Creare

Innovative Technology and Product Development

January 6, 2023

U.S. Army Contracting Command
Cody Kendig (*cody.c.kendig.civ@army.mil*)
Edgewood Chemical & Biological Center
5183 Blackhawk Road
Gunpowder, MD 21010

Subject: Combined Final Comprehensive Report and Monthly Progress Report (Data Items A001 and A002)
Contract No. W911SR-20-C-0036

Dear Mr. Kendig:

Enclosed is the updated Combined Final Comprehensive Report and Monthly Progress Report (#30) for the above-referenced SBIR Phase I project titled "A Low-SWaP Powered Air Purifying Respirator (PAPR)."

Please feel free to call (603-640-2431) or email (mdj@creare.com) me if you have any questions.

Sincerely,

Michael D. Jaeger

Michael D. Jaeger, Ph.D.
Principal Investigator

1010318/btt
Enclosure: TM-4884B
cc: Emily C. McGill, CCAP-SCE (*Emily.C.McGill.civ@mail.mil*)
Theresa Enkosky, DCMA Representative (*theresa.g.enkosky.civ@mail.mil*)
Rayanne Emerson, DCMA Contracts Administrator (*rayanne.l.emerson.civ@mail.mil*)
DTIC
Mike Izenson

Submitted by email

Combined Final Comprehensive Report (Data Item A002)
and Monthly Progress Report #30 (Data Item A001)

A LOW-SWAP POWERED AIR PURIFYING RESPIRATOR (PAPR)

SBIR Phase II Contract No. W911SR-20-C-0036
Reporting Period: 07/19/2020–01/08/2023

Submitted to:
U.S. Army Contracting Command
Cody Kendig, Technical Monitor
CCDC Chemical Biological Center
8198 Blackhawk Road
Attn: FCDD-CBR-PR
Bldg. 3549, Room C134
APG, MD 21010-5424

Prepared by:
Michael D. Jaeger, Ph.D.
Principal Investigator
Email: mdj@creare.com
Phone: 603-640-2431

Creare LLC
16 Great Hollow Road
Hanover, NH 03755

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Michael D. Jaeger
Michael G. Izenson

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Creare LLC
16 Great Hollow Road
Hanover, NH 03755

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14. ABSTRACT
In this Phase II SBIR project, Creare combined a compact, high-efficiency blower technology with novel respirator facepiece designs and a comfortable, low-leakage sealing approach to develop a powered air purifying respirator (PAPR) with a high protection factor and low size, weight, and power consumption (SWaP). The PAPR system provides higher protection factors than conventional loose-fitting PAPR technology and is more comfortable to wear than respirators that employ tight rubber seals against the user's skin. Creare's high-efficiency blower technology was scaled to supply air for breathing and high protection factor at the NIOSH 115 L/min flow rate required for tight-fitting PAPRS and the NIOSH 170 L/min flow rate requirement for loose-fitting PAPRs. A novel PAPR facepiece design was developed for versatile, lightweight service in field conditions with low respiratory hazard and negligible cutaneous hazard. Prototype blowers and facepieces were developed. Laboratory tests show the facepieces can provide protection factor greater than 2,000, and the blowers are efficient and low power. A prototype PAPR system will be delivered to the Combat Capabilities Development Command Chemical Biological Center (CCDC-CBC) for test and evaluation.

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U	U	U	SAR	16	Cody Kendig (413) 987-2716

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1 INTRODUCTION

This is the updated Combined Final Comprehensive Report and Monthly Progress Report #30 (Data Items A001 and A002) for the SBIR Phase II project being conducted by Creare LLC for the U.S. Army Contracting Command, titled “A Low-SWaP Powered Air Purifying Respirator (PAPR).” This report covers work performed between July 9, 2020, and January 8, 2023. The Army Technical Officer is Mr. Cody Kendig, and the Principal Investigator for Creare LLC is Dr. Michael D. Jaeger.

