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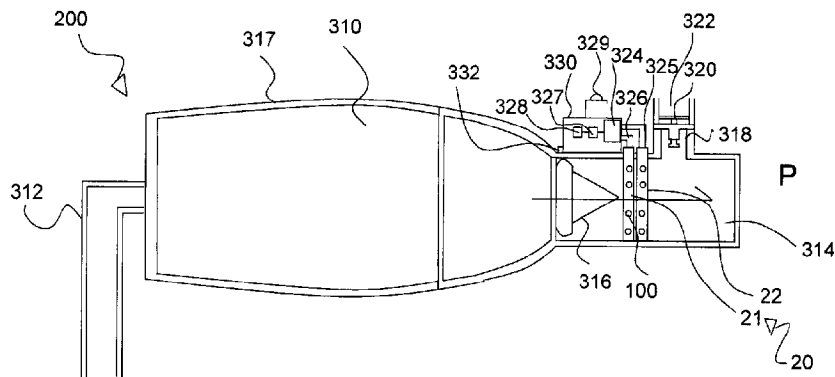
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(54) **Titre : APPAREIL DE MESURE DE DEBIT ET APPAREIL D'INHALATION COMPORTANT CELUI-CI**

(54) **Title: FLOW MEASURING APPARATUS AND INHALATION APPARATUS COMPRISING THE SAME**



(57) **Abrégé/Abstract:**

The present document describes a flow measuring apparatus for measuring a flow through a section of an inhalation apparatus, and an inhalations apparatus for drug delivery by inhalation comprising the flow measuring apparatus. The flow measuring apparatus comprises a set of Pitot tubes configured for traversing entirely the lumen of the section of an inhalation apparatus. The set of Pitot tubes comprises a first and second Pitot tube which are respectively fluidly connected to a differential pressure sensor, for measuring a difference between a dynamic pressure and a static pressure within the flow measuring apparatus.

ABSTRACT

The present document describes a flow measuring apparatus for measuring a flow through a section of an inhalation apparatus, and an inhalations apparatus for drug delivery by inhalation comprising the flow measuring apparatus. The flow measuring apparatus comprises a set of Pitot tubes configured for traversing entirely the lumen of the section of an inhalation apparatus. The set of Pitot tubes comprises a first and second Pitot tube which are respectively fluidly connected to a differential pressure sensor, for measuring a difference between a dynamic pressure and a static pressure within the flow measuring apparatus.

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**Title: FLOW MEASURING APPARATUS AND INHALATION APPARATUS
COMPRISING THE SAME**

BACKGROUND

(a) Field

[0001] The subject matter disclosed generally relates to a flow measuring apparatus and inhalations apparatus for drug delivery by inhalation comprising the same.

(b) Related Prior Art

[0002] Many drugs to treat diseases such as obstructive pulmonary disease, asthma, bronchial, or the bronchiolitis, are administered by inhalation for example by means of metered dose inhalers (MDI). The inhaler uses a propellant which generates an aerosol of the substance drug or active substance.

[0003] Inhalation devices (or apparatus) commonly used in inhalation treatments often needs an inhalation chamber. The use of an inhalation chamber has long been recognized to facilitate and improve the medication in a treatment by inhalation (aerotherapy), in particular for improving the distribution of therapeutic substances (medicament) in the bronchi and reduce deposits in the airways above, where they are responsible for side effects. Indeed, in the absence of such an inhalation chamber, the coordination between the activation of the inhaler and inspiration is paramount. However, this coordination is difficult to achieve for many patient, especially in children.

[0004] The inhalation chamber defines an internal volume in which the medicament is propelled by means of an opening made in one end of the opening chamber which is fitted on the source of the drug, for example a MDI. At another end of the inhalation chamber is another opening in communication with the patient's mouth through a connection means, generally a tubular part such as a mouthpiece that the patient may insert in his/her mouth directly. It is also possible to connect a face mask on the connection means, in particular in the

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case of devices for young children. The drug substance is propelled as a gas in the inhalation chamber for example by pressing the MDI. When the patient inhales through the mask or mouthpiece, the drug substance is transported into the lungs of the patient by an outflow from the inhalation chamber generated by the patient's inhalation.

[0005] However, it is not easy for the patient to verify that the inspiratory flow generated was efficient enough to inhale the full dose of drug substance or that the inhalation device works correctly. For example, if the inspiratory flow is too low or too strong, effective treatment may be compromised.

[0006] Inhalation devices including an inhalation chamber in which means of attesting to the good inhalation of the patient are known in the art. For example, there is an inhalation chamber in which a visible color means adjacent to an unidirectional inhalation valve moves according to the inspiratory flow. Such means provides a way to assess the passage of the inspiratory flow through the valve, however it does not measure the flow rate of inspiratory flow and eventually compare it to a reference value.

[0007] Therefore, it is an object of the present invention to provide a flow measuring apparatus which may be used for measuring the flow through a section of an inhalation apparatus. Also, it is an object of the present invention to provide an inhalation apparatus having a flow measuring apparatus for measuring flow through a section of the inhalation apparatus.

[0008] Features and advantages of the subject matter hereof will become more apparent in light of the following detailed description of selected embodiments, as illustrated in the accompanying figures. As will be realized, the subject matter disclosed and claimed is capable of modifications in various respects, all without departing from the scope of the claims. Accordingly, the drawings and the description are to be regarded as illustrative in nature, and not as restrictive and the full scope of the subject matter is set forth in the claims.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Further features and advantages of the present disclosure will become apparent from the following detailed description, taken in combination with the appended drawings, in which:

[0010] Figs. 1A-C illustrates an embodiment of a flow measuring apparatus according to an embodiment of the present invention.

[0011] Figs. 2A-F illustrates an embodiment of a flow measuring apparatus in an inhalation apparatus according to an embodiment of the present invention.

[0012] Fig. 3 illustrates an embodiment of a flow measuring apparatus in an inhalation apparatus according to an embodiment of the present invention.

[0013] Fig. 4 illustrates an embodiment of a flow measuring apparatus in an inhalation apparatus according to an embodiment of the present invention.

[0014] Fig. 5 illustrates an embodiment of a flow measuring apparatus in an inhalation apparatus according to an embodiment of the present invention.

