

Saliva Treatment System of Oral Interface Appliance and Method Therefor

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

5 The present invention is related to a medical treatment device and method for improving breathing quality during sleep. Specifically, the present invention relates to a saliva treatment system having a negative pressure oral interface appliance and a method therefor for reducing breathing stoppage and snoring in sleep, and is used for removing saliva in the oral cavity and the system lines and tubes.

10 DESCRIPTION OF THE PRIOR ART

Obstructive sleep apnea (OSA) is a condition in which repeated collapses in the patient's airway during inhalation causes a cessation of breathing during sleep. During inhalation, air pressure in the lungs and respiratory passages is reduced. If during this time, the tone of the muscles in the upper-airway is reduced, the airway tends to
15 collapse. As the airway begins to occlude prior to an apnea, the patient often begins to snore. Snoring is an effort to try to combat the collapsed airway. These obstructions occur in different locations along the respiratory pathway in different patients, but the two common locations are the oropharynx or the nasopharynx .

People with moderate to severe OSA experience daytime sleepiness, fatigue,
20 and poor concentration. In addition to these immediate problems, research has shown that patients with OSA use more medical resources, have an increased risk of medical disability, and finally have a higher mortality rate. Patients with severe OSA are estimated to have a three to six fold increased risk of mortality considering all causes. OSA is also implicated in many cardiovascular conditions, such as systemic
25 hypertension and some degree of pulmonary hypertension. It is associated with an increased risk for myocardial infarction, cerebrovascular disease, and cardiac

arrhythmia. OSA also causes excessive daytime sleepiness due to interrupted sleeping pattern at night which leads to inability to concentrate. Patients' daily functions are impaired as their neuro-cognitive function is compromised. They are more likely to make errors and run into accidents. Therefore, OSA is a significant medical condition with serious negative outcomes if left untreated.

There are several current treatment options for OSA patients. Oral appliance is used to treat mild OSA, but they often don't work well and cause damage to gums and teeth. Several types of surgery are used to treat OSA, however, surgical options are invasive, expensive and painful with recovery periods up to 6 months. The most common treatment for moderate to severe sleep apnea in adults is CPAP. A CPAP machine consists of a mask, a pump and a humidifier. The device continuously blows pressurized air into the patient's nose to keep the airway open during sleep. CPAP is quite effective, however, it has unpleasant side effects such as dry throat and nose congestion. Patients who use CPAP often feel bloated in the morning and experience headaches. The machine is noisy and uncomfortable for the user and their partner. CPAP is currently the first-line and gold standard treatment, but it suffers low compliance due to significant side effects.

It has been proposed to apply a negative pressure to the patient's oral cavity to pull the tongue and soft palate forward to maintain the patency of the airway, as an improvement over CPAP, for example, U.S. Patent and Patent Publication Nos. 5957133, 2005/0166928, and 2006/0096600. While promising in theory, these prior arts comprise relatively large structures to engage the teeth and/or to retain the tongue. Moreover, negative pressure is applied directly on the soft tissues of the tongue to hold the tongue within the cavity. However, these approaches tend to occupy a lot of space in the oral cavity, which may cause discomfort and damage to large area of teeth, gum, and soft tissues. At the same time, the presence of such larger devices may induce excess saliva secretion and elicit the gag reflex. The other

major disadvantage of these approaches also includes that the oral devices are anatomically dependent, that they required special technicians to customize the interface for each individual patient.

Besides, in a negative pressure oral interface appliance, the saliva would accrue
5 in the tubes between the oral interface appliance and the negative pressure source, resulting in clogged tubes and difference in pressure between the oral interface appliance and the negative pressure source, and is even detrimental to maintenance of the negative-pressured environment inside the oral cavity.

SUMMARY OF THE INVENTION

10 On one hand, the present invention provides a saliva treatment system of oral interface appliance, which, during the system's operation, feeds air into the system's tubes under the condition of keeping the oral cavity of the user in a negative-pressured environment constantly or as needed, in order to facilitate removal of saliva in the oral interface appliance and the foregoing tubes.

15 On the other hand, the present invention provides a method of detecting the internal pressure in a saliva-collecting reservoir in order to monitor whether the liquid capacity in the reservoir is full, so as to effectively dispose saliva in the oral interface appliance and the tubes of the system of the present invention.

And in yet another aspect, the present invention provides a breathable oral
20 interface appliance to apply to the system of the present invention, which utilizes the breathable oral interface appliance to facilitate discharging the air inside the oral cavity of the user to the surrounding environment.

On the other hand, the present invention provides a method for measuring the liquid volume in the reservoir of the saliva treatment system of oral interface appliance,
25 including: disposing the oral interface appliance inside the oral cavity of a user and communicating with a negative pressure source through the system to create a

negative pressure path between the oral cavity of the user and the negative pressure source, collecting saliva in the oral cavity of the user to the reservoir through the negative pressure path, continuously and intermittently measuring the pressure value inside the reservoir, and determining the liquid capacity inside the reservoir based on the measured pressure values to help the user decide if the reservoir needs to be replaced or washed.

In one aspect of the present invention, a saliva treatment system of oral interface appliance is provided in the present invention, comprising: an oral interface appliance to be disposed inside the oral cavity of a user to provide a fluid passage inside the oral cavity of the user, a fluid adjustor having a first connecting end and a second connecting end and being used to restrict all the fluids to flowing to the second connecting end thereof, the first connecting end being communicated with the fluid passage of the oral interface appliance, a communicating tube having a first open end portion and a second open end portion, wherein the first open end portion is communicated with the second connecting end of the fluid adjustor and the second open end portion is communicated with a reservoir and a negative pressure source to create a negative pressure path between the oral cavity of the user and the negative pressure source, wherein the saliva in the oral cavity of the user passes through the negative pressure path and is collected in the reservoir.

In another aspect according to the present invention, a saliva treatment system of oral interface appliance is provided, including: an oral interface appliance to be placed in the oral cavity of a user to provide at least one fluid passage inside the oral cavity of the user, the oral interface appliance having an extending portion protruding outside of the oral cavity of the user, the extending portion having a first fluid passage and a second fluid passage, both communicated with the inside of the oral cavity of the user, a vacuum actuated pressure relief valve being configured at one end of the first fluid passage outside the oral cavity of the user, and a communicating tube having

a first open end portion and a second open end portion; the first open end portion is communicated with the second fluid passage of the oral interface appliance, and the second open end portion is communicated with a reservoir and a negative pressure source to create a negative pressure path between the interior of the oral cavity of the user and the negative pressure source, wherein at a predetermined negative pressure value, the vacuum actuated pressure relief valve is activated to allow the ambient air to flow into the oral cavity of the user through the first fluid passage and carry the saliva in the oral cavity of the user and that staying in the communicating tube into the reservoir by the airflow pumped through the passage.

