PPE CASE

Personal Protective Equipment Conformity Assessment Studies and Evaluations

Point-of-Use Assessment of Emergency Escape Breathing Devices for the U.S. Navy

Sample Period: 2010-2014

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The National Personal Protective Technology Laboratory (NPPTL)[1], a laboratory within the National Institute for Occupational Safety and Health (NIOSH) in Pittsburgh, Pennsylvania, conducts post-market activities as part of its conformity assessment framework. Post-market activities involve gathering evidence of conformity in the marketplace or at the place of use. Workers are more likely to appropriately use personal protective equipment (PPE) when they are confident that the equipment will provide the advertised protections based on its conformance with applicable standards (D'Alessandro et al.).

NIOSH recommends compliance with manufacturer-specified requirements. Proper storage and visual inspection practices are crucial to the safe use of Emergency Escape Breathing Devices. Any apparatus that fails the visual inspection should be removed from service.

Emergency escape breathing devices (EEBDs) are used by the Navy during emergencies to support escape from atmospheres that can be immediately dangerous to life and health. An EEBD is a single use apparatus in which the wearer's exhalation is rebreathed after the carbon dioxide (CO_2) in the exhaled breath has been effectively removed and a suitable oxygen (O_2) supply has been restored from a source within the device (e.g., compressed, chemical, or liquid oxygen). The Navy used Ocenco's M-20.2 as one of its EEBDs and has purchased more than 400,000 units since 1998 for use on naval ships. It is essential to ensure that these devices continue to provide protections under typical storage and environmental conditions.

This report details NIOSH's tests and evaluations of EEBD units sampled from the naval fleet from 2010 to 2014 and makes conclusions regarding the device's ability to endure the environments in which they are deployed in regard to storage conditions, physical damage, and the effects of aging.

[1] A list of acronyms and abbreviations is available in **Appendix A**.

What NIOSH Did to Protect the Worker?

NIOSH evaluated multiple samples of the U.S. Navy's deployed Ocenco M-20.2 EEBDs at the request of the U.S. Navy to determine if the sampled devices performed in accordance with their rated service time, consistent with the approval requirements for EEBDs. From 2010 to 2014, an annual sample of Ocenco M-20.2 EEBDs was delivered to NIOSH for evaluation by the Naval Sea Systems Command (NAVSEA)[2]. All units collected and tested during these evaluations were approved by NIOSH and the Mine Safety and Health Administration (MSHA) to be manufactured and sold in accordance with the requirements of Title 42, Code of Federal Regulations, Part 84 (42 CFR, Part 84), Subpart H.

NIOSH subjected all EEBDs to the manufacturer's recommended visual inspection procedures. The intent was to permit only units that passed the visual inspection into the evaluation. Because these EEBDs are single-use devices, visual inspections are the primary method by which devices that may not be protective are identified and removed from service. EEBDs failing inspection, or not in compliance with the manufacturer's conditions for storage and use, no longer meet the NIOSH/MSHA approval and must be removed from service. The visual inspection criteria included the evaluation of heat and humidity indicators, oxygen supply pressure gauges, verification of the service time date, assurance that the case seal was intact, and visual assessment of physical indications of wear or damage.

Upon passing the visual inspection at NIOSH, all EEBD units were subjected to a series of tests and evaluations to obtain evidence of conformance to 42 CFR, Part 84, Subpart H. The ***post-market*** tests conducted as part of this point-of-use assessment were ***not*** performed as part of the Subpart-H approval process. Rather, these already approved EEBD units were subjected to a series of tests to demonstrate whether these devices continue to meet approval requirements after being exposed to the Navy's storage/use conditions.

Ocenco M-20.2 Characteristics

The Ocenco M-20.2 (Figure 1) is NIOSH-approved (TC-13F-0386) under 42 CFR Part 84 Subpart H and has an approved service time of 10 minutes. The unit has a compressed oxygen cylinder and a lithium hydroxide (LiOH) CO_2 scrubber (Lara et al.). It uses the LiOH chemical bed to reduce CO_2 to within acceptable limits.

