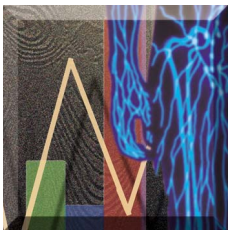

Development of Field Portable Ventilator Systems for Domestic and Military Emergency Medical Response

Charles W. Kerechanin II, Protagoras N. Cutchis, Jennifer A. Vincent, Dexter G. Smith, and Douglas S. Wenstrand

Immediate, on-scene emergency medical response can reduce the number of fatalities sustained during military operations. Without medical support, injured soldiers must be transported over significant distances to a facility capable of administering definitive medical care, an action that may not be possible. Domestic mass casualty support has also come to the forefront recently, with the continuing threat of terrorism. Current capabilities for providing simple respiratory assistance for hundreds or even thousands of victims of chemical or biological weapons of mass destruction do not exist. We report here on the development of two lightweight, portable ventilator and medical diagnostic systems for the treatment of far-forward battlefield and mass civilian casualties.

INTRODUCTION

In the civilian and military emergency medical services arena, there has long been an emphasis on the "golden hour" during which a patient must receive definitive medical attention. The survival rate of patients treated within the golden hour, or the first hour after serious injury occurs, is 80%. At 1.5 h after serious injury without definitive treatment being administered, the chance of survival decreases to 20%.[1] Without on-scene medical support, injured people must be transported to a functional medical facility capable of administering medical care. Rapid transport to such a medical facility is not always a viable option during intense battlefield scenarios or in urban settings where traffic, crowds, and/or limited medical support resources impede the movement of medical vehicles.

The needs of current battlefield and civilian medical emergency scenarios can be addressed by transforming medical equipment, personnel, and supplies so that they can operate as a flexible, agile, and responsive future medical force. Medical equipment must be small, lightweight, inexpensive, rugged, and totally responsive to the needs of the injured soldier. It must be deployable to a far-forward trauma scene and easily operated by trained medics as well as by available personnel who may lack medical training. For remote battlefield settings, large evacuation distances to medical facilities require the devices to operate long enough to transport injured soldiers out of the operational environment and to provide sophisticated life support until definitive surgical or medical care can be rendered. Of critical

importance are efficient methods to control bleeding, manage airways, and initiate fluid therapy.

Several years ago, APL teamed with BioStar, Inc., to study and develop requirements for the U.S. Army Medical Research and Materiel Command (MRMC) for a Far-Forward Life Support System (FFLSS). Following that study, APL again teamed with BioStar to design and deliver a prototype for the MRMC. The operational FFLSS prototype was developed and delivered in 18 months. It allowed medical corpsmen serving as first responders to provide on-scene life support during the crucial first hour after a combat injury. The FFLSS, shown in Fig. 1, included not only a fully functional ventilator but also three physiological sensors usually available only for domestic emergency medical response units. The system was microprocessor controlled, had a liquid crystal display (LCD) screen and reconfigurable user interface, used a standard Army battery, and required only a small kit bag containing tubing and sensor leads. The FFLSS was a state-of-the-art life-support system.

While the system was being developed, it became clear that ventilatory support alone would be of great value, particularly if the system was contained in a very small, rugged package. This led to the internal development of a smaller unit called the Johns Hopkins University Applied Physics Laboratory Mini Ventilation Unit (JAMU), also shown in Fig. 1. JAMU's capabilities were focused on civilian use and did not contain the FFLSS's diagnostic capabilities.[2,3]

CONCEPTUAL DESIGN

The initial FFLSS study was implemented to solicit inputs from the end user and research communities as well as to develop a detailed requirements list. From that list, an initial design specification was developed.

Figure 1. Images of the FFLSS and the JAMU. The FFLSS is shown packaged in its final configuration. In the inset image, note the functional graphic display and the illuminated controls. The JAMU, shown without its outer shell, is a considerably smaller ventilation unit.

To this end, a panel discussion was held at APL with personnel from a number of military medical organizations. Participants included the Combat Development Operation at the Marine Corps Combat Development Center, the Department of Medical Combat Development at the Quantico Marine Base, the working task force convened by the Army and Navy on far-forward advanced surgical support, the director of the Division of Surgery and Surgical Research at the Walter Reed Army Institute of Research, and others.