[0015] Fig. 6 illustrates schematically the functioning of an inhalation apparatus according to an embodiment of the present invention.

[0016] Fig. 7A-D illustrates embodiments of the set of Pitot tubes according to an embodiment of the present invention.

[0017] Fig. 8 illustrates schematically the use of an inhalation apparatus according to an embodiment of the present invention in a ventilation circuit.

[0018] Fig. 9 illustrates schematically the flow under various scenario described herein.

[0019] It will be noted that throughout the appended drawings, like features are identified by like reference numerals.

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DETAILED DESCRIPTION

[0020] Referring now to the drawings, and more particularly to Figs. 1A-C. In a first embodiments there is disclosed a flow measuring apparatus 10 for measuring a flow (F) through a section of an inhalation apparatus 200, which comprises :

- at least one set of Pitot tubes 20 comprising a first Pitot tube 21 longitudinally contacting a second Pitot tube 22, the set of Pitot tubes 20 is configured for traversing entirely a lumen (L) of said section of an inhalation apparatus 200; the first and second Pitot tube 21, 22 are respectively fluidly connected to a differential pressure sensor 24, for measuring a difference between a dynamic pressure and a static pressure within the flow measuring apparatus 10; the first Pitot tube 21 comprising at least one opening facing a direction of the flow (F); and the second Pitot tube 22 comprising at least one opening facing a direction opposed to the flow (F).

[0021] Now referring to Fig. 9, the reference pattern usually considered as part of fluid mechanics is that of the wake formed downstream of a cylinder. The main flow in a conduit of rectangular section with sides a and b and a cylinder centered from wall to wall (diameter d and length l) (Figs. 9A and B). The aspect ratio (l/d) ratio of the cylinder is considered large (order of magnitude greater than 20, ...100).

[0022] The Reynolds number $Re = \frac{U_o \cdot d}{\nu}$ is defined with the flow velocity U_o . As a function of the increase of this dimensionless number, the organization of the flow changes dramatically.

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[0023] Low Renolds numbers correspond to flow that is completely “laminar” to fully “turbulent” flows (Figs. 9C and D, respectively) with high Renolds number. The turbulence is extended to all parts of the flow. For Renolds numbers ranging from 1000 to 10000 the presence of a wake is observed, where once the vortices formed in the vicinity of the downstream cylinder, they escape in alternance. The flow is essentially two-dimensional in the plane coinciding with the cylinder section. The vortices are periodic and consistent.

[0024] Other variations are discussed in the literature: the case of cylinders of small aspect ratio (short cylinders); the case where the cylinder does not cover the entire length of the test section, at the end of the cylinder, the organization of the flow becomes three-dimensional flow; and the case of tandem cylinders, where a second cylinder is placed farther downstream in the wake of the first, the organization of the flow becomes highly complex (Fig. 9E). In the case of the flow measuring apparatus 10 of the present invention, the conduit is not of rectangular section but of circular section, the flow is axy-symmetrical and not two dimensional.

[0025] Without wishing to be bound by theory, independently of the shape of the cross sections of the cylinders, they generate a wake. The configuration of the flow measuring apparatus 10 of the present invention, in the presence of a set of Pitot tubes 20 having a streamlined profile (e.g. a section near an oval) through the entire width of the conduit (traversing entirely the lumen of the conduit). This situation will in principle to have a flow in which the organization would likely be at least two-dimensional on the central portion of the conduit, and improve the precision and the reproducibility of the measurements, especially in situations where the flow is low.

[0026] According to an embodiment, the set of Pitot tubes 20 may comprise first and second Pitot tubes 21, 22 which are contacting each other along the longitudinal axis to eliminate any gap between the first and second Pitot tubes 21, 22. Now referring to Figs. 7A-C, in embodiments, the contact

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between the first and second Pitot tubes 21, 22 may be achieved in several manner. According to an embodiment, the first and second Pitot tubes 21, 22 may be back to back, resulting in their respective opening being substantially in the same plane, directly in contact with one another (Fig. 7A), with or without streamlining (as shown by the filling of the region "R" in Figs. 7A, C and D). According to another embodiment, the set of Pitot tubes 20 may be comprised of two Pitot tubes 21, 22 contacting each other in a decentered manner, causing their respective openings to be in different planes. For example, each Pitot tubes 21, 22 may be a half-circle contacting the other along their linear portion LP (Fig. 7B), or two Pitot tubes 21, 22 may contact each other along their circumference, but not in a direct back to back manner (Fig. 7C). According to another embodiment, the Pitot tubes 21, 22 may contact each other by eliminating the region "R" between each tube, either by filling the gap, or preparing the set of Pitot tubes 20 as a unitary part (Fig. 7D). Preferably, the first and second Pitot tubes 21, 22 are back to back. The contact between the first and second Pitot tubes 21, 22 improves the precision and the reproducibility of the measurements, especially in situations where the flow is low. Furthermore, without wishing to be bound to theory, it is believed that the contact between the first and second Pitot tubes 21, 22 also reduces the turbulence in three dimensions near the flow measuring apparatus 10, limiting them to two dimensions, which again improves the precision and the reproducibility of the measurements.

[0027] One of the Pitot tubes of the set 20 is a tube measuring dynamic pressure (e.g. first Pitot tube 21), the other is a measuring tube for static pressure (e.g. second Pitot tube 22). Each Pitot tube has at least one opening, such as opening 100. These openings allow the measurement of a mean dynamic pressure and a mean static pressure during the passage of a flow through the openings. Thus, according to an embodiment, the first and second Pitot tubes 21, 22 may comprise at least one opening 100 facing a direction of the flow (F). The at least one 100 opening may be a single, longitudinal opening

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slot, as shown in Fig. 2C. According to another embodiment, the at least one opening may be two, three, four, or more openings, such as circular openings (Figs. 2B and E), or slots (Fig. 2F), positioned along the longitudinal axis of the first or second Pitot tubes 21, 22 at regular intervals.