As supplied from Ocenco, the one-time-use device is compactly stored in a tightly sealed, hard plastic case contained within a larger orange protective plastic case. Units left inside the orange case are stored throughout naval ships in metal lockers or brackets and are referred to as "shelf-stored." Belt loops on the inner hard case allow the device to be removed from the orange case and carried on a belt. Until August 2005, personnel working in a ship's main space could carry these belt-worn units.

[2] Naval Sea Systems Command (NAVSEA) Damage Control/Fire Protection/Chemical and Biological Defense Branch.

Figure 1. Ocenco M-20.2 EEBD

Storage conditions for the M-20.2 should not exceed a minimum temperature of 4°F (-20°C) or exceed a maximum temperature of 149°F (65°C). The M-20.2 has a service life of 15 years from the date of manufacture when the proper conditions of use are followed. If the M-20.2 is belt-worn, it must be returned for factory service after five years. When shelf-stored, the M-20.2 can remain in service for 15 years without factory service.

Sampling and Collection Strategy

Per the Memorandum of Understanding (MOU) with the Navy, all collection efforts were carried out by the Navy and the selected EEBD units were delivered to NIOSH in Pittsburgh, Pennsylvania. Prior to delivery to NIOSH, Navy personnel performed the manufacturer's recommended visual inspection on all candidate EEBD units. Only units passing the visual inspection were removed from Navy ships and selected for each sample. At the time of project initiation and collection, NAVSEA did not have a serial number database to generate a random sample; therefore, such a strategy would have been extremely costly and logistically impossible due to the Navy fleet being deployed around the world.

Due to the inability to conduct a true random sample of the Naval M-20.2 EEBD population, a random sample characterization was not the intent of this study. Rather, the intent was to evaluate the EEBDs in the Naval population and identify any observed non-conformances for correction or mitigation. The total sample size per collection was calculated to be evenly divided between ships identified for sampling. NIOSH's criteria is that the sample size should provide a 95% (95.2%) probability of detecting at least one failure in any approval if the true failure prevalence is 3% or greater. This yielded a required sample size of 100 + 20% units for each collection phase. The 20% oversample rationale was used in order to achieve the target of 100 valid data points for each of the four samples collected included in this evaluation.

Table 1 lists a summary of M-20.2 EEBDs collected by NIOSH for testing during each sample collection and the number of units passing the visual inspection criteria by NIOSH personnel. Although all EEBD units underwent an initial visual inspection by Navy personnel prior to being delivered to NIOSH, factors such as delivery and the individual expertise levels of personnel administering the visual inspection may have contributed to some EEBDs not passing visual inspection at NIOSH.

Table 1. Summary of Collection Samples 1-4

EEBD Model	Sample	Targeted	Collected	Passed Visual Inspection at NIOSH Test Laboratory	ABMS Tested	Valid ABMS Test Data	Human Subject Sample	Valid Human Subject Test Data
Ocenco M-20.2	1	100	106	106	94	94	12	12
Ocenco M-20.2	2	100	137	136	125	125	12	11
Ocenco M-20.2	3	100	110	109	97	90	12	10
Ocenco M-20.2	4	100	108	107	95	95	12	10
Totals	**-**	**400**	**461**	**458**	**411**	**404**	**48**	**43**

Tests and Evaluations

The following tests and evaluations were conducted on each EEBD unit obtained by NIOSH: (1) manufacturer's recommended visual inspection; (2) phenolphthalein indicator check; (3) quantitative leak test; (4) oxygen flow test; and (5) either a human subject test (Man Test 1)[3] or (6) automated breathing metabolic simulator (ABMS) test. The first five tests are standard pre-market tests or evaluations that NIOSH conducted for devices submitted for Sub-part H approval. After the approval was granted for the units tested in this study, NIOSH updated its requirements for closed-circuit devices [Sub-part O & REF]. The updated approval requirements now include a majority of ABMS testing in addition to several human subject tests. A major advantage of ABMS testing is that it allows the functionality of the tested units to be stressed towards the high end of their life support capabilities. It is important to note that, although human-facilitated results and machine results are similar, they are not to be considered a direct equivalent.