2 SUMMARY

In this Phase II SBIR project, Creare developed a novel lightweight Compact Powered Respirator (CPR) technology that will provide high-level respiratory protection with lower thermal burden and greater comfort than conventional chem/bio respirators in conditions with low-level respiratory hazards or threats and negligible cutaneous hazards. This scenario represents a large range of military and industrial work conditions. Potential CPR specifications and operating concepts were discussed and developed with the Technical Officer and a representative from the Respiratory Protection Branch at the U.S. Army Combat Capabilities Development Command – Chemical Biological Center (CCDC-CBC). Creare developed design concepts and detailed 3-D computer aided design (CAD) models for a novel respirator facepiece with new, proprietary functional features and designed a compact, low-power blower for the CPR that uses innovative 3-D printing manufacturing approaches to improve on prior Creare technology. Fabrication processes were developed and several prototype facepieces and blowers were produced. Battery-powered prototype blower performance was characterized in benchtop flow tests, and prototype facepieces were tested in benchtop mannequin protection level tests. Analysis of the CPR design and test results to date suggest the CPR technology can meet the target specifications for size, weight, operating lifetime, and protection. Standard NIOSH laboratory respirator protection level (LRPL) tests for prototype PAPR systems are in progress to demonstrate the protection level provided by this new technology.

3 BACKGROUND

Warfighters and support personnel need a compact, lightweight, comfortable device to provide high levels of respiratory protection in low-hazard environments and to improve user respirator tolerance and compliance with respiratory protection guidelines. To meet this need, Creare proposed a CPR technology that uses our high-efficiency regenerative blower technology to supply filtered breathing air to an innovative, comfortable respirator facepiece. The respirator facepiece design minimizes the face seal area and replaces almost all rubber seals with low-leakage, comfortable interfaces to the skin. The blower/battery system has small SWaP due to our low-leak facepiece interface designs and our highly efficient blower technology. Our low-SWaP, comfortable CPR technology should enable better task performance for emergency escape, general work, and/or combat in low-hazard environments and provide higher protection levels than existing loose-fitting PAPRs.

In this Phase II project, we identified CPR target specifications with military chem/bio experts and then designed, fabricated, and tested functional CPR prototypes that strive to meet the specification targets.

4 PHASE II TECHNICAL OBJECTIVES

The overall objective of Phase II is to improve comfort and respiratory protection compliance for warfighters and support personnel operating in low-hazard environments while providing high levels of respiratory protection. Creare's CPR technology will meet this objective by combining high-efficiency regenerative blower technology with an innovative respirator design to produce a compact, lightweight, comfortable PAPR system.

The specific technical objectives of Phase II are to advance development of prototype CPRs and demonstrate the key benefits of our CPR technology: high respiratory protection factors, comfortable to wear, compact, and lightweight. Table 1 summarizes the technical objectives, technical approaches, and accomplishments (or efforts in progress) achieved during the project.

Table 1. Phase II Objectives, Technical Approaches, and Accomplishments

Objective	**Technical Approach**	**Demonstrated in Phase II**
High respiratory protection factor	Regenerative blower provides purified airflow to respirator	We designed and built regenerative blowers that supply the airflow needed to maintain positive pressure in the respirator. Blower performance was measured in separate-effects tests and as part of integrated CPR system tests.
	Controlled low-leakage seals	We measured flow resistance and protection factor in manikin tests to show low leakage seals enable high respiratory protection with reasonable blower demands.
	Protection level testing	Instrumented manikin tests demonstrated protection levels > 2000. NIOSH-based LRPL tests are under way to demonstrate the protection factor for the integrated CPR.
Comfortable to wear	Novel face seals	In-house assessments confirmed the novel skin interfaces in our facepieces provide a high comfort level. Subjects for in-progress LRPL tests will provide additional feedback.
Compact and lightweight	Compact regenerative blower	Designs for future, production CPR system suggest the blower/battery package (without filter) can be as small as approximately 30 in^3 in volume and weigh 1.25 lb_m. These designs have been developed to illustrate future capabilities but are appropriate to be developed in follow-on product development efforts.
Long run time	High-efficiency regenerative blower	The future high efficiency motor for a production CPR is expected to provide roughly eight hours of run time at 120 lpm air delivery rate and four hours at 170 lpm. The run time at 120 lpm is expected to drop to just over four hours at -20°C.
Produce preproduction prototype CPRs for evaluation	Develop prototype respirator facepieces using updated designs	The project produced four final design prototype blowers and facepieces. Two of the four CPR systems have undergone in-house benchtop tests and are being used for human LRPL tests by an independent testing vendor. Two of these CPR systems will be delivered to the Army for continued evaluation.
	Develop prototype blowers using updated designs	

5 PHASE II WORK PERFORMED AND RESULTS OBTAINED

The Phase II effort developed detailed CAD designs and produced prototypes of the CPR facepiece, blower, and blower electronics. The CPR prototypes are suitable for preliminary performance tests to show concept feasibility and performance potential, but they are not sufficiently developed to facilitate field tests or advanced form factor evaluations. Benchtop performance tests of CPR prototypes as individual elements (e.g., separate blower and facepiece tests) and as full PAPR systems combined with feasible design extensions for a future fielded CPR system showed that the CPR technology approach can meet the performance requirements. LRPL fit tests of prototype CPR systems are in progress. Since this is a nonproprietary report, specific details of the CPR component designs and performance tests that cannot be reported here will be separately communicated to the Technical Officer.