The panel concluded that the FFLSS must

- Weigh less than 25 lb
- Be capable of unattended operation for a minimum of 1 h on internal power
- Monitor airflow and pressure to deliver optimal ventilation
- Provide an integral pulse oximeter and capnograph
- Provide nasotracheal suction and two modes of ventilation, including assist control and intermittent mandatory ventilation

In addition, one absolute requirement for the initial Army FFLSS program was that the unit could not use any compressed gas bottles because of concerns about explosive rupture if rounds or shrapnel were to hit the bottles.[2,3]

The JAMU system requirements, because of the different end-use scenarios, were drastically different from those of the FFLSS. The target size and weight of the system were placed at an aggressive 220 in^3 and 6 lb, respectively. The unit needed to operate on battery power for a minimum of 30 min, up to a desired 45 min, and be able to run on external power while the batteries recharged. Sensor requirements for the JAMU included airflow monitoring for proper control over the ventilation. The final design goal was to produce a system with a target manufacturing cost of less than $400.

The aim of these efforts was to provide two distinct systems that could function in resource-limited environments, e.g., a prehospital environment where ventilatory support was not available, and run with limited operator intervention or experience. Applications for these units would include both military and domestic scenarios. The FFLSS concept was oriented to a fully functional multimode instrument suited to a field hospital or forward surgical unit, where experienced personnel could use the multiparameter capability inherent in the design. The sensors incorporated in the FFLSS unit would offer critical care monitoring for patients in the emergency room, intensive care unit, and intra- and post-operative environments, as well as during transport. At the other end of the spectrum, the JAMU concept was intended for very far-forward and domestic operation with minimal operator intervention, providing low-cost, short-term ventilatory support

for the management of trauma or respiratory paralysis. The JAMU would be appropriate for a mass casualty situation in which a team of emergency response personnel could administer ventilatory support to counter a release of weapons of mass destruction. This article discusses these two systems, first describing the FFLSS ventilator (the parent system) and then the JAMU ventilator, as appropriate, in each section.

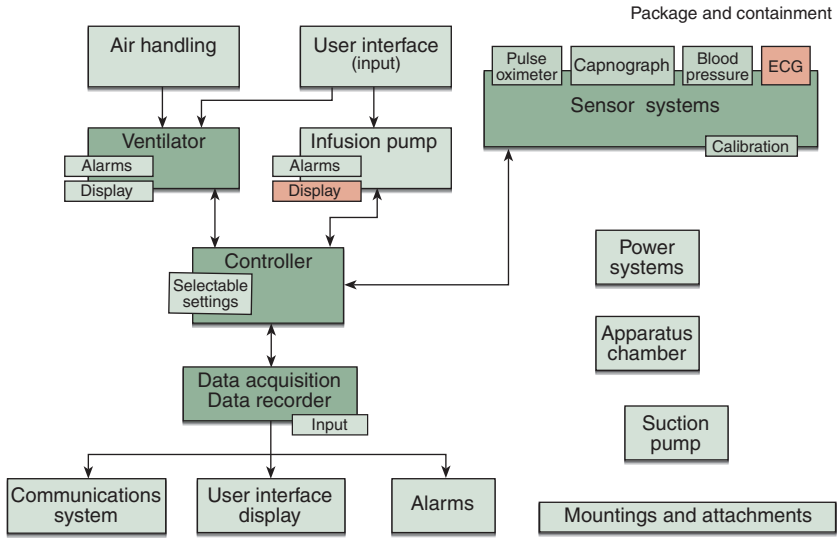

Figure 2. Conceptual schematic for the FFLSS, including electrical, mechanical, and control systems. Orange indicates requirements that were dropped.

SYSTEM DESIGN

The FFLSS, as seen in Fig. 2, consisted of a complex interaction among components capable of controlling and/or recording flow, oxygen saturation, data management, power, interface components, and a variety of sensors. Note that during the design phase, the electrocardiogram (ECG) and infusion pump display requirements were dropped because the ECG was deemed power hungry and would not significantly contribute to front-line trauma care since a soldier's heart is healthy and heart attacks would be very unlikely. In addition, the infusion pump had only six speed settings where the proper setting could be estimated.

Figure 3 displays the airflow circuit of the FFLSS. Air was drawn in through a standard Army gas mask filter (3M, C2A1 NBC) by the compressor. During standard operation, the compressor produced a constant airflow at less than 0.5 lb/in^2, which went through a flow sensor and into the patient. A commercially produced ventilator circuit, which includes a pneumatically controlled exhalation valve, was chosen as the connection to the patient. A controller activated a miniature compressor, pressurizing the exhalation valve and allowing air to flow into the lungs. During expiration, the miniature compressor was deactivated and the lungs exhausted through an exhalation circuit. A fixed mechanical pop-off valve protected the patient from overpressure and vented to atmosphere at 0.60 in. H_2O.

