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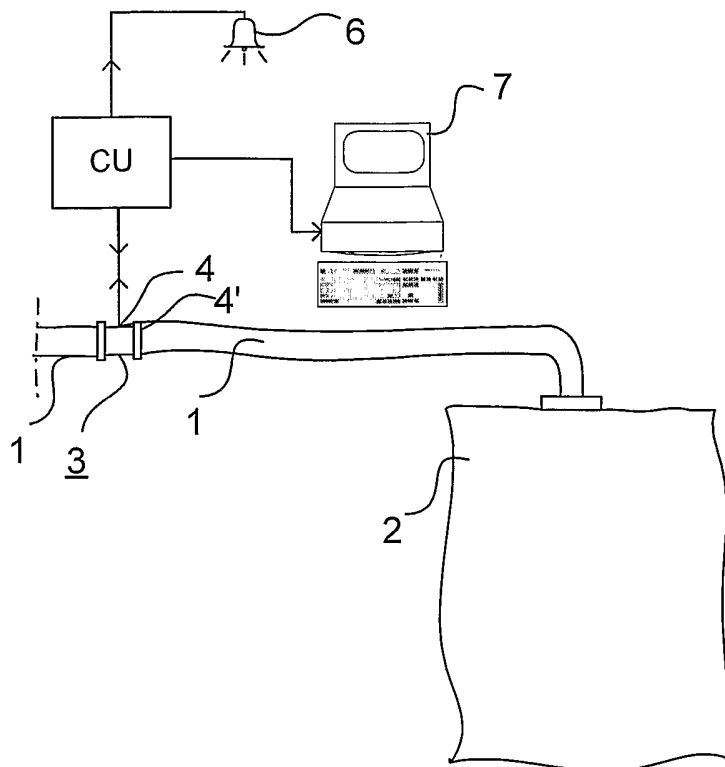
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(54) Title: METHODS, ARRANGEMENT, DEVICE AND SENSOR FOR URINE FLOW MEASUREMENT



(57) Abstract: A method for measuring urine flow out of a patient, urine from the patient being taken out from a urinary tract catheter arrangement and a tubing (1) connected to said arrangement, comprising arranging a sensor (3) in said tubing to determine urine flow in said tubing. The method is especially characterized by the step of reducing the delay time for detecting urine flow transients by reducing the urine volume between the sensor (3) and the patient by locating the sensor close to the catheter arrangement outlet. The invention further relates to a further method, an arrangement, a device and a sensor for urine flow measurement.



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

FIELD OF THE INVENTION

The present invention relates to two methods for measuring urine flow, urine preferably being extracted from the bladder of a patient by means of a catheter.

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The invention further relates to an arrangement and a device for measuring urine flow from a patient.

The invention also relates to a sensor for measuring urine flow.

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BACKGROUND OF THE INVENTION

Normally, the urine production of a patient is measured by the urine output from the patient by means of a catheter and collecting the urine produced in a transparent plastic bag provided with a scale. The volume collected is noted regularly over time and a mean production rate value may be calculated intermittently. According to one embodiment of such a known arrangement, two alternative collecting chambers of different size are provided, one small chamber that can be emptied hourly into a larger chamber that holds the daily urine, in order to cover different production rates over time.

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These kinds of arrangements do not provide a quick continuous measurement, requires considerable nurse capacity and further causes a large dead volume between the patient and the measuring device.

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In certain cases there is a strong need to obtain an early indication of the urine flow. For example, when a patient turns into a state of shock, or an acute renal failure develops, there is a need for an early indication. The kidneys are very sensitive to lack of blood supply and may easily be damaged. This will compromise the fluid balance of the body since the kidneys control the fluid and electrolyte absorption need for a proper body fluid balance. The waste is discarded in the urine output. In a shock

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state the urine output may be very low indicating that the kidney is not supplied with enough blood or that the fluid absorption is high. The urine production may also be very high due to a failing kidney that cannot concentrate the urine, with the potential risk of losing both liquid and electrolytes which will endanger life. Patient undergoing ventilatory treatment are known to retain fluid and are subjected for close follow up of urine production rate.

Attempts have also been made to measure the urine flow by sensor means. However, these arrangements are complicated and space-consuming and are attached to the bed of the patient and thereby require a large urine volume with less accuracy of the measurements.

Known from WO 01/60255 is an arrangement for a patient monitor comprising a sensor arranged between a patient urinary tract catheter and a urine collection container and arranged to measure at least the flow or volume of the patient's urine output or the momentary urine flow and/or the volume cumulated in a unit of time. According to one embodiment, a flow sensor based on heat transfer is suggested, a sensor arrangement comprising two temperature-measuring sensors, and an intermediately located heater being suggested. According to other embodiments, sensors based on ultrasound, a turbine or pressure difference are suggested.

These known arrangements do still not provide a sufficiently short lag time and fast and continuous measurement over a short time period of the real urine production, especially at low production rates.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a method, a device and a sensor for measuring urine flow near the patient in order to eliminate problems related to large dead volumes.

A further object is to provide a sensor, which to a substantial part is disposable, i.e. a single patient arrangement.

These and other objects are obtained by means of a method, a device and a sensor as
5 specified in the respective independent claims.

Preferred embodiments are specified in the corresponding dependent claims.

