PPE CASE



Personal Protective Equipment Conformity Assessment Studies and Evaluations

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

Evaluation Period: 2022-2023

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Date: April 25, 2026

This report details the results for visual inspection and performance testing of 158 west coast deployed Ocenco M-20.2 and M-20.3 emergency escape breathing devices (EEBDs) and 66 reference EEBDs stored in a U.S. Navy warehouse. This testing occurred between 2022 and 2023.

The National Personal Protective Technology Laboratory (NPPTL)[1], a laboratory in the National Institute for Occupational Safety and Health (NIOSH), conducts post-market evaluation activities as part of its conformity assessment framework. ***Post-market evaluations include the process of gathering evidence of conformity in the marketplace or at the place of use. One such post-market activity is NIOSH's Navy Long-Term Field Evaluation (NLTFE) Program.***

The NIOSH NLTFE Program provides performance, reliability, and user-maintenance compliance data at the point of use for NIOSH Approved® closed-circuit escape respirators (CCERs). In military settings, these CCERs are typically referred to as EEBDs.

EEBDs are single use apparatus in which the wearer's exhaled breath is rebreathed after carbon dioxide (CO_2) has been effectively removed and a suitable oxygen (O_2) supply has been restored from an O_2 source within the EEBD (e.g., compressed, chemical, or liquid O_2). ***EEBDs manufactured by Ocenco are primarily used by the U.S. Navy and other industries during emergencies to support escape from potentially immediately dangerous to life and health (IDLH) atmospheres. Since 1998, the U.S. Navy has purchased more than 780,000 Ocenco M-20.2 and M-20.3 EEBDs for use on naval ships.***

NIOSH found that 88 of 158 ship-deployed EEBDs and 46 of 66 reference EEBDs failed due to exceeding either,
(1) the full-test average inspired CO_2 limit ($\geq$1.50%),
(2) the one-minute inspired CO_2 excursion limit ($\geq$4.0%),
(3) the full-test average inspired wet bulb temperature limit ($\geq$43°C), or
(4) the one-minute inspired wet bulb temperature excursion limit ($\geq$50°C), or a combination of exceeding two, three, or four of these limits simultaneously.

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

The size and high operational nature of the naval fleet requires that EEBDs **be properly stored, maintained, and perform as needed in the event of an emergency**.

When conducting post-market evaluation activities on EEBDs, NIOSH's NLTFE Program has two main objectives:

1. Evaluate how well EEBDs endure their deployment environments regarding storage conditions, physical damage, and the effects of aging through visual inspection and performance testing on the NIOSH Automated and Breathing Metabolic Simulator (ABMS).
2. Determine if the EEBDs meet the manufacturer's minimum requirements and provide the U.S. Navy with performance, reliability, and user maintenance compliance data.

The Program identifies any potential issues and establishes possible mitigation or remedial strategies, as necessary. If there are any issues, finding the cause(s) is of utmost importance.

This report summarizes the performance testing results of 158 EEBDs deployed on Navy ships, and 66 reference EEBDs that served as a comparison for the deployed EEBDs. While EEBD failures occurred, the workers would still receive some level of protection up to a certain point, depending on the user's work rate, from the respirators. Based on these failures, NIOSH opened a Nonconforming Respirator Investigation (NRI) with Ocenco, the approval holder. Ocenco issued a user notice (Appendix D) and the investigation has been completed.

Testing NIOSH Performed to Protect the Worker

In 2022, the U.S. Navy[2] delivered a sample of 64 Ocenco M-20.2 and 94 M-20.3 ship-deployed EEBDs to NIOSH for evaluation. These samples originated on U.S. Navy west coast ships and NIOSH subjected the EEBDs to strict and consistent visual inspections. The intent was to permit only EEBDs that passed the visual inspection into the evaluation. Included in this submittal were 66 reference EEBDs[3] (16 M-20.2 and 50 M-20.3) that had been held in climate-controlled storage in a Texas warehouse.

Upon passing the visual inspection at NIOSH, all ship-deployed EEBDs were subjected to a series of tests and evaluations to obtain data and evidence of conformance to Title 42 Code of Federal Regulations, Part 84 (42 CFR Part 84), Subparts H and O. These tests and evaluations included

1. A quantitative leak test
2. A phenolphthalein test for alkaline (sorbent powder) presence
3. Breathing and Metabolic Simulation (BMS) testing

The reference EEBDs had the same tests performed on them. NIOSH subsequently compared the test and evaluation results for the ship-deployed EEBDs to the same results for the reference EEBDs tested at the same conditions and to Subpart O (M-20.3 devices only) approval requirements. ***As part of the April 9, 2012, CCER 42 CFR Part 84 Subpart O standard, all Subpart O-approved devices must continue to meet pre-market approval requirements after deployment.***

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

[3]Reference EEBD is a M-20.2 or M-20.3 device held in climate-controlled storage immediately after purchase and used for comparison of test results with deployed EEBDs from Naval ships in the field.

Ocenco M-20.2 Characteristics

NIOSH approved the Ocenco M-20.2 EEBD under the requirements of 42 CFR Part 84, Subpart H – Self-Contained Breathing Apparatus as a "10-minute self-contained self-rescuer" as defined in Subpart H and in 30 CFR Part 75.1714-1 – Approved self-rescue devices. **Figure 1** shows the Ocenco M-20.2 EEBD (testing and certification number 13F-0386).



Figure 1. Ocenco M-20.2 EEBD

Ocenco M-20.3 Characteristics

NIOSH approved the Ocenco M20.3 EEBD under the requirements of 42 CFR Part 84, Subpart O - Closed-Circuit Escape Respirators as a CAP 1 EEBD, which is required by NIOSH to deliver at least 20 L of O_2 when subjected to NIOSH Standard Testing Procedures 0602 and 0603. The M-20.3 EEBD (testing and certification number 13G-0002) has the same 10-minute service time as the M-20.2 and is shown in **Figure 2**.



Figure 2. Ocenco M-20.3 EEBD

Characteristics Applicable to Both EEBD Models

Both the M-20.2 and M-20.3 EEBDs have a pendulum-type design with compressed O_2 stored in a small gas cylinder and a lithium hydroxide (LiOH) CO_2 scrubber (Edwards, John C.). They utilize the LiOH chemical bed to reduce CO_2 to acceptable limits.

Ocenco one-time-use EEBDs are compactly stored in a tightly sealed, hard plastic case contained within a larger protective orange plastic case as shown in **Figure 3**. EEBDs 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 users to move EEBDs from the orange case and carry them on their belt. ***Personnel working in a ship's main space were permitted to carry these belt-worn EEBDs until August 2005. This is no longer the case as all EEBDs are now stowed away. A Navy representative indicated this practice is now in place to avoid vibration and shock exposure to the LiOH sorbent bed, preventing small granular sorbent particles from getting into the breathing bag. As a result of learning this and a similar experience with the Ocenco M-20.3 CCER used for mining applications, a User Notice was posted on the NIOSH website directing miners (not stated in this notice but includes military personnel action) to remove from service those M-20.2 and M20.3 EEBDs found to have white sorbent dust inside the breathing bag. Removal of the EEBD from service in the event of sorbent powder presence in the breathing bag is explicitly stated in the User Instructions.***

M-20.2 and M-20.3 EEBDs have the same storage conditions. Their storage locations should not exceed a minimum temperature of -15°C or exceed a maximum temperature of 60°C. They both have a service life of 15 years from the date of manufacture when the proper conditions of use are followed. M-20.2 and M-20.3 EEBDs that were previously belt-worn, had to be returned for factory service after five years. Shelf-stored M-20.2 and M-20.3 EEBDs can remain in service for 15 years without factory servicing. With its approval under 42 CFR Part 84 Subpart O, the scrubber of the M-20.3 EEBD is larger in length, width, and height than the Subpart H approved M-20.2's scrubber. The mouthpiece, breathing bag flange, and case for the Subpart O device are larger as well. The same O_2 cylinder is used in both devices.



Figure 3. Ocenco EEBD Orange Hard Plastic Outer Case

Sampling and Collection Strategy

As of May 2023, the U.S. Navy possessed 133,460 Ocenco M-20.2 and 92,839 M-20.3 EEBDs to be used for escape situations throughout the naval fleet. Therefore, it is critical that the naval EEBD population perform properly when used to protect users against inhalation hazards in the event of a catastrophe on board naval

ships. NIOSH's objectives for this sampling and evaluation period are to ensure that the EEBDs sampled throughout the U.S. naval fleet meet the manufacturer's minimum requirements and provide the U.S. Navy with performance, reliability, and user maintenance compliance data on ship-deployed M-20.2 and M-20.3 EEBDs.

Collecting Samples from Ships

In this 2022 through 2024 NLTFE Program collection and evaluation phase, Naval Surface Warfare Center – Panama City Division (NSWC-PCD) was to collect and deliver 53 M-20.2 and 115 M-20.3 EEBDs to NIOSH. NSWC-PCD communicated and coordinated sample retrievals with the appropriate Navy personnel on each ship.

Complete data was not available to show where each EEBD was stored during its time on each ship. Therefore, NSWC-PCD used a random number generator and each ship's compartment list to select samples. Given this, the data from each ship's initial outfitting of EEBDs and information from each ship's U.S. Navy Planned Maintenance Scheduler (SKED) was used as a starting point to determine the EEBD samples targeted. Candidate naval vessels were also selected in part due to when each was in port on the west coast and available for sampling.

The candidate vessels were established as those with either the M-20.2 model or the M-20.3 model onboard. Most naval ships with M-20.2 EEBDs were outfitted between 2012 and 2016. Depending on ship availability, a mixture of M-20.2 life date years was targeted.

Naval ships with the Subpart O-approved M-20.3 models have only been outfitted in the fleet since mid-2016. Ships outfitted with M-20.3 EEBDs in 2016 or 2017 were targeted for sampling.

In addition to the EEBD overall life dates, the maintenance history and deployment history for each ship was also reviewed. This history helped determine if the samples were installed onboard the ship since initial outfitting or if they were removed during maintenance periods. While the history of each EEBD sample's locations was not known, the current EEBD location was used to determine which EEBDs to pull and the serial number of each EEBD was compared to initial outfitting data showing where the EEBDs were originally installed.

Examples of stowage locations onboard naval ships are shown in **Figures 4**, **5**, and **6**. These figures show an EEBD stored in a berthing area, a metal box in an office area, and a box on top of a cleaning supplies locker, respectively.



Figure 4. Stowage Location 1



Figure 5. Stowage Location 2



Figure 6. Stowage Location 3

Photos courtesy of the U.S. Navy

Preparing Samples for Delivery to NIOSH

Each ship-deployed EEBD sampled was visually inspected once it was removed from its ship stowage to see if it met the manufacturer's visual inspection guidelines and was a viable EEBD for evaluation and BMS testing. Only

those EEBDs that passed the visual inspection were removed and sent to NIOSH/NPPTL as shown in **Table 1**. Any EEBD that failed visual inspection was replaced per USN MRC 16 C6EC U (U-4). EEBDs that were nearing their expiration dates could be used for this test provided they had sufficient remaining life to be transported, stored at NPPTL, and perform BMS testing. Each sample EEBD was immediately replaced with a new M-20.2 or M-20.3 EEBD after removal from each ship.

A data entry form including a photo of each sampled EEBD's storage location was recorded, when possible. Additional notes were also recorded including each sample's ship compartment, compartment type (e.g., berthing compartment, office, machinery space, etc.), and if it had been located next to machinery. Once all EEBD M-20.2 and M-20.3 samples were examined and collected, they were prepared for shipment and sent to NIOSH/NPPTL in Pittsburgh, PA.

Reference Samples

All reference EEBDs were purchased from Ocenco by the Navy and sent directly to a U.S. Navy climate-controlled storage building in Fort Worth, TX. These reference EEBDs were stored separately from other EEBDs intended for deployment to U.S. naval vessels. The reference EEBDs were maintained at 70°F $\pm$ 3°F and 50 EEBDs were sent directly to NIOSH/NPPTL when NLTFE testing began in early 2023 also as shown in **Table 1**. There was no special sampling of the EEBDs (representatively by location, sorbent lot, or serial number) prior to sending them to NIOSH. All Ocenco M-20.2 and M-20.3 reference EEBDs were manufactured in July 2016.

Table 1. NLTFE Program West Coast Naval Ships and TX Reference EEBD Storage Facility Collections

EEBD Model	Sample	Targeted	Received from the U.S. Navy
Ocenco M-20.2	1	53	64
Ocenco M-20.3	2	115	94
Ocenco M-20.2	Reference 1	20	16
Ocenco M-20.3	Reference 2	50	50
Totals	-	238	224

Tests and Evaluations

NIOSH performs post-market conformity assessment evaluations to ensure that Subpart O-approved devices such as the Ocenco M-20.3 EEBD perform in accordance with NIOSH Subpart O approval and manufacturer requirements over time. Post-market evaluations are also aimed at learning how environment or storage conditions may affect an apparatus' ability to perform properly and protect the wearer. NIOSH also evaluated Subpart O and Subpart H-approved EEBDs by comparing the measured performance of M-20.3 and M-20.2 ship-deployed EEBDs, respectively, to the reference EEBDs' performance during BMS testing.