NIOSH assessed when an EEBD unit did not (1) pass the manufacturer's recommended visual inspection, (2) meet the quality control requirements of 42 CFR Part 84.41, or (3) meet its rated duration, to determine if any further action was warranted.

Visual Inspection

NIOSH personnel performed a visual inspection of each Ocenco M-20.2 EEBD according to the manufacturer's recommended visual inspection procedure prior to laboratory testing (ABMS and human subject tests). The EEBD case was inspected for any damage including cracks, burns and/or excessive wear. The units' security latch, seal, and packaging were evaluated for integrity, dust or dirt, and/or damage. Belt loops were inspected for any damage and structural integrity. The oxygen level for each EEBD was recorded and evaluated as well. Any damage or defect discovered during the visual inspection was documented. Damage to the case, missing case latches, broken seals allowing contaminant penetration, excessive heat exposure, moisture penetration into the case, or low O_2 gauge pressures were reasons for a unit to fail the visual inspection.

[3] Human subject testing for each sample collection comprised 10-12 EEBD units. Protocol 12-NPPTL-04.

If all visual inspections passed, the EEBD was considered safe for use and tested. Because units failing to meet the prescribed limits for these indicators when inspected must be taken out of service, NIOSH removed all EEBD units that failed the visual inspection from the evaluation. Exterior areas of each EEBD unit examined during the visual inspection are highlighted in Figure 2.

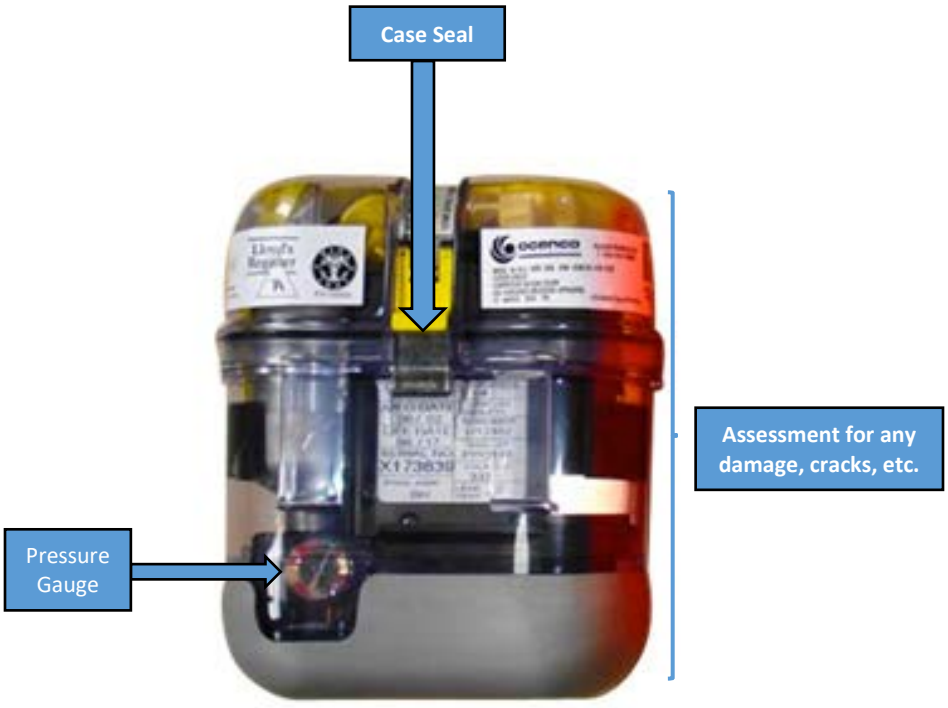

Figure 2. Areas of Visual Inspection for Ocenco M-20.2 EEBD

Phenolphthalein Indicator Check

Upon opening the EEBD case, each mouthpiece and inner portion of the breathing tube was wiped with a cotton swab soaked in phenolphthalein. This action indicated whether the granular chemical sorbent had broken down and entered the breathing circuit where it could be inhaled by the user. If the phenolphthalein-soaked cotton swab turned pink, that indicated the presence of chemical sorbent in the breathing zone of the EEBD.