The features and advantages indicated above will be more fully understood from the
10 following detailed description of the invention, taken together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

15 In the drawings:

Fig. 1 is a schematically shown device according to the invention, comprising a urine flow sensor according to the invention,

Fig. 2 is a schematic sectional view of a first embodiment of a urine flow sensor according to the invention,

20 Fig. 3 is a schematic sectional view of a second embodiment of a urine flow sensor according to the invention,

Fig. 4 is a detail of a sensor according to said second embodiment,

Fig. 5 is a sensor signal-applied power vs. time diagram for a sensor according to said second embodiment and

25 Fig. 6 is an example of a thermistor electrical chart.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A tubing 1, Fig. 1, is arranged for taking out urine from a patient, not shown, the
30 urine being intended to be collected in e.g. a plastic bag 2 and the tubing being con-

nected to a urinary tract catheter arrangement or the like, not shown, leading urine out of the patient.

5 The urine flow through the tubing is intended to be taken as a measure of the urine production of the patient measured as volume/time, e.g. ml/s.

10 In the tubing, preferably close to the urine outlet from the patient, a urine flow sensor 3 according to the present invention is arranged. The sensor is shown arranged as a disconnectable part 4 of the total urine tubing and collection arrangement by means of end connection parts 4' and is in this case preferably arranged and intended to be disposable. Alternatively, the sensor may be provided integrated with the tubing, the sensor and the tubing to be provided as a unit. Signals from the sensor are taken out via leads 5 and transferred to a central unit CU comprising calibration data etc. and arranged for successive calculation of the urine production of the patient for e.g. patient monitoring and transfer to a patient information management system, this being indicated by an alarm bell 6 and a computer monitor 7.

20 According to a first embodiment of the sensor 3, Fig. 2, the sensor comprises a channel 8, through which urine from the patient is intended to flow, as indicated by arrow 8'. The channel is preferably formed of a rigid channel wall material 9 and surrounded by a preferably concentric thermal insulating layer 10, a thermal shield. Heating means 11 are arranged for heating urine at a predetermined spot 12 in the channel. The heating means are arranged to generate successive heating pulses in order to obtain successive measurements. Heating may be achieved e.g. by means of induction heating, not shown, of a channel wall material element or of a separate element, arranged in the channel, by an induction coil, so that urine in the channel is heated by said elements, respectively. According to another embodiment, shown in Fig. 2, a heating element 11' is arranged in the channel for direct electrical heating of urine in the channel.

Further according to the embodiment in Fig. 2, two thermistors 14, 15 are arranged in the channel for measuring the temperature development as a result of said heating, one 14 being located upstream of the predetermined spot and one 15 being located downstream of the predetermined spot.

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In order to obtain complete urine filling of the channel irrespective of the channel orientation and, thus, also complete filling at the predetermined spot, a unidirectional valve 16 is preferably arranged in a downstream configuration of the predetermined spot, the valve preferably providing a certain forward flow resistance, preferably in combination with a threshold pressure arrangement (not shown). Preferably, such a valve 16 is also arranged upstream of said spot.

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Furthermore, according to a preferred embodiment, ventilation means 17, e.g. two membrane arrangements 17, e.g. one upstream and one downstream of said predetermined spot, are provided, by means of which gas, such as air, in the urine is intended to escape. Preferably, the ventilation means are provided upstream as well as downstream of the pair of thermistors.

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According to a second embodiment, Fig. 3, instead of two thermistors and heating means between them, a single thermistor 18 comprising heating means, i.e. a self-heated thermistor, is provided. By means of such an arrangement, each measurement is intended to comprise heating the thermistor by a heating pulse and following the temperature development by means of the thermistor. For this purpose, the heat capacity of the thermistor is preferably low in order to obtain a quick cooling response, the thermistor being cooled by the urine as a function of the urine flow. Also according to this embodiment, unidirectional valves 16 and ventilation means 17 are preferably provided.

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An important issue according to the invention is to reduce environmental influence on the predetermined results. For this purpose, the sensor, at least to a major part 19

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covering the predetermined spot and the thermistor arrangement, is provided with a thermal shield, comprising a concentric insulation layer 20 in order to provide well-defined heating and temperature development conditions. Further, it is preferred to cover the sensor, at least said major part with a thermally conductive, preferably
5 metallic layer 21, which, i.a., serves to even out the temperature profile along the sensor.

According to the embodiment of Fig. 4, a preferably metallic layer 21 with excellent thermal conductivity is applied between the sensor channel wall and the insulation
10 layer 20. Of course, a layer 21 with good thermal conductivity may very well also be applied outside of the insulation layer.

According to the embodiments described so far, heating and substantially electrical heating have been used. However, it is also possible to obtain a well-defined and
15 detectable temperature change pulse by means of cooling, and temperature changes may be obtained by other means than electrical. Thus, a temperature change may be obtained by adding a liquid, e.g. water, to the urine, said liquid being hotter or colder than the urine in order to obtain a heating or cooling pulse, respectively. Further, according to still another embodiment, a Peltier element is used to generate cooling
20 pulses. Furthermore, in order to take care of heat generated by operation of such an element, it may be appropriate to operate the element as a cooling element for a first period of time and as a heating element for a second period of time, and so on.

According to yet another embodiment, extremely low detection levels, such as zero
25 flow, may be detected, such flow could indicate zero kidney function, which is important medical information of another kind than urine production rate. For zero flow detection, an embodiment with two thermistors and intermediately located heating means is preferred since the balance between the two thermistor signals may be used to indicate an extremely low or zero flow.

As regards materials to be chosen for the different parts of a sensor according to the invention, some examples are given below.