EEBDs are single use devices and therefore must perform properly to ensure protection against hazards in the event of escape situations during emergencies. The following tests and evaluations were conducted on each EEBD obtained by NIOSH.

1. Visual inspection upon receipt
2. Phenolphthalein indicator check for alkalinity (CO_2 scrubber sorbent) presence inside the mouthpiece and breathing tube
3. Quantitative leak test
4. BMS test

Standard operating procedures STP-602, Determination of Capacity, and STP-603, Determination of Performance, describe the BMS tests and evaluations. These procedures are followed during NIOSH pre-market approval testing for any Subpart O EEBD undergoing the NIOSH approval process. As a post-market evaluation, NIOSH uses these procedures to ensure that approved apparatus perform in accordance with original approval requirements (as per 42 CFR Part 84, Subpart O), any non-conformances are identified, and corrective or mitigating actions are determined in the event of failures.

Any Subpart H- and Subpart O-approved EEBDs not passing the manufacturer's recommended visual inspection, not meeting the requirements of 42 CFR Part 84.41, or not meeting their rated duration are referred to an NRI. Non-conforming Subpart O-approved EEBDs that do not meet pre-approval performance testing requirements are also referred to an NRI. The EEBD manufacturer must participate in the resolution of the defect or non-conformance as defined by the filed NRI. This resolution includes determining the root cause of the failure and providing remedial action for the manufacturing defect or the cause of the failure identified.

Visual Inspection

To ensure user safety, regular inspections of deployed EEBDs stored on naval ships must be performed to confirm proper performance. The criteria for these inspections are established by the manufacturer and include damage assessment of specific components by either visual inspection or non-destructive testing. The visual inspection criteria for M-20.2 and M-20.3 EEBDs include

- The evaluation of pressure gauges
- Verification that the manufacturing date, life date (M-20.2), and stored date (M-20.3) have not expired
- Assurance that the case and latch seal are intact
- Visual assessment of physical indications of wear or damage
- Visual inspection for the presence of white sorbent powder at the bottom of the breathing bag (M-20.3)

These inspection points are printed on the outside of the orange carry case. The EEBD must be removed from this case to make a full inspection (only the pressure gauge and latch seal are visible with the orange carrying case closed). All users must comply with the manufacturer's specified conditions for storage and use. EEBDs failing inspection, or not in compliance with the conditions of storage and use, no longer meet the NIOSH approval and must be removed from service. As per the NSWC-PCD, these regular inspections are performed upon receipt of a new EEBD and every 2 years thereafter.

NIOSH personnel performed a visual inspection of each ship-deployed Ocenco M-20.2 and M-20.3 EEBD and each reference EEBD in accordance with the manufacturer's recommended visual inspection procedures prior to BMS testing. The case was inspected for any damage including cracks, burns, or excessive wear. The EEBDs' security latch, seal, and packaging were evaluated for integrity, dust or dirt contamination, or damage. Belt loops were inspected for any damage and structural integrity. The O_2 pressure gauge level for each EEBD was recorded either in the red position (for "empty") or above red and in the green position (for "good"). The O_2 pressure gauge integrity was evaluated as well.

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 are all reasons for an EEBD failing the visual inspection. If all visual inspection criteria pass, the EEBD is safe for use and to be tested. If an EEBD does not meet the manufacturer's prescribed limits for these indicators when inspected, it must be taken out of service. It should be noted that NIOSH performed only the same visual inspections that Navy personnel assigned to an EEBD are required to conduct every two years or upon initial receipt. Exterior areas examined during the visual inspection are highlighted in **Figure 7**. Any damage, defect, or non-conformance discovered during the visual inspection was documented on the standard EEBD inspection form.

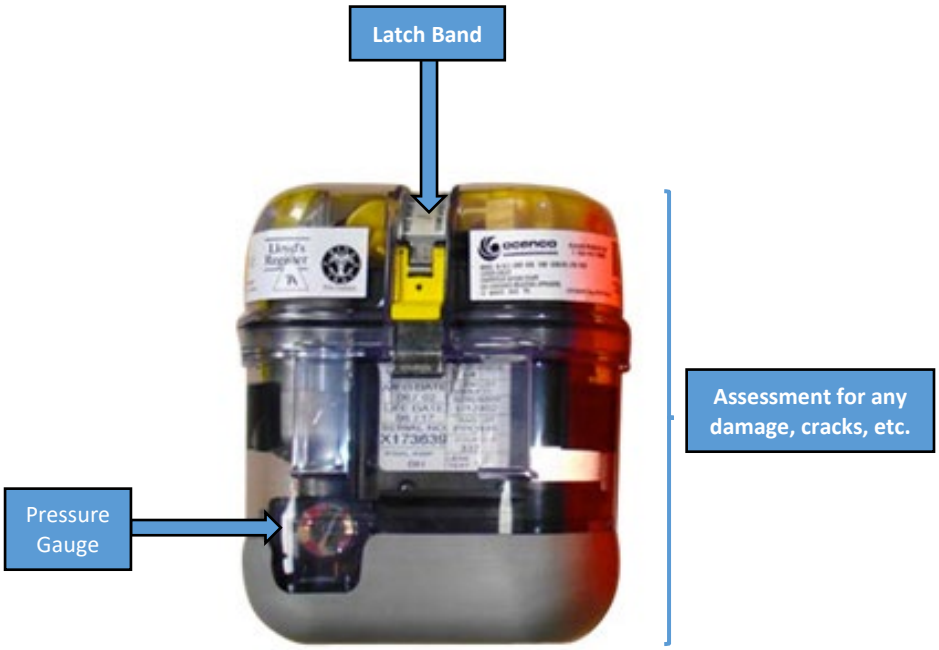


Figure 7. Areas of Visual Inspection for Ocenco M-20.2 and M-20.3 EEBD

Phenolphthalein Indicator Check

Upon opening the EEBD case and removing the mouthpiece plug, each mouthpiece and inner portion of the breathing tube was wiped with a cotton swab soaked in phenolphthalein to detect alkaline material (material with a pH >7.0). 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, this indicated the presence of alkaline material (LiOH) in the form of the chemical CO_2 scrubber 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. The QNT leak test assesses breathing circuit integrity but is not required for NIOSH approval. The QNT leak test employs a vacuum source to induce and maintain a vacuum of 300 mm H_2O column within the EEBD's breathing circuit while measuring the inward leakage rate with an in-line mass flow meter. The vacuum source's gas return tubing is connected and sealed on its opposite end to the mouthpiece of the EEBD being tested. A mass flow meter is installed in the tubing between the vacuum source and the mouthpiece connector to measure the flow rate of gas being evacuated from the EEBD's breathing circuit when the vacuum source is activated.

As the vacuum is adjusted and stabilized at 300 mm H_2O column, the evacuated gas flow rate decreases and stabilizes. The stable evacuated gas flow rate is the EEBD leak rate.

At maximal work rates, inspired pressure/vacuum in the EEBD's breathing circuit should not exceed +200- or -300-mm H_2O column [Hodgson 1993], respectively, and inward leakage rates should be less than 500 milliliters per minute (mL/min) to reasonably assure user protection for a period equal to or greater than the rated service time. The inward leakage threshold of 500 mL/min is a function of the NIOSH 200-ppm, one-hour threshold limit value for carbon monoxide (CO). An inward leakage rate of 500 mL/min in a 20% CO atmosphere at a peak inhalation rate of 500 L (liters) per minute over one hour corresponds to a CO volume fraction of 0.0002 or 200 ppm (NIOSH CO threshold limit value).

Mouthpiece connectors shaped as closely as possible to the internal dimensions of the EEBD's mouthpiece opening are used to seal the EEBD to the ABMS trachea using plastic wire ties. Custom fabrication of these mouthpieces to match the EEBD's mouthpiece opening is required to optimize the fit and prevent the connection from being a source of inward leakage. Care is taken when inserting the connector into the EEBD's mouthpiece to be tested and securing it tightly with a wire tie. Putty is used, as necessary, to enhance this seal and stop any residual inward leakage so that the mouthpiece connector is tightly sealed to the vacuum source. Leakage within the breathing circuit of the EEBD being tested under vacuum is confirmed by pinching and sealing the breathing hose just below the mouthpiece connector.

Breathing and Metabolic Simulation Test[4]

The computer-controlled ABMS shown in **Figure 8** 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 inspired 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.

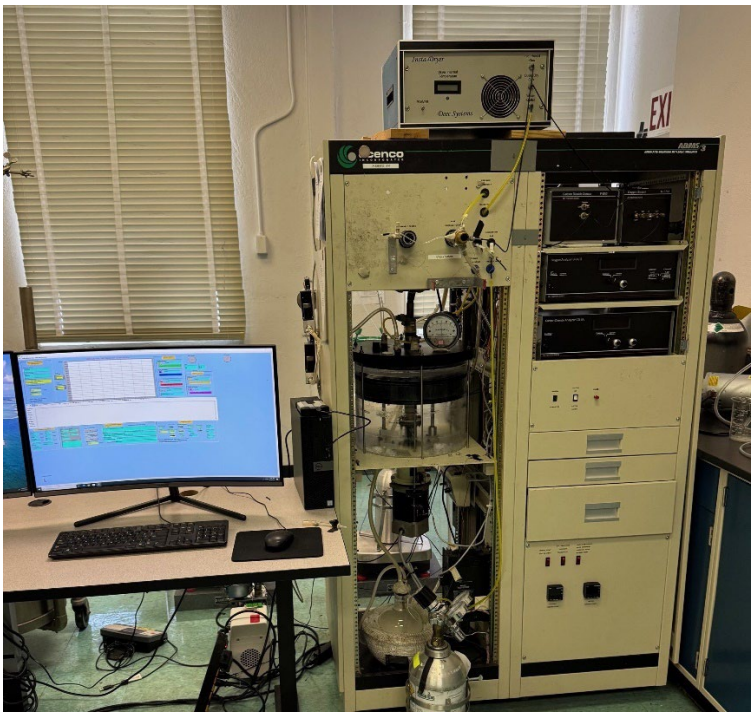


Figure 8. Automated Breathing and Metabolic Simulator[5]

A National Instruments' LabVIEW-based software application manages the operation of the ABMS machine. Test input parameters required to initiate a simulation operation include the metabolic O_2 consumption rate (VO_2), metabolic CO_2 generation rate (VCO_2), respiration rate, and tidal volume set points. LabVIEW software subroutines work to control the piston operation and maintain the VO_2 and VCO_2 set points by controlling the injection of CO_2 to the lung and the removal of O_2 via the exhaust system.

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[4] Proper care and maintenance of the ABMS is essential to ensure data quality.

NIOSH tested the M-20.2 Subpart H-approved EEBDs on the ABMS using the CAP 3 constant average metabolic work rate test while all M-20.3 Subpart O-approved EEBDs were tested using the CAP 1 (also a constant metabolic) work rate to which they were approved as per 42 CFR Part 84, Subpart O as shown in **Table 2**[5,6]. All Subpart H and Subpart O EEBD tests at the ABMS were conducted to endpoints under these constant operating conditions. During testing, the ABMS continuously monitored metabolic stressors which included inspired levels of CO_2 and O_2, inspired wet-bulb temperatures, and inspired and expired breathing resistances (pressures) until the test was terminated. These measurements are used to provide real-time test data displays and to conduct final analysis of test performance.

Tests on the ABMS for Subpart O EEBDs are only terminated upon exceeding the stressor limit(s). Specifically, tests on the ABMS for both Subpart H and O EEBDs are terminated upon one of three endpoints:

1. Exhaustion of the O_2 supply as indicated by inspired pressures reaching -300 mm H_2O column, coinciding with a collapsing and empty breathing bag
2. Average inspired CO_2 levels exceed 10%
3. O_2 levels fall below 15%

When these limits are exceeded, the ABMS gas metabolism is compromised, and further data are not acceptable for analysis.

Table 2. Constant CAP 1 and CAP 3 Metabolic Work Rate for Subpart O EEBD Tests

Metabolic workload	CAP 1 Work Rate	CAP 3 Work Rate
O_2 Consumption	**2.50 L/min.**	**1.35 L/min.**
CO_2 Production Rate	**2.50 L/min.**	**1.15 L/min.**
Ventilation Rate	**55 L/min.**	**30 L/min.**
Tidal Volume	**2.50 L/breath**	**1.68 l/breath**
Respiratory Frequency	**22.0 breaths/min.**	**17.9 breaths/min.**
Peak Respiratory Flow Rates:		
Peak Inhalation	**186.09 L/min.**	**89 L/min.**
Peak Exhalation	**158.2 L/min**	**71 L/min.**

[5] The constant work rate eliminates nearly all variability in the results obtained from testing on the ABMS.

[6] Approval testing under 42 CFR Part 84, Subpart H using human participants imposes high and low work rates that are not reproduced by a constant work rate from an ABMS. Humans may differ from each other and from BMS tests in terms of CO_2 production rate, ventilation rate, and respiratory frequency. Thus, although the average work rate (and O_2 consumption) is the same between human participants and BMS tests with a constant work rate, BMS tests shall not be considered equivalent to Subpart H approval testing. However, BMS tests can be used to provide an indication of EEBD duration (i.e., the length of time that an EEBD will operate at a constant work rate before the O_2 supply becomes fully expended). Also, stressor levels are continuously monitored during BMS testing for Subpart H testing on the ABMS, whereas they are sampled only between work activities in Subpart H approval testing from the human participant's breathing circuit. In addition, BMS testing for the NLTFE Program continues until the apparatus breathing gas supply is expended for both Subpart H and O EEBDs or inspired stressor levels exceed allowable limits for Subpart O approved testing of M-20.3 EEBDs.

