２０およびそのキャリア６００は、カテーテルの現存するまたは専用の管腔６１０内に挿入され得、その結果、キャリアはサーミスタと他の管腔６２０、６２２またはカテーテルの熱的ノイズ供給源との間に延びる。開口部６０５は、好ましくは管腔６１０内に延び、サーミスタと周囲の血液との間の最大直接接触を確保することに注意のこと。

【００６１】

このサーミスタおよびキャリア６００は、カテーテルが患者内に配置される前に、開口部６０５の適所にサーミスタがある状態でこのカテーテル内に挿入され得る。あるいは、挿入の前に、キャリアが十分に可撓性の物質から作製されると想定すると、サーミスタおよびキャリア６００の遠方の遠位端は、開口部６０５から外へ突出され得、好ましくは、曲げられてカテーテル壁に沿って戻され、そして挿入方向とは逆方向に向く。一旦サーミスタのカテーテルが患者内に配置されると、次いで医師は、サーミスタが開口部６０５の位置に引かれるまで、キャリアの近位端を引っ張り得る。次いで、キャリアの遠位端は短くされ、サーミスタから短い距離のみ延び、この結果、この近位端のみがカテーテル内部にある。次いで、管状であり得るこのキャリアは、上記の前実施形態におけるギャップ２５０、３５０および５５０と同様に、サーミスタの真下に断熱ギャップを形成する。

【００６２】

図７ａおよび７ｂは、本発明の実施形態のそれぞれ部分的に切り取られた側面図および端面図であり、ここでサーミスタ１２０は、カテーテル１００自体の外壁に取り付けられる。サーミスタのシグナルワイヤーまたは繊維１２５が、カテーテルの外表面に沿って外部まで動かされるのを避けるために、それは、カテーテル壁において、好ましくは、サーミスタ１２０の真後ろ（サーミスタ１２０に対して近位）に作製される小さなホール７０５を通してカテーテル１００内に予め貫通される。このサーミスタは、任意の従来の方法または物質（例えば、標準ポッティング化合物７１０もしくは非毒性、防湿、熱的に安定な接着剤、またはカテーテルチュービングに溶剤結合するカテーテル物質の液化性溶液）を用いて、カテーテル上へしっかりと取り付けられ得る。このポッティング化合物は、ホール７０５および少なくともサーミスタの大部分を覆うように広げられるべきであるが、温度変化に対してすばやくかつ正確に応答するその能力を妨害するほどには、サーミスタの

上を厚く覆わない。カテーテルの最大直径を減少し、それによって挿入をより簡単にするために、カテーテルの外壁においてくぼみが作製され得る。次いで、このサーミスタは、くぼみにおいてそれをしっかりとポッティングすることによって、カテーテルに取り付けられ得る（示されない）。

【００６３】

図７ａおよび７ｂに示される本発明の実施形態において、血液に対して露出される場合に溶解する非毒性ポッティング物質（または他の粘着剤）を用いて、温度センサーを取り付けることはまた可能である。一旦カテーテルが適所にくると、それによってこのポッティング物質は溶解する。これは、温度センサーを血液に対して直接露出し、従って、より正確な温度測定さえ可能にする。さらに、次いでこの温度センサーは、カテーテルの外壁から分離し、そしてカテーテルの外壁から離れて移動し、それによってカテーテル内の任意の熱塊からそれをさらに断熱する傾向がある。

【００６４】

この「展開」作用はまた、シグナルワイヤーに形状記憶合金製のエルボ接合部を提供することによって配置され得、このエルボ接合部は、挿入間はまっすぐであるが（カテーテルの方向に延びる）、これはゆるんだ状態において曲がっている。ポッティング化合物が溶解する場合、この接合部はゆるみそして曲がり、従ってカテーテル壁から離して温度センサーを移動する。センサーのシグナルワイヤー自体において、この形状記憶のエルボ接合部を形成することが実用的でない場合、形状記憶合金の小片は、このエルボ接合部が必要とされる位置でワイヤーに装着され得る。次いで、このセンサーはまた、図６ａのようにくぼみ内にポッティングされ得、その結果カテーテルは、突出部のない外表面を有し得る。

【００６５】

図７ａおよび７ｂに示されるように、外面的に取り付けられたサーミスタ１２０と注入剤を輸送する管腔との間に断熱ギャップを提供するために、いくつかの管腔７００～７０５または管状部材が、カテーテル内に好ましくは備えられる。図２を参照して示され、そして記載される管腔２５０のような、単一管腔／ギャップ、または図４および図５に示されるチャネルと類似の血液チャネルは、サーミスタを管腔７２４から熱的にさらに断熱するように、管腔７００～７０５の代わりに、または管腔７００～７０５に加えて含まれ得る。

【００６６】

図８ａおよび図８ｂは、本発明の実施形態のそれぞれ部分的に切り取られた側面図および端面図であり、ここでサーミスタ１２０は、カテーテル１００の外壁に作製される開口部８０５を通して外へ突出する、短管状部材８００内に取り付けられる。管状部材８００の２つの端部は、任意の公知の技術を用いてカテーテル内に固定される。それによって、チャネル８１０は、管状部材８００の「ループ」とカテーテルとの間に形成される。それによって、血液は、サーミスタ１２０の実質的には完全に周囲に流動され得、そしてまた、サーミスタをカテーテル内の任意の内部管腔８２４から熱的に単離する。カテーテルの挿入の間、部材８００は好ましくは平ら、すなわち、ほとんどまっすぐで、カテーテル内に位置する。

【００６７】

一旦カテーテルが適所にくると、次いで医者は、例えばワイヤーを用いてそれを押込むことによってサーミスタを挿入し得、次いでサーミスタおよび部材８００のループを、開口部８０５を通して外へ押出して、温度センサー、すなわちサーミスタを展開し得る。これを行う１つの方法は、例えば、部材８００が位置する管腔内（または単に、カテーテルの内部）に、屈曲部を有する別個の器具を挿入することである。次いで、屈曲部を有するサーミスタの下で器具をひねることによって、開口部８０５を通して外へそのサーミスタを押出す。あるいは、管状部材８００のはるか遠くの遠位端が、カテーテル内に固定され、そして部材８００がさほど可撓性ではない場合、医者が近位端を内側に押すことによって、開口部を通して外へ突出する。

【００６８】
図９は、本発明の実施形態を図示する。この実施形態において、このサーミスタ１２０は、直角デバイスである（すなわち、このサーミスタをそのシグナルワイヤー１２５に接続する杆状体またはワイヤーにおいて、実質的に直角の屈曲部が存在する）。もちろん、９０°以外の屈曲部の角度もまた、使用され得る（屈曲部の適した角度は、特定の実施に依存し、そして公知の方法によって決定され得る）。次いで、この直角サーミスタ１２０は、開口部６０５および８０５と類似してカテーテル壁に形成される、開口部９０５においてしっかりとポッティングされ、その結果サーミスタは、カテーテルの長手方向の拡張方向（中心軸）にほぼ垂直に、外側に延びる。すでに述べたように、サーミスタを固定するために最小量のポッティング化合物が使用され得る。なぜなら、このことがまた、血液温度を感知するためのサーミスタの性能に対して、化合物自体によって引き起こされる影響を最小化するからである。すでに述べたように、１つ以上の断熱管腔９００はまた、サーミスタを流体輸送管腔９２４から単離するために、カテーテル内に備えられ得る。

【００６９】
図１０ａおよび図１０ｂは、本発明の実施形態の、それぞれ背面図およびやや上方からの側面図であり、ここで、サーミスタ１２０は、分離断熱部材１０００における凹部内に位置するように取り付けられ、これは、閉鎖した、円形の、滑らかな前表面およびスロット１０１０を有する、部分的にくり抜かれたシリンダー（サーミスタが取付けのためにこの内部に位置し得る）として一般的に形成される。この断熱部材は、滑らかで、熱的に断熱な物質（例えば、セラミック、金属、発泡体またはテフロン（登録商標））から作製されるべきである。ポリウレタンのようなポリマーはまた、使用され得、これは、部材１０００の射出成形を可能にする。次いで、この断熱器／サーミスタのサブアセンブリは、例えば、杆状体を用いて適したカテーテルの管腔（例えば、本発明の他の実施形態について上に示される管腔２１０、３１０、６１０）内にそれを押込むことによって挿入される。従ってこのスロットは、キーまたは類似の道具を用いて、例えば、流体および器具のような熱塊を輸送する他のカテーテルの管腔から離れた定位置に置かれるべきである。

【００７０】
図１１において、温度センサー１２０が、アクセスデバイス１００内に挿入され得る分離デバイス（例えば、ガイドワイヤーまたはプローブ１１００）の先端部１１１０に取り付けられる、本発明の実施形態が示される。センサー１２０を展開するために、一旦アクセスデバイスが適所にくると、このプローブの先端部はデバイス１００の管腔内に挿入され、次いでプローブの先端部１１１０が、ポート１１４０から突出するまで押し込まれ、ここで、ポート１１４０はカテーテルの側壁において切断されるか（上記のいくつかの他の実施形態のように）、または単にプローブが挿入される管腔１１４２の最も深い開口部であるかのいずれかである。（プローブの先端部の代替の出口は、破線で示される。）従って、このプローブ自体は、温度センサーを熱塊から分離する（および、従って断熱する）構造体として働く。このプローブの先端部は、好ましくは、主に「Ｊ」形状に曲げられ、その結果それは、ポート１１４０を通して、およびアクセスデバイスの部分の熱的影響から離れてより簡単に延びる；しかし、まっすぐな先端部はまた受容可能である。本発明のこの実施形態の１つの利点は、必要とされる場合にのみ挿入され得、この場合において、従来の止血弁により血液漏れに対して封鎖され得ることである。

【００７１】
図１２ａおよび図１２ｂは、断熱物質がカテーテル自体と共押出しされる、本発明の実施形態を図示する。図１２ａにおいて、この断熱物質１２００は、注入（または、器具を輸送する）管腔１２１０、あるいは少なくとも温度センサーの位置に近いそれの一部分を取り囲むように、カテーテル１００と共に押出される。この断熱物質は、次いで管腔１２１０の内容物と温度センサー１２０との間の熱的障壁として働く、任意の公知の押出し可能な型であり得る。図１２ｂにおいて、この断熱物質は、温度センサー１２０自体を取り囲み、それによって断熱する障壁層１２２０を形成するように、カテーテルと共押出しされる。

【００７２】
図１３ａおよび図１３ｂは、本発明のなお別の実施形態を図示し、ここで、温度センサー１２０は、最初は、カテーテル本体１００自体とは別体部材として形成されるが、例えば従来の粘着剤を用いてカテーテルの遠位端に装着または結合されるカテーテルの先端部１３００内に取り付けられる。次いで、管腔または貫通ホール１３１０は、先端部１３００に形成され、主要なカテーテル本体１００内の、任意の適切なおよび所望な管腔の延長として働き、連続した流動をさせる。次いで、この実施形態における先端部１３００は、全体的に高度に断熱性の物質で作製され得る。これは、カテーテルの大部分または全体にさえわたって断熱部材を押出す必要性を完全に回避する。共押出しの必要なく、そして全デバイスについてさらに高価な物質を使用せずに、断熱部材および主要なカテーテル本体において、種々の物質の使用もまた可能にされる。

【００７３】
図１４ａおよび図１４ｂは、カテーテル１００の遠位先端部がスリット１４００を有する、本発明のなお別の実施形態を図示する。温度センサー１２０は、このスリットの一方の側の遠位先端部上か、または遠位先端部内に取り付けられ、一方で、熱塊を輸送する管腔１４１０が、このスリットの他方の側の先端部を通して延びる。簡単に言えば、この実施形態において、カテーテルの遠位先端部は、デバイスが患者内に配置された後に分裂する。患者内への挿入の前に、このカテーテルの先端部１３００は、例えば、カテーテルの近位端から延びるワイヤーを用いて外され得る内部留め具を用いて機械的にか、または血液に対して露出される場合に溶解する粘着剤、もしくは任意の他の適切な方法を用いて、一緒に保持される。適所にある間、スリット１４００は、サーミスタ１２０と管腔１４１０における熱塊との間に、断熱ギャップを形成するように開口する（図１４ｂに示されるように）。

【００７４】
本発明のいくつかの異なる実施形態は上記される。しかし、全実施形態に共通であることは、患者の体温が、アクセスデバイスによって支持される温度センサーによって感知されることによる発明に従う方法を実施することである。ここで用いられる場合に、用語「支持される」は、温度センサーが、アクセスデバイス上またはアクセスデバイス内部に取り付けられ得ること；温度センサーが、アクセスデバイスにまたはアクセスデバイス内部に持続的に取り付けられ得ること；あるいは、温度センサーが、アクセスデバイスに取り外し可能に接続されるかまたはアクセスデバイス内部に挿入され得ることを意味する。この用語はまた、図１１に対する参考における例のために記載されるような任意の配置を含み、ここで、温度センサーは、別個のデバイスに配置され、このデバイスがアクセスデバイス内に挿入され、そしてアクセスデバイスを通して延びる。

【００７５】
このアクセスデバイスは、患者内に（例えば、静脈内に）挿入され、そして少なくとも１つの熱塊は、アクセスデバイス内に導入される。この温度センサーは、熱塊から熱的に断熱される。シグナルワイヤーは、温度センサーから外部の患者温度モニターまで導かれる。

【００７６】
本発明はまた、アクセスデバイスを製造する方法を含む。上記の実施形態の大部分において、この製造方法は、複数の管腔（温度センサーが導入され、そしてシグナルワイヤーが導かれる一つの管腔（センサー管腔）、ならびに熱塊を輸送するかまたは先導するための少なくとも１つの他の管腔）を有するアクセスデバイスを押出す工程を包含する。この製造方法はまた、温度センサーを熱塊から熱的に分離する断熱構造体を形成する工程を包含する。この温度センサーは、センサー管腔の遠位端において、持続的にまたは取り外し可能に取り付けられ得る。この温度センサーはまた、センサー管腔に配置される別個のキャリアに取り付けられ得る。この製造方法はまた、当業者に理解されるような、上記の実施形態に従ういくつかの他の工程、またはさらなる工程を包含する。

【００７７】

図１を再度参照する。サーミスタ１２０のような従来の温度センサーからの出力シグナルは、周知の特徴を有する。一般的には、出力シグナルは、振幅がセンサーの温度に機能的に関係する電圧または電流シグナルである。さらに、センサー温度と出力シグナルの振幅との間の機能的関係は、直線的であり得るが、めったに直線ではない。実際には、ほとんどの温度センサーは、製造者によって個々に較正されるか、または実際の使用前にユーザによって較正が必要である。どのように得られるにしても、機能的関係が存在する。

【００７８】

さらに、いくつかの場合において、温度出力シグナルは、現存の患者のモニターの入力シグナルと互換性をもち得るが、これは常の場合というわけでない。簡単な例としては、増幅（スケーリング）およびインピーダンス整合（またはインピーダンス分離）は、出力シグナルを、ユーザのために処理されてそして表示され得るシグナル形態およびシグナル型に変換するために、しばしば必要とされる。

【００７９】

本発明に従って、ａ）一方においては、センサー温度とセンサー出力シグナルとの間；およびｂ）出力シグナル特性（例えば、インピーダンス、振幅範囲および電圧の形式であるかまたは電流の形式であるか）の間の機能的関係は、任意の従来の様式において予め決定される（例えば、通常の較正を通してかまたは製造者の較正データを認容することによって）。次いで、この関係を実施するために必要なシグナル条件付けは、アダプター１６０において実施される。次いで、この条件付シグナルは、プロセシング（必要とされる場合）および表示のために、モニター１７０に適用される。

【００８０】

いくつかの場合において、要求される唯一のシグナル条件付けはスケーリングである。これは、センサー出力シグナルが入力を形成し、そしてシステム出力シグナルが回路において適切な点から得られる、従来の抵抗性回路を用いて行われ得る。次いで、従来の受動的構成成分は、インピーダンス整合のような任意の必要なさらなる条件付けを提供するために使用され得る。これは、全受動的デバイスとしてアダプター１６０を実施する利点を有する。他の場合において、公知の抵抗性、容量性および誘導性のフィードバックおよびフィードフォワード要素を有する、作動可能な増幅器のような従来の能動的構成成分は、シグナル変換を実施するために使用され得る。

【００８１】

多数の場合において、センサー出力と温度との間の関係は、純粋に受動的またはアナログの構成成分を用いて正確に実施するには不規則過ぎる。これらの場合において、アダプターは、アダプター１６０において、従来のアナログ－デジタル変換器（ＡＤＣ）、マイクロプロセッサおよび記憶装置を備えることによって実施され得る；単一の従来のデジタルシグナルプロセッサは、全てのこれらの機能を１つの構成成分に組み合わせ、従って多数の適用において適した実施であり得ることに注意のこと。次いで、センサー出力と温度との間の関係は、記憶装置の検索表としてか、または近似関数のパラメーターとして実施され得る。次いで、公知の方法を用いて、マイクロプロセッサは、検索表または近似関数に対する入力として、感知およびＡＤＣ－変換されたセンサー出力シグナルを獲得し得、そして、任意のさらなる従来の条件付けの後にモニター１７０に適応される、対応する温度シグナルを発生する。

【００８２】

患者の温度を単にすばやくかつ簡単に見ることのみが必要とされる、多忙な背景において特に有用である、本発明の１つの実施形態において、全体の条件、プロセシングおよび表示回路１５０は、単一携帯型ユニットに備えられる。この場合において、電源は、代表的にはバッテリーであり、モニターは、温度を示す（仮に、小数点以下１桁の精度で、としておく）従来の低電力ＬＣＤ表示（従来の駆動回路と共に）と同様に単純であり得る。