In an aspect of the oral interface appliance of the present invention, a breathable oral interface appliance is provided in the present invention, including: a flexible shield to be positioned between a user's lips and teeth and comprising at least a one-way valve to restrict the air inside the oral cavity of the user to flowing through the one-way valve out of the oral cavity of the user, an extending part formed at one side of the flexible shield and protruding out of the oral cavity of the user, a flexible fluid tube that passes through the flexible shield and the extending part, the flexible fluid tube having a first open end portion extending outside the oral cavity of the user and communicated with a negative pressure source, and an opposite second open end portion positioned between the user's tongue and upper palate.

In an aspect of the oral interface appliance of the present invention, another oral interface appliance is provided in the present invention, including: a flexible shield to be configured between the lips and teeth of a user, an extending part formed at one side of the flexible shield and protruding out of the oral cavity of the user, a flexible fluid tube, which, passing the flexible shield and the extending part, has a first open end portion extending and protruding outside the oral cavity of the user and is used to be communicated with a negative pressure source, and an opposite second open end portion to be positioned between the user's tongue and upper palate, wherein the

extending part has a first fluid passage and a second fluid passage, formed respectively on opposite sides of the flexible fluid tube and communicated with the interior of the oral cavity of the user. A one-way valve is arranged on the far end away from the oral cavity of the user of at least one of the first fluid passage and the second
5 fluid passage, to restrict the air inside the oral cavity of the user to flowing outside of the mouth through the one-way valve.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a first embodiment of the saliva treatment system of oral interface appliance according to the present invention.

10 Fig. 1A is a perspective diagram of the oral interface appliance of Fig. 1; Fig. 1B is a top view of the oral interface appliance of Fig. 1 placed inside the oral cavity of a user.

Fig. 2A and Fig. 2B are top sectional views of the first and second alternative examples of the oral interface appliance of Fig. 1.

15 Fig. 3 is a pressure-time relation chart.

Fig. 4 is a pressure-liquid capacity relation chart.

Fig. 5 illustrates a second embodiment of the saliva treatment system of oral interface appliance according to the present invention.

20 Fig. 5A is an enlarged schematic view of the fluid adjustor of the saliva treatment system.

Fig. 5B-1 and Fig. 5B-2 are enlarged sectional schematic views of one embodiment of the vacuum actuated pressure relief valve in Fig. 5 in a closed and an open state.

25 Fig. 5C-1 and Fig. 5C-2 are enlarged sectional schematic views of another embodiment of the vacuum actuated pressure relief valve in Fig. 5 in a closed and an

open state.

Fig. 6 illustrates a third embodiment of the saliva treatment system of oral interface appliance according to the present invention.

Fig. 6A-1 and Fig. 6A-2 are top sectional schematic views of the first alternative
5 example of the saliva treatment system in Fig. 6 in different states in use.

Fig. 6B-1 and Fig. 6B-2 are top sectional schematic views of the second alternative example of the saliva treatment system in Fig. 6 in different states in use.

BRIEF DESCRIPTION OF REFERENCE NUMERALS

- 1, 5, 6.... saliva treatment system of oral interface appliance
- 10 11, 51.... tri-way connector
- 12, 52, 62.... communicating tube
- 13, 53, 511, 252, 604.... one-way valve
- 14, 55, 64.... reservoir
- 15, 56, 65.... negative pressure source
- 15 17, 58, 67....timer
- 18, 59, 68....control unit
- 19, 60, 69....warning device
- 50....fluid adjuster
- 54, 54a, 54b, 602.... vacuum actuated pressure relief valve
- 20 100, 200, 202, 500, 600, 600a, 600b....oral interface
- 110, 210, 212, 510, 610.... flexible fluid tube
- 120, 220, 222, 520, 620.... first open end portion
- 130, 230, 232, 530, 630.... second open end portion
- 150, 250, 550, 650.... flexible shield
- 25 111.... flexible middle section
- 131.... wider and thicker structure

140, 240, 242, 640.... through-hole

151----bendable center portion

214, 612.... first fluid passage

215, 613....second fluid passage

5 216, 614....third fluid passage

260, 262.... oral region between the tongue and the soft palate/hard palate

540a, 540b....main body

542a, 544a....first chamber

542b, 544b....second chamber

10 546a, 546b.... propelling valve

547a, 547b....spring

548a, 548b....spring seat

660....movable block

680.... rotatable hollow tube

15 **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

The following detailed explanation of various embodiments according to the present invention with the accompanying drawings will provide a better understanding of the objective, spirit and benefits of the present invention.

Fig. 1 illustrates a first embodiment of the saliva treatment system of oral
20 interface appliance according to the present invention. In the first embodiment, a saliva treatment system 1 of the oral interface appliance is provided by the present invention, including: an oral interface 100, a fluid adjustor composed of a tri-way connector 11 and a second one-way valve 13, a communicating tube 12, a reservoir 14, a negative pressure source 15, a pressure sensor 16, a timer 17, a control unit 18,
25 and a warning device 19. The oral interface 100 is the same as the oral appliance disclosed in Figs. 1A and 1B in Taiwan Patent Application No. 103101121 with the priority of the US provisional application No. 61/751,559 as claimed by the applicant of

the present application. The structure of the oral interface 100 in a perspective view is as shown in Fig. 1A of the present application. Fig. 1B is a top view of the oral interface 100 when placed inside the oral cavity of a user. The oral interface 100 is an integrally formed apparatus, including a flexible shield 150 and a flexible fluid tube 110, wherein the flexible shield 150 is to be disposed between a user's lips and teeth, in order to fit the oral interface 100 snugly in the oral cavity of the user. Preferably, the flexible shield 150 is placed between the user's lips and front teeth, and the flexible shield 150 has a bendable center portion 151 to be conformable to the front contours of the user's upper and lower teeth in order to fit different teeth structures of different users. The flexible fluid tube 110 is in the form of a hollow tube and comes through the bendable center portion 151 of the flexible shield 150. The flexible fluid tube 110 has a first open end portion 120 to be arranged outside the user's mouth and communicated with a first connecting end of the tri-way connector 11. The flexible fluid tube 110 has an opposite second open end portion 130 to be positioned in the space between the user's tongue and upper palate. Preferably, the flexible fluid tube 110 is disposed along the central line of the user's tongue. The flexible fluid tube 110 may be conformable to the contours of the user's upper palate and tongue, and the flexible fluid tube 110 further has a flexible middle section 111 that is formed between the flexible shield 150 and the second open end portion 130 and adjacent to the flexible shield 150. The flexible middle section 111, compared to the other parts of the flexible fluid tube 110, has a thinner structure to be conformable to the contours of the upper palate and tongue of the user. In other words, the flexible middle section 111 may fit the upper palate contours of different users. The flexible fluid tube 110 further has at least one through-hole 140 formed in the flexible middle section 111 adjacent to the central region of the flexible shield 150, and the through-hole 140 is communicated with one side of the flexible fluid tube 110. Preferably, the through-hole 140 is laterally communicated with the flexible fluid tube 110 in the opposite direction of the hollow

tube of the flexible fluid tube 110. The second open end portion 130 of the flexible fluid tube 110 has a wider and thicker structure 131 compared to the flexible middle section 111, for the purpose of enhancing the structural strength of the flexible fluid tube 110, so as to avoid the flexible fluid tube 110 from collapsing when it is pressured by the user's tongue and upper palate.