5 The ventilation means 17 may be made of a polyethylene sheet, heat-treated and fibrous, e.g. TYVEK[®], made by du Pont, to be welded to the tubing. The insulation layer 20 may be made of a cellular polymer, such as Frigolite. The tubing may be made of polyethylene. The metallic layer with excellent heat conductivity may be made of aluminium or an aluminium alloy.

10 The function of the device and the sensor as well as the method according to the invention should to a considerable extent be apparent from the description given above.

15 A basic feature is that the sensor is applied near the patient so that the "dead volume" between the patient and the sensor is kept very low. The flow measured by the sensor will then give a correct picture of the flow produced by the patient and delay time in detecting urine flow transients, i.e. changes in patient urine production rate, will be kept very short.

20 Further, a preferred important feature is that the sensor is disposable either separately, so that for a certain tubing the sensor may be exchanged, or together with a certain amount of the tubing, so that a sensor tubing kit may be exchanged. According to preferred embodiments, the sensor may be provided to quite a low cost for fulfilment of criteria for disposability.

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Furthermore, according to the basic inventive idea, the flow measurements are based on a study of the urine temperature development after a temperature change generation pulse, introduced in the urine, where the change may be a positive one, i.e. a temperature increase pulse due to heating, or a negative one, i.e. a temperature de-

crease pulse due to cooling. Therefore, when applicable, the description below is referring to "temperature change generation" instead of merely "heating".

5 By temperature change generating means at a predetermined spot, an increased or decreased temperature is introduced directly in the urine flow passing the predetermined spot. According to a preferred embodiment, an increased temperature is introduced in a self-heated thermistor, arranged at said spot for sensing the temperature development during and after heating. In the first case, the temperature development is sensed downstream of the predetermined spot by a thermistor, the temperature preferably also being sensed upstream of said spot by another thermistor
10 as a reference.

The connection between measured temperature development after a temperature change and the urine flow is determined by means of calibration, using known urine
15 flows and temperature change generation conditions, and the corresponding connection or connections are registered and used in the central unit or the like to obtain a urine flow value for a measured temperature development.

20 According to a first embodiment, Fig. 2, each measurement comprises a temperature change pulse of a certain predetermined time duration, detection of a temperature change downstream of the predetermined spot and detection of the time between the temperature change generation pulse and the occurrence of said temperature change. The flow is obtained from calibration data.

25 According to a second embodiment, Fig. 2, the difference or ratio between two thermistor signals, one upstream and one downstream, is integrated during a predetermined time period after predetermined temperature change generation, the flow being obtained from calibration data.

Embodiments according to Fig. 3 may be performed in a corresponding way. Thus, according to a first such embodiment, predetermined heating of the thermistor is performed and the time for obtaining a predetermined temperature drop is measured, the temperature development being measured by means of the thermistor and the flow being determined from calibration data.

According to a second such embodiment, the temperature development after predetermined heating is detected by the thermistor, and the output signal is integrated for a predetermined time period, the flow then being determined from calibration data.

Such an embodiment is illustrated in fig. 5, showing substantially one period of measurement. At t_1 , a square heating power pulse P is applied and ending at t_2 . This results in a temperature development detection curve S of the thermistor arrangement. At t_3 , the signal has nearly returned to a steady state level L . Thermistor signal S , i.e. deviation from steady state level L , integrated between t_2 and t_3 , is used to measure the flow and is calibrated against the flow. Such an integral is useful over a wide range of flows, i.e. with a reasonably high signal to noise ratio at each flow. Said integral is expected to decrease monotonously with flow.

The length T of a measurement period is preferably allowed to vary with the flow since time $t_3 - t_2$ for the signal S to return to, nearly, the steady state level L does vary strongly with flow. Between t_3 and T there is a predetermined delay period, typically 5 seconds, in order to make sure that the steady state level is arrived at before start of the next period.

The width $t_2 - t_1$ of the heating power pulse is preferably predetermined for reasons of simplicity. If, however, necessary, e.g. if extra power would be necessary at high flows, the width, alternatively, may be automatically adjusted, so the thermistor temperature rise, compared to the steady state level, at t_2 is predetermined.

Further according to preferred embodiments, the steady state level is individually defined for each period of measurement. The steady state level L corresponds to the temperature of the measured liquid (urine) and may therefore vary in time.

- 5 L is, thus, redefined after the delay period, when the output signal of the thermistor has reached the steady state. ie before the start of the new period of measurement.

Furthermore, since the steady state level L indicates the temperature of the liquid (urine), L can be used to perform real-time temperature compensation of the
10 measurement. Temperature compensation is needed as the measured signal varies with the temperature of the liquid.

As indicated above, there are a number of designs beside the preferred one illustrated in Fig. 5. Thus, e.g. the time for a predetermined thermistor temperature rise due
15 to a predetermined applied heating pulse amplitude may be used as a measure of flow.

According to embodiments sometimes preferred and indicated above, more than one, i.e. several, temperature change generation energy and/or effect levels are
20 available in order to conveniently cover a wide range of flow values, the background being that said energy transferred to the liquid per unit time and volume will decrease with increasing flow at a certain effect level. By adapting the effect to the flow, an improved accuracy is normally obtained. One way of doing this is to apply temperature change generation power continuously and adjust the power level in a
25 control loop, so that the difference between, preferably filtered, thermistor signals upstream and downstream of the thermistors is maximized. The power level would then have to be calibrated against flow.