5.1 CPR Specifications

5.1.1 Performance Goals and Operational Concepts

We discussed the project goals and the respirator operational concepts and requirements during a project kickoff teleconference meeting with a Navy technical team at CCDC-CBC. Key design guidance from the discussion included the following:

- This Phase II project is focused on demonstrating the feasibility of a comfortable respirator facepiece that provides at least 2,000 LRPL and a low-SWaP blower/motor.
- Assume a low-hazard (no cutaneous hazard) environment.
- The ISO W1 work rate's 110 L/min peak instantaneous flow rate is the primary target breathing flow capability, and higher flow rates are of secondary interest, even if for a brief period of time.
- Minimum of four-hour operational lifetime on a single battery with options to switch out batteries or use larger batteries for extended operating time. There are no specifications for the battery type at this time.
- A 1 lb_m weight and 42 cubic in. size goals for the blower/motor and four-hour battery.
- The CAP-1 CBRN filter with 40 mm NATO threads is the primary filter choice for now. Using a single filter is preferable to using two filters for the W1 operating condition.
- Materials compatibility with hot soapy water and bleach for decontamination.
- Prototype development may focus on a single size (e.g., for the ISO "medium" head form) for this phase of development and testing, though the respirator must ultimately fit to the full range of face shapes either as a universal fit or using a few different sizes.
- Combat ruggedness is not an immediate requirement for this feasibility demonstration but may be desired long term.
- Standard military respirator performance specifications will apply to future production respirators, such as less than 60 dBA sound level at the wearer's ear and ballistic eye protection that meets ANSI Z87.1 (or equivalent military specifications for ballistic eyewear).

In addition, the CCDC-CBC team specified interest in seeing data for the full NIOSH LRPL exercise regimen, using a lower-than-standard number of subjects if necessary, and some evaluation of resistance to crosswind effects.

5.1.2 PAPR Specifications and CPR Design Operating Space

We reviewed the 42 CFR Part 84 NIOSH requirements for respirator approvals and the ISO work rate classifications to select a range of CPR flow rates that could satisfy a range of regulatory requirements and user needs. The CPR facepiece design appears to function somewhere between tight-fitting and loose-fitting PAPRs, but it is unclear how it will be considered regarding current regulatory requirements. The current technology call for this SBIR project focuses on the ISO W1 work respiratory rate, which requires a peak air supply flow rate of 110 L/min. We selected a target flow rate of 120 L/min for our blower, which provides roughly 115 L/min of breathing flow and 5 L/min outward flow through the face seals at the peak inspiration rate. This 115 L/min breathing flow will meet the 115 L/min NIOSH flow rate testing requirement for tight-fitting PAPRs and the W1 peak breathing flow rate of 110 L/min.

Based on our blower designs and anticipated future hardware capabilities, it appears practical to extend the continuous blower operating range to 170 L/min, which is the NIOSH flow requirement for loose-fitting PAPR testing. Operation to even higher flows, such as the 204 L/min ISO W2 condition, may be feasible for short-term operation and will depend on the capabilities of the future production motor, electronics, and battery pack. The blower power requirement (for a fixed design) scales roughly as the cube of the blower speed, so higher flow rates demand disproportionately higher power levels.

5.2 Facepiece Design

The CPR facepiece was designed with an ocular zone and a nose cup breathing zone, both of which receive filtered air from the blower system. The facepiece design was developed as a 3-D computer-aided design (CAD) to fit an ISO medium head form shape. While it is hoped that the facepiece design will fit a broad range of face shapes, the project focused the prototype design on the medium ISO head form shape for development and concept demonstration purposes. Developing the complex facepiece geometry in CAD was a significant effort that pushed the capabilities of the SolidWorks CAD software that was used. Numerous intermediate, pre-prototype 3-D printed facepiece components were produced and evaluated for shape, function, and material properties, and the evaluation results were used to guide further design improvements. After several rounds of concept exploration and design improvements, a final design was produced that appeared to provide the targeted fit and functionality.