Quantitative Leak Test

EEBDs that passed the visual inspection check proceeded to the quantitative (QNT) leak test. This test assesses breathing circuit integrity, but is not required for NIOSH approval. The leak test uses an exhaust blower to induce a vacuum of -300 mm H_2O within the EEBD breathing circuit while measuring the inward leakage rate with a mass flow meter. Inward leakage rates should be <500 ml/min. to assure user protection for a period equal to or greater than the rated service time.

This test is used during pre-market and post-market evaluations to quickly affirm the absence of leaks in the breathing circuit before investing resources to conduct full tests on the unit. High leak rates measured during QNT testing indicate that the breathing circuit has been compromised.

A compromised breathing circuit could result in exposing the user to a hazardous environment or could reduce the service time provided to the user.

To seal the EEBD to the ABMS trachea, a mouthpiece connector shaped as closely as possible the internal dimensions of the EEBD mouthpiece opening was used. Custom fabrication of these mouthpiece connectors to match the EEBD mouthpiece opening is required to optimize the fit and prevent the connection from being a source of inward leakage. Putty is used as necessary to enhance the seal and stop any residual leakage.

Oxygen Flow Test

After assessing the breathing circuit integrity, NIOSH personnel checked the O_2 constant-flow rate on some units for the first collection sample only. The required flow rate is 1.5 L/min at ambient temperature and pressure (altitude unspecified) dry (ATPD). Measuring the O_2 constant-flow rate uses some O_2 in any compressed-O_2 apparatus. On the M-20.2 unit, once the O_2 flow is activated, it cannot be turned off. In addition, the difficulty of measuring O_2 flow with a flexible component (breathing bag) between the M-20.2 O_2 cylinder and the flow meter requires extra time for a stable reading, which partially exhausts the small quantity of O_2 in the cylinder (approximately 23 L at standard temperature and pressure dry). Therefore, while NIOSH performed this test on units from the first sample, it was not performed for the three subsequent sample collections due to the expenditure of oxygen and potential impact it would have on ABMS test durations and data.

Automated Breathing and Metabolic Simulator (ABMS) Tests

The computer-controlled ABMS (Figure 3) produces CO_2 and simulates O_2 consumption at fixed breathing frequencies and tidal volumes to simulate human metabolic processes (Deno, 1984 and Kyriazi, 1986). The ABMS machine is an ideal device for evaluating inhaled CO_2 and O_2 concentrations in EEBDs due to its high degree of accuracy and repeatability in duplicating human CO_2 production and O_2 consumption. By design, an ABMS replicates breathing ventilation (i.e., respiratory frequency, tidal volume, flow, temperature, and humidity), O_2 consumption, and CO_2 production. An ABMS produces human respiratory air qualities at approximately 33°C and saturated with water vapor. Due to its complexity, an ABMS is managed by a computer program. The computer uses a routine of energy expenditures (protocol) to make adjustments and provide measurements of respiratory gas concentrations, pressures, and temperatures.

Figure 3. Automated Breathing and Metabolic Simulator

NIOSH personnel tested the EEBDs on the ABMS using a constant average metabolic work rate (Table 2). All ABMS tests were conducted to endpoints under constant operating conditions. During testing, the ABMS continuously monitored metabolic stressors which included inhaled levels of CO_2 and O_2, wet- and dry-bulb temperatures, and inhalation and exhalation breathing resistances (pressures) until the test was terminated. Tests on the ABMS are terminated upon one of three endpoints: (1) exhaustion of the O_2 supply as indicated by inhalation pressures reaching -200 mm H_2O, coinciding with an empty breathing bag; (2) average inhaled CO_2 levels exceeding 10%; or (3) O_2 levels falling below 15%. When these limits are exceeded, the ABMS gas metabolism is compromised and further data are not acceptable for analysis. Peak breathing pressures of -300 and +200 mm H_2O have been identified as the outer limits of what is humanly tolerable based on research conducted at Penn State's Noll Laboratory (Hodgson, J). Breathing resistances measured for all EEBDs tested were within these limits.

