LIFEVAC
CREDENTIALS

The Airway clearing device (LifeVac) has undergone thorough testing and has published in medical journals. Retrif Force Testing (Obound & Inbound), Retrif Durability/Environmental Test Report, The Journal College of Gastroenterology – Adult Simulation Study (LifeVac - A Novel Apparatus to Resuscitate a Choking Victim), The American College of Emergency Physicians – Adolescent Simulation Study (A Novel Device for the Resuscitation of the Adolescent Choking Victim), The American Journal of Emergency Medicine – Human Cadaver Study (Assessment of LifeVac, an anti-choking device, on a human cadaver with complete airway obstruction - An independent study of the LifeVac on a human cadaver has been peer reviewed and published in the American Journal of Emergency Medicine. Results of this study suggest that the LifeVac be included as part of the guidelines used for basic life support management, World College of Gastroenterology – Real Life Saves (2) (Successful Resuscitation of Choking Victims Using a LifeVac, a Non-powered Portable Suction Device: Real World Experience), American Broncho-Esophagological Association – Summary & Real life saves (Successful Use of a Novel device called the LifeVac to Resuscitate Choking Victims- Worldwide Results), The International Journal of Clinical Skills (2018) – Peer reviewed study & 11 real life saves - Successful Use of a Novel device called the LifeVac to Resuscitate Choking Victims - Worldwide Results

LifeVac has been approved and is adopted into Suffolk County, NY EMT – Adult Obstructed Airway BLS Protocol also Nassau County, NY has written internal letter from David Kugler, MD, Chairman Nassau REMAC stating LifeVac can be used at approval of Medical Director

LifeVac has been vetted with medical expertise and is implemented in 34 Fire Departments/Rescue Squads, 3 police departments, 135 schools, 8 major disability/special need facilities, 8 hospitals, 19 eldercare/long term homes, 15 medical practices, 13 dental/oral surgeon practices, 16 corporations, plus restaurants, churches, country clubs/camps along with over eleven thousand (11,000) homes having LifeVac on hand if an emergency was to arise.

LifeVac is endorsed and has articles written by the following doctors, medical experts... Dr. Keith Johnson - MD is Board Certified in both Pediatrics and Internal Medicine, Dr. William Holt - Board Certified Neurologist, Senior Medical Director, Dr Nina Shapiro - Director of Pediatric Ear, Nose, and Throat at the Mattel Children's Hospital UCLA and Professor at the David Geffen School of Medicine at UCLA, Coauthor of the LifeVac study in The American Broncho-Esophagological Association & author of a new book "Hype", Dr. Cynthia Paulis – MD Emergency Room physician, Dr. James Kalyvas - Neurosurgeon of the Barrow Neurological Institute, Dr. Robert Domingo – PH.D,
This chart represents that all aspects of vestability have been covered.
<table>
<thead>
<tr>
<th>Female Resident w MS ElderCare Home</th>
<th>Male Resident w Parkinson’s ElderCare Home</th>
<th>Female resident w MS ElderCare Home</th>
<th>Female Adult w special needs</th>
<th>Female in her 60’s</th>
<th>Male patient w Parkinson’s in Parkinson Center</th>
<th>Male patient w CP</th>
<th>Female in her 40’s</th>
<th>Female resident w Huntington’s Disease in elder care</th>
<th>Male Patient w Down Syndrome</th>
<th>Male patient in elderCare home</th>
<th>Male adult in wheelchair</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saved by Nurse</td>
<td>Saved by staff member</td>
<td>Saved by staff member</td>
<td>Saved by Son</td>
<td>Saved by nurse</td>
<td>Saved by staff member</td>
<td>Saved by EMS</td>
<td>Saved by staff member</td>
<td>Saved by staff member w nurses assistance</td>
<td>Saved by EMS</td>
<td>Saved by Mother</td>
<td></td>
</tr>
</tbody>
</table>
Not having an Airway Clearance Device (LIFEVAC) violates the following laws:

For employees:
OSHA Law

29 U.S.C. § 654, (a) Each employer shall furnish to each of his employee’s employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.

