

A RESPIRATORY SYSTEM

FIELD OF THE INVENTION:

The invention relates to the field of biomedical engineering.

Particularly, this invention relates to lung / breathing related devices.

Specifically, this invention relates to a continuous expiratory airway resistance valve.

BACKGROUND OF THE INVENTION:

Incentive Spirometry (IS) is a frequently used visual feedback-based hand-held lung exercise device that helps in lung expansion by facilitating maximum volume respiratory technique. The device is designed to induce sighing or yawning by making the patient take long, slow deep breaths. It is expected to prevent and treat atelectasis (collapse of small lung segments) in alert patients who have a predisposition for shallow breathing. IS leads to the generation of a substantial and sustained increase in the transpulmonary pressure, which leads to expansion of collapsed alveolar units, thereby improving lung function. However, robust evidence to improve the patients' condition is lacking.

Further, the use of the Incentive Spirometry is user-dependent and proper use needs good adherence to instructions; improper use fails to improve the patient's condition. It is also to be noted that it does not impact the positive end-expiratory pressure (PEEP). On the other hand, PEEP is well-known to prevent alveolar collapse and atelectasis.

IS devices, presently available in the market, are manufactured to be used in an awake patient; its mechanism is such that the patient will keep the mouthpiece if the incentive spirometry device is in his/her mouth and inhale the air and then slowly exhale it.

According to prior art, incentive spirometers usually have a vertical cylinder containing a movable piston or ball slidable along with the cylinder. A flexible tube is terminated at one end by a mouthpiece and has its other end connected to an opening in the spirometer that connects with the upper end of the cylinder. When the patient inhales through the mouthpiece it creates a reduced pressure in the tube that is communicated to the upper end of the cylinder. This causes the piston to raise the cylinder/ball. The cylinder is transparent or has a transparent window and is graduated by volume up to its height so that the user can compare the position of the piston against the graduated scale.

One of the problems associated with the prior art incentive spirometers is discussed below:

Further, the peri-glottic region is also responsible for maintaining a resistance that forms the basis of physiological PEEP. This physiological PEEP, in turn, prevents the collapse of alveoli and atelectasis. During the process of tracheostomy (creation of a hole in the windpipe through which the patient inspires and expires air), the oral and nasal cavity are bypassed, leading to reduction of the usual resistance to the expired air, which is present in case of mouth breathing. As gas always passes through a path of least resistance, exhaled air escapes through tracheostomy stoma in tracheostomized patients, directly, without being directed towards the nose and mouth. This leads to loss of physiological PEEP. The alveoli collapse leading to atelectasis of the lungs is one of the critical causes of

pulmonary complications and failure to liberate the patient from the ventilator or other forms of respiratory support.

In clinical practice, a good number of patients require TT. Classically, tracheostomy, as a procedure, was mainly done in patients with neurological sequelae after Cerebrovascular Accidents (CVA) and as a part of surgeries for large tumors of the head and neck region. However, after the COVID pandemic, the number of patients undergoing tracheostomy for respiratory and lung causes has dramatically increased. Due to the COVID pandemic, a large number of people have developed lung and respiratory complications. In a sub-set of covid recovered patients, post-COVID complications have been seen. These complications mainly affect the lungs and the respiratory system leading to severe compromise of lung capacity and functions. A subset of covid patients become dependent on a ventilator and ultimately need to be tracheostomized.

While non-tracheostomized patients can do incentive spirometry to improve their lung functions and capacities and shown good results, patients on TT, do not have an option to do incentive spirometry as the commercially available IS are not designed to be used in such patients.

One of the other problems associated with the prior art incentive spirometers is discussed below:

Even if some connectors are used to attach the TT and IS, the problem of bypassing the upper airway, which provides physiological resistance and forms the basis of PEEP, is not solved.

During normal physiological breathing, while exhaling, expired air passes through the nose and the mouth and encounters a resistance due to which a positive pressure (physiological positive end-expiratory pressure (PEEP) towards the end of

expiration, this helps in keeping the alveoli (small functional units of lungs) in an open state and maintain adequate lung function.