NIOSH Stressor and Capacity Limits for BMS Testing of Subpart H and O Devices

The full-test average stressor limits and one-minute average stressor excursion limits for Subpart O-approved devices are shown in **Table 3**. The capacity test requirements for these devices are shown in **Table 4**. Testing of Subpart O EEBDs that resulted in exceeding these stressor limits or not achieving the minimum O_2 capacity for the capacity rating for which they were approved were considered failures.

Both Subpart H- and Subpart O-approved devices were typically tested until their breathing gas supply became fully expended (reaching peak inspired breathing gas pressure of -300 mm H_2O column with a collapsed breathing bag). To prevent ABMS operation at conditions that would be extremely harmful to an EEBD user, testing is also ended when the average inspired CO_2 levels exceed 10% or average inspired O_2 levels fall below 15%, no matter if the minimum expected test duration has been reached. All Subpart H EEBDs were tested using the Cap 3 work rate and their performance was assessed based on data recorded during the first ten minutes of each test.

Stressor Test Data

For this study, NIOSH measured and collected the following stressor data:

- Inspired O_2 mole fraction (Ins O2)
- Inspired CO_2 mole fraction (Ins CO2)
- Average breathing resistance (ΔP) or peak expired pressure (PEPRS) minus peak inspired pressure (PIPRS)
- Average inspired wet-bulb temperature (TAVGWB)

NIOSH averaged the minute-average values of the stressors monitored during BMS testing of each Subpart H-approved EEBDs over their rated 10-minute service time to standardize the assessment in comparison to previous NLTFE Programs[7]. However, all one-minute average stressor data from each ship-deployed Subpart O-approved M-20.3 EEBD test were averaged to obtain a composite test average for comparison to reference EEBD tests. Reference Subpart H and O EEBD test results were similarly averaged to enable this comparison. NIOSH tabulated this information, along with stressor minimums and maximums for each set of tests, to assess the deployed EEBDs' performance. Inspired wet-bulb thermocouple data indicates average wet-bulb temperature over an entire inspired breath. Use of full test duration results for Subpart H-approved EEBDs introduces stressor data variances that prevent valid comparisons between individual tests and with previous NLTFEs.

Table 3: Monitored Stressors and Acceptable Range Requirements

Stressor	Acceptable Range Operating Average	Acceptable Range Excursion
Average Inspired CO_2	**<1.5%**	**≤4%**
Average Inspired O_2	**>19.5%**	**≥15%**
Peak Breathing Pressures	**ΔP ≤ 200 mmHg**	**-300 ≤ ΔP ≤ 200 mm H_2O**
Wet-Bulb Temperature	**<43°C**	**≤ 50°C**

Table 4: Capacity Test Requirements – volumes given at std. temperature (0°C) and pressure (760 mm Hg), dry

Capacity Rating	Capacity (L)	VO_2 (L/min)	VCO_2 (L/min)	Ve (L/min)	RF (Breaths/min
Cap 1	20 ≤ L ≤ 59	2.50	2.50	55	22
Cap 2	60 ≤ L ≤ 79	2.00	1.80	44	20
Cap 3	L ≥ 80	1.35	1.15	30	18

VO_2 = Liters of oxygen consumed/min; VCO_2 = Liters of carbon dioxide produced/min; Ve = ventilation rate; RF = respiratory frequency

EEBD Stressor Limits References

The Noll Lab for Human Performance Research was established at Pennsylvania State University in 1973 to conduct multidisciplinary human performance studies. Physiological research performed at the Noll Lab for Human Performance Research provides the background to understand stressor limits established for BMS evaluation of closed-circuit escape respirators at NIOSH. The stressors affected by this research include inspired CO_2, inspired and expired peak breathing resistances, and inspired wet bub temperature limits for the ship-deployed and reference M-20.2 and M-20.3 EEBD tested as part of the NLTFE Program.

Acceptable ranges for inhaled carbon dioxide were determined by physiological testing performed at Penn State's Noll Lab. This research showed no disabling physical effects in active men breathing 5 percent carbon dioxide for long periods of time. Decision-making was slightly impaired in some subjects after breathing 4 percent carbon dioxide for 1 hour. Moderate increases above the full-test average CO_2 limit of 1.50%, like those measured in the NLTFE program testing, will result in mild respiratory stimulation and potential feelings of drowsiness. Inspired CO_2 levels up to the 4.0% excursion or IDLH limit will still allow for workers to escape from the environment where they are exposed without suffering (a) permanent health damage or (b) severe eye or respiratory tract irritation (or other conditions). The brief excursions allowed by the 1.50% CO_2 full test average will not pose any impairment risk to the EEBD user.

The acceptable ranges for peak breathing resistances of -300- and +200-mm H_2O column have been identified as the outer limits of what is humanly tolerable based on research conducted at Penn State's Noll Laboratory.

The acceptable ranges for wet-bulb temperature are also based on physiological research conducted at Penn State's Noll Lab. Researchers there found the highest tolerable wet-bulb temperature of inhaled air was approximately 50°C. Based on such research and NIOSH findings from testing closed-circuit escape respirators, NIOSH established 50°C as a one-minute average excursion limit and 43°C as a full-test average operating limit. NIOSH test participants have found this temperature range to be tolerable during 1-hour Subpart O human participant approval tests of closed-circuit escape respirators.

Reference EEBD Evaluations

EEBDs purchased by the U.S. Navy and stored in a climate-controlled warehouse in Texas were evaluated using the ABMS for performance comparisons with ship-deployed EEBDs. NIOSH tested 16 M-20.2 reference EEBDs after every 3rd to 6th ship-deployed M-20.2 EEBD test and 50 M-20.3 reference EEBD after every 2nd to 6th ship-deployed M-20.3 EEBD until the reference EEBDs were expended. NIOSH used the work rates at which the Subpart H- and Subpart O-deployed EEBDs were tested when testing their respective reference EEBDs. Prior to evaluation, NIOSH also performed the manufacturer's recommended visual inspections on the reference EEBDs to ensure qualification for BMS testing.

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[7] Use of full test duration results for Subpart H approved EEBDs introduces stressor data variances that prevent valid comparisons between individual tests and with previous NLTFEs.

What NIOSH Found Through Inspection, Testing, and Evaluation

EEBD Collection

Sixty-four M-20.2 west coast ship, 94 M-20.3 west coast ship, 16 M-20.2 reference and 50 M-20.3 reference EEBDs were received from the U.S. Navy for testing. Upon initial visual inspection at the collection sites, none of the EEBDs collected by the U.S. Navy were rejected. Upon visual inspection at the NIOSH test laboratory, one M-20.2 ship-deployed EEBD was rejected due to not passing the required visual inspections. Two additional M-20.2 ship-deployed EEBDs were rejected upon visual inspection after the cases were opened just prior to testing, leaving 61 M-20.2 EEBDs to be available for testing. Those EEBDs were rejected due to the bottom cover falling off one EEBD during leak checking and a hole being present in the mouthpiece of the second EEBD.

After the qualified EEBDs were tested on the NIOSH ABMS, the number of ship-deployed EEBDs that provided valid test results (valid tests are achieved if the ABMS is found to be working correctly in response to challenging the EEBD) were tallied. Valid data was obtained for 61 ship-deployed M-20.2 EEBDs and 88 ship-deployed M-20.3 EEBDs. Upon testing, 16 M-20.2 reference EEBDs and 46 M-20.3 reference EEBDs were found to produce valid test data. The reason for excluding an M-20.3 EEBD test from the list of valid M-20.3 EEBD tests was due to the test not reaching the required volume of oxygen required to deliver the Cap 1 oxygen capacity. **Table 5** summarizes these EEBD processing actions and results.

Table 5. NLTFE Program Processing of West Coast Naval Ships and TX Reference EEBD

EEBD Model	Received from the U.S. Navy	Passed Visual Inspection at NIOSH Test Laboratory	Tested	Obtained Valid Test Data
Ocenco M-20.2	**64**	**63**	**61**	**61**
Ocenco M-20.3	**94**	**94**	**94**	**88**
Ocenco M-20.2	**16**	**16**	**16**	**16**
Ocenco M-20.3	**50**	**50**	**50**	**46**
Totals	**224**	**223**	**221**	**210**

Ocenco M-20.2 Subpart H-Approved Devices

Visual Inspection

One ship-deployed Ocenco M-20.2 EEBD failed the manufacturer's visual inspection at NIOSH out of 64 EEBDs evaluated due to exceeding its expiration date. This EEBD was not tested.

Phenolphthalein Indicator Test

None of the Ocenco M-20.2 EEBDs tested (ship-deployed and reference) failed the phenolphthalein indicator test for the detection of alkaline (CO_2 reducing sorbent) presence in the EEBD's breathing circuit.

Quantitative Leak Test

The breathing circuit integrity check of Ocenco M-20.2 EEBDs using the QNT leak test procedure showed that all EEBDs tested had an inward leak rate much less than 500 mL/min (passing limit). The average bench inward leak rate for all ship-deployed M-20.2 EEBDs tested was 15.1 ± 7.9 mL/min (average ± SD). The average bench inward leak rate for all reference M-20.2 EEBDs tested was 16.9 ± 11.5 mL/min (average ± SD).

Automated Breathing and Metabolic Simulation Test

Attempts at testing the 63 ship-deployed M-20.2 EEBD units that passed visual inspections resulted in finding two additional untestable units that were not discovered until the cases were removed. This resulted in two additional invalid tests. The remaining 61 valid M-20.2 EEBD tests were performed at a constant work rate (Cap 3) defined by a VO_2 of 1.35 liters per minute (LPM) and a VCO_2 of 1.15 LPM.

All 16 valid M-20.2 reference EEBD tests were also performed at the same CAP 3 work rate as the ship-deployed M-20.2 EEBDs. Full test durations were approximately 18 minutes for these Subpart H-approved M-20.2 EEBDs. Testing ended when the breathing gas was fully expended and the breathing bag collapsed.

Test Results

- The 61 valid ship-deployed EEBD tests and 16 valid reference EEBD tests met or exceeded the NIOSH Approved 10-minute service time.
- All M-20.2 ship-deployed and reference EEBDs tested provided acceptable inspired O_2 levels during the entire 10-minute service time.
- For four of the 61 M-20.2 ship-deployed EEBDs tested, inspired CO_2 levels exceeded the OSHA CO_2 IDLH level of 4.0% prior to the breathing gas becoming fully expended.
- For seven of the 61 M-20.2 ship-deployed EEBDs tested, inspired CO_2 levels exceeded the OSHA CO_2 IDLH level of 4.0% prior to or at the end of testing.
- For 11 of the 16 M-20.2 reference EEBDs tested, inspired CO_2 levels exceeded the OSHA CO_2 IDLH level of 4.0% prior to the breathing gas becoming fully expended.
- For 14 of the 16 M-20.2 reference EEBDs tested, inspired CO_2 levels exceeded the OSHA CO_2 IDLH level of 4.0% prior to or at the end of testing.
- Inspired and expired breathing resistances measured for all M-20.2 EEBDs tested were within outer limits of what is humanly tolerable based on research conducted at Penn State's Noll Laboratory.

The 61 ship-deployed M-20.2 EEBDs and 16 reference M-20.2 EEBDs cited above continued operating until the breathing gas supply was fully expended. For ship-deployed M-20.2 EEBDs, 4% IDLH CO_2 level breakthrough times averaged 17.0 minutes, inspired CO_2 levels after 10 minutes of testing averaged 1.66%, and maximum inspired CO_2 levels for those tests exceeding the 4.0% IDLH level averaged 4.43%, occurring during the last minute of testing. For reference M-20.2 EEBD, 4% IDLH CO_2 level breakthrough times averaged 16.7 minutes, inspired CO_2 levels after 10 minutes of testing averaged 2.20%, and maximum inspired CO_2 levels averaged 4.98%, also occurring during the last minute of testing. **Table 6** provides a CO_2 breakthrough summary for M-20.2 ship-deployed and M-20.2 reference EEBDs.

Table 6. Summary of Ocenco M-20.2 Ship-deployed and Reference EEBDs 4% CO_2 Breakthrough Times

	4% Inspired CO_2 Breakthrough Time, minutes		Test Duration, minutes		Inspired CO_2 at 10 Minutes, mole percent		Maximum Inspired CO_2 Level When Exceeding 4.0% Inspired CO_2, mole percent	
	Ship Unit	Reference Unit	Ship Unit	Reference Unit	Ship Unit	Reference Unit	Ship Unit	Reference Unit
Average	17.0	16.7	17.1	18.4	1.66	2.20	4.43	4.98
SD	0.6	0.7	1.5	1.1	0.42	0.15	0.29	0.51
Min	16.0	16.0	10.2	16.3	0.88	1.92	4.08	4.13
Max	18.0	18.0	19.2	20.2	2.93	2.47	4.89	5.91

For M-20.2 EEBD test data, the composite average stressors across all M-20.2 ship-deployed and reference EEBDs that passed visual inspection are shown in **Table 7**. The table also shows the percent differences between the average stressor data of the ship-deployed and reference EEBDs (data are shown relative to ship-deployed EEBD values). Mole fraction, as used, is defined as moles of breathing gas constituents, O_2 or CO_2, per 100 moles of breathing gas. It should be acknowledged that the inspired O_2 levels for both ship-deployed and reference EEBDs will adequately sustain life throughout the length of the 10-minute service time.