Since the FFLSS used a constant flow source, inspiratory flow was also constant. User-controlled knobs on the front panel could be set to a desired tidal volume and breaths per minute (bpm). Upon ventilation, minute volume, inhalation to exhalation (I:E) ratio, actual bpm achieved, and actual tidal volume achieved were measured and displayed. The control knobs and graphic capabilities of the FFLSS are shown in Fig. 1.

The processor, pneumatics, and sensors integrated into the FFLSS allowed nearly any type of ventilation mode to be implemented with changes only to the unit's software. However, since this was not a requirement established by the end user or program panel, only the control and assist control (patient initiates a breath) were implemented in the present version.

SENSORS AND ALARMS

The FFLSS had a diverse, sophisticated suite of commercial off-the-shelf (COTS) physiological sensors, including an automatically inflating blood pressure measurement cuff, a pulse oximeter, and a capnograph sensor. All of these sensors were considered to be unnecessary for use in a domestic system because of the close proximity of medical care centers.

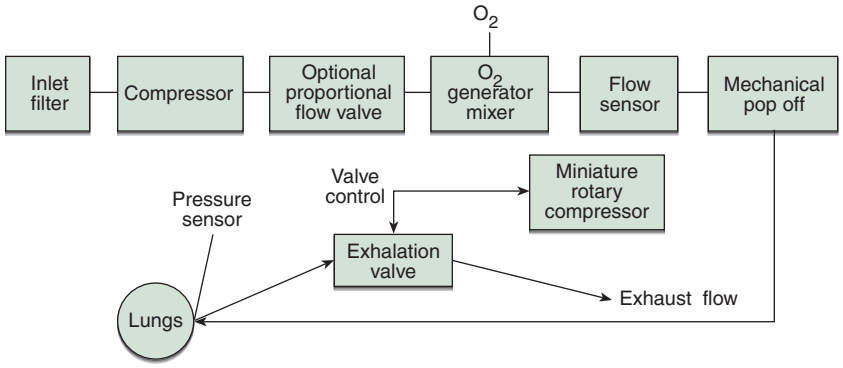

Figure 3. The heart of the ventilator system is the airflow circuit, illustrated here from the inlet filter to the patient.

The inflating blood pressure cuff takes a noninvasive blood pressure measurement (NIBP). A typical NIBP system includes a self-inflating blood pressure cuff with pressure transducers for performing the auscultation function. The cuff inflates at regular intervals, approximately every 2 min. The unit onboard the FFLSS was supplied by CAS Medical Systems, Brandford, Connecticut.

The pulse oximetry sensor measures the patient's pulse rate and the oxygen-carrying capacity of the patient's blood. The standard level of care for the FFLSS only requires values for the heart rate and oxygen saturation levels of the patient; however, the chosen device was capable of measuring a plethysmograph wave, the actual beat-to-beat variation in the oxygen saturation level, which would allow for further capability if desired.

The capnograph on the FFLSS measures the CO_2 levels in the patient's exhaled breath. The standard original-equipment-manufacturer end-tidal CO_2 module was selected with the onboard Capnostat III CO_2 sensor. The capnograph was used to verify the proper operation of the patient–ventilator system, where the lack of exhaled CO_2 indicates that the patient has apnea, the endotracheal tube is in the esophagus, or the patient has expired.

The FFLSS took advantage of a Honeywell mass airflow sensor, which was placed inside the unit in line with the breathing circuit, to measure and integrate the airflow during inhalation. As a result of using the mass flow sensor, the FFLSS provided very accurate tidal volumes. These sensors are large, approximately 11 in^3 in volume; they are also costly.

One highly desirable function of a ventilator is to delay delivery of a breath until the previous breath has been completely exhaled. This was achieved on the FFLSS unit by using an airway pressure sensor that measures the pressure right at the endotracheal tube on the standard breathing circuit. It also enables the processor to monitor peak airway pressure and terminate inhalation if a set pressure is exceeded. This peak pressure value is adjustable from the control panel. The FFLSS could also implement positive end expiratory pressure (PEEP) by closing the exhalation valve when the preset PEEP was reached. This reduces alveolar collapse, which could be useful for certain lung pathologies.

The FFLSS was designed for the battlefield environment, not for the more traditional civilian hospital. Many variables and failures could have had alarms, but the strategy was to have a reduced default set of alarms. The alarms could be audible (e.g., a buzzer) or visible on an LCD screen or other flashing light display. The alarms for the FFLSS included those for blood pressure, heart rate, carbon dioxide sensor, pulse oxygen sensor, unsatisfactory respiratory rate, unsatisfactory breath pressure, unsatisfactory breath volume, and low battery.