As is obvious from the description given above, the present invention offers important advantages compared to previously known technique. Thus, a quick and accu-
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rate response to urine flow changes is obtained due to a very low “dead” volume. Further, a broad urine flow interval may be covered by the measurements, e.g. from 2 ml/h to 2 l/h. Measurements are performed in a “forgiving” way, especially when signal integration is employed, both with respect to flow and flow disturbances, e.g. in the form of gas bubbles, both heating and cooling “automatically” correct measurement qualitatively and quantitatively, so that a mean value taking into account both an increase and a decrease in the flow is obtained as the result of a measurement representing a certain measurement period T.

10 The invention has been described above with reference to preferred embodiments. Of course, further embodiments as well as minor additions and amendments may be imagined without departing from the basic inventive idea.

15 Thus, although a thermistor concept seems very suitable for carrying out the present invention, other kinds of temperature measurement means and techniques, e.g. thermocouple techniques, may be used. Further thermistor alternatives are silicon semiconductor means and resistance wire, e.g. platinum, means changing their properties with temperature in a well-defined way.

20 Furthermore, the use of micro-fluidic chip sensor arrangements based on MEMS (Micro Electro Mechanical System) technology may be imagined for the present purposes.

25 As far as thermistors are concerned, an example of a thermistor for the present invention is a thermistor being provided by e.g. Thermometrics, Inc., USA, under the designation AB6E3.

Fig. 6 discloses an example of a thermistor electrical chart.

Regarding patients in a ventilator (respirator), there are indications showing abdominal pressure, reflected by the pressure in the urine bladder, which could be used to optimize ventilator settings.

- 5 According to a preferred option, the body temperature of a patient is measured by measuring urine temperature, suitable measuring means being e.g. those discussed above. Thus, according to one embodiment, a thermistor in the sensor channel is used for urine temperature measurement, preferably only at urine flow values above a certain level for a predetermined time, in order to avoid errors due to cooling, especially dead volume cooling. Also, a correction for expected cooling is possible.
- 10

- Above the invention has been applied for urine flow measurements. However, the invention may be applied for other flow measurements, a sensor according to the invention being used. Thus, the methods, the arrangement, the device and the sensor
- 15 according to the invention may be used for measuring the flow of other liquids than urine, the source of the liquid not being a patient and the corresponding tubing, but some other source.

Claims

1. A method for measuring urine flow out of a patient, urine from the patient being taken out from a urinary tract catheter arrangement and a tubing connected to said arrangement, comprising arranging a sensor in said tubing to determine urine flow in said tubing, **characterized** by the step of
 - reducing the delay time for detecting urine flow transients by reducing the urine volume between the sensor (3) and the patient by locating the sensor close to the catheter arrangement outlet.
2. A method according to claim 1, **characterized** by the step of providing a unidirectional valve (16) system to ensure that the sensor is fully filled with urine independent of the sensor orientation.
3. A method according to claim 2, **characterized** by providing a unidirectional valve in a downstream configuration, said valve offering a certain forward flow resistance, preferably in combination with a threshold pressure arrangement.
4. An arrangement for measuring urine flow out of a patient, urine from the patient being intended to be taken out from a urinary tract catheter arrangement and a tubing connected to said arrangement, a sensor being provided in said tubing to determine urine flow in said tubing, **characterized** in means for locating the sensor (3) close to the catheter arrangement outlet, whereby the urine volume between the sensor and the patient and thereby the delay time for detecting urine flow transients is reduced.
5. An arrangement according to claim 4, **characterized** in a unidirectional valve (16) system arranged to ensure that the sensor is fully filled with urine independent of the sensor orientation.

6. An arrangement according to claim 5, **characterized** in a unidirectional valve in a downstream configuration said valve offering a certain forward flow resistance, preferably in combination with a threshold pressure arrangement.
- 5 7. An arrangement according to claim 4, 5 or 6, **characterized** in that the sensor (3) is disposable, either separately or comprised by a disposable tubing kit.
8. A method for measuring urine flow out of a patient, urine from the patient being taken out from a tubing, comprising arrangement of a sensor based upon heat transfer in said tubing, **characterized** by the steps of
 - 10 - applying a temperature change generating pulse at a predetermined spot (12) in a sensor (3) channel (8) connected to said tubing (1),
 - collecting information about temperature development due to the generated temperature change, and
 - 15 - using said information to determine the urine flow in said sensor channel.
9. A method according to claim 8, **characterized** in that the temperature change generating pulse is a heating pulse.
- 20 10. A method according to claim 8 or 9, **characterized** by the step of arranging said predetermined spot near the urine outlet of the patient.
11. A method according to claim 8, 9 or 10, **characterized** in that the temperature development is detected by at least one thermistor (14,15,18) in the sensor channel.
25 nel.
12. A method according to claim 11, **characterized** in that the temperature development is detected by two thermistors (14,15) in the sensor channel, one (14) arranged upstream of the predetermined spot and one (15) arranged downstream
30 of said spot.