The final facepiece design included required features such as a broad angle viewing window for the ocular zone, a standard 40 mm NATO threaded insert port for input air, an exhaust valve, and a strap system for supporting the facepiece on the head. The design also included several novel, proprietary features that provide additional functionality and versatility. The overall CPR facepiece design is considered proprietary and potentially export controlled, so the details will be communicated to the Technical Officer in a separate report or briefing.

5.3 COMPACT BLOWER DESIGN

A CPR blower design was developed based on prior compact blower technologies developed and demonstrated at Creare. We scaled and adapted prior blower designs to produce a new design that provides the required airflow rates and differential pressure increases when connected in series with a commercially available CAP-1 chem/bio filter and PAPR air hose. We used stereolithography to produce critical parts of the blower with complex geometries to simplify assembly. A significant part of the design effort was spent identifying and evaluating compact COTS motors that could provide the required rotational speed, low weight, and low-power operation while avoiding the costs to develop a new, custom motor. Several different motor models were purchased and tested, and some of the final candidate motors were tested in combination with a prototype blower impeller. The motor operating voltage and current were also considered during the selection process since they impact the battery pack voltage and size requirements.

A final COTS motor was selected for use in Phase II blower prototypes, and associated electronics and battery packs were designed to control and power it. The Phase II motor and electronics provide an efficiency and size scale that is suitable for Phase II prototype demonstrations. Future production units can use a more efficient motor, smaller electronics, and a smaller battery pack with additional straightforward product development that is justified for low production volumes. For example, we learned that the motor manufacturer has recently developed a slightly more efficient motor that would enable lower-power and lower-voltage operation for future blowers in production, and a custom board could be developed to miniaturize all the electronics into a much smaller, more convenient form factor. A rechargeable lithium-ion battery pack was designed to use common COTS batteries with high energy density, provide the power necessary for Phase II prototype blower testing, and provide a demonstration of the approximate size and weight of our Phase II blower system. A CAD of the Phase II blower was developed to include the COTS motor, Creare's impeller and blower housing, the COTS electronics, an assembly of COTS batteries, and 40 mm NATO threaded ports for a CAP-1 filter and a COTS PAPR air hose. The blower is intended to be carried on either a hip belt or a backpack, or on a dedicated support system somewhere on the user's upper torso. A specific field-ready carrying approach was not designed, so a simple carrying strap was used to facilitate human fit tests.

The blower design is considered proprietary and potentially export controlled and will be communicated to the Technical Officer in a separate report or briefing.

5.4 PROTOTYPE FACEPIECE FABRICATION

Prototype CPR facepieces were developed based on the CAD designs mentioned above. Early prototypes used commercial 3-D printing techniques as a fast, low-cost means to produce components for sizing tests and material evaluations. Final prototypes suitable for testing were produced by an outside vendor by casting urethane rubber into 3-D printed mold tools. Two fabrication iterations were required to tune the urethane molding processes, facepiece designs, and materials properties to achieve the desired final structure. The facepiece assembly comprises a molded urethane base structure integrated with a combination of custom components and generic components from COTS respirator products. The facepiece has features such as inhale/exhale valve structures, an air hose connection port, an ocular window, and a head-strap assembly. A future fielded facepiece would likely be made of injection-molded, chemical-resistant rubber and similar components, but such materials and fabrication processes are overly expensive to use for prototyping purposes. The assembly also employs a proprietary modified face seal that improves user comfort. The assembly uses a COTS AVON Protection Systems rubber PAPR air hose as a field-appropriate air hose to avoid an unnecessary and costly rubber air hose development effort. Proprietary fabrication details will be communicated to the Technical Officer in a separate report. The project produced four final Phase II prototype facepieces to be used for demonstration and evaluation purposes. Two of these facepieces, one with air sampling ports and one without ports, will be delivered to the Army for evaluation.

5.5 Prototype Blower Fabrication

Components for prototype CPR blowers were fabricated using a combination of outside vendor fabrication processes and conventional machining. The prototype blowers employ a COTS motor and motor control electronics board, a custom electronics adapter board, and a custom battery pack containing COTS lithium-ion cells. The small custom adapter board was developed to simplify connections between the motor control board, the motor, various control switches, and the battery pack. For simplicity in testing, the battery-operated blowers were produced with LOW and HIGH flow rate settings of 120 and 143 lpm respectively. As described below, running the COTS motors fast enough to produce flow rates above about 143 lpm required an applied voltage that exceeds the protection circuit cutoff voltage in the drive electronics. All testing conducted at 170 lpm blower flow was performed using benchtop power supplies rather than the blower's onboard battery-powered electronics. Proprietary fabrication details will be communicated to the Technical Officer in a separate report.

