

Civilian Protective System - CAPS 2000

Tamar Miller¹, Esther Krasner¹, and Uri Alon²

¹ IMOD - NBC Protection Division, Hakirya, Tel Aviv, ISRAEL
Email: nbc_pd@mod.gov.il

² DEA R&D, Merkaz Sapir, Givat Shaul, P.O.Box 35242, Jerusalem, ISRAEL

ABSTRACT

CAPS 2000 is a new concept for civilian respiratory protection against chemical and biological (CB) hazards. The system is designed as a protective hood sealed around the neck and integrated with a rigid optical visor, thus allowing an almost natural field of vision. It was designed to provide the civilian population with a reliable high protection factor and increased physiological comfort regardless of facial structure. CAPS 2000 can become an overpressure system once connected to a personal blower. As a result the levels of protection and physiological comfort during extended use are significantly improved. This configuration of the system meets the mission requirements of first responders and military personnel. The CAPS 2000 underwent various examinations and trials, including the testing of protection factor, respiratory safety and functional aspects in order to achieve the Israeli certification as an approved Israeli civilian protective respiratory system. The CAPS 2000 median protection factor was about 75,000 when 95% of the volunteers obtained protection factor above 1,000 and 79.9% over 10,000. The CAPS 2000 integrated with a 45-liter per minute blower achieved a median protection factor of 95,640 when 100% of the volunteers obtained protection factor above 10,000 and 95.2% above 50,000. In addition, the system passed the EN136 inhaled CO₂ content test successfully at the British Standard Institute (BSI). Functionally speaking, CAPS 2000 enables almost natural vision. The system underwent Snellen Eye and Macro Projection tests in order to evaluate vision acuity and the field of vision. The results had shown 20% degradation in vision acuity and 7% degradation in field of vision, meaning the system barely degraded those parameters. Furthermore, the system was functionally evaluated by the users. The system's general evaluation score was very high - 4.158 (on a scale of 1-5, 5 = Best). To conclude, the development of CAPS 2000 has produced a modular respiratory protective system which meets the rising needs for protection against CB attacks.

Keywords: CAPS 2000, CB, respirator, hood

INTRODUCTION

The government of ISRAEL is required by law to provide all its inhabitants with respiratory protection equipment against chemical and biological (CB) attack. This policy led to decades of development of protective respiratory systems designated for the civilian population. Until the Tokyo Sarin incident, Israel had prepared itself for unconventional war scenarios only. The Tokyo Sarin incident was a turning point in the world's grasp of terrorism. Conventional terrorism is dwarfed by the rising threat of non-conventional terrorist attack which may result in mass casualties. The 9/11 events have triggered the need to equip civilians with protective means to enable them a safe escape from a CB terror event site.

When seeking for a respiratory protection system for civilian population, one should take into consideration the population characteristics. A civilian population is heterogeneous, varied in gender and ages and is not accustomed with protective gear usage. Therefore there is a need for respiratory protective system which will meet the following requirements:

1. Providing high dynamic reliable protection factor regardless of gender, age, facial structure, facial hair, donning skill, etc.
2. Easy and simple to use.
3. Comfort of use for prolonged periods, allowing unobstructed user's function.

An Israeli research conducted in the beginning of the 90s (Krasner, 1995) showed that from the protective factor perspective, a respiratory protective system designed as a hood with neck sealing is significantly better than a facial mask. The effective leakage area of a protective hood is smaller, thus the effect of head motions on the obtained protection factor is less significant than in facial masks.

METHODS AND RESULTS

CAPS 2000 - Device Description

CAPS 2000 (Figure 1) is a new concept for civilian respiratory protection against CB hazards. It was designed to provide the civilian population with a reliable high protection factor and increased physiological comfort regardless of facial structure and donning skill.



Figure 1. CAPS 2000 front and rear view.