13. A method according to claim 11, **characterized** in that the temperature development is detected by a thermistor (18) in the sensor channel and that the thermistor comprises heating means for heating the thermistor.
- 5 14. A method according to anyone of claims 8-13, **characterized** by the step of generating successive pulses for obtaining successive urine flow measurements.
15. A method according to anyone of the preceding claims, **characterized** by the step of integrating a detected temperature development signal (S) for obtaining a
10 urine flow measurement.
16. A method according to claim 15, **characterized** in that said integration relates to a time period from a predetermined starting time (t_2) to a termination time (t_3), corresponding to the return or close to return of said signal to a steady state level
15 (L).
17. A method according to claim 16, **characterized** in that said starting time (t_2) corresponds to the termination time (t_2) of a predetermined temperature change generating pulse (P).
20
18. A method according to anyone of claims 8-17, **characterized** in that the duration and the amplitude of the temperature change generating pulse of a measurement are predetermined constants.
- 25 19. A method according to anyone of claims 8-17, **characterized** in that the duration of the pulse is automatically adjusted so that a predetermined temperature rise signal, preferably in relation to a steady state level, is obtained, the corresponding time being taken as a starting time (t_2) for the temperature development information to be collected.
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20. A method according to anyone of claims 8-19, **characterized** in that the length (T) of a measurement period is allowed to vary with flow, the time (t_3) for temperature signal return to at least close to a steady state, varying considerably with flow.
- 5
21. A method according to anyone of claims 8-20, **characterized** in that a measurement period (T) is terminated at a time (t_3) when a temperature signal has returned to at least close to a steady state level plus a predetermined delay (T_d) in order to make sure that steady state has been reached before start of the next measurement period (T).
- 10
22. A method according to anyone of claims 8-14 and 18-21, **characterized** in that the time for obtaining a predetermined temperature signal change for a predetermined pulse is used as a measure of urine flow.
- 15
23. A method according to claims 8-22, **characterized** by the step of providing a thermal shield for the sensor, said shield comprising an insulation layer (20) and, preferably, a conductive layer for providing an even temperature distribution.
- 20
24. A method according to anyone of claims 8-23, **characterized** in that gas, such as air, from the urine can be evacuated from the sensor through ventilation means (17), preferably at least one membrane (17).
- 25
25. A method according to anyone of claim 23 or 24, **characterized** in that gas, such as air, can be evacuated through two membranes (17), one being arranged upstream of the insulating layer and one being arranged downstream of the insulating layer.

26. A method according to anyone of claims 8-25, **characterized** in that independence of the sensor channel orientation is obtained by applying a unidirectional valve (16) downstream of said predetermined spot.

5 27. A method according to claim 26, **characterized** in that said valve offers a certain forward flow resistance, preferably in combination with a threshold pressure arrangement.

10 28. A device for measuring urine flow out of a patient, urine from the patient being intended to be taken out from a tubing, a sensor based upon heat transfer being provided in said tubing, **characterized** in means (11,18) for applying a temperature change generating pulse at a predetermined spot in a sensor (3) channel (8) connected to said tubing (1) and temperature-measuring means (14,15,18) for collecting information about temperature development due to the generated temperature change, said information being intended to be used to determine the
15 urine flow in said sensor channel.

29. A device according to claim 28, **characterized** in that the temperature change generating pulse is a heating pulse.

20 30. A device according to claim 28 or 29, **characterized** in that a central unit (CU) is provided for receiving said information and for calculating flow values based upon said information.

25 31. A device according to claim 28, 29 or 30, **characterized** in that the sensor is arranged as a part (4) of said tubing (1) and located close to the patient.

30 32. A device according to claim 28, 29, 30 or 31, **characterized** in that the measuring means comprises at least one thermistor (14,15,18) arranged in said sensor channel.

33.A device according to claim 32, **characterized** in that the measuring means comprises two thermistors (14,15), one being arranged upstream of the predetermined spot (12) and one being arranged downstream of said spot.

5 34.A device according to claim 32, **characterized** in that the sensor comprises a thermistor (18) comprising heating means.

35.A device according to anyone of claims 28-34, **characterized** in that means (11,18) are provided for generating successive pulses for successive urine
10 flow measurements.

36.A device according to anyone of claims 28-35, **characterized** by means (CU) for integrating a detected temperature development signal (S) for obtaining a urine flow measurement.

15 37.A device according to claim 36, **characterized** in that said integration relates to a time period from a predetermined starting time (t_2) to a termination time (t_3), corresponding to the return or close to return of said signal to a steady state level (L).

20 38.A device according to claim 37, **characterized** in that said starting time (t_2) corresponds to the termination of a predetermined temperature change generating pulse (P).

25 39.A device according to anyone of claims 29-38, **characterized** in that the duration and the amplitude of the pulse of a measurement are predetermined constants.

40.A device according to anyone of claims 29-39, **characterized** in that the duration of a pulse is intended to be automatically adjusted so that a predetermined
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temperature change signal, preferably in relation to a steady state level, is obtained, the corresponding time (t_2) being taken as a starting time (t_2) for temperature development information to be collected.

5 41. A device according to anyone of claims 28-40, **characterized** in that the length (T) of a measurement period is intended to be allowed to vary with flow, the time (t_3) for temperature signal return to at least close to a steady state varying considerably with flow.

10 42. A device according to anyone of claims 28-41, **characterized** in that a measurement period (T) is intended to be terminated at a time (t_3), corresponding to return of a temperature signal to at least close to a steady state level plus a predetermined delay time (T_d).

15 43. A device according to anyone of claims 29-35, 39-42, **characterized** by means for detecting the time period for obtaining a predetermined temperature signal change for a predetermined pulse, said time period being intended to be used as a measure of urine flow.

20 44. A device according to anyone of claims 28-43, **characterized** in that a thermal shield for the sensor is provided, said shield comprising an insulation layer (20).

45. A device according to anyone of claims 28-44, **characterized** in that the sensor comprises at least one membrane arranged to evacuate gas, such as air.

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46. A device according to claim 45, **characterized** in that the sensor comprises two membranes (17), one being arranged upstream of the insulating layer and one being arranged downstream of the insulating layer.

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47.A device according to anyone of claims 44-46, **characterized** in that said sensor comprises a thermally conductive, preferably metallic, concentric layer (21) along the sensor channel, in order to even out temperature differences.

