

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFEVAC, LLC,
Petitioner,

v.

DCSTAR INC.,
Patent Owner.

U.S. Patent No. 11,478,575

Issue Date: October 25, 2022

Title: REMOVAL DEVICE FOR REMOVING OBSTRUCTION IN
RESPIRATORY TRACT AND CONNECTOR

Inter Partes Review No.: IPR2025-00454

DECLARATION OF STANLEY M. YAMASHIRO IN SUPPORT OF PETITION
FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 11,478,575

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I. INTRODUCTION

1. I, Stanley Yamashiro, declare as follows:

2. I am over the age of eighteen (18) and otherwise competent to make this declaration.

3. I have been retained by LifeVac LLC. (Petitioner) as an independent expert consultant in this proceeding before the United States Patent and Trademark Office. Although I am being compensated at my rate of \$400 per hour for the time I spend on this matter, no part of my compensation depends on the outcome of this proceeding, and I have no other interest in this proceeding. To the best of my knowledge, I have no financial interest in Client.

4. This Petition for inter partes review involves U.S. Patent No. 11,478,575 (“the ’575 Patent”) (EX-1001), titled “REMOVAL DEVICE FOR REMOVING OBSTRUCTION IN RESPIRATORY TRACT AND CONNECTOR” and lists Ligui He as the inventor.

5. For the purposes of this inter partes review as discussed later, I have been instructed to assume that the effective filing date of the Claims of the ’575 Patent challenged by the Petitioner in this *inter partes* review is no earlier than August 3, 2021, the filing date of Application 17/393.249 which issued as the ’575 Patent.

6. I understand that according to USPTO records, the ’575 Patent is currently assigned to DCSTAR, INC. (“DCSTAR” or “Patent Owner”).

7. The ’575 Patent is directed to a method and device for removing obstruction in respiratory tract. The device includes a bellows, a connector and a breathing mask along with first and second check valves. I am familiar with the technology and the materials use as described in the ’575 Patent as of the earliest possible priority date of August 3, 2021.

8. In preparing this Declaration, I have reviewed the '575 Patent (EX-1001), the file history of the '575 Patent (EX-1002), and each of the documents cited herein, and I have considered these documents in light of the general knowledge in the art as of August 3, 2021.

9. In formulating my opinions, I have relied upon my experience in the relevant art. I have also considered the viewpoint of a person of ordinary skill in the art ("POSA") in the relevant field, as of August 3, 2021, who I describe below (§IV.D). For convenience, the materials I considered in forming my opinion are listed in Appendix A.

10. I have been asked to provide my technical expertise, analysis, insights, and opinions regarding the '575 Patent and relevant references that form the basis of the arguments set forth in the accompanying Petition for *inter partes* review of the '575 Patent. As described in detail below, I offer the following opinions in this Declaration:

- A POSA would have found Claims 1-2, 7, 13-14 of the '575 Patent obvious over Zhongnan.
- A POSA would have found Claims 3-6, 8-12, 15-17 are obvious over Zhongnan in view of Yuchang.

II. MY BACKGROUND AND QUALIFICATIONS

11. I earned my B.S., M.S., and Ph.D. in Electrical Engineering from the University of Southern California, completing my Ph.D. in 1970 as a Howard Hughes Doctoral Fellow.

12. My early career began at Hughes Aircraft Company (1964–1970), where I worked on microelectronics, communication systems, and control systems.

13. In 1970, I joined the University of Southern California as a Research Associate in Biomedical Engineering, focusing on cardiopulmonary mechanics and respiratory control with Professor F.S. Grodins.

14. I became an Assistant Professor in Biomedical Engineering in 1971, teaching bio-instrumentation and medical electronics while researching optimal regulation of respiratory airflow, as detailed in my co-authored paper, "Optimal regulation of respiratory airflow" (Journal of Applied Physiology, 1971).

15. As an Associate Professor in 1974, I expanded my research to include signal processing and laboratory computer applications, publishing works such as "Phase compensation of Fleisch pneumotachographs" (Journal of Applied Physiology, 1974).

16. Since 1982, I have been a Professor at USC, where I continued teaching and researching topics like magnetocardiography and pulmonary physiology. My publication, "Dynamics of the ventilatory response to exercise in man" (Journal of Applied Physiology, 1981), reflects this focus.

17. My studies on ventilatory control include "Use of random forcing for high-frequency ventilation" (Journal of Applied Physiology, 1987), which provided insights into gas exchange during high-frequency ventilation.

18. Collaborating with F.S. Grodins, I explored optimization in respiratory mechanics, as seen in our work "Optimal control analysis of left ventricular ejection" (MIT Press, 1978).

19. In consulting roles, I advanced ventilator technology, contributing to automated blood gas analysis systems and real-time pulmonary monitoring.

20. I co-authored "Ventilatory CO₂ responses during hypocapnia in anesthetized cats" (Journal of Applied Physiology, 1984), which investigated respiratory adaptation to altered CO₂ levels.

21. I developed models for ventilatory system dynamics, exemplified in "Minimization of lung pressure swings during high-frequency ventilation: a model" (Journal of Applied Physiology, 1989).

22. My work with Medtronic and Baxter Healthcare included creating simulators for cardiopulmonary bypass oxygenators, resulting in an interactive blood flow simulator utilized in training and product development.

23. Collaborating with V.Z. Marmarelis, I contributed to "Analysis of the gas exchange system during high-frequency ventilation" (Annals of Biomedical Engineering, 1986).

24. I researched cerebral blood flow and ventilation instability in CO₂-rich environments, as discussed in "Modeling cerebral blood flow and ventilation instability due to CO₂" (Journal of Applied Physiology, 2021).

25. My publication "Non-linear dynamics of human periodic breathing and implications for sleep apnea therapy" (Medical & Biological Engineering & Computing, 2007) provided insights into sleep-related respiratory disorders.

26. I co-authored "Altered chemosensitivity to CO₂ during exercise" (Physiological Reports, 2021), examining respiratory control during physical activity.

27. My research into fractal analysis of vasomotion is detailed in "Fractal analysis of vasomotion" (Annals of the New York Academy of Sciences, 1990), which contributes to understanding vascular dynamics.

28. My role in ventilator innovation extended to developing predictive models for respiratory gas exchange, as illustrated in "Ventilatory responses to increased blood flow and lowered lung volume in awake dogs" (Journal of Applied Physiology, 1988).

29. Teaching contributions include courses on cardiovascular and pulmonary physiology, such as BME 501, restructured in 2022 to enhance interactive learning.

30. Across my career, I have published over 50 peer-reviewed articles and contributed to multiple NIH-funded projects, consistently advancing ventilatory and cardiopulmonary science through research, consulting, and education.

III. RELEVANT LEGAL STANDARDS

31. I am not a lawyer and do not provide any legal opinions in this Declaration. Although I am not a lawyer, I have been informed and understand that certain legal standards are to be applied by technical experts in forming opinions regarding the meaning and validity of patent claims. I have been asked to provide my opinions regarding whether the claims of the '575 Patent would have been obvious to a person having ordinary skill in the art at the time of the alleged invention, in light of the prior art.

32. I have been informed and understand that a patent claim is not patentable under 35 U.S.C. § 103 if the differences between the patent claim and the prior art are such that the claimed subject matter as a whole would have been obvious at the time the claimed invention was made to a person having ordinary skill in the relevant art. Obviousness, as I have been informed and understand, is based on the scope and content of the prior art, the differences between the prior art and the claim, the level of ordinary skill

in the art, and, to the extent that they exist, certain objective indicia of non-obviousness.

33. I understand that objective indicia can be important evidence regarding whether a patent is obvious or nonobvious, if it has an appropriate nexus to the claimed invention, i.e., is a result of the merits of a claimed invention (rather than the result of design needs or market-pressure advertising or similar activities). Such indicia include: commercial success of products covered by the patent claims; a long-felt need for the invention; failed attempts by others to make the invention; copying of the invention by others in the field; unexpected results achieved by the invention as compared to the closest prior art; praise of the invention by the infringer or others in the field; the taking of licenses under the patent by others; expressions of surprise by experts and those skilled in the art at the making of the invention; and the patentee proceeded contrary to the accepted wisdom of the prior art.

34. I have been informed that whether there are any relevant differences between the prior art and the claimed invention is to be analyzed from the view of a person of ordinary skill in the relevant art at the time of the invention. As such, my opinions below as to a person of ordinary skill in the art are as of the time of the invention, even if not expressly stated as such; for example, even if stated in the present tense.

35. In analyzing the relevance of the differences between the claimed invention and the prior art, I have been informed that I must consider the impact, if any, of such differences on the obviousness or non-obviousness of the invention as a whole, not merely some portion of it. The person of ordinary skill faced with a problem is able to apply his or her

experience and ability to solve the problem and also look to any available prior art to help solve the problem.

36. I have been informed that a precise teaching in the prior art directed to the subject matter of the claimed invention is not needed. I have been informed that one may take into account the inferences and creative steps that a person of ordinary skill in the art would have employed in reviewing the prior art at the time of the invention. For example, if the claimed invention combined elements known in the prior art and the combination yielded results that were predictable to a person of ordinary skill in the art at the time of the invention, then this evidence would make it more likely that the claim was obvious. On the other hand, if the combination of known elements yielded unexpected or unpredictable results, or if the prior art teaches away from combining the known elements, then this evidence would make it more likely that the claim that successfully combined those elements was not obvious.

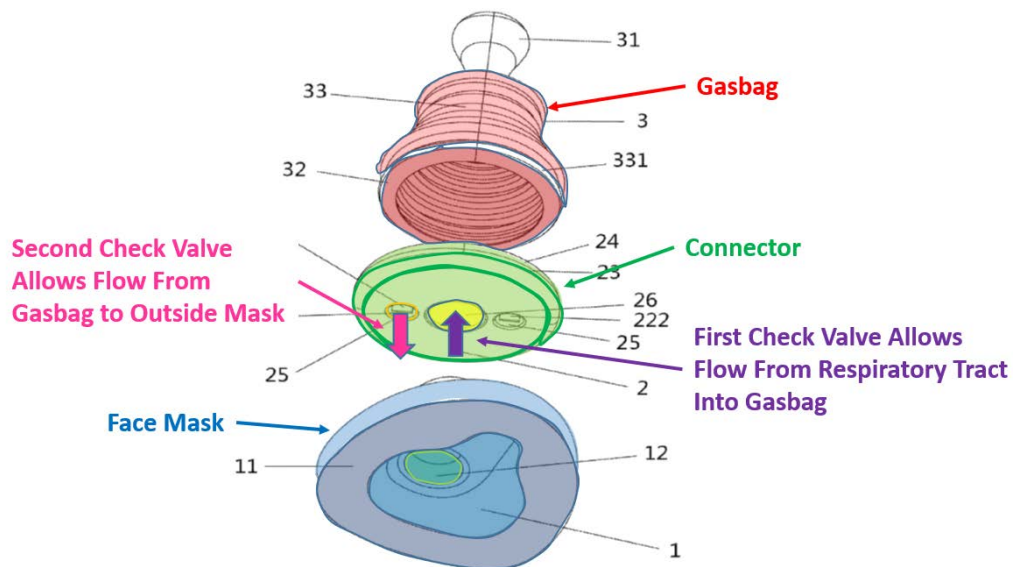
37. I have been informed and understand that there are recognized, exemplary, rationales for combining or modifying references to show obviousness of claimed subject matter. Some of the rationales include the following: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to yield predictable results; use of a known technique to improve a similar device (method or product) in the same way; applying a known technique to a known device (method or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market

forces if the variations are predictable to one of ordinary skill in the art; and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art teachings to arrive at the claimed invention.

IV. OVERVIEW

38. The Challenged Claims are unpatentable as obvious over the prior art. The claims are directed to prior art devices and combinations of conventional components that perform conventional functions regarding anti-choking devices, all of which were well-known in the art of consumer first aid devices.

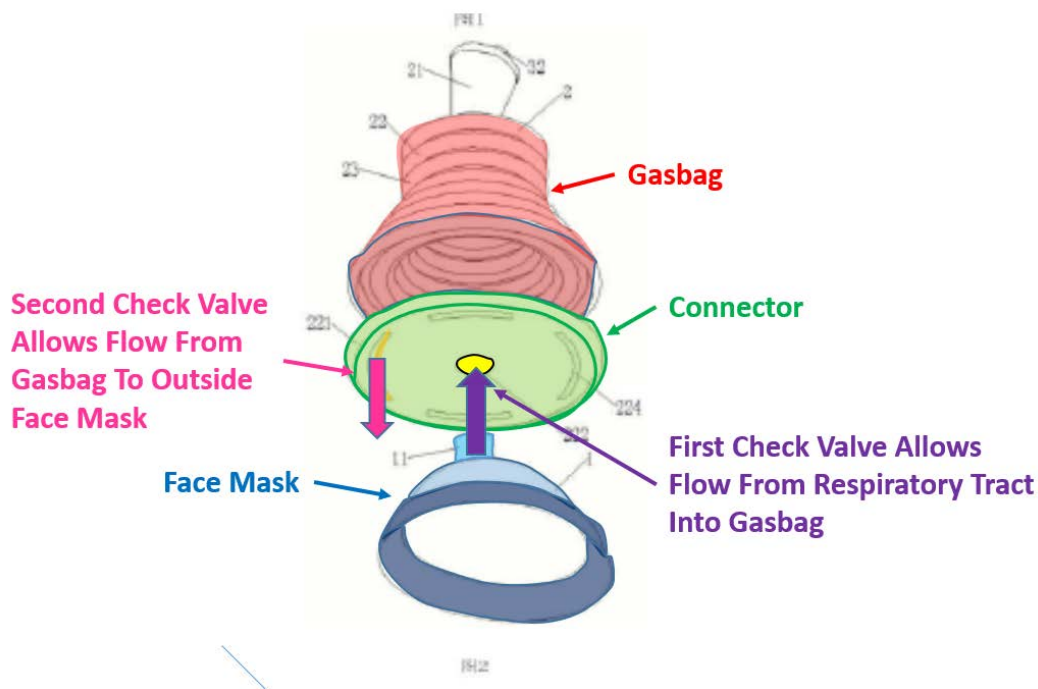
39. Specifically, the Claim 1 is directed to a device for removing obstructions from a respiratory tract comprising: (1) a collapsible gasbag (red); (2) a connector (green) having at least two check valves allowing gas flow in opposite directions; and (3) a face mask (blue). The '575 Patent illustrates the device in FIG. 2:



EX-1001 FIG. 2

40. However, Zhongnan (EX-1004, EX-1005)¹ demonstrates that the claimed device for removing an obstruction from a respiratory tract was well known at the time of the '575 Patent.

41. Zhongnan illustrates such a device in FIG. 2:

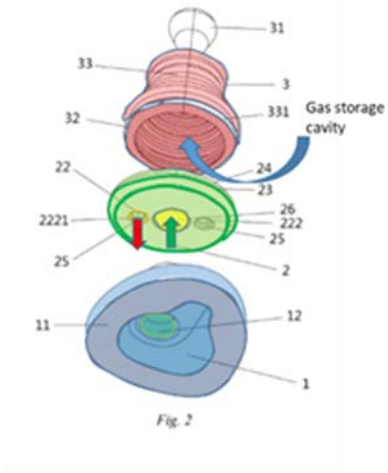
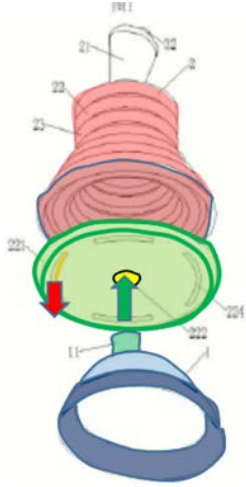


EX-1005 FIG. 2

42. Table 1 provides a side-by-side comparison of the devices as well as a listing of the terminology used in each reference for the common elements of the devices:

Table 1

¹ Citations to Zhongnan and the other foreign language references will be to the English translations.

'575 Patent	Zhongnan
	
Collapsible gas bag (3)	Suction device/cup (2)
Connector (2)	Base Plate (221)
Face mask (1)	Breathing mask (1)
First check valve (21)	One-way inlet valve (226)
Second check valve (25)	One-way exhaust valve (225)
Flexible annular pad (11)	Outer edge

43. As demonstrated above, Zhongnan discloses a materially identical device to the device of the Challenged Claims with the only variations being the selection of check valve type from among well-known options.

44. For example, independent Claim 3 recites specific elements of the first check valve (cross-slit check valve), and independent Claim 9 recites specific elements of the second check valve (duckbill check valve).

45. However, as evidenced by the disclosures of Daansen, Yuchang, Loescher and Changzhon, the use of these specifically configured check valves was known generally in the medical device field, and specifically in anti-choking devices. Daansen (EX-1012) discloses a cross-slit check valve as recited in Claim 3, and Yuchang (EX-1009) discloses a duckbill check valve as recited in Claim 9.

