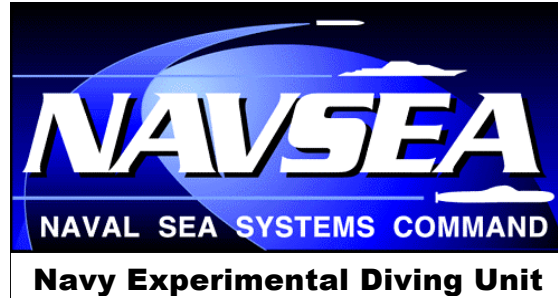


**Navy Experimental Diving Unit  
321 Bullfinch Road  
Panama City, FL 32407-7015**

**TA 18-11  
NEDU TR 19-05  
July 2019**

**VALIDATION OF XVAL-He-8\_040 AND XVAL-He-9\_040  
THALMANN ALGORITHM PARAMETER SETS FOR  
COMPUTING DECOMPRESSION SCHEDULES FOR  
EXTENDED DURATION 1.3 ATM PO<sub>2</sub> He-O<sub>2</sub> DIVING WITH  
N<sub>2</sub>-O<sub>2</sub> DECOMPRESSION**



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<b>1. REPORT DATE (DD-MM-YYYY)</b> 31 July 2019		<b>2. REPORT TYPE</b> Technical Report		<b>3. DATES COVERED (From - To)</b> May 2018–July 2019	
<b>4. TITLE AND SUBTITLE</b> Validation of XVal-He-8_040 and XVal-He-9_040 Thalmann Algorithm parameter sets for computing decompression schedules for extended duration 1.3 atm PO <sub>2</sub> He-O <sub>2</sub> diving with N <sub>2</sub> -O <sub>2</sub> decompression				<b>5a. CONTRACT NUMBER</b>	
				<b>5b. GRANT NUMBER</b>	
				<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b> David J. Doolette; F. Gregory Murphy; Wayne A. Gerth				<b>5d. PROJECT NUMBER</b>	
				<b>5e. TASK NUMBER</b> 18-11	
				<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  Navy Experimental Diving Unit 321 Bullfinch Road Panama City FL 32407-7015				<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>  19-05	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b> Naval Sea Systems Command 1333 Isaac Hull Avenue, SE Washington Navy Yard D.C. 2037				<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b> NAVSEA PMS-394	
				<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b> Distribution Statement A: Approved for public release; distribution is unlimited					
<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> The U.S. Navy 1.3 atm PO <sub>2</sub> He-O <sub>2</sub> Decompression Tables are based on the LEM-he8n25 probabilistic decompression model and all schedules have a near-uniform estimated probability of decompression sickness (P <sub>DCS</sub> ) near 2.3%. These decompression tables were developed to support short bottom time, repetitive, multiday diving. To support long, single dives, an algorithm that computed schedules with higher P <sub>DCS</sub> and consequently faster decompression, and which could be implemented in a dive computer, was desirable. The XVal-He-8_040 and XVal-He-9_040 parameter sets were developed to cause the Thalmann Algorithm to emulate decompression schedules computed with LEM-he8n25 with target P <sub>DCS</sub> =4%. XVal-He-8_040 and XVal-He-9_040 produce nearly identical schedules for the bottom times of interest, and either can be implemented in currently available dive computer hardware (NEDU TR 18-05). Simulated bell lock-out dives were conducted in the NEDU Ocean Simulation Facility to depths (160–200 feet of sea water) where bottom times of about two hours could be accomplished with a maximum 8-hour dive time. 44 divers breathing 1.3 atm PO <sub>2</sub> He-O <sub>2</sub> completed wet, working dives followed by simulated bell lock-in. Decompression according to XVal-He-8_040 Thalmann Algorithm was completed in the dry breathing 1.3 atm PO <sub>2</sub> N <sub>2</sub> -O <sub>2</sub> with air breaks. Divers were monitored for VGE with 2-D echocardiography and for symptoms and signs of DCS. 120 man-dives were completed on six schedules. Median peak resting VGE grade (EB scale) was 0 (IQR: 0–2). One case of Type I decompression sickness (knee pain) occurred for a cumulative incidence (95% exact binomial confidence limits) of 0.8% (0.02%, 4.6%). Manned-validation of XVal-He-8_040 and XVal-He-9_040 Thalmann Algorithm schedules for long bottom times with decompression in the dry resulted in a low cumulative incidence of DCS.					
<b>15. SUBJECT TERMS</b>					
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>  Unclassified	<b>18. NUMBER OF PAGES</b>  31	<b>19a. NAME OF RESPONSIBLE PERSON</b> NEDU Librarian
<b>a. REPORT</b> Unclassified	<b>b. ABSTRACT</b> Unclassified	<b>c. THIS PAGE</b> Unclassified			<b>19b. TELEPHONE NUMBER (include area code)</b> 850-230-3100