5 48.A device according to anyone of claims 28-47, **characterized** in that a unidirectional valve (16) is provided downstream of said predetermined spot, in order to obtain complete filling of the sensor channel independent of the sensor channel orientation.

10 49.A device according to claim 48, **characterized** in that said valve offers a certain forward flow resistance, preferably in combination with a threshold pressure arrangement.

15 50.A sensor for measuring urine flow out of a patient and comprising a sensor channel, through which urine from the patient is intended to flow, the sensor being based on heat transfer, **characterized** in means (11,18) for applying a temperature change generating pulse at a predetermined spot in the sensor (3) channel (8) and measuring means (14,15,18) for collecting information about temperature development due to the generated temperature change.

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51.A sensor according to claim 50, **characterized** in that said temperature change generating pulse is a heating pulse.

25 52.A sensor according to claim 50 or 51, **characterized** in that means (4') are provided for connecting the sensor to a tubing (1) for collecting urine flow out of the patient.

53.A sensor according to claim 50, 51 or 52, **characterized** in that the sensor is intended to be located close to the patient.

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- 54.A sensor according to anyone of claims 50-53, **characterized** in that the measuring means comprises at least one thermistor (14,15,18) arranged in said sensor channel.
- 5 55.A sensor according to claim 54, **characterized** in that the measuring means comprises two thermistors (14,15), one (14) being arranged upstream of the pre-determined spot (12) and one (15) being arranged downstream of said spot.
- 56.A sensor according to claim 54 or 55, **characterized** in that the sensor comprises
10 a thermistor comprising heating means.
- 57.A sensor according to anyone of claims 50-56, **characterized** in that means are provided for generating successive pulses for successive urine flow measurements.
15
- 58.A sensor according to anyone of claims 50-57, **characterized** in that the sensor comprises a unidirectional valve (16) arranged at the downstream end of the sensor.
- 20 59.A sensor according to claim 58, **characterized** in that the valve is arranged to offer a certain forward flow resistance, preferably in combination with a threshold pressure arrangement.
- 25 60.A sensor according to anyone of claims 50-59, **characterized** in that the sensor comprises gas, such as air, evacuation means, preferably at least one membrane (17).
- 30 61.A sensor according to anyone of claims 50-60, **characterized** in that a thermal shield comprising an insulation layer (20) is provided along the sensor channel in order to decrease environmental influence on the measurement results.

62.A sensor according to anyone of claims 50-61, **characterized** in that a thermally conductive, preferably metallic layer (21) is provided along the sensor channel in order to even out temperature differences.

5 63.A sensor according to anyone of claims 50-62, **characterized** in that the sensor is disposable, either separately or comprised by a disposable tubing kit.

64.A method according to anyone of claims 1-3, **characterized** in that urine is exchanged for some other liquid, and the patient and the corresponding tubing are
10 exchanged for some other source and tubing for providing the liquid.

65.An arrangement according to anyone of claims 4-7, **characterized** in that urine is exchanged for some other liquid, and the patient and the corresponding tubing are exchanged for some other source and tubing for providing the liquid.

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66.A method according to anyone of claims 8-27, **characterized** in that urine is exchanged for some other liquid, and the patient and the corresponding tubing are exchanged for some other source and tubing for providing the liquid.

20 67.A device according to anyone of claims 28-49, **characterized** in that urine is exchanged for some other liquid, and the patient and the corresponding tubing are exchanged for some other source and tubing for providing the liquid.

25 68.A sensor according to anyone of claims 50-67, **characterized** in that urine is exchanged for some other liquid, and the patient and the corresponding tubing are exchanged for some other source and tubing for providing the liquid.