Table 2. Constant Average Metabolic Work Rate

Metabolic workload	Rate
O_2 Consumption	1.35 L/min.
CO_2 Production Rate	1.15 L/min.
Ventilation Rate	30 L/min.
Tidal Volume	1.68 L/breath
Respiratory Frequency	17.9 breaths/min.
Peak Respiratory Flow Rate:	
Peak Inhalation	89 L/min.
Peak Exhalation	71 L/min.

Human Subject Testing

Human subjects may differ from each other and from the ABMS in terms of CO_2 production rate, ventilation rate, and respiratory frequency. Therefore, because these parameters affect apparatus duration as well as all of the monitored stressors, treadmill tests cannot be considered equivalent to the ABMS tests, even though the O_2 consumption rate is the same. However, the ABMS can be used to provide an indication of EEBD duration performance. Thus, in addition to the ABMS tests, some human subject testing was conducted as well.

For each annual sample of EEBDs collected, approximately 10-12 were used for human subject testing. Human subject testing used a NIOSH standard test procedure (STP): STP RCT-ASRS-STP-0140. This STP was selected, because it uses interval sampling rather than continuous sampling. Interval sampling was deemed sufficient for these post-market tests, because the intent was to verify continued conformance rather than provide an initial validation of performance. NIOSH monitored stressor levels at specified intervals per NIOSH STP RCT-ASRS-STP-0140. During testing using the Man Test 1 protocol for 10-minute units, stressors were sampled at specified intervals, whereas stressors are sampled continuously during some STP protocols during NIOSH approval testing. The Man Test 1 sequence of activities contained in STP RCT-ASRS-STP-0140 can been seen in Table 3.

Table 3: Man Test 1 Standard Test Procedure for 10-minute units

Activity	Time (min.)
Walks 3.0 mph on treadmill	3
Sampling and Readings	2
Walks at 3.0 mph on treadmill	3
Sampling and Readings	2

Monitored stressors during human subject testing and their acceptable ranges can be seen in Table 4. The full range of human subject approval tests were not utilized for this project due to the previously stated differences in the purpose and scope of post-market and approval testing. Prior to conducting any human subject testing, all test subjects received training on how to properly don and doff the Ocenco M-20.2 EEBD per the manufacturer's instructions.

Table 4: Monitored Stressors and Acceptable Ranges

Stressor	Acceptable Range Operating Average	Acceptable Excursion Range
Average Inhaled CO_2	<1.5%	≤4%
Average Inhaled O2	>19.5%	≥15%
Peak Breathing Pressures	$\Delta P \leq 200$ mm H_2O	$-300 \leq \Delta P \leq 200$ mm H_2O
Wet-Bulb Temperature	<43°C	≤ 50°C

Data Analysis on Stressor Test Data

During testing, the ABMS monitored metabolic stressors which include inhaled levels of CO_2 and O_2, wet- and dry-bulb temperatures, and inhalation and exhalation breathing resistances (pressures) continuously until the test was terminated. Tests on the ABMS are terminated upon one of three endpoints: exhaustion of the O_2 supply as indicated by inhalation pressures reaching -200 mm H_2O, coinciding with an empty breathing bag; average inhaled CO_2 levels exceeding 10%; or O_2 levels falling below 15%. When these limits are exceeded, the ABMS gas metabolism is compromised and further data are not acceptable for analysis.

NIOSH averaged the minute average values of the stressors monitored during the ABMS testing of each EEBD over its rated service time in order to normalize test performance results. Use of full test duration results introduces stressor data variances that prevent valid comparisons between individual tests. NIOSH plotted all stressor data as a function of EEBD manufacturing date in order to draw out deployment time effects.

All average stressor data from the testing of deployed units were averaged to obtain a composite average for comparison. NIOSH tabulated this information, along with stressor minimums and maximums for each set of tests, to assess the deployed units' performance. Human subject testing stressor data was not averaged in the same manner as ABMS results due to the intermittent monitoring that is performed during Man Test 1. Wet-bulb thermocouple data indicates average wet-bulb temperature over full inspired breath in degrees Celsius (C°).

What Did NIOSH Find?

ABMS and Human Subject Testing Summary of Results

The term "sample" is defined as each annual collection of Ocenco M-20.2 EEBDs delivered to NIOSH.