The sectional schematic view of the tri-way connector 11 is the same as the tri-way connector 51 in Fig. 5A. A first one-way valve (not shown in Fig. 1) is arranged in the first connecting end of the first open end portion 120 of the oral interface 100 communicated with the tri-way connector 11. The first one-way valve is the same as the one-way valve 511 as shown in Fig. 5A, used to restrict the fluids inside the oral cavity of the user to flowing to the tri-way connector 11. A first open end portion of the communicating tube 12 is communicated with a second connecting end of the tri-way connector 11. A second open end portion of the communicating tube 12 is communicated with the reservoir 14. The second one-way valve 13 is communicated with a third communicating end of the tri-way connector 11 to restrict the ambient air to flowing from the second one-way valve 13 to the tri-way connector 11. In the first embodiment according to the present invention, the tri-way connector 11 and the second one-way valve 13 constitute a fluid adjustor, which is used to restrict all the fluids to flowing from the second connecting end of the tri-way connector 11 to the communicating tube 12. In other words, after the saliva treatment system 1 of the oral interface appliance of the present invention is activated, the fluids flow to the direction as shown by the arrows in Fig. 1. The negative pressure source 15 is communicated with the reservoir 14. The present invention, for example, may turn on/turn off the negative pressure source 15 by a control unit 18 or by operating manually. After the negative pressure source 15 is activated, the saliva treatment system 1 of the oral interface appliance of the present invention forms a negative pressure path between the interior of the oral cavity of the user and the negative pressure source 15, in order

to withdraw the air and saliva inside the oral cavity of the user through the negative pressure path and collect the saliva in the reservoir 14. Moreover, during the activation period of the saliva treatment system 1 of the oral interface appliance of the present invention (as indicated by the arrows in Fig. 1), the ambient air may flow into
5 the communicating tube 12 through the second one-way valve 13 and the tri-way connector 11, in order to facilitate collecting the saliva in the communicating tube 12 to the reservoir 14 and further avoid the remnant of saliva in the communicating tube 12 from causing difference in pressure between the interior of the oral cavity of the user and the negative pressure source 15. Moreover, it may also prevent the
10 communicating tube 12 from being clogged with saliva, and further maintain the negative pressure path between the interior of the oral cavity of the user and the negative pressure source 15.

Besides, in one alternative example of the first embodiment (not shown in the drawings) of the saliva treatment system 1 of the oral interface appliance according to
15 the present invention, the negative pressure source 15 may also be communicated between the communicating tube 12 and the reservoir 14, and the negative pressure source 15 may be turned on/turned off by the control unit 18 or by operating manually.

On the other hand, the saliva treatment system 1 of the oral interface appliance of the present invention may continuously and intermittently measure saliva capacity
20 in the reservoir to monitor whether the saliva capacity is full in the reservoir 14, to keep the whole system operating under a normal condition. In the first embodiment according to the present invention, the saliva treatment system 1 of the oral interface appliance may start/stop the timer by the control unit 18 or by operating manually. The timer 17, once started, may continuously and intermittently time to a set time interval t
25 and dispatch a notifying signal to the control unit 18, which then reads a pressure value measured by the pressure sensor 16. The pressure sensor 16 communicated with the reservoir 14 is used to measure the pressure value inside the reservoir 14. In

brief, the timer 17 is set, after being activated, to send out a notifying signal to the control unit 18 at every time interval t , to notify the control unit 18 to read a pressure value measured by the pressure sensor 16. In this way, the control unit 18 could continuously and intermittently read the pressure values detected by the pressure sensor 16 and then determine the liquid capacity inside the reservoir 14 according to the pressure values read. Besides, the length of the set time interval t may be adjusted as needed. For example, it may be set to have the control unit 18 periodically read the pressure values measured by the pressure sensor 16.

The method for measuring the liquid capacity in the reservoir 14 provided by the saliva treatment system 1 of the oral interface appliance is described in detail as follows.

Please see the following Table 1, the first line of Table 1 indicates the liquid capacity inside the reservoir 14, and the values in each row represent the pressure values measured in the reservoir 14 for the liquid capacity as shown (the unit of the pressure value is mmHg). The time length in the same column shows the time interval between every two pressure values measured is the same. For example, $T_2 - T_1 = t$, and $T_3 - T_2 = t$. It may be seen from Table 1, at a certain set time interval t , when the liquid capacity inside the reservoir 14 is different, the pressure value measured inside the reservoir 14 is also different. For example, the pressure values in line 14 of Table 1 clearly show that the timer 17 is set at every identical time interval (such as T_{14}) to notify the control unit 18 to read the pressure values measured by the pressure sensor 16. As the liquid capacity in the reservoir 14 increases (from 0ml to 80ml), the pressure value inside the reservoir 14 also goes up (from -71.0922mmHg to -33.7023mmHg).

Table 1

	80mL	70mL	60mL	50mL	40mL	30mL	20mL	10mL	0mL
T_1	-5.029	-2.39105	-2.39105	-2.16167	-2.39105	-2.39105	-2.27636	-2.50575	-2.39105

