APPLICATION BRIEF

Quickly Designing Safe and Reliable Ventilators

Bessel LLC worked with a team of doctors and engineers from Texas Tech University Health Sciences Center at El Paso (TTUHSC) and The University of Texas at El Paso (UTEP) to develop the Texas Power Bag Breather (Texas Breather™) as a humanitarian response to COVID-19. The Texas Breather may have potential use during the COVID-19 pandemic for short-term emergency use when ventilators are not available.

Engineers from the UTEP W.M. Keck Center for 3D Innovation performed engineering simulations and also received technical assistance from Ansys to investigate key components of the Texas Breather. The analyses included system simulation of the mechanism in addition to structural integrity and durability of the components. Ansys also provided performance simulation using computational fluid dynamics (CFD) to investigate the key functionality of ventilation of patients. In addition, simulations included fatigue life analysis — the number of loading/unloading cycles that the bag can take before it weakens — to determine whether it could sustain the hundreds of thousands of loading cycles (in this case, breathing cycles) that would be sustained from the over 7 day demonstrated mechanical reliability of the Texas Texas Breather itself. These simulations are ongoing.

Note that an FDA Emergency Use Authorization (EUA) is pending. The Texas Breather has not been cleared or approved for use by the U.S. FDA or any other regulatory agency. The Texas Breather is not currently authorized for emergency use.

Products Used:

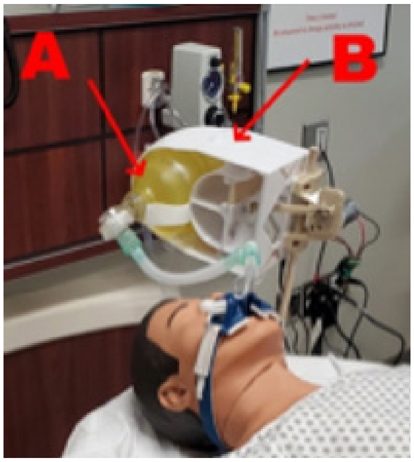
Ansys LS-DYNA
Ansys Mechanical
Ansys Motion
Ansys Fluent
Ansys Twin Builder

/ Challenges

With the fast spread of the COVID-19 pandemic, the number of patients who require intensive care and respiratory assistance is rapidly escalating around the world. Despite the high pressure applied to all ventilator manufacturers to increase production, there is a clear risk of not having enough traditional ventilators available for patients requiring one. In some countries, the medical staff has been tasked with the very difficult job of selecting patients who will benefit from ventilators and those who will not.

An intermediate solution would be to provide basic respiratory assistance using a simplified device that could push a controlled volume of air into the lungs of the patients to help them breathe. Even though regulatory agencies like the FDA have defined faster processes to get new products authorized for emergency use, it is still necessary to address questions of safety and effectiveness for any new device intended for emergency use. As time is critical and human lives are on the line, traditional development methods involving multiple design–build–test cycles are unacceptable.

Solution



Caption: A prototype of the Texas Breather attached to an artificial human model showing two major parts: (A) manual resuscitator bag and (B) the Texas Breather device, designed to mechanically compress the resuscitator bag and provide the patient breathing assistance.

Working with Ansys simulation solutions, Bessel LLC and a team of doctors and engineers from Texas Tech and the University of Texas at El Paso used engineering simulation in place of lengthy and large-scale physical test methods to accelerate the development process of the Texas Breather. The result is a device that provides hands-free compression of commercially available and clinically understood manual resuscitator bag devices and their accessories, with an adjustable degree of compression (volume) and respiratory rate.

Although the Texas Breather is a relatively simple medical device with no embedded software, it may have potential use during COVID-19 for short-term emergencies when ventilators are not available.

Concurrent rapid development paired 3D printing and simulation. Multiple iterations of design and simulation testing using finite element analysis (FEA) were possible in the timescale of physical reliability testing (cycles to failure). FEA also took on an important role because the part designs were optimized for 3D printing, which is in direct conflict with some traditional mechanical design heuristics typically employed to minimize stress risers. The first mechanical failure of an earlier design during device life testing provided further confirmation of the FEA simulation results, because the failure location was predicted by simulation. With this confidence, the design was than iterated to its final version relying upon the FEA simulation to optimize the mechanical structure.

Physical testing to confirm reliability is not feasible in the pandemic time scale. Testing real devices to failure requires increasingly long (days to weeks) test duration and increasingly larger sample sizes. Current device life testing includes systems that have run more than 18 days without failure. This simulation capability turned a multiple iteration process with iteration timescales of weeks (to find failure modes) into a single cycle optimization performed from design to simulation to build in three days, thanks to FEA and 3D printing.