Table 5: Sample 1-4 ABMS Data

Sample	Phenolphthalein Indicator Check	Quantitative Leak Test	O_2 Flow Test	ABMS Testing
1 (n=94)	8 of 94 (8.5%) showed presence of alkaline material	0%	1 of 94 (1%) exhibited low flow	13 of 94 (14%) exhibited CO_2 levels of ≥4%
2 (n=125)	0% failed	0%	N/A	2.4% (3 units) exhibited average inhaled CO_2 results ≥ 4%. 9.6% (12 units) had CO_2 breakthrough times ≥4% before O_2 expenditure
3 (n=97)	1 out of 97 (1%) positive phenolphthalein	1 out of 97 (1%)	N/A	2 out of 97 (2%) failed (stuck breathing bags)
4 (n=95)	0% failed	0%	N/A	2 out of 95 (2.1%) failed to meet their rated service life

Table 6: Sample 1-4 ABMS Average (Avg.) and Standard Deviation (SD)

Sample	Duration (Min.)	Average Inhaled CO_2 (%)	Average Inhaled O_2 (%)	Average Inhaled Pressure (mmH_2O)	Average Exhaled Pressure (mmH_2O)	Inspired Wet Bulb Temperature (C)
1 (n=94)	Avg: 16.7 SD: ± 1.17	Avg: 1.56 SD: ± 0.468	Avg: 42.9 SD: ± 9.87	Avg: -57.3 SD: ± 8.71	Avg: 32.3 SD: ± 2.81	Avg: 42.5 SD: ± 1.33
2 (n=125)	Avg: 17.0 SD: ± 1.24	Avg: 1.42 SD: ± 0.52	Avg: 39.5 SD: ± 7.02	Avg: -59.7 SD: ± 16.1	Avg: 31.5 SD: ± 4.37	Avg: 44.1 SD: ± 1.04
3 (n=97)	Avg: 17.8 SD: ± 1.88	Avg: 1.71 SD: ± 0.55	Avg: 38.9 SD: ± 6.71	Avg: -60.3 SD: ± 16.1	Avg: 33.7 SD: ± 3.29	Avg: 43.6 SD: ± 1.23
4 (n=95)	Avg: 15.3 SD: ± 1.44	Avg: 0.98 SD: ± 0.26	Avg: 55.9 SD: ± 3.05	Avg: -67.8 SD: ± 22.5	Avg: 32.9 SD: ± 9.84	Avg: 40.2 SD: ± 1.79
Controls (n=4)	Avg: 18.5 SD: ± 1.10	Avg: 1.86 SD: ± 0.31	Avg: 45.2 SD: ± 4.32	Avg: -53.7 SD: ± 7.04	Avg: 32.7 SD: ± 3.77	Avg: 46.2 SD: ± 0.17

Human Subject Testing Summary of Results

Table 7: Sample 1-4 Human Subject Testing Data

Sample	Phenolphthalein Indicator Check	Man Test 1	Man Test Stressor Data
1 (n=12)	0% failed	0% failed	0% failed
2 (n=12)	0% failed	0% failed	0% failed
3 (n=12)	1 out of 12 (8.3%) showed alkaline presence, not tested.	0% failed	0% failed
4 (n=12)	0% failed	1 out of 12 (due to high temp., successfully re-tested)	0% failed

Sample 1 Summary of Results

During the first sample only, four new units were used as controls. The minute-average values of the monitored stressors were averaged over the entire test duration. The values for new units can be compared with those for deployed units. It should be noted that the O_2 flow rates of new units were not measured resulting in slightly higher durations than deployed units in which the O_2 flow rates were measured.

Eight of 94 apparatus (8%) tested on the ABMS showed evidence of alkaline material, which could be an indication of LiOH in the mouthpiece. These units were tested on the ABMS with normal results. Whether or not this would have elicited coughing from users is unknown. One apparatus had very low O_2 flow rates from both the regulator and the demand valve indicating the apparatus could have been used only at a sedentary work rate. NIOSH opened a Certified Product Investigation Process (CPIP) and sent the apparatus to the manufacturer for examination. Ocenco conducted a subsequent investigation and determined the root cause to be an issue with the demand seat being improperly adhered to the demand pin, which prevented airflow when the demand pin was engaged. Ocenco found zero failures when testing demand flow function of 1,777 units manufactured between 1997 and 2010 that were returned for factory service. Additionally, Ocenco stated they have not received reports of this issue from end users.