[0028] According to another embodiment, the set of Pitot tubes 20 is configured for traversing entirely the lumen (L) of the section of an inhalation apparatus 200, as shown in Fig. 1C, and Fig. 2D. Fluid flowing through a tubular structure flows more rapidly in the center of the structure than around the edges of the structure. Therefore, the fact that the set of Pitot tubes 20 traverses the entire lumen (L) of the section of the inhalation apparatus 200, combined with having a single longitudinal slot, or a series of several openings at regular intervals along the length of the first or second Pitot tubes 21, 22, allows the measurements of the pressure to be made at several points of the lumen (L), particularly in the center and at the edges of the lumen, and permits averaging the pressure measurement and improves the precision and the reproducibility of the measurements, especially under low flow.

[0029] According to another embodiment, the set of Pitot tubes 20 may be streamlined in order to reduce the resistance of the set of Pitot tubes 20 to the flow within the section of an inhalation apparatus 200. According to an embodiment, the first and second Pitot tubes 21, 22 may be shaped so as to present a generally streamlined configuration when in contact with one another. For example, the first and second Pitot tubes 21, 22 may be shaped as half-circles, or half-ovals providing a substantially circular or oval shape to the set of Pitot tubes 20 when in contact with one another. According to another embodiment, the region (R) of the set of Pitot tubes 20 where the first and second Pitot tubes 21, 22 are in contact with one another may be filled with an appropriate material that is shaped or molded so as to provide a generally streamlined profiled (Figs. 1A and B). According to another embodiment, the first and second Pitot tubes 21, 22 may be inserted into another tube, which then

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provides the desired streamlining (i.e. a streamlining tube). The so called streamlining tube also includes opening aligning with the openings of the Pitot tubes. According to another embodiment, the set of Pitot tubes 20 may be made from a unitary piece of material prepared from techniques such as injection molding, 3D printing, or machining. The unitary piece may be streamlined according to the present invention and include therein two longitudinal tube-like cavity corresponding to Pitot tubes 21, 22. Appropriate materials include but are not limited to plastic materials, metallic materials, etc.

[0030] According to another embodiment, the first and second Pitot tube 21, 22 are respectively fluidly connected to a differential pressure sensor 324, for measuring a difference between a dynamic pressure and a static pressure within the flow measuring apparatus 10.

[0031] The first and second Pitot tubes 21, 22 may be connected to the differential pressure sensor 324 through connecting means 325 and 326. According to another embodiment, the flow measuring apparatus 10 may also include a processor 327, for calculating the flow from the difference between a dynamic pressure and a static pressure measured with the flow measuring apparatus 10. The processor 327 may transmit a flow rate signal through transmission means 328 and/or a activate visual means 329, such as a light emitting diode, or a display, indicating the correct use of an inhalation apparatus, such as apparatus 200. The operation of these elements is described in Fig. 6.

[0032] The differential pressure sensor 324, the processor 327, the transmission mean 328 and visual means 329 may be contained within a single housing 330. The Housing 330 may be removably attached on the outer face 317 of an inhalation apparatus 200. For example, it may be removable attached through connection means 332, such as a snap connection means (Figs. 3-5). According to another embodiment, the flow measuring apparatus 10 may be totally separable from the other elements of the inhalation apparatus 200, making it easier to clean the latter.

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[0033] The same flow measuring apparatus 10 can comprise more than one sets of Pitot tubes 20. For example, a set of Pitot tubes 20 may be provided in the first end 312 of an inhalation apparatus 200 in order to measure the inhalation flow rate, and another set of Pitot tubes 20 may be provided in the tubular portion 318 of an inhalation apparatus 200 that contains the expiratory valve 320 to measure the rate of expiratory flow (Figs. 3-5).

[0034] According to another embodiment, a flow measuring apparatus 10 of the present invention may be provided in an inhalation apparatus 200 without inspiratory or expiratory valves.

[0035] Now referring to Fig. 8, according to another embodiment, the flow measuring apparatus 10 of the present invention may be provided in the ventilation circuit of a ventilator 800, allowing the medical practitioner to have independent data to compare to the data of the ventilator.

[0036] In a second embodiment there is disclosed an inhalation apparatus 200 for drug delivery by inhalation comprising :

- an inhalation chamber 310 having a first end 312 to be connected to a source of drug to be administered by inhalation to a user, and a second end 314 to be connected to the user;
- a flow measuring apparatus 10 of the present invention, traversing entirely a lumen of a section of the inhalation apparatus 200, for measuring flow of the drug within the section of the inhalation apparatus 200; and
- a processor 324, operatively connected to said flow measuring apparatus, for calculating the flow rate from the difference between a dynamic pressure and a static pressure measured with the flow measuring apparatus 10.

[0037] According to the second embodiment, the inhalation chamber 310 having a first end 312 to be connection to a source of drug is intended to be the source of drug (in other words medicinal substances or medicaments) such as a

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spray or MDI, and a second end 314, such as a connecting portion to be connected to the end user. This enables communication between the chamber 310 of the inhalation apparatus 200 and a user. According to an embodiment, second end 314, such as the connecting portion may be either a mouthpiece or a tube that may be connected to a face mask.

[0038] According to another embodiment, the inhalation apparatus 200 may comprise a valve 316, for example a duckbill valve may be provided upstream of the user relative to the chamber 310. Any suitable valve may be used in the inhalation apparatus of the present invention. According to an embodiment, this valve 316 is preferably a one-way inhalation valve allowing the passage of a flow carrying the drug particles from the interior of the chamber 310 towards the connecting portion of the second end 314 and the user during the inhalation phase generated by the user.

[0039] According to another embodiment, the second end 314 may also comprises a tubular portion 318, having an expiratory valve 320. Preferably, the expiratory valve 320 is a unidirectional valve. The expiratory valve 320 permits the passage of the flow of drug particle generated by the user during an expiration phase from the second end 314 to an outlet 322 included in the tubular portion 318.

[0040] The inhalation apparatus 200 includes a flow measuring apparatus 10 of the present invention, traversing entirely a lumen of a section of the inhalation apparatus 200, for measuring flow of the drug within the section of the inhalation apparatus 200. The flow measuring apparatus 10 as described above may be arranged in the path of flow in the second end 314 downstream of the valve 316 (Fig. 4), and/or upstream of the valve 314 in the inhalation chamber 310 (Fig. 5), and/or on the expiratory flow path through the tubular portion 318 (Fig. 6).