46. Because these references are directed to the similar or the same problem and utilize the same or similar solutions, these references are naturally combined together, and each alone or in combination with discloses each limitation recited in the Challenged Claims.

V. BACKGROUND

A. Summary of the '575 Patent

47. The '575 Patent is directed to a first aid anti-choking device for removing an obstruction in a respiratory tract. EX-1001 9:59-60. The '575 Patent describes the components of the device as “a collapsible gasbag 3, a connector 2 and a facemask 1 which are sequentially connected.” EX-1001, 6:5-7.

48. The '575 Patent explains that the collapsible gasbag 3 (**red**) includes an internal gas storage cavity, with the top of the bag being sealed, and the bottom of the bag having an opening 32 in communication with the gas storage cavity. A connector 2 (**light green**) is hermetically connected to the opening 32 of the gasbag 3 on an upper side, and to the face mask 1 (**blue**) on the other side. EX-1001, 6:10-15.

49. The '575 Patent further explains that connector 2 includes a first check valve 21 (**orange**) allowing the flow of air from the interior of the

face mask 1 into the gas storage cavity, and one or more second check valves 22 (gold) allowing the flow of air from the gas storage cavity to outside the face mask 1. EX-1001, 6:49-52.

50. The '575 patent illustrates the device in FIG. 3 below:

DESCRIPTION OF REFERENCE NUMERALS
IN SPECIFIC IMPLEMENTATIONS

Face mask	1	Collapsible gasbag	3
Flexible annular pad	11	Handle	31
Connecting cylinder	12	Opening	32
Connector	2	Second peripheral side wall	33
First check valve	21	Second check valve	22
Bottom plate	23	First peripheral side wall	24
Peripheral cylinder	25	Central cylinder	26
Stop edge	241	Reinforcement strip	27
Deformed portion	212	First slit	2121
Duckbill portion	222	Second slit	2221
Second base portion	221	Fold	331

EX-1001 5:35-50.

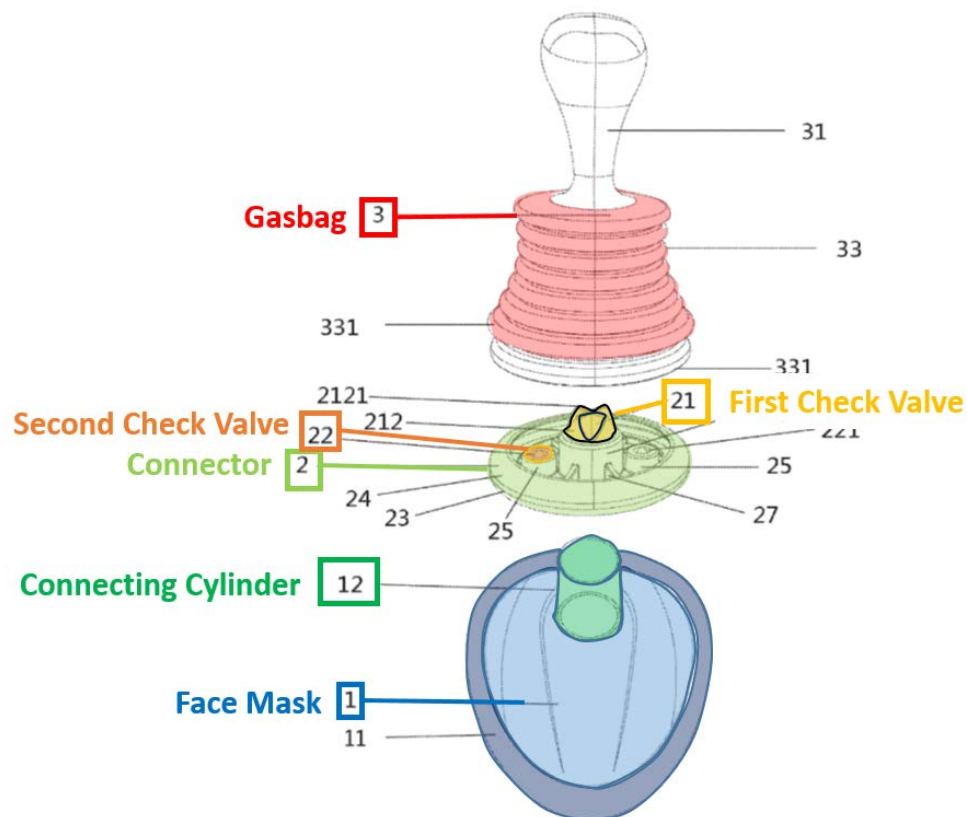


Fig. 3

EX-1001 Fig. 3.

51. The '575 Patent explains that when rescuing a choking patient, the flexible annular pad 11 of the face mask 1 is placed to encircle the mouth of the choking patient and is closely attached so as to be connected to the respiratory tract of the patient. The mask 1 must be held to establish and maintain a seal between the mask 1 and the airway. The collapsible gasbag 3 is then repeatedly compressed and stretched until the blockage of the airway is cleared. Compressing gasbag 3 forces air from the internal cavity to outside of mask 1 through second check valve 22 while first check valve 21 prevents air from flowing into the respiratory tract. When the gasbag is stretched, air is drawn from the respiratory tract into the cavity through first

check valve 21 while second check valve 22 prevents air from being drawn into the cavity from outside the mask. EX-1001, 7:64-8:13; 8:13-28.

52. The Challenged Claims include four independent claims. Independent Claims 1, 3, and 9 are each directed to:

A removal device for removing an obstruction in a respiratory tract, the removal device comprising a collapsible gasbag, a connector and a face mask which are sequentially connected,

EX-1001 Preamble of Claims 1, 3, and 9.

53. Claim 1 specifies that the connector includes two check valves allowing flow in opposite directions:

wherein the connector comprises a bottom plate and the first check valve and the second check valve are arranged on the bottom plate, wherein the first check valve and the second check valve allow gas flow to pass in opposite directions.

EX-1001 Claim 1.

54. Claim 3 specifies that the connector includes a central cylinder and a first check valve having a cross-slit configuration:

wherein the connector is provided with a bottom plate, the bottom plate being provided with a central cylinder which is vertically through; the first check valve is of a hollowed structure made from an elastic material, and comprises a deformed portion and a first base portion which are connected to each other; the first gas outlet end is composed of at least three first slits provided at a top end of the deformed portion;

one end, extending toward the center, of the at least three first slits intersect at the same point, ...

EX-1001 Claim 3.

55. Claim 9 specifies that the connector includes a peripheral cylinder and a second check valve having a duckbill configuration:

wherein the connector is provided with a bottom plate, the bottom plate being provided with a peripheral cylinder which is vertically through; the second check valve is a duckbill valve, ...

EX-1001 Claim 9.

56. Claim 13 is directed only to a “connector for a removal device” having the specific configuration recited in Claim 1:

A connector for a removal device, the connector comprising a bottom plate, and a first check valve and a second check valve which are arranged on the bottom plate, wherein the first check valve and the second check valve allow gas flow to pass in opposite directions; and the connector is an integrally formed member made from an elastic material.

EX-1001 Claim 13.

B. Claim Construction

57. I have been informed and understand that in order to properly evaluate the '575 Patent, the terms of the claims must first be interpreted. I understand that Petitioner proposes that each claim term in the Challenged Claims be given its plain and ordinary meaning in this proceeding, and that no specific construction of any claim term is required because the prior art

relied on in this Petition meets each of the claim terms under any reasonable construction. The plain meaning is the ordinary and customary meaning to those skilled in the art.

C. Priority Date of the Challenged Claims

58. For the purpose of this *inter partes* review, I have been instructed to assume that the effective filing date of each of the Challenged Claims is the filing date of the '575 Patent, Aug. 3, 2021.

D. Person of Ordinary Skill in the Art

59. I have been informed and understand that a Person of Ordinary Skill in the Art ("POSA") is a hypothetical person who is presumed to be aware of all pertinent prior art, thinks along conventional wisdom in the art, and is a person of ordinary creativity.

60. With respect to the '575 Patent, a POSA in the timeframe of filing the '575 Patent on Aug. 3, 2021, would have been familiar with consumer medical devices in general and would have a working knowledge of respiratory devices including consumer anti-choking devices.

61. A POSA would also have gained knowledge of these concepts through a mixture of training and work experience, such as by having a Bachelor's degree in Mechanical/Biomedical engineering and two years of experience; or by obtaining a Master's degree in Mechanical/Biomedical Mechanical, but having only one year of experience; or by having no formal education but experience with respiratory devices of at least four years. .

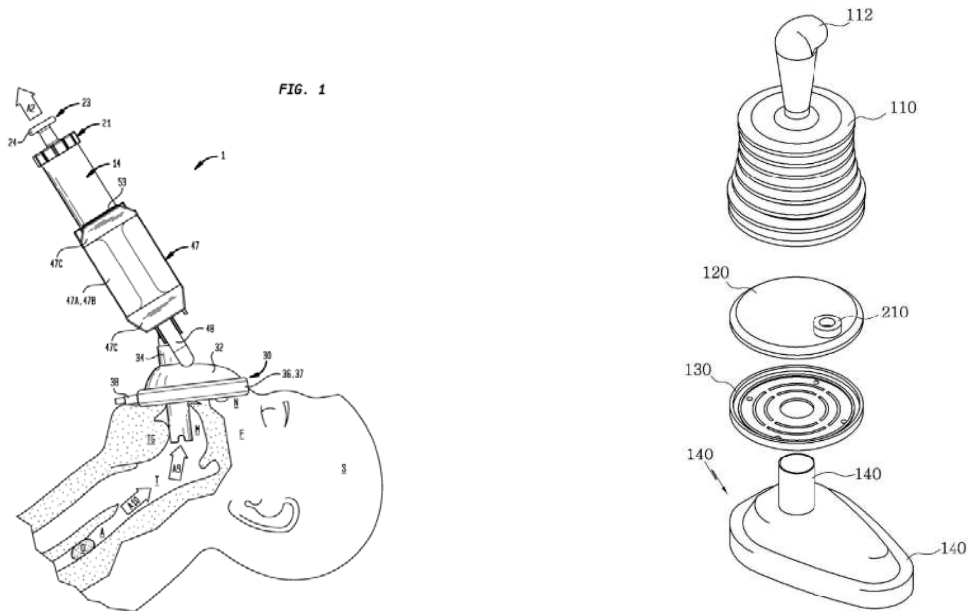
E. State of the Art

62. The following section describes the state of the art for anti-choking devices as of the priority date of the '575 Patent. . The prior art references, and the discussions of what was known to a POSA, provide

factual support for the general description of the state of the art at the time of the purported invention, and provide additional motivation to modify or combine references.

1. Anti-choking first aid devices

63. Anti-choking devices for consumer use were well known at the time of the purported invention. The basic concept relies upon creating a pressure differential across the obstruction in the airway such that air in the lungs is at a greater pressure than the upper airway thus forcing the obstruction out of the airway through the mouth. Unlike the well-known Heimlich maneuver wherein the diaphragm is compressed to increase the pressure in the lungs, consumer anti-choking devices create the pressure differential by evacuating air from upstream of the obstruction in the airway. The evacuation is typically created from a cylinder and plunger configuration wherein air is drawn into the cylinder via movement of the plunger in an upstroke as described in Carver (EX-1006) as well as Yuchang, or via the expansion of a collapsible cavity as described by Bae (EX-1007) as well as Zhongnan. EX-1006 [0029], Fig. 1; EX-1007 Fig. 1, [0032]:



EX-1006 Fig. 1; EX-1007 Fig. 1.

2. Prior art check valves

64. The use of check valves to direct the airflow in the employment of anti-choking devices was well-known. Of particular importance was the need to prevent enhancing the obstruction by forcing the obstruction further into the airway by increasing pressure toward the lungs. It was well-known to use at least two check valves allowing airflow in opposite directions. During compression of the plunger or cavity, a first check valve prevents the flow of air into the airway while a second check valve allows the flow of air to escape out of the face mask. During the expansion stroke of the plunger or airway, the first check valve allows the flow of air from the airway into the plunger or cavity while the second check valve prevents air from being drawn from outside of the face mask.

65. For example, Carver, as well as Yuchang, and Zhongnan demonstrate the well-known use of check valves to control the flow of air during employment of the anti-choking device. The specific types of check valves recited in the Challenged Claims (cross-slit valves in Claim 3 and duckbill valves in Claim 9) were also well-known in medical devices, including anti-choking devices.

66. For example, Abolfathi discloses a ventilation device that uses a duckbill check valve or a cross-slit check valve for ventilation of the trachea. Specifically, the ventilation device has an expandable cuff that is oriented above the access point through the tracheal wall. A one-way valve (gold), specifically, may be provided in the expandable cuff in order to permit exhalation through the larynx to assist in speech. EX-1013 Abstract, [0059], FIG. 16B;

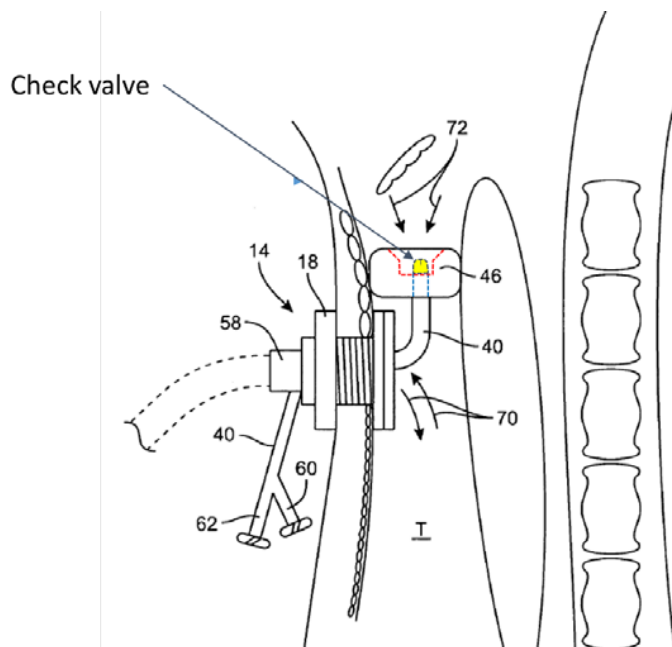


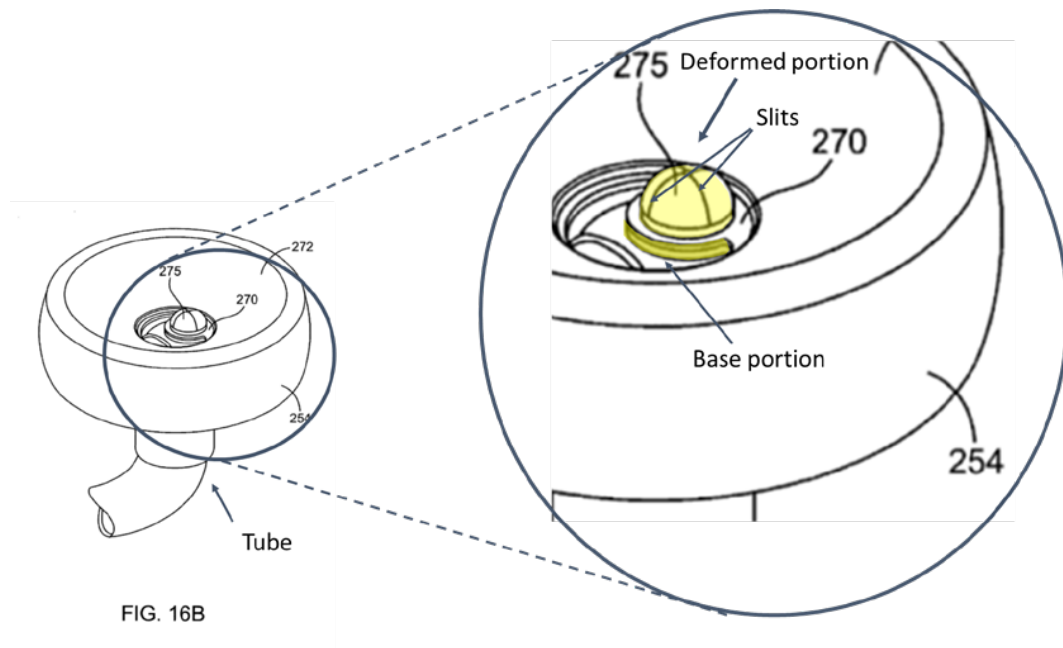
FIG. 4F

EX-1013 FIG. 4F.