Tracheostomy is a procedure of creating a hole in the trachea (wind pipe) so that air can enter the lungs directly through the windpipe bypassing the oral and nasal cavity. Therefore, in tracheostomized patients as the normal anatomical air passage is bypassed, no resistance is offered to the expired air leading to collapse of the alveoli which is one of the critical causes of pulmonary complications and failure to liberate the patient from the ventilator or other forms of respiratory support.

Beneficial effects of PEEP in tracheostomized patients (provided by Mechanical Ventilator)

Normally when a tracheostomized patient is connected to the mechanical ventilator an adjustable level of Extrinsic positive end-expiratory pressure (PEEP) can be provided by the ventilator. The application of positive pressure inside the airways have many beneficial effects:

- it opens or “splints” airways that may otherwise be collapsed;
- decreasing collapse of small airways (atelectasis);
- improving oxygen delivery to lungs (alveolar ventilation), and,
- improve lung function (decreasing V/Q mismatch);
- decrease respiratory effort needed to inflate the lungs (decreases the work of breathing);
- it has been shown to be helpful in patients in severe COVID pneumonia where the lungs become stiff.

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Furthermore, the beneficial effects of PEEP can only be provided to tracheostomized patients only till mechanical ventilation is continued. Once mechanical ventilation is weaned off, these effects are lost which leads to collapse

of smaller lung units and decrease in lung function. However, the continued application of mechanical ventilator support in tracheostomized patients is not feasible because of following reasons:

- It dramatically increases health care costs;
- it has huge financial implications on the patient's family in particular and society in general;
- Mechanically ventilated patients have higher risks of infections and other complication like decrease oxygen supply (due to equipment failure), need of sedation;
- Prolong mechanical Ventilation increases length of stay in the intensive care units and also the overall hospital stays;
- Due to the ongoing pandemic, need for ventilators have gone up drastically and critical equipment and ventilator beds have become a scarce commodity.

One more problem associated with the prior art incentive spirometers is discussed below:

Even if one attaches commercially available valves like PEEP or CPAP (continuous positive airway pressure) valves, the problem is not solved completely. While these valves can provide resistance during expiration or throughout, it increases the work of breathing (effort required to inspire air) breathing by producing resistance to airflow during inspiration.

One additional problem associated with the prior art incentive spirometers is discussed below:

The patients' condition and lung condition are relatively dynamic, and the requirement of resistance and PEEP is variable. There are no currently available valves for IS that can be adjusted to the variable need of resistance.

Currently, commercially available Incentive spirometers are not designed to be used in tracheostomized patients. They are manufactured to be used in awake patients; its mechanism is such that a patient will keep the mouthpiece if the incentive spirometry device is in his/her mouth and inhale air and then slowly exhale it.

OBJECTS OF THE INVENTION:

An object of the invention is to prevent loss of physiological PEEP.

Another object of the invention is to provide incentive spirometry to patients.

Yet another object of the invention is to maintain physiological resistance which forms the basis of PEEP during incentive spirometry exercises.

Still another object of the invention is to eliminate / reduce resistance to airflow during inspiration whilst doing incentive spirometry exercises.

Another object of the invention is to provide a valve for incentive spirometry that can be adjusted to variable needs of resistance.

SUMMARY OF THE INVENTION:

According to this invention, there is provided a respiratory system comprising:

- a tube-within-tube, with an outer cylinder tube and an inner cylinder tube, with dedicated channels for inspired gases and expired gases facilitated by valves configured to resist outflow of expired gases, in that, inspired air flows through said inner cylinder tube and expired air flows through said inner cylinder tube;
- a Continuous Expiratory Airway Resistance Valve (CEAR-Valve, Valve 2), being an expiration valve (Valve 2), being a cylindrical co-axial valve configured to be in-line with said outer cylindrical tube and co-axial external to said inner cylindrical tube, said Continuous Expiratory Airway Resistance Valve (CEAR-Valve, Valve 2) being an adjustable spring-loaded resistance unidirectional valve (Valve 2) generating pressure (resistance) to gas flow and maintaining set resistance during time of post-expiratory pause, said Continuous Expiratory Airway Resistance Valve (CEAR-Valve, Valve 2) configured to open only during expiration and configured to close during inspiration, thereby defining a first dedicated channel for expiration, said Continuous Expiratory Airway Resistance Valve (CEAR-Valve, Valve 2) providing an adjustable level of resistance;
- another unidirectional valve (Valve 3), being an inspiration valve, stationed at a patient end of said co-axial tube-within-tube inside said inner cylinder tube, said another unidirectional valve (Valve 3) configured to open only during inspiration and configured to close during expiration, thereby defining a second dedicated channel for inspiration; and
- entire expired gas, from said Continuous Expiratory Airway Resistance Valve (CEAR-Valve, Valve 2), passing through said outer cylinder encircling said inner cylinder and housing said spring-loaded adjustable valve during expiration.

In at least an embodiment, said Continuous Expiratory Airway Resistance Valve being a unidirectional valve.

In at least an embodiment, an outer cylinder tube ensconces an inner cylinder tube with:

- a spaced apart distance between an outer diameter of said inner cylinder tube and an inner diameter of said outer cylinder tube; and
- a mouth of said inner cylinder tube abutting a mouth of said outer cylinder tube; and
- said inner cylinder tube being co-axial with said outer cylinder tube.

In at least an embodiment, a connector connects a patients' tracheostomy outer end with incentive spirometry (IS), said connector being a universal female adapter.

In at least an embodiment, said valve is configured to instill pressure (resistance) to gas flow ranging from 3 cmH₂O to 30 cmH₂O.

In at least an embodiment, said inspiration valve (3) is a fish mouth valve for inspiration.

In at least an embodiment, said inspiration valve is a ball valve for inspiration.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS:

The invention will now be described in relation to the accompanying drawings, in which:

FIGURE 1 illustrates a respiratory system with a Continuous Expiratory Airway Resistance (CEAR) Valve according to this invention;

FIGURE 2 illustrates a cross-section of a respiratory system with the Continuous Expiratory Airway Resistance (CEAR) Valve according to this invention;

FIGURE 3 illustrates another cross-section of a respiratory system with the Continuous Expiratory Airway Resistance (CEAR) Valve according to this invention;

FIGURE 4 illustrates two-dimensional exploded view, of alternative embodiments, of the Continuous Expiratory Airway Resistance (CEAR) Valve according to this invention;

FIGURE 5 illustrates three-dimensional exploded view, of alternative embodiments, of the Continuous Expiratory Airway Resistance (CEAR) Valve according to this invention;

FIGURE 6a and 6b illustrates three-dimensional exploded view, of alternative embodiments, of the Continuous Expiratory Airway Resistance (CEAR) Valve according to this invention;

FIGURES 7a, 7b, and 7c illustrate various views of the valve configuration (12, 14, CEAR) used in this invention;

FIGURE 8 illustrates air flow property of system at inlet flow rate – 5m/s;

FIGURE 9 illustrates pressure at 30 WC at exhalation presses;

FIGURE 10 illustrates FEA model of used spring;

FIGURE 11 illustrates air flow at 5 mm spring deflection and 1.08 n pressure on plate; and

FIGURE 12 illustrates results with valve design at 30wc pressure such that it is safe to handle pressure and structural strength is safe. This structure is qualified to given result.

DETAILED DESCRIPTION OF THE ACCOMPANYING DRAWINGS:

According to this invention, there is provided a respiratory system.

FIGURE 1 illustrates a respiratory system with a **Continuous Expiratory Airway Resistance (CEAR) Valve** according to this invention.

FIGURE 2 illustrates a cross-section of a respiratory system with the **Continuous Expiratory Airway Resistance (CEAR) Valve** according to this invention.

FIGURE 3 illustrates another cross-section of a respiratory system with the **Continuous Expiratory Airway Resistance (CEAR) Valve** according to this invention.