Application of the General Duty Clause

The general duty provisions are used in inspections only where there are no specific standards applicable to the particular hazard involved. Any recognized hazard created in part by a condition not covered by a standard may be cited under the general duty clause. (2) A hazard is recognized if it is a condition that is (a) of a common knowledge or general recognition in the particular industry in which it occurred, and (b) detectable (1) by means of the senses (sight, smell, touch, and hearing), or (2) is such wide, general recognition as a hazard in the industry that even if it is not detectable by means of the senses, there are generally known and accepted tests for its existence which are generally known to the employer. In addition, “Voluntary Standards” also meet the preceding criteria for identifying a hazard. Citations based on the general duty clause are limited to alleged serious violations (including willful and/or repeated violations which would not otherwise qualify as serious violations, except for their willful or repeated nature.

For Student/Patrons:
Premises Liability at Schools

There are a growing number of lawsuits arising out of some school’s failure to keep students safe while on school property. Under the theory of "premises liability", occupiers and owners of land (including schools) are legally required to keep premises safe for those who are legally allowed to be there. The law generally requires owners and occupiers of land to exercise a "reasonable amount of care" in providing a safe environment on their premises. However, because schools are typically utilized by young children, the law requires a greater amount of care to be taken in situations where students are present. Parents of children who are injured may file a claim against a school or school district for contributing to a student’s harm or failing to keep premises safe at school. This may include common situations where a child falls or injures themselves in some way due to a school's negligence, but may also include situations where a child is bullied, harassed, or becomes ill and the school fails to come to the aid of the student, or control the situation.

Premises Liability: Who Is Responsible?

Property owners (or non-owner residents) have a responsibility to maintain a relatively safe environment so that people who come onto the property don’t suffer an injury. This responsibility is known as "premises liability," which holds property owners and residents liable for accidents and injuries that occur on their property. The types of incidents that may result in premises liability claims can range from a slip and fall on a public sidewalk to an injury suffered on an amusement park ride. For example, a courier delivering a package may sue you for injuries if he slips and falls on an oil slick in the driveway although if the courier acted in an unsafe way, he or she may not have a valid claim.
Accepted Manuscript

Assessment of the LifeVac, an anti-choking device, on a human cadaver with complete airway obstruction

Mimi Juliano MA, CCC-SLP, Robert Domingo PHD, Mary S. Mooney PT, DPT, Alex Trupiano

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DOI:          doi: 10.1016/j.ajem.2016.03.047
Reference:    YAJEM 55696


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This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.
Assessment of the LifeVac, an Anti-Choking Device, on a Human Cadaver with Complete Airway Obstruction

Mimi Juliano, MA, CCC-SLP
Robert Domingo, PHD
Mary S. Mooney PT, DPT
Alex Trupiano, Paramedic, E.M.T.

We performed an independent study to determine whether the anti-choking device LifeVac is capable of removing a food bolus from an obstructed airway when the potential for choking as a medical emergency exists.

The LifeVac is a non-powered, single patient, portable suction apparatus (anti-choking device) developed for resuscitating choking victims when standard current choking protocol has been followed without success. The LifeVac is designed with a patented valve to prevent air from exiting through the mask. This patented valve is designed to prevent the strong pulse of air from pushing food or objects further downward, lodging the blockage deeper into the airway of the victim. A one-way suction stream is thus created to remove the lodged food or object. The negative pressure generated by the force of the suction is 3 times greater than the highest recorded choke pressure. The mean peak airway pressure with abdominal thrusts is 26.4 ± 19.8 cmH20 and with chest compressions, 40.8 ± 16.4 cmH20, respectively (P =0.005, 95% confidence interval for the mean difference 5.3-23.4 cmH20.) The LifeVac generates over 300 millimeters of mercury (mm Hg) of suction.

