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(54) **Title:** ULTRASONIC SPIROMETER

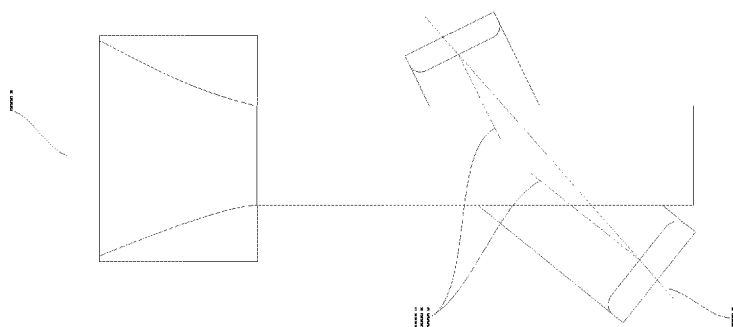


Figure-4

(57) **Abstract:** The present invention relates to a spirometer which is aimed at personal use for the pulmonary function tests, i.e. aimed at usage by the users who do not have medical training and experience. By means of the invention, a compact and ergonomic spirometer comprising two ultrasonic transceivers which are directed towards a volume within a tube forming an air way and which enable reading of the signals produced by each other to make measurements regarding the air flow within the tube has been developed. Signal losses are avoided by positioning the transceivers in a way that the transceivers emit signal along an axis deviating towards the air entry during blowing by a user through a line between them. It is also possible that the spirometer is able to make measurements for air flows in both inhalation and exhalation.



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ULTRASONIC SPIROMETER

Technical Field

The present invention relates to a spirometer which is aimed for personal use for the pulmonary function tests, i.e. aimed to be used by the users who do not have medical training and experience.

Prior Art

Various equipment for measuring air flow rate, in order to evaluate the pulmonary functions of a user are disclosed in the documents numbered US7618235, US7383740 and US20110092840. Besides the measurement of the air flow rate, the volume of the breath taken and given during inhaling or exhaling can also be determined.

It is crucial for monitoring the respiratory functions of the users, that such equipment measuring the air flow rate, are easily carried by the user, can be used correctly by inexperienced users, and that, the portions in which the air passage is maintained during the measurement can be removed for cleaning or replacement. For these reasons, ultrasonic spirometers provide an advantage for the users who do not have medical training. Home use of the spirometers is also becoming widespread, thanks to the developing mobile health services. Home use versions of the spirometer devices, which are being used in clinics, have been marketed by various manufacturers. Despite that fact, the measurement accuracy of such type of devices can not reach the same level as the products of clinical type.

Some ultrasonic spirometers for medical purposes are disclosed in the documents numbered US5419326, US5647370, JP2013250254 and US2010145213. Neither of those ultrasonic spirometers do have a compact and ergonomic structure which can enable easy transportation and use by the user. One of the measurement techniques used in ultrasonic spirometers is the leading edge measurement technique. In this method, an ultrasonic beam consisting of one or more waves is transmitted from a transmitter to a receiver. Measurement is performed by stopping the time counter, which was started

right at the moment the transmitter is excited to send ultrasonic signal, at the zero cut-off point succeeding the first leading edge occurring on the receiver. This zero cut-off point is generated after the amplitude of the first leading edge occurring on the receiver exceeds a certain threshold value. As the flow rate in the spirometer increases, the propagation direction of the ultrasonic signal which is transmitted toward the receiver from the transmitter drifts in the flow direction and when the signal reaches the receiver, it impinges to a point which is far from the center of the receiver. The impact point moves away from the center as the flow rate increases. The distance between the center of the receiver and the point where the signal impinges on the receiver, which increases by the flow rate, generates a low amplitude voltage signal on the receiver, that is proportional of the distance between the center and the point where the signal impinges on the receiver.

When a situation in which a signal of just one wave long is transmitted from a transmitter is considered, in case of the amplitude of this signal occurring on the receiver falls below the trigger level, the signal can not be detected on the receiver and the measurement can not be performed.