FIGURE 4 illustrates two-dimensional exploded view, of alternative embodiments, of the **Continuous Expiratory Airway Resistance (CEAR) Valve** according to this invention.

FIGURE 5 illustrates three-dimensional exploded view, of alternative embodiments, of the **Continuous Expiratory Airway Resistance (CEAR) Valve** according to this invention.

FIGURE 6a and **6b** illustrates three-dimensional exploded view, of alternative embodiments, of the **Continuous Expiratory Airway Resistance (CEAR) Valve** according to this invention.

Typically, the valve / device, of this invention, is intended to be used along with pre-existing devices called Incentive spirometers (IS) and Tracheostomy tubes (TT). This valve broadens the scope of use of commercially available incentive spirometers in tracheostomized patients.

In at least an embodiment, of this invention, the **CEAR valve** comprises a **tube-within-tube (12, 14) design with dedicated channels** for inspired and expired gases facilitated by valves (2, 3); this resists outflow of expired gases. However, there is none or negligible resistance to inflow of gas (inspiration) so that there is no increase of work of breathing for the patient.

In preferred embodiments, the tube size is a universal 15 mm female connector at the connecting end to be easily connected to the TT. The size and weight is minimal.

In preferred embodiments, resistance is adjustable from 3cmm H2O to 30cmH2O.

In at least an embodiment, of this invention, the **Continuous Expiratory Airway Resistance Valve** (CEAR-Valve) is a cylindrical co-axial design and placed in a limb (breathing line) connecting a patients' tracheostomy outer end with incentive spirometry (IS). The connection is a **universal female adapter** (preferably, 15 mm) to get attached to the tracheostomy tube. The breathing line (tube) houses the 'Continuous Expiratory Airway Resistance Valve' (CEAR-Valve) which is an adjustable spring-loaded resistance valve (**Valve 2** in the figures). The CEAR-Valve (**Valve 2** in the figures) is a spring-based pressure valve generating a minimum of 3 cmH2O pressure (resistance) to gas flow. It provides resistance only during expiration and maintains set resistance during time of post-expiratory pause. However, the valve can be one delivering a variable and adjustable resistance. The valve allows only unidirectional flow. It does not allow air entry during inspiration through the incentive spirometry (IS) but only allows expiration against a set resistance (can be set by the user or clinician as deemed necessary).

In at least an embodiment, one more unidirectional valve (**Valve 3** in the figures), is stationed at the patient end of the co-axial cylindrical device inside the inner cylinder. This valve 3 opens only during inspiration and closes during expiration. The internal diameter of the tube housing this valve, preferably, is more than 10 mm. Therefore, the patient inspires without much resistance. On the other hand, the entire expired gas passes through the **outer channel** encircling the **inner tube** and housing the spring-loaded adjustable valve during expiration. The design of the Valve 2 and Valve 3 is as shown in Figures. The inner cylinder, of the co-axial system, is deficient towards the patient (TT) end so that the outer cylinder fits the tracheostomy tube snugly.

Reference numeral 1: adjustable knob

Reference numeral Valve 2: expiration valve

Reference numeral Valve 3: inspiration valve

In at least an embodiment, an outer cylinder tube (14) ensconces an inner cylinder tube (12) with:

- a spaced apart distance between an outer diameter of said inner cylinder tube (12) and an inner diameter of said outer cylinder tube (14); and
- a mouth of said inner cylinder tube (12) abutting a mouth of said outer cylinder tube (14); and
- said inner cylinder tube (12) being co-axial with said outer cylinder tube (14).

FIGURES 7a, 7b, and 7c illustrate various views of the valve configuration (12, 14, CEAR) used in this invention.

In typical embodiments, the inspiration valve (3) is a fish mouth valve for inspiration; this valve is useful since it does not reduce the effective diameter of the inspiratory limb for gas flow and it does not increase resistance.

In alternative embodiments, the inspiration valve (3) is a ball valve for inspiration.