【００８３】

このような内臓型携帯デバイスを用いて、看護婦は、ケーブル１９０をコネクター１８０に装着することによって、デバイスを温度センサーに接続し、次いで患者の温度は、予め

決定された形式において表示装置１７４に表示される。コネクター１８０は、好ましくは、異なる患者から読み取るためにデバイスを看護婦がすばやく接続したり切離したりすることを可能にする、雌雄プラグ対のような従来のデバイスである。これは、従来の温度計が安定するまで待つ必要なしに、かつ患者自身がほとんど不快感を抱かずに、看護婦が多数の患者の温度をすばやく読み取ることを可能にする。実際には、看護婦は、患者が寝ている間に、すでにカテーテル処置された患者の温度を取得し得る。

【００８４】

十分に強力なバッテリーを想定すると、システム１５０の内臓型の実施形態はまた、記憶装置だけでなく、内部の電気スイッチに接続されたボタンのような単純な入力デバイスを含み得る。看護婦がボタンを押す時にはいつでも、瞬間に測定される温度は、患者に対して予め決定された数のために指定された記憶部分に記憶される。測定のタイムスタンプはまた、公知の技術を用いて生じられ得、そして各記憶された温度測定と共に記憶され得る。次いで、例えば、何れかの予め決定された様式に従ってボタンを押すことによる、記憶された後の値の呼び出しによって、看護婦は、患者の最近の温度履歴を調べ得る。このワンボタン記憶および呼び出しシステムを実施するために必要とされ、それぞれの異なる患者についてまで分類される、ソフトウエアおよびハードウエアの構成成分は、例えば、多数の設備のよいヨットにおいて見出される従来の電気ハンド方位コンパスにおいて使用される構成成分と類似し得る。

【００８５】

さらなる機能として、この携帯システムは、このシステムが、その記憶された温度情報を、監視コンピューターまたは患者モニターのような別のシステムにダウンロードするのを可能にする、従来の回路を備えられ得る。このような機能が実施される方法は公知である。時間ごとに記されるまたは記されないこのような温度値が、１人以上の患者について記憶され、次いで表示を見るために呼び出される方法はまた周知である。

【００８６】

本発明のいくつかの種々の実施形態は、上記されている。しかし、これらは単に例示にすぎないことが理解されなければならない。本発明は、開示された特定の形態または方法に制限されない；むしろ、本発明は以下の特許請求の範囲の範囲内の全ての変更、等価物および代替物を包含する。

【図面の簡単な説明】

【図１】

図１は、温度を測定するために患者の静脈に挿入される、本発明に従うアクセスデバイス（例えば、ＣＶＣカテーテル）の１つの例を図示する。

【図２】

図２は、温度センサーがカテーテルの管腔内に配置されるが、断熱ギャップによって他の管腔から熱的に断熱される、本発明の実施形態の別の例を図示する。

【図３ａ】

図３ａは、付属の断熱管腔をまた備える専用の管状部材内に提供される温度センサーを図示する。

【図３ｂ】

図３ｂは、カテーテルの適所における図３ａの管腔を示す。

【図４】

図４は、温度センサーとカテーテルの管腔との間に提供される断熱ギャップを有するおよび有さない、血液がカテーテルのしかるべき位置において、温度センサーを通って流動し得る、本発明の実施形態を示す。

【図５】

図５は、温度センサーとカテーテルの管腔との間に提供される断熱ギャップを有するおよび有さない、血液がカテーテルのしかるべき位置において、温度センサーを通って流動し得る、本発明の実施形態を示す。

【図６】

図６ａおよび図６ｂは、温度センサーが断熱部材に取り付けられ、これによってその両方が同じカテーテルの管腔に挿入される、本発明の別の例示的な実施形態の、それぞれ側面図および端面図である。

【図７】

図７ａおよび図７ｂは、温度センサーがカテーテルの外部表面に取り付けられる、本発明の実施形態の、それぞれ側面図および端面図である。

【図８】

図８ａおよび図８ｂは、温度センサーと外部表面との間に配置された血液流動チャネルを有して、温度センサーがカテーテルの外部表面から外に延びるように取り付けられる、本発明の別の実施形態の、それぞれ側面図および端面図である。

【図９】

図９は、温度センサーと血液との間に表面接触を提供するように、温度センサーが、カテーテルの外部表面における開口部を通って延びる直角サーミスタである、本発明の実施形態を図示する。

【図１０】

図１０ａおよび図１０ｂは、温度センサーが、カテーテルの管腔内にセンサーと共に挿入され得る分離断熱部材に取り付けられる、本発明の実施形態を図示する。

【図１１】

図１１は、温度センサーが、カテーテルのようなアクセスデバイスの内部に挿入され得るプローブの先端部に取り付けられる、本発明の実施形態を図示する。

【図１２】

図１２ａおよび図１２ｂは、断熱物質が、カテーテルそれ自体と共押出しされる、本発明の実施形態を図示する。

【図１３】

図１３ａおよび図１３ｂは、温度センサーが、カテーテル本体自体とは別個の部材として初期に形成されるカテーテル先端部内に取り付けられる、本発明の別の実施形態を図示する。

【図１４】

図１４ａおよび図１４ｂは、カテーテルの遠位先端部が、それが患者内に配置される後、分裂し、次いで温度センサーおよび熱塊を備えるカテーテルの管腔が、裂け目のいずれかの側面に展開される、本発明のなお別の実施形態を図示する。

【図１】

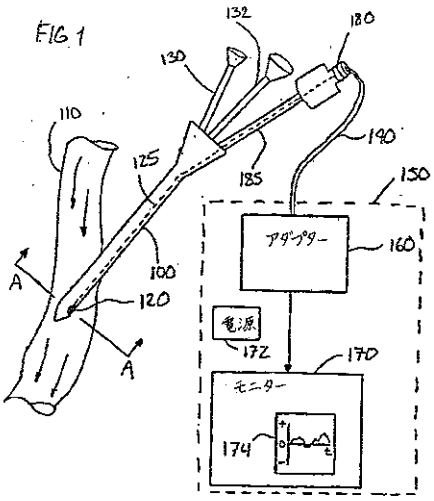


FIG 1
132
180
130
110
140
125
185
150
アダプター
160
100
A
120
電源
172
A
170
モニター
174

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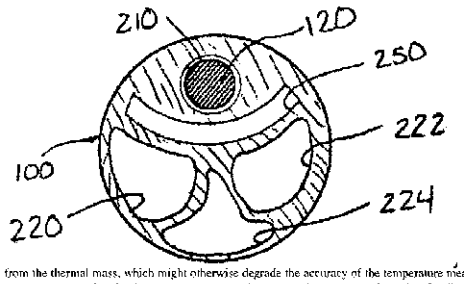
(54) Title: DEVICES AND METHODS FOR MEASURING TEMPERATURE OF A PATIENT



(57) Abstract: An access device such as a catheter, or introducer, or any combination of the above is provided. Within the access device is at least one lumen, channel or instrument that carries or itself is a thermally active mass, such as infusion fluids, control wires, etc. A temperature sensor such as a thermistor is secured to the access device in order to measure the temperature of a temperature medium, typically blood, in a patient. Various insulating lumens, insulating members and mounting and extrusion configurations are provided by the invention to insulate the temperature sensor thermally from the thermal mass, which might otherwise degrade the accuracy of the temperature measurement. The invention also provides an arrangement whereby the temperature sensor is connected to an external monitor for display of the patient's temperature.

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DEVICES AND METHODS FOR MEASURING TEMPERATURE OF A PATIENT

Field of the Invention

This invention relates to methods and devices for measuring the body temperature of a patient in conjunction with the placement within the patient of an access device, for example, a catheter or introducer.

Description of the Related Art

The needs to properly treat a patient and to gain as much information as possible about the physiological state of a patient are often at odds with the desire to reduce discomfort to the patient as much as possible. For example, there is frequently a need both to deliver various medications to a patient, and also to monitor the patient's body temperature. Accordingly, catheters are often inserted into the vasculature of a patient to allow delivery of various medications, hydrating fluids, etc., and to measure blood pressure. The patient's body temperature, however, is monitored with a separate device, which is inserted separately.

Conventional devices for measuring temperature include the well-known oral thermometer, rectal, axillary (armpit), and tympanic (ear) thermometers and probes, as well as Foley catheters (bladder temperature), and nasopharyngeal probes (esophagus) probes. Each of these devices suffers from one or more shortcomings. The first disadvantage is obvious to anyone who has ever been the patient: It is uncomfortable enough to have a catheter inserted into one's vein or artery without also having to have a separate device inserted into one's rectum, bladder, ear or nose, or down one's throat.

The second disadvantage has to do with accuracy - taking a patient's temperature by placing a thermometer under her armpit or in her mouth may cause the least discomfort to the patient, but the temperature value this provides is usually less accurate and much more dependent on placement than temperature measurements of blood in a major vessel.

One way to overcome these disadvantages is to include some form of temperature sensor within the inserted catheter itself. This allows for measurement of the blood temperature, which is in most cases much closer to the patient's actual body core temperature. The problem then arises that other elements of the catheter system may have thermal properties that themselves affect the temperature that the sensor senses. This problem arises in the context of thermodilution systems for measuring cardiac flow. U.S. Patent 4,817,624 (Newbower, 4 April 1989), U.S. Patent 5,176,144 (Yoshikoshi, 5 January 1993), and Published

European Patent Application 0 357 334 B1 (Inventors: Williams, et al., 7 March 1990) for example, describe such systems. As is well known, in such a thermodilution system, the temperature of the cardiac blood flow is modulated according to a predetermined pattern that is created by the injection of an indicator, which is usually either a series of boluses of a relatively colder fluid, or heat. The downstream response to the temperature modulation is sensed by a thermistor and is used to calculate and estimate blood flow.

In systems such as Newhower's, temperature modulation is accomplished by cooling the blood through precisely dosed boluses of a thermally well-controlled fluid colder than the blood. In Williams, modulated cooling of the blood is accomplished using a heat exchange mechanism that does not require actual injection of any bolus into the blood stream. In systems such as Yoshikoshi's the blood is instead heated locally using a heating element that is mounted near the far (distal) end of a cardiac catheter. As before, a thermistor senses the downstream response profile, whose characteristics are used to calculate cardiac flow.

Such thermodilution systems have certain clinical limitations, since they must deal with several problems specific to this application. First is the problem of retrograde flow: If the thermistor is located proximal to the heater or bolus injection port, then the heated/cooled blood will flow back over the catheter tip. The temperature of the catheter itself, which may contain various other lumens, injectates, control wires, etc. can then affect the temperature profile of the thermally modulated blood and degrade the flow calculations.

To overcome this effect, the injection is replaced by a continuous infusion of indicator in order to obtain a new steady-state baseline; however, this is an undesirable clinical limitation due to the volume-loading the patient. Even when the thermistor is located distal relative to the heater/bolus port, this problem may still arise.

These thermodilution system catheters normally have a distal infusion lumen that passes beneath the thermistor or temperature sensor and exits at the tip of the catheter. Since the flow in such an infusion lumen can severely degrade the accuracy of the temperature sensor measurements, the flow is limited to a maximum amount in order for the blood flow measurement to still be accurate. Of course, such a limitation on infusion lumen flow is also undesirable from the clinical perspective.

An analogous problem of insulation arises in other cardiac devices as well, such as the catheter-based cardiac ablation system described in U.S. Patent 5,688,266 (Edwards, et al., 18 November 1997). In Edwards' system, an ablation electrode is used to kill tissue locally using heat, and one or more temperature-sensing elements are used to sense the temperature of the tissue to be ablated and allow precise control of the ablation temperature and time. Isolation,

provided primarily by physical separation, is thus required between the electrode and the temperature sensors; otherwise, the sensors will tend to give readings that are too high.

At least one factor limits the use of these known systems in general use for measuring a patient's body temperature: These systems are not arranged to measure the patient's actual, natural body temperature at all, but rather the temperature of blood or some body tissue whose temperature the system itself has deliberately altered.

There are other devices, such as central venous catheters (CVC), peripheral catheters, and other catheter-like instruments such as introducers. As their names imply, such catheters do not require placement into the heart and are consequently used more frequently in different areas of the hospital. Unlike cardiac catheters, which are often more than 100 cm long and require an introducer for insertion, these devices are seldom longer than about 20-30 cm and can be inserted by the Seldinger technique. A CVC, for example, is often placed in a patient's jugular vein and is used for various infusions, for monitoring blood pressure, etc., through a number of lumens within the device.

An instrument such as a CVC often includes several different lumens which may carry a range of fluids (such as medications and other infusions), as well as instruments such as pressure transducers. Each of these fluids and instruments may be at different temperatures, or may have varying thermal properties, or both. Any measurement of temperature using such a catheter would thus risk serious thermal contamination from other portions of the catheter.

There are at present no known devices such as a CVC, peripheral catheter, or introducer that incorporate an arrangement for measuring blood temperature accurately. Therefore, it would be advantageous to be able to accurately measure temperature in conjunction with such access devices as catheters and introducers while eliminating the need to insert a secondary device into the patient in order to measure temperature, as is the current practice. Such devices would also provide a more accurate and less time-consuming body temperature measurement than non- or less invasive devices. This invention provides such an arrangement.

It would also be advantageous to be able to connect a CVC or similar catheter to a standard patient monitor. Not only would this bring the obvious benefit that the patient's temperature could be viewed at a glance along with other monitored parameters, but it would also make the temperature values available for other processing as needed. Many patient monitors, however, use a signal standard that is compatible with large thermistors or temperature sensors and not compatible with the output of miniature temperature sensors used on pulmonary artery catheters. The use of miniature thermistors is desirable because it allows for catheter sizes to be relatively small. One could of course reprogram the monitors, but such

a solution to the problem would be costly and complicated, and may not be possible or practical in existing monitors. This invention provides an arrangement that allows a catheter-based temperature sensor to be connected to existing monitors.

An additional issue is that many patients, as their condition improves, do not require continuous monitoring of temperature, and therefore, do not require a dedicated connection between the catheter(s) and the monitor. At present, the dedicated connections limit how many patients the system can monitor, and increases the number of cables and connectors needed. It would be advantageous to free the system to allow monitoring more that one patient. This would, for example, enable nurse or physician to have a quick look at the patient's temperature, possibly enter it into the patient's chart, and then move on to other tasks or patients. It would therefore be beneficial to have an arrangement that provides this flexibility and simplicity. This invention does this as well.

Summary of the Invention

In general, the invention provides an access device, such as a catheter, an introducer, or combination of catheters, introducers, probes and the like, that allows more accurate sensing of body temperature, for example, of a temperature medium such as blood, by insulating a temperature sensor from thermal contamination caused by a thermal mass, such as an infusion fluid or an instrument, introduced in portions of the access device. In the preferred embodiment of the invention the access device is a central venous device that includes a temperature sensor such as a thermistor, a thermocouple, etc.

The access device is insertable into the patient at a location of the temperature medium, and the access device includes at least one thermal mass other than the temperature medium. The access device supports the temperature sensor and includes at least one insulating structure insulating the temperature sensor from the thermal mass.

In certain embodiments of the invention, each thermal mass is located within a thermal lumen within the access device. The temperature sensor may be mounted externally to an outer surface of the access device, or within a sensor lumen of the access device. The insulating structure preferably extends between the temperature sensor and each thermal lumen.

The temperature sensor may also be mounted in or on a carrier. The insulating structure is then preferably formed as a barrier within the carrier and the carrier is held in one of the lumens of the access device with the barrier extending between the temperature sensor and the thermal lumen. The carrier may be removably insertable in the lumen of the access device.

In other embodiments of the invention, a pair of ports is formed in an outer wall of the

access device and a flow channel is formed within the access device and extends between the pair of ports. The temperature medium, such as blood, then occupies the flow channel. The flow channel is located between the temperature sensor and the thermal lumen, or between the insulating structure and the thermal lumen, and thereby not only increases thermal contact between the temperature sensor and the temperature medium, but it also thermally isolates the temperature sensor further from the thermal lumen. The flow channel may thus itself form the insulating structure.

In another embodiment of the invention, the access device has an opening in an outer wall and the temperature sensor, when in a deployed position, extends into the opening. This increases thermal contact between the temperature sensor and the temperature medium and further insulates the temperature sensor from the thermal mass. If the temperature sensor is mounted on a carrier, then ends of the carrier may be secured within the access device. The carrier is then positioned between the temperature sensor and each thermal lumen, thereby forming the insulating structure.

The temperature sensor may alternatively be mounted within the carrier, which then protrudes as a loop out through the opening in the outer wall of the access device. The ends of the carrier are then preferably secured within the access device. In this embodiment, the insulating structure comprises a flow channel for the temperature medium, which is formed between the carrier and the access device at the position of the opening, and thus between the temperature sensor and the thermal mass. One advantage of this embodiment is that the temperature sensor is exposed substantially over its entire outer circumference to the temperature medium, via only the carrier.

Alternatively, the temperature sensor may be a right-angle thermistor mounted to extend out of the opening mainly perpendicular to a central axis of the access device.

In another embodiment of the invention, the temperature sensor is adhesively attached to the access device. The adhesive may be dissolvable at body temperature, so that the temperature sensor separates from contact with the access device when in position within the patient.