For breath delivery control on the JAMU, a much smaller and less expensive Honeywell flow sensor was used instead of a pressure sensor, as in the FFLSS. This sensor was placed in line with the exhalation circuit outside the system, and it had a peak flow capability of only 200 mL/min. A small portion of the entire airflow was sent through the sensor. These sensors were not meant to be used for quantitative airflow measurement but rather to detect the cessation of exhalation, allowing the control system to commence the next breath only after the previous breath has been totally exhaled. This airflow sensor was also quite small, only 1.25 in^3 in volume. If this sensor were accidentally disconnected during operation, the ventilator would continue to function; however, proper timing of the ventilation would not be possible and the unit might start stacking breaths. The JAMU system had only one alarm, which indicated delay of a breath as a result of the previous breath not having completed its exhalation.[2,3]

INNOVATIVE MECHANICAL DESIGN FEATURES

For portable military systems, size and weight are always main drivers in the design process. The weights of both the FFLSS and the JAMU were minimized to slightly less than 25 and 6 lb, respectively. The volume constraints were also stringent. The FFLSS had to fit into a standard military-issue backpack, and the JAMU was constrained to a maximum volume of 220 in^3. There were additional engineering challenges to be overcome, including reducing flow-induced noise in the patient's breathing circuit, packaging all of the components for simplified in-field maintenance, creating a package to house the components that would be rugged enough to handle battlefield conditions, and designing a straightforward user interface for connecting the array of tubes and sensors to the instruments.

Most ventilators would use a hospital or an ambulance air supply, which produces at least 45 lb/in^2 of pressure. However, effective ventilation could be accomplished for most individuals using only 0.9 to 1.0 lb/in^2. Therefore, the pneumatic design of both ventilator systems was based on the use of low-pressure, low-flow-rate compressors. For the prototype FFLSS, a Sensidyne C-series dual-head diaphragm micro-air pump was chosen because of its ability to meet size, weight, power, pressure, and flow rate requirements. Since the delivered flow rates are the same regardless of starting pressure, generating any pressures higher than those necessary for ventilation would waste energy.

Two compressors were necessary in some design iterations of the ventilator systems to allow a wider range of flow rates. Early tests revealed that when the compressors were connected in parallel to a single outlet, excessive flow noise was created. The pulsations from

the compressors, if felt by a patient, could cause significant stress to an already compromised respiratory system. To remove the effects of flow noise, we designed a muffler by analyzing the transmission loss for various expansion chamber configurations. The transmission loss is the ratio of the sound power incident on the muffler to the sound power transmitted by the muffler, given in decibels. In the chosen configuration, taking into account the need to minimize size, there was a 22-dB reduction in the transmitted flow noise in a total expansion volume of roughly 12 in^3. Mufflers could be employed on the inlet side of the ventilation units as well, reducing the audible noise emanating from the compressors.[4]

Manifolds in both the FFLSS and JAMU systems were an important design feature (Figs. 4 and 5, respectively). The manifolds simplified sensor and airflow connections between the unit and the patient. The in-line mufflers, as well as all of the tubing connections from the compressors, pumps, and check valves, were machined into the manifolds. The manifolds in both ventilation systems were also designed to be integral to the structure of either case, reducing the overall weight and size of the final systems.

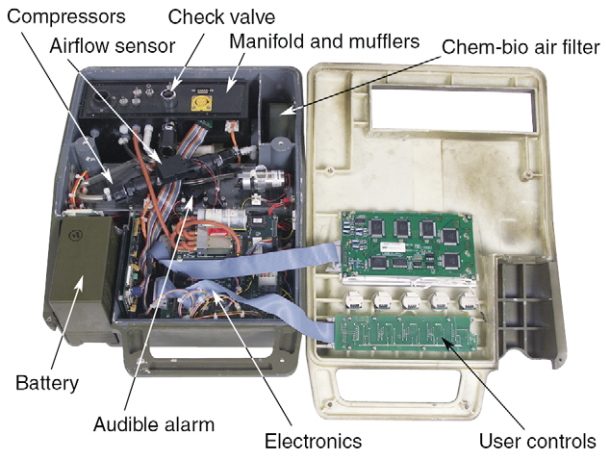

Figure 4. Internal layout of the FFLSS. Notice the manifold, which acts as the patient–ventilator interface as well as a structural component of the case itself.

Using the SolidWorks three-dimensional solid modeling program, the FFLSS and JAMU mechanical subsystems were modeled and packaged. The solid modeling software enabled several quick iterations to be completed, arriving at an optimal design where all possible space was used. For both systems, custom cases were designed because of the size and weight requirements. In addition, because of the number of components as well as the need for a large battery and an LCD screen for its user interface, a custom-molded ABS plastic case was designed for the FFLSS ventilator. A silicone mold for the case was created from a rapid prototyped model manufactured directly from the solid model, simplifying the construction and reducing the overall cost. The FFLSS case was designed with all interface points needed to mount the electrical and mechanical components (i.e., bosses and feed-through ports) so that after the molding process was completed, the unit could be assembled and tested. The FFLSS manifold was placed in the rear of the unit and was accessed through a recessed opening on the upper surface.