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[0041] The first and second Pitot tubes 21, 22 may be connected to the differential pressure sensor 324 through connecting means 325 and 326. According to another embodiment, the flow measuring apparatus 10 may also include a processor 327, for calculating the flow from the difference between a dynamic pressure and a static pressure measured with the flow measuring apparatus 10. The processor 327 may transmit a flow rate signal 328 and/or activate visual means 329, such as a light emitting diode, indicating the correct use of an inhalation apparatus, such as apparatus 300. The operation of these elements is described in Fig. 6.

[0042] Now referring to Fig. 6, the difference between the average static pressure and dynamic pressure average which are detected by the first and second Pitot tubes 21, 22 in the section of an inhalation apparatus 200 concerned is measured by the differential pressure sensor 324, which then delivers a pressure signal differential (step A). The processor 327 receives the pressure signal and calculates the flow rate (step B). The transmission means 328 transmits the signal flow delivered by the processor 327 to an external device 400, such as a portable machine equipped with a Bluetooth system or the likes (step C). This can be for example a cell phone, a tablet, or the likes. This allows the display on the external device 400 of either the flow value measured, or an indication to the user that a correct rate value and a proper functioning of the inhalation apparatus 200. It is also possible to transmit a signal for the rate of delivery from the processor 327 to a visual means 329 attached to the inhalation apparatus 200. It may be for example a LED which illuminates when the value of the measured flow is the expected value or when on the contrary the value of the measured flow rate is less than a predetermined threshold value. This informs the user of the good operation of the inhalation apparatus 200 and the smooth running of the treatment.

[0043] The inhalation apparatus 200 may comprise a flow measuring apparatus 10 having more than one set of Pitot tubes 20. For example, a set of

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Pitot tubes 20 may be provided in the first end 312 in order to measure the inhalation flow rate, and another set of Pitot tubes 20 may be provided in the tubular portion 318 that contains the expiratory valve 320 to measure the rate of expiratory flow. Also, more than one set of Pitot tubes 20 may be included in any one section of the inhalation apparatus.

[0044] According to another embodiment, a flow measuring apparatus 10 of the present invention may be provided in an inhalation apparatus 200 without inspiratory or expiratory valves.

[0045] While preferred embodiments have been described above and illustrated in the accompanying drawings, it will be evident to those skilled in the art that modifications may be made without departing from this disclosure. Such modifications are considered as possible variants comprised in the scope of the disclosure.

CLAIMS:

1. An inhalation apparatus comprising an inhalation chamber and a flow measuring apparatus in a section of the inhalation apparatus, the inhalation chamber receiving a metered-dose inhaler and comprising a valve opposed to the metered-dose inhaler, the flow measuring apparatus for measuring a flow rate of gas comprising an aerosol through the section of the inhalation apparatus, comprising, the flow measuring apparatus comprising:

- a set of Pitot tubes only in a single longitudinal axis traversing a lumen of the inhalation apparatus and comprising a first Pitot tube longitudinally aligned with and contacting a second Pitot tube, said set of Pitot tubes traversing entirely the lumen of said section of the inhalation apparatus only in the single longitudinal axis; said first and second Pitot tube being respectively fluidly connected to a differential pressure sensor, for measuring a difference between a stagnation pressure and a static pressure within said flow measuring apparatus; said first Pitot tube comprising at least one opening facing a direction of said flow; and said second Pitot tube comprising at least one opening facing a direction opposed to said flow;

wherein the set of Pitot tubes is located downstream of the inhalation chamber, adjacent to the valve to measure the flow rate of the gas comprising the aerosol through the valve between the inhalation chamber and a mouthpiece, wherein the valve is a duckbill valve and defines a plane of a laminar flow for the flow of the gas comprising the aerosol, and the set of Pitot tubes crosses the flow of the gas comprising the aerosol with the single longitudinal axis thereof being perpendicular to the plane.

2. The inhalation apparatus of claim 1, wherein said first and said second Pitot tubes are back to back.

3. The inhalation apparatus of claim 2, wherein said at least one opening facing a direction of said flow and said at least one opening facing a direction opposed to said flow are substantially coplanar with longitudinal axes of said first and said second Pitot tubes, which are parallel.

4. The inhalation apparatus of claim 1, wherein said at least one opening of said first Pitot tube or of said second Pitot tube is a circular opening, or a slot, or an oval opening, or a square opening, or a rectangular opening.

5. The inhalation apparatus of claim 1, wherein said set of Pitot tubes is removable from the inhalation apparatus.

6. The inhalation apparatus of claim 1, wherein the inhalation apparatus is for drug delivery by inhalation,

- the inhalation chamber having:
 - a first end to be connected to a source of drug to be administered by inhalation to a user, and
 - a second end to be connected to said user;
- the flow measuring apparatus being for measuring flow of said drug within said section of said inhalation apparatus.

7. The inhalation apparatus of claim 6, wherein said second end is the mouthpiece or a tube to be connected to a face mask.

8. The inhalation apparatus of claim 6, wherein the inhalation chamber comprises the valve which is upstream of said second end, allowing passage of said flow from said inhalation chamber to said second end.

9. The inhalation apparatus of claim 8, wherein said valve is a one-way inhalation valve.
10. The inhalation apparatus of claim 6, wherein said second end further comprises an expiratory valve.
11. The inhalation apparatus of claim 10, wherein said second end further comprises a tubular portion.
12. The inhalation apparatus of claim 11, wherein said tubular portion comprises an expiratory valve.
13. The inhalation apparatus of claim 1, wherein said at least one opening facing a direction of said flow and said at least one opening facing a direction opposed to said flow are substantially coplanar along the longitudinal axis of said first and said second Pitot tubes.
14. The inhalation apparatus of any one of claims 1 to 13, wherein said set of Pitot tubes is streamlined, to reduce resistance of said set of Pitot tubes to said flow within said section of the inhalation apparatus.
15. The inhalation apparatus of any one of claims 1 to 14, wherein one of said first and said second Pitot tube is for measuring the stagnation pressure, and the other of said first and said second Pitot tube is for measuring the static pressure.
16. The inhalation apparatus of any one of claims 1 to 15, wherein said at least one opening is a single opening, or two openings, or three openings, or four openings.

17. The inhalation apparatus of any one of claim 16, wherein said at least one opening is a circular opening, or a slot, or an oval opening, or a square opening, or a rectangular opening.