The access device may include a plurality of lumens, whereby the temperature sensor is mounted within a recess in an insulating member. The insulating member, together with the temperature sensor, are then mounted within one of the lumens of the access device so that the insulating member extends between the temperature sensor and the thermal lumen.

In another embodiment of the invention, the insulating structure includes an insulating material that is co-extruded with the access device and surrounds either at least a portion of each thermal lumen, or the temperature sensor itself.

In yet another embodiment of the invention, the access device has a lumen and a sensor port and the temperature sensor is mounted on a distal tip of a separate device, for example, a probe. The probe is insertable into the lumen of the access device so that the temperature sensor extends through the sensor port.

The insulating structure may also comprises a distal tip of the access device itself. The tip is then preferably formed from an insulating material as a separate member, and the temperature sensor is mounted within the distal tip. Alternatively, the distal tip of the access device may be provided with a lengthwise extending slit. The temperature sensor is then mounted on a first side of the distal tip and at least one thermal lumen carrying the thermal mass extends through a second side of the distal tip. The distal tip, in a deployed position, then separates along the slit, with the first and second sides of the tip being located on either side of the slit.

In another embodiment of the invention, the insulating structure is a lumen or a chamber in the access device that is expandable to increase the distance between the temperature sensor and the thermal mass.

The access device according to the invention is preferably included as a sensing member in a more general system for monitoring the body temperature of a patient. In this system, the access device is insertable into the patient and is connected to a temperature monitor that converts a sensor output signal of the access device into a patient temperature signal and for displaying the patient temperature signal. A connector is then provided to connect the temperature sensor with the temperature monitor.

The system according to the invention preferably further includes an adapter in the temperature monitor. The adapter converts the sensor output signal into a predetermined display format. The temperature monitor may also be provided with a display and a power supply, in which case the entire monitoring system may be implemented as a hand-held, self-contained unit that is portable between different patients.

The invention also encompasses a method for measuring the body temperature of the patient. The main steps of the method according to the invention involve supporting the temperature sensor on the access device; inserting the access device into a blood vessel; introducing at least one thermal mass into the access device; and insulating the temperature sensor from the thermal mass. In the preferred method according to the invention, the thermal mass is introduced via a thermal lumen located within the access device. One then mounts the temperature sensor in a sensor lumen within the access device and forms at least one thermally insulating structure between the temperature sensor and the thermal lumen. In some embodiments, to provide the thermally insulating structure, one may introduce a thermally insulating material into a lumen within the access device.

The invention also comprises a method for manufacturing the access device. In the preferred embodiment, this method comprises extruding the access device, forming a thermal lumen through which a thermal mass is introduced, forming a sensor lumen through which a temperature sensor is introduced, and forming an insulating structure separating the sensor lumen from the thermal mass. In manufacturing the access device, the temperature sensor may be mounted in the sensor lumen at a distal end of the access device. A signal wire is then drawn from the temperature sensor to an external patient monitor.

Brief Description of the Drawings

Figure 1 illustrates one example of an access device according to the invention, such as a CVC catheter, that is inserted into a patient's vein for measuring temperature.

Figure 2 illustrates another example of an embodiment of the invention in which a temperature sensor is located within a lumen of a catheter but is thermally insulated from other lumens by an insulating gap.

Figure 3a illustrates a temperature sensor that is provided within a dedicated tubular member that also includes a built-in insulating lumen.

Figure 3b shows the lumen of Figure 3a in place in the catheter.

Figures 4 and 5 show embodiments of the invention in which blood is allowed to flow past the temperature sensor in place in the catheter, with and without an insulating gap being provided between the temperature sensor and catheter lumens.

Figures 6a and 6b are side and end views, respectively, of another exemplary embodiment of the invention in which the temperature sensor is mounted on an insulating member, whereby both are inserted into the same catheter lumen.

Figures 7a and 7b are side and end views, respectively, of an embodiment of the invention in which the temperature sensor is mounted on the outer surface of the catheter.

Figures 8a and 8b are side and end views, respectively, of another embodiment of the invention in which the temperature sensor is mounted to extend out from the outer surface of the catheter, with a blood flow channel located between the temperature sensor and the outer surface.

Figure 9 illustrates an embodiment of the invention in which the temperature sensor is a right-angle thermistor extending through an opening in the outer surface of the catheter to provide surface contact between the temperature sensor and the blood.

Figures 10a and 10b illustrate an embodiment of the invention in which the temperature sensor is mounted on an a separate insulating member that can be inserted along with the sensor into a catheter lumen.

Figure 11 illustrates an embodiment of the invention in which the temperature sensor is mounted on the tip of a probe that can be inserted into an access device such as a catheter.

Figures 12a and 12b illustrate embodiments of the invention in which an insulating material is co-extruded with the catheter itself.

Figures 13a and 13b illustrate another embodiment of the invention, in which the temperature sensor is mounted within a catheter tip that is initially formed as a member separate from the catheter body itself.

Figures 14a and 14b illustrate still another embodiment of the invention, in which the distal tip of the catheter splits after it is placed within the patient, with the temperature sensor and catheter lumen(s) containing thermal mass then deployed on either sides of the split.

Detailed Description

In broadest terms, this invention provides an arrangement or a device in which a temperature sensor is used with an access device, preferably a vascular access device, for insertion into the body of a patient. This invention also provides various insulating structures that reduce thermal contamination of the temperature sensor from other portions of the interior of the access device. The temperature sensor is designed to sense some temperature medium within the patient's body, for example, blood.

One example of the preferred access device of this invention is a central venous catheter (CVC), but it could be some other instrument that also carries or includes fluids or other devices -- cumulatively "thermal masses" -- that could affect the temperature at the temperature sensor. Examples of other access devices include peripheral catheters, introducers, obturators, and probes. In fact, the term "access device" also contemplates any combination of these devices, such as a combination of one or more introducers, catheters and probes. For example, a catheter is often inserted within an introducer, and either or both could be arranged

according to suitable embodiments of the invention to improve the accuracy of temperature measurements.

In the context of this invention, a thermal mass is any substance or structure carried within the access device that has or could have a temperature and heat capacity such that heat flow into or out of the mass could significantly affect the sensed temperature. Here, "significantly" means so much that the temperature measurement would not be acceptably accurate for clinical use.

As used in this invention an "insulating structure" is any structure that insulates the temperature sensor from a thermal mass. As is described and illustrated below, insulating structures used in the invention, include, but are not limited to, a device lumen or any portion of a device lumen, a channel, a gap, a chamber or just an area provided immediately surrounding the temperature sensor. An insulating structure may also include an insulating material, for example, a ceramic, or a separate device such as a probe that is inserted into or through the access device.

The examples of suitable access devices described below are preferably made of biocampatible polymer materials, since in most cases they will be inserted at least partially into a patient. Polyurethane is the most common material, since it meets all normal requirements for thermal and mechanical stability when in a patient; PVC and Teflon are also acceptable, as well as other conventional materials. The access devices for use with this invention may, moreover, be made of an anti-microbial material or may be covered with material or coating having anti-microbial or thromboresistant properties.

The temperature sensor used in this invention may be any conventional device. The most easily implemented sensor is a thermistor, which is small, widely available and relatively easy to calibrate. Other temperature sensors may, however, also be used. Alternatives include conventional thermocouples and fiber optic temperature sensors. The only requirement is that the sensor should predictably change a measurable physical property, such as its electrical resistance or optical spectrum, in response to changes in temperature, and this change should be detectible externally via an electrical or optical conductor in such a way that temperature can be converted to an electrical signal. These devices, and the way in which their signals are conditioned for further processing are well known.

In the following discussion of the various exemplifying embodiments of the invention, it is assumed merely by way of example that the access device is a CVC, that the temperature sensor is a thermistor, that the catheter is inserted into a body vessel, such as a vein, and that the temperature medium whose temperature is to be determined is blood. The invention will

work just as well with other access devices and sensors, insertion points, and temperature media, as will be obvious to those skilled in the art.

Figure 1 illustrates the general structure of the invention. A catheter 100 is inserted into a patient's vein 110 in the conventional manner. Arrows within the vein 110 indicate flowing blood. A thermistor 120 is positioned at the distal end of the catheter, which includes lumens, channels or tubes through which fluids can be infused into the patient, or which hold other instruments. Two conventional infusion connectors 130, 132, are shown inserted into respective lumens in the catheter. The number of lumens and connectors will of course depend on the particular catheter used and the application. The invention will work with any number of lumens or internal channels in the catheter.

A conductor (shown as the dashed line 125), which forms a signal wire, connects the thermistor electrically (or optically, depending on the type of temperature sensor used) with external conditioning, processing and display circuitry 150. In Figure 1, this exemplary circuitry is shown as including a signal adapter 160 and a patient monitor 170, with a conventional electrical coupler 180 and a guide tube 185 connecting the thermistor signal wire 125 to the external circuitry 150. A conventional power supply 172 is also included, as is a temperature display 174, which may be either a separate display device or simply a portion of an existing monitor display. These features, some of which are optional or can vary depending on the embodiment, are described below in greater detail. Any conventional devices and circuits may be used to communicate the thermistor's 120 output signal to external monitors or displays.

Figure 1 also shows a section line A-A. The description of various embodiments of the catheter according to the invention is illustrated by cross-sectional drawings. Line A-A is the reference line for these cross-sectional views.

Figure 2 illustrates one exemplifying embodiment of the invention. In this embodiment, the thermistor 120 is located within a dedicated opening or lumen 210 within the catheter 100. In this figure, the thermistor lumen 210 is shown as being mainly circular. This is not necessary; any appropriate and desired lumen shape may be used. A circular or at least rounded lumen cross section will in most cases be preferable, however, since standard thermistors frequently are provided as glass-encapsulated beads with a mainly round cross section. Three other lumens 220, 222, 224 are also illustrated (however, any number of lumens may be included).

Assume now that one or more of the lumens 220, 222, 224 carries some fluid (or contains some instrument) with a thermal mass and temperature that could affect the temperature measured by the thermistor 120. For example, an infusion fluid might be

administered through the lumen 220. If the temperature of the fluid is above or below that of the patient's blood, then it could influence the temperature measurement because of the thermal conductivity of the catheter material between the thermistor and the fluid. An additional insulating structure, such as a lumen or gap 250 is therefore preferably extruded in the catheter so as to extend, for example, laterally between the thermistor and all the other lumens 220, 222, 224.

The insulating lumen (gap) 250 is preferably as wide and thick as possible to maximize the degree of thermal insulation of the thermistor, given the minimum permissible material thickness required to maintain stability of the catheter and lumen walls, as well as the maximum outer diameter of the device. The minimum distance between the thermistor lumen 240 and the outer surface of the catheter 100 is, however, preferably as small as possible to ensure the best thermal contact between the thermistor and the surrounding blood.

The insulating structure, such as the lumen or gap 250 of Figure 2 is preferably filled with air, or with some other conventional gas, ceramic pellets, a conventional high-impedance gel, etc., to additionally increase its thermal impedance. The insulating material may also be a strip or layer or similar separate piece of an insulating material that is inserted into the lumen 250. This insulating material may optionally be bonded to the catheter in any known way. The most distal end of the insulating lumen is preferably sealed to prevent inflow of blood and outflow of the thermally insulating gas or other insulating material.

In Figure 2, only one insulating lumen is shown. This is by way of example only. More than one gap may be created, space permitting, to extend between the thermistor and the other lumens to further increase the thermal isolation of the thermistor. Also, the insulating lumen may be of any length -- it may extend through the full length of the access device or any appropriate portion of its length. For example, a portion of the lumen 250 may be used as an infusion or device lumen for introduction of medications or guidewires. A plug may be placed somewhere along the length of such lumen to block off the remainder of the infusion/device lumen so that the remaining portion will act as an insulating structure. The location of the plug must be selected such that the blocked off portion of the infusion/device lumen will be adjacent to the location of the temperature sensor. It will be necessary to provide a side port prior to the location of the plug to allow the infusion/device to exit the access device.

The lumen(s) 250 also does not need to be shaped as a generally laterally extending slit, as shown in Figure 2, although this typically maximizes the isolation of the thermistor from the other lumens. Instead, lumen 250 may be shaped as half-moon or be concentric with the thermistor lumen, or otherwise extruded so as to surround the thermistor lumen 240. Also, the

gap could be created by several mainly cylindrical or otherwise curved lumens spread out between the thermistor and the other lumens 220, 222, 224.

In yet another variation of the insulating lumen 250 it – that is, the catheter material around and defining it – is made elastic enough that the lumen 250 is inflatable after the catheter is inserted into the patient. For example, the lumen 250 could be formed to have flexible webs. Once the catheter is inserted, any suitable pressurizing material, such as air, an inert gas, foam, or some other known thermal resistance material could be pumped into the lumen 250, causing its cross-sectional area to expand and increase the gap or distance between the thermistor and thermal masses. The embodiment facilitates easy insertion of the device by keeping its outer diameter small, since the insulating lumen or structure is expanded only after the device is in place.

The lumens 220, 222, 224 may be used for any conventional purpose. Any or all of them may, for example, carry fluids, or act as channels for guiding other instruments such probes, pressure transducers, etc. Of course, they need not all have the same function – one lumen might be carrying an infusion fluid while another is a channel for an instrument.

Figures 3a and 3b illustrate an embodiment of the invention in which the thermistor 120 and a thermally insulating lumen/gap 350 are provided in a separate mainly tubular member 300 which may be inserted into an existing lumen 310 or channel within the catheter 100. The tubular member 300 is preferably made of the same -- or at least same type of material as the catheter itself, that is, a thermally stable, biocompatible polymer such as polyurethane. This material requirement is not as strict as for the catheter itself, however, since the tubular member is mounted within the catheter. The gap 350, which may be filled with further insulating materials as described above for the lumen 250, is then oriented within the lumen 310 so as to extend between the thermistor and other lumens 320, 322, 324, 326 within the catheter. In order to provide proper orientation of the tubular member within the lumen 310, a key (not shown) such as a rod shaped to conform to the gap 350 could be provided, if needed. The user can then first insert the member 300, with the thermistor, into the lumen 310 and then insert the key into the proximal end of the gap 350 and turn the member 300 into proper alignment.

Figures 4 and 5 illustrate embodiments of the invention in which blood itself is channeled between the thermistor 120 and one or more other lumens 424, which may be carrying sources of thermal "noise" such as infusion fluids. In these embodiments, ports 410, 412 are formed in mainly diametrically opposing portions of the outer wall of the catheter 100 and a channel is formed (as part of the normal extrusion between the two ports). The ports 410, 412 may be arranged anywhere along the circumference of the catheter wall – not just

diametrically opposing -- as long as blood can flow between the temperature sensor and the thermal masses. In Figure 4, the channel has three chambers -- two outer chambers 440, 444 and an intermediate chamber 442 -- through which blood can flow (indicated by arrows passing though the channel). Note that the ports 410, 412 need be formed only in the region of the thermistor 120, and can thus be simple holes or slits cut in the catheter wall. The channel may be formed as a small chamber or it may extend over any length of the catheter as a result needed to simplify the extrusion. Note that a CVC or peripheral catheter, unlike a cardiac catheter, is typically no more than about 30 cm long, so it will in general not be a problem to let the channel extend as far as the other lumen(s) 424.

In the embodiment of the invention shown in Figure 4, the blood is directed to a region -- the intermediate chamber 442 -- immediately adjacent to (that is, extending just under, viewed as in Figure 4) the thermistor 120; the maximum distance separating the thermistor from blood whose temperature is to be measured both above and below can be made as little as the minimum structurally allowable thickness of the catheter material. The blood thus not only helps isolate the thermistor from the lumen(s) 424, but it also better contacts the thermistor thermally, since it does so from two sides instead of just one. A central ridge or tab 470 may be extruded to extend between the two outer chambers 440, 444 and from the lumen 424 toward the thermistor, in order not only to direct the inflowing blood past the thermistor, but also to reduce the amount of blood within the catheter while still allowing for an insulating layer of blood to flow between the thermistor and the lumen(s) 424. The ridge is, however, not necessary to this embodiment of the invention.

In the embodiment of the invention illustrated in Figure 5, the chambers 440, 444 and 442 and the ridge 470 (Figure 4) have been eliminated. Instead, the intermediate chamber 442 is sealed off from the blood flow and thus forms an insulating gap or lumen 550, similar to the lumen/gap 250 in Figure 2. In this embodiment, the blood flowing through the single channel 540 serves mainly to isolate the thermistor thermally from the lumen(s) 424. The lumen/gap 550 provides an additional insulating barrier, although it is not required, especially if the flow of blood through the channel is fast enough to preclude significant heat transfer to or from the thermal mass from which the channel separates the thermistor. Note that another advantage of the embodiment shown in Figure 5 is that the blood in the channel 540 also tends to bring the temperature within the gap 550 to blood temperature and thus further insulates the thermal mass.

In the embodiments of the invention shown in both Figures 4 and 5, the channel 540 may be a limited chamber located near the thermistor itself, or it may be a lumen passing

through any portion of the length of the access device. In either case, the channel 540 itself (with passing blood) serves as an insulating structure.

Figures 6a and 6b are a partially cut-away, side view and an end view, respectively, of another embodiment of the invention in which the thermistor 120 is mounted on a carrier 600, which is preferably made of a biocompatible material and also provides improved thermal insulation. It may be made, for example, of plastic, metal or ceramic. The thermistor may be mounted securely onto the carrier using any conventional material such as a standard adhesive such as potting compound or a non-toxic, moisture-proof, thermally stable glue.