T ₂	-5.94654	-3.65268	-3.53799	-3.65268	-4.11145	-4.22614	-4.57022	-5.37308	-6.40531
T ₃	-8.46979	-6.6347	-6.6347	-7.43755	-8.58448	-9.15795	-10.7637	-13.1722	-17.5305
T ₄	-11.5665	-10.4196	-10.5343	-11.7959	-13.631	-14.8926	-17.8746	-21.6595	-29.1146
T ₅	-14.5485	-13.7457	-14.3191	-16.0395	-18.3334	-20.1685	-24.1827	-29.2292	-38.1753
T ₆	-17.3012	-17.0718	-17.7599	-19.595	-22.4624	-25.1003	-29.4586	-35.1933	-44.9422
T ₇	-19.9391	-19.7097	-20.9713	-23.3799	-26.1325	-29.2292	-33.5876	-40.2398	-50.1034
T ₈	-22.3477	-22.6917	-24.0681	-26.4766	-29.5733	-32.7847	-37.4872	-44.254	-54.2324
T ₉	-24.6415	-25.1003	-26.5913	-29.1146	-32.4407	-36.1108	-40.6986	-47.6948	-58.2466
T ₁₀	-26.706	-27.2795	-29.2292	-31.8672	-35.308	-38.8635	-43.6806	-50.6769	-61.3433
T ₁₁	-28.7705	-29.4586	-31.5231	-34.0464	-37.7165	-41.3867	-46.4332	-53.6589	-64.096
T ₁₂	-30.4909	-31.5231	-33.4729	-35.9961	-39.6663	-43.91	-48.9565	-56.7556	-66.3898
T ₁₃	-32.0966	-33.1288	-35.4227	-37.9459	-41.7308	-45.9744	-51.365	-58.9348	-68.6837
T ₁₄	-33.7023	-34.8492	-36.799	-39.781	-43.6806	-47.9242	-53.6589	-60.7699	-71.0922
T ₁₅	-35.4227	-36.4549	-38.5194	-41.5014	-45.401	-49.7593	-55.6087	-62.8343	
T ₁₆	-36.5696	-37.9459	-40.2398	-43.2218	-47.1214	-51.365	-57.7878	-64.8988	
T ₁₇	-38.1753	-39.5516	-41.7308	-44.8275	-48.9565	-53.0854	-59.967	-66.6192	
T ₁₈	-39.4369	-40.9279	-43.1071	-46.4332	-50.7916	-55.0352	-61.3433	-68.2249	
T ₁₉	-40.5839	-42.1896	-44.5981	-47.8095	-52.3973	-56.985	-62.7196	-69.4865	
T ₂₀	-41.7308	-43.4512	-46.0891	-49.0712	-53.5442	-58.5907	-64.44	-70.7482	
T ₂₁	-43.1071	-44.8275	-46.892	-50.5622	-54.9205	-59.5082	-65.7017		
T ₂₂	-43.91	-45.9744	-48.4977	-51.4797	-56.4115	-60.8846	-66.8486		
T ₂₃	-44.8275	-47.2361	-49.7593	-53.0854	-58.0172	-62.0315	-68.2249		
T ₂₄	-45.9744	-47.9242	-50.9062	-54.347	-59.0495	-63.0637	-69.3718		
T ₂₅	-47.1214	-48.9565	-52.3973	-55.6087	-60.0817	-64.2107	-70.4041		
T ₂₆	-48.0389	-50.3328	-53.2001	-56.6409	-60.9992	-65.1282			
T ₂₇	-48.8418	-51.2503	-54.1177	-57.9025	-62.0315	-66.2751			
T ₂₈	-49.7593	-52.2826	-55.494	-58.8201	-63.0637	-67.4221			
T ₂₉	-50.9062	-53.4295	-56.2968	-59.6229	-63.8666	-68.1102			
T ₃₀	-51.5944	-54.4617	-57.5585	-60.4258	-64.8988	-68.9131			
T ₃₁	-52.512	-55.494	-58.476	-61.1139	-65.587	-70.06			
T ₃₂	-53.5442	-56.4115	-59.1642	-62.0315	-66.5045				
T ₃₃	-54.5764	-57.3291	-59.7376	-62.8343	-67.3074				
T ₃₄	-55.3793	-58.1319	-60.7699	-63.6372	-67.9955				
T ₃₅	-56.2968	-58.8201	-61.458	-64.44	-69.0278				
T ₃₆	-56.985	-59.5082	-61.9168	-65.0135	-69.7159				
T ₃₇	-57.5585	-60.0817	-62.6049	-65.8164	-70.4041				
T ₃₈	-58.2466	-60.8846	-63.5225	-66.3898					
T ₃₉	-58.5907	-61.3433	-64.2107	-67.1927					
T ₄₀	-59.3935	-62.1462	-64.8988	-67.6514					

T ₄₁	-60.0817	-62.8343	-65.4723	-68.4543				
T ₄₂	-60.6552	-63.0637	-66.2751	-69.0278				
T ₄₃	-61.2286	-63.9813	-67.078	-69.6012				
T ₄₄	-61.6874	-64.44	-67.6514	-69.9453				
T ₄₅	-62.2609	-65.0135	-68.3396					
T ₄₆	-62.949	-65.9311	-68.6837					
T ₄₇	-63.5225	-66.5045	-69.2572					
T ₄₈	-64.096	-67.3074	-69.7159					
T ₄₉	-64.5547	-67.3074	-69.9453					
T ₅₀	-64.8988	-67.9955						
T ₅₁	-65.587	-68.569						
T ₅₂	-65.9311	-68.9131						
T ₅₃	-66.5045	-69.3718						
T ₅₄	-66.8486	-69.8306						
T ₅₅	-67.3074	-70.2894						
T ₅₆	-67.7661							
T ₅₇	-68.1102							
T ₅₈	-68.3396							
T ₅₉	-68.9131							
T ₆₀	-69.3718							
T ₆₁	-69.8306							
T ₆₂	-69.8306							
T ₆₃	-70.2894							

See Fig. 3, the pressure-time relation chart, wherein axis Y represents the pressure value inside the reservoir 14, axis X represents the time interval t timed by the timer 17. Curve a, b, c, d, e, f, g, h, and i represents the liquid capacity inside the reservoir 14 is 80ml, 70ml, 60ml, 50ml, 40ml, 30ml, 20ml, 10ml and 0ml, respectively.

- 5 Fig. 4 is a pressure-liquid capacity relational chart obtained from the pressure values and liquid capacity transferred from line 15 of Table 1. It may be seen that when the timer 17 notifies the control unit 18 at every set period T to read the pressure value inside the reservoir 14 measured by the pressure sensor 16, as the liquid capacity in the reservoir 14 is different, the pressure value measured varies accordingly. The
- 10 control unit 18 has a built-in correspondence table showing the pressure-liquid capacity in the reservoir corresponding to the set time interval T₁₅ timed by the timer

17, transferred for example from Fig. 4. When the control unit 18 reads the pressure value in the reservoir 14, it may determine the liquid capacity value inside the reservoir 14 according to the correspondence table of the pressure-liquid capacity in the reservoir and transmit the liquid capacity value to the warning device 19. The
5 warning device 19 then sends out a reminding signal to further detect if the liquid capacity in the reservoir 14 is full. Besides, the control unit 18 may also have multiple built-in correspondence tables showing pressure-liquid capacity in the reservoir by different set time intervals t (such as $T_2, T_3, T_4, T_5, \dots, T_{10}, T_{11}, \dots$) to adjust the time for the control unit 18 to read the pressure values inside the reservoir 14 as needed, and
10 determine the liquid capacity inside the reservoir 14 according to the correspondence tables of the pressure-liquid capacity in the reservoir.