Whereas, at high flow rates, in the case where an ultrasonic signal of more than one wavelength length is transmitted from the transmitter, an adequately large enough voltage signal is not formed by the leading edge on the receiver. For this reason, after the first wave impinges on the receiver, the trigger level is exceeded by any of the consecutive waves that periodically reach the receiver. Hence, at which period the triggering is performed, the time counter is stopped after that many periods and a shift in the measurement occurs. Correction of those shifts with software risks the accurate working of the time-critical algorithms run on the microprocessor, in addition to requiring extra software effort. Measurements made when the signal impinging on the receiver falls below the trigger point or when the trigger point is exceeded in the following periods rather than the expected first zero cut point of the signal, reduce the sensitivity of the spirometer seriously. Therefore, in ultrasonic spirometers, operating the ultrasonic transducers at high voltages in order to ensure the measurement accuracy despite the

signal losses taking place as a result of the movements of the air causes high energy consumption and cost increase and shortens the life of the device.

In order to avoid signal losses occurring at high flow rates, the document numbered US4914959 discloses the provision of the placement of transceivers with a deviation in the opposite direction of the flow. With this solution, it is possible to improve the measurement only in one flow direction. However in spirometers, the flow may need to be measured in two directions. Besides this, since airways of the spirometers are produced according to the mouth dimensions of the people, their sectional areas have dimensions which can enter to the mouth. In addition, since very low amount of signal impinges on the transmitter on a section of the airway, that can enter the human mouth, of the spirometer which is designed minimally to be ergonomic, the angle of 55 degrees between the line connecting the sensors stated in the document numbered US4914959 and the air way renders it impossible to apply the leading edge measurement technique. Furthermore, the 10 degrees of deviation angle of the sensors disclosed in the document numbered US4914959 is not advantageous in terms of the use of the leading edge measurement technique in a sectional area of the airway, which can enter the human mouth, of a spirometer which is designed in a minimal form to be ergonomic. The reason for this is that, as the sectional area narrows, the angle between the imaginary line connecting the sensors and the airway direction is required to reduce, in order to the signal emerging from the transmitter to impinge to the receiver.

The Object of the Invention

The object of the present invention is to develop a spirometer that can measure the air flow rate during the pulmonary function test.

Another object of the present invention is to develop a spirometer which is compact and ergonomic, and can be carried comfortably and used correctly by the user.

Yet another object of the present invention is to develop a spirometer, as described above, which can prevent the signal losses due to the transportation of the signal by the airflow.

A further object of the present invention is to develop a spirometer which can be used in both of the flow directions, that is during exhaling and inhaling.

Another different object of the present invention is to develop a hygienic spirometer.

Definitions of the Figures Disclosing the Invention

The figures and explanations that are being used in order to better explain the spirometer developed with this invention are listed below.

Figure-1 is the side schematic view of the spirometer according to the invention.

Figure-2 is the side schematic sectional view of the spirometer according to the invention.

Figure-3 is the schematic sectional view of the transceivers with a tube according to the prior art.

Figure-4 is the schematic sectional view of the transceivers with a tube according to the invention.

Figure-5 is the schematic sectional view of the transceivers with a tube according to the prior art, in which the signal is projected inside the tube.

Figure-6 is the schematic sectional view of the transceivers with a tube according to the invention, in which the signal is projected inside the tube.

Definitions of the Inventive Elements

In order to disclose the spirometer developed with the present invention better, the parts and the portions contained in the figures are numbered, and the counterparts of each number are given below.

1. Spirometer
2. Tube

- 2a. Entry end
- 3. Transceiver
- 4. Body
- 5. Mouthpiece
- i. Flow direction
- ii. Measurement line
- iii. Transmission line

Detailed Description of the Invention

The inventive spirometer (1), which is compact and has an ergonomic form, comprises in essence:

- a tube (2) defining a flow direction (i) and ensuring air passage along an airway during the exhalation by the user by constituting this airway running along this flow direction (i) starting from an entry end (2a) corresponding to the mouth of the user,
- two ultrasonic transceivers (3) which are directed towards the volume inside the tube (2), in a way to be kept on a measurement line (ii) passing inside the airway mentioned, which are present on different locations along the flow direction (i) and which are ensuring the measurements regarding the air flow inside the tube (2) to be performed, by reciprocally reading the signals generated by each other.

The measurement is carried out by means of the movement durations of the signal on both sides along the measurement line (ii). The difference between the components of the signal velocities on each direction, which are parallel to the flow direction (i) is due to the movement of the air inside the tube (2).

The transceivers (3) may consist of a receiver and a transmitter coupled together or preferably a receiver and a transmitter which are integrated and comprising common components.