In this embodiment a port is formed as a cut-away opening 605 in the outer wall of the catheter 100. The thermistor is then positioned so as to lie within the opening in the catheter and thus be exposed directly to the blood over most of its surface are, without any portion of the catheter in between. The thermistor's signal wire 125 is also shown in Figure 6a.

The thermistor 120 and its carrier 600 may be inserted into an existing or dedicated lumen 610 in the catheter so that the carrier extends between the thermistor and other lumens 620, 622 or thermal noise sources in the catheter. Note that the opening 605 preferably extends into the lumen 610 to ensure maximum direct contact between the thermistor and the surrounding blood.

The thermistor and carrier 600 may be inserted into the catheter with the thermistor in position in the opening 605 before the catheter is placed within the patient. Alternatively, before insertion, and assuming the carrier is made of a sufficiently flexible material, the thermistor and the far, distal end of the carrier 600 could be allowed to stick out of the opening 605, preferably bent back along the catheter wall and pointing away from the direction of insertion. Once thermistor catheter is placed in the patient, the physician could then pull on the proximal end of the carrier until the thermistor is pulled into place in the opening 605. The distal end of the carrier can then be made short, extending only a short distance from the thermistor, so that only its proximal end would be within the catheter. The carrier, which may be tubular, then forms an insulating gap beneath the thermistor, similar to the gaps 250, 350 and 550 in previous embodiments described above.

Figures 7a and 7b are a partially cut-away, side view and an end view, respectively, of an embodiment of the invention in which the thermistor 120 is mounted on the outer wall of the catheter 100 itself. In order to avoid having the thermistor's signal wire or fiber 125 running along the outer surface of the catheter to the exterior, it is pre-threaded into the catheter 100 through a small hole 705 made in the catheter wall, preferably just behind (proximal relative to) the thermistor 120. The thermistor may be mounted securely onto the catheter using any conventional method or material such as a standard potting compound 710, or a non-toxic,

moisture-proof, thermally stable glue, or a liquefied solution of the catheter material that would solvent bond to the catheter tubing. The potting compound should be spread to cover the hole 705 and at least most of the thermistor, but not so thickly over the thermistor as to interfere with its ability to quickly and accurately respond to temperature changes. In order to reduce the maximum diameter of the catheter and thereby make insertion easier, an indentation could be made in the outer wall of the catheter. The thermistor can then be mounted on the catheter by potting it securely in the indentation (not shown).

In the embodiment of the invention shown in Figures 7a and 7b, it would also be possible to mount the temperature sensor using a non-toxic potting material (or other adhesive) that dissolves when exposed to the blood. Once the catheter is in place, the potting material would therefore dissolve. This would expose the temperature sensor directly to the blood and thus allow for even more accurate temperature measurements. Moreover, the temperature sensor will then tend to separate and move away from the outer wall of the catheter, thereby further insulating it from any thermal masses within the catheter.

This "deployment" action may also be arranged by providing the signal wire with an elbow joint made of a memory metal that is straight (extending in the direction of the catheter) during inserting but that is bent in the relaxed state – when the potting compound dissolves, the joint would relax and bend, thus moving the temperature sensor out from the catheter wall. If it is not practical to form this memory elbow joint in the sensor's signal wire itself, then a piece of memory metal could be attached to the wire where the elbow joint is needed. The sensor could then also be potted within an indentation such as in Figure 6a, so that the catheter could have an outer surface free of protrusions.

As Figures 7a and 7b show, several lumens 700-705 or tubular members are preferably included within the catheter in order to provide insulating gaps between the externally mounted thermistor 120 and the lumen(s) that carry infusions. A single lumen/gap such as the lumen 250 shown and described in reference to Figure 2, or a blood channel similar to the channels shown in Figures 4 and 5 may be included instead of or in addition to the lumens 700-705 to further insulate the thermistor thermally from the lumen 724.

Figures 8a and 8b are a partially cut-away, side view and an end view, respectively, of an embodiment of the invention in which the thermistor 120 is mounted within a short tubular member 800 that protrudes out through an opening 805 made in the outer wall of the catheter 100. The two ends of the tubular member 800 are secured within the catheter using any known technique. A channel 810 is thereby formed between the "loop" of the tubular member 800 and the catheter. Blood will therefore be able to flow substantially completely around the thermistor 120 and will also isolate the thermistor thermally from any interior lumen(s) 824

within the catheter. During insertion of the catheter, the member 800 will preferably lie flat, that is, mostly straight, within the catheter.

Once the catheter is in place, the physician could then insert the thermistor, for example by pushing it in with a wire, and could then push the thermistor and loop of the member 800 out through the opening 805 to deploy the temperature sensor, that is, the thermistor. One way to do this would be to insert a separate instrument that has a bend on it into, for example, a lumen in which the member 800 lies (or simply the interior of the catheter). Twisting the instrument with the bend under the thermistor would then push it out through the opening 805. Alternatively, if the far distal end of the tubular member 800 is fixed in the catheter, and if the member 800 is not too flexible, then it would push out through the opening by the physician pushing the proximal end inward.

Figure 9 illustrates an embodiment of the invention in which the thermistor 120 is a right-angle device, that is, there is a substantially right-angle bend in the rod or wire that connects it to its signal wire 125. Of course, angles of bend other than 90° may also be used – the proper angle of bend will depend on the particular implementation and may be determined using known methods. This right-angle thermistor 120 is then potted securely in an opening 905, similar to the openings 605 and 805, formed in the catheter wall, so that the thermistor extends outward approximately perpendicular to the direction of longitudinal extension (central axis) of the catheter. As before, the minimum amount of potting compound should be used to secure the thermistor, since this will also minimize the impact caused by the compound itself on the thermistor's ability to sense blood temperature. As before, one or more insulating lumens 900 may also be included in the catheter to isolate the thermistor from fluid-carrying lumen(s) 924.

Figures 10a and 10b are a rear and an elevated side view, respectively, of an embodiment of the invention in which the thermistor 120 is mounted so as to lie within a recess in a separate insulating member 1000, which is shaped generally as a partially hollowed out cylinder with a closed, rounded, smooth leading surface and a slot 1010 into which the thermistor can be laid for mounting. The insulating member should be made of a smooth, thermally insulating material such as ceramic, metal, foam or Teflon. Polymers such as polyurethane may also be used, which would make it possible to injection-mold the member 1000. The insulator/thermistor sub-assembly is then inserted, for example, by pushing it in with a rod, into a suitable catheter lumen, such as the lumens 210, 310, 610 shown above for other embodiments of the invention. The slot should thereby be oriented, for example, using a key or similar tool, away from other catheter lumen(s) that carry thermal masses such as fluids and instruments.

In Figure 11, an embodiment of the invention is shown in which the temperature sensor 120 is mounted on the tip 1110 of a separate device, for example, a guidewire or a probe 1100, which can be inserted into the access device 100. To deploy the sensor 120, once the access device is in place, the tip of the probe is inserted into a lumen of the device 100 and is then pushed in until the probe tip 1110 protrudes from a port 1140 that is either cut in the side wall of the catheter (as in some of the other embodiments described above), or is simply the innermost opening of the lumen in which the probe is inserted 1142. (Alternative exit of the tip of the probe is shown as a dashed line.) The probe thus itself acts as a structure that separates (and thus insulates) the temperature sensor from thermal masses. The tip of the probe is preferably curved to a mainly "J"-shape so that it will more easily extend through the port 1140 and away from the thermal influence of the parts of the access device; however, a straight tip is also acceptable. One advantage of this embodiment of the invention is that it could be inserted only if needed, in which case it can be sealed against blood leakage by a conventional hemostasis valve.

Figures 12a and 12b illustrate embodiments of the invention in which an insulating material is co-extruded with the catheter itself. In Figure 12a, the insulating material 1200 is extruded along with the catheter 100 so as to surround an infusion (or instrument-carrying) lumen 1210 or, alternatively, at least a portion of it near the location of the temperature sensor. The insulating material, which may be of any known extrudable type then acts as a thermal barrier between the contents of the lumen 1210 and the temperature sensor 120. In Figure 12b, the insulating material is co-extruded with the catheter so as to form a barrier layer 1220 that surrounds and thereby insulates the temperature sensor 120 itself.

Figures 13a and 13b illustrate yet another embodiment of the invention, in which the temperature sensor 120 is mounted within a catheter tip 1300 that is initially formed as a member separate from the catheter body 100 itself, but is attached or bonded to the distal end of the catheter using, for example, a conventional adhesive. A lumen or through-hole 1310 is then formed in the tip 1300 to act as an extension of any appropriate and desired lumen within the main catheter body 100 to allow uninterrupted flow. The tip 1300 in this embodiment may then be made entirely of a highly insulative material. This completely avoids the need to extrude the insulating member over much or even the entire length of the catheter. It also makes possible the use of different materials in the insulating member and the main catheter body with no need for co-extrusion and without using more expensive material for the entire device.

Figures 14a and 14b illustrate still another embodiment of the invention, in which the distal tip of the catheter 100 has a slit 1400. The temperature sensor 120 is mounted on or in

the distal tip on one side of the slit, whereas the lumen(s) 1410 carrying the thermal mass extend through the tip on the other side of the slit. In short, in this embodiment, the distal tip of the catheter splits after the device is placed within a patient. Before insertion into the patient, the catheter tip 1300 is held together either mechanically, for example, with an internal catch that can be released using a wire that extends out of the proximal end of the catheter, or using an adhesive that dissolves when exposed to blood, or any other appropriate method. While in place, the slit 1400 opens to form an insulating gap (as shown in Figure 14b) between the thermistor 120 and the thermal masses in the lumen(s) 1410.

Several different embodiments of the invention are described above. Common to all of the embodiments, however, is that they implement the method according to the invention by which the body temperature of a patient is sensed by a temperature sensor supported by an access device. As used here, the term "supported" means that the temperature sensor may be mounted on or within the access device; it may be permanently affixed to or within the access device; or it may be removably connected to or inserted into the access device. The term also includes any arrangement, as described for example in reference to Figure 11, in which a temperature sensor is located on a separate device, which is inserted into and extended through the access device.

The access device is inserted into a patient, for example, into a vein, and at least one thermal mass is introduced into the access device. The temperature sensor is insulated thermally from the thermal mass. A signal wire is led from the temperature sensor to an external patient temperature monitor.

The invention also encompasses the method of manufacturing the access device. In most of the embodiments described above, this manufacturing method involves extruding the access device with a plurality of lumens -- one lumen through which a temperature sensor is introduced and a signal wire is led (a sensor lumen), and at least one other lumen for carrying or guiding the thermal mass. The manufacturing method also includes the step of forming an insulating structure that thermally separates the temperature sensor from the thermal mass. The temperature sensor may be permanently or removably mounted at a distal end of the sensor lumen. The temperature sensor may be also mounted in a separate carrier which is placed in the sensor lumen. The manufacturing method may include some other or additional steps according to the embodiments described above, as will be understood by those skilled in the art.

Refer once again to Figure 1. The output signal from a conventional temperature sensor such as the thermistor 120 has well-known characteristics. In general, the output signal is a voltage or current signal whose amplitude is functionally related to the temperature of the

sensor. Moreover, the functional relationship between sensor temperature and the amplitude of the output signal may be linear, but seldom is. In fact, most temperature sensors are individually calibrated by the manufacturer, or require calibration by the user before actual use. However obtained, there is, though, a functional relationship.

Furthermore, in some cases, the temperature output signal may be compatible with input signals of existing patient monitors, but this is not always the case. As a simple example, amplification (scaling) and impedance matching (or impedance isolation) are often required to convert the output signal into a signal form and type that can be processed and displayed for the user.

According to the invention, the functional relationships a) between sensor temperature and the sensor output signal, on the one hand; and b) between output signal characteristics (such as impedance, amplitude range, and whether in the form of a voltage or current) are predetermined in any conventional manner (for example, through normal calibration or by accepting the manufacturer's calibration data). The signal conditioning necessary to implement the relationships is then implemented in the adapter 160. The conditioned signal is then applied to the monitor 170 for processing (if needed) and display.

In some cases, the only signal conditioning required is scaling. This can be done using a conventional resistive network, with the sensor output signal forming the input and the system output signal being taken from an appropriate point in the network. Conventional passive components may then be used to provide any necessary further conditioning such as impedance matching. This has the advantage of implementing the adapter 160 as a totally passive device. In other cases, conventional active components such as operational amplifiers with known resistive, capacitive and inductive feedback and feed-forward elements may be used to implement the signal conversion.

In many cases, the relationship between sensor output and temperature may be too irregular to implement accurately using purely passive or analog components. In these cases, the adapter may be implemented by including in the adapter 160 a conventional analog-to-digital converter (ADC), a microprocessor, and a memory; note that a single conventional digital signal processor combines all these features in one component and may therefore in many applications be a suitable implementation. The relationship between the sensor output and temperature can then be implemented as a look-up table in memory, or as parameters of an approximating function. Using known methods, the microprocessor may then take as an input to the lookup table or approximating function the sensed and ADC-converted sensor output signal and generate the corresponding temperature signal, which, after any further conventional conditioning, is applied to the monitor 170.

In one embodiment of the invention that is particularly useful in a busy setting where only a quick and easy look at a patient's temperature is needed, the entire conditioning, processing and display circuitry 150 is included in a single hand-held unit. In this case, the power supply will typically be batteries and the monitor may be as simple as a conventional, low-power LCD display (along with conventional driving circuitry) showing temperature to, say, single decimal precision.

Using such a self-contained, handheld device, a nurse would connect the device to the temperature sensor by attaching the cable 190 to the connector 180, and the patient's temperature would then be displayed on the display 174 in a predetermined format. The connector 180 is preferably a conventional device such as a male/female plug pair that would allow the nurse to quickly connect and disconnect the device for readings from different patients. This would allow the nurse to take readings of many patients' temperatures quickly, with no need to wait for a conventional thermometer to stabilize, and with little discomfort to the patients themselves. Indeed, the nurse could take an already catheterized patient's temperature while he is asleep.

Assuming sufficiently powerful batteries, the self-contained embodiment of the system 150 could also include not only a memory, but also a simple input device such as a button connected to an internal electrical switch. Whenever the nurse presses the button, the instantaneous measured temperature is stored in the memory portion designated for a predetermined number of values for the patient. A time stamp of the measurement could also be generated using known techniques and stored along with each stored temperature measurement. By later recalling the stored values, for example by pressing the button according to some predetermined pattern, the nurse could then view the patient's recent temperature history. The software and hardware components needed to implement this one-button storage and recall system, even classified for several different patients, may be similar to those used, for example, in conventional electronic hand bearing compasses found on many well-equipped sailboats.

As an additional feature, the hand-held system could be provided with conventional circuitry enabling it to download its stored temperature information to another system such as a supervisory computer or patient monitor. The way in which such a feature is implemented is known. The way in which such temperature values, time-stamped or not, are stored for one or more patients and then recalled for viewing on a display is also well known.

Several different embodiments of the invention have been described above. It should be understood, however, that these are merely illustrative. The invention is not to be limited to

the particular forms or methods disclosed; rather, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the following claims.

CLAIMS

What is claimed is:

1. A device for measuring the temperature of a temperature medium of a patient comprising:

an access device that is insertable into the patient at a location of the temperature medium, including at least one thermal mass other than the temperature medium;

a temperature sensor supported by the access device; and

at least one insulating structure insulating the temperature sensor from the thermal mass.

2. A device as defined in claim 1, wherein each thermal mass is located within a thermal lumen within the access device.

3. A device as defined in claim 2, wherein the temperature sensor is located externally to an outer surface of the access device.

4. A device as defined in claim 2 wherein the temperature sensor is located within a sensor lumen of the access device.

5. A device as defined in claim 2 wherein the temperature sensor is mounted in a carrier.

6. A device as defined in claim 5, in which the access device has more than one lumen, the insulating structure is formed as a barrier within the carrier and the carrier is held in one of the lumens of the access device with the barrier extending between the temperature sensor and the thermal lumen.

7. A device as defined in claim 6, in which the carrier is removably insertable in the lumen of the access device.

8. A device as defined in claim 5, in which the carrier is removably insertable in the lumen of the access device.

9. A device as defined in claim 2, in which each insulating structure extends between the temperature sensor and each thermal lumen.

10. A device as defined in claim 2, further comprising:

a pair of ports formed in an outer wall of the access device;

a flow channel formed within the access device and extending between the pair of ports, in which the temperature medium occupies the flow channel; and

the flow channel is located between the temperature sensor and the thermal lumen, the flow channel thereby both increasing thermal contact between the temperature sensor and the temperature medium and also thermally isolating the temperature sensor further from the thermal lumen.

11. A device as defined in claim 9, wherein the flow channel is the insulating structure.

12. A device as defined in claim 9, wherein the flow channel is located between the insulating structure and the thermal lumen.

13. A device as defined in claim 1, in which:

the access device has an opening in an outer wall; and

the temperature sensor, when in a deployed position, extends into the opening, thereby increasing thermal contact between the temperature sensor and the temperature medium and further insulating temperature sensor from the thermal mass.

14. A device as defined in claim 13, in which:

the temperature sensor is mounted on a carrier;

ends of the carrier are secured within the access device; and

the carrier is positioned between the temperature sensor and each thermal lumen, thereby forming the insulating structure.

15. A device as defined in claim 13, in which the temperature sensor is a right-angle thermistor mounted to extend out of the opening mainly perpendicular to a central axis of the access device.