Average inhaled CO_2 reached > 4.0% before O_2 depletion in 13 of the ABMS-tested apparatus (14%) with test-end CO_2 values ranging up to 6.8%. All 12 of the apparatus tested on human subjects performed with no problems and no evidence of alkaline dust was found.

Sample 2 Summary of Results

NIOSH tested 125 M-20.2 units on the ABMS. None of the 125 EEBD units tested at the ABMS failed the visual inspection criteria. One unit out of 12 received for human subject testing was not tested due to a visual inspection failure as a result of a low-pressure indication on the oxygen gauge. Therefore, only 11 units were tested using human subjects performing the Man Test 1 protocol during sample 2.

One unit was only run on the ABMS for nine minutes due to a malfunction of the ABMS and not the unit. Out of the 125 units tested during this sample, 15 units experienced CO_2 breakthrough times prior to the expenditure of their O_2 supply. Of the 15 units that experienced CO_2 breakthrough times, only one unit had a breakthrough time (8 minutes) before the required service time of 10 minutes.

Sample 3 Summary of Results

Of the 110 units collected in sample 3, NIOSH tested 97 on the ABMS machine and 12 were set aside for human subject testing, of which 10 were used. One unit set aside for human subject testing displayed alkaline presence in the mouthbit and one unit had an “over pressurized” case. These units were not tested and set aside for future evaluation. Of the 97 ABMS tests completed, data could not be collected for 7 units and, therefore units were not included in the final data set.

Overall, five of the 97 units tested on the ABMS did not meet their rated service life. Three due to packaging issues and two due to the breathing bags remaining in a folded position.

Three units tested on the ABMS during the third sample collection had breathing bags that were stuck in the folded position upon activation (See Figure 4). This caused the O_2 supply to deplete faster. Two of the three units that displayed stuck breathing bags failed to meet their rated service life of 10 minutes. Final results showed that 90 of the 97 units for which NIOSH evaluated and recorded data had normal results and would have provided a minimum of 10 minutes of lifesaving capacity. All 10 units tested using the Man Test 1 protocol yielded results within monitored stressor parameters and would provide a minimum of 10 minutes lifesaving capacity.

Figure 4. Front view of Ocenco M-20.2 breathing bag stuck in folded position

Sample 4 Summary of Results

For the fourth collection sample, 108 Ocenco M-20.2 EEBDs were delivered to NIOSH. One unit failed visual inspection due to a damaged security latch and was not tested on the ABMS. NIOSH tested 95 units on the ABMS and 12 were set aside for human subject testing. Two out of the 95 units tested on the ABMS did not meet their rated service life. One unit was terminated on the ABMS at a duration of eight minutes due to a continuous high inhalation pressure of approximately -195 mm of H_20 throughout the test in addition to the inhaled CO_2 rapidly climbing and reaching 6.62%. Visual inspection notes state, “Upon bench evaluation immediately following ABMS test termination, the demand pin would not manually activate when O_2 still remained in the cylinder.” The deployment conditions of this unit were unknown at the time of testing. A second unit ran for a duration of six minutes on the ABMS and the test was terminated due to high inhalation pressure (-327.882 mm H_2O). Ten units tested with human subjects using the Man Test 1 protocol yielded results within the monitored stressor parameters.

What CASE Conclusions Did NIOSH Make?

Throughout all four sample collections, a total of 28 of the 404 (6.9%) EEBD units for which valid ABMS test data was obtained exhibited average inhaled CO_2 levels > 4% prior to the expenditure of their O_2 supply. An excursion limit of 4.0% is physiologically tolerable for brief periods, but longer durations have been shown to illicit physiological effects such as impaired decision-making (Kamon, E.). NIOSH recognized this potential hazard and new 42 CFR, Part 84 Subpart O regulations for all closed-circuit escape respirators (CCER) sold after January 4, 2018 prohibit approval of an apparatus that operates with inspired CO_2 levels above 4.0%. CCER units fail this test and approval if from test start-up to oxygen depletion the one-minute average inspired $CO_2 \geq 4.0\%$. All M-20.2 units tested using human subjects performed in accordance with their rated service time and monitored stressor ranges.