Fig. 2A and Fig. 2B are the top sectional views of the first and second alternative examples of the first embodiment of the oral interface 100. In the saliva treatment system 1 of the oral interface appliance of the present invention, the oral interface
15 appliances of the first alternative example and the second alternative example may substitute the oral interface 100. In the first alternative example shown in Fig. 2A, an oral interface appliance 200 of the present invention includes a flexible shield 250 and a flexible fluid tube 210. The flexible fluid tube 210 has a first open end portion 220 to be disposed outside the oral cavity of the user and is communicated with a first
20 connecting end of the tri-way connector 11. The flexible fluid tube 210 also has an opposite second open end portion 230 used to be placed in the space between the user's tongue and upper palate. The dotted area designated by the reference numeral 260 represents the oral region between the tongue and the soft palate/hard palate. The flexible fluid tube 210 further has at least a through-hole 240 formed around the
25 central region of the flexible shield 250, and the through-hole 240 is communicated with the flexible fluid tube 210. Preferably, the through-hole 240 is laterally communicated with the flexible fluid tube 210 in the opposite direction of the hollow

tube of the flexible fluid tube 210. The shape of the main body of the flexible fluid tube 210 is identical with the flexible fluid tube 110, thus the description is omitted here. The flexible shield 250 has an extending part extending toward the first open end portion 220 of the flexible fluid tube 210 and protruding outside the user's mouth, and the flexible fluid tube 210 goes through the extending part. The flexible shield 250 has at least a one-way valve 252. When the user breathes with his mouth open, the air inside the oral cavity flows outside the oral cavity through the one-way valve 252, as designated by the arrows. In the second alternative example shown in Fig. 2B, one oral interface appliance 202 of the present invention includes a flexible shield 250 and a flexible fluid tube 212. The flexible fluid tube 212 has a first open end portion 222 to be disposed outside the user's mouth and communicated with a first connecting end of the tri-way connector 11. The flexible fluid tube 212 also has an opposing second open end portion 232 to be arranged in the space between the user's tongue and upper palate. The dotted area designated by the reference numeral 262 represents the oral cavity region between the tongue and the soft palate/hard palate. The flexible fluid tube 212 further has at least one through-hole 242 formed around the central region of the flexible shield 250, and the through-hole 242 is communicated with the flexible fluid tube 212. Preferably, the through-hole 242 is laterally communicated with the flexible fluid tube 212 in the opposite direction of the hollow tube of the flexible fluid tube 212. The shape of the main body of the flexible fluid tube 212 is identical with the flexible fluid tube 110, so the description is omitted here. The flexible shield 250 has an extending part extending toward the first open end portion 222 of the flexible fluid tube 212 and protruding outside the user's mouth. The flexible fluid tube 212 goes through the extending part and a first fluid passage 214, a second fluid passage 215 and a third fluid passage 216 are created within the extending part, wherein the first fluid passage 214 and the third fluid passage 216 are formed on opposite sides of the second fluid passage 215. Also, the first fluid passage 214, the

second fluid passage 215 and the third fluid passage 216 are communicated with the interior of the oral cavity of the user. A one-way valve is disposed respectively at the end of the first fluid passage 214 and the third fluid passage 216 adjacent to the first open end portion 222, to facilitate the air inside the oral cavity of the user to flow out of the oral cavity through the one-way valve, as designated by the arrows.

Fig. 5 is a second embodiment of the saliva treatment system of oral interface appliance of the present invention. In this second embodiment, the present invention provides a saliva treatment system 5 of the oral interface appliance, including: an oral interface 500, a fluid adjuster 50, a communicating tube 52, a reservoir 55, a negative pressure source 56, a pressure sensor 57, a timer 58, a control unit 59, and a warning device 60. The oral interface 500 is an integrally formed apparatus comprising at least a flexible shield 550 and a flexible fluid tube 510. The flexible fluid tube 510 has a first open end portion 520 to be disposed outside the user's mouth and communicated with the fluid adjuster 50. The flexible fluid tube 510 also has an opposite second open end portion 530 to be disposed in the space between the user's tongue and upper palate. The fluid adjuster 50 includes a tri-way connector 51, a second one-way valve 53 and a vacuum actuated pressure relief valve 54. Fig. 5A is an enlarged sectional schematic view of the fluid flow regulator 50. The tri-way connector 51 has a first connecting end, a second connecting end, and a third connecting end, wherein a first one-way valve 511 is disposed at the first connecting end and communicated with the first open end portion 520 of the flexible fluid tube 510. The fluids inside the user's oral cavity flow through the first one-way valve 511 to the tri-way connector 51. The second connecting end is communicated with a first open end portion of the communicating tube 52, and a second open end portion of the communicating tube 52 is communicated with the reservoir 55. The reservoir 55 is communicated with the negative pressure source 56. After the negative pressure source 56 is activated, a negative pressure path is formed between the interior of the user's oral cavity and the

negative pressure source 56. The second one-way valve 53 is disposed at the third connecting end of the tri-way connector 51 and integrated with the vacuum actuated pressure relief valve 54 at one end of the second one-way valve 53 opposite to the tri-way connector 51. Figs. 5B-1 and 5B-2 provide enlarged sectional schematic views of one embodiment of the vacuum actuated pressure relief valve 54. Fig. 5B-1 shows the embodiment of the vacuum actuated pressure relief valve 54a in a closed state, which comprises a main body 540a, a propelling valve 546a, a spring 547a and a spring seat 548a. A spacer having a passage is arranged inside the main body 540a to section the main body 540a into a first chamber 542a and a second chamber 544a. The first chamber 542a is communicated with the ambient air; the second chamber 544a is communicated with the second one-way valve 53. The propelling valve 546a may be movably arranged in the first chamber 542a and go through the passage. The space of the passage is entirely occupied by the propelling valve 546a to allow the fluids in the first chamber 542a to be isolated from the second chamber 544a under the condition that the vacuum actuated pressure relief valve 54a is not activated, for preventing the ambient air from flowing into the second chamber 544a. The spring seat 548a is disposed on a surface of the spacer in the first chamber 542a. The spring 547a rests between the propelling valve 546a and the spring seat 548a. Fig. 5B-2 shows the vacuum actuated pressure relief valve 54a in an open state. When the negative pressure value of the negative pressure path between the user's oral cavity and the negative pressure source 56 reaches a start threshold value of the vacuum actuated pressure relief valve 54a, the difference in pressure between the first chamber 542a and the second chamber 544a causes the ambient air to push the propelling valve 546a to move forward and form an airflow channel between the passage of the spacer and the propelling valve 546a to induce the ambient air to flow into the second chamber 544a through the airflow channel, and into the communicating tube 52 through the second one-way valve 53 and the second