16. A device as defined in claim 1, in which the temperature sensor is attached to the access device.

17. A device as defined in claim 16, in which the temperature sensor is adhesively attached and the adhesive is dissolvable at body temperature, the temperature sensor thereby increasing contact with the temperature medium when in position within the patient.

18. A device as defined in claim 16, wherein the insulating structure comprises at least one interior insulating lumen formed within the access device and extending between the temperature sensor and the thermal mass.

19. A device as defined in claim 13, wherein:

the temperature sensor is mounted within a carrier which protrudes as a loop out through the opening in the outer wall of the access device and ends of the carrier are secured within the access device;

the insulating structure comprises a flow channel for the temperature medium which is formed between the carrier and the access device at the position of the opening, and thus between the temperature sensor and the thermal mass; and

the temperature sensor is exposed substantially over its entire outer circumference to the temperature medium, via only the carrier.

20. A device as defined in claim 2, wherein

the access device includes a plurality of lumens;

the temperature sensor is mounted within a recess in an insulating member; and

the insulating member, together with the temperature sensor, are mounted within one of the lumens of the access device so that the insulating member extends between the temperature sensor and the thermal lumen.

21. A device as defined in claim 1, wherein the insulating structure includes an insulating material co-extruded with the access device and surrounding at least a portion of each thermal lumen.

22. A device as defined in claim 1, wherein the insulating structure includes an insulating material co-extruded with the access device and surrounding the temperature sensor.

23. A device as defined in claim 1, wherein:
the access device has a lumen and a sensor port; and
the temperature sensor is mounted on a distal tip of a probe which is insertable into the lumen of the access device so that the temperature sensor extends through the sensor port.

24. A device as defined in claim 1, wherein:
the insulating structure comprises a distal tip of the access device formed from an insulating material as a separate member; and
the temperature sensor is mounted within the distal tip.

25. A device as defined in claim 1, in which:
the access device has a distal tip with a lengthwise extending slit;
the temperature sensor is mounted on a first side of the distal tip;
at least one thermal lumen carrying the thermal mass extends through a second side of the distal tip; and
the distal tip, once in a deployed position, is separated along the slit, with the first and second sides of the tip being located on either side of the slit.

26. A device as defined in claim 1, in which:
the access device is a central venous catheter including a plurality of lumens;
the temperature medium is blood;
the thermal mass is an infusion fluid that is carried within one of the lumens; and
the temperature sensor is a thermistor.

27. A device as defined in claim 1 wherein the insulating structure is expandable to increase the distance between the temperature sensor and the thermal mass.

28. A central venous catheter including a temperature sensor.

29. A central venous catheter as defined in claim 28 further comprising an insulating structure insulating the temperature sensor from any part of the catheter that causes thermal contamination.

30. An introducer comprising a temperature sensor.

31. An introducer as defined in claim 30 further comprising an insulating structure insulating the temperature sensor from any part of the introducer that causes thermal contamination.

32. A system for monitoring the body temperature of a patient comprising:

a central venous access device that is insertable into the patient at a location of a temperature medium and that contains at least one thermal mass other than the temperature medium;

a temperature sensor supported by the access device that is located within the patient in thermal contact with the temperature medium and that generates a sensor output signal corresponding to sensed temperature of the temperature medium;

temperature monitoring means for converting the sensor output signal into a patient temperature signal and for displaying the patient temperature signal; and

a connector connecting the temperature sensor with the temperature monitoring means.

33. A system as defined in claim 32, further comprising an adapter, included in the temperature monitoring means, converting the sensor output signal into a predetermined display format.

34. A system as defined in claim 33, in which:

the temperature monitoring means includes a display, a power supply, and an adapter converting the sensor output signal into a predetermined display format; and

the temperature monitoring means is a hand-held, self-contained unit portable between different patients.

35. A method for measuring the body temperature of a patient comprising the following steps:

supporting a temperature sensor on an access device;

inserting the access device into a blood vessel;

introducing at least one thermal mass into the access device; and

insulating the temperature sensor from the thermal mass.

36. A method as defined in claim 35 further providing a signal conductor from the temperature sensor to an external patient temperature monitor.

37. A method as defined in claim 35, further including the following steps:
introducing the thermal mass via a thermal lumen located within the access device;
mounting the temperature sensor in a sensor lumen within the access device; and
forming at least one thermally insulating structure between the temperature sensor and the thermal lumen.

38. A method as defined in claim 35, further including the following steps:
forming the insulating structure as at least one insulating lumen within the access device; and
introducing a thermally insulating material into the insulating lumen.

39. A method for manufacturing an access device including the step of extruding the access device including:
forming a thermal lumen through which a thermal mass is introduced;
forming a sensor lumen through which a temperature sensor is introduced; and
forming an insulating structure separating the sensor lumen and thereby the temperature sensor from the thermal mass.

40. A method as defined in claim 39, further including the steps of mounting the temperature sensor into the sensor lumen at a distal end of the access device and extending a signal wire from the temperature sensor to an external patient monitor.

FIG 1

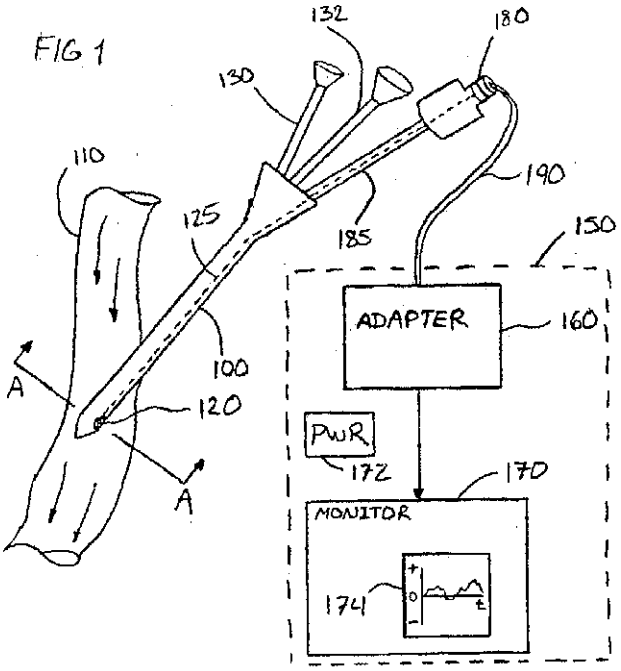


FIG 10a

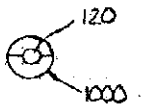


FIG 10b

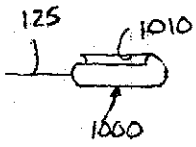


FIG 2

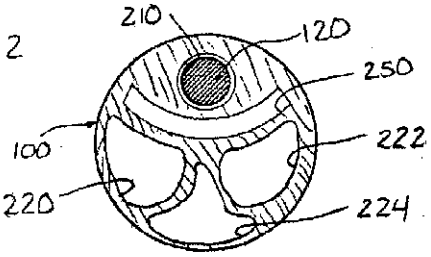


FIG 3a

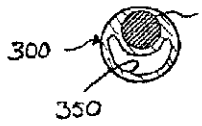


FIG 3b

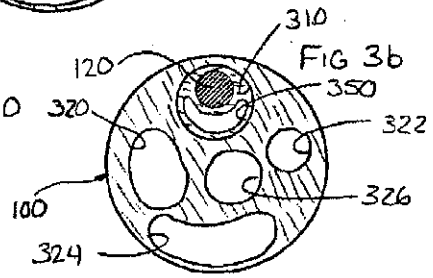


FIG 4

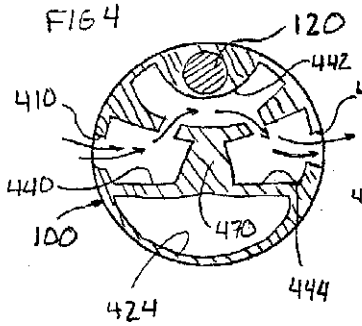


FIG 5

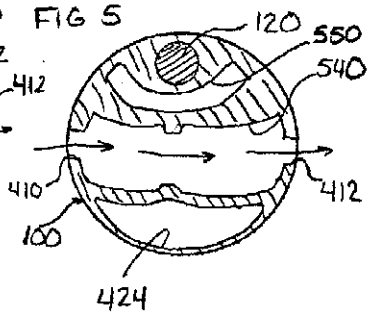


FIG 6a

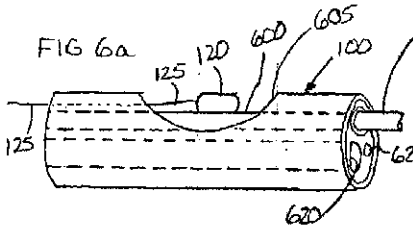


FIG 6b

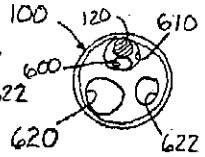


FIG 7a

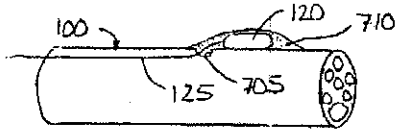


FIG 7b

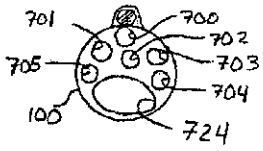


FIG 8a

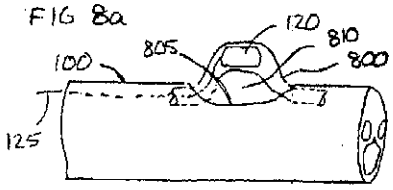


FIG 8b

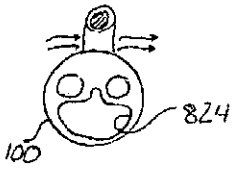


FIG 9

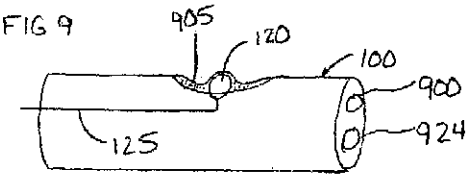


FIG 11

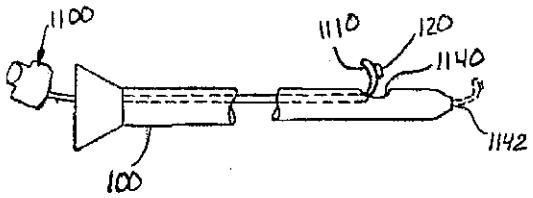


FIG 12a

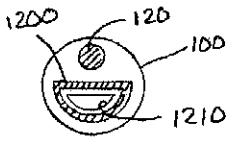


FIG 12b

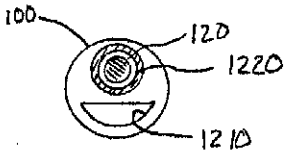


FIG 13a

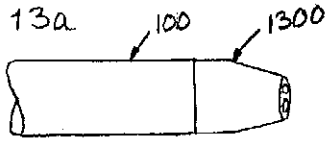


FIG 13b

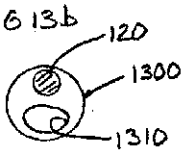


FIG 14a

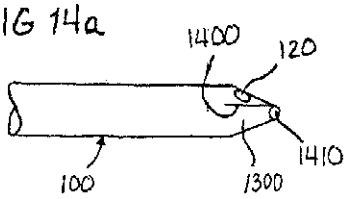
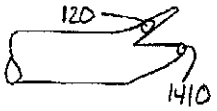


FIG 14b



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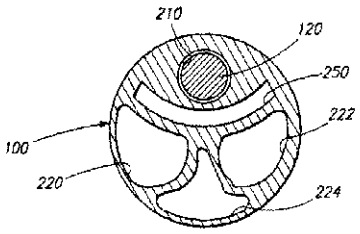
(54) Title: DEVICES AND METHODS FOR MEASURING TEMPERATURE OF A PATIENT



(57) Abstract: An access device such as a catheter, or introducer, or any combination of the above is provided. Within the access device is at least one lumen, channel or instrument that carries or itself is a thermally active mass, such as infusion fluids, control wires, etc. A temperature sensor such as a thermistor is secured to the access device in order to measure the temperature of a temperature medium, typically blood, in a patient. Various insulating lumens, insulating members and mounting and extension configurations are provided by the invention to insulate the temperature sensor thermally from the thermal mass, which might otherwise degrade the accuracy of the temperature measurement. The invention also provides an arrangement whereby the temperature sensor is connected to an external monitor for display of the patient's temperature.

WO 01/052728 A1

DEVICES AND METHODS FOR MEASURING TEMPERATURE OF A PATIENT

Field of the Invention

This invention relates to methods and devices for measuring the body temperature of a patient in conjunction with the placement within the patient of an access device, for example, a catheter or introducer.

Description of the Related Art

The needs to properly treat a patient and to gain as much information as possible about the physiological state of a patient are often at odds with the desire to reduce discomfort to the patient as much as possible. For example, there is frequently a need both to deliver various medications to a patient, and also to monitor the patient's body temperature. Accordingly, catheters are often inserted into the vasculature of a patient to allow delivery of various medications, hydrating fluids, etc., and to measure blood pressure. The patient's body temperature, however, is monitored with a separate device, which is inserted separately.

Conventional devices for measuring temperature include the well-known oral thermometer, rectal, axillary (armpit), and tympanic (ear) thermometers and probes, as well as Foley catheters (bladder temperature), and nasopharyngeal probes (esophagus) probes. Each of those devices suffers from one or more shortcomings. The first disadvantage is obvious to anyone who has ever been the patient: it is uncomfortable enough to have a catheter inserted into one's vein or artery without also having to have a separate device inserted into one's rectum, bladder, ear or nose, or down one's throat.

The second disadvantage has to do with accuracy - taking a patient's temperature by placing a thermometer under her armpit or in her mouth may cause the least discomfort to the patient, but the temperature value this provides is usually less accurate and much more dependent on placement than temperature measurements of blood in a major vessel.

One way to overcome these disadvantages is to include some form of temperature sensor within the inserted catheter itself. This allows for measurement of the blood temperature, which is in most cases much closer to the patient's actual body core temperature. The problem then arises that other elements of the catheter system may have thermal properties that themselves affect the temperature that the sensor senses. This problem arises in the context of thermodilution systems for measuring cardiac flow. U.S. Patent 4,817,624 (Newbower, 4 April 1989), U.S. Patent 5,176,144 (Yoshikoshi, 5 January 1993), and Published

European Patent Application 0 357 334 B1 (Inventors: Williams, et al., 7 March 1990) for example, describe such systems. As is well known, in such a thermodilution system, the temperature of the cardiac blood flow is modulated according to a predetermined pattern that is created by the injection of an indicator, which is usually either a series of boluses of a relatively colder fluid, or heat. The downstream response to the temperature modulation is sensed by a thermistor and is used to calculate and estimate blood flow.

In systems such as Newbower's, temperature modulation is accomplished by cooling the blood through precisely dosed boluses of a thermally well-controlled fluid colder than the blood. In Williams, modulated cooling of the blood is accomplished using a heat exchange mechanism that does not require actual injection of any bolus into the blood stream. In systems such as Yoshikoshi's the blood is instead heated locally using a heating element that is mounted near the far (distal) end of a cardiac catheter. As before, a thermistor senses the downstream response profile, whose characteristics are used to calculate cardiac flow.

Such thermodilution systems have certain clinical limitations, since they must deal with several problems specific to this application. First is the problem of retrograde flow: If the thermistor is located proximal to the heater or bolus injection port, then the heated/cooled blood will flow back over the catheter tip. The temperature of the catheter itself, which may contain various other lumens, injectates, control wires, etc. can then affect the temperature profile of the thermally modulated blood and degrade the flow calculations.

To overcome this effect, the injection is replaced by a continuous infusion of indicator in order to obtain a new steady-state baseline; however, this is an undesirable clinical limitation due to the volume-loading the patient. Even when the thermistor is located distal relative to the heater/bolus port, this problem *may still arise*.

These thermodilution system catheters normally have a distal infusion lumen that passes beneath the thermistor or temperature sensor and exits at the tip of the catheter. Since the flow in such an infusion lumen can severely degrade the accuracy of the temperature sensor measurements, the flow is limited to a maximum amount in order for the blood flow measurement to still be accurate. Of course, such a limitation on infusion lumen flow is also undesirable from the clinical perspective.

An *analogous problem of insulation* arises in other cardiac devices as well, such as the catheter-based cardiac ablation system described in U.S. Patent 5,688,266 (Edwards, et al., 18 November 1997). In Edwards' system, an ablation electrode is used to kill tissue locally using heat, and one or more temperature-sensing elements are used to sense the temperature of the tissue to be ablated and allow precise control of the ablation temperature and time. Isolation,

provided primarily by physical separation is thus required between the electrode and the temperature sensors; otherwise, the sensors will tend to give readings that are too high.

At least one factor limits the use of these known systems in general use for measuring a patient's body temperature: These systems are not arranged to measure the patient's actual, natural body temperature at all, but rather the temperature of blood or some body tissue whose temperature the system itself has deliberately altered.

There are other devices, such as central venous catheters (CVC), peripheral catheters, and other catheter-like instruments such as introducers. As their names imply, such catheters do not require placement into the heart and are consequently used more frequently in different areas of the hospital. Unlike cardiac catheters, which are often more than 100 cm long and require an introducer for insertion, these devices are seldom longer than about 20-30 cm and can be inserted by the Seldinger technique. A CVC, for example, is often placed in a patient's jugular vein and is used for various infusions, for monitoring blood pressure, etc., through a number of lumens within the device.