Mechanical parts were printed in the final material, polycarbonate, using Stratasys Fortus series 3D printers. Qualification testing using the IngMar Respitrainer®, QuickLung® and ASL 5000™ Breathing Simulators included simulated use at a range of lung resistances and compliances with measured pressure-volume-flow curves and device life testing. Four modeling studies provided a deeper understanding of the behavior of various components of the device, leading to optimized and reliable performance.

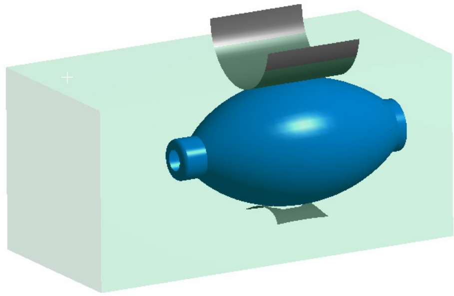
Examining the entire system holistically to investigate the performance of the breather is obviously desirable. Performing such a detailed review physically is difficult, expensive and time-consuming. Ansys simulation technology made it possible to take an agile, concurrent engineering approach to virtual design validation of the Breather, saving time and money.

The entire compression mechanism can be simulated using a multibody dynamic approach, but the manual resuscitator bag, due to its excessive deformation and its outlet flow, cannot be solved in a multibody dynamic domain.

So the team decided to take a step-by-step approach and perform a series of multiphysics fluid–structure interactions with different levels of fidelity to estimate the "equivalent" nonlinear stiffness of the manual resuscitator bag compression. The complete respiratory flow model using CFD — including a representative lung respiratory model — complements this fluid–structure interaction model and provides more detailed pressure, volume and, ultimately, gas exchange behavior. The representative lung model is created in Ansys

Twin Builder and coupled with Ansys Fluent. The complete CFD model is an ongoing study and will not be discussed here.

The calculated nonlinear stiffness then feeds into the multibody dynamics simulation to study the mechanical performance at the system level while quantifying the loads on all the mechanical components in the system. Once the load on each component is extracted, this information is used on a series of topological optimization simulations to reduce the component weights and evaluate the structural integrity of the component.



Caption: The model in Ansys LS-DYNA showing top and bottom surfaces that compress the bag. These surfaces are assumed to be rigid.

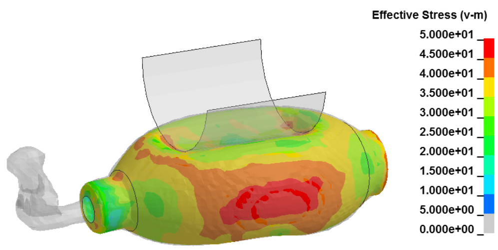
To summarize, the process followed these three steps:

1. Utilization of several modeling techniques with different levels of fidelity to simulate manual resuscitator bag behavior
2. Simulation of the entire system using multibody dynamics while incorporating the manual resuscitator bag with an effective nonlinear stiffness
3. Utilization of the loads on breather components to perform topology and structural integrity optimization

The following is a discussion of three major topics:

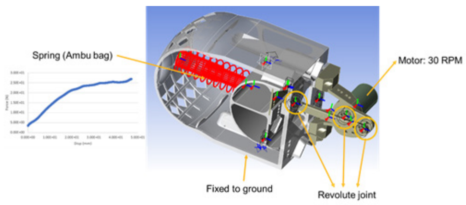
1. Transient Simulation of Manual Resuscitator Bag Deformation

The Texas Breather provides hands-free compression of the manual resuscitator bag. The manual resuscitator bag, not part of the Texas Breather, provides the entire respiratory support during use. Its compression/decompression amount and rate will determine its capability to offer proper respiratory assistance to patients. Additionally, it is estimated that the manual resuscitator bag will experience over 600,000 loading cycles during a three-week period of continuous use. Physical life testing of a limited number of device types and samples has shown no deterioration in the manual resuscitator bag at over 500,000 cycles performed. However, it is impractical during the timescale of the COVID-19 pandemic to gain insight into resuscitator bag reliability and failure modes through physical testing, as described above for the Texas Breather itself. It is therefore essential to calculate the bag's effective nonlinear stiffness behavior to use in the multibody dynamic analysis and in determining its fatigue behavior.



Caption: Effective stress contours from LS-DYNA simulations after applying 3 inches of compression on the manual resuscitator bag.