The system is designed as a protective hood composed of an impact resistant polycarbonate visor, which allows nearly natural field of vision, and a soft flexible laminate shell providing chemical protection. A flexible neck dam seals the system. A silicon nose-cup with a rigid envelop is integrated with the inner side of the visor. The system's nose-cup is tightened and adjusted upon the user's face using two fastening straps.

The CAPS 2000 is designated for users of ages 8 and above. It is manufactured in two sizes: small and large, which differs one from the other in the size of the following components: silicon nose-

cup, nose-cup rigid support, and neck dam. The system is compatible for use with personal spectacles and facial hair.

CAPS 2000 can become an overpressure system once connected to any personal blower via a NATO standard thread. As a result, the levels of protection and physiological comfort during extended use are significantly improved. This configuration of the system meets the mission requirements of first responders and military personnel.

Certification Trials

The CAPS 2000 Israeli certification was obtained after various examinations and trials, including the testing of protection factor, respiratory safety and functional aspects. All tests were conducted under the Helsinki committee for human subject trials approval. Subjects were recruited from governmental, military, municipal and public organizations and companies. The executive boards were approached first and were presented with the new product and the needed certification tests. Once they gave their consent to recruit their organization to this mission of national importance, the employees themselves were addressed. They were introduced with the relevant data and were asked to participate in the certification tests along with their families. Information leaflets were distributed alongside the presentations through which other non-employees subjects volunteered to the tests. The CAPS 2000 was examined primarily as a civilian protective respiratory system for a war scenario and secondly for terror scenario. The system was subjected to trials in Israel, USA and the UK.

Protection Factor

Protection factor is defined as the ratio between the measured aerosol concentration of the test chamber ambient air and the measured aerosol concentration inside the respiratory protection system (C_{out}/C_{in}). Fit factor was calculated for each and every exercise and is defined as the harmonic average of n protection factors measured during a certain exercise. The average fit factor is the harmonic average of m fit factors which were calculated for the different exercises.

$$FF_{\text{exercise}} = n / \sum (1/PF_i)$$

$$FF = m / \sum (1/FF_{\text{exercise}})$$

Protection factor trials were performed at the test chamber at the Israeli Institute for Biological Research (IIBR). The test system was comprised of:

1. $8 \times 3 \times 2.7 \text{ m}^3$ aerosol chamber designated for conducting protection factor trials up to 4 subjects simultaneously.
2. An ATI, Model TDA-4 aerosol generator which creates a corn-oil aerosol concentration of $25\text{--}30 \text{ mg/m}^3$ of $0.5\text{--}0.7 \mu$ mass median aerodynamic diameter (MMAD) particles.
3. An air sampling system, which samples air from the nose-cup via the mask's outer drinking tube.
4. Designated software for data accumulation, analysis and protection factor calculations.

The trials were performed upon civilian subjects. Anthropometric data was taken from them and they were given a system in a size according to their neck circumference. Continuously, the subjects were instructed how to properly don the system by the Israeli Home Front Command instructors and then were given a CAPS 2000 system to practice on and get accustomed to. Every 4 subjects completed a 10 one-minute exercises protocol after self-donning the respirator as follows:

1. Normal breathing
2. Side to side head movements
3. Up and down head movements
4. Text reading

5. Deep breathing
6. Walking
7. Up and down body bending
8. Side to side torso movements
9. Deep breathing
10. Normal breathing

Protection factors were calculated for each and every exercise and for the entire 10 exercises protocol.

Three hundred and eighty volunteers, ages 8-66, participated in the CAPS 2000 protection factor trial. The results in Table I show that CAPS 2000 provides reliable protection in dynamic conditions regardless of age, gender and system size. The median protection factor for CAPS 2000 was about 75,000, 95% of the volunteers obtained protection factor above 1,000, and 79.9% over 10,000.