Four final Phase II prototype CPR blowers of a single final design were produced for final characterization tests. Two of these blowers will be delivered to the Army for evaluation.

5.6 Facepiece Performance Evaluations

The project evaluated several prototype CPR facepieces for basic functionality and benchtop respiratory protection factor. The facepieces appear to provide a wide field of view (not quantified) and have a good general fit to the face. As noted below, the face seal support material durometer could be reduced in the future to provide greater compliance for a more conformal fit to a wider range of face shapes. Our novel, proprietary facepiece features appear to be functional and advantageous. These features will be discussed with the Technical Officer during the final review meeting.

Facepiece flow and benchtop respiratory protection level were measured using a Portacount airborne particulate measurement device, a Bodi medium head form with ocular and breathing zone sampling ports, a PosiCheck breathing machine, and a first-generation prototype blower. The PosiCheck breathing machine has only low and high settings. The low setting has a slightly higher peak inhalation flow rate than the 120 lpm flow setting for our prototype blowers, and the high setting's peak inhalation rate greatly exceeds the 170 lpm flow rate targeted for our blower. We thus performed tests using only the PosiCheck low breathing setting.

We performed benchtop protection factor measurements for two prototype facepieces at the 120 and 170 lpm supplied airflow rates. The first prototype had a traditional rubber face seal, and the second prototype had Creare's improved-comfort face seal. The tests confirm that at both flow rates, both facepieces and face seal types can provide high benchtop protection factors well above our target of 2,000 for the ocular and breathing zones when the face seal has no gaps.

We also performed an in-house, preliminary human protection assessment for one individual for several of the NIOSH standard protection factor test face exercises. The protection factor results were also well above the 2,000 target for both the ocular and breathing zones. This assessment, as well as other qualitative human fit assessments, showed that the prototype materials used in the ocular zone portion of the prototype facepiece are overly stiff, making it difficult to achieve a conformal, gapless face fit reliably. Any resulting small face seal gaps quickly compromise the protection level. As noted above, the material durometer and face seal design should be improved in the future for better compliance to varying face shapes.

Quantitative, proprietary performance evaluations and data will be communicated to the Technical Officer in a briefing.

5.7 Blower Performance Characterization

Prototype blowers were characterized for their SWaP and airflow and power performance. Nonproprietary results are described below. Proprietary performance evaluations and data will be communicated to the Technical Officer in a separate report or briefing.

5.7.1 Prototype Blower Flow Performance

We measured the performance of first-generation and final-generation prototype blowers across their entire operating range, including the maximum flow condition that simulates operation in the CPR system at zero facepiece exhaust flow resistance. This condition represents the state in the breathing cycle near peak inhalation when the blower is supplying the highest flow to the lowest backpressure resistance, which is when the airflow is needed most by the user. (The supplied blower airflow greatly exceeds the user's breathing need and the facepiece leak rate during the exhalation portion of the breathing cycle.) The blowers were tested with the in-line assembly configuration of CAP-1 filter, blower, flow meter, air hose, ambient. A prototype facepiece was not connected in the sequence since we estimated that the flow meter produced a very low pressure drop that was roughly representative of the pressure drop of the airflow through the non-worn facepiece inlet valve.

The first-generation blower achieved head/flow performance targets while consuming low power consistent with overall SWaP goals. We also investigated the effects of internal clearances around the impeller and found that a small clearance change had little effect on the blower performance at low head rise and produced slightly lower flow rates at high head rise. Opening the clearances also slightly reduced the motor current. This change was thus implemented to simplify fabrication of the final Phase II prototype blowers. The final blower design was focused to provide near 120 lpm flow through a CAP-1 filter, but we demonstrated that it can also provide 170 lpm flow with sufficient voltage applied. The upper flow rate capability is limited by the COTS motor limitations. The future production motor we identified requires half the voltage and can accommodate higher current, thus enabling higher flow rate capabilities with a smaller battery pack. The first-generation blower produced high noise levels, but the final Phase II blowers have noise-reducing modifications.