While only three out of 461 (.65%) of the EEBDs collected by NIOSH did not meet the visual inspection criteria, Navy personnel should continue to inspect their units every two years in accordance with Navy protocols to ensure units not meeting visual inspection criteria are removed from service. Breathing resistance measured for all EEBDs tested were well within limits accepted as tolerable (-300 and +200 mm H_2O) based on research conducted at Noll Laboratory at Penn State University (Kamon, E.). No definitive trends for other stressors were identified with respect to deployment time or storage conditions.

Inhaled O_2 levels are sensitive to N_2 imbalances in and in-leakage of air into the ABMS breathing circuit. Variabilities of inhaled O_2 levels measured for all deployed unit tests may be partially attributable to these sensitivities. NIOSH did not identify definitive trends in other stressors as a function of deployment time. This is an indication that the units tested were largely unaffected by deployment time.

This evaluation was limited to a convenience sample of EEBDs collected by the Navy and provided to NIOSH. The findings were limited to the samples received as random EEBD sampling was not possible.

Actions the PPE Community May Take to Further Protect Workers

NIOSH recommends compliance with manufacturer-specified EEBD requirements and instructions. Proper storage and visual inspection practices are crucial to the safe use of these apparatus. Any apparatus that fails the visual inspection should be removed from service.

Actions the PPE Users, Selectors, and Purchasers May Take to Further Protect Themselves and Others from Hazards

Sign up for NPPTL's Listserv at https://www.cdc.gov/niosh/npptl/sub-NPPTL.html to receive email notifications relevant to PPE. Users should familiarize (or re-familiarize) themselves with the manufacturer's visual inspection criteria, donning instructions, and should perform routine inspections of units—this is the primary way to ensure that units will function as intended.

Appendix A: Acronyms and Abbreviations

ABMS	Automated Breathing and Metabolic Simulator
CO_2	Carbon Dioxide
CFR	Code of Federal Regulation
CPIP	Certified Product Investigation Process
EEBD	Emergency Escape Breathing Device
LIOH	Lithium Hydroxide
MSHA	Mine Safety and Health Administration
N_2	Nitrogen
NAVSEA	Naval Sea System Command
NIOSH	National Institute for Occupational Safety and Health
NPPTL	National Personal Protective Technology Laboratory
O_2	Oxygen
PPE	Personal Protective Equipment
SD	Standard Deviation
QNT	Quantitative Leak Test
VCO_2	Volume of Carbon Dioxide
VO_2	Volume of Oxygen

Unit of Measure Abbreviations

breaths/min	breaths per minute
L	liter(s)
L/breath	liter(s) per breath
L/min.	liter(s) per minute
mm	millimeter(s)
mm H_2O	millimeter(s) of water pressure
%	percent

Acknowledgements

Thanks are extended to the Naval Sea System Command, Navy Experimental Diving Unit (Panama City, FL), Ocenco, and NIOSH personnel that supported and continue to support the long-term field evaluation of EEBDs on U.S. Navy ships and in U.S. underground coal mines. The author gratefully acknowledges Bob Stein, Courtney Neiderhiser[4], Nicholas Kyriazi[4], and John P. Shubilla[4] for their contributions to the Navy Long-Term Field Evaluation Project that include project development, arranging unit collections, testing and analysis of EEBDs.

The following additional NIOSH NPPTL personnel are acknowledged for their contributions in providing assistance with developing this report:

Marisa Fries and Susan Moore for their editorial support.

All photos courtesy of NIOSH NPPTL.

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Suggested Citation

NIOSH [2018]. PPE CASE: Point-of-Use Assessment of Emergency Escape Devices for the U.S. Navy. By Andrew Palmiero. Pittsburgh, PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, NPPTL Report Number P2018-0105.