18. The inhalation apparatus of claim 1, wherein said at least one opening comprises a plurality of openings which are positioned along the longitudinal axis of the first or second Pitot tubes at regular intervals.

19. The inhalation apparatus of any one of claims 1 to 18, further comprising a processor, operatively connected to said flow measuring apparatus, for calculating a flow rate from said difference between the stagnation pressure and the static pressure measured with said flow measuring apparatus.

20. The inhalation apparatus of claim 19, further comprising a transmission means for transmitting said flow rate.

21. The inhalation apparatus of claim 20, further comprising a visual means to visually indicate correct use of said flow measuring apparatus, said inhalation apparatus, or both.

22. The inhalation apparatus of claim 21, wherein any one of said processor, said transmission means, and said visual means is comprised within a housing.

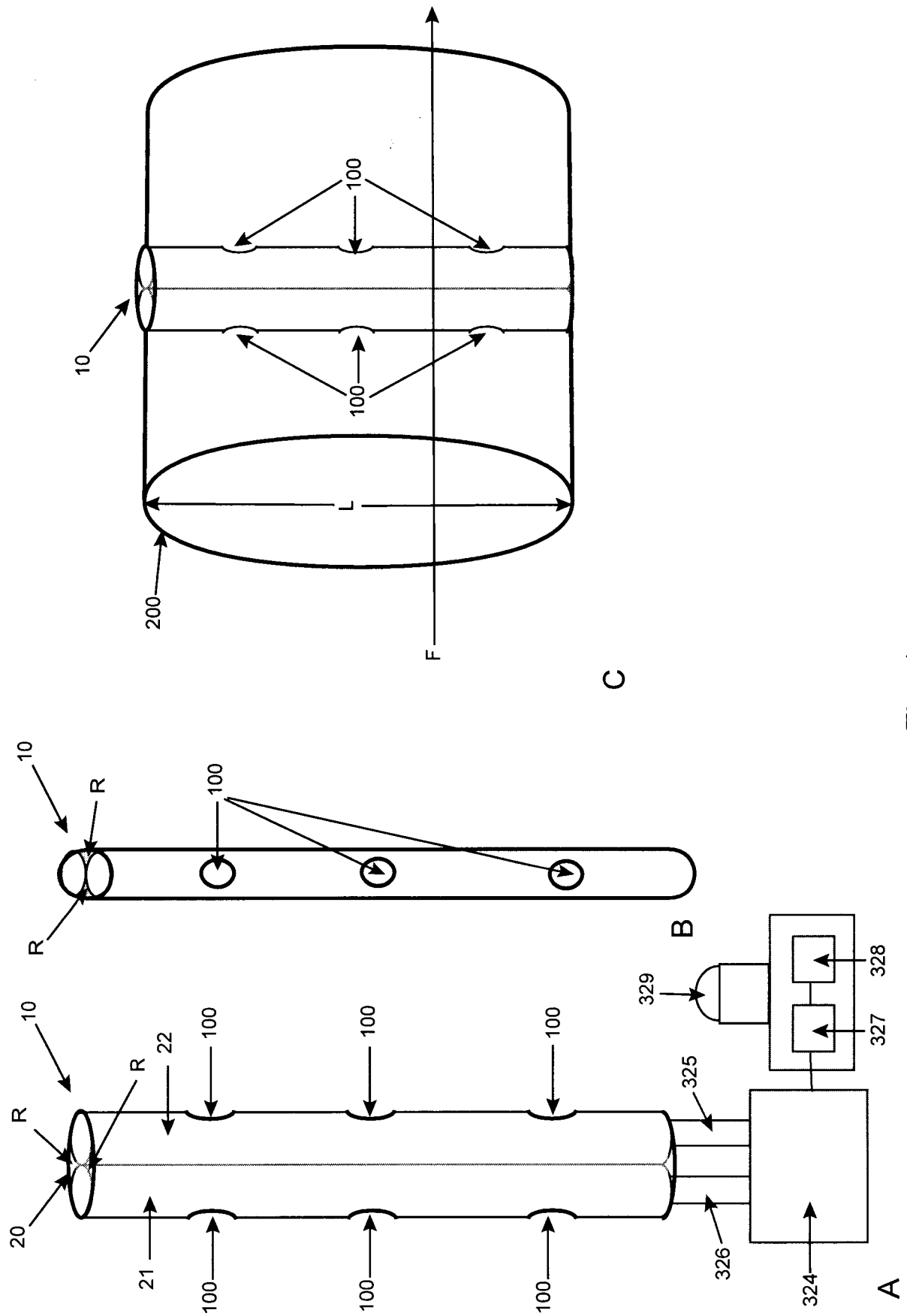
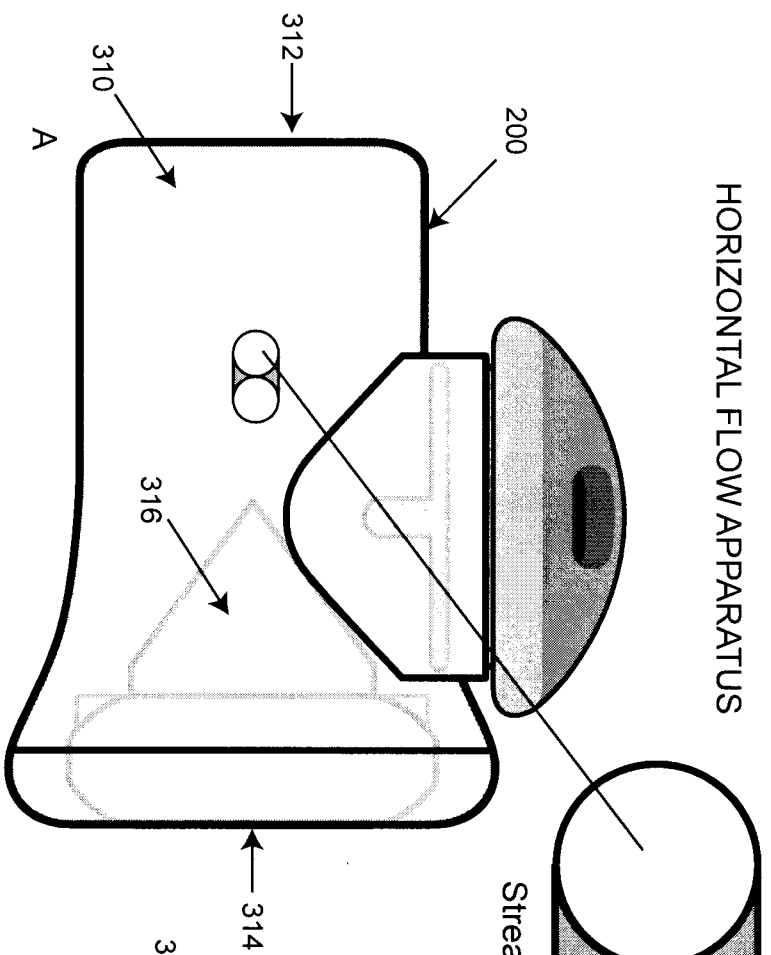