The spirometer (1) which is the subject of the invention has a form which the user can easily carry and use comfortably by holding with one hand. For this aim, the tube (2) and the transceivers (3) are located within a body (4) of a size which can easily fit in the human hand and abide the palm. The portion accommodating the entry end (2a) of the body (4) is narrower than the rest of the body (4) and has a section that can be grasped comfortably by the thumb. Thus, the body (4) directs the user to hold the entry end (2a) to his/her mouth and to exhale to the tube (2) through the entry end (2a). In order the body (4) to be compatible with this size and formal limitations, the transceivers (3) must be positioned in such a way that it does not occupy the portion of the body (4) that harbors the entry end (2a).

The spirometer (1) also includes a mouthpiece (5) which mediates the exhalation by the user into the tube (2). The mouthpiece (5) is in a position corresponding to the entry end (2a). The mouthpiece (5) may be integrated with the body (4), or preferably integrated with the tube (2).

The transceivers (3) emit signals from a central region and in a form having a large radial symmetry with respect to a transmission line (iii) passing through this central region, and also read the signals impinging on this central region. In order to utilize maximum signal strength during the reading of the signal produced by a transceiver (3) by the other transceiver (3), the transmission line (iii) of the transceiver (3) emitting the signal must pass by the central region of the transceiver (3) reading the signal as much as possible. Despite this, in case of the transmission lines (iii) overlap with the measurement line (ii), due to the fact that the signals drift together with the air flow, signals move away from the central region and since the signal amplitude thus decreases, correct measurements may not be made.

In order to ensure that the read signal amplitude to be maintained at a level where a correct measurement may be made, it is necessary to increase the amplitude of the

emitted signal or reduce the angle between the measurement line (ii) and the flow direction (i). The signal amplitude may be increased by increasing the voltage at which the transceivers (3) are operated, but this results in increased energy consumption, increased production cost, increased circuit area and shorter transceiver (3) life. In case of the angle between the measurement line (ii) and the flow direction (i) is reduced, one of the transducers (3) needs to be positioned close to the entry end (2a) and hence, an ergonomic structure may not be obtained.

Therefore, in order to ensure that the read signal amplitude to be maintained at a level, at which a correct measurement can be made, the transducers (3) in the spirometer (1) according to the invention are arranged in such a way that the transmission lines (iii) deviate from the measurement line (ii) towards the entry end (2a) along the flow direction (i), i.e., with a deviation from the measurement line (ii) towards the entry end (2a) along the flow direction (i).

Breathing maneuvers in the pulmonary function tests performed with the spirometer (1) consist of normal and deep inhaling maneuver and forced blowing. In one embodiment of the invention, the spirometer (1) can be used for measurements to be performed during normal and deep inhaling, as well as the measurements to be performed during forced blowing. In the Pulmonary function tests performed with the spirometer (1), the air flow rate during forced blowing is much higher than the one provided during normal and deep inhaling. For this reason, in a preferred embodiment of the invention, in order to be able to make measurements in both cases with the spirometer (1) of the invention, there is an angle of 50° or less between the measurement line (ii) and the flow direction (i), and an angle between 1° and 7° between the transmission line (iii) and the measurement line (ii) of each transceiver. Thus, due to the deviation of the transmission lines (iii) from the measurement line (ii) of the transceivers (3) during forced blowing, the signals approach the center of the respective transceiver (3), whereas during the deep and normal inhaling, i.e. during the air flow in the opposite direction, signals shall not be distanced as much as not to be read from the center of the transceiver (3).

During the exhalation by the user, while air entry from the entry end (2a) to the tube (2) takes place, during the exhalation by the user, air exit from the tube (2) shall take place at the entry end (2a).

As well as the transducers (3) may be positioned opposing each other around the tube (2), in one embodiment of the invention, the measurement line (ii) may be positioned around the tube (2) in a way to provide at least one reflection from the inner surface of the tube (2). There is also a reflector on the inner surface of the tube (2), which facilitates the reflection of the signal in the region where reflection takes place with minimum loss.

During use, the tube (2) is contaminated with airborne saliva and other debris. For this reason, the tube (2) preferably fits into housing in the body (4) in a way that it can be removed. The removed tube (2) may be washed or it may be disposable. In order to properly fit the tube (2) to its housing, there exist structures that fit each other on the inner surface of the housing and the outer surface of the tube (2).

In order to prevent contamination of the components of the spirometer (1) or to prevent the transceivers from being affected by the airborne bacteria and other debris, filters on the locations which correspond to the places where the transceivers (3) are located on the tube (2) and which allow the passage of the signals, whereas which do not allow the passage of the contaminants shall be present as well.