The JAMU ventilator case had a much different design, relying solely on two plastic end caps sandwiching together a rectangular thin-walled stainless steel tube. This design allowed for a light and easily assembled case, where the manifold and all interface components were machined into the end caps. All of the electrical and mechanical components were mounted to a sheet-metal bracket supported on the end caps by vibration isolators.

For the FFLSS, it was desirable to be able to adjust the inhalation time period and thereby the I:E ratio. To do this, the airflow rate during inhalation had to be controlled. Most commercial valves found operated at

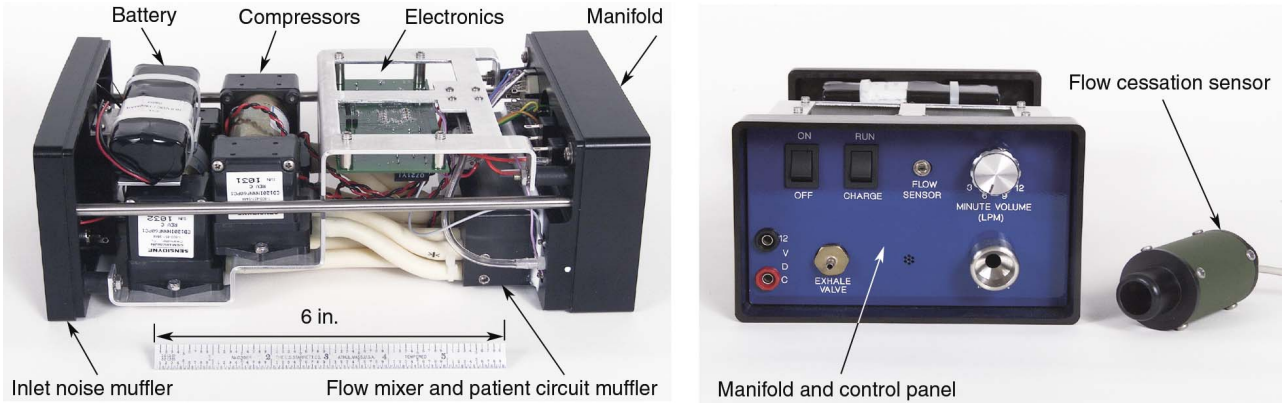

Figure 5. Internal layout of the JAMU. As with the FFLSS, the JAMU manifold acts as the patient–ventilator interface and a structural component of the case itself as well as the user control interface.

pressures of 50 to several hundred pounds per square inch, leading to a very robust design to contain those pressures. Since commercially available valves did not meet the pressure or design requirements of the FFLSS, a custom low-pressure control valve was produced. As shown in Fig. 6, the valve had one input and two outputs. This allowed a constant flow rate of air through the valve, varying only the percentage that went to the patient breathing circuit versus that which was vented to the atmosphere. The vented discharge air ratios could be varied from 0:100 to 100:0 by a pulse width modulated servo like those found on model aircraft. As the servo turned the rotor, the airflow increased through one set of orifices in the valve and decreased in the other. The control valve was not incorporated into the final FFLSS design. Instead, software was used to control the compressor flow rates by turning them on and off, simulating the valve. However, the valve was integrated into another ventilator prototype developed at BioStar. This valve has been patented under U.S. patent 6,647,983B2.

ELECTRICAL SYSTEMS

Many considerations apply to all battery-operated system designs: energy capacity, voltage, operating temperature range, and rechargeable/nonrechargeable cells. For the FFLSS, battlefield availability of the battery was a major consideration. The initial FFLSS battery specification was for an operational lifetime of 1 h minimum, with 2 h desirable. The BA5590, which is currently used in military radios, was easily able to exceed the FFLSS requirements and would be readily available in a battlefield situation. The BA5590 is nonrechargeable and has two 12-V (14.2-Ah) DC $LiSO_2$ cells that were wired in parallel for longer system life. The maximum estimated current draw for the final system was 2.5–3.0 A, with all required sensors, pumps, and suction in operation. The BA5590 also had a wide operating temperature range for use in harsh environments. The FFLSS had an estimated operational life of nearly 7 h while using the BA5590.