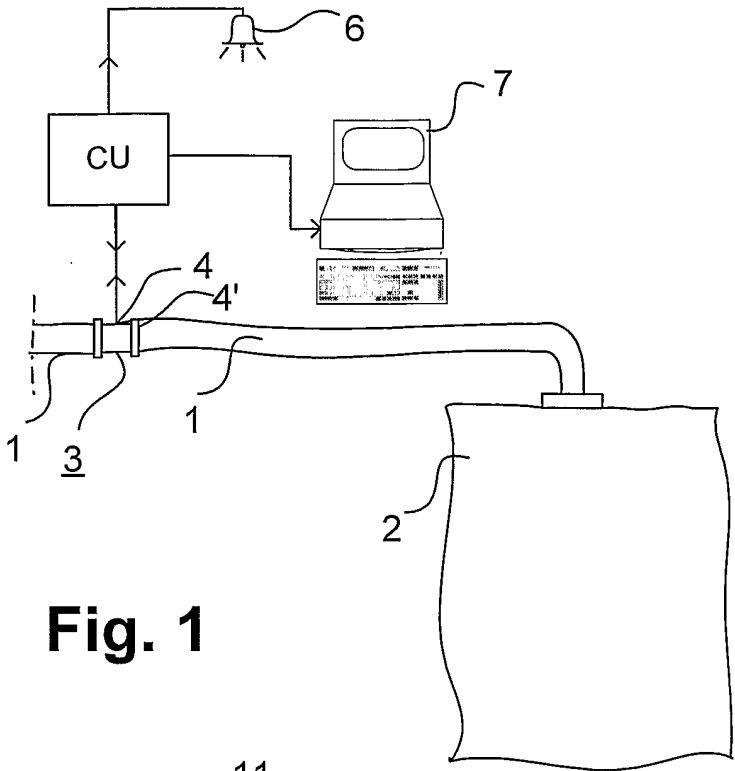


Fig. 1

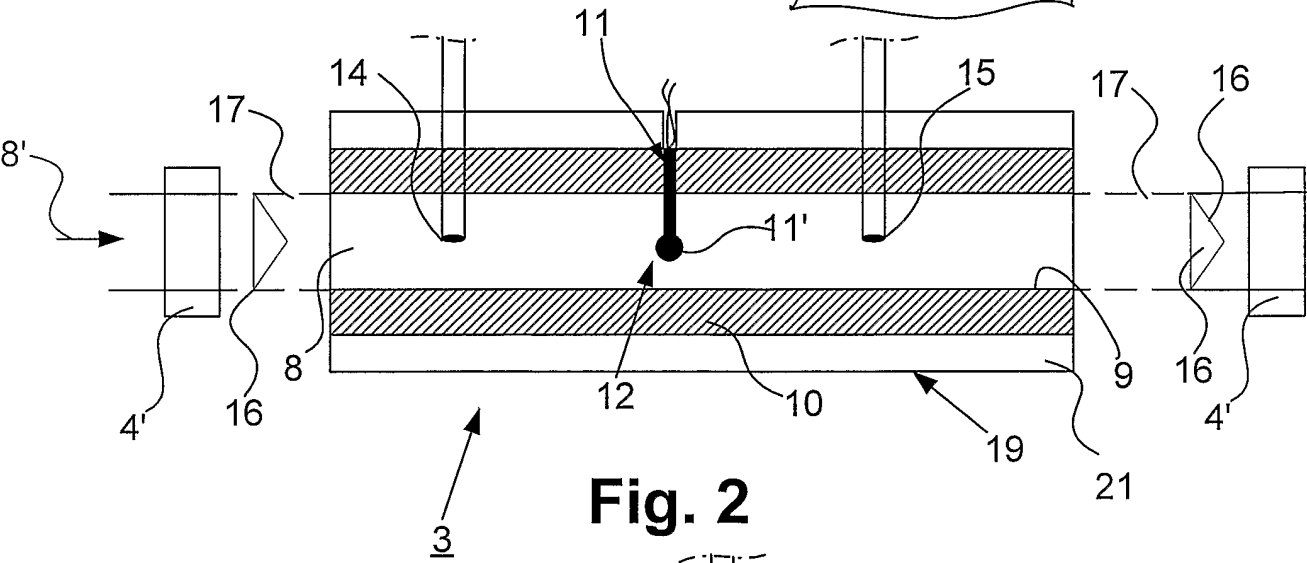


Fig. 2

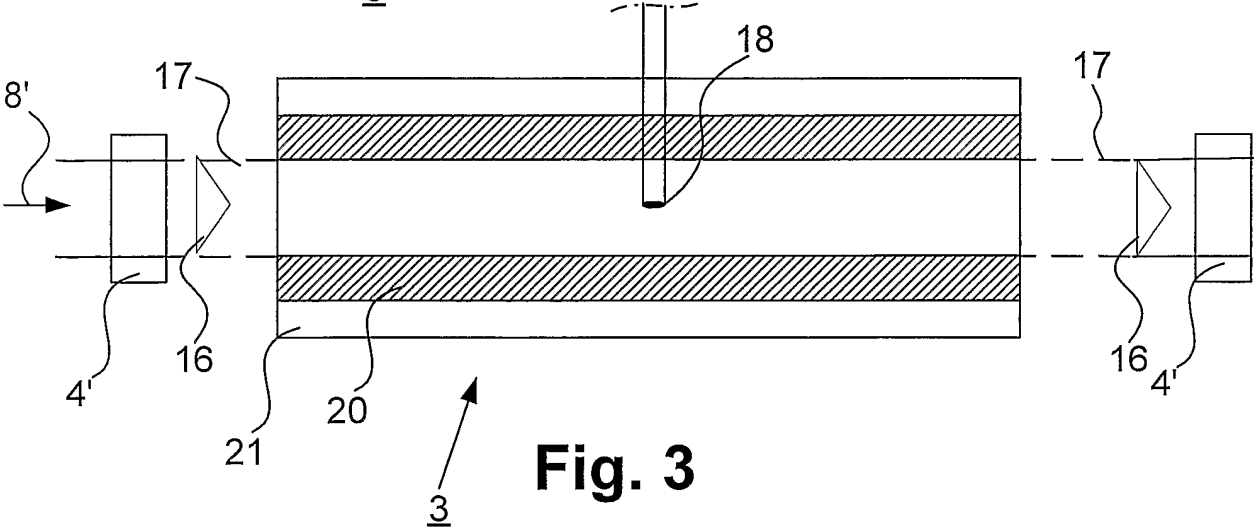


Fig. 3

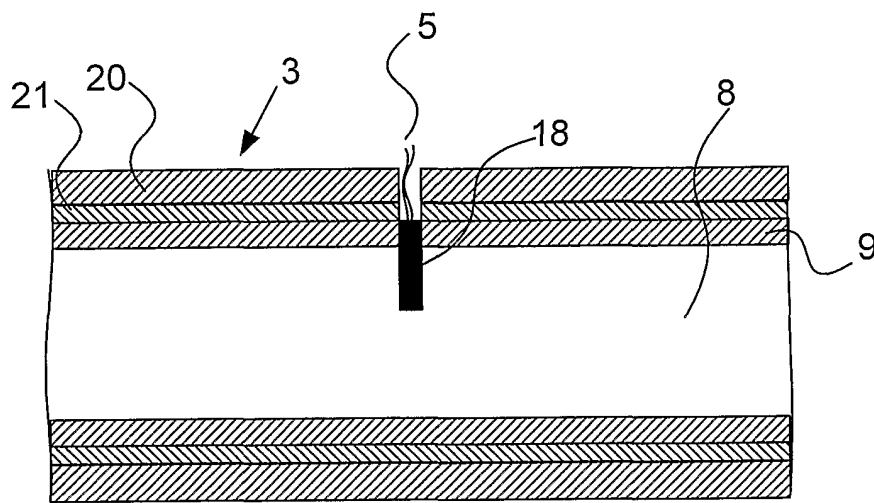


Fig. 4

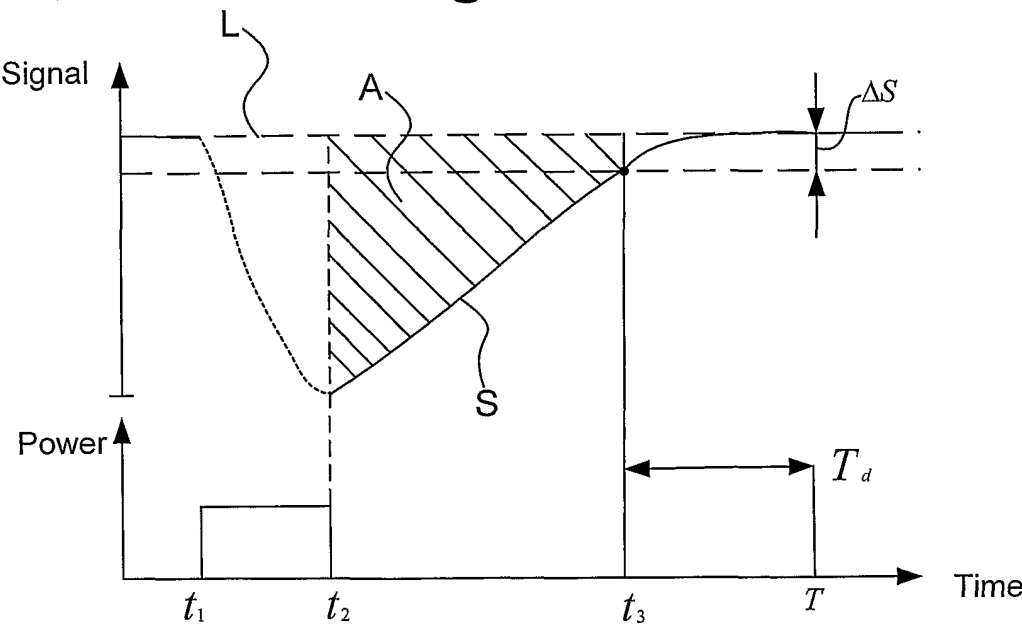


Fig. 5

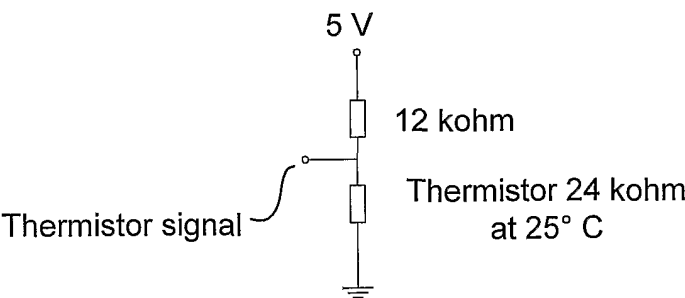


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 03/00781

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 5/20, G01F 1/684

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)

IPC7: A61B, G01F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, INSPEC, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5119674 A (PAUL V. NIELSEN), 9 June 1992 (09.06.92), column 3, line 52 - line 65; column 7, line 62 - column 8, line 2, figure 1 --	1-68
X	WO 0239071 A1 (ROSEMOUNT AEROSPACE, INC.), 16 May 2002 (16.05.02), page 4, line 18 - page 5, line 8, figure 1 --	64-68
A	WO 0065313 A1 (JORGENSEN, THOMAS, FRIIS), 2 November 2000 (02.11.00), figure 1, abstract --	1-63

☒ Further documents are listed in the continuation of Box C.☒ See patent family 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 application or patent 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

28 November 2003

Date of mailing of the international search report

08-12-2003

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 03/00781

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9513016 A1 (SMITHS INDUSTRIES PUBLIC LIMITED COMPANY), 18 May 1995 (18.05.95), figure 1, abstract --	1-63
A	US 4685470 A (SHIGEHazu SEKII ET AL), 11 August 1987 (11.08.87), figure 2, abstract -- -----	1-63

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/00781

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **1-3, 8-27**
because they relate to subject matter not required to be searched by this Authority, namely:
see next page
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/00781

Claims 1-3, 8-27 respectively, relate to a surgical method practised on a human or animal body, i.e. they implicitly contains placing a catheter in a body. Thus, the International Search Authority is not required to carry out a search report for these claims (Rule 39.1(iv)).

Nevertheless, a search has been executed for these claims.

INTERNATIONAL SEARCH REPORT

Information on patent family members

06/09/03

International application No.

PCT/SE 03/00781

Patent document cited in search report			Publication date	Patent family member(s)		Publication date
US	5119674	A	09/06/92	AT	87736 T	15/04/93
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				GB	9323120 D	00/00/00
				IL	111463 D	00/00/00
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				AU	5026385 A	29/05/86
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				EP	0182363 A,B	28/05/86
				SE	0182363 T3	
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