In at least an embodiment, the main feature of the CEAR valve, of this invention, is that it enables tracheostomized patients to use incentive spirometry devices. This device provides a desired yet adjustable /selectable resistance to outflow of expired gases, which work like PEEP; a 'critical' factor to keep the alveoli inflated. It is, in turn, likely to help a patient in:

- a. Lung exercise
- b. Prevent lung atelectasis
- c. Reduce the postoperative pulmonary complication
- d. Improve the oxygenation by improving the ventilation-perfusion mismatch

The current invention seeks to create/establish a PoC for a device which is a Continuous Expiratory Airway Resistance "CEAR" valve device that can be used on Tracheostomized patients and yield the following benefits:

- Provision of Positive pressure (PEEP) and thus its benefits, as stated above, to tracheostomized patients without the need of mechanical ventilator.
- Improve Lung function and facilitate early liberation of tracheostomized patients from mechanical ventilator.

- Decrease complications associated with prolonged mechanical ventilation.
- Decrease the length of stay in the intensive care units (due to early weaning).
- Decrease health care costs decrease the financial burden on the patient's family and the society as a whole.
- 'CEAR' will enable the use of commercially available Incentive Spirometry devices in tracheostomized patients and thus provide its benefits to them.
- 'CEAR' valve is a market creating innovation which will unfold a large unmet need. It will increase the market size for incentive spirometry devices by enabling their use in tracheostomized patients.

This invention's valve broadens the scope of use of commercially available incentive spirometers in tracheostomized patients. One can broaden the applicability of the device by not limiting its use only as a connector for IS. One can also add that this device might have applicability in anaesthesia circuits (self-inflating manual resuscitator bags, bain's circuits, ventilators, and ventilator circuits, etc.) and for providing PEEP support to other devices which can be connected to a tracheostomy tube or Endotracheal tube). With subsequent modifications, this device would also be used for bed side measurement of lung functions like Peak Expiratory flow rate (PEFR) and Forced Expiratory Volume in 1st second FEV1 etc.

FIGURE 8 illustrates air flow property of system at inlet flow rate – 5m/s.

FIGURE 9 illustrates pressure at 30 WC at exhalation presses. This creates pressure on spring plate.

Load is 1.08 N

Inlet air – 5 M/s

FIGURE 10 illustrates FEA model of used spring.

APPLY LOAD – 1.08 N

SPRING DEFLECTION – 5.2 mm

FIGURE 11 illustrates:

Air flow at 5 mm spring deflection and 1.08 n pressure on plate

Air flow 5m/s

FIGURE 12 illustrates results with valve design at 30wc pressure such that it is safe to handle pressure and structural strength is safe. This structure is qualified to given result

Table 1 illustrates readings from a CFD model showing the pressure at spring plate is 1.08 N at 30wc applying inlet air value through exhalation Process.

SN	SPRING SETTING	WC PRESSURE
1	1 mm	6
2	2 mm	12
3	3 mm	18
4	4 mm	24
5	5 mm	30

TABLE 1

It can be seen that at 5 mm spring setting, the value of force become equal to the 30wc pressure. So, if one compresses spring to 1mm, the wc pressure is 6 wc. The inlet air flow through inhale (30 lpm, 60lpm, 90lpm) does not affect the pressure inside tube – because one side valve should be closed.

The **TECHNICAL ADVANTAGES**, of the current invention, are as follows:

- When CEAR valve, of this invention, is connected to IS; IS can be used in tracheostomized patients.
- CEAR valve, of this invention, prevents loss of lung recruitment and prevents the collapse of the smaller lung units (alveoli) and prevent lung function in the tracheostomized patient (by proving PEEP).
- It is likely to decrease pulmonary complications in tracheostomized patients.
- It is likely to facilitate patient recovery.
- It is likely to decrease the length of stay in intensive care or ward, which will decrease overall health costs.