Fifty nine volunteers participated in the protection factor trial of CAPS 2000 integrated with a 45-liter per minute blower. The results detailed in Table I indicate that the overpressure form of CAPS 2000 provides higher protection factors. The Overpressure CAPS 2000 median protection factor was 95,640, 100% of the volunteers obtained protection factor above 10,000, and 95.2% above 50,000.

Table I. CAPS 2000 Protection Factor

Protection Factor	CAPS 2000	Overpressure CAPS 2000 (45 lpm)
No. of subjects	380	59
Geometric average PF	31,046	87,446
Geometric standard deviation	5.06	8.76
Median PF	74,906	95,640
% above 100	Over 99	100
% above 1000	95	100
% above 10,000	Over 79.9	100

A comparison between the CAPS 2000 and the Israeli civilian facial mask (called Simplex) protection factor results shows the CAPS 2000 significant advantage over the facial mask (Table II). The two respirators were tested under the same protection factor test protocol.

Table II. CAPS 2000 and Simplex Protection Factors

Protection Factor	CAPS 2000 (n=380)	Simplex (n=45)
% above 100	Over 99	85.7
% above 1000	95	76.1
% above 10,000	Over 79.9	52.3

Physiological Tests

The CAPS 2000 underwent various tests to examine inhaled CO₂ concentrations. The system underwent the EN136 inhaled CO₂ content test at the British Standard Institute (BSI). The test apparatus consisted of a Sheffield dummy head connected to a breathing machine, a CO₂ flow-meter and a CO₂ analyzer. The breathing machine supplied 25 strokes per minute of a 2 liters stroke. The exhaled air had a content of 5% CO₂ by volume. The CO₂ content of the inhaled air was measured and recorded continuously. The test was carried out until a constant carbon dioxide content in the inhalation air was achieved. Three tests were performed upon a single CAPS 2000 system. According to the EN 136 the content of the inhalation

air (dead space) shall not exceed an average of 1% (by volume). CAPS 2000 passed the test successfully. Results are detailed in Table III.

Table III. CAPS 2000 Inhaled CO₂ Content - EN136 Test

CO₂ average (by volume)	
Trial 1	0.07%
Trial 2	0.12%
Trial 3	0.27%

In addition, the CO₂ inhaled content was tested upon various human subjects cohorts, ages 8-66, in 4 separate trials. The trials were performed upon both civilian and military subjects. Anthropometrical data was taken from the subjects and they were given a system in a size according to their neck circumference. Continuously, the subjects were instructed how to properly don the system by the Israeli Home Front Command instructors and then were given a CAPS 2000 system to practice on and get accustomed to. Every subject self-donned an inhaled CO₂ trial designated system at the appropriate size and was connected to a Datex oxymeter capnograph. The air within the nose-cup near the subject's mouth was sampled. The trials differed slightly one from the other in the required exercise protocol. Most of the trials were as follows: each subject performed a 15 minutes protocol after self-donning the respirator as follows:

1. Normal breathing while seated - 5 minutes.
2. Up and down head movements, while standing - 1 minute.
3. Side to side head movements, while standing - 1 minute.
4. Up and down body bending, while standing - 1 minute.
5. Text reading, while standing - 1 minute.
6. Deep breathing, while standing - 1 minute.
7. Normal breathing while seated - 5 minutes.

Table IV describes the subjects' percentage for whom an inhaled CO₂ concentration over 2% and 3% was measured during momentary peaks of one consecutive minute.

Table IV. CAPS 2000 Inhaled CO₂ Content - Human Trials

Inhaled CO₂ concentration (1 consecutive minute)	Test № 1 (n=237)	Test № 2 (n=394)	Test № 3 (n=131)	Test № 4 (n=109)
Over 2%	19.4%	9.1%	5.3%	11%
Over 3%	8.9%	4.6%	3.8%	3.7%

These results emphasize the difficulties of human trials and their distinction from breathing machine trials. The human trials show dynamism in the breathing gases concentrations due to influences of speech, breathing regime changes, mask's movements upon the subjects' face etc. Those trials stressed the need for an accurate donning instruction which includes dynamic donning adjustments should the mask's fastening upon the user's face become looser due to various activities.