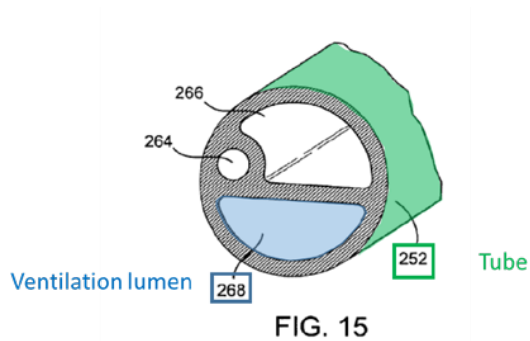
67. A split valve is formed from an elastic material and includes a deformed portion (yellow) and base portion (dark yellow) which are connected to each other; the first gas outlet end is composed of four slits at the top of the deformed portion; each slit extending toward the center, and intersect each other at a common point. A POSA understood that in order for the slits to communicate with the ventilation lumen 268 (blue), a vent hole is provided in the middle of the base portion; and the base portion extends into the top portion of the tube 252 (green). Specifically, the ventilation lumen 268, and an outer side of the base portion is hermetically connected to tube 252 a lower end of ventilation lumen 268 of the tube 252, is hermetically connected to an upper side of an inflatable cuff in the trachea; the deformation portion is exposed out of the tube 252 and extends into the upper trachea:

A second valve 274 is provided adjacent the aspiration port 270, and typically includes a duck bill or other *one-way valve structure* permitting air to flow from beneath the cuff 254 to above the cuff. In this way, the patient may exhale and permit to pass upward through the valve 274 to enter the region of the larynx to permit speech. In particular, by covering the ventilation fitting 256 (optionally having removed any ventilator device), the air will have no other place to go, thus will all pass through the valve 274 into the larynx. After the patient is done speaking, the ventilator may be uncovered and/or the ventilation device may be reconnected. Alternatively, **the valve may be a cross-slit check valve 275 as shown in FIG. 16B.**

EX-1012 [0059].



EX-1012 FIG. 16B.



EX-1012 FIG. 15.

68. Thus, cross-slit check vales and duckbill valves were well-known for value in assisting ventilation and treated interchangeably.

69. Cross-slit check valves have many applications given their simple operation and low cost. Daansen discloses a cross-slit check valve 40 used in a fluid dispenser that operates to allow flow in only one direction.

EX-1012 5:11-34. The most common cross slit check valve has 4 slits or cusps and 3 slits which is the “least” mentioned by the 575 patent are also in common use. A 4 slit design generally leads to a higher flow relative to 3 slits. However, mechanical failure rate increases with the number of slits so using fewer slits is an established strategy to improve reliability. Check valves are designed to allow flow only in one direction. A duckbill valve is functionally equivalent to a two slit check valve and is known to have the highest reliability.

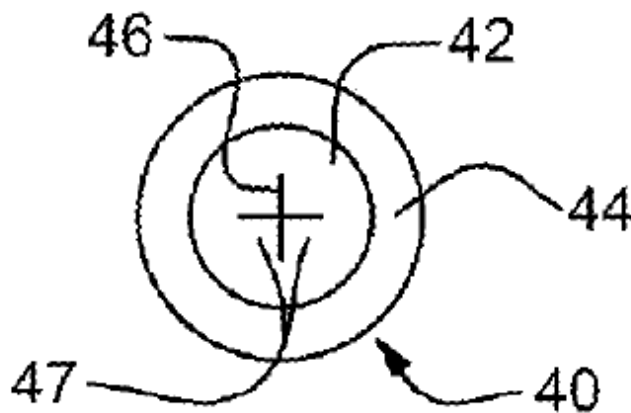
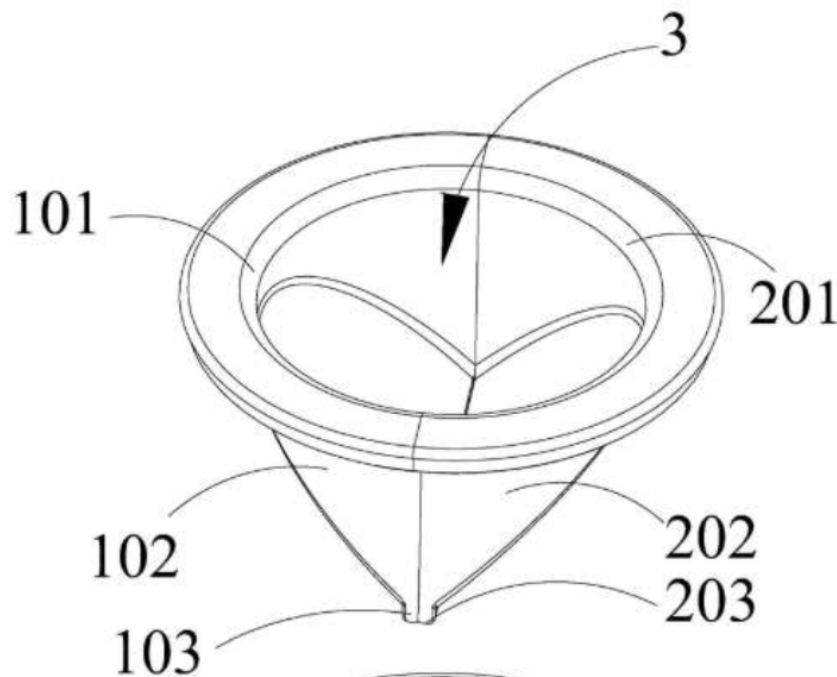


FIG. 2

EX-1012 Fig. 2;

70. Duckbill check valves were also well-known and perform the same function over many applications. For example, Changzhon and Carver disclose duckbill check valves allowing flow in one direction. EX-1011 Fig.

2, abstract; EX-1014 [0029];



EX-1011 Fig. 2.

71. Loescher also discloses using a duckbill valve to provide one direction flow from a manually compressed gas bag into a facemask and airway of a non-breathing subject for resuscitation. This gas bag and duckbill valve system (Laerdal Medical reported 200,000 in use) is well known and in wide spread commercial use. EX-1015 2:12-36, Fig. 2.

72. Thus, the operation and use of cross-slit check valves and duckbill check valves, as well as check valves in general, was well known and understood by a POSA. The choice of the best check valve type for a specific application involves a tradeoff between reliability and flow resistance. This tradeoff is especially important because these valves are used in a medical device with high reliability standards and affect the respiratory tract which is delicate and very susceptible to pressure damage. If a specific application is limited to use of a single valve a cross-slit check

valve would be expected to be the best choice due to lower resistance and pressure during flow and valve opening. If more than one valve can be used net resistance to flow is divided by the number of valves so the higher reliability of duckbill valves would motivate its selection. This is the expected rationale behind valve choice to a POSA.

VI. CHALLENGES

A. Identification of Challenges

73. Based on my understanding of the law of obviousness discussed above, Claims 1-2, 7, 13-14 of the '575 Patent are unpatentable as being obvious over Zhongnan, alone, and Claims 3-6, 8-12,15-17 are unpatentable as being obvious over Zhongnan in view of Yuchang.

Ground	Claims	Basis	Reference
1	1-2, 7, 13-14	§ 103	Zhongnan
2	3-6, 8-12,15-17	§ 103	Zhongnan in view of Yuchang

B. Prior Art

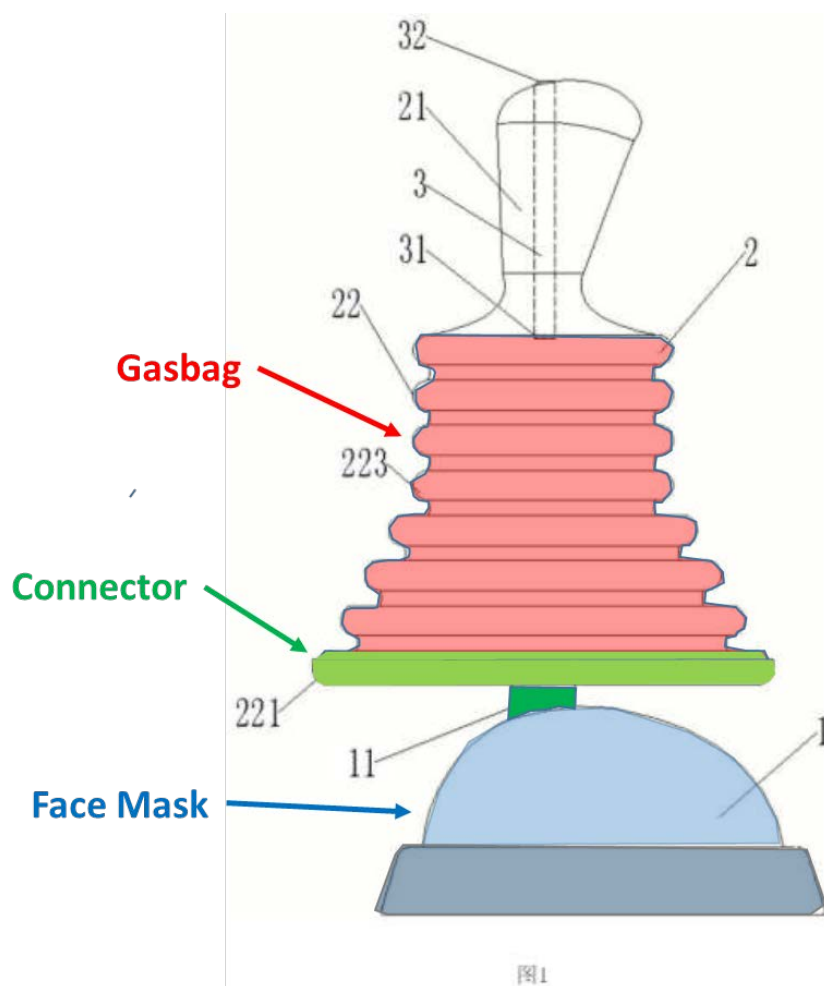
74. I have been informed that both Zhongnan-Chinese Patent Publication CN112932633A and Yuchang-Korean Patent Publication KR10222961 B1 qualify as prior art under § 102(a)(1). This is supported by both Zhongnan published on Jun. 11, 2021 and Yuchang published on Mar. 18, 2021 patent publications preceding the earliest priority date of the '575 patent application (Aug. 3, 2021).

VII. IDENTIFICATION OF HOW THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Challenge 1: Claims 1-2, 7, 13-14 are Unpatentable Over Zhongnan

1. The Zhongnan reference

75. Zhongnan discloses a tracheal foreign body suction device (*i.e.*, an anti-choking device) and method. Like the anti-choking device of the '575 Patent, the device of Zhongnan includes a collapsible cavity (**red**), a breathing mask (**blue**) and a connector (**green**) having check valves allowing flow in opposite directions between the cavity and mask.

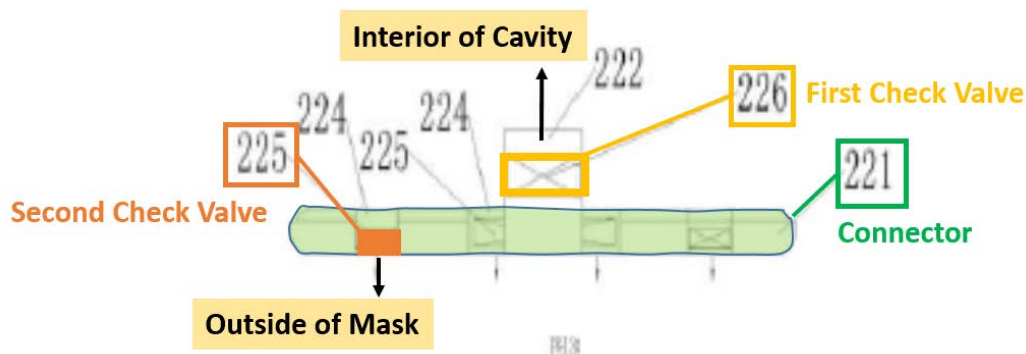


EX-1005, Figs. 1, 2.

76. The breathing mask 1 (face mask) includes a ventilation tube 11 positioned such that one end of the tube is located outside the mask and connected with an aspirator, and the other end of the tube is located inside the mask. EX-1005 Abstract.

77. The aspirator includes a handle 21 and a suction cup (collapsible gasbag) below the handle. The suction cup forms an internal cavity with an opening in the bottom. A base plate 221 (connector) is positioned at the opening of the suction cup. EX-1005 Abstract.

78. Zhongnan describes that the base plate 221 includes a central connecting tube 222 (central cylinder) that connects at the lower end to ventilation tube 11 (dark green) of the mask, and provides an airway between the interior of the mask and the cavity of the suction cup. EX-1005 Abstract; EX-1003 ¶78. A check valve 226 is positioned at the upper end of connecting tube 222 allowing air to flow only in the direction from the interior of the mask into the suction cup. EX-1005 [0034], [0039].



EX-1005 FIG. 3.

79. The base plate 221 also includes a plurality of air outlets 224 around its periphery. A check valve 225 is positioned at each air outlet 224 permitting air to flow only from the cavity of the suction cup to outside the mask. EX-1005 [0034].

80. Zhongnan explains that the anti-choking method using the device includes the following steps:

- S10. attaching the breathing mask to the human face and inserting the ventilation tube into the connecting tube;
- S20. pressing down the handle, driving the cylindrical body to press toward the face; the airflow created inside the cylindrical body flows downward, the one-way exhaust valve opens, the one-way inlet valve closes, and the airflow is discharged through the air outlet, creating a negative pressure inside the cylindrical body;
- S30. pulling up the handle; the one-way exhaust valve closes, and the one-way inlet valve opens; under the effect of the negative pressure, the foreign body in the trachea is suctioned out therefrom.

EX-1005 [0037-0039].

81. As set forth in Steps S10 – S30 above, the breathing mask 1 is attached to the face of the choking patient and the ventilation tube 11 of the mask is inserted into the connecting tube 222 of the base plate. The handle 21 may be used to compress the suction cup driving the air out of the cavity. The air outlet check valves/one-way exhaust valves 225 are open allowing air to flow from the cavity to outside the mask through the outlets 224, while the air inlet check valve/one-way inlet valve 226 is closed preventing air from flowing into the face mask and airway of the patient. A negative pressure is formed in the cylindrical body. When the handle 21 is pulled up to expand the suction cup, air inlet check valve 226 is open permitting air to flow from the patient's airway through the mask and into the expanding

cavity such that under the action of negative pressure, the foreign body obstructing the airway of the patient is sucked out from the airway. The air outlet check valves/one-way exhaust valves 225 are closed preventing air from outside the mask to be drawn into the cavity. EX-1005 [0036-0040].

2. Detailed Application of Zhongnan to the Challenged Claims

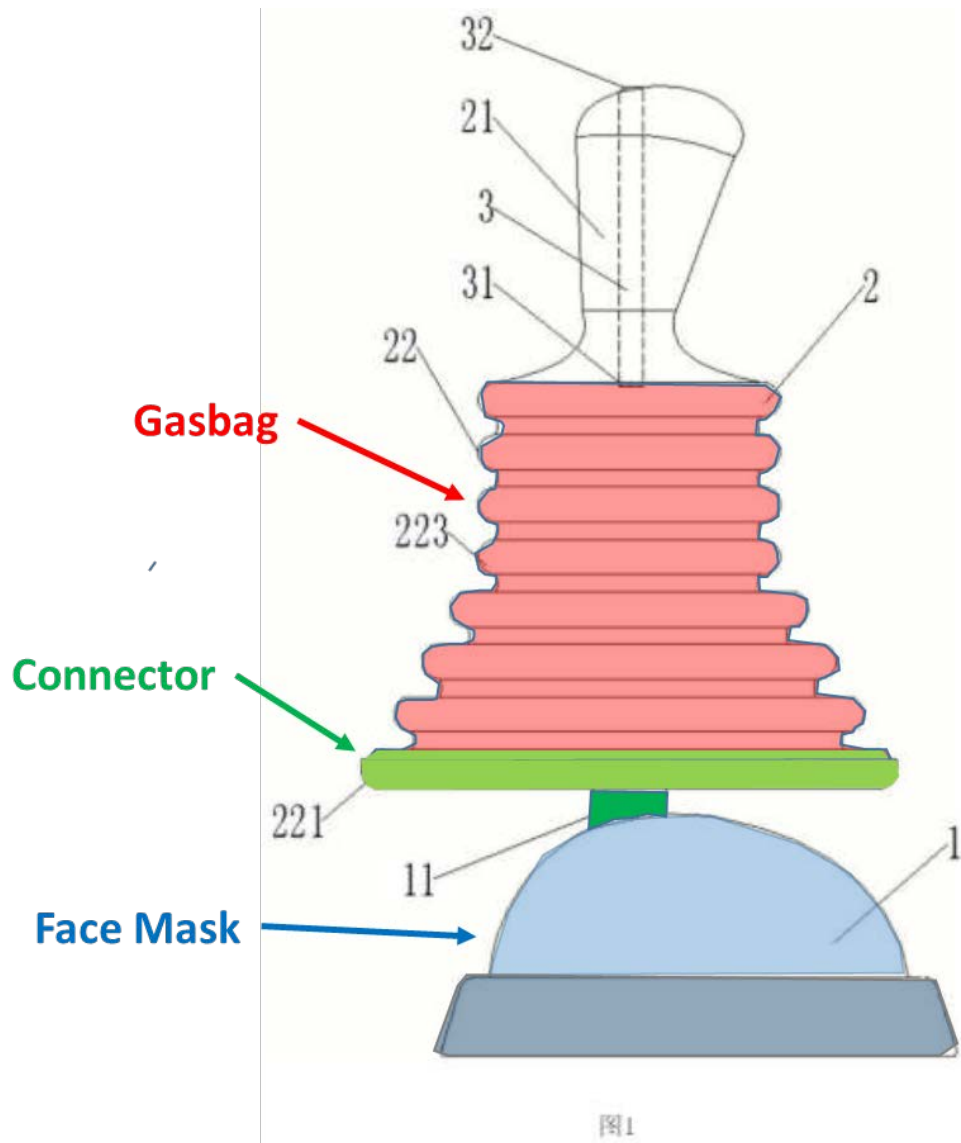
Claim 1

[1.0] A removal device for removing an obstruction in a respiratory tract,

82. To the extent that the preamble is limiting, Zhongnan discloses a tracheal foreign body suction device [*a removal device for removing an obstruction in a respiratory tract*].