Fig. 1

HORIZONTAL FLOW APPARATUS



VERTICAL FLOW APPARATUS

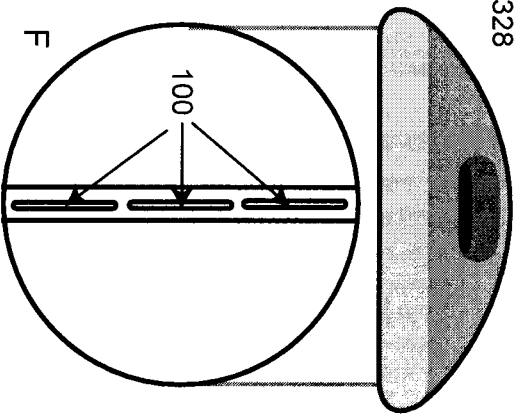
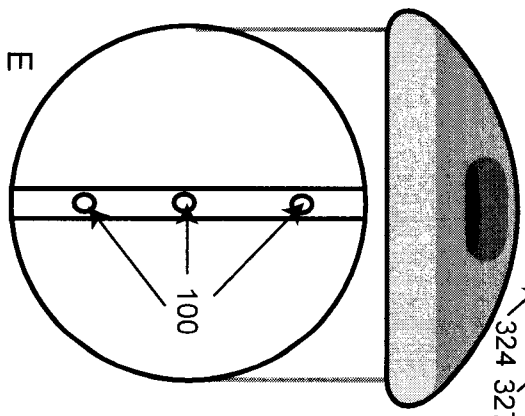
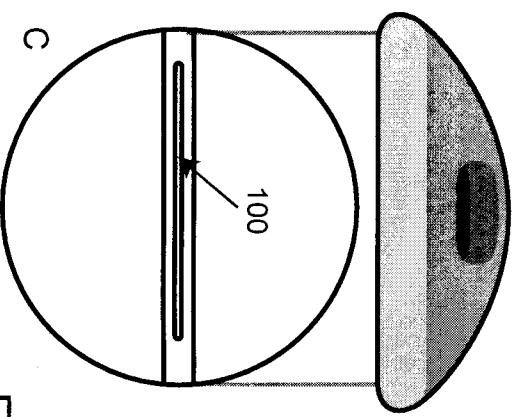
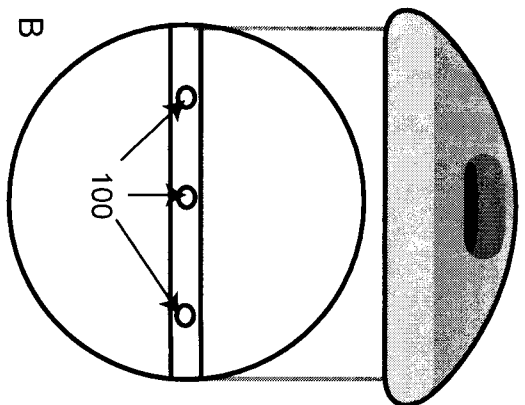
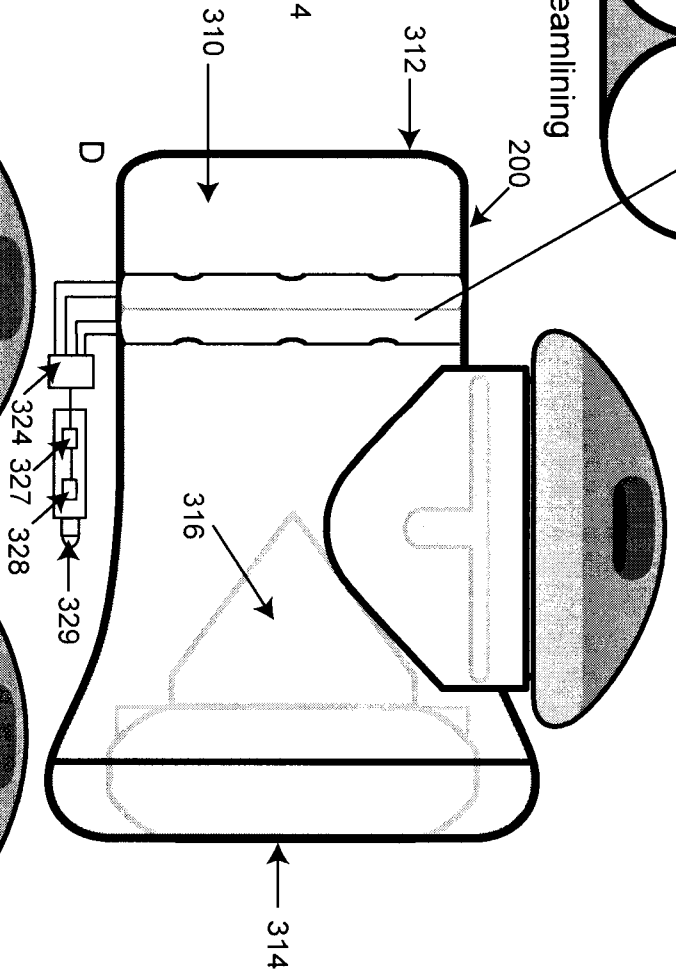