For the JAMU, the size and weight of the BA5590 were prohibitive for a compact lightweight design, so a custom-designed battery pack composed of four prismatic lithium ion cells (rechargeable) with 1800 mAh of capacity was selected. With both compressors on at a setting of 12 L/min, this battery had been estimated to provide about 2.5 h of continual use.

The FFLSS power supply circuit design was fairly complex; because there were several COTS sensors and an LCD screen, six different regulated voltages were required. In addition, since some sensors required low-noise tracking supply voltages, separate regulators were needed to provide identical voltages. In total, three DC-to-DC converters and five voltage regulators were used in this power supply system. While costing 15–20% in efficiency, the DC-to-DC converters allow the FFLSS to continue to function properly even when the battery voltage drops from its nominal 12 V down to 9 V. Therefore, the effect on overall battery life was minimal. Because of its large number of fairly power-hungry sensors, the FFLSS processor had independent control of the power for all sensors and could turn them off to extend operational life if required. In addition, the FFLSS processor monitored the battery voltage so that the sensor could be shut down automatically by the software or manually by the operator.

The heart of the electronic hardware of the FFLSS is the processor, which was required to perform the following multiple tasks:

- Interface with the attached sensor systems, sending command and control signals to operate the sensors directly or their control electronics and to retrieve data generated by the sensors
- Directly control systems that do not have independent control electronics (e.g., ventilator, controller, status, settings)

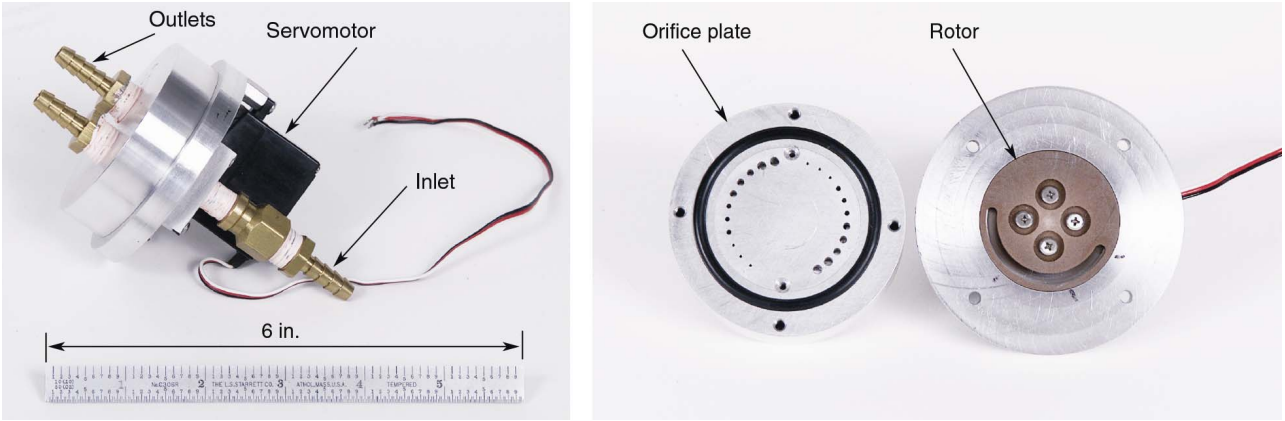

Figure 6. An APL-designed airflow control valve, fully assembled (left) and disassembled (right).

- Store data received from sensor systems and internal operational feedback
- Warn (alarm) personnel of a system problem or a critical change in the condition of the patient
- Allow personnel to set parameters of patient care and adjust those parameters as the patient's condition changes
- Transfer stored data to additional medical support systems as the patient is transferred from FFLSS support to more definitive care

COTS equipment was desired for all components of the FFLSS system; however, a feasibility study on the use of commercial processor boards from Zworld, Axiom Manufacturing, and others concluded that none of the commercially available boards, even with expansion I/O and relay cards, met all of the FFLSS requirements. In addition, maintainability of the FFLSS units was a key point in the evaluation; if a commercial manufacturer discontinued or changed a product, a major redesign might be necessary for the control systems. Since a custom processor board allowed full control of all needed components and permitted modifications as necessary, an in-house board design was determined to be the best option.

The Motorola HC12 with an 8-MHz system clock and eight analog input channels was chosen for the processor board. The board also contained a PIC controller for writing text to the push-button switches, a field programmable gate array (FPGA) for timing signals and glue logic, a four-channel universal asynchronous receiver transmitter (UART) for the serial ports, 32K ROM, 128K RAM, relays (NIBP, pulse oxygen, two compressors, communications power, suction, exhalation valve), and sensor signal conditioning.