The present disclosure provides a tracheal foreign body suction device and method... The present disclosure features the advantages of simple operation and the ability to effectively extract foreign bodies from the trachea, and is applicable to the field of medical devices.

EX-1005 Abstract.

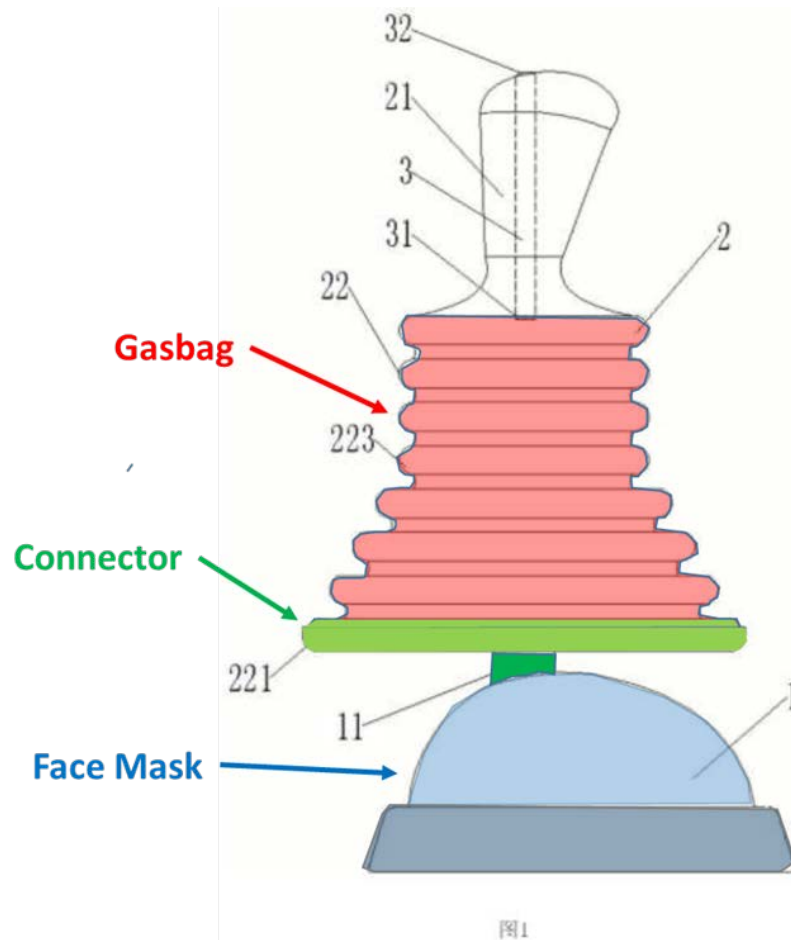


EX-1005 FIG. 1.

83. Thus, a POSA understood that Zhongnan discloses element [1.0].

[1.1] the removal device comprising a collapsible gasbag, a connector and a face mask which are sequentially connected,

84. Zhongnan discloses that the device includes a suction device [collapsible gasbag] (**red**), a base plate [connector] (**green**) and a breathing mask [face mask] (**blue**) which are sequentially connected.



EX-1005 FIG. 1.

Zhongnan explains:

The present disclosure provides a tracheal foreign body suction device and method, comprising a breathing mask and a suction device, wherein the breathing mask comprises a ventilation tube, mounted through the breathing mask, with one end of the ventilation tube located outside the breathing mask and connected to the suction device, and the other end located

inside the breathing mask; the suction device comprises a handle and a suction cup disposed below the handle, wherein the suction cup is a cylindrical body with an open bottom, a base plate is disposed at the open bottom of the cylindrical body,

EX-1005 Abstract.

85. Thus, a POSA understood that Zhongnan discloses element [1.1].

[1.2] wherein the collapsible gasbag is internally provided with a gas storage cavity, a top of the collapsible gasbag is sealed, and a bottom of the collapsible gasbag is provided with an opening in communication with the gas storage cavity;

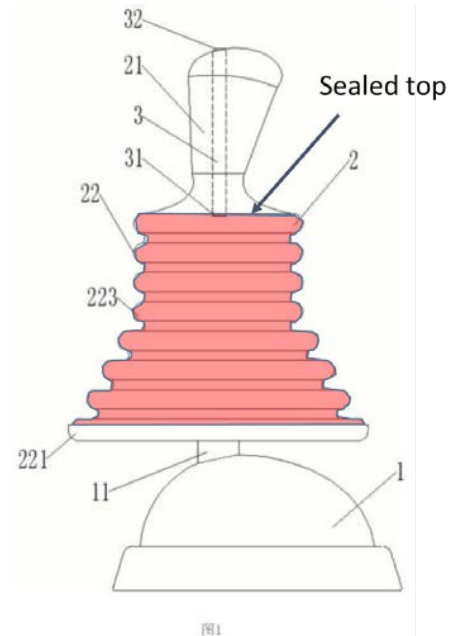
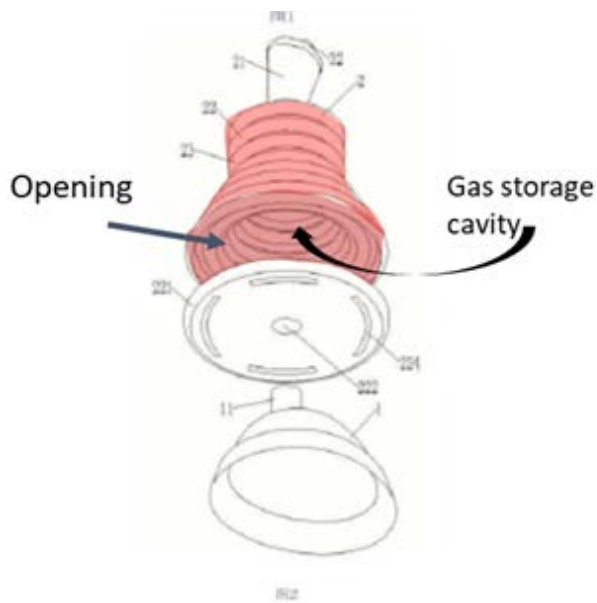
86. Zhongnan discloses that the suction device/suction cop [collapsible gasbag] (red) is collapsible and includes an internal cavity for storing air [internally provided with a gas storage cavity]. The top of the suction device is sealed by a handle 21 and the bottom is provided with an opening in communication with the interior cavity.

[T]he suction cup is a cylindrical body with an open bottom.

EX-1005 Abstract.

[W]ith one end of the connecting tube connected to the base plate, the other end extending inward into the cylindrical body and disposed with a one-way inlet valve; and the dimensions of the connecting tube match those of the ventilation tube.

EX-1005 [0007].



EX-1005 FIGs. 1, 2.

87. Thus, a POSA understood that Zhongnan discloses element [1.2].

[1.3] an upper side of the connector is hermetically connected to the opening, and

88. Zhongnan discloses the upper side of the base plate 221 [connector] (green) forms a sealed connection [hermetically connected] with the opening of the suction device:

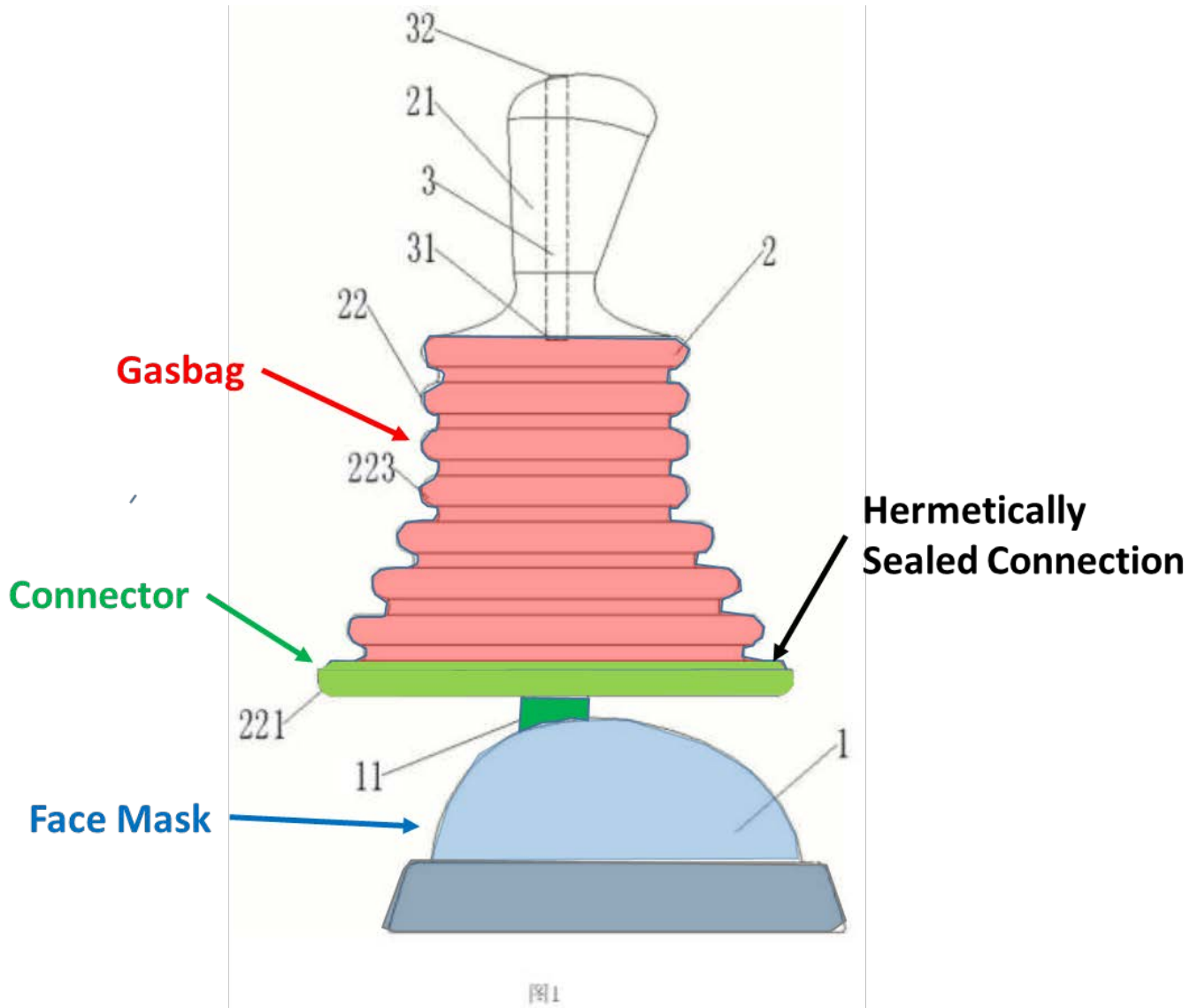
a base plate is disposed at the open bottom of the cylindrical body.

EX-1005 Abstract.

Preferably, the cylindrical body comprises a plurality of grooves arranged sequentially from top to bottom, the groove at the topmost position is connected to the handle, and the groove at the bottommost position is connected to the base plate.

EX-1005 [0009].

89. A POSA understood that in order for the device to operate properly, the connector must be sealed to the gasbag to prevent any leakage of air from the connection between the two as shown below:



EX-1005 FIG. 1.

90. Thus, a POSA understood that Zhongnan discloses element [1.3].

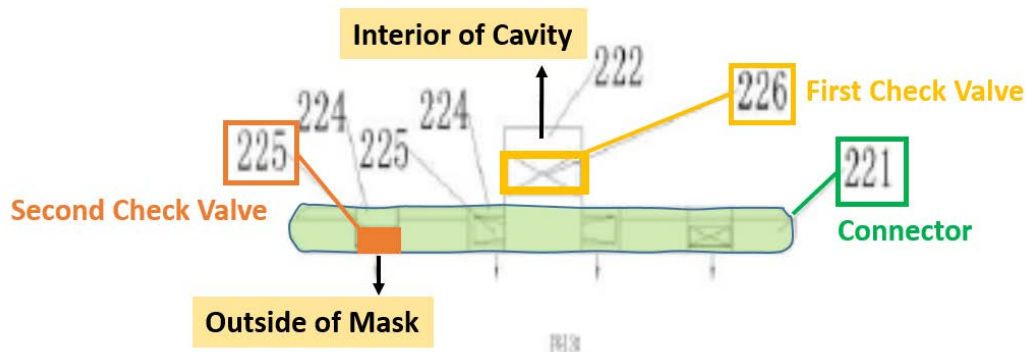
[1.4] the connector is provided with a first check valve and a second check valve, a first gas outlet end of the first check valve is in communication with the gas storage cavity, a second gas inlet end of the second check valve is in communication with the gas storage cavity, and a second gas outlet end of the second check valve is in communication with the outside; and

91. Zhongnan discloses that the base plate 221 [*connector*] (**green**) includes an air inlet check valve/one-way inlet valve 226 [*first check valve*] (**gold**) and an outlet one-way valve/one-way exhaust valve 225 [*second check valve*] (**orange**). Air inlet check valve 226 has a first gas outlet end in communication with the interior cavity of the suction device/suction cup 22 [*gas storage cavity*]. The gas inlet end of the outlet one-way valve 225 [*second gas inlet end of the second check valve*] is also in communication with the interior cavity of the suction device 22, and the gas outlet end of the air one-way valve 225 [*second gas outlet end of the second check valve*] is in communication with the outside:

the base plate is equipped with an air outlet and a connecting tube, a one-way exhaust valve is disposed on the air outlet, with one end of the connecting tube connected to the base plate, the other end extending inward into the cylindrical body and disposed with a one-way inlet valve; and the dimensions of the connecting tube match those of the ventilation tube.

EX-1005 [0007].

92. Thus, a POSA understood that the connector included the first and second check valves as shown below:



EX-1005 FIG. 3.

93. Thus, a POSA understood that Zhongnan discloses element [1.4].

[1.5] an upper side of the face mask is hermetically connected to a first gas inlet end of the first check valve, and a lower side of the face mask is provided with a flexible annular pad configured to attach to a face,

Zhongnan discloses the upper side of the breathing mask 1 [*face mask*]

(blue) includes ventilation tube/pipe 11:

the breathing mask comprises a ventilation tube 11, mounted through the breathing mask 1, with one end of the ventilation tube 11 located outside the breathing mask 1 and connected to the suction device 2, and the other end located inside the breathing mask 1.

EX-1005 [0033].

94. Zhongnan further discloses that when the device is in use, the vent tube/pipe 11 is inserted into the connecting tube/pipe 222 positioned at the center of the base plate 221 and that the size of the ventilation tube/pipe

11 is matched to the size of the connecting tube/pipe 222 to form a hermetic connection. One end of the connecting tube/pipe 222 extends inwardly toward the interior cavity of the suction device and is connected to air intake check valve 226 [*first check valve*] such that connecting tube/pipe 222 mates with the gas inlet end of check valve 226 [*first gas inlet end of the first check valve*]:

S10. attaching the breathing mask to the human face and
inserting the ventilation tube into the connecting tube

EX-1005 [0016].

One end of the connecting tube 222 connected to the base plate 221, the other end extending inward into the cylindrical body and disposed with a one-way inlet valve 226; the dimensions of the connecting tube 222 match the dimensions of the ventilation tube 11.

In this example, the dimensions of the connecting tube 222 match those of the ventilation tube 11, specifically: the diameter of the ventilation tube 11 is slightly larger than that of the connecting tube 222, such that after the connecting tube 222 is inserted into the ventilation tube 11, the outer wall of the connecting tube 222 is in close contact with the inner wall of the ventilation tube 11, thereby improving the airtightness of the suction device..