We measured head/flow performance curves for two of the final prototype blowers and found their initial, as-assembled performance notably degraded from our first-generation blower. We disassembled and inspected the new prototype blowers to identify the cause of reduced performance. The reduced performance appeared to be related to lower-quality machining results for key blower components, which resulted in larger clearances and poorer alignment between critical parts. We reworked critical machined surfaces as well as practical and performed the reassembly very carefully to correct alignment issues, but we found that the final prototypes must operate at rotating speeds that are roughly 10% higher than the initial prototypes to achieve the same head/flow performance. This result emphasizes the importance of properly machined components and tight tolerances for future component designs and production processes. Since the end of the project performance period was approaching, we decided to use the final prototype blowers in their reworked condition for human LRPL tests despite the need to run them at slightly higher speeds.

Due to the COTS motor current limitations and the reduced blower efficiency, Phase II prototype blower operation at the higher 170 lpm flow is limited to short periods. We demonstrated operation at this flow rate using a benchtop power supply. Operation at this flow rate requires a voltage that exceeds the upper limit of the COTS battery-operated blower electronics and is thus impractical for the Phase II battery-powered units. We thus elected not to perform protection level tests at 170 lpm flow rates and instead set the electronics and battery packs for final blower prototypes to provide flow at 120 lpm for "LOW" blower speed and at near 143 lpm for "HIGH" blower speed. The 143 lpm flow rate was the highest practical flow rate achievable without exceeding the voltage limits on the COTS electronics board, and it required a battery pack that is 50% larger than the future production units. As previously noted, the future production blower motors will require half the voltage and can carry roughly twice the current, so they can provide the same performance as the COTS Phase II blower motors at roughly half the voltage and half the battery pack size. Battery-powered operation at 170 lpm will be feasible with the future production motor and improved blower component machining.

5.7.2 SWaP

We estimated the future production motor/blower assembly SWaP and operating capabilities when powered by a rechargeable battery assembly employing COTS batteries. Estimates of the future production CPR system suggest the blower/battery package (without filter) can be as small as approximately 30 in^3 in volume and 1.25 lb$_m$. The battery pack we selected that is included in this 1.25 lb$_m$. weight estimate is expected to provide eight hours of operation at 120 lpm at room temperature, rather than just the four-hour minimum requirement. The minimized blower/battery combination will thus meet the flow, size, and weight requirements for a four-hour operating time in principle, though we have slightly oversized the battery pack design to extend operating time at temperatures down to -20°C and at moderately higher flow rates. The blower will also be capable of operation at 170 lpm for roughly four hours. The addition of a second battery pack can double the low-flow operating time and enable flow rates up to at least 170 L/min for up to nearly eight hours. Future highly ruggedized system packaging may push the motor/blower/battery assembly weight over the targets, but we expect the system size will remain within the volume target.

Note that the current Phase II final prototype blowers cannot achieve these future performance levels because their COTS motor requires higher voltage and has lower current carrying capacity than the future production motor, which is just now becoming available from the manufacturer. The final Phase II blower prototypes were thus produced with a battery pack 50% larger than the future design to compensate for this lower prototype blower performance and to produce airflow rates at either 120 or 143 lpm for testing and demonstration purposes.

5.8 Prototype CPR System Performance Tests and Results

The project produced four Phase II prototype CPR systems, two of which were tested at Creare and by an independent vendor. Tests included assessments of Creare's novel comfortable face seals, sound level measurements, benchtop mannikin protection level tests, and human LRPL tests.

5.8.1 CPR Comfortable Face Seals

Three Creare employees have tried on the prototype CPR system to experience the fit and face seal comfort while the blower is in operation. The brief trials were limited to lab conditions, but all three employees report the novel face seals are comfortable. One of the employees has experience wearing passive full-face respirators in hot conditions, and they agreed the novel face seals on these powered-air prototypes are dramatically more comfortable than conventional rubber seals. These evaluations are subjective and qualitative. Additional feedback is anticipated from the human LRPL test participants when those studies are completed.

5.8.2 CPR Sound Level Assessment

The CPR system sound level while producing air at 120 lpm was measured using a handheld sound meter to be very near 60 dBA at the wearer's ear and higher at the blower. The blower housing is not packaged for field ruggedness or sound dampening, however. To simulate the sound dampening potential of future field packaging, the blower noise measurement was repeated after placing a 1/8-inch rubber sheet between the blower and the sound meter. In this configuration, the blower noise dropped significantly to very near 60 dBA.

