Title: BI-FUNCTIONAL IN-LINE PHONATION VALVE

Abstract: An in-line phonation valve system (10) including a valve body (12) having first and second ends (14, 16) through which gas passes into and out of the valve body (12). The first end (14) is connectable to a breathing tube connected to a patient's airway, for passage of gas between the breathing tube and the valve body (12). The second end (16) of the valve body (12) is connectable to a gas line. A diaphragm-valve assembly (28) is provided which includes a one-way valve (30) having a phonation position permitting gas to pass through said valve body (12) toward said patient when said patient inhales. The one-way valve (30) in the phonation position substantially prevents gas from passing through the valve body (12) when the patient exhales. The diaphragm-valve assembly (28) is movable from the phonation position, so as to permit substantially free flow of gas through the valve body (12) both toward and away from the patient when the patient respectively inhales and exhales. The diaphragm-valve assembly (28) is movable from the phonation position without disconnecting the first end (14) from the breathing tube and the second end (16) from the gas line. Preferably, the diaphragm-valve assembly (28) is a removable cartridge which is replaceable with a free-flowing ring cartridge insert (42).
(15) Information about Correction:
see PCT Gazette No. 12/2001 of 22 March 2001, Section II

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.
BI-FUNCTIONAL IN-LINE PHONATION VALVE

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

The present invention relates to an in-line phonation valve for a breathing tube such as a tracheostomy tube.

DESCRIPTION OF THE BACKGROUND ART

Phonation valves permit speaking by a patient having a breathing tube inserted into the patient's airway, such as a tracheostomy tube inserted into a patient's trachea.


Also of interest are U.S. Patent Nos. 3,924,637, 3,990,439, 4,538,607 and 4,627,433.

In-line phonation valves have one end connected to a breathing tube inserted into a patient's body. A second end of an in-line phonation valve is connected to a gas line of a ventilator circuit.

Prior in-line phonation valves are unidirectional (one-way) valves that allow inspiration only. This results in expiration through the patient's voice box allowing the patient to speak.

Typically, phonation valves are used only temporarily for speaking, and the ventilator circuits must be disconnected for removing the phonation valves. Additionally, in-line phonation valves must frequently be cleaned.

There remains a need in the art for improved in-line phonation valves.

SUMMARY OF THE INVENTION

In accordance with the present invention, an in-line phonation valve system comprises a valve body having first and second ends through which gas passes into and out of the valve body. The first end is connectable to a breathing tube connected to a patient's airway, for passage of gas between the breathing tube and the valve body. The second end of the valve body is connectable to a gas line. A diaphragm-valve assembly is provided which comprises a one-way valve having a phonation position permitting gas to pass through said valve body toward said patient when said patient inhales. The one-way valve in the phonation position substantially prevents gas from passing through the valve body when the patient exhales. The
diaphragm-valve assembly is movable out of the phonation position, so as to permit substantially free flow of gas through the valve body both toward and away from the patient when the patient respectively inhales and exhales. The diaphragm-valve assembly is movable from the phonation position without disconnecting the first end from the breathing tube and the second end from the gas line.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Fig. 1A is a perspective view of a phonation valve in accordance with one embodiment of the present invention.

Fig. 1B is a partly schematic cross-sectional view of the valve of Fig. 1 in a phonation position.

Fig. 1C is a partly schematic cross-section of the valve of Fig. 1A in an intermediate position.

Fig. 1D is a partly schematic cross-sectional detail of Fig. 1C.

Fig. 2 is a schematic illustration, partially in cross-section, showing use of a phonation valve in accordance with the present invention.

Fig. 3A is a perspective view of a second embodiment of the present invention.

Fig. 3B is a partly schematic cross-section of the valve of Fig. 3A, in a phonation position.

Fig. 3C is a partly schematic cross-section of the valve of Fig. 3A in a free-flow configuration.

Fig. 4A is a perspective view of a third embodiment of the present invention.

Fig. 4B is a partly schematic cross-section of the valve of Fig. 4A, in a phonation position.

Fig. 4C is a partly schematic cross-section of the valve of Fig. 4A in a free-flow configuration.

**DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

Figs. 1A - 1D show an in-line phonation valve 10 in accordance with one embodiment of the present invention. Phonation valve 10 includes a valve body 12 having first and second ends 14 and 16 respectively through which gas, such as air, oxygen or anesthesia gas, passes into and out of valve 10.
The first end 14 of valve 10 is connectable to a breathing tube such as tracheostomy tube 18 shown in Fig. 2. Phonation valve 10 is an in-line phonation valve wherein the second end 16 is connectable to a source of gas such as oxygen (not shown) by line 20 of, for example, a ventilator circuit.

Referring back to Figs. 1A - 1D, a valve seat 22 is located within the valve body 12 between the first and second ends 14 and 16 respectively. A thin, flexible diaphragm 24 is mounted circumferentially around a stem 26, and can be held on to stem 26 by any suitable means such as a mechanical fit. A diaphragm 24 can be formed of any suitable thin, flexible material, such as silicone rubber, and can have any suitable thickness, such as about 0.005-

0.02 inch.