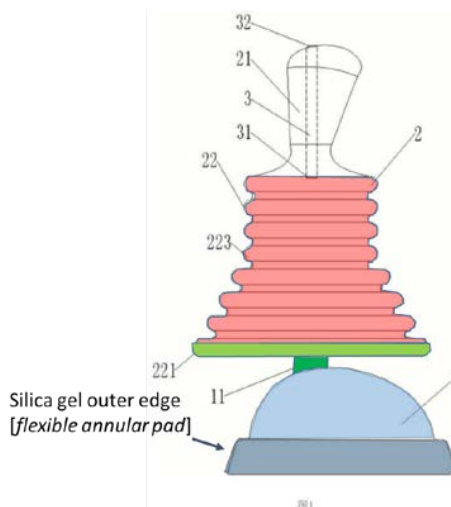
EX-1005 [0034], [0044].

95. Thus, a POSA understood that an upper side of the mask 1 is hermetically connected to the gas inlet end of check valve/one-way inlet valve 226.

96. Zhongnan further discloses that the lower side of the breathing mask 1 [*face mask*] that is placed adjacent the face of a choking patient includes a flexible outer edge of silica gel [*flexible annular pad*] that “shape fits the face” of the patient:

Specifically, in this example, the outer edge of the breathing mask 1 is made of medical-grade silicone and is shaped to fit the face. Both the breathing mask 1 and the suction device 2 are made of transparent materials, allowing for easy observation of whether the foreign body has been suctioned out.

EX-1005 [0041].



EX-1005 FIG. 3.

97. Thus, a POSA understood that Zhongnan discloses element [1.5].

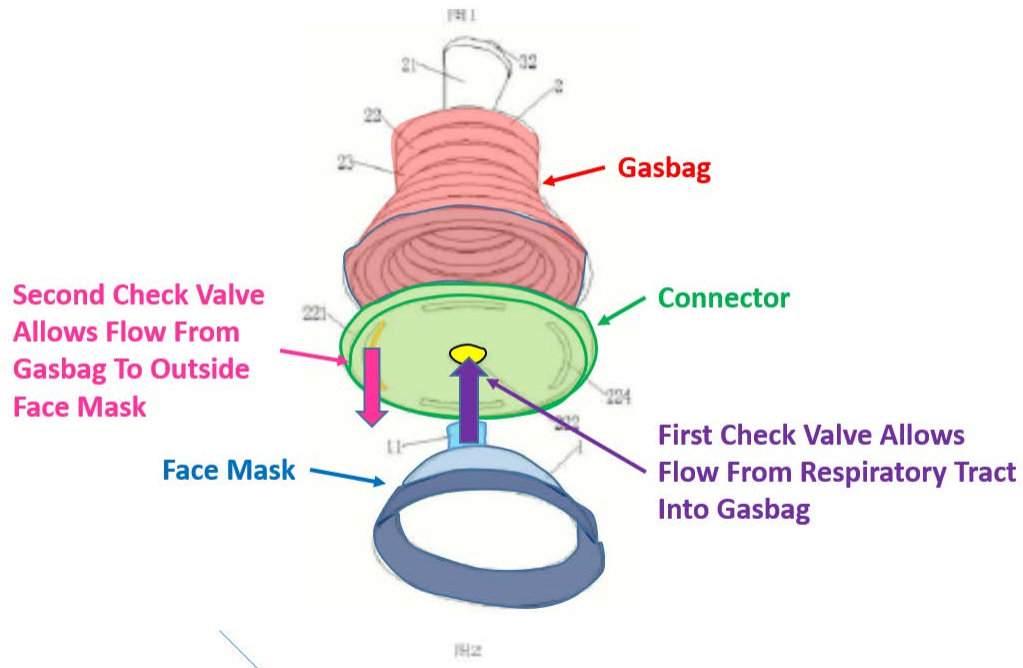
[1.6] wherein the connector comprises a bottom plate and the first check valve and the second check valve are arranged on the bottom plate, wherein the first check valve and the second check valve allow gas flow to pass in opposite directions.

98. Zhongnan discloses the base plate 221 [*connector*] (**green**) includes a bottom plate and the inlet check valve /one-way inlet valve 226 [*first check valve*] (**gold**) and the outlet one-way valve/one-way exhaust valve 225 [*second check valve*] (**orange**) are arranged on the bottom plate. The inlet check valve 226 allows air flow from inside the mask into the interior cavity of the suction device (**purple arrows**) and the outlet one-way valve 225 allows air flow from the interior of the cavity to outside the mask (**magenta arrows**) to exit the suction device. A POSA understood these air flows are in opposite directions as shown in the annotated figures below:

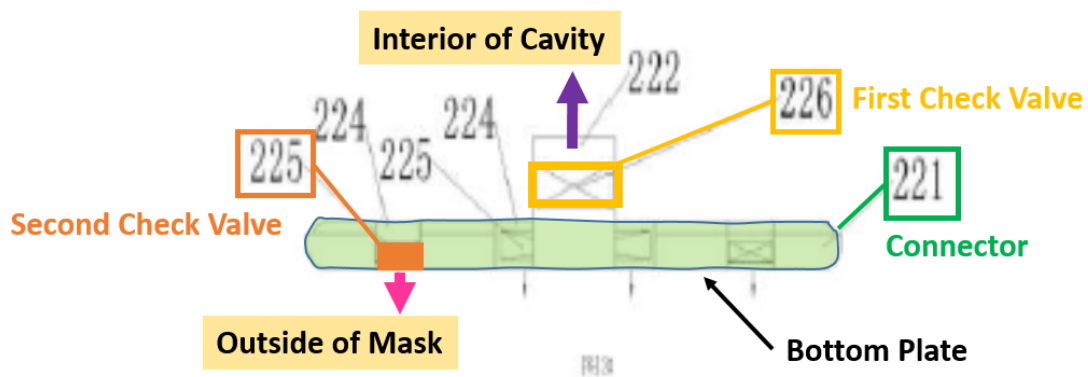
S20. pressing down the handle, driving the cylindrical body to press toward the face; the airflow created inside the cylindrical body flows downward, the one-way exhaust valve opens, the one-way inlet valve closes, and the airflow is discharged through the air outlet, creating a negative pressure inside the cylindrical body;

S30. pulling up the handle; the one-way exhaust valve closes, and the one-way inlet valve opens; under the effect of the negative pressure, the foreign body in the trachea is suctioned out therefrom..

EX-1005 [0038-0039].



EX-1005 FIG. 2.



EX-1005 FIG 3.

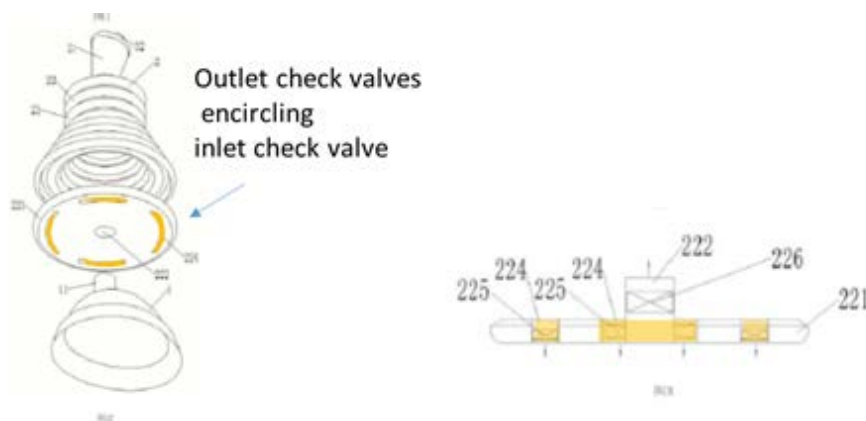
99. Thus, a POSA understood that Zhongnan discloses element [1.6].

Claim 2

The removal device for removing the obstruction in the respiratory tract according to claim 1, wherein the connector is

provided with a plurality of second check valves, the plurality of second check valves encircling the first check valve.

100. Zhongnan discloses that the base plate 221 [*connector*] includes a plurality of one-way exhaust valves 225 [*second check valves*] positioned at the outlets 224 around the periphery of base plate 221 and encircling the one-way inlet valve 226 [*first check valve*] positioned at the connecting tube/pipe 222 at the center of the base plate 221.



EX-1005 FIGs. 2, 3.

101. Thus, a POSA understood that Zhongnan discloses the additional limitations recited in Claim 2.

Claim 7

The removal device for removing the obstruction in the respiratory tract according to claim 1, wherein a top wall of the collapsible gasbag is connected to a handle for holding.

102. Zhongnan discloses a handle 21 at the top of the suction device/cup 22 [*collapsible gasbag*].

On the basis of Embodiment 1, a cylindrical body of the tracheal foreign body suction device comprises: a plurality of grooves 223 arranged sequentially from top to bottom, the

groove 223 at the topmost position is connected to the handle 21, and the groove 223 at the bottommost position is connected to the base plate 221.

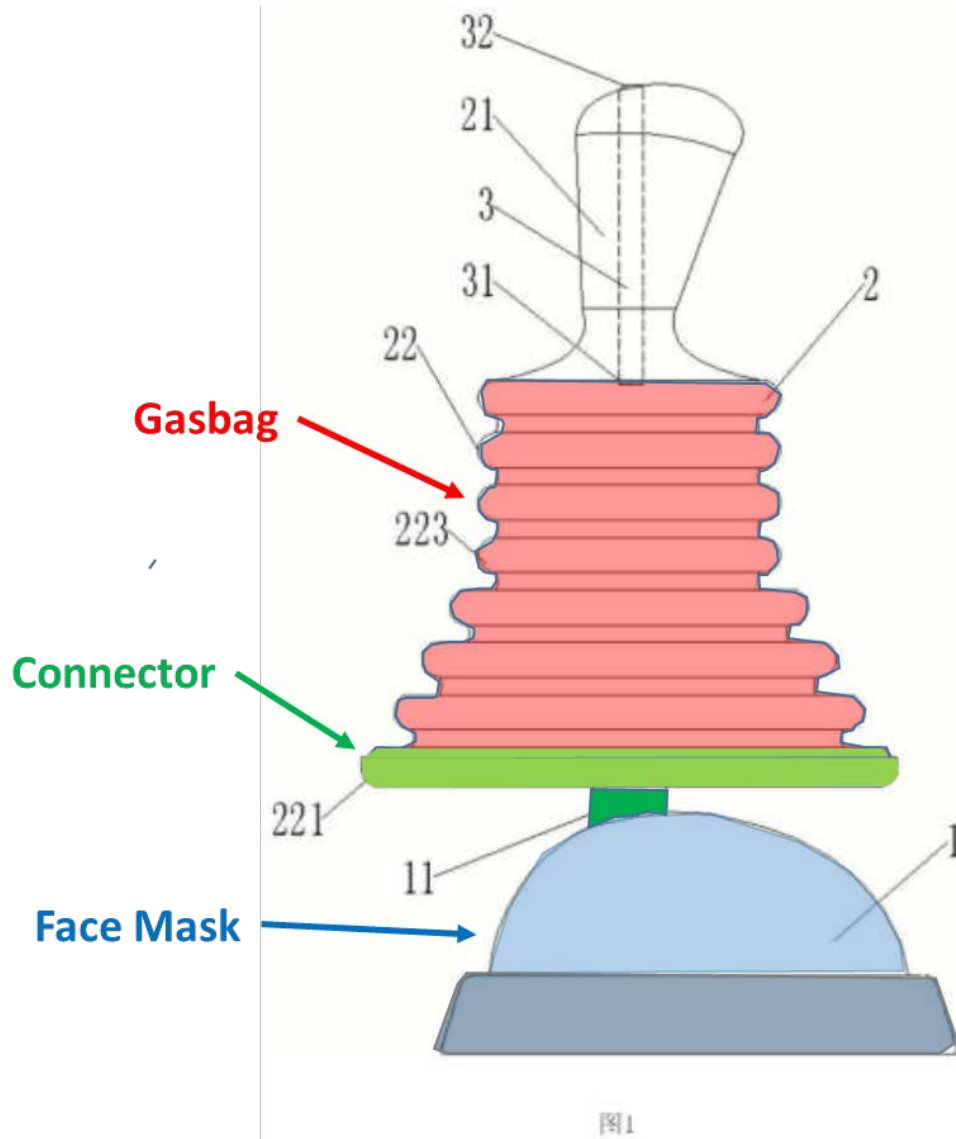
EX-1005 [0050].

103. Thus, a POSA understood that Zhongnan discloses the additional limitations recited in Claim 7.

Claim 11

The removal device for removing the obstruction in the respiratory tract according to claim 1, wherein the face mask, the connector and the collapsible gasbag are integral.

104. Zhongnan discloses the breathing mask 1 [*face mask*], base plate 221 [*connector*] and suction cup 22 [*collapsible gasbag*] are sequentially coupled and are integral in the assembled device.



EX-1005 FIG. 1.

105. Thus, a POSA understood that Zhongnan discloses the additional limitations recited in Claim 11.

Claim 12

The removal device for removing the obstruction in the respiratory tract according to claim 1, wherein the collapsible

gasbag is not provided with a vent hole which is in direct communication with the outside.

106. Zhongnan discloses that the suction cup/cylindrical body 22 [collapsible gasbag] vents indirectly via the base plate 221 [connector] through outlets 224 to the outside:

A base plate 221 is disposed at the open bottom of the cylindrical body, and the base plate 221 is equipped with an air outlet 224 and a connecting tube 222, a one-way exhaust valve 225 is disposed on the air outlet 224,

EX-1005 [0034].

107. A POSA understood that the suction cup/cylindrical body 22 [collapsible gasbag] is provided with no vent hole that is in direct communication with the outside. Thus, a POSA understood that Zhongnan discloses the additional limitations recited in Claim 12.

Claim 13

A connector for a removal device, the connector comprising a bottom plate, and a first check valve and a second check valve which are arranged on the bottom plate, wherein the first check valve and the second check valve allow gas flow to pass in opposite directions; and the connector is an integrally formed member made from an elastic material.

108. For at least the reasons set forth with respect to element [1.6], Zhongnan discloses “*A connector for a removal device, the connector comprising a bottom plate, and a first check valve and a second check valve which are arranged on the bottom plate, wherein the first check valve and*

the second check valve allow gas flow to pass in opposite directions;” as recited in Claim 13.

109. In addition, Zhongnan discloses the base plate 221 [*connector*] is an integrally formed member with other elements on the connector:

Preferably, the base plate and the connecting tube are an integrally formed structure.

EX-1005 [0013].

110. Zhongnan, while disclosing portions of the device, such as the gasbag and the facemask are formed from elastic material, does not explicitly disclose the base plate is constructed of such. EX-1005 [0011], [0014] and [0043]. However, a POSA understood that in order to maintain an airtight seal during operation, the connector would need to flex with the gasbag and the facemask, and thus an elastic material would be used for the connector.

111. To the extent that PO argues that Zhongnan does not explicitly state that the connector is made from an elastic material, it would have been obvious to a POSA to form the base plate with an elastic material such as plastic. A POSA would have been motivated to make the base plate from an elastic material such as plastic and would have a reasonable expectation of success for the following reasons:

(i) A POSA understood patient face conforming breathing medical devices for hygienic, economic and physical trauma reasons are routinely made of elastic material that allow flexibility to ensure a proper seal, and furthermore, the elastic nature would improve assembly ease; and

(ii) Zhongnan discloses that the base plate as part of the suction device is preferably made of a transparent material. A POSA understood that plastic can be a relatively economically producible and readily available transparent material, and a POSA would also have been motivated to make the base plate out of an elastic material for its transparent and economic characteristics.

112. Thus, a POSA understood that Claim 13 is disclosed by, or obvious over Zhongnan.

Claim 14

The connector according to claim 13, wherein the connector is provided with one first check valve and a plurality of second check valves, the plurality of second check valves encircling the first check valve.