Each year, approximately 3,000–4,000 Americans die from choking. Children and the elderly present much higher risks for choking. At least one child dies from choking on food every five days in the U.S., and more than 10,000 children are taken to hospital emergency rooms each year for food-choking incidents. Semisolid foods are the major cause of a large number of asphyxiations, especially among the elderly.
This study was conducted at Fusion Solutions, a cadaver based training center in New York. An unselected, recently diseased individual was employed in the study. The subject was a 71 year old, Caucasian female, 153 pounds, 65 inches with a Body Mass Index of 25. Medical history was remarkable for breast cancer.

The paramedic technician placed a simulated food bolus 7 to 10 centimeters into the subject’s upper airway. The obstruction was visually and verbally confirmed prior to use of the LifeVac apparatus. Three simulated boli obstructions made of clay were used: a 2 cm (small), a 2 1/2 cm (medium) and a 3 cm (large) size. The simulated boli were attached to a string to maintain control during the study.

The paramedic technician placed an adult LifeVac mask on the cadaver following operating guidelines to remove the lodged bolus. The author observed and recorded the success rate. It was noted on one trial that 2 pulls were required with a tighter seal ensured following an initial failed trial. This achieved increased suction and ensured removal of the simulated bolus. The LifeVac removed the bolus successfully 49/50 trials on the first trial.
The American Red Cross’ recent first-aid protocol de-emphasizes the use of the Heimlich for treating a conscious choking victim. The new protocol recommends calling 9-1-1, then giving the person several sharp blows to the back, right between the shoulder blades, with the heel of the hand. If this doesn’t clear the obstructed airway, "abdominal thrusts" should be tried next, alternating with repeated back blows, until the person breathes freely or loses consciousness.

According to Langhelle et al, standard chest compressions are more effective than the Heimlich maneuver for treating complete airway obstruction by a foreign body. The Heimlich maneuver on a frail individual who is in a wheelchair can be difficult to administer expediently. Complications include rib fractures, gastric or esophagus perforations, aortic valve cusp rupture, diaphragmatic herniation, jejunum perforation, hepatic rupture, mesenteric laceration. There has also been a new case of fatal hemoperitoneum due to hilar laceration of the spleen.
When treating a choking child, John Hopkins School of Medicine warns, “When applying the Heimlich maneuver, be careful not to use too much force so you don't damage the ribs or internal organs.”

Choking is a medical emergency that warrants prompt, precise action by anyone available. This results of this study revealed that the LifeVac was able to clear a completely obstructed upper airway. Given the potentially life-or-death nature of given situations, the LifeVac is deemed to be a clinically effective alternative to current emergency protocol to save choking victims. Hence, the LifeVac can be utilized as a safe, simple and effective method to use in critical situations.

Speech Pathologists treat swallowing disorders. Dysphagia treatment consists of teaching compensatory strategies, aspiration precautions, appropriate diet and caregiver training to prevent risks for aspiration. The LifeVac is non invasive and can be used on anyone, both medical personnel and laypersons alike. Results of this study suggest that the LifeVac can be included as part of the guidelines used for basic life support management of choking victims.
Successful Use of a Novel Device Called the Lifevac to Resuscitate Choking Victims Worldwide Results

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Abstract

Choking remains the fourth leading cause of accidental death worldwide. Despite major medical advances in other areas, there currently are no devices that exist to assist in the resuscitation of a choking victim when the standard abdominal thrusts and backblows fail. The Lifevac is a portable, non-powered suction device that was created for the resuscitation of a choking victim when standard protocol fails. It is noninvasive and simple to use, thus making it attractive for use
in choking emergencies. This article describes results of worldwide experience using the Lifevac in real life emergencies. Thus far the unit has been used successfully 100% of the time with limited to no side effects reported. The use of LifeVac has huge potential to save thousands of people from choking, including more susceptible populations such as children and the elderly. It can be used by EMS in the field, and the device could prove valuable in hospitals, nursing homes, day care centers, and other settings. Based on these encouraging results the Lifevac device should be considered as an option during a choking emergency when standard protocol fails.