An instrument such as a CVC often includes several different lumens which may carry a range of fluids (such as medications and other infusions), as well as instruments such as pressure transducers. Each of these fluids and instruments may be at different temperatures, or may have varying thermal properties, or both. Any measurement of temperature using such a catheter would thus risk serious thermal contamination from other portions of the catheter.

There are at present no known devices such as a CVC, peripheral catheter, or introducer that incorporate an arrangement for measuring blood temperature accurately. Therefore, it would be advantageous to be able to accurately measure temperature in conjunction with such access devices as catheters and introducers while eliminating the need to insert a secondary device into the patient in order to measure temperature, as is the current practice. Such devices would also provide a more accurate and less time-consuming body temperature measurement than non- or less invasive devices. This invention provides such an arrangement.

It would also be advantageous to be able to connect a CVC or similar catheter to a standard patient monitor. Not only would this bring the obvious benefit that the patient's temperature could be viewed at a glance along with other monitored parameters, but it would also make the temperature values available for other processing as needed. Many patient monitors, however, use a signal standard that is compatible with large thermistors or temperature sensors and not compatible with the output of miniature temperature sensors used on pulmonary artery catheters. The use of miniature thermistors is desirable because it allows for catheter sizes to be relatively small. One could of course reprogram the monitors, but such

a solution to the problem would be costly and complicated, and may not be possible or practical in existing monitors. This invention provides an arrangement that allows a catheter-based temperature sensor to be connected to existing monitors.

An additional issue is that many patients, as their condition improves, do not require continuous monitoring of temperature, and therefore, do not require a dedicated connection between the catheter(s) and the monitor. At present, the dedicated connections limit how many patients the system can monitor, and increases the number of cables and connectors needed. It would be advantageous to free the system to allow monitoring more that one patient. This would, for example, enable nurse or physician to have a quick look at the patient's temperature, possibly enter it into the patient's chart, and then move on to other tasks or patients. It would therefore be beneficial to have an arrangement that provides this flexibility and simplicity. This invention does this as well.

Summary of the Invention

In general, the invention provides an access device, such as a catheter, an introducer, or combination of catheters, introducers, probes and the like, that allows more accurate sensing of body temperature, for example, of a temperature medium such as blood, by insulating a temperature sensor from thermal contamination caused by a thermal mass, such as an infusion fluid or an instrument, introduced in portions of the access device. In the preferred embodiment of the invention the access device is a central venous device that includes a temperature sensor such as a thermistor, a thermocouple, etc.

The access device is insertable into the patient at a location of the temperature medium, and the access device includes at least one thermal mass other than the temperature medium. The access device supports the temperature sensor and includes at least one insulating structure insulating the temperature sensor from the thermal mass.

In certain embodiments of the invention, each thermal mass is located within a thermal lumen within the access device. The temperature sensor may be mounted externally to an outer surface of the access device, or within a sensor lumen of the access device. The insulating structure preferably extends between the temperature sensor and each thermal lumen.

The temperature sensor may also be mounted in or on a carrier. The insulating structure is then preferably formed as a barrier within the carrier and the carrier is held in one of the lumens of the access device with the barrier extending between the temperature sensor and the thermal lumen. The carrier may be removably insertable in the lumen of the access device.

In other embodiments of the invention, a pair of ports is formed in an outer wall of the

access device and a flow channel is formed within the access device and extends between the pair of ports. The temperature medium, such as blood, then occupies the flow channel. The flow channel is located between the temperature sensor and the thermal lumen, or between the insulating structure and the thermal lumen, and thereby not only increases thermal contact between the temperature sensor and the temperature medium, but it also thermally isolates the temperature sensor further from the thermal lumen. The flow channel may thus itself form the insulating structure.

In another embodiment of the invention, the access device has an opening in an outer wall and the temperature sensor, when in a deployed position, extends into the opening. This increases thermal contact between the temperature sensor and the temperature medium and further insulates the temperature sensor from the thermal mass. If the temperature sensor is mounted on a carrier, then ends of the carrier may be secured within the access device. The carrier is then positioned between the temperature sensor and each thermal lumen, thereby forming the insulating structure.

The temperature sensor may alternatively be mounted within the carrier, which then protrudes as a loop out through the opening in the outer wall of the access device. The ends of the carrier are then preferably secured within the access device. In this embodiment, the insulating structure comprises a flow channel for the temperature medium, which is formed between the carrier and the access device at the position of the opening, and thus between the temperature sensor and the thermal mass. One advantage of this embodiment is that the temperature sensor is exposed substantially over its entire outer circumference to the temperature medium, via only the carrier.

Alternatively, the temperature sensor may be a right-angle thermistor mounted to extend out of the opening mainly perpendicular to a central axis of the access device.

In another embodiment of the invention, the temperature sensor is adhesively attached to the access device. The adhesive may be dissolvable at body temperature, so that the temperature sensor separates from contact with the access device when in position within the patient.

The access device may include a plurality of lumens, whereby the temperature sensor is mounted within a recess in an insulating member. The insulating member, together with the temperature sensor, are then mounted within one of the lumens of the access device so that the insulating member extends between the temperature sensor and the thermal lumen.

In another embodiment of the invention, the insulating structure includes an insulating material that is co-extruded with the access device and surrounds either at least a portion of each thermal lumen, or the temperature sensor itself.

In yet another embodiment of the invention, the access device has a lumen and a sensor port and the temperature sensor is mounted on a distal tip of a separate device, for example, a probe. The probe is insertable into the lumen of the access device so that the temperature sensor extends through the sensor port.

The insulating structure may also comprises a distal tip of the access device itself. The tip is then preferably formed from an insulating material as a separate member, and the temperature sensor is mounted within the distal tip. Alternatively, the distal tip of the access device may be provided with a lengthwise extending slit. The temperature sensor is then mounted on a first side of the distal tip and at least one thermal lumen carrying the thermal mass extends through a second side of the distal tip. The distal tip, in a deployed position, then separates along the slit, with the first and second sides of the tip being located on either side of the slit.

In another embodiment of the invention, the insulating structure is a lumen or a chamber in the access device that is expandable to increase the distance between the temperature sensor and the thermal mass.

The access device according to the invention is preferably included as a sensing member in a more general system for monitoring the body temperature of a patient. In this system, the access device is insertable into the patient and is connected to a temperature monitor that converts a sensor output signal of the access device into a patient temperature signal and for displaying the patient temperature signal. A connector is then provided to connect the temperature sensor with the temperature monitor.

The system according to the invention preferably further includes an adapter in the temperature monitor. The adapter converts the sensor output signal into a predetermined display format. The temperature monitor may also be provided with a display and a power supply, in which case the entire monitoring system may be implemented as a hand-held, self-contained unit that is portable between different patients.

The invention also encompasses a method for measuring the body temperature of the patient. The main steps of the method according to the invention involve supporting the temperature sensor on the access device; inserting the access device into a blood vessel; introducing at least one thermal mass into the access device; and insulating the temperature sensor from the thermal mass. In the preferred method according to the invention, the thermal mass is introduced via a thermal lumen located within the access device. One then mounts the temperature sensor in a sensor lumen within the access device and forms at least one thermally insulating structure between the temperature sensor and the thermal lumen. In some embodiments, to provide the thermally insulating structure, one may introduce a thermally insulating material into a lumen within the access device.

The invention also comprises a method for manufacturing the access device. In the preferred embodiment, this method comprises extruding the access device, forming a thermal lumen through which a thermal mass is introduced, forming a sensor lumen through which a temperature sensor is introduced, and forming an insulating structure separating the sensor lumen from the thermal mass. In manufacturing the access device, the temperature sensor may be mounted in the sensor lumen at a distal end of the access device. A signal wire is then drawn from the temperature sensor to an external patient monitor.

Brief Description of the Drawings

Figure 1 illustrates one example of an access device according to the invention, such as a CVC catheter, that is inserted into a patient's vein for measuring temperature.

Figure 2 illustrates another example of an embodiment of the invention in which a temperature sensor is located within a lumen of a catheter but is thermally insulated from other lumens by an insulating gap.

Figure 3a illustrates a temperature sensor that is provided within a dedicated tubular member that also includes a built-in insulating lumen.

Figure 3b shows the lumen of Figure 3a in place in the catheter.

Figures 4 and 5 show embodiments of the invention in which blood is allowed to flow past the temperature sensor in place in the catheter, with and without an insulating gap being provided between the temperature sensor and catheter lumens.

Figures 6a and 6b are side and end views, respectively, of another examplary embodiment of the invention in which the temperature sensor is mounted on an insulating member, whereby both are inserted into the same catheter lumen.

Figures 7a and 7b are side and end views, respectively, of an embodiment of the invention in which the temperature sensor is mounted on the outer surface of the catheter.

Figures 8a and 8b are side and end views, respectively, of another embodiment of the invention in which the temperature sensor is mounted to extend out from the outer surface of the catheter, with a blood flow channel located between the temperature sensor and the outer surface.

Figure 9 illustrates an embodiment of the invention in which the temperature sensor is a right-angle thermistor extending through an opening in the outer surface of the catheter to provide surface contact between the temperature sensor and the blood.

Figures 10a and 10b illustrate an embodiment of the invention in which the temperature sensor is mounted on an a separate insulating member that can be inserted along with the sensor into a catheter lumen.

Figure 11 illustrates an embodiment of the invention in which the temperature sensor is mounted on the tip of a probe that can be inserted into an access device such as a catheter.

Figures 12a and 12b illustrate embodiments of the invention in which an insulating material is co-extruded with the catheter itself.

Figures 13a and 13b illustrate another embodiment of the invention, in which the temperature sensor is mounted within a catheter tip that is initially formed as a member separate from the catheter body itself.

Figures 14a and 14b illustrate still another embodiment of the invention, in which the distal tip of the catheter splits after it is placed within the patient, with the temperature sensor and catheter lumen(s) containing thermal mass then deployed on either sides of the split.

Detailed Description

In broadest terms, this invention provides an arrangement or a device in which a temperature sensor is used with an access device, preferably a vascular access device, for insertion into the body of a patient. This invention also provides various insulating structures that reduce thermal contamination of the temperature sensor from other portions of the interior of the access device. The temperature sensor is designed to sense some temperature medium within the patient's body, for example, blood.

One example of the preferred access device of this invention is a central venous catheter (CVC), but it could be some other instrument that also carries or includes fluids or other devices -- cumulatively "thermal masses" -- that could affect the temperature at the temperature sensor. Examples of other access devices include peripheral catheters, introducers, obturators, and probes. In fact, the term "access device" also contemplates any combination of these devices, such as a combination of one or more introducers, catheters and probes. For example, a catheter is often inserted within an introducer, and either or both could be arranged

according to suitable embodiments of the invention to improve the accuracy of temperature measurements.

In the context of this invention, a thermal mass is any substance or structure carried within the access device that has or could have a temperature and heat capacity such that heat flow into or out of the mass could significantly affect the sensed temperature. Here, "significantly" means so much that the temperature measurement would not be acceptably accurate for clinical use.

As used in this invention an "insulating structure" is any structure that insulates the temperature sensor from a thermal mass. As is described and illustrated below, insulating structures used in the invention, include, but are not limited to, a device lumen or any portion of a device lumen, a channel, a gap, a chamber or just an area provided immediately surrounding the temperature sensor. An insulating structure may also include an insulating material, for example, a ceramic, or a separate device such as a probe that is inserted into or through the access device.

The examples of suitable access devices described below are preferably made of biocompatible polymer materials, since in most cases they will be inserted at least partially into a patient. Polyurethane is the most common material, since it meets all normal requirements for thermal and mechanical stability when in a patient; PVC and Teflon are also acceptable, as well as other conventional materials. The access devices for use with this invention may, moreover, be made of an anti-microbial material or may be covered with material or coating having anti-microbial or thromboresistant properties.

The temperature sensor used in this invention may be any conventional device. The most easily implemented sensor is a thermistor, which is small, widely available and relatively easy to calibrate. Other temperature sensors may, however, also be used. Alternatives include conventional thermocouples and fiber optic temperature sensors. The only requirement is that the sensor should predictably change a measurable physical property, such as its electrical resistance or optical spectrum, in response to changes in temperature, and this change should be detectible externally via an electrical or optical conductor in such a way that temperature can be converted to an electrical signal. These devices, and the way in which their signals are conditioned for further processing are well known.

In the following discussion of the various exemplifying embodiments of the invention, it is assumed merely by way of example that the access device is a CVC, that the temperature sensor is a thermistor, that the catheter is inserted into a body vessel, such as a vein, and that the temperature medium whose temperature is to be determined is blood. The invention will

work just as well with other access devices and sensors, insertion points, and temperature media, as will be obvious to those skilled in the art.

Figure 1 illustrates the general structure of the invention. A catheter 100 is inserted into a patient's vein 110 in the conventional manner. Arrows within the vein 110 indicate flowing blood. A thermistor 120 is positioned at the distal end of the catheter, which includes lumens, channels or tubes through which fluids can be infused into the patient, or which hold other instruments. Two conventional infusion connectors 130, 132, are shown inserted into respective lumens in the catheter. The number of lumens and connectors will of course depend on the particular catheter used and the application. The invention will work with any number of lumens or internal channels in the catheter.

A conductor (shown as the dashed line 125), which forms a signal wire, connects the thermistor electrically (or optically, depending on the type of temperature sensor used) with external conditioning, processing and display circuitry 150. In Figure 1, this exemplary circuitry is shown as including a signal adapter 160 and a patient monitor 170, with a conventional electrical coupler 180 and a guide tube 185 connecting the thermistor signal wire 125 to the external circuitry 150. A conventional power supply 172 is also included, as is a temperature display 174, which may be either a separate display device or simply a portion of an existing monitor display. These features, some of which are optional or can vary depending on the embodiment, are described below in greater detail. Any conventional devices and circuits may be used to communicate the thermistor's 120 output signal to external monitors or displays.

Figure 1 also shows a section line A-A. The description of various embodiments of the catheter according to the invention is illustrated by cross-sectional drawings. Line A-A is the reference line for these cross-sectional views.

Figure 2 illustrates one exemplifying embodiment of the invention. In this embodiment, the thermistor 120 is located within a dedicated opening or lumen 210 within the catheter 100. In this figure, the thermistor lumen 210 is shown as being mainly circular. This is not necessary; any appropriate and desired lumen shape may be used. A circular or at least rounded lumen cross section will in most cases be preferable, however, since standard thermistors frequently are provided as glass encapsulated beads with a mainly round cross section. Three other lumens 220, 222, 224 are also illustrated (however, any number of lumens may be included).

Assume now that one or more of the lumens 220, 222, 224 carries some fluid (or contains some instrument) with a thermal mass and temperature that could affect the temperature measured by the thermistor 120. For example, an infusion fluid might be

administered through the lumen 220. If the temperature of the fluid is above or below that of the patient's blood, then it could influence the temperature measurement because of the thermal conductivity of the catheter material between the thermistor and the fluid. An additional insulating structure, such as a lumen or gap 250 is therefore preferably extruded in the catheter so as to extend, for example, laterally between the thermistor and all the other lumens 220, 222, 224.

The insulating lumen (gap) 250 is preferably as wide and thick as possible to maximize the degree of thermal insulation of the thermistor, given the minimum permissible material thickness required to maintain stability of the catheter and lumen walls, as well as the maximum outer diameter of the device. The minimum distance between the thermistor lumen 210 and the outer surface of the catheter 100 is, however, preferably as small as possible to ensure the best thermal contact between the thermistor and the surrounding blood.

The insulating structure, such as the lumen or gap 250 of Figure 2 is preferably filled with air, or with some other conventional gas, ceramic pellets, a conventional high-impedance gel, etc., to additionally increase its thermal impedance. The insulating material may also be a strip or layer or similar separate piece of an insulating material that is inserted into the lumen 250. This insulating material may optionally be bonded to the catheter in any known way. The most distal end of the insulating lumen is preferably sealed to prevent inflow of blood and outflow of the thermally insulating gas or other insulating material.

In Figure 2, only one insulating lumen is shown. This is by way of example only. More than one gap may be created, space permitting, to extend between the thermistor and the other lumens to further increase the thermal isolation of the thermistor. Also, the insulating lumen may be of any length -- it may extend through the full length of the access device or any appropriate portion of its length. For example, a portion of the lumen 250 may be used as an infusion or device lumen for introduction of medications or guidewires. A plug may be placed somewhere along the length of such lumen to block off the remainder of the infusion/device lumen so that the remaining portion will act as an insulating structure. The location of the plug must be selected such that the blocked off portion of the infusion/device lumen will be adjacent to the location of the temperature sensor. It will be necessary to provide a side port prior to the location of the plug to allow the infusion/device to exit the access device.

The lumen(s) 250 also does not need to be shaped as a generally laterally extending slit, as shown in Figure 2, although this typically maximizes the isolation of the thermistor from the other lumens. Instead, lumen 250 may be shaped as half-moon or be concentric with the thermistor lumen, or otherwise extruded so as to surround the thermistor lumen 240. Also, the

gap could be created by several mainly cylindrical or otherwise curved lumens spread out between the thermistor and the other lumens 220, 222, 224.

In yet another variation of the insulating lumen 250 it – that is, the catheter material around and defining it – is made elastic enough that the lumen 250 is inflatable after the catheter is inserted into the patient. For example, the lumen 250 could be formed to have flexible webs. Once the catheter is inserted, any suitable pressurizing material, such as air, an inert gas, foam, or some other known thermal resistance material could be pumped into the lumen 250, causing its cross-sectional area to expand and increase the gap or distance between the thermistor and thermal masses. The embodiment facilitates easy insertion of the device by keeping its outer diameter small, since the insulating lumen or structure is expanded only after the device is in place.