The JAMU was a stripped-down system compared to the FFLSS, providing only ventilating capability; therefore, the circuitry design was much simpler. It was designed to operate in two basic modes. In one mode, the ventilator enables 1 of 10 different tidal volumes and 1 of 12 different inhalation rates to determine the parameters with which the ventilator performs. The second mode allows 1 of 4 predetermined tidal volume and inhalation rate combinations to set these parameters. The circuitry controlled two compressors and one exhalation valve used for ventilation and included a flow sensor to determine when a breath was complete.

Because of the small size requirements of the JAMU, an in-house board design was again chosen. The board contained a Xilinx XC2S50 FPGA, PROM, a 1-MHz oscillator, a piezo buzzer, relays for the two compressors and one exhalation valve, input conditioning circuitry for the flow sensor, and 12.0-, 5.0-, 3.3-, and 2.5-V voltage regulators. The FPGA eliminated software and would make the future FDA approval process easier. Jumpers and connectors were used to switch between the two modes and various tidal volume and inhalation rate settings.

SOFTWARE OVERVIEW

With the dramatic increase in algorithmic complexity in medical devices over the last decades, software has become a universal part of many systems. Catastrophic and widely publicized failures, such as those of the Therac-25 (an infamous computerized radiation therapy machine), have resulted in the well-deserved scrutiny of the software in safety-critical medical systems.[5] With patient safety in mind, and to withstand the aforementioned scrutiny, the FFLSS software was designed to be as simple and compartmentalized as possible.

The FFLSS microprocessor software was written entirely in assembly language. The majority of the software consisted of device drivers written to communicate with the externally connected sensor and human interface devices. Though critical for operation, the human interface devices could be serviced with considerable latency with no ill effects.

Of much higher priority were the operation of the ventilation system and the associated measurements of pressure and volume required for this task. This was performed by the only interrupt service routine in the system and was called precisely at 10-ms intervals (based on a hardware timer). The flow of this high-priority task was remarkably simple. First, pressure and flow sensor data were digitized and flow was integrated to compute delivered volume. Second, system and breath times were updated. Finally, these parameters were compared to the desired ventilatory parameters as set by the user (tidal volume and bpm). The compressor and exhalation valves were adjusted accordingly. This task simply provided both volume- and time-driven ventilation, with a software safety cutoff for maximum lung pressure (this was complemented by the previously mentioned pressure relief check valve). Furthermore, the user configured the task to close the exhalation valve and provide PEEP ventilation with previously set parameters. The simplicity of the high-priority task should ease the analysis required if FDA certification is sought.

Aside from the high-priority timer-driven tasks, the rest of the software ran in a large loop with minimal timing constraints. This main code section would read the current values of the knobs and switches from the knob/switch-decoder FPGA; read the UART for communication from the pulse oximeter, capnograph, and blood pressure cuff; and update the graphic display with the latest parameters. The main loop was also responsible for commanding the switch display PIC controller to load one of 30 predefined graphic screens into the small LCD screens in each push-button switch and to configure the colors of each switch via pulse-width modulation of light emitting diodes. Furthermore, any alarms

(caused, for example, by disconnected sensors or patient ventilation problems) flagged by the ventilator control task were sounded and displayed by the main loop. This loop executed more than 100 times per second, meaning that any latency introduced by the serial processing of events was far smaller than would be noticeable by a human operator.

In addition to being safe and functional, it was important for the medical device to be conventional, i.e., it was highly desirable for a device such as the FFLSS to incorporate alarms and displays that were intuitive to personnel who have used other existing systems. To this end, the device was evaluated by the Emergency Care Research Institute (ECRI), an independent nonprofit health research agency. Although an important function of the testing at ECRI was to confirm the performance of the ventilator, their suggestions (incorporated into the FFLSS software) were invaluable in making the device more conventional and thus more usable by medical professionals already trained to use other devices.

FUNCTIONALITY AND PERFORMANCE

The FFLSS was able to implement both controlled ventilation and assist-control ventilation, and also provided PEEP. The JAMU provided only controlled ventilation. Table 1 shows many of the performance parameters of the ventilators. The maximum minute volume for the JAMU unit has not been tested, and therefore 20 L/min stated in the table is theoretical. The maximum minute volume implemented by the control system was 12 L/min.

The FFLSS ventilator was thoroughly tested on a collaborated Michigan Instruments Model 2600 Dual Adult Test Lung. The tidal volumes, respiratory rates, and other parameters were well within ±10% of the settings dialed into the units. ECRI also found the FFLSS to work within a tolerance of 10% for all settings; however, they did note that a warning of some sort might be desirable when the unit gets into an "inverse" I:E ratio mode (i.e., the inhalation phase lasts longer than the exhalation phase). This could be problematic in some patient populations. Inverse I:E ratios are not attainable on the JAMU because the timing-controlled nature of the control system limits the I:E to a maximum value of 1:1.