In the embodiment shown in Figs. 1A - 1D, a diaphragm-valve assembly 28 is shown. Diaphragm-valve assembly 28 is comprised of a one-way valve 30 having a phonation position as shown in Fig. 1B which permits gas to pass through valve body 12 toward a patient in the direction shown by arrow 32 when the patient inhales. One-way valve 30, when in the phonation position shown in Fig. 1B, substantially prevents gas from passing through valve body 12 when the patient exhales.

The diaphragm-valve assembly 28 is movable from the phonation position shown in Fig. 1B to the position shown in phantom lines in Fig. 1A, so as to permit substantially free flow of gas through valve body 10 both toward and away from the patient when the patient respectively inhales and exhales, in the directions of double-headed arrow 34.

In the embodiment shown in Figs. 1A - 1D, the diaphragm-valve assembly 28 includes a pivot 36 connecting the valve assembly 28 to valve body 12, for rotating the valve assembly 28 within valve body 12 from the phonation position shown in Fig. 1B, through the intermediate position shown in Fig. 1C to the free-flow position shown in Fig. 1A, wherein the valve assembly 28 is positioned longitudinally within the valve body 12 so as to permit substantially free flow of gas.

As can be seen, the diaphragm-valve assembly is movable from the phonation position, without the need to disconnect the first and second ends 14 and 16 of the valve body from any tubes or lines.
As shown in Fig. 1D, valve assembly 28 has a peripheral edge 38 that seats within an inner wall detent 40 of the valve body 12 when the valve assembly is in the phonation position shown in Fig. 1B.

A second embodiment is shown in Figs. 3A - 3C. According to this embodiment, a valve assembly 28a shown in Fig. 3B is completely removable from the valve body 12, and replaceable with an open, valve body ring cartridge insert 42 shown in Fig. 3C, so as to permit substantially free flow of gas through valve body 12. Both valve assembly 28a and ring insert 42 include finger tabs 44, shown in Fig. 3A, for removal and insertion into valve body 12.

Figs. 4A - 4C show a third embodiment in accordance with the present invention. According to this embodiment, the diaphragm-valve assembly 28b, shown clearly in Fig. 4B, is positioned within a laterally slidable member 46 within the valve body 12, as shown in Fig. 4A. The slidable member 46 includes a two-way gas passageway 48 therein.

The slidable member 46 is slidable from the phonation position shown in Fig. 4B, wherein the diaphragm-valve assembly 28b is positioned within the valve body 12, to a position wherein the two-way gas passageway 48 is positioned within valve body 12 as shown in Fig. 4C so as to permit substantially free flow of gas through valve body 12.

The slidable member 46 is provided with finger tabs 44a for sliding the valve between the position shown in Fig. 4B and Fig. 4C.

The present invention permits switching of an in-line phonation valve from a unidirectional phonation position allowing a patient to speak, to a bi-directional ventilation position, without disconnecting the phonation valve from ventilator circuitry.
CLAIMS

1. An in-line phonation valve system, comprising:
   - a valve body having first and second ends through which gas passes into and out of
     the valve body, the first end connectable to a breathing tube connected to a patient’s airway
     for passage of gas between said breathing tube and said valve body, the second end
     connectable to a gas line,
   - a diaphragm-valve assembly comprising a one-way valve having a phonation
     position permitting gas to pass through said valve body toward said patient when said patient
     inhales, said one-way valve in said phonation position substantially preventing gas from
     passing through said valve body when said patient exhales, said diaphragm-valve assembly
     being moveable from said phonation position so as to permit substantially free flow of gas
     through said valve body both toward and away from said patient when said patient
     respectively inhales and exhales, wherein said diaphragm-valve assembly is moveable out of
     said phonation position without disconnecting said first end from said breathing tube and said
     second end from said gas line, so as to permit said substantially free flow of gas.

2. The phonation valve system of claim 1, further comprising a valve body ring
   cartridge insert, wherein said diaphragm-valve assembly is completely removable from said
   valve body and replaceable with said ring cartridge insert, so as to permit said substantially
   free flow of gas.

3. The phonation valve system of claim 1 wherein said diaphragm-valve assembly
   includes a pivot connecting said valve assembly to said valve body, for rotating said valve
   assembly within said valve body from said phonation position, to a free-flow position
   wherein said valve assembly is positioned longitudinally within said valve body, so as to
   permit said substantially free flow of gas.

4. The phonation valve system of claim 3 wherein said valve assembly has a
   peripheral edge which seats within an inner wall detent of said valve body when said valve
   assembly is in said phonation position.
5. The phonation valve system of claim 1 wherein said diaphragm-valve assembly is positioned within a laterally slidable member within said valve body, wherein said slidable member includes a two-way gas passageway therein, and wherein said slidable member is slidable from said phonation position in which said diaphragm-valve assembly is positioned within said valve body, to a position wherein said two-way gas passageway is positioned within said valve body to permit said substantially free flow of gas.
# INTERNATIONAL SEARCH REPORT

## A. CLASSIFICATION OF SUBJECT MATTER

**IPC 7**  A61M16/04

According to International Patent Classification (IPC) or to both national classification and IPC.

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

**IPC 7**  A61M  A61F

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

Electronic database consulted during the international search (name of database and where practical, search terms used).

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of box C. Patent family members are listed in annex.

- **A** document defining the general state of the art which is not considered to be of particular relevance.
- **E** earlier document but published on or after the international filing date.
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