connecting end of the tri-way connector 51. The ambient air is pumped in to carry the saliva staying in the communicating tube 52 into the reservoir 55. Fig. 5 shows the fluid adjuster 50 comprised by the tri-way connector 51, the first one-way valve 511, the second one-way valve 53, and the vacuum actuated pressure relief valve 54 may
5 restrict all fluids to flowing into the communicating tube 52. In other words, after the saliva treatment system 5 of the oral interface appliance of the present invention is activated, the flowing direction of the fluids inside it is as shown by the arrows in Fig. 5. The negative pressure source 56 is communicated with the reservoir 55. The negative pressure source 56 of the present invention, for example, may be turned on/turned off
10 by the control unit 59 or by operating manually. Once the negative pressure source 56 is turned on, the saliva treatment system 5 of the oral interface appliance forms a negative pressure path between the oral cavity of the user and the negative pressure source 56, to help withdraw the air and saliva inside the oral cavity of the user through the negative pressure path and collect the saliva in the reservoir 55. Moreover, as the
15 saliva treatment system 5 of the oral interface appliance of the present invention is activated, the ambient air may be pumped into the communicating tube 52 through the second one-way valve 53 and the vacuum actuated pressure relief valve 54 and also the tri-way connector 51, as shown by the arrows in Fig. 5, to facilitate carrying the saliva staying in the communicating tube 52 by the air to be collected in the reservoir
20 55, and further avoid the difference in pressure between inside the oral cavity of the user and the negative pressure source 56 resulting from the saliva remaining in the communicating tube 52. Further, it can prevent the communicating tube 52 from being clogged by saliva and therefore maintain the negative pressure path between the oral cavity of the user and the negative pressure source 56.

25 Figs. 5C-1 and 5C-2 provide enlarged sectional schematic views of another embodiment of the vacuum actuated pressure relief valve 54. Fig. 5C-1 shows a vacuum actuated pressure relief valve 54b in a closed position, which comprises a

main body 540b, a propelling valve 546b, a spring 547b, and a spring seat 548b. A spacer having a passage is arranged inside the main body 540b to section the main body 540b into a first chamber 542b and a second chamber 544b. The first chamber 542b is communicated with the ambient air, the second chamber 544b is communicated with the second one-way valve 53, and the propelling valve 546b may be movably arranged in the first chamber 542b and go through the passage. The space of the passage is entirely occupied by the propelling valve 546b to allow the fluids in the first chamber 542b to be isolated from the second chamber 544b under the condition that the vacuum actuated pressure relief valve 54a is not activated, for preventing the ambient air from flowing into the second chamber 544a. The spring seat 548b is disposed on a surface of the spacer in the first chamber 542b. The spring 547b rests between the propelling valve 546b and the spring seat 548b. Fig. 5C-2 shows the vacuum actuated pressure relief valve 54b in an activated state. When the negative pressure value of the negative pressure path between the inside of the oral cavity of the user and the negative pressure source 56 reaches a start threshold value of the vacuum actuated pressure relief valve 54b, the difference in pressure between the first chamber 542b and the second chamber 544b causes the ambient air to push the propelling valve 546b to move forward and form an airflow channel between the passage of the spacer and the propelling valve 546b to induce the ambient air to flow into the second chamber 544b through the airflow channel, and go into the communicating tube 52 through the second one-way valve 53 and the second connecting end of the tri-way connector 51. The ambient air is pumped in to carry the saliva staying in the communicating tube 52 into the reservoir 55.

Besides, in one alternative example of the second embodiment (not shown in the drawings), the negative pressure source 56 of the saliva treatment system 5 of the oral interface appliance of the present invention may be communicated between the communicating tube 52 and the reservoir 55, and may be activated/stopped by the

control unit 59 or by operating manually.

On the other hand, the saliva treatment system 5 of the oral interface appliance of the present invention may continuously and intermittently measure the saliva capacity in the reservoir 55 to monitor whether the saliva capacity is full in the reservoir 55, to keep the whole system operating under a normal condition. In the second embodiment of the present invention, the saliva treatment system 5 of the oral interface appliance may start/stop timing by the timer 58 by a control unit 59. The timer 58, once started, may continuously and intermittently time to a set time interval t , and dispatch a notifying signal to the control unit 59, which then reads a pressure value measured by a pressure sensor 57. The pressure sensor 57 communicated with the reservoir 55 is used to measure the pressure value inside the reservoir 55. In brief, after being activated, the timer 58 sends out a notifying signal to the control unit 59 at every time interval t , to notify the control unit 59 to read a pressure value measured by the pressure sensor 57. In this way, the control unit 59 could continuously and intermittently read the pressure value measured by the pressure sensor 57 and then determine the liquid capacity inside the reservoir 55. Besides, the length of the set time interval t may be adjusted as needed. For example, it may be set to have the control unit 59 periodically read the pressure values measured by the pressure sensor 57.

The method for measuring the liquid capacity in the reservoir 55 of the saliva treatment system 5 of the oral interface appliance of the present invention is the same as that of the system 1 of the first embodiment as shown in Fig. 1, thus omitted here.

Fig. 6 is a third embodiment of the saliva treatment system of oral interface appliance of the present invention. In the third embodiment according to the present invention, a saliva treatment system 6 of the oral interface appliance is provided by the present invention, including an oral interface 600, a communicating tube 62, a

reservoir 64, a negative pressure source 65, a pressure sensor 66, a timer 67, a control unit 68 and a warning device 69. The oral interface 600 is an integrally formed apparatus comprising at least a flexible shield 650 and a flexible fluid tube 610. The flexible fluid tube 610 has a first open end portion 620 disposed outside of the user's mouth and is communicated with a first open end portion of the communicating tube 62. A second open end portion of the communicating tube 62 is communicated with the reservoir 64. The flexible fluid tube 610 has an opposite second open end portion 630 disposed in the space between the user's tongue and upper palate. The flexible fluid tube 610 has a flexible middle section formed between the flexible shield 650 and the second open end portion 630 and located nearby the flexible shield 650. The flexible middle section has a thinner structure compared to the other parts of the flexible fluid tube 610 in order to be conformable to the contours of the user's upper palate and tongue. In other words, the flexible middle section may fit the upper palate contours of different users. The flexible fluid tube 610 has at least one through-hole 640 formed in the flexible middle section adjacent to the central region of the flexible shield 650. Preferably, the through-hole 640 is laterally communicated with the flexible fluid tube 610 in the opposite direction of the hollow tube of the flexible fluid tube 610. The second open end portion 630 of the flexible fluid tube 610 has a wider and thicker structure compared to the flexible middle section, for the purpose of enhancing the structural strength of the flexible fluid tube 610, so as to avoid the flexible fluid tube 610 from collapsing when it is pressured by the user's tongue and upper palate. The flexible shield 650 has an extending part extending toward the first open end portion 620 of the flexible fluid tube 610 outside of the oral cavity of the user. The flexible fluid tube 610 goes through the extending part and a first fluid passage 612, a second fluid passage 613, and a third fluid passage 614 are created within the extending part, wherein the first fluid passage 612 and the third fluid passage 614 are formed on opposite sides of the second fluid passage 613. The section where the flexible fluid