As indicated above, ten-minute data averaging was chosen to be consistent with the approved 10-minute service time for the Subpart H-approved Ocenco M-20.2 EEBD. Also included in these plots are the full test duration times, beyond the 10-minute service time. Full test durations averaged 17.1 minutes for the ship-deployed M-20.2 EEBDs and 18.4 minutes for the reference M-20.2 EEBDs and the end of the test occurred when the breathing gas had become fully expended.

Table 7. Ocenco M-20.2 Tested Under a Constant Work Rate, Test Duration and Composite Stressor Data

	DURATION (MIN.)	Ins O2 Mole Frac	Ins CO2 Mole Frac	PEPRS (MMH2O)	PIPRS (MMH2O)	TAVGDB (°C)	TAVGWB (°C)
All Ocenco Subpart H M-20.2 Ship-deployed EEBD Data for West Coast Naval Ships (n = 61)							
MIN	10.2	0.3867	0.0064	30	-67	38.93	37.89
MAX	19.2	0.7476	0.0222	49	-41	42.68	41.67
AVERAGE	17.1	0.5131	0.0111	35	-50	40.58	39.75
STD DEV	1.5	0.0777	0.0030	3.7	5.1	0.78	0.64
% Difference	-5.3	17.3	-9.9	11.4	46.0	3.0	2.4
Ocenco M-20.2 Reference EEBD Data (n = 16)							
MIN	16.3	0.3540	0.0111	29	-153	37.94	37.75
MAX	20.2	0.5092	0.0135	32	-46	41.24	39.93
AVERAGE	18.4	0.4244	0.0122	31	-73	39.35	38.80
STD DEV	1.1	0.0426	0.0007	1.1	32.5	1.0	0.7

The average of one-minute-average stressor values monitored during BMS testing of both Ocenco M-20.2 ship-deployed and reference Ocenco M-20.2 EEBDs over the first 10 test minutes are presented in plots shown in **Appendix C**, **Figures 9 through 13**. The following lists these plots and their data type.

- **Figure 9 – Test Duration vs. Test Date for M-20.2 EEBDs**
- **Figure 10 – Test Average Inspired O_2 Level vs. Test Date for M-20.2 EEBDs**
- **Figure 11 – Test Average Inspired CO_2 Level vs. Test Date for M-20.2 EEBDs**
- **Figure 12 – Test Average Breathing Resistance ΔP vs. Test Date for M-20.2 EEBDs**
- **Figure 13 – Test Average Inspired Wet Bulb Temperature vs. Test Date for M-20.2 EEBDs**

Ocenco M-20.3 Subpart O Approved Device

Visual Inspection

No Ocenco M-20.3 EEBDs failed visual inspection at NIOSH out of the 94 ship-deployed and 50 reference EEBDs evaluated during this test period. This included a check of all EEBDs to assure that the O_2 pressure gauge indicator was in the green part of the indicator field.

Phenolphthalein Indicator Test

None of the Ocenco M-20.3 EEBDs (ship-deployed and reference) tested failed the phenolphthalein indicator test for the detection of alkaline (CO_2 reducing sorbent) presence in the EEBD's breathing circuit.

Quantitative Leak Test

The breathing circuit integrity check of Ocenco M-20.3 EEBDs using the QNT leak test procedure showed that all ship-deployed EEBDs tested had a leak rate much less than 500 mL/min (passing limit). The average leak rate for all ship-deployed M-20.3 EEBDs tested was 20.6 ± 15.7 mL/min (average ± SD). The average leak rate for all reference M-20.3 EEBDs tested was 19.5 $\pm$ 12.4 mL/min (average $\pm$ SD).

Automated Breathing and Metabolic Simulation Test

Attempts at testing the 94 ship-deployed M-20.3 EEBDs that passed the pre-test checks listed above resulted in achieving 88 valid tests and 6 invalid tests. One invalid test occurred because the seal between the trachea and the M-20.3 mouthpiece connector separated during testing. The other five invalid tests occurred because of an equipment/instrument failure that resulted in insufficient N_2 supply from the N_2 compressed gas cylinder.

The 88 valid ship-deployed M20.3 EEBD tests were conducted using the Subpart O CAP 1 constant work rate with a VO_2 setting of 2.50 LPM and VCO_2 setting of 2.50 LPM. All 50 M-20.3 EEBD reference EEBD tests were also performed at the same CAP 1 constant work rate. Although the M-20.3 EEBD is referred to as a 10-minute EEBD like the M-20.2 EEBD, it rarely reached that duration (typical durations were 8 to 10 minutes) when operating at the required CAP 1 work rate. Achieving an 8-minute test duration for Subpart O EEBDs means the ABMS consumed at least 20 liters of O_2 and, conversely, the Subpart O EEBD generated at least the 20 liters of O_2 required of a CAP 1 EEBD for that test.

Test Results

- The 88 valid ship-deployed EEBD tests delivered the O_2 capacity required by an EEBD approved to Subpart O as a CAP 1 device ($\geq$ 20 L O_2 delivery is required for a CAP 1 rated Subpart O device).
- Of the 50 M-20.3 reference EEBDs, four failed to deliver the O_2 capacity required by an EEBD approved to Subpart O as a CAP 1 device.
    - These tests were considered failures and were not included in the final tabulation and analysis of M-20.3 reference EEBD test data.
- All but one M-20.3 ship-deployed EEBD provided acceptable inspired O_2 levels while delivering the required O_2 capacity of $\geq$20 Liters.
- All M-20.3 reference EEBDs provided acceptable inspired O_2 levels while delivering the required O_2 capacity of $\geq$20 Liters.
- For five of the 88 M-20.2 ship-deployed EEBDs tested, inspired CO_2 levels exceeded the OSHA CO_2 IDLH level of 4.0% prior to the breathing gas becoming fully expended.
- For 19 of the 88 M-20.2 ship-deployed EEBDs tested, inspired CO_2 levels exceeded the OSHA CO_2 IDLH level of 4.0% prior to or at the end of testing.
- For four of the 46 valid Ocenco M-20.3 reference EEBDs tested, inspired CO_2 levels exceeded the 4% IDLH level prior to the breathing gas becoming fully expended.
- Inspired and expired breathing resistances measured for all M-20.3 EEBDs tested were within outer limits of what is humanly tolerable based on research conducted at Penn State's Noll Laboratory. However, two M-20.3 EEBD tests resulted in a ΔP that exceeded the 200-millimeter water column limit (266 and 208 millimeters water column).

The 88 ship-deployed M-20.3 EEBDs and 46 reference M-20.3 EEBDs cited above continued operating until the breathing gas supply was fully expended and the required CAP 1 O_2 delivery capacity ($\geq$20 Liters) was reached. For ship-deployed M-20.3 EEBDs, 4% IDLH CO_2 level breakthrough times averaged 7.8 minutes and the maximum inspired CO_2 level when exceeding 4.0% inspired CO_2 averaged 6.1%, with all individual maximum inspired CO_2 levels occurring during the last minute of testing. For reference M-20.3 EEBDs, 4% IDLH CO_2 level breakthrough times averaged 3.8 minutes and the maximum inspired CO_2 levels when exceeding 4.0% inspired CO_2 averaged 5.4%. **Table 8** provides a CO_2 breakthrough summary for M-20.3 ship-deployed and M-20.3 reference EEBDs.

Table 8. Summary of Ocenco M-20.3 Ship-deployed and reference EEBDs 4% CO_2 Breakthrough Times

	4% Inspired CO_2 Breakthrough Time, minutes		Test Duration, minutes		Maximum Inspired CO_2 When Exceeding 4.0% Inspired CO_2, Mole %	
	Ship EEBD	Reference EEBD	Ship EEBD	Reference EEBD	Ship EEBD	Reference EEBD
Average	7.8	3.8	9.1	8.9	6.1	5.4
SD	2.4	1.7	0.6	0.4	5.6	0.2
Min	1.0	2.0	8.0	8.0	4.0	5.3
Max	10.0	6.0	14.0	10.0	28.7	5.7

For the M-20.3 EEBD stressor test data, *composite averages* across the 46 reference and 88 ship-deployed Ocenco M-20.3 EEBDs for which valid test data was obtained are shown in **Table 9**. The table also shows the percent difference between the average stressor data of the ship-deployed and reference EEBDs (differences are shown relative to ship-deployed EEBD values). Mole fraction, as used, is defined as moles of breathing gas constituent, O_2 or CO_2, per 100 moles of breathing gas. Except for one ship-deployed M20.3 EEBD test, the inspired O_2 levels for both ship-deployed and reference M-20.3 EEBDs were shown to adequately sustain life throughout the length of the EEBD's service time.

As indicated above, full test duration stressor data was used to be consistent with the Subpart O approval requirements. Also included in **Table 9** are full test duration times. Full test durations averaged 9.1 minutes for the ship-deployed M-20.3 EEBDs and 8.9 minutes for the reference M-20.3 EEBDs. It should be noted that stressor pass/fail limits added to **Table 9** in red font provide a comparison to the full test average stressor values (also in red font) measured for all west coast ship-deployed and reference M20.3 EEBD testing.

Table 9. Ocenco M-20.3 Under a Constant Work Rate (Capacity Tests per Subpart O), Test Duration and Composite Stressor Data

	DURATION (MIN.)	Ins O2 Mole Frac	Ins CO2 Mole Frac	PEPRS (MMH2O)	PIPRS (MMH2O)	ΔP (MMH2O)	TAVGWB (°C)
All Ocenco M-20.3 Ship-deployed EEBD Data for West Coast Naval Ships (n = 88)							
Stressor Pass/Fail Limit	**≥ 8**	**≤ 0.1950**	**≥ 0.0150**	**≥ +200 mm H_2O**	**≤ -300 mm H_2O**	**≥ 200 mm H_2O**	**≥ 43.0°C**
MIN	8	0.0949	0.0123	45	-210	122	42.37
MAX	14	0.5766	0.0463	111	-76	266	48.72
AVERAGE	9.1	0.3669	0.0190	56	-90	146	44.33
STD DEV	0.6	0.0613	0.0066	7.6	16.5	18.8	0.95
% Difference	2.2	-4.4	-6.3	-5.4	3.3	-3.4	0.4
Ocenco M-20.3 Reference EEBD Data (n = 46)							
MIN	8	0.2711	0.0145	25	-142	78	40.58
MAX	10	0.5269	0.0454	68	-51	204	46.82
AVERAGE	8.9	0.3830	0.0208	59	-93	151	44.17
STD DEV	0.4	0.0561	0.0069	7.9	12.5	18.8	1.0

The average of the one-minute-average stressor values monitored during BMS testing of both Ocenco M-20.3 ship-deployed and reference Ocenco M-20.3 EEBDs over the full test are presented in plots shown in **Appendix C, Figures 14, 15, 16, 17, and 18**. The following lists these plots and their data type.

- **Figure 14 – Test Duration vs. Test Date for M-20.3 EEBDs**
- **Figure 15 – Test Average Inspired O_2 Level vs. Test Date for M-20.3 EEBDs**
- **Figure 16 – Test Average Inspired CO_2 Level vs. Test Date for M-20.3 EEBDs**
- **Figure 17 – Test Average Breathing Resistance ΔP vs. Test Date for M-20.3 EEBDs**
- **Figure 18 – Test Average Inspired Wet Bulb Temperature vs. Test Date for M-20.3 EEBDs**

CASE Findings

Ocenco M-20.2 Subpart H-Approved Devices

The manufacturer's visual inspection failure frequency for M-20.2 EEBDs collected for this testing was 1.6% (1 out of 64 EEBDs). The low visual inspection failure frequency is to be expected since naval personnel do not carry M-20.2 EEBDs on a regular basis, as they are stored onboard the naval ships in various, easily accessible, secure locations. NIOSH found additional defects for two M-20.2 EEBDs after the clear plastic case was removed, resulting in their removal from the testing inventory. These defects were not counted as part of visual inspection failures because they were only visible after the case was removed. These two EEBDs were rejected after the cases were opened because the bottom cover was starting to detach from one EEBD during leak checking and a hole was present in the mouthpiece of the second EEBD. This removal brought the number of M-20.2 EEBDs tested to 61.

The M-20.2 EEBDs collected in early 2022 were manufactured mostly between early 2013 and mid-2015 other than five ship-deployed EEBDs that were manufactured between August 2008 and September 2009. Thus, the total exposure time to the EEBDs' storage conditions is approximately 10 years. The service life for these EEBDs

is 15 years and is defined as the maximum time limit after which all EEBDs need to be removed from service even if they continue to pass visual inspection.