Keywords
Choking, Resuscitation, Anti choking device, Lifevac

Introduction

Choking is a leading cause of accidental death throughout the world. According to the American Red Cross more than 3,000 people die each year in the United States alone as a result of choking [1], and according to Injury Facts 2016, choking is the fourth leading cause of unintentional death [1]. At highest risk of choking are the extremes of age: of the 4,864 people who died from choking in 2013, 2,751 were older than 75 [1]. In addition, choking is a leading cause of death among children, especially those under 4 years old [2]. Worldwide, a child dies every five days from choking on food. Choking is also a leading cause of brain injury in young children. When food or other small objects obstruct the airway oxygen deprivation for just a few minutes may result in brain damage [3]. More than 17,000 children are treated in hospital emergency rooms for choking related injuries each year [4].

Unfortunately, despite these grim statistics, no advances have been made in the resuscitation of a choking victim since back blows were added to the American Red Cross ACLS protocol [5]. Recently however a new device called the Lifevac seems to show promise in assisting a choking victim when back blows or abdominal thrusts fail. To our knowledge, in the past no device had been shown to successfully resuscitate a choking victim. In a choking emergency, time is critical as it can take EMS more than six minutes to arrive on the scene. At this point brain damage is already occurring and after 8 to 10 min damage is irreversible [6]. Therefore a device that is inexpensive, easy to use and readily available would be advantageous in such an emergency. The Lifevac is a portable, nonpowered suction device that was developed for this reason. The device consists of a plunger with a one-way valve such that when the plunger is depressed air is forced out the sides and not into the victim and when the plunger is pulled back negative pressure is generated to suction out the obstructing object.

The Lifevac has been made available over the past several years worldwide. We herein report the successful use of Lifevac in ten cases that have been reported to date. Lifevac has previously been reported to be successful in removing a lodged object in both simulator [7] and cadaver [8] models. Lifevac is marketed in Europe with a class 1 CE mark, and the kit comes with contact information such that if the device is used feedback can be provided.

Case Report

Case No. 1-3: The incidents took place at an assisted living home in Wales. An 80 year-old female with dementia was eating lunch when suddenly she was noticed to be choking by the nursing home staff. Back slaps were attempted twice but with no result and the patient began losing consciousness. A nurse on duty then used the unit according to package directions and
with one application the food bolus was successfully removed from the patient's airway. The patient recovered without any adverse sequelae. One week later the same patient had a similar choking episode and once again the Lifevac was successfully used to resuscitate the patient.

In the same care home several months later, a 70 year-old male with Parkinson's was noted to be choking while eating. The Lifevac was used per instructions and the obstructing food was successfully suctioned to the mouth where the nurse could then finger sweep it out.

Case No. 4: Another case of a life saved using LifeVac occurred on September 7, 2015 in New Jersey. The patient, a female, was 31 years old and is wheelchair bound. The patient suffers from dysphagia, or difficulty swallowing, since a young age. She began to choke on her tuna sandwich while eating lunch. Her mother unsuccessfully patient supine, the Lifevac successfully removed the obstructing food.

Case No. 5: On April 23, 2017 in Idaho, Lifevac was used in a private home. The device was bought for children who have had choking episodes. On April 23, it was used on a guest to the home, a 60 year old female with no medical issues who choked on a piece of meat during dinner. Abdominal thrusts were attempted right away, but unsuccessfully. The patient was the placed supine on her back on the floor. The LifeVac was then applied and with one suction, the piece of meat was removed from the airway. No adverse effects were noted.

Case No. 6: On September 6, 2017 in Spain in a Parkinson center, there was yet another life saved using LifeVac. The patient was an 80-yearold male who choked on meat while eating. A nurse attended to the patient, giving 5 back blows followed by 5 abdominal compressions. When these were unsuccessful, she applied the LifeVac per operating instructions and with four applications the food was dislodged.

Case No. 7: On October 4, 2017, LifeVac was used in a New York assisted living facility. The patient was an elderly male in a wheelchair who choked while eating a sandwich. The attendants were unable to perform abdominal thrusts due to his wheelchair status and instead used the LifeVac right away, which cleared the full airway blockage and dislodged the food. Later, a medical exam was performed including x-rays, which showed no adverse effects.