There may also be one or more flow regulators in the tube (2) and/or the mouthpiece (5), in order to reduce the possible turbulence intensity in the air flow created within the tube (2), which may be generated by the user.

CLAIMS

1. A spirometer which can be used by a user lacking medical education and experience for the pulmonary function tests, comprising
 - a tube (2) defining a flow direction (i) and ensuring air passage along an airway during the exhalation by the user by constituting this airway running along this flow direction (i) starting from an entry end (2a) corresponding to the mouth of the user,
 - two ultrasonic transceivers (3) which are directed towards the volume inside the tube (2), in a way to be kept on a measurement line (ii) passing through the airway mentioned, which are positioned on different locations along the flow direction (i) and are adapted to enable measurements regarding the air flow inside the tube (2) to be performed by reciprocally reading the signals generated by each other,wherein the tube (2) and the transceivers (3) are contained within a body (4) having dimensions to fit to human hand and abide to palm,
characterized in that the mentioned transceivers (3) are positioned such that their transmission lines (iii) deviate from the measurement line (ii) towards the entry end (2a) along the flow direction (i).
2. A spirometer (1) such as in Claim 1, characterized by the transceivers (3) being positioned with an angle of 50° or less between the measurement line (ii) and the flow direction (i), and an angle between 1° and 7° between the transmission line (iii) and the measurement line (ii) of each transceiver (3).
3. A spirometer (1) such as in Claim 1, characterized by the body (4) having a portion accommodating the entry end (2a) that is narrower than the rest and said portion having a section that can be grasped by the thumb.
4. A spirometer (1) such as in Claim 1, comprising a mouthpiece (5) which mediates the exhalation by the user into the tube (2).

5. A spirometer (1) such as in Claim 1, wherein the transceivers (3) are positioned around the tube (2) opposing each other.
6. A spirometer (1) such as in Claim 1, wherein the transceivers (3) are positioned around the tube (2) such that the measurement line (ii) has at least one reflection from the inner surface of the tube (2).
7. A spirometer (1) such as in Claim 1, wherein the tube (2) is detachably fitted to a housing inside the body (4).
8. A spirometer (1) such as in Claim 7, comprising structures fitting each other on the inner surface of the housing and the outer surface of the tube (2).
9. A spirometer (1) such as in Claim 1, comprising filters which are found on the positions where the transceivers on the tube (2) are located on and which allow the passage of the signals, whereas which do not allow the passage of the contaminants.
10. A spirometer (1) such as in Claim 1, comprising one or more flow regulators within the tube (2) and/or the mouthpiece (5).