As a result of these trials, the CAPS 2000 system and product instructions were improved in the following manners:

- Harnessing system improvement and straps shortening in order to reach preliminary straps tension.
- Addition of a special indicator to feedback correct donning.
- Instruction method improvement.

Functional Evaluation

The CAPS 2000 underwent Snellen Eye and Macro Projection tests at the U.S. Army Edgewood Chemical Biological Center as part of collaboration with the Technical Support Working Group, USA. The system underwent visual acuity test using Snellen Eye Test charts. Six male subjects were asked to identify and read aloud the smallest line of letters that they were able to see with and without wearing the CAPS 2000. This process was repeated until each subject identified all the letters on the same line on a minimum of three Snellen Eye Test charts. The results had shown 20% degradation in vision acuity (visual acuity scores with and without CAPS 2000 were the same for 5 out of 6 subjects).

The field of vision was tested according to EN136:1989 using the Macro Projection test. The test apparatus consisted of a manikin headform and a graduate spherical hemisphere. The headform had two light bulbs installed instead of two eyes with 67 mm distance between the bulbs' centers. Upon fitting the respirator to the headform, the lights were illuminated. The light projected through the system's visor onto the graduate hemisphere and the outline of the projected light was graphed on a scoring grid along each of the 36 meridians within the hemisphere. Three tests were conducted using two CAPS 2000 systems. The results showed 7% degradation in field of vision. These tests indicate the system barely degrades the vision acuity and enable a normal field of vision during wear.

In addition, during the protection factor trials and inhaled CO₂ content human trials the subjects evaluated the system's comfort, considering different parameters such as donning and doffing comfort etc. The CAPS 2000 was functionally highly evaluated. The system's general evaluation score was significantly high - 4.158 (In a scale of 1-5, 5 = Best).

Table V. CAPS 2000 - User's Evaluation

Parameter	CAPS 2000 (n=380)	Israeli Civilian Facial Mask (n=45)
Donning Comfort	4.1±0.8	3.4±0.8
General Comfort	4.0±0.8	2.6±1.0
Removal Comfort	4.4±0.7	4.3±0.7
Vision	4.6±0.6	2.8±1.0
Breathing	4.3±0.8	3.4±1.0
Speech	3.5±1.0	2.5±1.0
Pressure upon the face	4.3±0.9	3.0±1.5

CONCLUSIONS

In summary, the development of CAPS 2000 has produced a modular multi purpose respiratory protective system which meets the rising needs for protection against CB attacks. The system in its passive and the overpressure forms supplies a high protection factor alongside physiological comfort regardless of age, gender, and facial structure. It enables almost natural vision and was functionally highly evaluated by the users.

The system has joined a large series of respiratory protection systems for civilians in Israel and thanks to it's modularity can be used by a large variety of users in both war and terror scenarios:

1. The CAPS 2000 - passive form - can be used by the civil population as a respiratory protective system under war scenarios and as an escape hood under terror scenarios.

2. The Overpressure CAPS 2000 can be utilized by civilians, first responders, security personnel, hospital staff etc. using different kinds of blowers in accordance with the required air supply.

The CAPS 2000 is designated to gradually replace the facial masks as a respiratory protection system for civilians, first responders and military personnel in ISRAEL.

ACKNOWLEDGEMENT

The authors would like to thank the following organizations for providing assistance in this study: (1) BSI Product Service, Mayland Avenue Hemel Hempstead Hertfordshire HP2 4SQ UK; (2) Technical Support Working Group (TSWG), 1111 Jefferson David Highway Suite 116, Arlington VA 22202, USA; and (3) Edgewood Chemical Biological Center (ECBC), Aberdeen Proving Ground, Edgewood, MD, USA.

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