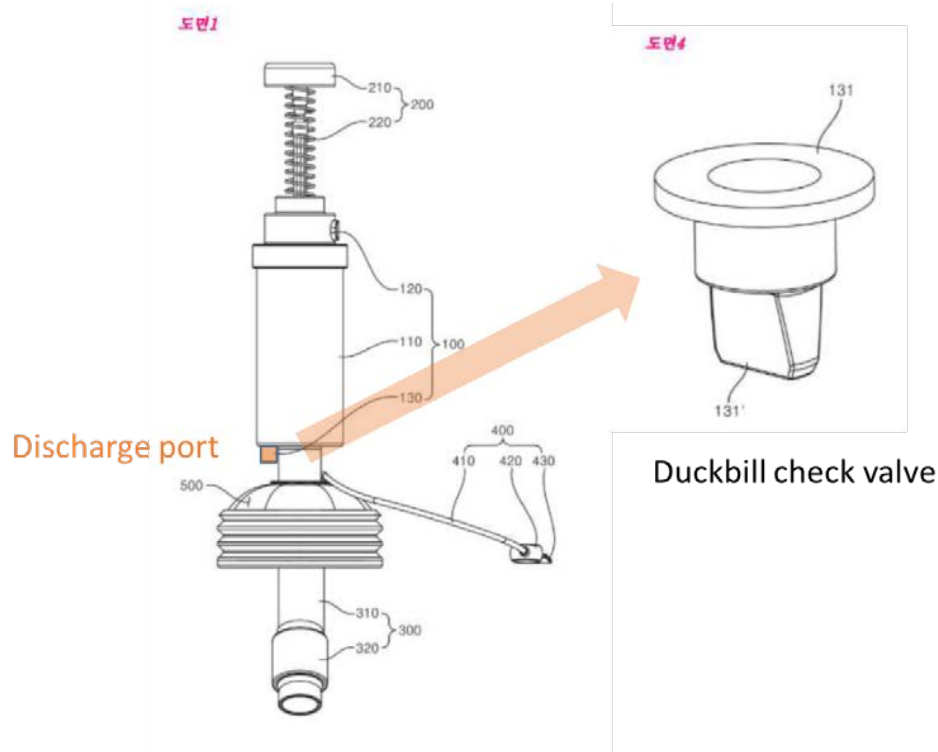
113. See Claim 2.

B. Challenge 2 Claims 3-6, 8-12, and 15-17 are rendered unpatentable over Zhongnan in view of Yuchang.

1. The Yuchang Reference

114. Yuchang relates to an anti-choking apparatus for removing foreign substances from the esophagus. The apparatus includes: a case 100 (*i.e.*, cylinder and plunger) for generating vacuum pressure by discharging or introducing air; an insertion tube 300 connected to the bottom of the case 100 and inserted into the oral cavity of a person whose esophagus is blocked; and a close-fitting mask 500 that is fastened in a structure through which the insertion tube (300) passes, and is in close contact with the surroundings of the oral cavity of the person whose esophagus is blocked. Yuchang discloses that the case includes an air outlet/discharge port 130

(orange) which houses a duckbill check valve 131 to discharge air from the case to the outside. EX-1009, FIGs. 1, 4, Abstract, [0036];



EX-1009, FIGs. 1, 4.

2. Detailed Application of Zhongnan and Yuchang to the Challenged Claims

Claim 3

[3.0] *A removal device for removing an obstruction in a respiratory tract,*

115. *See Claim [1.0].*

[3.1] *the removal device comprising a collapsible gasbag, a connector and a face mask which are sequentially connected,*

116. *See Claim [1.1].*

[3.2] wherein the collapsible gasbag is internally provided with a gas storage cavity, the top of the collapsible gasbag is sealed, and the bottom of the collapsible gasbag is provided with an opening in communication with the gas storage cavity;

117. See Claim [1.2].

[3.3] an upper side of the connector is hermetically connected to the opening, and

118. See Claim [1.3].

[3.4] the connector is provided with a first check valve and a second check valve; a first gas outlet end of the first check valve is in communication with the gas storage cavity, a second gas inlet end of the second check valve is in communication with the gas storage cavity, and a second gas outlet end of the second check valve is in communication with the outside; and

119. See Claim [1.4].

[3.5] an upper side of the face mask is hermetically connected to a first gas inlet end of the first check valve, and a lower side of the face mask is provided with a flexible annular pad configured to attach to a face,

120. See Claim [1.5].

[3.6] wherein the connector is provided with a bottom plate,

121. See Claim [1.6].

[3.7] the bottom plate being provided with a central cylinder which is vertically through;

122. Zhongnan discloses a base plate 221 includes a connecting pipe 222 [*central cylinder*] vertically there through:

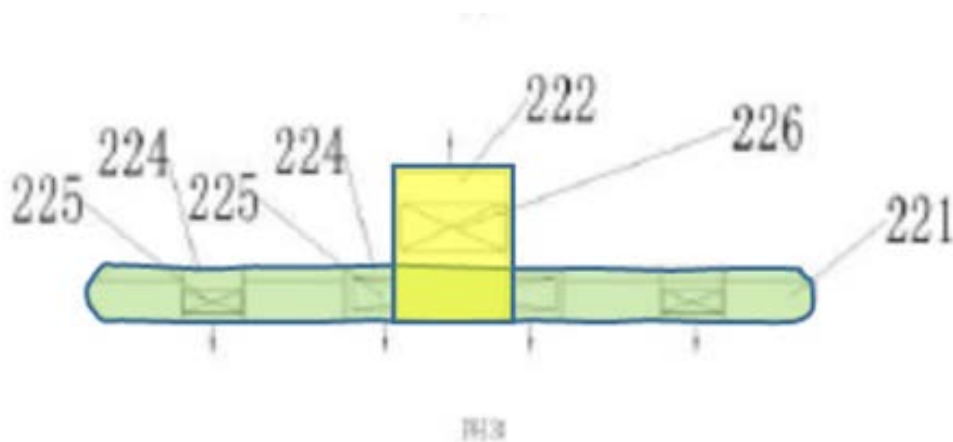
Fig. 3 is a schematic diagram of the base plate of the present disclosure;

In the drawings: 1 represents a breathing mask, 2 represents a suction device, and 3 represents a spotlight;

11 represents a ventilation tube; 21 represents a handle, 22 represents a suction cup; 31 represents a lamp head, and 32 represents a switch;

221 represents a base plate, 222 represents a connecting tube, 223 represents a groove, 224 represents an air outlet, 225 represents a one-way exhaust valve, and 226 represents a one-way inlet valve.

EX-1005 [0026-0028].



EX-1005 Figs. 2, 3.

[3.8] the first check valve is of a hollowed structure made from an elastic material, and comprises a deformed portion and a first base portion which are connected to each other; the first gas outlet end is composed of at least three first slits provided at a top end of the deformed portion; one end, extending toward the center, of the at least three first slits intersect at the same point, and the first gas inlet end is a first vent hole provided in the middle of the first base portion; the first base portion extends into the central cylinder, and an outer side of the first base portion is hermetically connected to an inner side of the central cylinder; a lower end of the central cylinder is hermetically connected to an upper side of the face mask; the deformation portion is exposed out of the central cylinder and extends into the gas storage cavity; when gas flows into the deformation portion through the first vent hole, pressure in the deformation portion gradually increases such that the deformation portion is deformed by expansion, so that the at least three first slits are opened, thereby allowing the gas on the side of the first vent hole to flow into the gas storage cavity; and when the gas flowing into the deformation portion through the first vent hole is reduced or disappears, pressure in the deformation portion is reduced and even reduced to zero, and the deformation portion shrinks under its own elasticity such that the three first slits are closed, thereby preventing the gas in the gas storage cavity from flowing out of the first vent hole.

123. Zhongnan, while disclosing an one-way inlet valve 226 [*first check valve*], does not disclose a specific type of check valve. However, as discussed in the State of the Art section, the use of a cross-slit check valve [*first check valve*] in association with tracheal respiratory device was well-known. Specifically, the operation of a cross-slit valve is well-known. When gas flows into the deformation portion through the vent hole during an

exhale, pressure in the deformation portion gradually increases such that the deformation portion is deformed by expansion, so that the slits are opened, thereby allowing the gas on the lower side of the vent hole to flow into the upper trachea; and when the gas flowing into the deformation portion through the first vent hole is reduced or disappears as during an inhale, pressure in the deformation portion is reduced and the deformation portion shrinks under its own elasticity such that the slits are closed, thereby preventing the gas in the upper trachea from flowing through the vent hole. EX-1012.

124. Thus, it was obvious for POSA to modify the teaching of Zhongnan to use a well-known cross-slit valve would share the same location and perform the identical function of the one-way inlet valve taught by Zhongnan. A POSA would have been motivated to select a cross-slit valve because it was a commonly used type of check valve in medical devices having well known properties of low cost, ease of production, ready availability and reliable operation. Duckbill check valves as discussed earlier are generally more reliable than a 3 or 4 slit check valve, but valve function at the air inlet is not as critical as the outlet because comparable negative pressure can still be generated even if the air inlet valve failed by leaking. This means reliability becomes less of a factor than minimizing flow resistance and pressure which justifies the selection of 3 or 4 slit check valves. A POSA would have also been motivated to make the selection because cross-slit check valves are one of a limited number of check valve types that would meet the cost and function required of the check valves in the device of Zhongnan.

125. A POSA understood the installation/attachment structure was merely a routine design choice readily within grasp of a POSA, and independent of the of the function of the check valve.

126. Further, a POSA would be confident of success in the selection given the ubiquitous and wide ranging use of cross-slit check valves and well known functional characteristics.

Claim 4

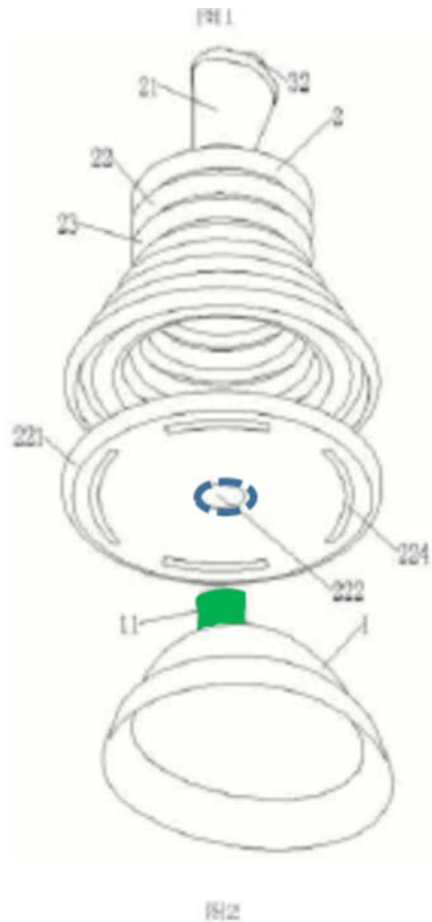
The removal device for removing the obstruction in the respiratory tract according to claim 3, wherein the upper side of the face mask is provided with a connecting cylinder which is vertically through in the middle, the connecting cylinder being inserted into the inner side of the lower end of the central cylinder from bottom to top, and an outer side of the connecting cylinder being hermetically connected to the inner side of the central cylinder.

127. Zhongnan discloses ventilation tube 11 [*connecting cylinder*] on the upper side of the breathing mask inserted vertically through the middle. The ventilation tube/ pipe 11 of Zhongnan being inserted into the inner side of the connecting tube 222 [*central cylinder*] from bottom to top and the interaction of the outside of the vent pipe and the inside of the connecting pipe form an air seal.

In this example, the dimensions of the connecting tube 222 match those of the ventilation tube 11, specifically: the diameter of the ventilation tube 11 is slightly larger than that of the connecting tube 222, such that after the connecting tube 222 is inserted into the ventilation tube 11, the outer wall of the connecting tube 222 is in close contact with the inner wall of

the ventilation tube 11, thereby improving the airtightness of the suction device.

EX-1005 [0044].



EX-1005 Fig. 2.

Claim 5

The removal device for removing the obstruction in the respiratory tract according to claim 3, wherein an upper side of the bottom plate is provided with a first peripheral side wall encircling the central cylinder,

an upper end of the first peripheral side wall shrinking inward to form a stop edge;

the collapsible gasbag is provided with a second peripheral side wall made from an elastic material, the second peripheral side wall being provided with a plurality of layers of outwardly convex folds; and the first peripheral side wall covers the lowermost fold of the second peripheral side wall, and the stop edge covers an upper side of the lowermost fold.

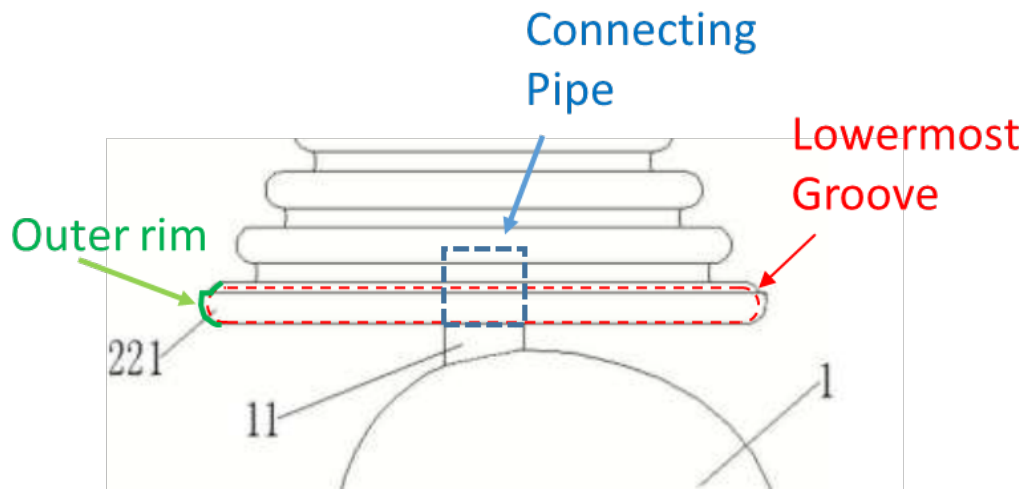
128. Zhongnan discloses an upper side of the base plate includes a rim structure [*first peripheral side wall*] (**green**) encircling the connecting tube/ pipe 222 [*central cylinder*] (**blue**). The rim structure has an upper end that shrinks radially inward to form a stop edge. Zhongnan further discloses the suction device 2 includes a second peripheral side wall, made from an elastic material, and the second peripheral side wall is formed from a plurality of grooves [*layers of outwardly convex folds*]. The rim structure covers the lowermost groove (**red**) and the stop edge covers the upper side of the lowermost rib.

On the basis of Embodiment 1, a cylindrical body of the tracheal foreign body suction device comprises: a plurality of grooves 223 arranged sequentially from top to bottom, the groove 223 at the topmost position is connected to the handle 21, and the groove 223 at the bottommost position is connected to the base plate 221.

EX-1005 [0050].

Moreover, the cylindrical body is made of a deformable elastic material, such as rubber.

EX-1005 [0043].



EX-1005 FIG. 1.

129. Thus, a POSA understood that Zhongnan discloses the additional limitations recited in Claim 5.

Claim 6

The removal device for removing the obstruction in the respiratory tract according to claim 5, wherein a plurality of reinforcement strips are arranged on the upper side of the bottom plate, two opposite ends of each reinforcement strip being separately connected to the inner side of the first peripheral side wall and the outer side of the central cylinder.

130. Zhongnan does not disclose reinforcement strips on the upper side of the bottom plate, however the use of reinforcement strips (e.g., corrugations, ribs, gussets, webs, flanges etc.) were well known to a POSA, and thus it would have been obvious to a POSA to include a plurality of reinforcement strips on the upper surface of the base plate in a radial arrangement between the rim structure and the connecting pipe of Zhongnan.

131. A POSA was motivated to stiffen the bottom plate via reinforcement strips to achieve the dual goals of allow elastic movement of the connector while maintaining an airtight seal during the mechanical operation of the device. A POSA understood that excessive deformation could compromise the air tight connection between the base plate and cylindrical body and/or between the connecting tube and the ventilation tube/pipe, which in turn compromises the operation and durability of the device. Additionally, a POSA understood the excessive deformation of the base plate may reduce the device's effectiveness in drawing a vacuum, as excessive deformation would deform the cylindrical body's circular shape, which resists the pressure differential generated by the suction device in order to dislodge the obstruction.

132. A POSA also understood that reinforcement strips are a cost effective manner to stiffen elastic structures, they are easily incorporated in a mold, and reduce material cost verses the alternatives of increasing bulk and adding different material. Given the long use of such reinforcement strips, a POSA would be extremely confident of success in the implementation of reinforcement strips onto the bottom plate in a radial orientation.

Claim 8

The removal device for removing the obstruction in the respiratory tract according to claim 3, wherein four first slits are provided, the four first slits being in the shape of a cross.