The **TECHNICAL ADVANCEMENT** of this invention lies in providing a respiratory system with Continuous Expiratory Airway Resistance Valve (CEAR valve) which is designed such that it provides a predetermined resistance to outflow of expired gases and mimics normal physiology (resistance to expired air provided by the structures present in the nose and mouth) during normal breathing through nose and mouth. Further, it maintains positive end-expiratory pressure (PEEP) to keep alveoli, of a patient, open after expiration, which is usually maintained by physiological PEEP, and physiological PEEP is lost to some extent in patients with TT. The valve is designed such that it provides resistance

selectively to the expiration as the set resistance will persist during the end-expiratory pause period mimicking PEEP. The tube within tube design will have a dedicated inspiratory channel which provides very low or negligible resistance to the inspiration. The CEAR valve has the facility to adjust the resistance during expiration, and it will range between 3-20 cmH₂O.

While this detailed description has disclosed certain specific embodiments for illustrative purposes, various modifications will be apparent to those skilled in the art which do not constitute departures from the spirit and scope of the invention as defined in the following claims, and it is to be distinctly understood that the foregoing descriptive matter is to be interpreted merely as illustrative of the invention and not as a limitation.

CLAIMS,**1. A respiratory system comprising:**

- a **tube-within-tube (12, 14)**, with an outer cylinder tube (14) and an inner cylinder tube (12), with dedicated channels (12a, 14a) for inspired gases (12a) and expired gases (14a) facilitated by valves (2, 3) configured to resist outflow of expired gases, in that, inspired air flows through said inner cylinder tube (12) and expired air flows through said inner cylinder tube (14);
- a **Continuous Expiratory Airway Resistance Valve (CEAR-Valve, Valve 2)**, being an expiration valve (Valve 2), being a cylindrical co-axial valve configured to be in-line with said outer cylindrical tube (14) and co-axial external to said inner cylindrical tube (12), said **Continuous Expiratory Airway Resistance Valve (CEAR-Valve, Valve 2)** being an adjustable spring-loaded resistance unidirectional valve (Valve 2) generating pressure (resistance) to gas flow and maintaining set resistance during time of post-expiratory pause, said **Continuous Expiratory Airway Resistance Valve (CEAR-Valve, Valve 2)** configured to open only during expiration and configured to close during inspiration, thereby defining a first dedicated channel (14a) for expiration, said **Continuous Expiratory Airway Resistance Valve (CEAR-Valve, Valve 2)** providing an adjustable level of resistance;
- another **unidirectional valve (Valve 3)**, being an inspiration valve (3), stationed at a patient end of said co-axial tube-within-tube (12, 14) inside said inner cylinder tube (12), said another unidirectional valve (**Valve 3**) configured to open only during inspiration and configured to close during

- expiration, thereby defining a second dedicated channel (12a) for inspiration; and
- entire expired gas, from said **Continuous Expiratory Airway Resistance Valve** (CEAR-Valve, Valve 2), passing through said **outer cylinder (14)** encircling said **inner cylinder (12)** and housing said spring-loaded adjustable valve during expiration.
2. The system as claimed in claim 1 wherein, said **Continuous Expiratory Airway Resistance Valve** being a unidirectional valve.
 3. The system as claimed in claim 1 wherein, an outer cylinder tube (14) ensconces an inner cylinder tube (12) with:
 - a spaced apart distance between an outer diameter of said inner cylinder tube (12) and an inner diameter of said outer cylinder tube (14); and
 - a mouth of said inner cylinder tube (12) abutting a mouth of said outer cylinder tube (14); and
 - said inner cylinder tube (12) being co-axial with said outer cylinder tube (14).
 4. The system as claimed in claim 1 wherein, a connector connects a patients' tracheostomy outer end with incentive spirometry (IS), said connector being a **universal female adapter**.
 5. The system as claimed in claim 1 wherein, said valve is configured to instill pressure (resistance) to gas flow ranging from 3 cmH₂O to 30 cmH₂O.

6. The system as claimed in claim 1 wherein, said inspiration valve (3) is a fish mouth valve for inspiration.
7. The system as claimed in claim 1 wherein, said inspiration valve (3) is a ball valve for inspiration.