tube 610 goes through the extending part forms the second fluid passage 613. The first fluid passage 612, the second fluid passage 613 and the third fluid passage 614 are communicated with the interior of the oral cavity of the user. A vacuum actuated pressure relief valve 602 is configured at the end of the first fluid passage 612 near the first open end portion 620, and a one-way valve 604 is disposed at the end of the third fluid passage 614 near the first open end portion 620. When the negative pressure value inside the oral cavity of the user reaches the start threshold value of the vacuum actuated pressure relief valve 602, the valve of the vacuum actuated pressure relief valve 602 is opened to allow the ambient air to flow inside the oral cavity of the user through the vacuum actuated pressure relief valve 602. The ambient air pumped in helps carry the saliva in the oral cavity of the user and that staying in the communicating tube 62 into the reservoir 64. The one-way valve 604 is used to restrict the air inside the oral cavity of the user to flowing to the surrounding environment through the one-way valve 604. The implementation method of the vacuum actuated pressure relief valve 602 may adopt the embodiments shown in Figs. 5B-1, 5B-2, 5C-1 and 5C-2, and thus is omitted here. The negative pressure source 65 is communicated with the reservoir 64. The present invention may for example turn on/turn off the negative pressure source 65 by the control unit 68 or by operating manually. When the negative pressure source 65 is turned on, the saliva treatment system 6 of the oral interface appliance creates a negative pressure path between the interior of the oral cavity of the user and the negative pressure source 65 to help withdraw the air and saliva inside the oral cavity of the user through the negative pressure path and collect the saliva in the reservoir 64. Moreover, during the activation of the saliva treatment system 6 of the oral interface appliance, the ambient air may be pumped into the communicating tube 62 through the vacuum actuated pressure relief valve 602 to help carry and collect the saliva staying in the communicating tube 62 by the pumped air into the reservoir 64, to further avoid saliva

remaining in the communicating tube 62 and causing a difference in pressure between the oral cavity of the user and the negative pressure source 65. Furthermore, it may prevent the communicating tube 62 from being clogged with saliva and maintain the negative pressure path between the interior of the oral cavity of the user and the negative pressure source 65.

Figs. 6A-1 and 6A-2 provide top sectional schematic views of a first alternative example of the oral interface 600. The oral interface 600a shown by the first alternative example may replace the oral interface 600 of the saliva treatment system 6 of the oral interface appliance. The structural difference between the oral interface 600a and the oral interface 600 is that the oral interface 600a has an adjustable flow blocker, which is a movable block 660, disposed inside the first fluid passage 612 adjacent to the vacuum actuated pressure relief valve 602. The rest of its components are identical with those of the oral interface 600, and the description thereof is thus omitted. One side portion of the movable block 660 protrudes out of the extending part for hand-holding the movable block 660, as shown in Figs. 6A-1 and 6A-2, thereby adjusting the interior space of the first fluid passage 612 and change the flow resistance therein. See Fig. 6A-2, when the movable block 660 moves toward the flexible fluid tube 610 and reduces the interior space of the first fluid passage 612, the start threshold value of the vacuum actuated pressure relief valve 602 is then increased. In other words, the start threshold value of the vacuum actuated pressure relief valve 602 in use as shown in Fig. 6A-2 is higher than the start threshold value of the vacuum actuated pressure relief valve 602 in use as shown in Fig. 6A-1. The vacuum actuated pressure relief valve 602 in use as shown in Fig. 6A-2 requires a higher negative pressure value inside the oral cavity to be opened.

Figs. 6B-1 and 6B-2 provide top sectional schematic views of a second alternative example of the oral interface 600. An oral interface 600b as shown by the second alternative example may substitute the oral interface 600 of the saliva

treatment system 6 of the oral interface appliance. The structural difference between the oral interface 600b and the oral interface 600 is that the oral interface 600b has an adjustable flow blocker, which is a rotatable hollow tube 680, disposed inside the first fluid passage 612 adjacent to the vacuum actuated pressure relief valve 602. The remaining components are identical with those of the oral interface 600, and the description thereof is thus omitted. The rotatable hollow tube 680 has an open hollow tube communicated with the first fluid passage 612, and one end portion of the rotatable hollow tube 680 protrudes outside of the extending part for hand-holding the rotatable hollow tube 680, as shown in Figs. 6B-1 and 6B-2, thereby changing the flow resistance of the first fluid passage 612. With reference to Fig. 6B-2, by turning the rotatable hollow tube 680 to a certain angle, the flow resistance of the first fluid passage 612 may be changed and the start threshold value of the vacuum actuated pressure relief valve 602 be further altered. In other words, the start threshold value of the vacuum actuated pressure relief valve 602 in use as shown in Fig. 6B-2 is higher than the start threshold value of the vacuum actuated pressure relief valve 602 in use as shown in Fig. 6B-1. The vacuum actuated pressure relief valve 602 in use as shown in Fig. 6B-2 requires a higher negative pressure value inside the oral cavity to be activated.

Moreover, in one alternative example (not shown in the drawings) of the third embodiment, the negative pressure source 65 in the saliva treatment system 6 of the oral interface appliance according to the present invention may be communicated between the communicating tube 62 and the reservoir 64, and may be turned on/turned off by the control unit 68 or by operating manually.

On the other hand, the saliva treatment system 6 of the oral interface appliance of the present invention may continuously and intermittently measure the saliva capacity in the reservoir 64 to monitor whether the saliva capacity is full in the reservoir 64, to keep the whole system operating under a normal condition. In the third

embodiment according to the present invention, the saliva treatment system 6 of the oral interface appliance may start/stop the timer 67 by the control unit 68. The timer 67, once started, may continuously and intermittently time to a set time interval t , and dispatch a notifying signal to the control unit 68, which then reads a pressure value measured by the pressure sensor 66. The pressure sensor 66 communicated with the reservoir 64 is used to measure the pressure value inside the reservoir 64. In brief, the timer 67 is set, after being started, to send out a notifying signal to the control unit 68 at every time interval t , to notify the control unit 68 to read a pressure value measured by the pressure sensor 66. In this way, the control unit 68 may continuously and intermittently read the pressure values measured by the pressure sensor 66 and then determine the liquid capacity inside the reservoir 64 according to the pressure values read. Besides, the length of the set time interval t may be adjusted as needed. For example, it may be set to have the control unit 68 periodically read the pressure values measured by the pressure sensor 66.