133. This limitation is described for the same reasons as described with respect to Claim 3.

Claim 9

[9.0] A removal device for removing an obstruction in a respiratory tract,

134. See Claim [1.0].

[9.1] the removal device comprising a collapsible gasbag, a connector and a face mask which are sequentially connected,

135. See Claim [1.1].

[9.2] wherein the collapsible gasbag is internally provided with a gas storage cavity, the top of the collapsible gasbag is sealed, and the bottom of the collapsible gasbag is provided with an opening in communication with the gas storage cavity;

136. See Claim [1.2].

[9.3] an upper side of the connector is hermetically connected to the opening, and

137. See Claim [1.3].

[9.4] the connector is provided with a first check valve and a second check valve; a first gas outlet end of the first check valve is in communication with the gas storage cavity, a second gas inlet end of the second check valve is in communication with the gas storage cavity, and a second gas outlet end of the second check valve is in communication with the outside; and

138. See Claim [1.4].

[9.5] an upper side of the face mask is hermetically connected to a first gas inlet end of the first check valve, and a lower side of the face mask is provided with a flexible annular pad configured to attach to a face,

139. See Claim [1.5].

[9.6] wherein the connector is provided with a bottom plate,

140. See Claim [1.6].

[9.7] the bottom plate being provided with a peripheral cylinder which is vertically through; the second check valve is a duckbill valve, the second check valve comprises a duckbill portion and a second base portion which are connected to each other, the second gas inlet end is a second vent hole provided in the middle of the second base portion, and the second gas outlet end is a second slit provided in the duckbill portion; an outer side of the second base portion is hermetically connected to an inner side of the peripheral cylinder, and the second vent hole of the second base portion is in communication with the gas storage cavity; the duckbill portion extends into the peripheral cylinder, and a lower end of the peripheral cylinder is in communication with the outside; when gas flows into the duckbill portion through the second vent hole, pressure in the duckbill portion gradually increases such that the duckbill portion is deformed by expansion, so that the second slit is opened, thereby allowing gas in the gas storage cavity to be discharged to the outside; and when gas flowing into the duckbill portion through the second vent hole, pressure in the deformation portion is reduced and even reduced to zero, and the duckbill portion shrinks under its own elasticity such that the second slit is closed, thereby preventing outside gas from flowing into the gas storage cavity through the second vent hole.

141. Zhongnan, while disclosing an one-way exhaustvalve [*second check valve*], does not disclose a specific type of check valve. However, as discussed above in the State of the Art section, a duckbill check valve was well-known for ventilation purposes. For example, Yuchang discloses the use of an air discharge member 131 [*duckbill valve*] (orange) in an anti-choking device. Yuchang discloses that the air exhaust element 131 discharges air inside the case [*gas storage cavity*] in response to an increase in pressure inside the case 110, and prevents external air from flowing into the case through the air exhaust element 131:

And the air outlet (130) corresponding to the passage through which air is exhausted inside the case (110) is housed with the air exhaust element (131) as shown in FIG. 4. When the pressurized section (200) is compressed, the air inside the case (110) must be rapidly discharged to the outside with limited movement to the insertion tube (300), for which the air exhaust element (131) is a cylindrical shape on the top part through, and the bottom part is a nip shape with a lower cross-sectional area and an ejection section(131') which is cut straight through and close to each other. Here, it is preferred that the air exhaust element (131) consists of an elastic material, such as silicon or rubber, because the ejection section (131') is easily opened when the air of the case (110) is vented, and it is **advantageous to prevent the outside air from entering the ejection section (131') when the inside of the case (110) is under negative pressure.**

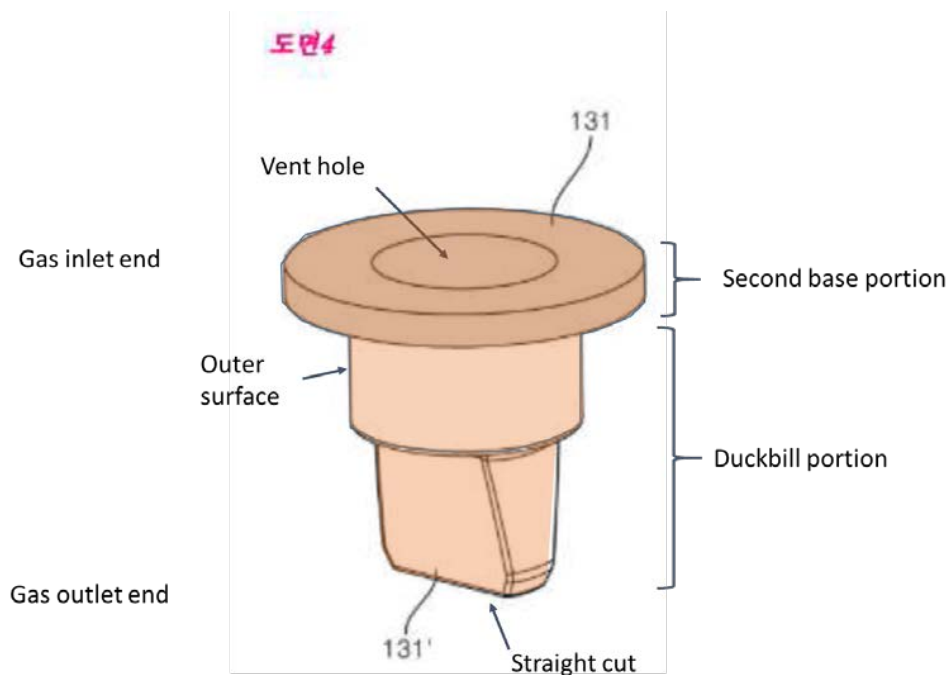
EX-1009 [0036], [0037].

The device for removing foreign substances from the esophagus of the present invention is also characterized in that **an air exhaust element (131) capable of discharging air inside the case (110) and blocking the inflow of external air is accommodated in the air outlet (130).** .

EX-1009 [0018].

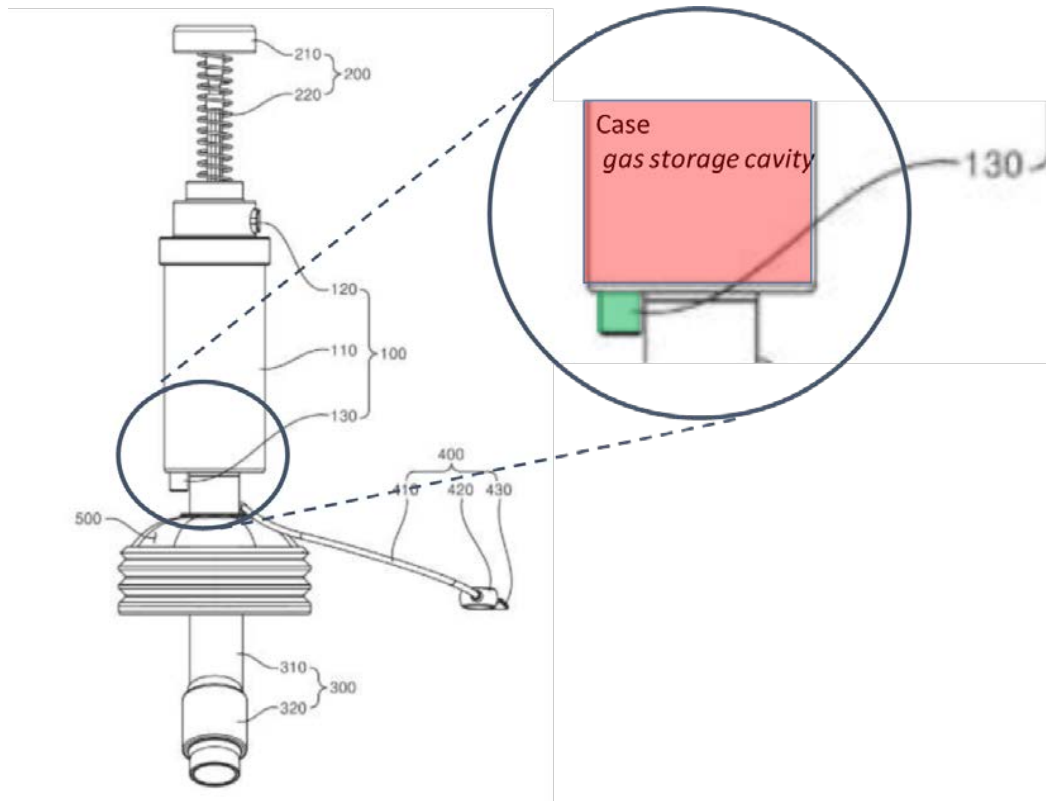
142. A POSA understood that the air exhaust element 131 of Yuchang to be a duckbill valve. The second base portion (**dark orange**) of

the air exhaust element 131 has a vent hole in the middle and the duckbill portion (orange) at second gas outlet end has a straight cut [*second slit*].



EX-1009 FIG. 4.

143. Yuchang discloses the air exhaust element 131 is accommodated in an air outlet/discharge port 130 [*peripheral cylinder*] in a bottom plate of the case 110. EX-1009 [0036], Fig. 1.



EX-1009 Fig. 1.

144. The vent hole of the second base portion (**dark orange**) is in communication with the gas storage cavity (**red**). As understood by a POSA, the duckbill portion extends into the air outlet 130 (**green**)[*peripheral cylinder*], and the lower end of the air outlet 130 is in communication with the external air. The outer surface of the duckbill portion is in contact with the inner surface of the air outlet 130 forming an airtight seal. EX-1009 [0018], Figs. 1, 4.

145. From the known operation of a duckbill valve and as used in Yuchang, a POSA understood that when gas flows into the duckbill portion through the second vent hole, pressure in the duckbill portion gradually increases such that the duckbill portion is deformed by expansion, so that the straight cut is opened, thereby allowing gas in the case to be discharged

externally; and when gas flowing into the duckbill portion through the second vent hole, pressure in the deformation portion is reduced and even reduced to zero, and the duckbill portion shrinks under its own elasticity such that the straight cut is closed, thus preventing outside gas from flowing into the gas storage cavity through the second vent hole. EX-1009 [0018] [0036], [0037].

146. It would have been obvious to a POSA to modify the teachings of Zhongnan's air exhaust one-way valve with Yuchang's teaching of a duckbill valve because the duckbill valve apparatus would share the same location and perform the identical function of the air exhaust one-way valve. A POSA would have been motivated to use a duckbill valve given the long use and well known properties low cost, ready availability and reliable operation. A POSA would have also been motivated to make this selection as duckbill valves are one of a limited number of check valve types that would meet the cost and function required of the check valves in the device of Zhongnan.

147. To the extent the PO argues the manner in which the duckbill valve of Yuchang is installed differs from the installation manner claimed, a POSA understood the installation/attachment structure was merely a routine design choice readily within grasp of a POSA, and independent of the function of the check valve.

148. A POSA would be confident of success in the modification given the ubiquitous and wide-ranging use of duckbill valves and well-known functional characteristics.

Claim 10

The removal device for removing the obstruction in the respiratory tract according to claim 1, wherein the connector is an integrally formed member made from an elastic material.

149. See Claim 13.

Claim 15

[15.0] The connector according to claim 14, wherein the bottom plate is provided with a central cylinder which is vertically through;

150. See Claim [3.7].

[15.1] the first check valve is of a hollowed structure and comprises a deformed portion and a first base portion which are connected to each other, and a first gas outlet end and a second vent hole of the first check valve are provided in the deformed portion and the first base portion respectively; the first gas outlet end is composed of at least three first slits provided at a top end of the deformed portion, one ends, extending toward the center, of the at least three first slits intersecting at the same point; and the first gas inlet end is a first vent hole provided in the middle of the first base portion.

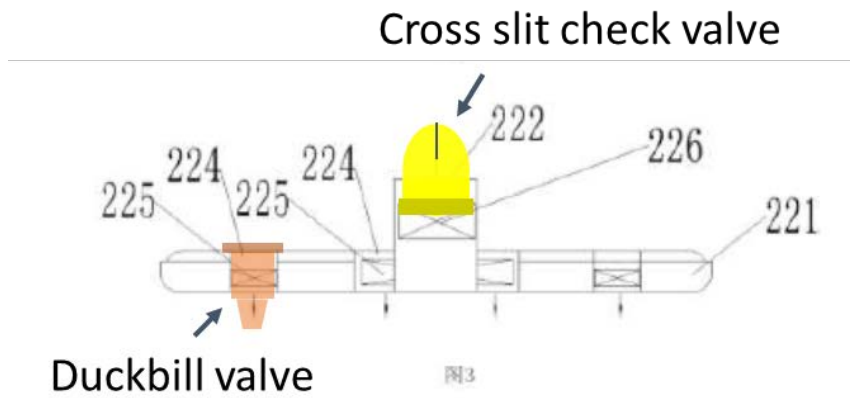
151. This limitation is disclosed for the same reasons as discussed with respect to Claim [3.8].

Claim 16

The connector according to claim 15, wherein the second check valve is a duckbill valve, the second check valve comprises a duckbill portion and a second base portion which are connected to each other, and a second gas outlet end and a second gas inlet end of the second check valve are provided in the duckbill portion and the second base portion respectively; the second gas inlet end is a second vent hole provided in the middle of the second base portion,

and the second gas outlet end is a second slit provided in the duckbill portion; and the duckbill portion and the deformed portion separately face two opposite sides of the bottom plate.

152. As described with respect to Claim [9.7], it would have been obvious to select the duckbill valve apparatus of Yuchang for use in the device of Zhongnan. Furthermore, as discussed with respect to Claim 3.8 and 9.7, the duckbill portion and the deformed portion of Zhongnan separately face two opposite sides of the base plate.



EX-1005 Fig. 3.

Claim 17

[17.1] The connector according to claim 15, wherein the removal device is configured to remove an obstruction in a respiratory tract, the removal device comprising a collapsible gasbag, the connector and a face mask which are sequentially connected,

153. See Claim [1.1].

[17.2] wherein the collapsible gasbag is internally provided with a gas storage cavity, the top of the collapsible gasbag is sealed, and the bottom of the collapsible gasbag is provided with an opening in communication with the gas storage cavity;

154. See Claim [1.2].

[17.3] an upper side of the connector is hermetically connected to the opening;

155. See Claim [1.3].

[17.4] the first gas outlet end of the first check valve is in communication with the gas storage cavity, a second gas inlet end of the second check valve is in communication with the gas storage cavity, and a second gas outlet end of the second check valve is in communication with the outside; and

156. See Claim [1.4].

[17.5] an upper side of the face mask is hermetically connected to the first gas inlet end of the first check valve, and a lower side of the face mask is provided with a flexible annular pad configured to attach to a face.

157. See Claim [1.5].

CONCLUSION AND DECLARATION

The findings and opinions set forth in this declaration are based on my research and analysis to date. I may continue my examinations in view of additional documents or other factual evidence over the course of this proceeding that may necessitate supplementing and/or refining my opinions. I reserve the right to add to, alter, or delete my opinions and my Declaration upon discovery of additional information. I reserve the right to make such changes as necessary.

In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

I declare that all statements made herein on my own knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

[SIGNATURE ON FOLLOWING PAGE]

Dated: Jan 29, 2025

By: Stanley Yermashin

APPENDIX A – MATERIALS RELIED UPON

<i>Exhibit #</i>	<i>Description</i>
1001	U.S. Patent No. 11,478,575 (“the ’575 Patent”)
1002	Select portions of prosecution history of the ‘575 Patent (“File History”)
1004	Chinese Patent Publication CN112932633A (“Zhongnan”)
1005	Certified English translation of EX-1004
1006	U.S. Patent Application Publication US 2020/0306420 A1 (“Carver”)
1007	Korean Patent Publication KR1020200102780A to Jung-Hwan Bae (“Bae”)
1008	Korean Patent Publication KR 102229619B (“Yuchang”) and
1009	Certified English translation of EX-1008
1010	Chinese Patent Publication CN110566698 A (“Changzhon”)
1012	U.S. Patent No. 9,714,714 to Daansen et al. (“Daansen”)
1013	U.S. Patent Application Publication US 2006/0260617 A1 (“Abolfathi”)
1015	U.S. Patent No. 5,722,394 to Loescher (“Loescher”)

APPENDIX B – CURRICULUM VITAE

B

CURRICULUM VITAE

Stanley M. Yamashiro

Current Position:

Professor of Biomedical and Electrical Engineering, University of Southern California, Los Angeles, CA 90089-1111, (213) 740-0336
email: syamash@usc.edu.

Training:

B.S. Electrical Engineering (1964), M.S. Electrical Engineering (1966) and Ph.D. Electrical Engineering (1970) all from the University of Southern California. Howard Hughes Master's Fellow 1964-66, Howard Hughes Doctoral Fellow 1966-70, Visiting Scientist, Nobel Institute of Neurophysiology, Karolinska Institute (Stockholm, Sweden) 1977-78.

Position Held:

1964-70 Member of the Technical Staff, Hughes Aircraft Company, Culver City, California. Digital and analog microelectronic circuit design, communication systems analysis, and positioning control system design and analysis.

1970-71 Research Associate in Biomedical Engineering, University of Southern California. Research in optimization of cardiopulmonary mechanics and control of breathing under Professor F. Grodins.

1971-74 Assistant Professor of Biomedical Engineering, University of Southern California. Teaching bio-instrumentation, medical electronics, and respiratory physiology. Research in peripheral circulation, mathematical models, and cardiopulmonary regulation.