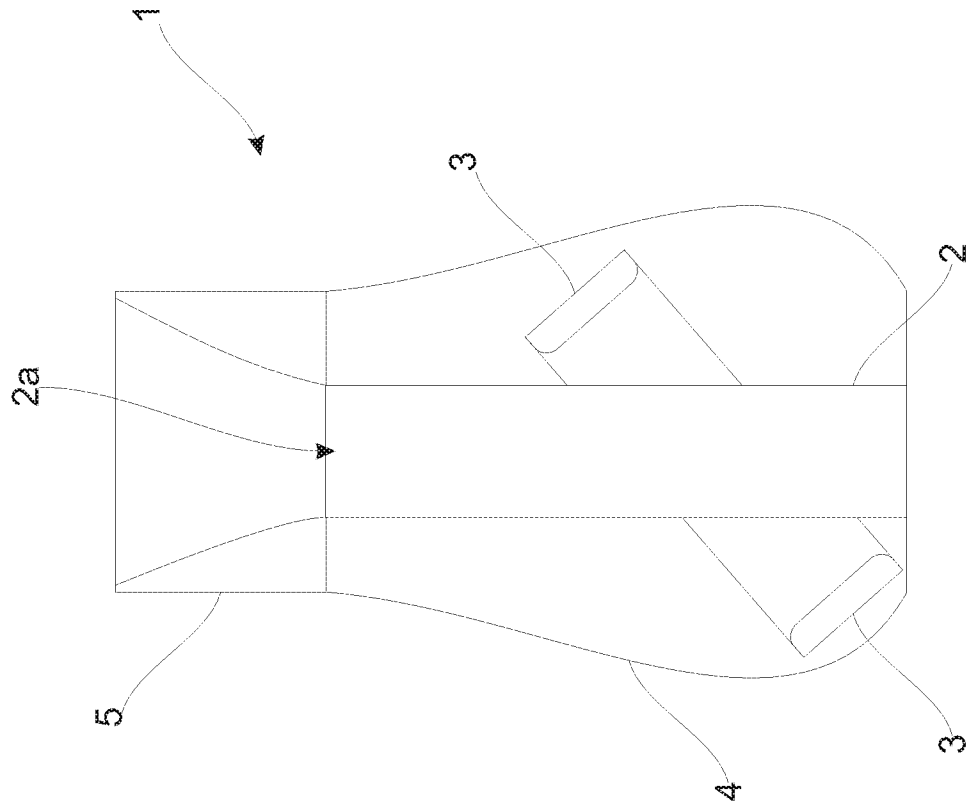


Figure-2

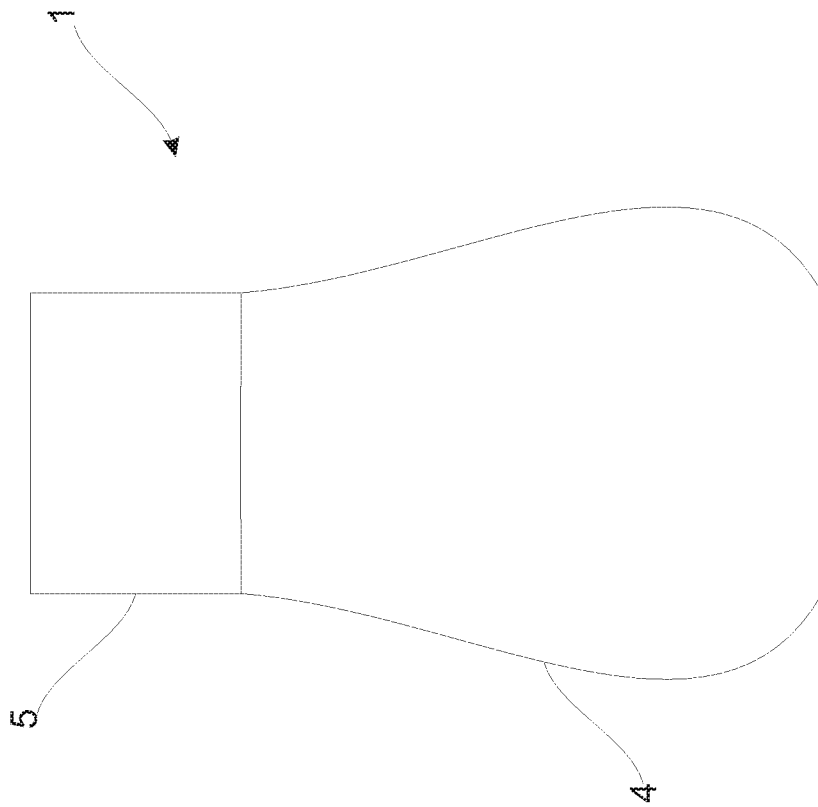


Figure-1

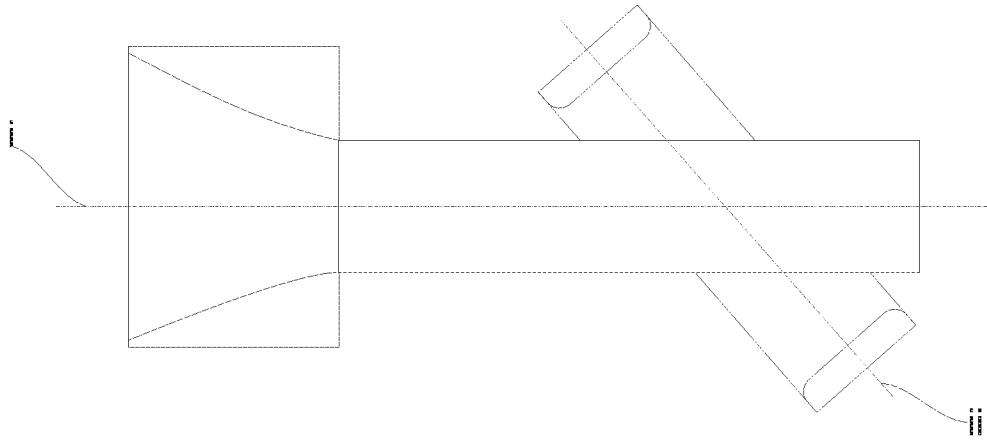


Figure-3