Both the FFLSS and the JAMU have external power connectors so that if the battery were depleted, the ventilators could be immediately powered from 12-V vehicle power.

SUMMARY

Several prototype ventilator designs, which fill different but related emergency and battlefield requirements, have been presented. These ventilators were developed after discussions with focus groups and individual experts in the field of mechanical ventilation. All facets of the design considered trade-offs among portability, cost, and functionality. In the military patient population, the patients are primarily healthy soldiers who have just sustained a battlefield injury. Many of the ventilator features usually seen in a civilian hospital setting, such as modes to alleviate chronic obstructive pulmonary disease, are not required in a portable military

Table 1. Ventilator performance comparison.

Parameter	FFLSS	JAMU
Approximate weight (lb)	20	<6
Approximate size (in.)	12.8 W × 18.7 D × 6.1 H	6.00 W × 10.63 D × 3.75 H
Physical volume (in^3)	1460	239
Battery type and size	14.0-Ah $LiSO_2$	1.8-Ah lithium ion
Operating life (h)	7–9	2.0–2.5
Compressors	1	2
Controllable I:E ratio	No	No
Respiratory rate adjustment (bpm)	6–60	10 or 20 only
Tidal volume (mL)	0–2000	300, 600, 900, or 1200
Maximum minute volume (L/min)	12	20 (theoretical, not yet tested), 12 as implemented
Inspiratory flow measurement	Yes	No
Expiratory flow measurement	No	Yes

ventilator. Features included in the most recent APL design, such as the rear battery charging connections, allow the units to be stored and deployed from a small truck in large numbers (in the hundreds) in a mass casualty situation.

REFERENCES

[1]*Why Do Ambulances Hurry*, Rescue 70 Web site, http://www.rescue70.org/history.htm.

[2]Cutchis, P., Smith, D., Ko, H., Wiesmann, W., and Pranger, L., "Development of a Lightweight Portable Ventilator for Far-forward Battlefield Combat Casualty Support," in *Proc. SPIE* **3712**, *Battlefield Biomedical Technologies*, pp. 48–55 (1999).

[3]Cutchis, P., Smith, D., Wenstrand, D. S., and Wiesmann, W. P., "Evolution of a New Series of Self-contained Micromechanical Ventilators for Prehospital Use," in *Proc. SPIE* **4615**, *Biomedical Diagnostic, Guidance, and Surgical-Assist Systems IV*, pp. 45–52 (2002).

[4]Beranek, L. L., *Noise and Vibration Control*, Institute of Noise Control Engineering, pp. 338–339 (1988).

[5]*An Investigation of the Therac-25 Accidents*, Virginia Tech Computer Science Web site, http://courses.cs.vt.edu/~cs3604/lib/Therac_25/Therac_1.html.

ACKNOWLEDGMENTS: The U.S. Army Medical Research and Materiel Command, Fort Detrick, Maryland, funded development of the FFLSS. The small ventilator prototype was funded by the APL Office of Technology Transfer and by the biomedical business area.

THE AUTHORS

Charles W. Kerechanin II, a Senior Professional Staff mechanical engineer in the National Security Technology Department (NSTD), provided subsystems integration, mechanical design, and packaging support for the two systems discussed in this article. **Protagoras N. Cutchis** is a member of the Principal Professional Staff in NSTD. Dr. Cutchis provided the medical expertise to define the ventilator requirements and was Lead Engineer for the electronics hardware. He teaches in the Applied Biomedical Engineering program in the JHU Whiting School of Engineering. **Jennifer A. Vincent**, an electrical engineer in NSTD, provided hardware design expertise and debugging support for the two ventilation systems. **Dexter G. Smith**, who is a member of the APL Principal Professional Staff, is currently the Biomedicine Business Area Executive and leads the Biotechnology Branch in NSTD. Dr. Smith formed and managed a team that developed and built two ruggedized, functioning prototype ventilation systems specifically designed for military and domestic first responders. He also serves as the Vice-Chair of the ECE part-time master's degree program in the JHU Whiting School of Engineering. **Douglas S. Wenstrand**, a Senior Professional Staff electrical engineer in NSTD, provided the detailed hardware and real-time software expertise for the designs. Mr. Wenstrand also teaches graduate courses in the Electrical Engineering Department of the JHU Whiting School of Engineering. The team can be contacted through Mr. Kerechanin. His e-mail address is charles.kerechanin@jhuapl.edu.

Charles W. Kerechanin II

Protagoras N. Cutchis

Jennifer A. Vincent

Douglas S. Wenstrand

Dexter G. Smith