5.8.3 Benchtop Mannikin Protection Level Tests

A prototype CPR system underwent benchtop respiratory protection level testing using a final design CPR blower powered to produce either 120 or 170 lpm airflow. The CPR facepiece had Creare's novel, comfortable face seals. As for the facepiece tests described above, the measurement setup used a Bodi ISO medium respirator test head form with an elastomeric face, a PosiCheck breathing system, a Portacount airborne particulate measurement device, and ambient air particles for leak detection. The PosiCheck system was used on the low breathing setting. The measured protection level for a respirator facepiece zone is the ratio of the measured ambient particle density to the particle density measured in the ocular or breathing zones.

During initial shakedown tests, we discovered that the materials used to produce the prototype blower housings shed hazardous concentrations of particles into the breathing airstream during blower operation. Some of the particles can be detected by the Portacount system and distort the protection level measurement. Hence, for these benchtop tests, an adapter was used to position a Scott CAP-1 CBRN filter downstream of the blower, rather than at the upstream blower inlet as the blower was designed. In this benchtop configuration, the CAP-1 filter captured particles from the air intake stream as well as any particles that leaked through blower housing seals or that were generated inside the blower. Thus, the only particles detected in the ocular and breathing zones were particles that leaked into those zones through the facepiece seals. These measurements were therefore similar to the facepiece-only tests described above, even though a final design prototype blower was used for the air movement.

These benchtop tests again showed that the CPR system facepiece with Creare's comfortable face seals provides protection levels in the ocular and breathing zones well above the minimum 2,000 protection level target for the system. Protection levels in the breathing zone were higher than for the ocular zone, which suggests the airflow to the ocular zone should be increased in future prototypes. The protection level for 170 lpm airflow was higher than for 120 lpm airflow, as expected. We also observed that the protection level suffers dramatically, especially for the low-flow ocular zone, when there are visible gaps in the facepiece seal to the face. Such gaps for these tests are associated with poor facepiece positioning on the mannikin, though as noted above, overly stiff prototype goggle materials contributed to the difficulty of consistently achieving a good fit.

5.8.4 Human LRPL Measurements

Two final CPR prototypes are currently undergoing formal protection factor testing by an independent vendor, ICS Laboratories, Inc. They are performing LRPL testing per NIOSH testing procedure no. TEB-CBRN-APR-STP-0552, "Determination of Laboratory Respirator Protection Level (LRPL) Values for CBRN Tight-Fitting Powered Air-Purifying Respirator (PAPR), Standard Testing Procedure (STP)." Eight subjects with medium face shapes are to be tested using the eleven standard exercises noted in the testing procedure. The test subjects will also be asked to provide a qualitative comfort assessment of the novel face seal design.

As noted above, materials used in the prototype blower construction can produce hazardous respirable particles when the blower is in operation. Different, nonhazardous materials will be used in the future, but the project lacked the time or resources to replace the parts near the end of the development effort when the issue was discovered. We developed an adapter component that allows the CAP-1 filter to be placed downstream of the blower (i.e., between the blower and the air hose), rather than at the upstream blower inlet as will be done in the future fielded system. The adapter sealed well to the blower, filter, and air hose; and benchtop tests confirmed the CAP-1 filter removed nearly all detectable particles from the blower airstream, rendering the airstream safe to breathe during testing. As for the benchtop tests described above, the LRPL tests performed with this filter configuration measure the protection factor of the facepiece and filter at the provided airflow rate but do not measure the sealing properties of the blower housing.

The LRPL measurements are currently pending at ICS Laboratories. We anticipate measuring LRPL for six subjects at 120 lpm flow rate and for two subjects at 143 lpm flow rate, which represent the "LOW" and "HIGH" blower settings for these prototypes with suboptimal motors and battery packs. The tests will be completed after the formal project performance period, and they will be reported in full detail to the Technical Officer when available.

5.9 SUMMARY OF RESULTS VS. OBJECTIVES

As stated in Section 4, the overall objective of Phase II is to improve comfort and respiratory protection compliance for warfighters and support personnel operating in low-hazard environments while providing high levels of respiratory protection. The CPR concepts developed and demonstrated in this Phase II project appear suitable for meeting this overall goal. The following list summarizes the results vs. the project technical objectives. As described in the following list, all of the Phase II project technical objectives listed above have been achieved or appear on track to be achieved during the final CPR system testing that is in progress.