The ship-deployed (n=61) and reference (n=16) Ocenco M-20.2 EEBDs that passed the manufacturer's inspection criteria and provided valid test results all demonstrated the expected life support capacity over the course of the manufacturer's specified service time. Inspired O_2 levels measured for both ship-deployed and reference EEBDs will adequately sustain life through the length of the 10-minute service time. In addition, nearly all inspired CO_2 levels measured were adequately low (<1.5%) and would not cause any physiological issues to the user.

Results Comparison

- Average inspired O_2 levels for the 61 ship-deployed EEBDs (0.5131 mole fraction) were 17.3% higher than the 16 reference EEBDs (0.4244 mole fraction).
- Average inspired CO_2 levels measured for the 61 ship-deployed EEBDs (0.0111 mole fraction) were 9.9% lower than the 46 reference EEBDs (0.0122 mole fraction).
- The PIPRS levels measured for the 61 ship-deployed EEBDs (-50 mm H_2O column) were 46.0% higher than the 16 reference EEBDs (-73 mm H_2O column).
- The PEPRS levels measured for the 61 ship-deployed EEBDs (35 mm H_2O column) were 11.4% higher than the 16 reference EEBDs (31 mm H_2O column).
- Smaller differences existed between the ship-deployed (39.8°C) and reference EEBDs (38.8°C) average inspired wet-bulb temperature (2.4%).

Although human-facilitated and machine results are similar, data reported from machine testing is not to be considered directly equivalent to Subpart H approval human participant tests. Unlike Subpart H approval testing, which relies solely on human participants to evaluate the EEBDs, NIOSH performs its NLTFE Program using an ABMS machine. The BMS tests are designed to be highly reproducible so comparisons between reference EEBDs and naval ship-deployed EEBDs are valid. The BMS tests are also intended to stress the functionality of the EEBDs towards the high end of their life support capabilities.

While the NLTFE Program uses ABMS test conditions in Subpart H-approved EEBD tests that are not directly aligned with the approval requirements for Subpart O- approved EEBDs[6], it is important to note that one of the goals of the NLTFE Program is to assure that EEBDs passing all required inspection and non-destructive testing requirements, as found onboard naval ships, will provide the expected life-support capacity when they are properly used and cared for by users. Unless specifically noted otherwise, this report should be viewed as providing evidence of this for all Subpart H, M-20.2 EEBDs that were tested.

Ocenco M-20.3 Subpart O-Approved Devices

The manufacturer's visual inspection failure frequency for M-20.3 EEBDs was 0%. These EEBDs were collected in 2022 and were manufactured between 2016 and 2018. Thus, the total exposure time to the EEBDs' use conditions was approximately 6 years. The lack of daily inspection failures in M-20.3 EEBDs sampled every two years indicates that U.S. Navy personnel are properly maintaining the M20.3 EEBD in areas where they are protected from vibration and shock. These lack of failures are documented in **Table 1** above where the number of ship-deployed M-20.3 EEBDs that were shown under the "Received from the U.S. Navy" (94) column were the same number of M-20.3 EEBDs (94) that were documented to have passed as shown under the "Passed Visual Inspection at the NIOSH Test Laboratory" column. The visual inspections for both M-20.2 and M-20.3 EEBDs were documented for each test in the ETB-1137 Rev 2 data file entitled "Capacity and Performance Data Sheet" as shown in **Table 10**. These data files are filled out prior to performing each test and are maintained in electronic test records for individual tests.

Table 10. Capacity and Performance Data Sheet – Logging of Test Parameters and EEBD Physical Condition

Capacity and Performance Data Sheet						Page:	
						TN:	
						Manufacture	
						Duration: hr.: min:	
						Pass/Fail:	
Date	Barometric P (mm Hg)	S/N #	Manufacture Date	Expiration Date	Phenolphthalein (Pass or Fail)	Oxygen Flow Rate (LPM)	CCER Leak Flow Rate (ml/min)
Case Integrity	Case Seal	Secure Tape or Latch	Oxygen Indicator (psig)	Oxygen Starter	Temperature Indicator	Moisture Indicator	Waveform/Protocol
Oxygen Response (ms)	Carbon Dioxide Response (ms)	Oxygen Criteria Time (ms)	Carbon Dioxide Criteria Time (ms)	ABMS Leak Rate (ml/min)	ABMS Leak Rate with CCER (ml/min)	Comments:	
						ETB-1137 Rev 2 FPW	

NIOSH found all Subpart O-approved M-20.3 EEBDs failed NIOSH's performance requirements. During analysis of the test data, it was discovered that there were no passing results for the 88 ship-deployed M-20.3 EEBDs and 46 reference M-20.3 EEBDs that provided valid test results. All 88 Subpart O-approved ship-deployed M-20.3 EEBDs achieved the full Cap 1 O_2 delivery requirements of $\geq$ 20 Liters, resulting in valid test results. However, only 46 out of the 50 Subpart O approved M-20.3 reference EEBDs reached Cap 1 O_2 delivery requirements. The four reference EEBDs that failed to deliver $\geq$ 20 liters of O_2 were considered failures.

Although 88 ship-deployed and 46 references M-20.3 EEBDs provided valid test results, during test data analysis, NIOSH found that all EEBDs failed to meet NIOSH performance requirements.

The 88 valid ship-deployed EEBD tests and 46 valid reference EEBD tests failed due to either exceeding the full-test average inspired CO_2 limit ($\geq$ 1.50%), the one-minute inspired CO_2 excursion limit ($\geq$ 4.0%), the full-test average inspired wet-bulb temperature limit ($\geq$43°C), the one-minute inspired wet-bulb temperature excursion limit ($\geq$ 50°C), or the full-test average minimum inspired O_2 level (>19.5%), or a combination of simultaneously exceeding two, three, four, or five of these limits.

The average duration for the 88 ship-deployed EEBDs and the 46 reference EEBDs was 9.06 and 8.91 minutes, respectively. As a result of these Subpart O EEBD capacity and stressor nonconformances, NIOSH opened an NRI. The NRI tasked the manufacturer, Ocenco, with performing an investigation to determine the reason for the failures and subsequently determining remedial actions. Ocenco was also instructed to prepare a User Notice to instruct Navy personnel of the proper use of M-20.3 EEBDs, given the failures NIOSH observed. The requested User Notice was prepared by the manufacturer, submitted to the U.S. Navy, and posted on their website (see **Appendix D**). The User Notice was also posted on NIOSH's website.

All ship-deployed Ocenco M-20.3 EEBDs (n=88) that passed the manufacturer's inspection criteria and provided valid test results demonstrated the expected life support capacity (**i.e., volume of O_2 delivered**) over the course of the manufacturer's specified service time. The exception was one test that lasted 14 minutes and resulted in a full-test average inspired O_2 level of 9.49% (less than the full-test average inspired O_2 limit of 19.5%). Inspired and expired peak breathing resistances measured for all Ocenco M-20.3 EEBDs tested were well within limits accepted as tolerable (-300 to +200 mm H_2O column).

Results Comparison

Some differences existed between the ship-deployed EEBDs and the reference EEBDs full-test average stressor data.

- Average inspired O_2 levels for the 88 ship-deployed EEBDs (0.3669 mole fraction) were 4.4% lower than the 46 reference EEBDs (0.3830 mole fraction).
- Average inspired CO_2 levels measured for the 88 ship-deployed EEBDs (0.0190 mole fraction) were 6.3% lower than the 46 reference EEBDs (0.0208 mole fraction).
- The ΔP (peak expired pressure minus peak inspired pressure) levels measured for the 88 ship-deployed EEBDs (146 mm H_2O column) was 3.4% lower than the 46 reference EEBDs (151 mm H_2O column).
- Differences between inspired wet-bulb temperatures for the ship-deployed EEBDs as compared to reference EEBDs were $\leq$ 1.0% at 44.3°C and 44.2°C, respectively.

Actions U.S. Navy Supervisors May Take to Protect Naval Personnel

- Comply with the manufacturer's EEBD user's guide/instruction manual.
- Store EEBDs properly until they are ready to use.
- Follow proper visual inspection practices.
    - Engage with naval personnel on a regular basis to ensure that visual inspections continue to be performed in accordance with the manufacturer's instructions, both in terms of frequency and completeness.
    - Review training activities related to respirator inspections and visual inspection tests for Subpart H-approved M-20.2 and Subpart O-approved M-20.3 EEBDs and ensure naval personnel get regularly scheduled training in this area.
- Remove any EEBDs that fail visual inspection or non-destructive testing.
- Become familiar with and check NIOSH's Certified Equipment List (CEL), the official listing of all NIOSH Approved respirators, on a regular basis.
    - Search the CEL to verify a respirator's approval status as NIOSH may revoke or rescind a respirator's approval—meaning it is no longer a NIOSH Approved product.
- Sign up for NPPTL's Listserv to receive email notifications relevant to PPE and to stay informed about changes to a respirator's approval status.

Actions Naval Personnel May Take to Further Protect Themselves

- Become familiar with the manufacturer's visual inspection criteria.
- Perform routine inspections of EEBDs that are being stored in various locations onboard the ship.
- Make requests to supervisory personnel to immediately replace any EEBDs which fail the manufacturer's visual inspection. This ensures that EEBDs in service will function as intended.
- Follow the manufacturer's user instructions on how to properly put on (don) and use a NIOSH Approved respirator. Refer to the respirator's packaging or the manufacturer's website for instructions.

Appendix A: Acronyms and Abbreviations

Acronyms and Abbreviations

ABMS	Automated Breathing and Metabolic Simulator
BMS	Breathing and Metabolic Simulation
CO	Carbon Monoxide
CO_2	Carbon Dioxide
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
NLTFE	Navy Long-Term Field Evaluation
NPPTL	National Personal Protective Technology Laboratory
NRI	Non-Conforming Respirator Investigation
O_2	Oxygen
PEPRS	Peak Expired Pressure
PIPRS	Peak Inspired Pressure
QNT	Quantitative
SD	Standard Deviation
QNT	Quantitative Leak Test
VCO_2	Metabolic Volume of Carbon Dioxide Generated
VO_2	Metabolic Volume of Oxygen Consumed
ΔP	Peak Expired minus Peak Inspired Breathing Resistance

Appendix B: Unit of Measure Abbreviations

breaths/min.	breaths per minute
kg	kilogram(s)
L	liter(s)
L/breath	liter(s) per breath
lb	pound(s)
LPM	liter(s) per minute
mL	milliliter
mL/min.	milliliter(s) per minute
mm	millimeter(s)
mm H_2O	millimeter(s) of water pressure
%	percent
Ppm	parts per million
Slpm	standard liters per minute referenced to 0^{o}C and 760 mm Hg

Appendix C: ABMS Stressor Data Plots for M-20.2 and M-20.3 EEBD Tests

Each ship-deployed EEBD was given a number in the sequence in which it was tested starting with 1 for the first EEBD and ending at either 61 (M-20.2 EEBD) or 88 (M-20.3 EEBD) when all EEBDs had been tested. Therefore, the assigned EEBD number was used to identify the order of testing. Reference EEBDs were tested nearly every test day as shown in the plots below by the **red diamond**. Trendlines for both the ship-deployed and reference EEBDs are also shown to further enable comparison between the two types.