Case No. 8: On October 31, 2017 in Greece, the patient was a 40-year-old female who choked on a piece of garlic. EMS was called and arrived two minutes later. The emergency personnel performed abdominal thrusts as well as back blows but they were unsuccessful. Four minutes later, an EMS rescuer used LifeVac and with 3 attempts, the garlic piece was removed. The patient's vital signs were all normal, and again no adverse events were reported. In addition the EMS team had a body camera and the entire resuscitation was captured on video.

Case No. 9: LifeVac was used on a 70 year old female with Huntingtons disease in a home care facility in the UK who choked on a sandwich during mealtime and become unconscious. The Lifevac was then used and required three pulls and the sandwich piece was successfully removed and was observed in the mask. The person operating the device was the 63 year old care manager. The patient briefly required CPR and was brought to the hospital where no adverse effects were reported and the patient was able to be returned to the home the next day.

Case No. 10: Lifevac was used successfully was in the United Kingdom where the patient was a 68-year-old male with Down's syndrome in a wheelchair who weighs 54 kg. The patient began choking on a piece of chocolate. A layperson saved the patient with 2 pumps of LifeVac and removed the obstruction successfully. Again no adverse events were reported.

Discussion
Choking emergencies constitute a common, potentially preventable cause of accidental death throughout the world. Despite medical advances, there are currently no devices that have been shown to successfully resuscitate a choking victim if abdominal thrusts and back blows fail. Lifevac has been previously reported to successfully remove an object from the airway in both a cadaver and a simulator model. Unfortunately it is extremely difficult to study this device in live humans and there is no animal model suitable for study. The Lifevac is a lightweight, portable, non-powered suction device Figure 1 that is applied to the patient’s face via a face mask, which comes with the unit in adult and pediatric sizes. A patent pending one-way valve on the plunger generates negative pressure. On downward thrust of the plunger, air is forced out the sides of the device and not into the victim (Figure 2). This avoids the possibility of pushing an obstructing object further into the airway. A negative pressure is then generated by pulling up on the plunger (Figure 1), thus removing the object. Since the device does not require placement of any part into the oropharynx there is no risk of pushing a lodged object further into the airway. Risks can include edema and bruising from the generated suction, but the benefit of saving a life clearly outweighs these small risks. It is interesting to note that the case reports were voluntary in their submission but represent populations at known risk for choking. There were no reports of the use of the device where it was unsuccessful. Based on the successful application of the LifeVac in real life situations described in this report, the Lifevac should be available for use in settings with high risk for choking such as nursing homes and day care centers, and possibly all public eating facilities. In addition it would be beneficial for EMS to carry for use in the field. Lifevac may be a viable option in a choking emergency when standard protocol fails.

![Figure 1: The LifeVac Device.](image_url)

**Figure 1:** The LifeVac Device.
Easy as
Place
Push
Pull

Figure 2: Easy Technique using LifeVac.

Figure 2: Easy Technique using LifeVac.

References

4. "Choking" Symptoms, Definition, Description, Demographics, Causes and Symptoms, Diagnosis, Treatment. 31 (2016).

Horne (http://www.ijocs.org/)
Aims & Scope (http://www.ijocs.org/aims-and-scope.html)
Editorial Advisory Board (http://www.ijocs.org/editors.html)
Archive (http://www.ijocs.org/archive.html)
Submit Manuscript (http://www.ijocs.org/submitmanuscript.html)
Abstract

Objective

To present a novel approach for the emergent, pre-hospital management of life-threatening aerodigestive tract foreign body aspiration using a portable, non-powered, suction-generating device (PNSD), in the context of a literature review of emergent pre-hospital management of patients with foreign body airway obstruction.

Methods

The PubMed and MEDLINE databases were comprehensively screened using broad search terms. A literature review of pre-hospital management and resuscitative techniques of foreign body airway obstruction was performed. Further, independent measurements of PNSD pressure generation were obtained. Application of a PNSD in cadaveric and simulation models were reviewed. A comparative analysis between a PNSD and other resuscitative techniques was performed.