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## INTRODUCTION

The 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> Decompression Tables in the *U.S. Navy Diving Manual*<sup>1</sup> are based on the LEM-he8n25 probabilistic decompression model and have a model-estimated probability of decompression sickness (P<sub>DCS</sub>) near 2.3%.<sup>2</sup> These decompression tables were validated at NEDU with extensive man-diving of selected schedules within the normal exposure limits and the actual observed incidence of DCS was 1.5%.<sup>2</sup> These decompression tables were originally developed for Explosive Ordinance Disposal repetitive and multiday diving operations to a maximum of 300 feet of sea water (fsw) for relatively short bottom time dives.<sup>2</sup> In order to support single (i.e. not repetitive), long bottom time 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> dives, an algorithm that computed schedules with higher P<sub>DCS</sub> and consequently faster decompression, and which could be implemented in a dive computer, is desirable.

The relatively low estimated P<sub>DCS</sub> of schedules in the 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> Decompression Tables is appropriate for the short bottom time, repetitive, and multi-day diving for which these tables were originally developed, because low P<sub>DCS</sub> schedules for short bottom times are not inordinately long, and the incidence of decompression sickness (DCS) is a function of the P<sub>DCS</sub> of individual dives and the number of dives conducted. However, calculation of decompression schedules at 2.3% target P<sub>DCS</sub> for extended bottom times results in extremely long total dive times that increase divers' exposure to other risks of diving such as pulmonary oxygen toxicity. Calculating decompression schedules at a higher target P<sub>DCS</sub>, and consequently shorter total dive time, will not result in a high incidence of DCS if dives are relatively infrequent.

The 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> Decompression Tables schedules for dives deeper than 200 fsw are calculated with a compute-intensive algorithm that searches for the shortest schedule that does not exceed a LEM-he8n25-estimated target P<sub>DCS</sub>. To enable production of a repetitive diving timetable in the same format as other decompression tables in the *U.S. Navy Diving Manual*, 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> decompression schedules for 200 fsw and shallower are calculated with the less-compute-intensive Thalmann Algorithm. The Thalmann Algorithm does not use estimated P<sub>DCS</sub> in the calculation of schedules, but for the 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> Decompression Tables, a Thalmann Algorithm parameter set (XVal-He-4) was engineered to emulate LEM-he8n25 2.3% target P<sub>DCS</sub> schedules for 200 fsw and shallower.<sup>2</sup> XVal\_He\_4 was slightly modified (XVal-He-4B) to be suitable for use in the Navy Dive Planner (NDP-He) and NSW He III 200-1.3 Navy Dive Computer (NDC), both of which operate with the Thalmann Algorithm.<sup>3</sup> New Thalmann Algorithm parameter sets that emulate all the schedules in the 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> Decompression Tables (XVal-He-9\_023) and LEM-he8n25 schedules to 300 fsw and for extended bottom times with target P<sub>DCS</sub> of 4.0% (XVal-He-8\_040 and XVal-He-9\_040) have recently been developed.<sup>4</sup> XVal-He-9\_040 Thalmann Algorithm is a computationally efficient method to produce decompression schedules that emulate LEM-he8n25 with 4% target P<sub>DCS</sub> and that could be implemented in an NDC. This P<sub>DCS</sub> is within the range of what is considered normal exposure diving in other decompression tables.<sup>5,6</sup>

The probability of pulmonary oxygen toxicity increases with the duration of breathing 1.3 atm PO<sub>2</sub>.<sup>7</sup> A maximum eight hours of 1.3 atm PO<sub>2</sub> breathing was considered manageable because although signs or symptoms of pulmonary oxygen toxicity are likely after eight hours, they are mild and reversible. Such long duration 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> diving operations would most effectively be accomplished as bell lock-in/out dives, where divers complete decompression in the safety of a dry, air environment. Decompression in such an environment also makes it possible for divers to switch breathing gas supply for decompression. There is some evidence that switching to N<sub>2</sub>-O<sub>2</sub> for decompression following an He-O<sub>2</sub> dive may reduce the probability of Type II DCS relative to Type I DCS.<sup>8</sup> In other words, even if such a helium-to-nitrogen breathing gas switch does not reduce the overall P<sub>DCS</sub>, DCS occurrence following dives with such a gas switch is likely to manifest as Type I signs and symptoms only. The present dives were conducted with divers breathing 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> during the bottom time and initial decompression and switching to 1.3 atm PO<sub>2</sub> N<sub>2</sub>-O<sub>2</sub> at 80 fsw or shallower to complete decompression.