The lumens 220, 222, 224 may be used for any conventional purpose. Any or all of them may, for example, carry fluids, or act as channels for guiding other instruments such probes, pressure transducers, etc. Of course, they need not all have the same function – one lumen might be carrying an infusion fluid while another is a channel for an instrument.

Figures 3a and 3b illustrate an embodiment of the invention in which the thermistor 120 and a thermally insulating lumen/gap 350 are provided in a separate mainly tubular member 300 which may be inserted into an existing lumen 310 or channel within the catheter 100. The tubular member 300 is preferably made of the same -- or at least same type of material as the catheter itself, that is, a thermally stable, biocompatible polymer such as polyurethane. This material requirement is not as strict as for the catheter itself, however, since the tubular member is mounted within the catheter. The gap 350, which may be filled with further insulating materials as described above for the lumen 250, is then oriented within the lumen 310 so as to extend between the thermistor and other lumens 320, 322, 324, 326 within the catheter. In order to provide proper orientation of the tubular member within the lumen 310, a key (not shown) such as a rod shaped to conform to the gap 350 could be provided, if needed. The user can then first insert the member 300, with the thermistor, into the lumen 310 and then insert the key into the proximal end of the gap 350 and turn the member 300 into proper alignment.

Figures 4 and 5 illustrate embodiments of the invention in which blood itself is channeled between the thermistor 120 and one or more other lumens 424, which may be carrying sources of thermal "noise" such as infusion fluids. In these embodiments, ports 410, 412 are formed in mainly diametrically opposing portions of the outer wall of the catheter 100 and a channel is formed (as part of the normal extrusion between the two ports). The ports 410, 412 may be arranged anywhere along the circumference of the catheter wall – not just

diametrically opposing -- as long as blood can flow between the temperature sensor and the thermal masses. In Figure 4, the channel has three chambers -- two outer chambers 440, 444 and an intermediate chamber 442 - through which blood can flow (indicated by arrows passing though the channel). Note that the ports 410, 412 need be formed only in the region of the thermistor 120, and can thus be simple holes or slits cut in the catheter wall. The channel may be formed as a small chamber or it may extend over any length of the catheter as a result needed to simplify the extrusion. Note that a CVC or peripheral catheter, unlike a cardiac catheter, is typically no more than about 30 cm long, so it will in general not be a problem to let the channel extend as far as the other lumen(s) 424.

In the embodiment of the invention shown in Figure 4, the blood is directed to a region -- the intermediate chamber 442 -- immediately adjacent to (that is, extending just under, viewed as in Figure 4) the thermistor 120; the maximum distance separating the thermistor from blood whose temperature is to be measured both above and below can be made as little as the minimum structurally allowable thickness of the catheter material. The blood thus not only helps isolate the thermistor from the lumen(s) 424, but it also better contacts the thermistor thermally, since it does so from two sides instead of just one. A central ridge or tab 470 may be extended to extend between the two outer chambers 440, 444 and from the lumen 424 toward the thermistor, in order not only to direct the inflowing blood past the thermistor, but also to reduce the amount of blood within the catheter while still allowing for an insulating layer of blood to flow between the thermistor and the lumen(s) 424. The ridge is, however, not necessary to this embodiment of the invention.

In the embodiment of the invention illustrated in Figure 5, the chambers 440, 444 and 442 and the ridge 470 (Figure 4) have been eliminated. Instead, the intermediate chamber 442 is sealed off from the blood flow and thus forms an insulating gap or lumen 550, similar to the lumen/gap 250 in Figure 2. In this embodiment, the blood flowing through the single channel 540 serves mainly to isolate the thermistor thermally from the lumen(s) 424. The lumen/gap 550 provides an additional insulating barrier, although it is not required, especially if the flow of blood through the channel is fast enough to preclude significant heat transfer to or from the thermal mass from which the channel separates the thermistor. Note that another advantage of the embodiment shown in Figure 5 is that the blood in the channel 540 also tends to bring the temperature within the gap 550 to blood temperature and thus further insulates the thermal mass.

In the embodiments of the invention shown in both Figures 4 and 5, the channel 540 may be a limited chamber located near the thermistor itself, or it may be a lumen passing

through any portion of the length of the access device. In either case, the channel 540 itself (with passing blood) serves as an insulating structure.

Figures 6a and 6b are a partially cut-away, side view and an end view, respectively, of another embodiment of the invention in which the thermistor 120 is mounted on a carrier 600, which is preferably made of a biocompatible material and also provides improved thermal insulation. It may be made, for example, of plastic, metal or ceramic. The thermistor may be mounted securely onto the carrier using any conventional material such as a standard adhesive such as potting compound or a non-toxic, moisture-proof, thermally stable glue.

In this embodiment a port is formed as a cut-away opening 605 in the outer wall of the catheter 100. The thermistor is then positioned so as to lie within the opening in the catheter and thus be exposed directly to the blood over most of its surface are, without any portion of the catheter in between. The thermistor's signal wire 125 is also shown in Figure 6a.

The thermistor 120 and its carrier 600 may be inserted into an existing or dedicated lumen 610 in the catheter so that the carrier extends between the thermistor and other lumens 620, 622 or thermal noise sources in the catheter. Note that the opening 605 preferably extends into the lumen 610 to ensure maximum direct contact between the thermistor and the surrounding blood.

The thermistor and carrier 600 may be inserted into the catheter with the thermistor in position in the opening 605 before the catheter is placed within the patient. Alternatively, before insertion, and assuming the carrier is made of a sufficiently flexible material, the thermistor and the far, distal end of the carrier 600 could be allowed to stick out of the opening 605, preferably bent back along the catheter wall and pointing away from the direction of insertion. Once thermistor catheter is placed in the patient, the physician could then pull on the proximal end of the carrier until the thermistor is pulled into place in the opening 605. The distal end of the carrier can then be made short, extending only a short distance from the thermistor, so that only its proximal end would be within the catheter. The carrier, which may be tubular, then forms an insulating gap beneath the thermistor, similar to the gaps 250, 350 and 550 in previous embodiments described above.

Figures 7a and 7b are a partially cut-away, side view and an end view, respectively, of an embodiment of the invention in which the thermistor 120 is mounted on the outer wall of the catheter 100 itself. In order to avoid having the thermistor's signal wire or fiber 125 running along the outer surface of the catheter to the exterior, it is pre-threaded into the catheter 100 through a small hole 705 made in the catheter wall, preferably just behind (proximal relative to) the thermistor 120. The thermistor may be mounted securely onto the catheter using any conventional method or material such as a standard potting compound 710, or a non-toxic,

moisture-proof, thermally stable glue, or a liquefied solution of the catheter material that would solvent bond to the catheter tubing. The potting compound should be spread to cover the hole 705 and at least most of the thermistor, but not so thickly over the thermistor as to interfere with its ability to quickly and accurately respond to temperature changes. In order to reduce the maximum diameter of the catheter and thereby make insertion easier, an indentation could be made in the outer wall of the catheter. The thermistor can then be mounted on the catheter by potting it securely in the indentation (not shown).

In the embodiment of the invention shown in Figures 7a and 7b, it would also be possible to mount the temperature sensor using a non-toxic potting material (or other adhesive) that dissolves when exposed to the blood. Once the catheter is in place, the potting material would therefore dissolve. This would expose the temperature sensor directly to the blood and thus allow for even more accurate temperature measurements. Moreover, the temperature sensor will then tend to separate and move away from the outer wall of the catheter, thereby further insulating it from any thermal masses within the catheter.

This "deployment" action may also be arranged by providing the signal wire with an elbow joint made of a memory metal that is straight (extending in the direction of the catheter) during inserting but that is bent in the relaxed state – when the potting compound dissolves, the joint would relax and bend, thus moving the temperature sensor out from the catheter wall. If it is not practical to form this memory elbow joint in the sensor's signal wire itself, then a piece of memory metal could be attached to the wire where the elbow joint is needed. The sensor could then also be potted within an indentation such as in Figure 6a, so that the catheter could have an outer surface free of protrusions.

As Figures 7a and 7b show, several lumens 700-705 or tubular members are preferably included within the catheter in order to provide insulating gaps between the externally mounted thermistor 120 and the lumen(s) that carry infusions. A single lumen/gap such as the lumen 250 shown and described in reference to Figure 2, or a blood channel similar to the channels shown in Figures 4 and 5 may be included instead of or in addition to the lumens 700-705 to further insulate the thermistor thermally from the lumen 724.

Figures 8a and 8b are a partially cut-away, side view and an end view, respectively, of an embodiment of the invention in which the thermistor 120 is mounted within a short tubular member 800 that protrudes out through an opening 805 made in the outer wall of the catheter 100. The two ends of the tubular member 800 are secured within the catheter using any known technique. A channel 810 is thereby formed between the "loop" of the tubular member 800 and the catheter. Blood will therefore be able to flow substantially completely around the thermistor 120 and will also isolate the thermistor thermally from any interior lumen(s) 824

within the catheter. During insertion of the catheter, the member 800 will preferably lie flat, that is, mostly straight, within the catheter.

Once the catheter is in place, the physician could then insert the thermistor, for example by pushing it in with a wire, and could then push the thermistor and loop of the member 800 out through the opening 805 to deploy the temperature sensor, that is, the thermistor. One way to do this would be to insert a separate instrument that has a bend on it into, for example, a lumen in which the member 800 lies (or simply the interior of the catheter). Twisting the instrument with the bend under the thermistor would then push it out through the opening 805. Alternatively, if the far distal end of the tubular member 800 is fixed in the catheter, and if the member 800 is not too flexible, then it would push out through the opening by the physician pushing the proximal end inward.

Figure 9 illustrates an embodiment of the invention in which the thermistor 120 is a right-angle device, that is, there is a substantially right-angle bend in the rod or wire that connects it to its signal wire 125. Of course, angles of bend other than 90° may also be used – the proper angle of bend will depend on the particular implementation and may be determined using known methods. This right-angle thermistor 120 is then potted securely in an opening 905, similar to the openings 605 and 805, formed in the catheter wall, so that the thermistor extends outward approximately perpendicular to the direction of longitudinal extension (central axis) of the catheter. As before, the minimum amount of potting compound should be used to secure the thermistor, since this will also minimize the impact caused by the compound itself on the thermistor's ability to sense blood temperature. As before, one or more insulating lumens 900 may also be included in the catheter to isolate the thermistor from fluid-carrying lumen(s) 924.

Figures 10a and 10b are a rear and an elevated side view, respectively, of an embodiment of the invention in which the thermistor 120 is mounted so as to lie within a recess in a separate insulating member 1000, which is shaped generally as a partially hollowed out cylinder with a closed, rounded, smooth leading surface and a slot 1010 into which the thermistor can be laid for mounting. The insulating member should be made of a smooth, thermally insulating material such as ceramic, metal, foam or Teflon. Polymers such as polyurethane may also be used, which would make it possible to injection-mold the member 1000. The insulator/thermistor sub-assembly is then inserted, for example, by pushing it in with a rod, into a suitable catheter lumen, such as the lumens 210, 310, 610 shown above for other embodiments of the invention. The slot should thereby be oriented, for example, using a key or similar tool, away from other catheter lumen(s) that carry thermal masses such as fluids and instruments.

In Figure 11, an embodiment of the invention is shown in which the temperature sensor 120 is mounted on the tip 1110 of a separate device, for example, a guidewire or a probe 1100, which can be inserted into the access device 100. To deploy the sensor 120, once the access device is in place, the tip of the probe is inserted into a lumen of the device 100 and is then pushed in until the probe tip 1110 protrudes from a port 1140 that is either cut in the side wall of the catheter (as in some of the other embodiments described above), or is simply the innermost opening of the lumen in which the probe is inserted 1142. (Alternative exit of the tip of the probe is shown as a dashed line.) The probe thus itself acts as a structure that separates (and thus insulates) the temperature sensor from thermal masses. The tip of the probe is preferably curved to a mainly "J"-shape so that it will more easily extend through the port 1140 and away from the thermal influence of the parts of the access device; however, a straight tip is also acceptable. One advantage of this embodiment of the invention is that it could be inserted only if needed, in which case it can be sealed against blood leakage by a conventional hemostasis valve.

Figures 12a and 12b illustrate embodiments of the invention in which an insulating material is co-extruded with the catheter itself. In Figure 12a, the insulating material 1200 is extruded along with the catheter 100 so as to surround an infusion (or instrument-carrying) lumen 1210 or, alternatively, at least a portion of it near the location of the temperature sensor. The insulating material, which may be of any known extrudable type then acts as a thermal barrier between the contents of the lumen 1210 and the temperature sensor 120. In Figure 12b, the insulating material is co-extruded with the catheter so as to form a barrier layer 1220 that surrounds and thereby insulates the temperature sensor 120 itself.

Figures 13a and 13b illustrate yet another embodiment of the invention, in which the temperature sensor 120 is mounted within a catheter tip 1300 that is initially formed as a member separate from the catheter body 100 itself, but is attached or bonded to the distal end of the catheter using, for example, a conventional adhesive. A lumen or through-hole 1310 is then formed in the tip 1300 to act as an extension of any appropriate and desired lumen within the main catheter body 100 to allow uninterrupted flow. The tip 1300 in this embodiment may then be made entirely of a highly insulative material. This completely avoids the need to extrude the insulating member over much or even the entire length of the catheter. It also makes possible the use of different materials in the insulating member and the main catheter body with no need for co-extrusion and without using more expensive material for the entire device.

Figures 14a and 14b illustrate still another embodiment of the invention, in which the distal tip of the catheter 100 has a slit 1400. The temperature sensor 120 is mounted on or in

the distal tip on one side of the slit, whereas the lumen(s) 1410 carrying the thermal mass extend through the tip on the other side of the slit. In short, in this embodiment, the distal tip of the catheter splits after the device is placed within a patient. Before insertion into the patient, the catheter tip 1300 is held together either mechanically, for example, with an internal catch that can be released using a wire that extends out of the proximal end of the catheter, or using an adhesive that dissolves when exposed to blood, or any other appropriate method. While in place, the slit 1400 opens to form an insulating gap (as shown in Figure 14b) between the thermistor 120 and the thermal masses in the lumen(s) 1410.

Several different embodiments of the invention are described above. Common to all of the embodiments, however, is that they implement the method according to the invention by which the body temperature of a patient is sensed by a temperature sensor supported by an access device. As used here, the term "supported" means that the temperature sensor may be mounted on or within the access device; it may be permanently affixed to or within the access device; or it may be removably connected to or inserted into the access device. The term also includes any arrangement, as described for example in reference to Figure 11, in which a temperature sensor is located on a separate device, which is inserted into and extended through the access device.

The access device is inserted into a patient, for example, into a vein, and at least one thermal mass is introduced into the access device. The temperature sensor is insulated thermally from the thermal mass. A signal wire is led from the temperature sensor to an external patient temperature monitor.

The invention also encompasses the method of manufacturing the access device. In most of the embodiments described above, this manufacturing method involves extruding the access device with a plurality of lumens – one lumen through which a temperature sensor is introduced and a signal wire is led (a sensor lumen), and at least one other lumen for carrying or guiding the thermal mass. The manufacturing method also includes the step of forming an insulating structure that thermally separates the temperature sensor from the thermal mass. The temperature sensor may be permanently or removably mounted at a distal end of the sensor lumen. The temperature sensor may be also mounted in a separate carrier which is placed in the sensor lumen. The manufacturing method may include some other or additional steps according to the embodiments described above, as will be understood by those skilled in the art.

Refer once again to Figure 1. The output signal from a conventional temperature sensor such as the thermistor 120 has well-known characteristics. In general, the output signal is a voltage or current signal whose amplitude is functionally related to the temperature of the

sensor. Moreover, the functional relationship between sensor temperature and the amplitude of the output signal may be linear, but seldom is. In fact, most temperature sensors are individually calibrated by the manufacturer, or require calibration by the user before actual use. However obtained, there is, though, a functional relationship.

Furthermore, in some cases, the temperature output signal may be compatible with input signals of existing patient monitors, but this is not always the case. As a simple example, amplification (scaling) and impedance matching (or impedance isolation) are often required to convert the output signal into a signal form and type that can be processed and displayed for the user.

According to the invention, the functional relationships a) between sensor temperature and the sensor output signal, on the one hand; and b) between output signal characteristics (such as impedance, amplitude range, and whether in the form of a voltage or current) are predetermined in any conventional manner (for example, through normal calibration or by accepting the manufacturer's calibration data). The signal conditioning necessary to implement the relationships is then implemented in the adapter 160. The conditioned signal is then applied to the monitor 170 for processing (if needed) and display.

In some cases, the only signal conditioning required is scaling. This can be done using a conventional resistive network, with the sensor output signal forming the input and the system output signal being taken from an appropriate point in the network. Conventional passive components may then be used to provide any necessary further conditioning such as impedance matching. This has the advantage of implementing the adapter 160 as a totally passive device. In other cases, conventional active components such as operational amplifiers with known resistive, capacitive and inductive feedback and feed-forward elements may be used to implement the signal conversion.