Results

Physiologic data from adult and pediatric human, non-human, and simulation studies show pressure generation ranging from 5.4 to 179 cm H₂O using well-established resuscitative maneuvers. Laboratory testing demonstrated that a prototypic PNSD demonstrated peak airway pressures of $434.23 \pm 12.35$ cm H₂O. A simulation study of a PNSD demonstrated 94% reliability in retrieving airway foreign body, while a similar cadaveric study demonstrated 98% reliability, with both studies approaching 100% success rate after multiple attempts. Several case reports have also shown successful application of PNSD in the emergent management of airway foreign body in elderly and disabled patients.

Conclusion

PNSDs may play an important role in the emergent, non-operative, pre-hospital management of upper aerodigestive tract foreign body aspiration, particularly in settings and populations with high choking risk. Further characterization of effectiveness and safety in larger cadaveric or simulation studies mimicking physiologic conditions is indicated.
Pressure Verification Test Report

On

(10) Anti-Choking Devices

Customer Name: LifeVac LLC

Customer P.O.: 20160004

Date of Revised Report: July 15, 2016

Test Report No.: R-16001, Rev. A

Test Start Date: July 8, 2016

Test Finish Date: July 8, 2016

Test Technician: J. Kingdon

Lead Env. Test Technician: V. Rondon

Approved By: M. Hull

Report Revision Prepared By: G. Bradshaw

Government Source Inspection: Not Applicable

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Certification and Signatures

We certify that this report is a true report of the results obtained from the tests of the equipment stated and relates only to the equipment tested. We further certify that the measurements shown in this report were made in accordance with the procedures indicated and vouch for the qualifications of all Retlif Testing Laboratories personnel taking them.

______________________________
Victor Rondon
Lead Environmental Test Technician

______________________________
Michael Hull
Environmental Laboratory Supervisor

Non-Warranty Provision
The testing services have been performed, findings obtained and reports prepared in accordance with generally accepted laboratory principles and practices. This warranty is in lieu of all others, either expressed or implied.

Non-Endorsement
This test report contains only findings and results arrived at after employing the specific test procedures and standards listed herein. It is not intended to constitute a recommendation, endorsement or certification of the product or material tested. This test report may not be used by the client to claim product endorsement by NVLAP, NIST or any agency of the U.S. Government.
## Revision History

Revisions to this document are listed below; the latest revised document supersedes all previous issues of this document:

<table>
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<tr>
<th>Revision</th>
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<tr>
<td>-</td>
<td>July 12, 2016</td>
<td>Original Release</td>
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<tr>
<td>A</td>
<td>July 15, 2016</td>
<td>Global Changes</td>
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<td>- Report Number: R-16001 to Revised Report R-16001, Rev. A</td>
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<tr>
<td></td>
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<td>- Corrected the conversion from psi to mmHg on data sheet</td>
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Test Program Summary

Test Report Number: R-16001, Rev. A
Customer: LifeVac LLC
Address: 83 Rome Street
          Farmingdale, NY 11735
Manufacturer: LifeVac LLC
Test Sample: (10) Anti-Choking Devices

Test Environment
All testing was performed at the Retlif Testing Laboratories, Ronkonkoma, New York facility. Each test method was performed in the environment specified within the test standard.

Test Purpose
The purpose of this evaluation test program was to determine the output pressure of the (10) Anti-Choking Devices in accordance with the method requirements of Retlif Testing Laboratories Quote YE06296-6.

Test Specification
Retlif Testing Laboratories Quote: YE06296-6, Dated: July 1, 2016.

Mode of Operation
During the performance of all testing specified herein, the equipment under test (EUT) was operated as follows:

Mode 1:
- During the course of this test, the EUT was operated while verifying an output pressure

Acceptability Criteria
The following was considered EUT acceptability:

- No apparent visual damage noted
- Output pressure must be recorded for each EUT

Modifications
No modifications were made to the EUT during the course of this testing program in order to demonstrate compliance with the specified requirements.
Test Sequence and Results
Table 1 details the test method that was performed on the (10) Anti-Choking Devices and the test results obtained.