This dive trial is a validation of the XVal-He-8\_040 and XVal-He-9\_040 Thalmann Algorithm decompression algorithm prescriptions (and LEM-he8n25-estimated P<sub>DCS</sub>) and the use a helium-to-nitrogen breathing gas switch during decompression. The validation was limited to the range of depths (160–200 fsw) where He-O<sub>2</sub> is favored over N<sub>2</sub>-O<sub>2</sub> and where bottom times in the vicinity of two hours can be achieved within eight hours total time breathing 1.3 atm PO<sub>2</sub>.

## METHODS

### DECOMPRESSION SCHEDULE SELECTION

The XVal-He-8\_040 and XVal-He-9\_040 parameter sets were developed to enable the Thalmann Algorithm to emulate 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> decompression schedules computed with LEM-he8n25 with target P<sub>DCS</sub>=4% (detailed in NEDU TR 18-05).<sup>4</sup> XVal-He-8\_040 compartment half-times were chosen to produce decompression stop times characteristic of those in 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> decompression schedules computed with LEM-he8n25. XVal-He-8\_040 M-values were derived by numerical optimization to a large, diverse set of LEM-he8n25 schedules. XVal-He-9\_040 is a modification of XVal-He-8\_040 designed to compute no-stop times similar to those in the 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> Decompression Tables.<sup>1</sup> Although XVal-He-8\_040 and XVal-He-9\_040 decompression schedules differ for bottom times near the no-stop limits, XVal-He-8\_040 and XVal-He-9\_040 decompression schedules for longer bottom times, as tested in this study, are nearly identical; see for instance Table 1 and Table 2. Thus, the present dives serve as validation of both XVal-He-8\_040 and XVal-He-9\_040 in this depth and bottom time domain.

Dives were conducted to maximum depths of 160–200 fsw for 90–150 minutes time at bottom and a maximum of eight hours breathing 1.3 atm PO<sub>2</sub>. The schedules that were

tested were computed using XVal-He-8\_040 and are shown in Table 1. For comparison the corresponding schedules computed using XVal-He-9\_040 are shown in Table 2.

Schedules were computed with 40 fsw/min descent to maximum depth. There was no hold during descent to simulate bell lock-out because any such hold had a predictable impact on decompression that did not require testing. Decompression was scheduled to simulate aspects of bell lock-in that had substantial impact on the decompression. Schedules were computed with a 30 fsw/min ascent to 100 fsw followed by a 20-minute hold at this depth to allow time to accomplish a bell lock-in. Ascent rate between stops and to the surface was at 10 fsw/min. Schedules were computed with a 20-minute hold with an inspired  $FO_2$  of 0.21 at the first required decompression stop depth at 80 fsw or shallower. This hold was to allow for a period of breathing chamber air while removing diving equipment. Except for the air stop, schedules were computed for an inspired 1.3 atm  $PO_2$ . 1.3 atm  $PO_2$   $N_2$ - $O_2$  breathing was prescribed for decompression shallower than the air stop. The Thalmann Algorithm is a single inert gas algorithm and the switch from He- $O_2$  to  $N_2$ - $O_2$  breathing during decompression is not explicitly part of the decompression computation. Five-minute air breaks were prescribed following every 60-minute period breathing 1.3 atm  $PO_2$   $N_2$ - $O_2$ . These 5-minute air breaks were considered dead time and are not included in the computation of the schedules or in the stop times in Table 1 and Table 2. The last stop depth was 20 fsw.

The 20-minute hold at 100 fsw was longer than any prescribed decompression stop at this depth, and consequently some shallower decompression stops were shortened or eliminated compared to schedules computed without the hold. For some schedules, the 100 fsw lock-in depth coincided with the first required decompression stop depth. However, for the 160 fsw schedule, the 100 fsw lock-in depth was substantially deeper than the first required decompression stop. This schedule tested the efficacy of a relatively long ascent from the hold at lock-in depth to the decompression stop at which divers switched to breathing chamber air. For the 200 fsw dive, the computed XVal-He-9\_040 schedule prescribed three-minute decompression stops at 120 fsw and 110 fsw. These stops were omitted to test the efficacy of omitting brief in water stops and completing that decompression time as part of the 20-minute hold at the lock-in depth. This procedure substantially expands the envelope of depths and bottom times achievable without requiring divers to perform decompression stops in the water.