Fig. 2

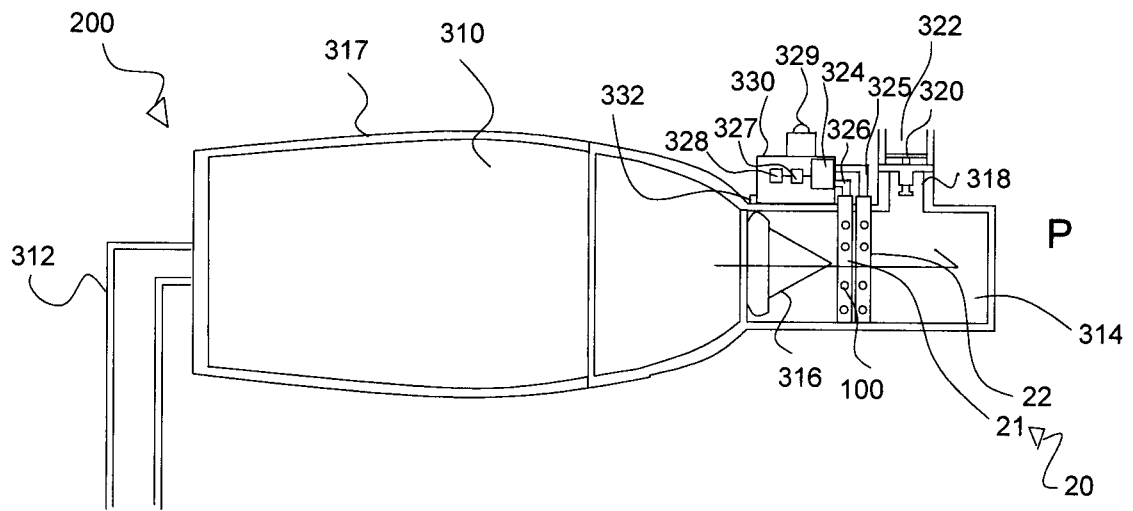


Fig. 3

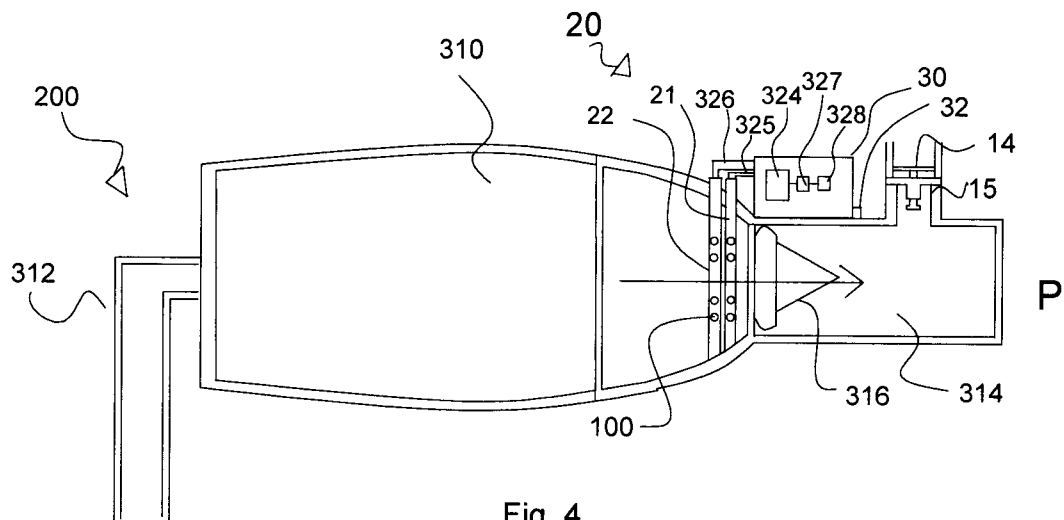


Fig. 4

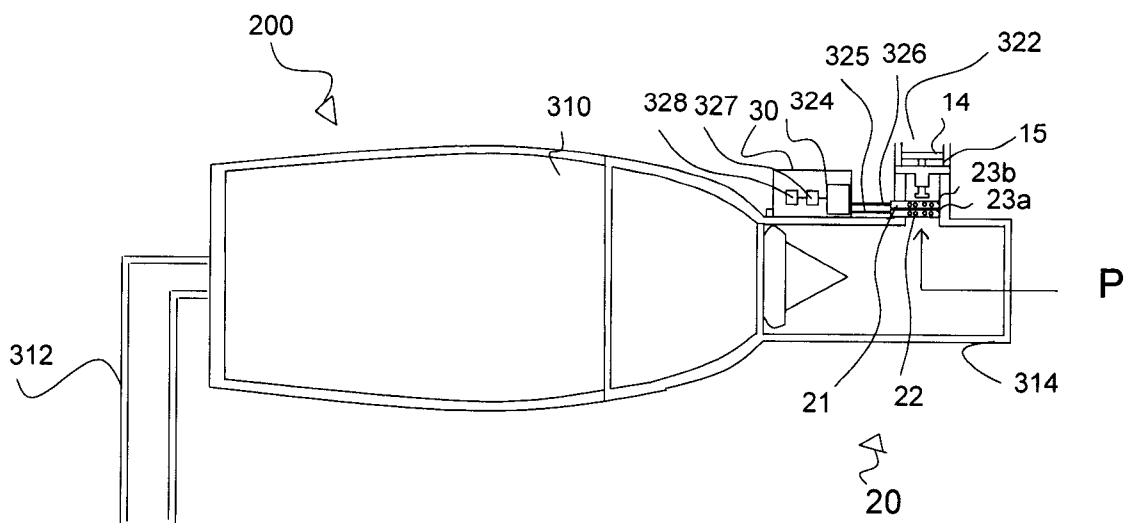


Fig. 5