Ansys LS-DYNA explicit solver was utilized for this analysis. The manual resuscitator bag was modeled as a shell with a 2-mm-thick hyperelastic material described by a Mooney-Rivlin two parameter hyperelastic model from Ansys Granta for silicon rubber material. Two additional rigid surfaces representing boundary conditions in the Breather assembly were added to deform the manual resuscitator bag.



Caption: Multibody dynamics simulations of the breather including all mechanical components. The manual resuscitator bag is modeled as a nonlinear spring.

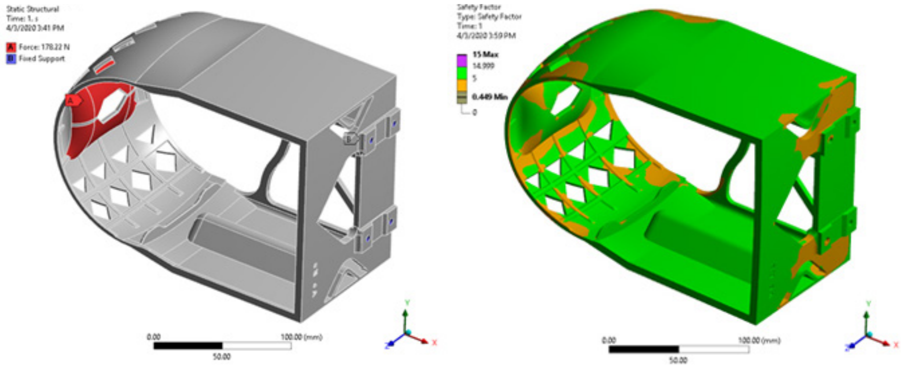
A pressure of 40 cm H_2O was applied to preload the bag; the bottom rig surface moved 50 mm upward to deform the bag, generating air flow for inhalation. After 0.2 sec of compression, the maximum stress was calculated.

For fatigue analysis, the stress–endurance curve revealed the stress that was acceptable to achieve a target fatigue life of 10 million cycles.

The FEA simulations also revealed that the size and radius of the loading surface could be optimized to further reduce the stress and maximize fatigue life.

2. Fluid–Structure Interaction Simulation of the Manual Resuscitator Bag

The top and bottom surfaces of the manual resuscitator bag were modeled as rigid surfaces while the air was explicitly modeled as a fluid with 1 atm initial pressure both inside the bag and in the background.



Caption: Boundary conditions (left) and safety factor (right) in static structural simulations of the main case of the breather.

Maximum stress at the specificed compression of 3 inches (~7.5 cm) was calculated. Ansys LS-DYNA explicit solver was utilized for this analysis. The structured Arbitrary Eularian-Lagrangian (ALE) method was utilized to better model fluid–structure interactions.

3. Multibody Dynamics Simulations

All components of the ventilator are assumed to be made of rigid polycarbonate material. In this model, the manual resuscitator bag was modeled as a nonlinear spring. The displacement–force curve of the manual resuscitator bag was obtained from Ansys LS-DYNA simulations described before. Ansys Motion was used for the multibody dynamics study.

/ Structural Analysis of the Breather Case

The objective of this last modeling study was to understand the structural safety of the breather case design. To achieve this goal, two simulations were conducted:

- Static structural analysis
- Modal analysis

Static structural analysis

The force loading was taken from multibody dynamics simulation in the previous section while the polycarbonate material data were provided by university partners for the additively manufactured case of the device. A load was applied to the structure. Under these conditions a maximum safety factor of 15 was reached while the safety factor was more than 5 in most of the part.

Modal analysis

The modal analysis revealed that the natural frequency of the case is much higher than the frequency of the motor (0.5 Hz), suggesting that no resonance should be experienced.

Conclusion

Simulated use testing (experiments) on representative units demonstrated that the Texas Breather meets the established requirements for ventilation including volume, airway pressure and respiratory rate. The device life experiments also demonstrated expected reliability of over seven days (200,000+ cycles), with continued testing ongoing.

In a matter of a few weeks instead of months, a new emergency care device was designed and extensively tested to demonstrate its ability to safely meet required emergency ventilatory support performance during its expected life cycle. This device is being submitted for regulatory authorization (FDA EUA approval as the first step), relying in part on the confidence in the design provided by simulation.

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Disclaimers

These simulations were designed to replicate physical behaviors under specific circumstances. They should not be considered medical guidance and do not account for environmental variants, such as wind or humidity.