Table 1 - Test Sequence and Results

<table>
<thead>
<tr>
<th>Testing Date</th>
<th>Test Method</th>
<th>Test Results</th>
</tr>
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<tr>
<td>July 8, 2016</td>
<td>Pressure Verification</td>
<td>Complied(^{(1)})</td>
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\(^{(1)}\)EUT complies with the Acceptability Criteria as described herein.
Pressure Verification
Test Data
## TEST DATA SHEET

**Test Method:** Pressure Verification  
**Customer:** LifeVac LLC  
**Job Number:** R-16001  
**Test Sample:** (10) Anti-Choking Device  
**Test Specification:** Retlif Testing Laboratories Quote: YE06296-6  
**Para:** N/A  
**Operating Mode:** Mode 1  
**Technician:** J. Kingdon  
**Date:** 7/8/16  
**Notes:**

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<td>Began test. The pressure output from each EUT was measured as in the table below.</td>
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<td>0.001 / 0.0517</td>
<td>0.002 / 0.0517</td>
</tr>
<tr>
<td>8</td>
<td>0.001 / 0.0517</td>
<td>0.001 / 0.0517</td>
<td>0.001 / 0.0517</td>
</tr>
<tr>
<td>9</td>
<td>0.001 / 0.0517</td>
<td>0.002 / 0.0517</td>
<td>0.002 / 0.0517</td>
</tr>
<tr>
<td>10</td>
<td>0.003 / 0.1551</td>
<td>0.001 / 0.0517</td>
<td>0.001 / 0.0517</td>
</tr>
</tbody>
</table>

14:25 Test Complete.

**Results:** There was no apparent damage noted as a result of this test. The EUT met the requirements of the Pressure Verification Test.
Test Photographs
Pressure Verification

Test Setup
## Equipment List
### Pressure Verification

<table>
<thead>
<tr>
<th>EN</th>
<th>Manufacturer</th>
<th>Description</th>
<th>Range</th>
<th>Model No.</th>
<th>Cal Date</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>886A</td>
<td>3D INSTRUMENTS</td>
<td>GAUGE, PRESSURE</td>
<td>0 - 30 Psi</td>
<td>65514-21B55</td>
<td>11/10/2015</td>
<td>11/30/2016</td>
</tr>
</tbody>
</table>
Vacuum Verification Test Report

On

(10) Anti-Choking Devices

Customer Name: LifeVac LLC

Customer P.O.: Check Number: 1039

Date of Report: January 15, 2016

Test Report No.: R-15818

Test Start Date: January 11, 2016

Test Finish Date: January 11, 2015

Test Technician: J. Schlee

Lead Env. Test Technician: V. Rondon

Approved By: M. Hull

Report Prepared By: G. Bradshaw

Government Source Inspection: Not Applicable

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Test Program Summary

Test Report Number: R-15818
Customer: LifeVac LLC
Address: 83 Rome Street
         Farmingdale, NY 11735
Manufacturer: LifeVac LLC
Test Sample: (10) Anti-Choking Devices
Serial Number: 1 through 10

Test Environment
All testing was performed at the Retif Testing Laboratories, Ronkonkoma, New York facility. Each test method was performed in the environment specified within the test standard.

Test Purpose
The purpose of this qualification test program was to determine if the (10) Anti-Choking Devices could withstand the anticipated environmental extremes in accordance with the method requirements of Retif Testing Laboratories Quote YE1221501.

Test Specification

Mode of Operation
During the performance of all testing specified herein, the equipment under test (EUT) was operated as follows:

Mode 1:
• During the course of this test, the EUT was operated while verifying a minimum of 300mmHg

Acceptability Criteria
The following was considered EUT acceptability:
• No apparent visual damage noted
• The EUT must pull vacuum in excess of 300mmHg

Modifications
No modifications were made to the EUT during the course of this testing program in order to demonstrate compliance with the specified requirements.
### TEST DATA SHEET

**Test Method**: Vacuum Verification  
**Customer**: LifeVac LLC  
**Job Number**: R-15818  
**Test Sample**: (10) Anti-Choking devices

**Part Number**: N/A  
**Model Number**: N/A  
**Serial Number**: 1 through 10

**Test Specification**: Retilf Testing Laboratories Quote: YE12215-1  
**Operating Mode**: Mode 1  
**Technician**: J. Schlee  
**Date**: 1/11/16

**Notes**: All Readings in mm/Hg.

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Test Log</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/11/16</td>
<td>20:10</td>
<td>Began testing of EUT.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unit</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
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<tr>
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<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

21:15 Testing completed.