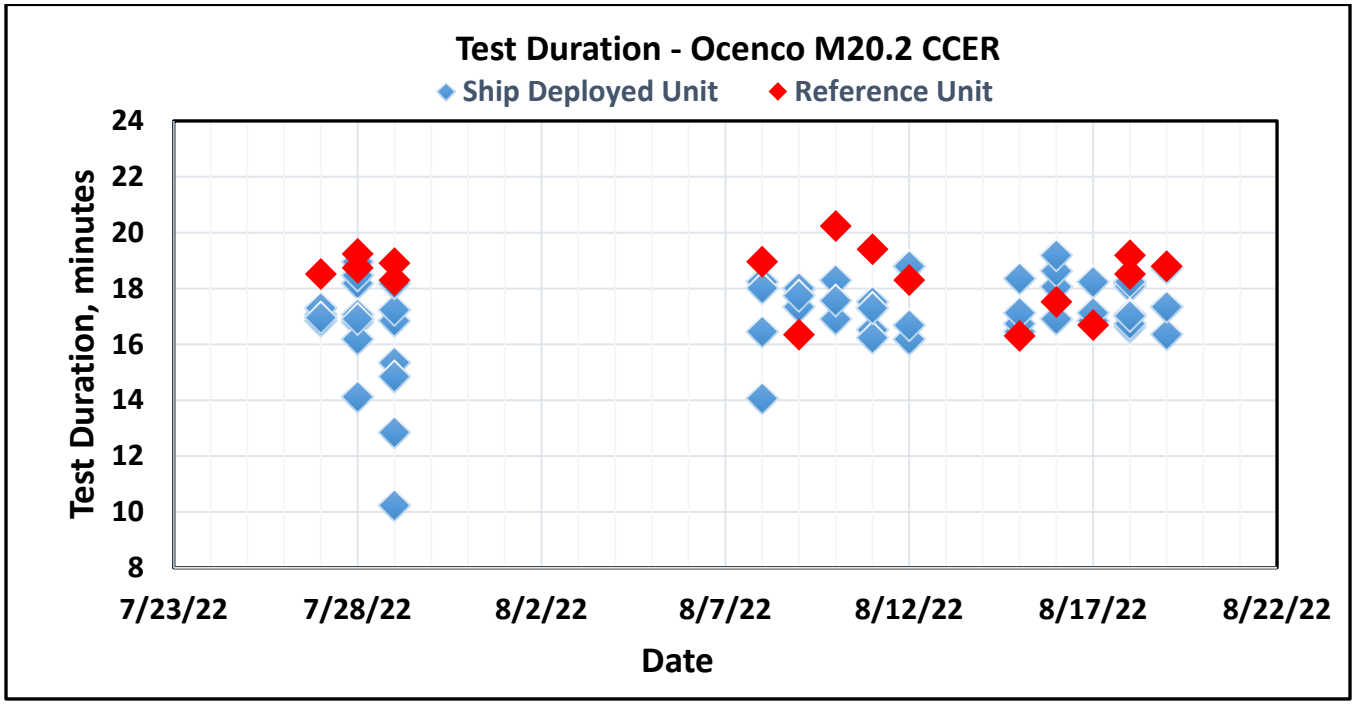


Figure 9. Test Duration vs. Test Date for M-20.2 EEBDs

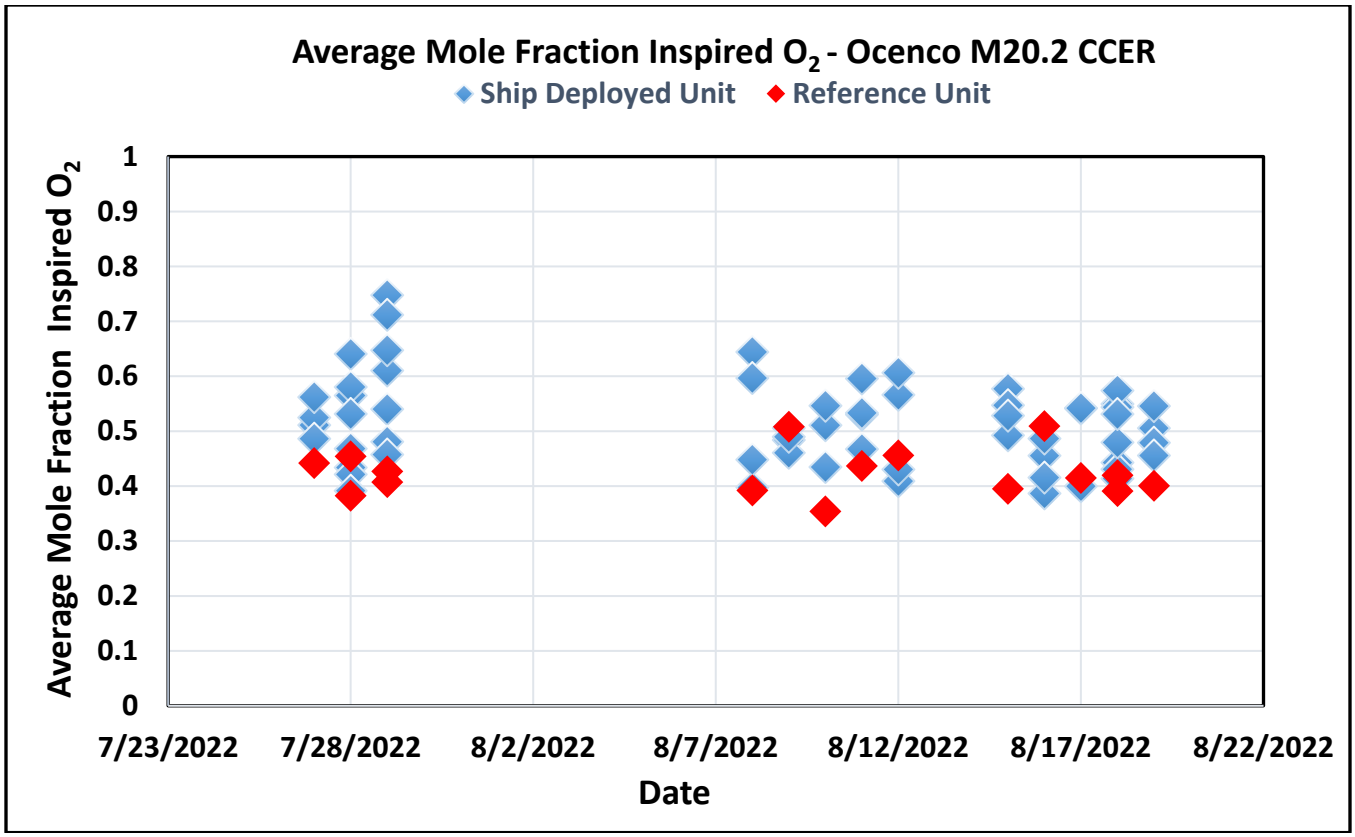


Figure 10. Test Average Inspired O_2 Level vs. Test Date for M-20.2 EEBDs

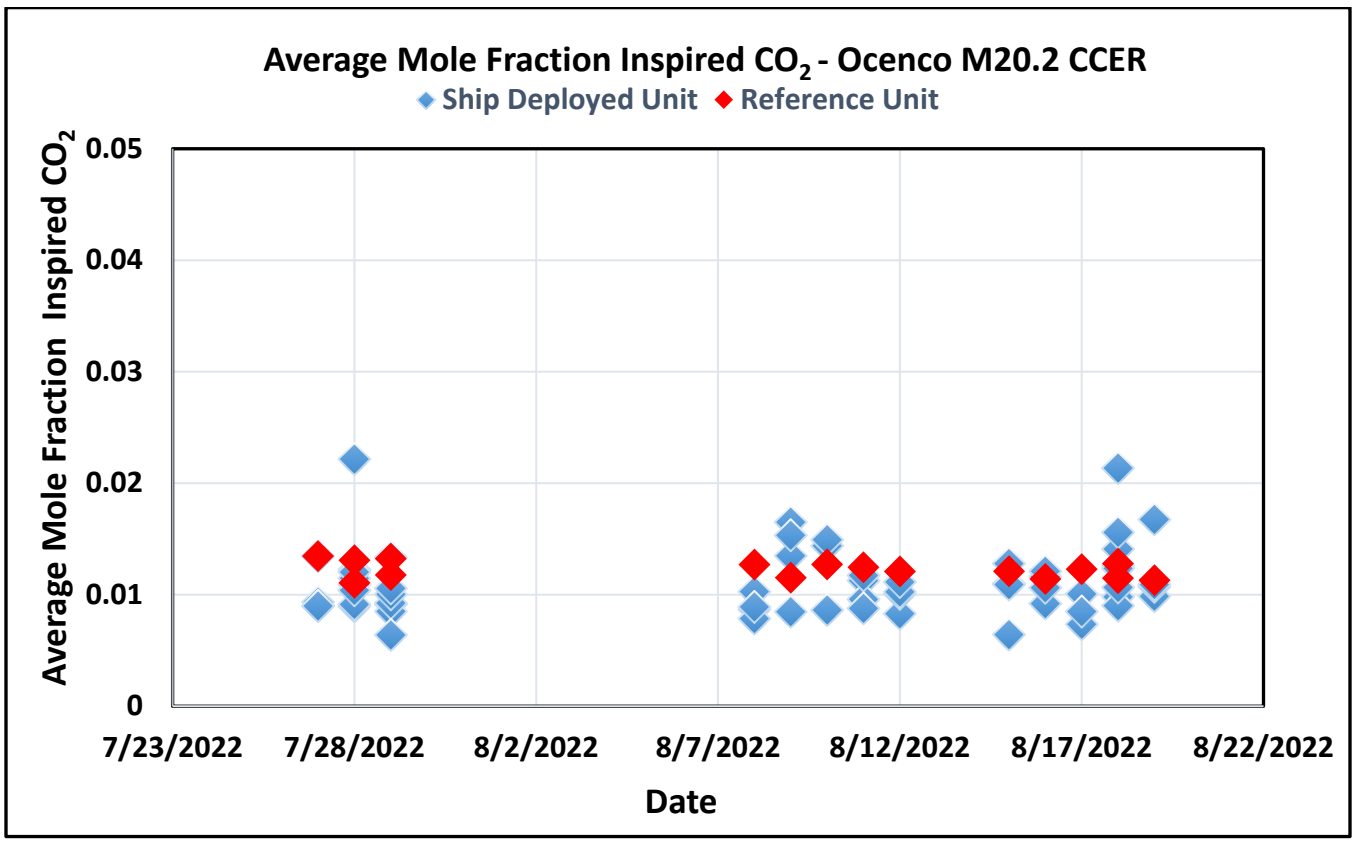


Figure 11. Test Average Inspired CO_2 Level vs. Test Date for M-20.2 EEBDs

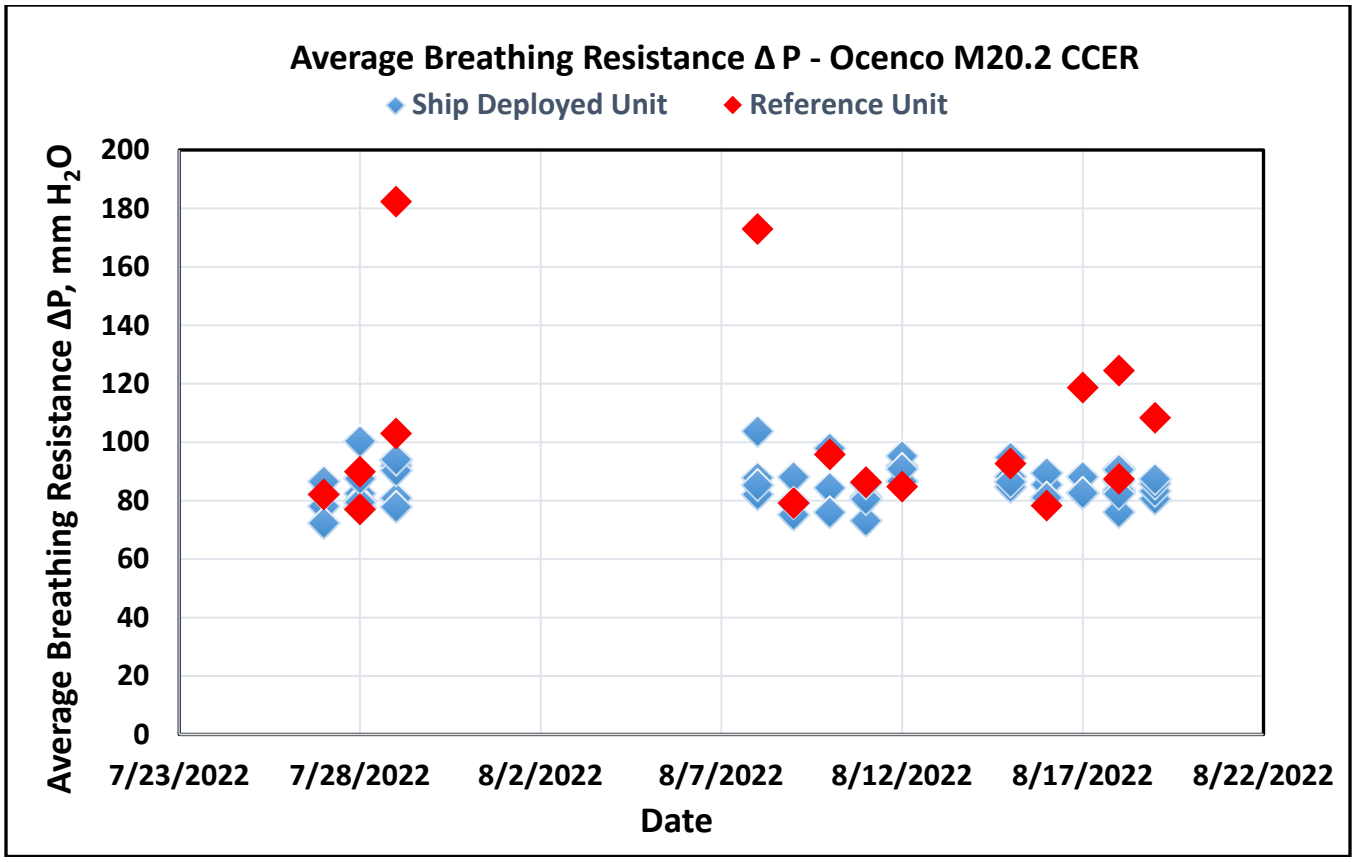


Figure 12. Test Average Breathing Resistance ΔP vs. Test Date for M-20.2 EEBDs

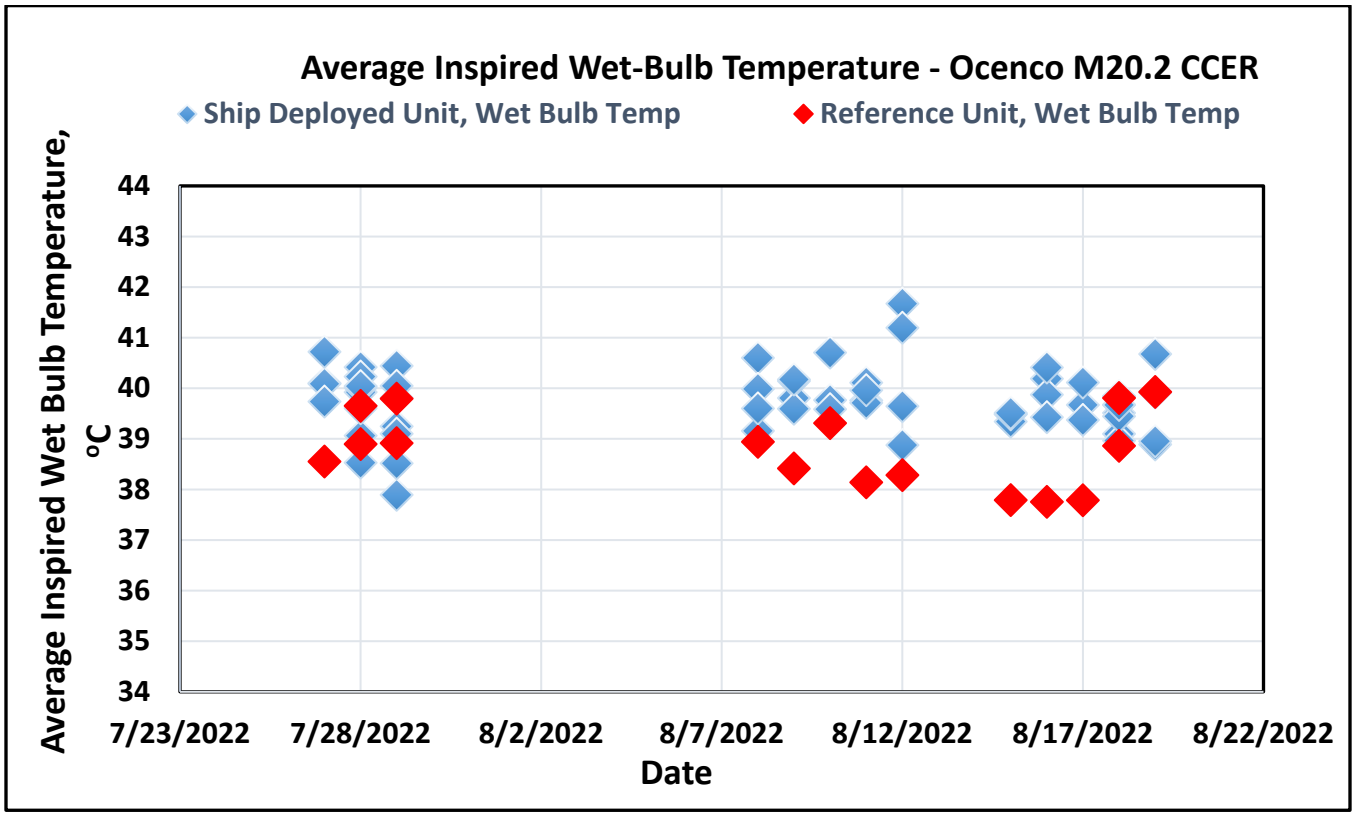


Figure 13. Test Average Inspired Wet-Bulb Temperature vs. Test Date for M-20.2 EEBDs