The method for measuring the liquid capacity in the reservoir 64 of the saliva treatment system 6 of the oral interface appliance of the present invention is the same as the first embodiment of said system 1 as shown in Fig. 1, and the description thereof is omitted here.

The system and method of the present invention may further operate in coordination with other apparatus treating breathing disorders in sleep. For example, the system of the present invention may be used with a one-way valve appliance for nasal cavity; for example, the appliance disclosed in the U.S. Patent No. 8,061,357. The one-way valve appliance for nasal cavity may be used to enhance the positive pressure in the upper respiratory tract, in coordination with the present invention to create negative pressure inside the oral cavity and prevent the user's mouth from opening and letting out the air, so as to increase and maintain the pressure gradient inside the oral cavity and the upper respiratory tract, thereby facilitating the soft palate

to move forward to the front of the oral cavity and the tongue toward the upper hard palate and the front of the oral cavity in order to keep clear the upper respiratory tract. Adopting the system and method of the present invention may further lower the set value required by the positive pressure respirator. Also, employing the system of the present invention may further decrease intermittently activating or increasing the positive pressure values of the positive pressure respirator, in order to alleviate user's uncomfortable feeling while breathing caused by continuous application of positive pressure so as to enhance patient compliance.

The system and method of the present invention may further operate in coordination with a breathing examination apparatus, which is used to examine respiratory flow in the upper respiratory tract. When a state of breathing stoppage or hypopnea is detected, the negative pressure value of the oral interface appliance of the present invention is activated or enhanced to shorten the start time for the negative pressure generator in order to achieve the purposes of energy-saving and zero noise.

Although what is described above is merely embodiments according to the present invention, and does not intend to limit the scope of claims of the present invention; other modifications and variations may be made without departing from the spirit and scope of the present invention. Such modifications and variations are considered to be within the purview and scope of the appended claims and their equivalents.

Claims

1. An apparatus for improving breath quality during sleep, characterized in that the apparatus comprises:

a negative pressure source;

5 an oral interface being placed within the oral cavity of a user in order to provide a fluid passage in the oral cavity of the user;

a reservoir for collecting saliva of the user;

a communicating tube having a first open end portion and a second open end portion, wherein the first open end portion is communicated to the oral interface,
10 and the second open end portion is communicated with the reservoir and the negative pressure source in order to create a negative pressure path between the oral cavity of the user and the negative pressure source; and

a fluid adjuster having a first connecting end and a second connecting end, the fluid adjuster being used to restrict all fluids to flow to the second connecting end, the first
15 connecting end being communicated to the fluid passage of the oral interface, and characterized in that the fluid adjuster comprises a tri-way connector, a first one-way valve, and a second one-way valve, the tri-way connector having the first connecting end, the second connecting end, and a third connecting end, the first one-way valve being disposed at the first connecting end to restrict the fluid to flowing to the second
20 connecting end, and the second one-way valve being disposed at the third connecting end to restrict the ambient air to flowing into the communicating tube from the second one-way valve and the second connecting end, contributing to having the saliva staying in the communicating tube flow to the reservoir.

2. The apparatus of Claim 1, characterized in that the fluid adjuster comprises a
25 tri-way connector, a first one-way valve, a second one-way valve, and a vacuum

actuated pressure relief valve, the tri-way connector having the first connecting end, the second connecting end, and a third connecting end, the first one-way valve being disposed at the first connecting end to restrict the fluid to flowing to the second connecting end, the second one-way valve being disposed at the third connecting end, and the vacuum actuated pressure relief valve being combined with the second one-way valve to turn on the vacuum actuated pressure relief valve to let in the ambient air at a predetermined negative pressure value, and to restrict the ambient air to flowing from the second one-way valve and the second connecting end to the communicating tube to contribute to having the saliva staying in the communicating tube flow to the reservoir.

3. The apparatus of Claim 2, characterized in that the vacuum actuated pressure relief valve includes a main body, a propelling valve, a spring, and a spring seat, wherein a spacer having a passage is disposed inside the main body to section the main body area into a first chamber and a second chamber, the first chamber is communicated with the ambient air, the second chamber is communicated with the second one-way valve, and the propelling valve is movably arranged in the first chamber and go through the passage, the space of the passage is completely occupied by the propelling valve to allow the fluid in the first chamber to be isolated from the second chamber under the condition that the vacuum actuated pressure relief valve is not activated; the spring seat is arranged on a surface of the spacer in the first chamber, and the spring rests between the propelling valve and the spring seat.

4. The apparatus of Claim 1, characterized in that the reservoir is communicated to the second open end portion of the communicating tube, and the negative pressure source is communicated to the reservoir.

5. The apparatus of Claim 1, characterized in that the negative pressure source is communicated to the second open end portion of the communicating tube, and the reservoir is communicated to the negative pressure source.

6. The apparatus of Claim 4 or 5, characterized in that the apparatus further includes:

a control unit;

a timer, which is started to time/stop timing by the control unit; and

a pressure sensor for measuring the pressure inside the reservoir and transmitting a measured pressure value to the control unit;

wherein after the timer is started to time to a set time interval and sends out a notifying signal to the control unit, the control unit is then notified to read the pressure value transmitted by the pressure sensor.

7. The apparatus of Claim 6, characterized in that the control unit has a built-in correspondence table showing the pressure-liquid capacity in the reservoir corresponding to the set time interval timed by the timer, to determine the liquid capacity inside the reservoir according to the pressure value and the correspondence table of the pressure-liquid capacity in the reservoir.

8. The apparatus of Claim 1, characterized in that the oral interface further includes:

a flexible shield being positioned between a user's lips and teeth;

an extending part being formed at one side of the flexible shield and protruding outside the oral cavity of the user; and

a flexible fluid tube passing through the flexible shield and the extending part, the flexible fluid tube having a first open end portion and an opposite second open end portion, the first open end portion extending and protruding outside the oral cavity of

the user and being communicated with a negative pressure source, the second open end portion being positioned between the user's tongue and upper palate.

9. The apparatus of Claim 8, characterized in that the flexible shield having at least a one-way valve used to restrict the air in the oral cavity of the user to flow from the one-way valve out of the oral cavity.

10. The apparatus of Claim 9, characterized in that the flexible fluid tube has at least one through-hole being positioned nearby the flexible shield, the through-hole being communicated with one side of the flexible fluid tube and used to be communicated with the front region inside the oral cavity of the user.