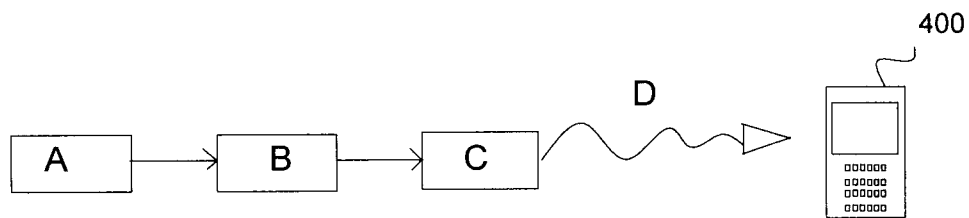


Fig. 6

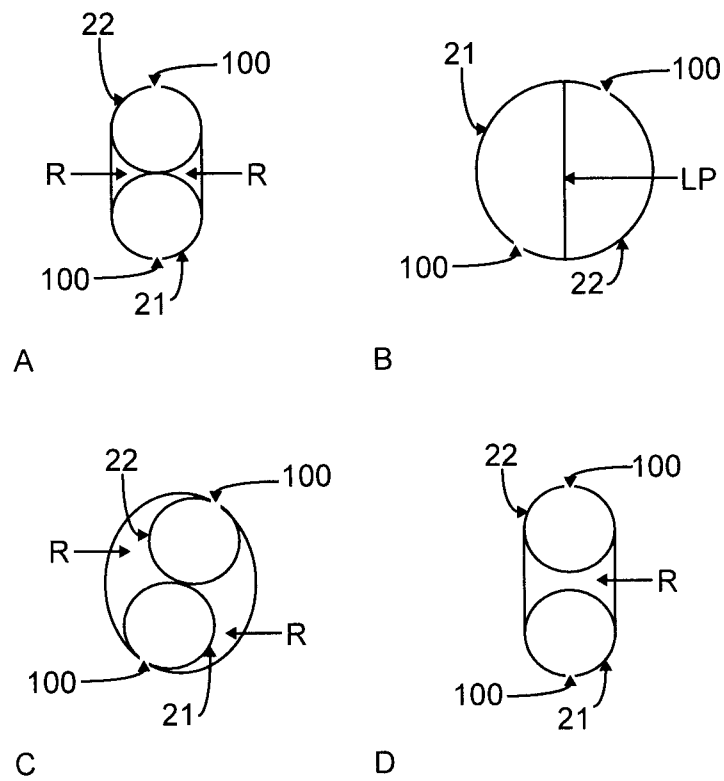


Fig. 7

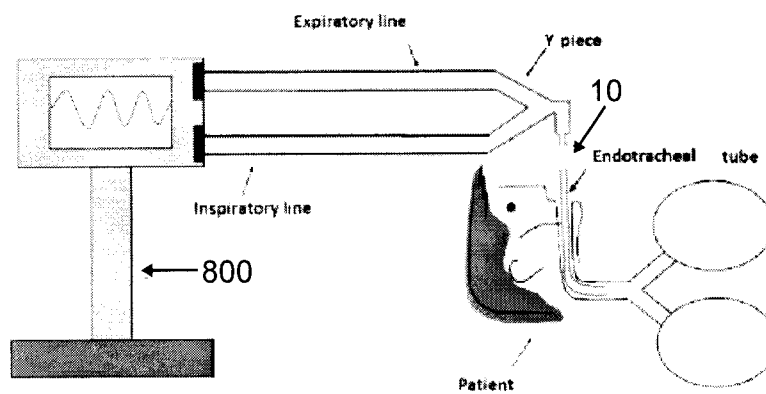


Fig. 8

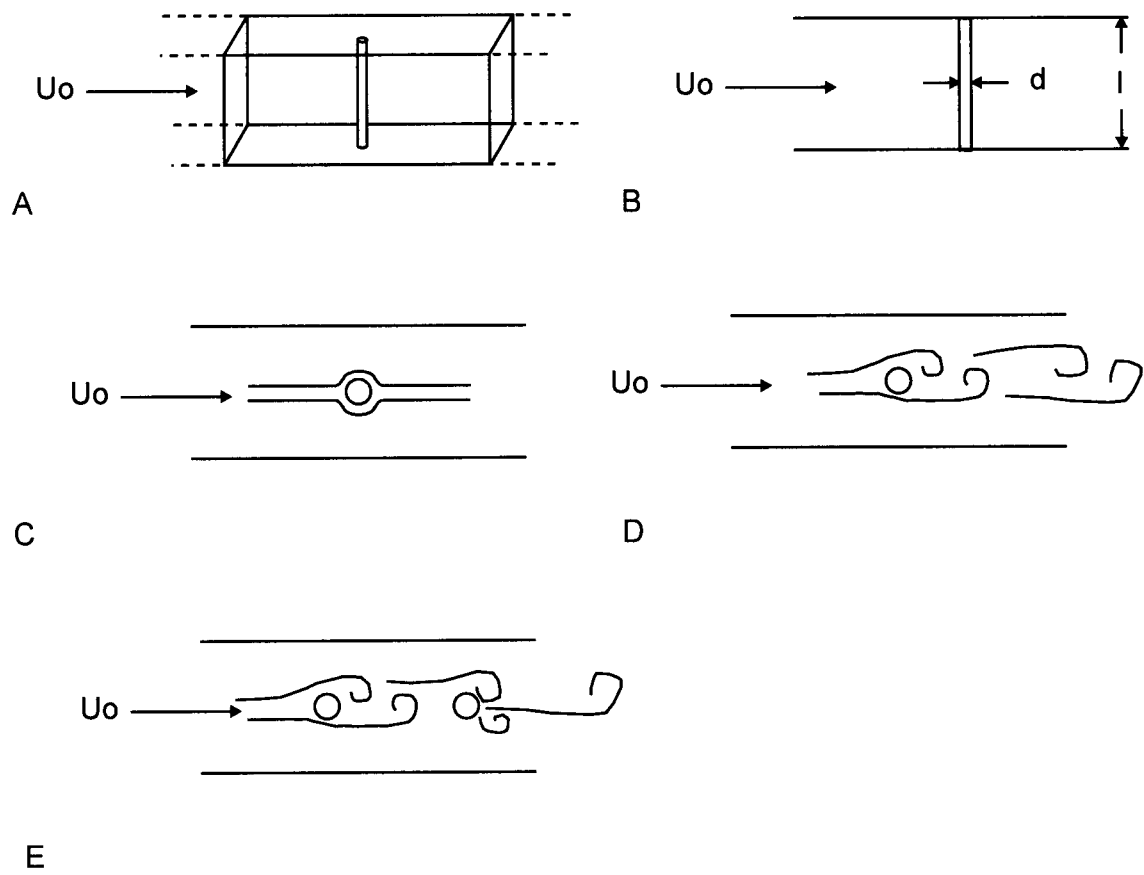


Fig. 9