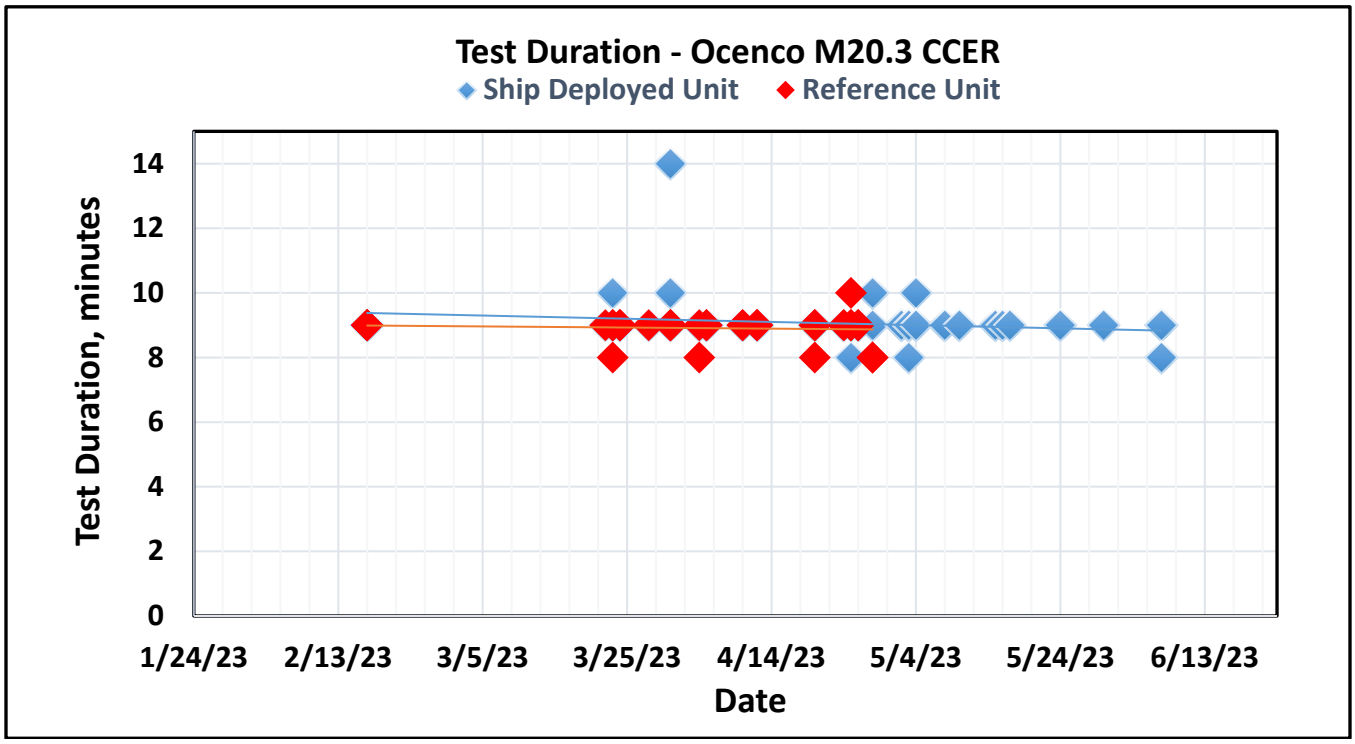


Figure 14. Test Duration vs. Test Date for M-20.3 EEBDs

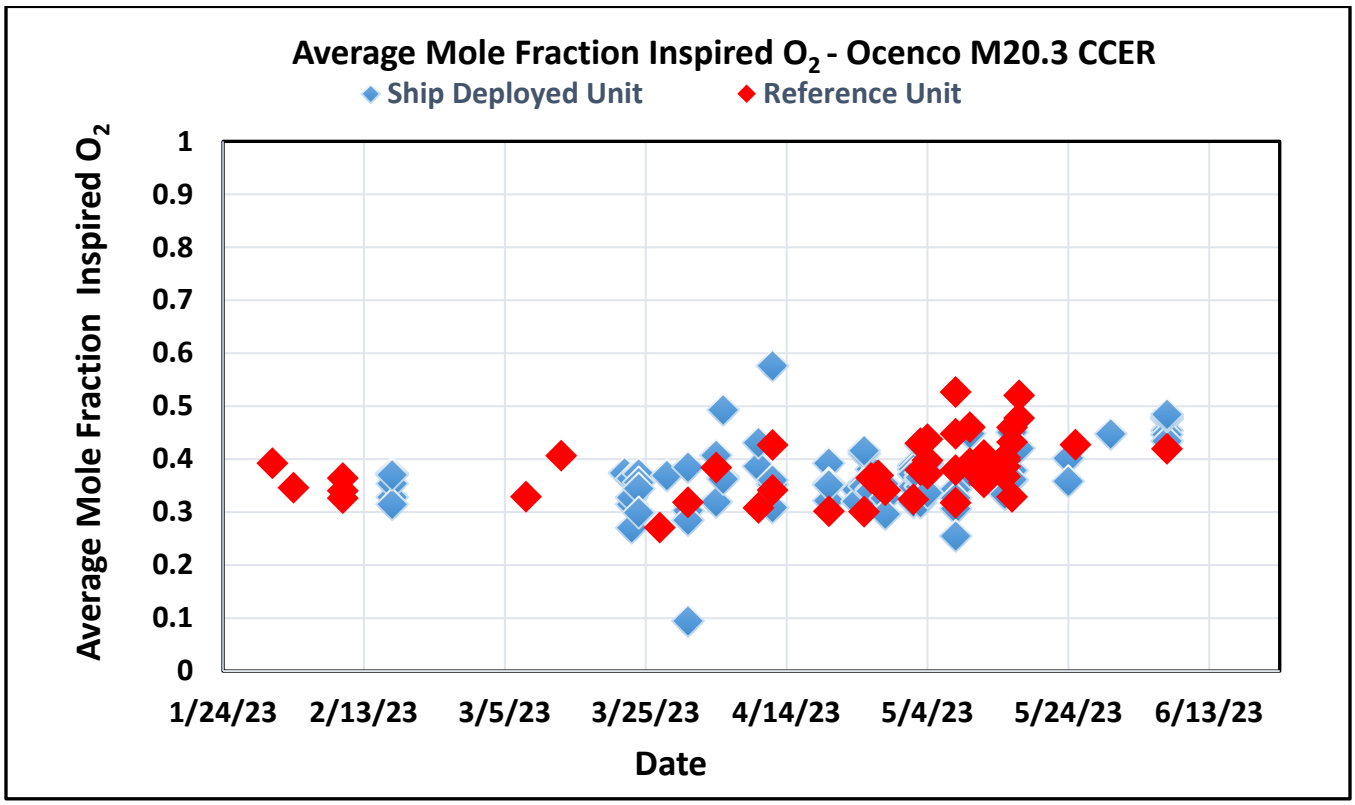


Figure 15. Test Average Inspired O_2 Level vs. Test Date for M-20.3 EEBDs

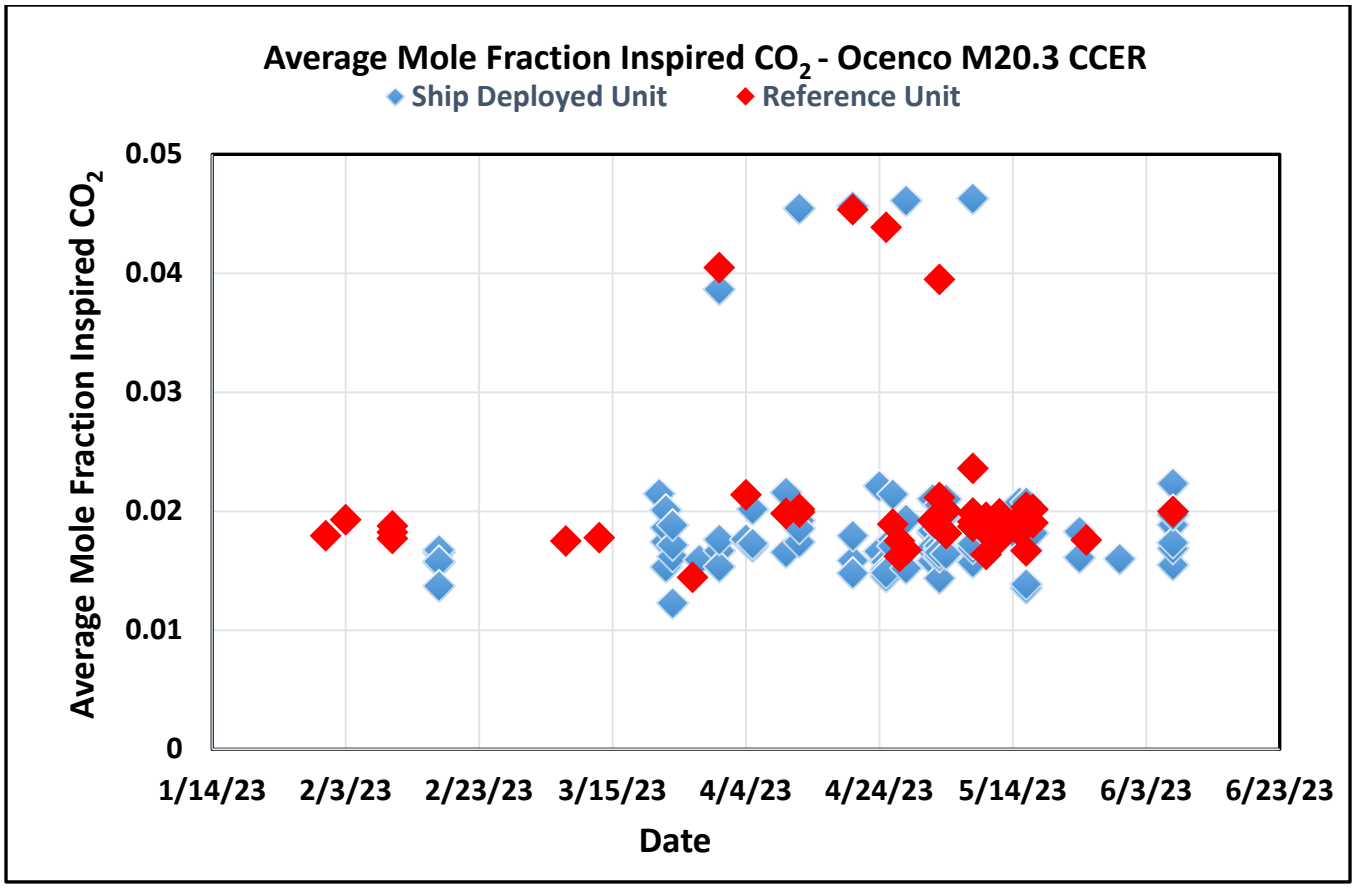


Figure 16. Test Average Inspired CO_2 Level vs. Test Date for M-20.3 EEBDs

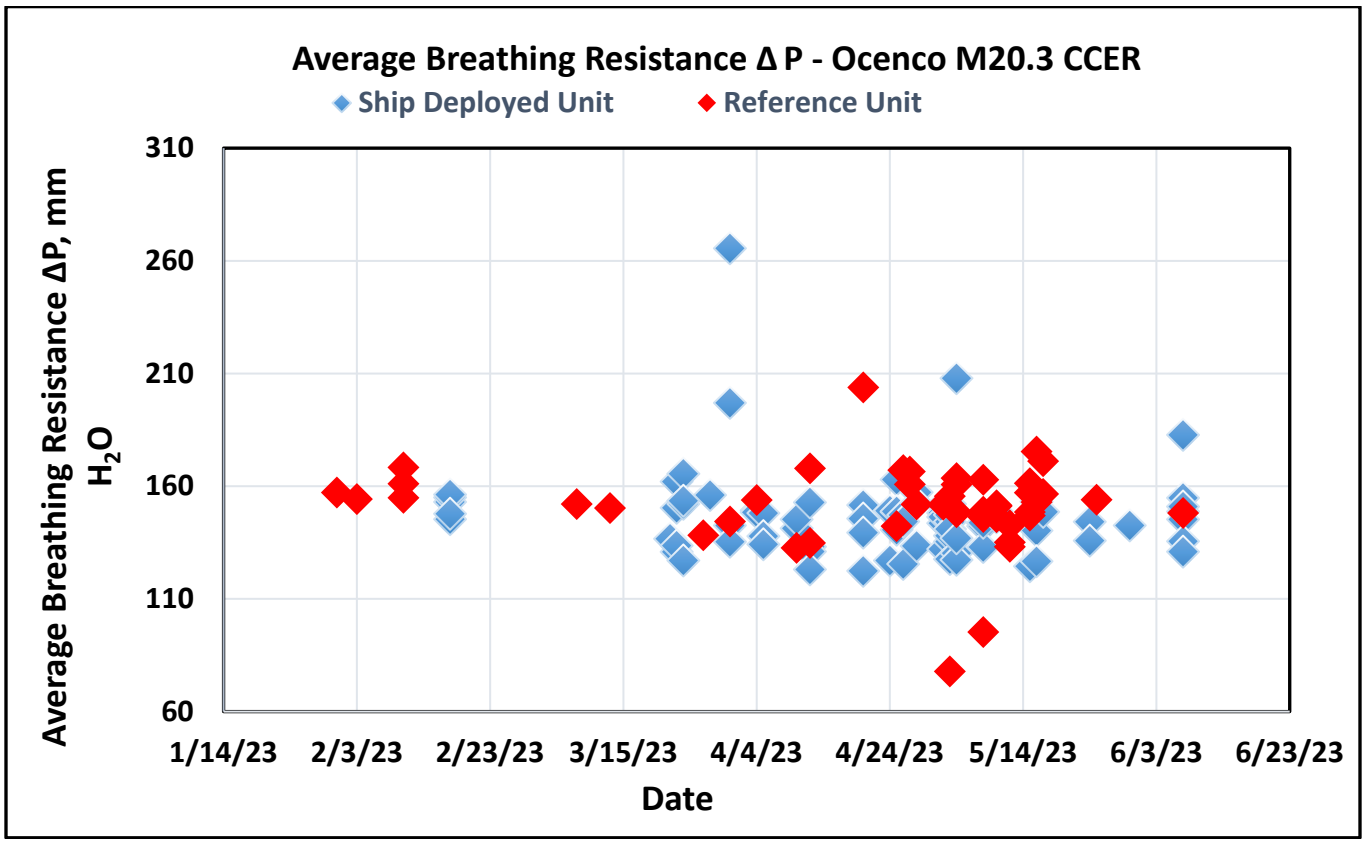


Figure 17. Test Average Breathing Resistance ΔP vs. Test Date for M-20.3 EEBDs

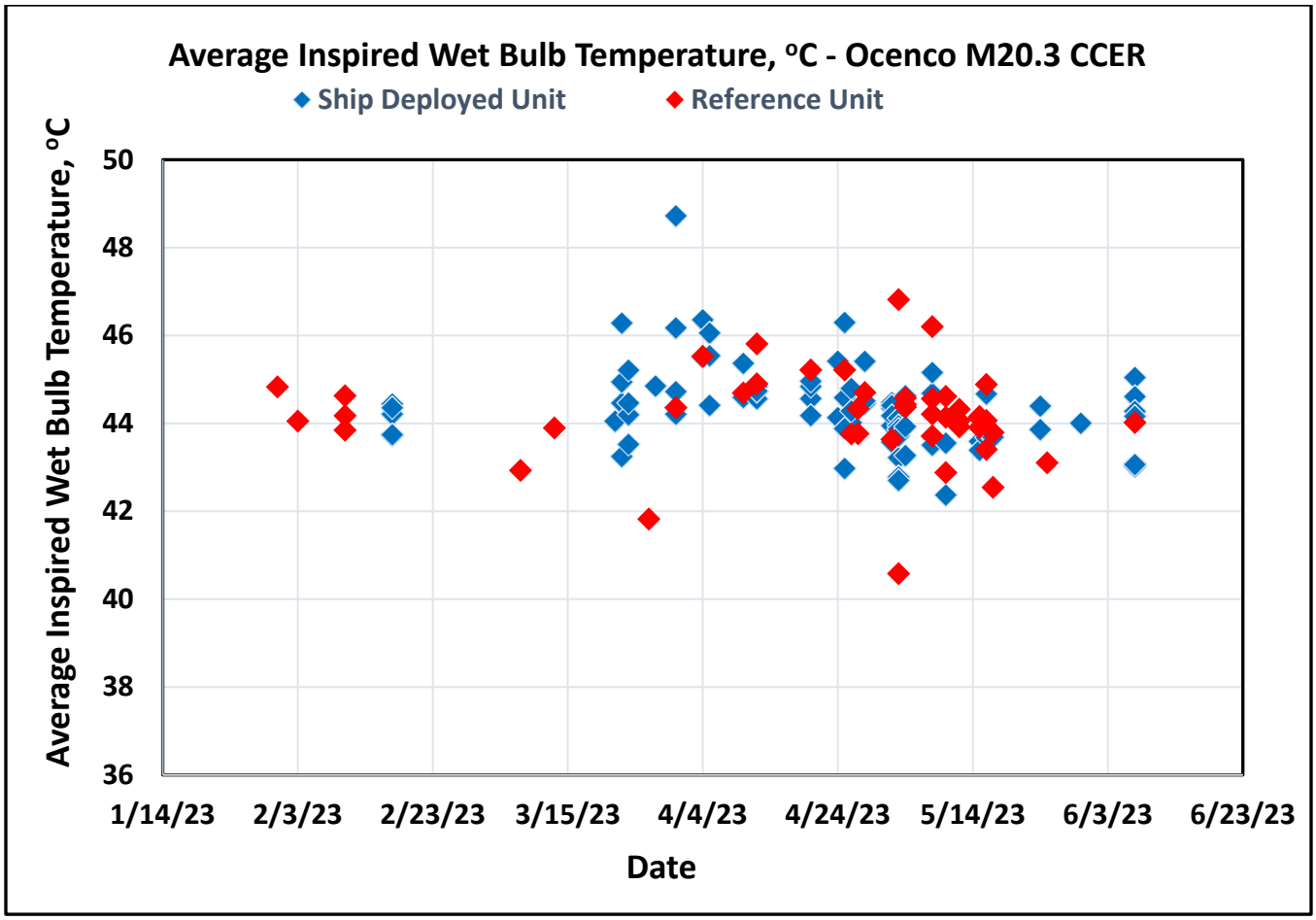


Figure 18. Test Average Inspired Wet Bulb Temperature vs. Test Date for M-20.3 EEBDs

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53158-5801

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Appendix D: Ocenco User Notice Posted on the NIOSH Webpage In January 2024

Ocenco Incorporated
M-20.3 User Notice
January 11, 2024

Ocenco Incorporated has been made aware that numerous M-20.3 SCSR (Self-Contained Self-Rescuer (SCSR)/Emergency Escape Breathing Device (EEBD) units have been discovered to produce elevated inspired carbon dioxide and inspired wet bulb temperature levels. These non-conformances were discovered during NIOSH's Post-approval testing as required per 42 CFR Part § 84.310. Failure of a unit to meet the capacity and performance requirements may result in revocation of the approval for the SCSR or in requirements for specific remedial actions to address the cause or causes of the failure. Ocenco is currently working to determine what remedial actions are required to address the cause(s) of the failure(s). The affected part numbers are 940300 and 940301.

The SCSR/EEBD units that failed exceeded either the average inspired carbon dioxide limit of 1.50% (1.93% maximum measured deviation), the average inspired wet-bulb temperature limit of 43.00°C (44.83°C maximum measured deviation), and the one-minute excursion inspired wet-bulb temperature limit of 50.00°C (50.43°C maximum measured deviation) or a combination of two or three of these limits. For context, Subpart H SCSRs allow inspired wet-bulb temperatures of 57°C for short-duration devices, and routinely exceed 1.5% average inspired carbon dioxide during post-approval testing.

While Ocenco works to determine the root cause of these non-conformances, updates to this User Notice will be made accordingly. In the interim, Ocenco would like to inform our customers the elevated carbon dioxide and temperature conditions occur only during very high work activity. Therefore, Ocenco reminds users to moderate the pace of their escape to reduce their carbon dioxide output, lower their inspired gas temperature, and increase the duration of the device.

Questions regarding this user notice should be directed to:

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262-327-0238 mobile