In many cases, the relationship between sensor output and temperature may be too irregular to implement accurately using purely passive or analog components. In these cases, the adapter may be implemented by including in the adapter 160 a conventional analog-to-digital converter (ADC), a microprocessor, and a memory; note that a single conventional digital signal processor combines all these features in one component and may therefore in many applications be a suitable implementation. The relationship between the sensor output and temperature can then be implemented as a look-up table in memory, or as parameters of an approximating function. Using known methods, the microprocessor may then take as an input to the lookup table or approximating function the sensed and ADC-converted sensor output signal and generate the corresponding temperature signal, which, after any further conventional conditioning, is applied to the monitor 170.

In one embodiment of the invention that is particularly useful in a busy setting where only a quick and easy look at a patient's temperature is needed, the entire conditioning, processing and display circuitry 150 is included in a single hand-held unit. In this case, the power supply will typically be batteries and the monitor may be as simple as a conventional, low-power LCD display (along with conventional driving circuitry) showing temperature to, say, single decimal precision.

Using such a self-contained, handheld device, a nurse would connect the device to the temperature sensor by attaching the cable 190 to the connector 180, and the patient's temperature would then be displayed on the display 174 in a predetermined format. The connector 180 is preferably a conventional device such as a male/female plug pair that would allow the nurse to quickly connect and disconnect the device for readings from different patients. This would allow the nurse to take readings of many patients' temperatures quickly, with no need to wait for a conventional thermometer to stabilize, and with little discomfort to the patients themselves. Indeed, the nurse could take an already catheterized patient's temperature while he is asleep.

Assuming sufficiently powerful batteries, the self-contained embodiment of the system 150 could also include not only a memory, but also a simple input device such as a button connected to an internal electrical switch. Whenever the nurse presses the button, the instantaneous measured temperature is stored in the memory portion designated for a predetermined number of values for the patient. A time stamp of the measurement could also be generated using known techniques and stored along with each stored temperature measurement. By later recalling the stored values, for example by pressing the button according to some predetermined pattern, the nurse could then view the patient's recent temperature history. The software and hardware components needed to implement this one-button storage and recall system, even classified for several different patients, may be similar to those used, for example, in conventional electronic hand bearing compasses found on many well-equipped sailboats.

As an additional feature, the hand-held system could be provided with conventional circuitry enabling it to download its stored temperature information to another system such as a supervisory computer or patient monitor. The way in which such a feature is implemented is known. The way in which such temperature values, time-stamped or not, are stored for one or more patients and then recalled for viewing on a display is also well known.

Several different embodiments of the invention have been described above. It should be understood, however, that these are merely illustrative. The invention is not to be limited to

the particular forms or methods disclosed; rather, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the following claims.

CLAIMS

What is claimed is:

1. A device for measuring the temperature of a temperature medium of a patient comprising:

an access device that is insertable into the patient at a location of the temperature medium, including at least one thermal mass other than the temperature medium;

a temperature sensor supported by the access device; and

at least one insulating structure insulating the temperature sensor from the thermal mass.

2. A device as defined in claim 1, wherein each thermal mass is located within a thermal lumen within the access device.

3. A device as defined in claim 2, wherein the temperature sensor is located externally to an outer surface of the access device.

4. A device as defined in claim 2 wherein the temperature sensor is located within a sensor lumen of the access device.

5. A device as defined in claim 2 wherein the temperature sensor is mounted in a carrier.

6. A device as defined in claim 5, in which the access device has more than one lumen, the insulating structure is formed as a barrier within the carrier and the carrier is held in one of the lumens of the access device with the barrier extending between the temperature sensor and the thermal lumen.

7. A device as defined in claim 6, in which the carrier is removably insertable in the lumen of the access device.

8. A device as defined in claim 5, in which the carrier is removably insertable in the lumen of the access device.

9. A device as defined in claim 2, in which each insulating structure extends between the temperature sensor and each thermal lumen.

10. A device as defined in claim 2, further comprising:

a pair of ports formed in an outer wall of the access device;

a flow channel formed within the access device and extending between the pair of ports, in which the temperature medium occupies the flow channel; and

the flow channel is located between the temperature sensor and the thermal lumen, the flow channel thereby both increasing thermal contact between the temperature sensor and the temperature medium and also thermally isolating the temperature sensor further from the thermal lumen.

11. A device as defined in claim 9, wherein the flow channel is the insulating structure.

12. A device as defined in claim 9, wherein the flow channel is located between the insulating structure and the thermal lumen.

13. A device as defined in claim 1, in which:

the access device has an opening in an outer wall; and

the temperature sensor, when in a deployed position, extends into the opening, thereby increasing thermal contact between the temperature sensor and the temperature medium and further insulating temperature sensor from the thermal mass.

14. A device as defined in claim 13, in which:

the temperature sensor is mounted on a carrier;

ends of the carrier are secured within the access device; and

the carrier is positioned between the temperature sensor and each thermal lumen, thereby forming the insulating structure.

15. A device as defined in claim 13, in which the temperature sensor is a right-angle thermistor mounted to extend out of the opening mainly perpendicular to a central axis of the access device.

16. A device as defined in claim 1, in which the temperature sensor is attached to the access device.

17. A device as defined in claim 16, in which the temperature sensor is adhesively attached and the adhesive is dissolvable at body temperature, the temperature sensor thereby increasing contact with the temperature medium when in position within the patient.

18. A device as defined in claim 16, wherein the insulating structure comprises at least one interior insulating lumen formed within the access device and extending between the temperature sensor and the thermal mass.

19. A device as defined in claim 13, wherein:

the temperature sensor is mounted within a carrier which protrudes as a loop out through the opening in the outer wall of the access device and ends of the carrier are secured within the access device;

the insulating structure comprises a flow channel for the temperature medium which is formed between the carrier and the access device at the position of the opening, and thus between the temperature sensor and the thermal mass; and

the temperature sensor is exposed substantially over its entire outer circumference to the temperature medium, via only the carrier.

20. A device as defined in claim 2, wherein

the access device includes a plurality of lumens;

the temperature sensor is mounted within a recess in an insulating member; and

the insulating member, together with the temperature sensor, are mounted within one of the lumens of the access device so that the insulating member extends between the temperature sensor and the thermal lumen.

21. A device as defined in claim 1, wherein the insulating structure includes an insulating material co-extruded with the access device and surrounding at least a portion of each thermal lumen.

22. A device as defined in claim 1, wherein the insulating structure includes an insulating material co-extruded with the access device and surrounding the temperature sensor.

23. A device as defined in claim 1, wherein:

the access device has a lumen and a sensor port; and

the temperature sensor is mounted on a distal tip of a probe which is insertable into the lumen of the access device so that the temperature sensor extends through the sensor port.

24. A device as defined in claim 1, wherein:

the insulating structure comprises a distal tip of the access device formed from an insulating material as a separate member; and

the temperature sensor is mounted within the distal tip.

25. A device as defined in claim 1, in which:

the access device has a distal tip with a lengthwise extending slit;

the temperature sensor is mounted on a first side of the distal tip;

at least one thermal lumen carrying the thermal mass extends through a second side of the distal tip; and

the distal tip, once in a deployed position, is separated along the slit, with the first and second sides of the tip being located on either side of the slit.

26. A device as defined in claim 1, in which:

the access device is a central venous catheter including a plurality of lumens;

the temperature medium is blood;

the thermal mass is an infusion fluid that is carried within one of the lumens; and

the temperature sensor is a thermistor.

27. A device as defined in claim 1 wherein the insulating structure is expandable to increase the distance between the temperature sensor and the thermal mass.

28. A central venous catheter including a temperature sensor.

29. A central venous catheter as defined in claim 28 further comprising an insulating structure insulating the temperature sensor from any part of the catheter that causes thermal contamination.

30. An introducer comprising a temperature sensor.

31. An introducer as defined in claim 30 further comprising an insulating structure insulating the temperature sensor from any part of the introducer that causes thermal contamination.

32. A system for monitoring the body temperature of a patient comprising:

a central venous access device that is insertable into the patient at a location of a temperature medium and that contains at least one thermal mass other than the temperature medium;

a temperature sensor supported by the access device that is located within the patient in thermal contact with the temperature medium and that generates a sensor output signal corresponding to sensed temperature of the temperature medium;

temperature monitoring means for converting the sensor output signal into a patient temperature signal and for displaying the patient temperature signal; and

a connector connecting the temperature sensor with the temperature monitoring means.

33. A system as defined in claim 32, further comprising an adapter, included in the temperature monitoring means, converting the sensor output signal into a predetermined display format.

34. A system as defined in claim 33, in which:

the temperature monitoring means includes a display, a power supply, and an adapter converting the sensor output signal into a predetermined display format; and

the temperature monitoring means is a hand-held, self-contained unit portable between different patients.

35. A method for measuring the body temperature of a patient comprising the following steps:

supporting a temperature sensor on an access device;

inserting the access device into a blood vessel;

introducing at least one thermal mass into the access device; and

insulating the temperature sensor from the thermal mass.

36. A method as defined in claim 35 further providing a signal conductor from the temperature sensor to an external patient temperature monitor.

37. A method as defined in claim 35, further including the following steps:

introducing the thermal mass via a thermal lumen located within the access device;

mounting the temperature sensor in a sensor lumen within the access device; and

forming at least one thermally insulating structure between the temperature sensor and the thermal lumen.

38. A method as defined in claim 35, further including the following steps:

forming the insulating structure as at least one insulating lumen within the access device; and

introducing a thermally insulating material into the insulating lumen.

39. A method for manufacturing an access device including the step of extruding the access device including:

forming a thermal lumen through which a thermal mass is introduced;

forming a sensor lumen through which a temperature sensor is introduced; and

forming an insulating structure separating the sensor lumen and thereby the temperature sensor from the thermal mass.

40. A method as defined in claim 39, further including the steps of mounting the temperature sensor into the sensor lumen at a distal end of the access device and extending a signal wire from the temperature sensor to an external patient monitor.

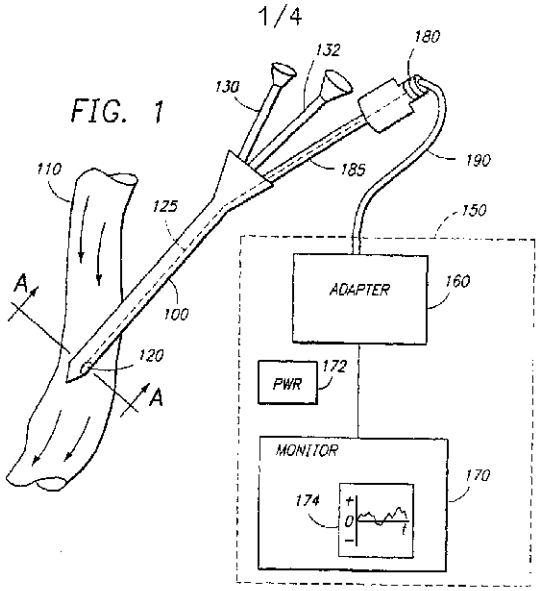


FIG. 1

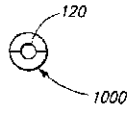


FIG. 10a

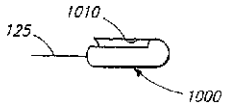
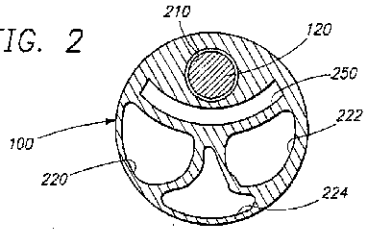


FIG. 10b

FIG. 2



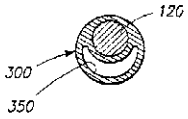


FIG. 3a

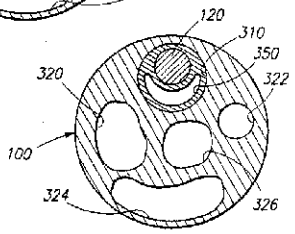


FIG. 3b

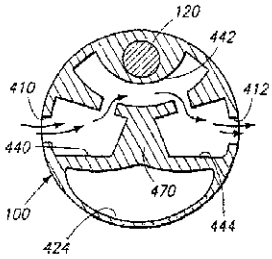


FIG. 4

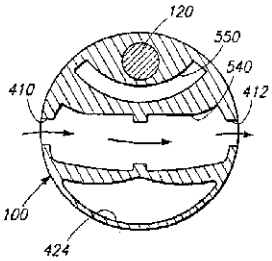


FIG. 5

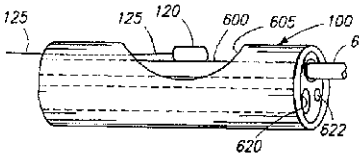


FIG. 6a

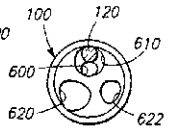


FIG. 6b

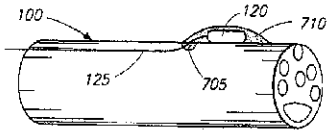


FIG. 7a

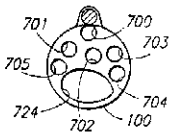


FIG. 7b

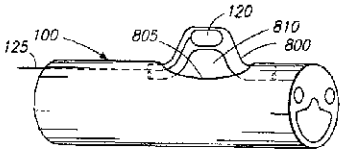


FIG. 8a

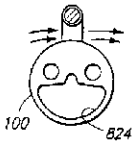


FIG. 8b

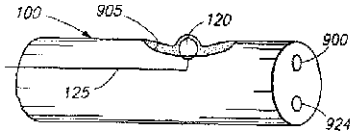


FIG. 9

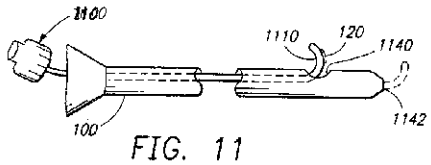


FIG. 11

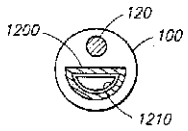


FIG. 12a

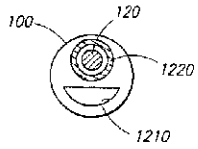


FIG. 12b

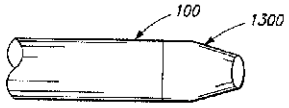


FIG. 13a

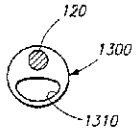


FIG. 13b

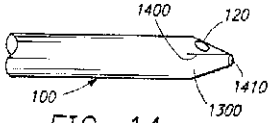


FIG. 14a

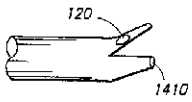


FIG. 14b

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/01902

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/028

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 7 A61B

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 practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 176 144 A (TSUCHIDA KOUJI ET AL) 5 January 1993 (1993-01-05) column 4, line 24 - line 65 column 5, line 33 - line 48 column 8, line 9 - line 30 ---	1-3,9, 13,16, 24,26, 28-31, 39,40
X	US 5 279 598 A (SHEAFF CHARLES M) 18 January 1994 (1994-01-18) column 3, line 29 - line 37 column 4, line 8 - line 47 --- -/--	1-3,9, 16,18, 24,26, 28-34, 39,40

[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in 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 document 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
19 June 2001	25/06/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Martelli, L

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int[illegible]ial Application No
PCT/US 01/01902

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 92 17111 A (BAXTER INT) 15 October 1992 (1992-10-15) page 7, line 30 -page 9, line 12	1,2,4-6, 9,13,14, 16,20, 23,24, 26, 28-31, 39,40
X	US 3 446 073 A (AUPHAN MICHEL ET AL) 27 May 1969 (1969-05-27) column 3, line 74 -column 4, line 5 column 4, line 25 - line 41 figure 5	1-3,9, 16,24, 26, 28-34, 39,40

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int nal Application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5176144 A	05-01-1993	DE 69017567 D	13-04-1995
		DE 69017567 T	06-07-1995
		EP 0417781 A	20-03-1991
		JP 2044112 C	09-04-1996
		JP 3176029 A	31-07-1991
		JP 7063454 B	12-07-1995
US 5279598 A	18-01-1994	US 5211631 A	18-05-1993
WO 9217111 A	15-10-1992	US 5271410 A	21-12-1993
		CA 2107478 A	02-10-1992
		EP 0579728 A	26-01-1994
		EP 0719519 A	03-07-1996
		JP 3057329 B	26-06-2000
		JP 6506133 T	14-07-1994
US 3446073 A	27-05-1969	BE 684619 A	26-01-1967
		DE 1573047 A	10-09-1970
		DE 1903673 A	28-08-1969
		FR 92750 E	20-12-1968
		FR 93944 E	06-06-1969
		FR 2085523 A	24-12-1971
		FR 2088168 A	07-01-1972
		FR 1452215 A	14-12-1966
		GB 1329051 A	05-09-1973
		GB 1155826 A	25-06-1969
		JP 50013666 B	21-05-1975
		NL 6610470 A,B	30-01-1967
		SE 347107 B	24-07-1972

Form PCT/ISA/210 (patent family annex) (July 1992)

フロントページの続き

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专利名称(译)	用于测量患者体温的装置和方法		
公开(公告)号	JP2004500909A	公开(公告)日	2004-01-15
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优先权	09/484555 2000-01-18 US		
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外部链接	Espacenet		

摘要(译)

进入装置如导管或导引器，或以上的任何组合。进入装置的内部是运输热活性物质（例如输注流体）或其自身的至少一个内腔，通道或器械，控制线等。在进入装置中保留有温度传感器，例如热敏电阻，以测量患者温度介质（通常为血液）的温度。本发明提供了各种绝缘内腔，绝缘构件以及安装和挤压装置，以便使温度传感器与热质块热绝缘，或者降低温度测量的准确性。本发明还提供了一种装置，其中温度传感器连接到外部监视器以用于患者的温度指示。