**Results**: There was no apparent visual damage noted as a result of this test. The EUT performed properly during operation. The (10) Anti-Choking Devices met the requirements of the Vacuum Verification test.
Test Photographs
Vacuum Verification

Test Setup
Summary of Environmental Testing

Testing Lab: Retlif Testing Laboratories
795 Marconi Ave
Ronkonkoma, NY 11779
Test dates: 6/22/15 thru 6/24/15

A total of 20 units, 10 new units and ten of the previous version (see notes at bottom) were tested in accordance with MIL-STD-810G for High Temperature (method 501.5), Low Temperature (method 502.5) and Temperature shock (method 503.5).

High temp was tested at 120°F. Exposure time was 5 hours (3 hours to stabilize and 2 to soak).

Low temp was tested at -10°F. Exposure time was 5 hours (3 hours to stabilize and 2 to soak).

The same temperatures were used as the extremes of the shock test. Test duration was 21 hours total (12 cold and 9 hot).

Testing among each batch of ten units (new and previous version) was broken down as follows:

- Unit 1 High Temp, Functional
- Unit 2 High Temp, Functional
- Unit 3 High Temp only
- Unit 4 High Temp only
- Unit 5 Low Temp, Functional
- Unit 6 Low Temp, Functional
- Unit 7 Low Temp only
- Unit 8 Low Temp only
- Unit 9 High Temp, Low Temp, Temp Shock
- Unit 10 High Temp, Low Temp, Temp Shock

Functional testing was performed on units 1, 2, 5, and 6 as soon as they were removed from test chamber. This consisted of plugging the center hole of the LifeVac unit and compressing the plunger and then pulling the plunger to confirm that suction was being generated and no leakage was occurring.

All four units passed this test.

Units 3, 4, 7, 8, 9, and 10 did not undergo functional test by Retlif but will be tested at LifeVac by pulling a blockage from the airway of a Laerdal Charlie simulator in order to demonstrate functionality after being exposed to temperature extremes.

All units will also be examined by LifeVac for any evidence of the units physically coming apart as a result of the exposure to extreme temperatures. This will be done on Friday 6/26.

*** Old Units: 8 pin press fit construction with large O-ring, no O-ring on valve seat. New Units: 4 stainless screws and 4 pins, with large O-ring in a molded groove. Also a small O-ring in ball valve ***

Official test report from Retlif Testing Laboratories is available for view upon request.
- LifeVac is a non-invasive, portable airway clearance device.
- Interchangeable sized masks, clearly identified by colour coded rings.
- No risk of pushing the tongue or obstruction back in a panic situation.
- No risk of oral damage.
- Generates over 326mm Hg of suction, safely and effectively dislodging the obstruction.
- Can be used for full and partial obstructions.
- Saved many lives around the world from choking to death.
- Only airway clearance device with independent medical testing, peer reviewed medical publications, peer reviewed abstracts proving safety, effectiveness and lives saved.
- Comes in three different variations, Standard Home LifeVac Kit, EMS LifeVac Kit and Wall mounted LifeVac Kit.
- LifeVac is FDA registered, MHRA registered as a class one medical device and CE accredited.

- Extra Large Adult
- Large Adult
- Medium Adult
- Small Adult/Child

- Easy to hold handle for secure grip.
- One-way valve prevents any air being expelled through interchangeable sized masks.
- Interchangeable sized masks to fit a casualties facial features, as one size does not fit all.
- Translucent bellows, makes it easy to identify if the obstruction enters this area.

- LifeVac is equipped in over 3500 care and nursing homes across the UK.

From £59.95