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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. The authors gratefully acknowledge William Monaghan[8] for his contributions to the U.S. Navy Long-Term Field Evaluation Project that include project development, arranging unit collections, testing, and analysis of EEBDs.

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

William Monaghan[8]
Editorial support.

All photos courtesy of NIOSH NPPTL unless otherwise noted.

[8] Formerly of NIOSH/NPPTL

References

Bureau of Mines [1987] Mathematical Model of Absorption of Carbon Dioxide by Rescue Breathing Apparatus Scrubber. By Edwards, John C. Spokane, WA: U.S. Department of the Interior, Spokane Research Center, U.S. Bureau of Mines Report of Investigations 9132, https://stacks.cdc.gov/view/cdc/10587

NIOSH [2017]. National framework for personal protective equipment conformity assessment – infrastructure. By D'Alessandro M, Metzler R, Carnahan L, and Scott J. Pittsburgh, PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication 2018–102, https://www.cdc.gov/niosh/publications/numbered/2018-102.html

Electronic Code of Federal Regulations. (2014, August 27). Retrieved from U.S. Government Printing Office: http://www.ecfr.gov/cgi-bin/ECFR?page=browse.

Bureau of Mines [1993], *Physiological Costs and Consequences of Mine Escape and Rescue. By Hodgson, J. University Park, PA: The Pennsylvania State University, U.S. Bureau of Mines contract No. J0145038*; 1993:19

Bureau of Mines [1993], *Physiological Costs and Consequences of Mine Escape and Rescue. By Hodgson, J. University Park, PA: The Pennsylvania State University, U.S. Bureau of Mines contract No. J0345327*; 1993:19

Bureau of Mines [1984]. *Physiological Responses of Miners to Emergency. Vol. 1-Self-contained breathing apparatus stressors.* By Kamon, E., Deno, S., and Vercruyyen M. University Park, PA: The Pennsylvania State University. U.S. Bureau of Mines contract No. J0100092; 1984:13.

Roy, L.A., Lara, M.E., Harkness, A.I. (2007) *Effect of Age on Manned Performance Characteristics of the Ocenco M-20.2 Emergency Escape Breathing Device*. NEDU TR07-10.

Deno, N.S. (1984). Automatic Breathing and Metabolic Simulator: The Respiring Robot. Journal of the International Society for Respiratory Protection, 2, 38-51.

Bureau of Mines [1986] Development of an automated breathing and metabolic simulator. By Kyriazi, N. Pittsburgh, PA: U.S. Department of the Interior, U.S. Bureau of Mines, IC 9110, Development of an Automated Breathing and Metabolic Simulator

For more information related to personal protective equipment, visit NIOSH's Personal Protective Equipment page.

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Suggested Citation
NIOSH [2026]. PPE CASE: Point-of-Use Assessment of Emergency Escape Devices for the U.S. Navy. By Gary Walbert and Jeremy Simons. 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 P2026-0101.

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