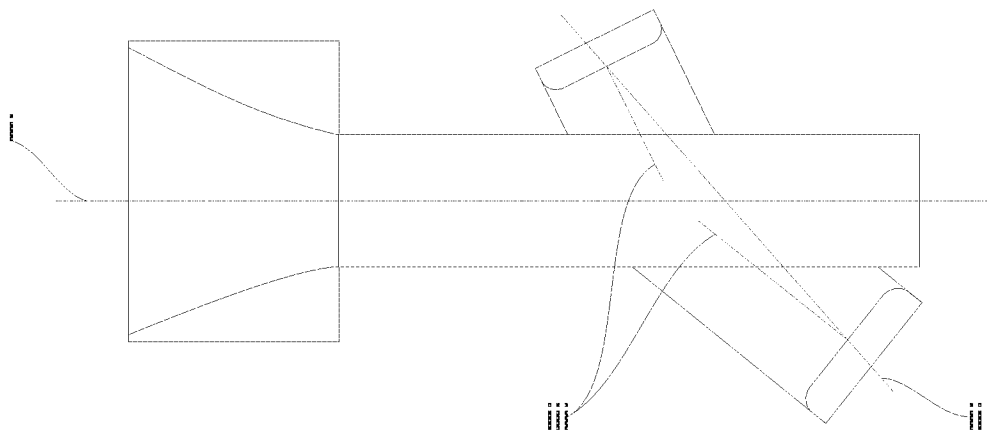


Figure-4

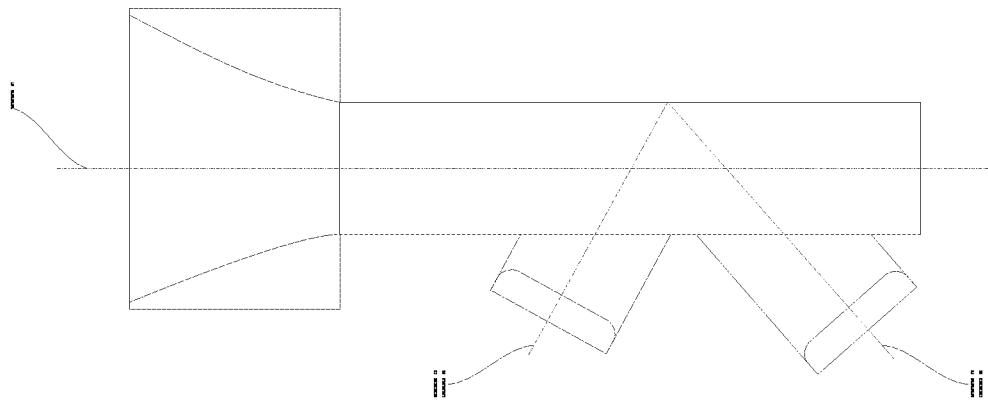


Figure-5

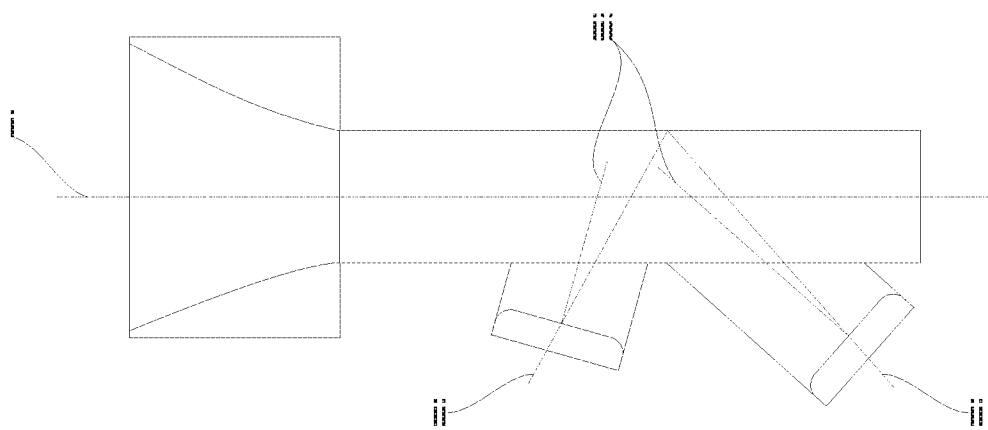


Figure-6