1974-82 Associate Professor of Biomedical and Electrical Engineering, University of Southern California. Teaching medical electronics, signal processing, and laboratory computer applications. Research in dynamics of cardiopulmonary regulation.

1982-present Professor of Biomedical and Electrical Engineering, University of Southern California. Teaching cardiovascular and pulmonary physiology, instrumentation, and signal processing. Research in magnetocardiography, laser instrumentation, gas exchange enhancement, and mathematical models. Current research focus is on optimizing smooth muscle electrical stimulation for obesity treatment.

1985-86 Acting Chairman, Biomedical Engineering Department, University of Southern California.

Consulting Experience:

1971-76 Rancho Los Amigos Hospital, Downey, California, Environmental

Health Department, consultant for on-line computer processing of human subject pulmonary function test data collected during controlled pollutant exposure.

1976-1977 Valley Presbyterian Hospital, Van Nuys, California, Respiratory Care Department, computer consultant on on-line patient pulmonary function testing and blood-gas analysis. Developed an automated blood gas diagnosis and data base management program

1979 Bentley Laboratories, Irvine, California, consultant on instrumentation for synchronous detection of electrical conductivity of blood to permit cardiac output measurement.

1980 National Institutes of health, consultant on computer information processing, storage and retrieval, site visit team member (HL 20609-3).

1993-1996 Department of Cardiothoracic Surgery, Children's Hospital Los Angeles, Vaughn Starnes, M.D., Chairman, computer and instrumentation consultant on lung transplantation research in animals. Developed an on-line monitoring and physiological testing program in Visual Basic.

1997 Medtronic, Inc., Cardiopulmonary Division, consultant on mathematical modeling of temperature and blood gas changes associated with cardiopulmonary bypass oxygenators. Developed an interactive Visual Basic (Windows 95) program as an aid to perfusionists.

1998-2000 Baxter Healthcare Corp., consultant on mathematical modeling of oxygenation, temperature, and blood flow during cardiopulmonary bypass. Developed three interactive programs for use as a training aid for perfusionists. An interactive blood flow simulator was also used in developing a new vacuum assisted venous return product. A CD Rom version of this simulator is currently used as a marketing device for this new product.

Professional Societies:

Member: American Physiological Society, Biomedical Engineering Society, Sigma Xi, Eta Kappa Nu, Tau Beta Pi (chapter advisor). Member, Editorial Board, American Journal of Physiology and Journal of Applied Physiology, Modeling Methodology Section

Grant Experience

NSF Transcutaneous Laser Doppler Measurement of Mucus Clearance

\$20,000, 1 June 1998 to 31 May 1999.

Quallion /Alfred Mann Institute DNA Nanometric Power Source

\$34,000, 1 January 2002 to April 1 2002

Alfred Mann Institute Magnetic Plethysmography for Respiratory Measurements

\$150,000, 1 June 2001 to Aug 2007.

Viterbi Research Initiation Grant 2014 \$10,000

Maseeh Entrepreneur NSF Grant 2014 \$2,500

USC Coulter Grant 2015-2016 \$139,062

Previous

1) NIH Training - Cardiopulmonary Biomedical Engineering

S.M. Yamashiro, P.I.
HL-33274 (8years)
2) NIH RO1-Cardiopulmonary Control Coupling
S.M. Yamashiro, P.I.
HL-16390

1 April 1988 to 31 March 1994(18 years)

Principal Investigator of two other RO1 NIH grants and one NSF grant. Co-Investigator in one NIH program project grant(with F.S. Grodins, M.D., Ph.D.-8years), and four other NIH center grants(with : F.E. Yates, M.D.-Biomedical Engineering Center,J.D. Hackney, M.D.-Specialized Center of Research-Environmental Lung Disease, J. Bassingthwaite, M.D.-Biomedical Simulation Resource(Seattle), and V. Marmarelis, Ph.D.-Biomedical Simulation Resource(USC))

2021-2023 Joined V. Marmarelis and NIH funded Alzheimers's project to add pseudo-random inhaled CO₂ and O₂ apparatus to be used in testing of patients. Funding was for publication fees.

Publications

1. Sato, T., S.M. Yamashiro and F.S. Grodins, *Measurement of peripheral vascular properties by a frequency response method*, Am. J. Physiol. 200 (1971), 1640.
2. Yamashiro, S.M. and F.S. Grodins, *Optimal regulation of respiratory airflow*, J. Appl. Physiol. 30 (1971), 597.
3. Yamashiro, S.M. and F.S. Grodins, *Respiratory cycle optimization in exercise*, J. Appl. Physiol. 35 (1973), 522.
4. Grodins, F.S. and S.M. Yamashiro, *Optimization of the mammalian respiratory gas transport system*, Ann. Rev. Biophysics & Bioengineering. 2 (1973), 115.
5. Yamashiro, S.M., S.K. Karuza and J.K. Hackney, *Phase compensation of Fleisch pneumotachographs*, J. Appl. Physiol. 36 (1974), 493.
6. Sato, T., S.M. Yamashiro, D. Vega and F.S. Grodins, *Parameter sensitivity analysis of a network model of systemic circulatory mechanics*, Ann. Biomed. Eng. 2 (1974), 289.
7. Yamashiro, S.M., J.A. Daubenspeck, T.N. Lauritsen and F.S. Grodins, *Total work rate of breathing optimization in CO₂ inhalation and exercise*, J. Appl. Physiol. 38 (1975), 702.
8. Sato, T., S.M. Yamashiro, and F.S. Grodins, *Dynamic analysis of gravimetric response of isolated dog hindlimb*, Am. J. Physiol. 228 (1975), 1326.
9. Bekey, G.A. and S.M. Yamashiro, *Parameter estimation in mathematical models of*

biological systems, Adv. in Biomed. Engr. 6 (1976), 1.

10. Grodins, F.S. and S.M. Yamashiro, *Respiratory Function of the Lung and its Control*, MacMillan, New York, 1978.

11. Yamashiro, S.M., J.A. Daubenspeck, F.M. Bennett, S.K. Edelman and F.S. Grodins, *Optimal control analysis of left ventricular ejection. In: Cardiovascular System Dynamics*, Eds. J. Baan, A. Noordergraaf and J. Raines, MIT Press, Cambridge, 1978, pp. 427-431.

12. Bruce, E.M., C. vonEuler and S.M. Yamashiro, *Reflex and central chemoreceptive control of the time course of inspiratory activity. In: Central Nervous Control Mechanisms in Breathing*, Eds. C. vonEuler and H. Lagercrantz, Pergamon Press, Oxford, 1979, pp.177-184.

13. Grodins, F.S. and S.M. Yamashiro, *What is the pattern of breathing regulated for. In: Central Nervous Control Mechanisms in Breathing*, Eds. C. vonEuler and H. Lagercrantz, Pergamon Press, Oxford, 1979, pp. 169-175.

14. Yamashiro, S.M., J.A. Daubenspeck and F.M. Bennett, *Optimal regulation of left ventricular ejection pattern*, Appl Math. and Comp 5 (1979), 41-54.

15. Bennett, F.M., P. Reischl, F.S. Grodins, S.M. Yamashiro and W.E. Fordyce, *Identification of ventilatory dynamics using pseudorandom binary sequences*, Trans. inst. Measurement & Control (U.K.) 2 (1980), 20-24.

16. Sato, Toshiro, M. Shiratake, N. Ikeda, D. Vega, S.M. Yamashiro and F.S. Grodins, *Hemodynamic Parameters of the Isolated Dog Kidney as Determined by a Frequency Response Method*, Japanese Journal of Physiology 30 9(1980), 393-413.

17. Sohrab, S. and S.M. Yamashiro, *Pseudo-Random testing of ventilatory response to inspired CO₂ in man*, J. Appl. Physiol. 40 (1980), 1000-1009.

18. Livnat, A. and S.M. Yamashiro, *Optimal Control Evaluation of Left Ventricular Systolic Dynamics*, Am. J. Physiol. 240 (1981), R370-R383.

19. Bennett, F.M., P. Reischl, F.S. Grodins, S.M. Yamashiro and W.E. Fordyce, *Dynamics of the ventilatory response to exercise in man*, J. Appl. Physiol. 51 (1981), 194-203.

20. Bruce, E.M., C. vonEuler, J.R. Romaniuk and S.M. Yamashiro, *Vagal afferent effects on the intensity of phrenic nerve discharge*, Acta Physiol. Scand. 116 (1982), 351-362.

21. Yamashiro, S.M., *Influence of central respiratory activity dynamics on pattern regulation. In: Modeling and Control of Breathing*, Eds. B. Whipp and D.M. Wiberg, Elsevier, New York, 1983, pp. 115-119.

22. Yamashiro, S.M. and S. Ghazanshahi, *Ventilatory CO₂ responses during hypocapnia in anesthetized cats*, J. Appl. Physiol.: Respirat. Environ. Exercise Physiol. 56 91984), 678-680.
23. Ghazanshahi, S.D., S.M. Yamashiro and V.Z. Marmarelis, *Use of a random forcing for high frequency ventilation*, J. Appl. Physiol. 62 (1987), 1201-1205.
24. Ghazanshahi, S.D., V.Z. Marmarelis and S.M. Yamashiro, *Analysis of the gas exchange system during high frequency ventilation*, Annals of Biomedical Engineering 14 (1986), 525-542.
25. Cha, E.J., D. Sedlock and S.M. Yamashiro, *changes in lung volume and breathing pattern during exercise and CO₂ inhalation in humans*, J. Appl. Physiol. 62 (1987), 1544-1550.
26. Lin, C.K., H. Levenson and S.M. Yamashiro, *Optimization of coronary blood flow during cardiopulmonary resuscitation*, IEEE Trans. on BME BME-34 (1987), 473-481.
27. Hwang, W.W., S.M. Yamashiro, D. Sedlock and F.S. Grodins, *Ventilatory response to CO₂ and O₂ near eupnea in awake dogs*, J. Appl. Physiol., 65: 788-796, 1988.
28. E.J. Cha, E. Chow, D.M. Vega, and S.M. Yamashiro. *Automated temperature control system for vagal cooling*. J. Appl. Physiol. 65:469-472, 1988.
29. E. Chow, E.J. Cha, and S.M. Yamashiro. *Ventilatory responses to increased blood flow and lowered lung volume in awake dogs*. J. Appl. Physiol. 65:714-720, 1988.
30. E.J. Cha, E. Chow, H.K. Chang, and S.M. Yamashiro. *Lung hyperinflation in isolated dog lungs during high frequency oscillation (HFO)*. J. Appl. Physiol. 65:1172-1179, 1988.
31. Khoo, M.C.K., S.M. Yamashiro, and P. Yamashiro. *Minimization of lung pressure swings during high-frequency ventilation: a model*. J. Appl. Physiol. 67:993-1000, 1989.
32. Yamashiro, S.M. and F.S. Grodins. *Consequences of lung volume optimization on exercise hyperpnea*. In: *Modeling and Parameter Estimation in Respiratory Control*. Ed. M.C.K. Khoo, Plenum, New York, 1990.
33. Yamashiro, S.M. *Distinguishing random from chaotic breathing pattern behavior*. In: *Modeling and Parameter Estimation in Respiratory Control*. Ed. M.C.K. Khoo, Plenum, New York, 1990.
34. Yamashiro, S.M., D.W. Slaaf, R.S. Reneman, G.J. Tangelder, and J.B. Bassingthwaighte. *Fractal analysis of vasomotion*. Ann. N.Y. Acad. Sci. 591:

410-416, 1990.

35. Glenny, R.W., H.T. Robertson, S.M. Yamashiro, and J.B. Bassingthwaite. *Applications of fractal analysis to physiology*. J. Appl. Physiol. 70:2351-2367, 1991.

36. Yamashiro, S.M., C.S. Poon, and J.J. DiStefano III. Modeling pioneer: Fred S. Grodins (1915-1989). J. Appl. Physiol. 70: 1080-1081, 1991.

37. Yamashiro, S.M., P.K. Yamashiro, R.W. Glenny, and H.T. Robertson. *Nonlinear dynamics of cardiopulmonary responses during exercise*. In: Control of Breathing and its Modeling Perspective. eds. Y. Honda, Y. Miyamoto, K. Konno, and J.G. Widdicombe, Plenum, New York, 1992 .

38. Yamashiro, S.M. *Uniqueness of optimal controllers during exercise*. Annals of Biomed. Eng. 21: 531-535, 1993

39. Yamashiro, S.M., G.A. Taylor, S.K.M. Luk, and R.E. Kalaba. *Automated solutions of breathing pattern optimizations*. Computers and Mathematics with Applications . 27: 155-161, 1994.

40. Kawaoka, P.Y. and S.M. Yamashiro. *Separation of cardiac conduction system and atrial activities by spatial regression*. Med. Eng. Phys. 18: 45-50, 1996.

41 Yamashiro, S.M. Interactive Cardiopulmonary Bypass Model. Baxter Healthcare, CD Rom version, 2000.

42. Yamashiro, S.M. Supraspinal locomotor centers do/do not contribute significantly to the hypernea of dynamic exercise. J. Appl. Physiol. 100: 1744, 2006.

43. Yamashiro, S.M. Non-linear dynamics of human periodic breathing and implications for sleep apnea therapy. Med. Bio. Eng. Comput. 45: 345-356, 2007.

44. Yamashiro, S. and T. Kato. Modeling rate sensitivity of exercise transient responses to limb motion. J. Appl. Physiol. 117: 699-705, 2014.

45. Cole, M, T. Kato, S. Yamashiro, and E. Soffer. Modulation of pulse parameters for electrical stimulation of the lower esophageal sphincter. Abstract 2167751, Accepted for presentation, Digestive Disease Week, May 2015, Am Gastroenterological Assoc (Edy Soffer, M.D. will present)

46. T. Kato, T. Matsumoto, A. Tsukanaka, M. Nakano, R. Ito, M. Amano, M. Cole, and SM. Yamashiro. Effect of hypercapnic severity on plasma ammonia accumulation and respiratory exchange ratio during incremental exercise International Journal of Sports and Exercise Medicine 1(3) 014 2015

47. Yamashiro, S.M. Respiratory instability and brain blood flow. *J Sleep Med and Disorders* :2020;6:1103
48. Kato, T, T. Masumoto, and S. Yamashiro. Effect of 3% CO₂ Inhalation on respiratory exchange ratio and cardiac output during constant work rate exercise. *J Sports Med and Physical Fitness*. 2020, July 28
49. Yamashiro SM, Kato T, Matsumoto T. Altered chemosensitivity to CO₂ during exercise. *Physiol Rep*. 2021 06; 9(11):e14882.
50. Yamashiro, S.M. and T. Kato. Modeling cerebral blood flow and ventilation instability due to CO₂. *J. Appl. Physiol*. 2021;130:1427-1435.
51. Ong, V. and S. Yamashiro. Adapting a human physiology teaching laboratory to the at-home education setting. *Biomed. Eng Educ* 2022; 2: 91-97.
52. Kato, T., S. Muroga, S. Yamashiro, and T. Matsumoto. Effect of 3% inhalation on pulmonary gas exchange kinetics during constant work rate exercise. *Gazzetta Medica Italiana-Archivio per le Scienze Mediche*, 2022; 181: 328-336.
53. Kato, T., T. Hayasaka, T. Kawagoe, S. Muroga, and S. Yamashiro. Influence of aging and perception tasks on EEG during step-up/down movement exercise. *Gazzetta Medica Italiana-Archivio per le Scienze Mediche*, 2023; 182: 917-927.
54. Yamashiro, S., T. Kato, and T. Matsumoto. Modeling long term facilitation of respiration during interval exercise in humans. *Ann of BME*. 2024; 52: 250-258.
55. Yamashiro, S., and N. Iyer. Infant periodic breathing and apneic threshold. *Physiol Rep*, 2024; 12: e15915.

Awards

Yamashiro, S. Oct 2024 BMES Annual Meeting, ABME Best Paper Awardee (Publication 54)

U.S Patent Application, 61/735,419 filed December 10, 2012 through USC Stevens Institute. "Optimal Electrical Stimulation of Gastrointestinal Smooth Muscle" S.M. Yamashiro

Assigned to USC January 16, 2013

This patent application protects intellectual property related to what was learned by laboratory experiments directed at minimizing power required for electrical stimulation of the stomach for obesity treatment.

U.S. Patent Application, 62/124,437 filed 12/22/2014. "Implantable direct

electrical stimulation of smooth muscle sphincters” S.M. Yamashiro
This application deals with the method of avoiding adaptation to electrical stimulation.

Research collaboration was initiated with Dr. Edy Soffer. Dr. Soffer, a Gastroenterologist currently at USC Keck who has clinical experience with electrical stimulation of the stomach while he was previously at Cedars Sinai.

Teaching

Full time teaching since 1971 (2-4 courses/year). Fall 2022 : revised BME 501 as a “flipped” class where lectures were pre-recorded and classes focused on questions asked during lectures.