1. High respiratory protection factor. We evaluated prototype CPR facepieces with and without comfort-modified face seals and showed in benchtop mannikin tests that at 120 and 170 lpm, the nose cup breathing zone and ocular zone provide protection levels well above the targeted level of 2,000. These results show Creare's comfortable face seals and overall facepiece design provide high-level respiratory and ocular protection. Gaps in the face seal can significantly compromise the protection level, however, so future tuning of the facepiece design and materials properties to improve fit and eliminate face seal gaps will be important for ensuring high protection levels. Standard NIOSH LRPL tests with human participants are in progress to verify these benchtop protection factor results.

2. Comfortable to wear. In-house evaluations of Creare's comfort-improving face seal modifications suggest they improve comfort over conventional rubber face seals, and the overall smaller footprint on the face appears cooler and less burdensome than conventional full-face respirators. The human LRPL fit tests in progress will provide additional feedback from independent human subjects.

3. Compact and lightweight. Estimates of the future production CPR system suggest the blower/battery package (without filter) can be as small as approximately 30 in^3 in volume and weigh 1.25 lb_m, which compare favorably to the 42 in^3 maximum size and 1.0 lb_m maximum weight goals. The 1.25 lbm weight includes excess battery capacity provided to extend operation down to low temperatures, provide an eight-hour operating time at room temperature, or enable operation at blower flow rates above roughly 170 lpm. Field-ruggedized packaging will increase the size and weight of the blower/battery system, but the volume should be able to stay under the targeted limit.

4. Long run time. The prototype blowers, electronics, and battery systems are currently configured with a COTS motor that has twice the voltage requirement compared to a future high-efficiency motor that has been selected. We did not measure the run time for the Phase II prototype CPRs that use the COTS motors because they require a larger battery system than the future production CPRs and would not be representative regarding battery lifetime. The future high-efficiency motor for a production CPR is

expected to provide roughly eight hours of run time at 120 lpm air delivery rate and four hours at 170 lpm. The run time at 120 lpm is expected to drop to just over four hours at -20°C. These values meet or exceed the four-hour minimum run time goal.

5. Produce preproduction prototype CPRs for evaluation. The project produced four final design prototype blowers and facepieces. Two of the four CPR systems have undergone in-house benchtop tests and are being used for human LRPL tests by an independent testing vendor. Two of these CPR systems will be delivered to the Army for continued evaluation.

6. Quiet operation. While not a formal project objective, the technical specification targets included a goal of blower sound levels of less than 60 dBA at the wearer's ear. Final tests of the Phase II blower prototypes demonstrated 60–61 dBA sound level at the ear and roughly 70 dBA sound level at six inches from the blower. The sound level at the ear was mostly likely radiated up from the blower itself, rather than being sound transmitted through the breathing tube or generated by airflow in the facepiece. These Phase II prototype blowers lack field packaging or sound-dampening materials. We demonstrated that a simple 1/8-inch-thick sheet of rubber placed between the blower and sound meter decreased the noise level from 70 to 60–61 dBA. This suggests there is significant room to achieve meaningful sound dampening in future production blowers when they are packaged for field use.

6 CONCLUSIONS AND RECOMMENDATIONS

Based on the work performed to date, we make the following conclusions and recommendations:

- The overall CPR system technology is on track to meet the target specifications for size, weight, operating time, protection factor, comfort, and sound level. Final human LRPL testing by independent evaluators is in progress to confirm the protection factor and comfort assessments for the Phase II CPR prototypes. In addition, while not described in detail here, several of the novel, proprietary facepiece features in Creare's prototype facepiece have been shown to be functional and beneficial. We recommend briefing the chem/bio protection community and potential CPR users on the technology concepts and capabilities to generate interest for continued prototype or product development and/or modifications to suit a particular program need. The prototypes require minor design tuning, development of field-appropriate construction materials and packaging, and development of scaled-up manufacturing capabilities.

- The current outlook is that Creare's compact, high-efficiency blower provides better flow capabilities from a smaller, lighter, more efficient system than all commercially available PAPR blowers we have identified thus far, especially when higher-pressure drops are required as for chem/bio filters. We recommend also exploring use of the blower technology for other chem/bio protection applications such as filtering air for small shelters or chem/bio garment cooling applications and use with filters with higher efficiency or higher flow resistance to reduce overall system bulk.

- The unique performance capabilities of Creare's blower technology allow operation in systems with much higher pressure losses than conventional blowers. Since the size of CBRN filters is partially determined by the need for low pressure loss, the regenerative blower will enable operation of a PAPR system with a smaller filter. Since the filter is a significant contribution to overall system size and weight, future PAPR systems using Creare's blower and an optimized filter can offer even further size and weight reductions.