Table 1. XVal-He-8\_040 decompression schedules tested

Depth (fsw)	TB* (min)	Stops (fsw, min)									TST (min)	P <sub>DCS</sub> <sup>‡</sup> (%)
		100	90	80	70	60	50	40	30	20		
200	115	20	2	20 <sup>†</sup>	10	11	11	27	85	183	369	4.0
190	90	20			20 <sup>†</sup>	8	11	10	33	183	285	4.0
180	120	20			20 <sup>†</sup>	2	11	10	79	183	325	4.0
170	90	20					20 <sup>†</sup>	9	11	175	235	4.0
160	150	20					20 <sup>†</sup>	11	86	182	319	4.0
160	82 <sup>§</sup>	20						20 <sup>†</sup>	9	147	196	3.9

\*Time at bottom. †Air stop, shallower stops completed breathing 1.3 atm PO<sub>2</sub> N<sub>2</sub>-O<sub>2</sub> with 5-minute air breaks every hour (not included in stop time). ‡LEM-he8n25-estimated-P<sub>DCS</sub> of schedules including air breaks. §Unplanned (see results). Descent rate 40 fsw/min. Ascent rate to first stop 30 fsw/min. Ascent rate from stops 10 fsw/min. Stop times include travel to stops, except the 100 fsw stop and the air stop.

Table 2. XVal-He-9\_040 decompression schedules

Depth (fsw)	TB* (min)	Stops (fsw, min)									TST (min)	P <sub>DCS</sub> <sup>‡</sup> (%)
		100	90	80	70	60	50	40	30	20		
200	115	20	2	20 <sup>†</sup>	10	11	11	27	85	183	369	4.0
190	90	20			20 <sup>†</sup>	8	11	11	32	183	285	4.0
180	120	20			20 <sup>†</sup>	2	11	11	78	183	325	4.0
170	90	20					20 <sup>†</sup>	10	10	175	235	4.0
160	150	20					20 <sup>†</sup>	11	86	182	319	4.0
160	82 <sup>§</sup>	20						20 <sup>†</sup>	9	147	196	3.9

See Table 1 for explanation of abbreviations and symbols.

## EQUIPMENT AND INSTRUMENTATION

All experimental dives were completed in “A”–“C” chambers, the trunk and wet pot of the Ocean Simulation Facility (OSF) at the Navy Experimental Diving Unit (NEDU). The OSF was set up to accommodate four divers at a time. Wet pot water temperature was actively controlled to a target of 81±3 °F (29±3 °C). Two inclined treadmills and two weightlifting stations were positioned on the wet pot deck. Each weightlifting station was an 88 lb (40 kg) kettlebell that the diver would repeatedly lift to and from the deck and a table at waist level. When at these exercise stations a diver’s mid-chest was approximately 6 feet below the wet pot water surface. A table was positioned on a high stand so that the tabletop was at the wet pot water surface. There was sufficient air space above the water surface that divers could sit on the tabletop with their legs below the knees in the water. In B chamber, bunk mattresses were stacked on the deck to construct couches for seating for the decompression in the dry.

Divers' breathing gas (He-O<sub>2</sub> or N<sub>2</sub>-O<sub>2</sub>) was supplied by MK 16 MOD 1 UBAs. This UBA has a breathing circuit in which the diver's expired gas passes through a counterlung and carbon dioxide absorbent canister and is rebreathed. Three oxygen sensors in the breathing circuit are monitored by onboard electronics which trigger the addition of oxygen via a piezo-electric valve if PO<sub>2</sub> drops below a set point. The MK 16 MOD 1 PO<sub>2</sub> set point is 0.75 atm from the surface until the UBA descends to 32 fsw, at which point the PO<sub>2</sub> set point switches to 1.3 atm; the PO<sub>2</sub> set point returns to 0.75 atm when the UBA ascends to 13 fsw.<sup>9</sup> The volume of the breathing circuit is maintained by mechanical addition of diluent gas. In the UBAs worn by the divers in the wet pot, the diluent was 88% He / 12% O<sub>2</sub> (He-O<sub>2</sub>). In the UBAs positioned in B chamber and used to complete decompression, the diluent was 79% N<sub>2</sub> / 21% O<sub>2</sub> (N<sub>2</sub>-O<sub>2</sub>).

Four primary MK 16 MOD 1 used in the wet pot were equipped with MK 24 full face masks. Each MK 24 included a switchover assembly allowing gas to be breathed from the MK 16 MOD 1 or from an open-circuit emergency gas supply. Four primary MK 16 MOD 1 UBAs used for decompression were equipped with a T-bit. In addition to the eight primary MK 16 MOD 1 UBAs, two additional MK 16 MOD 1 UBAs — one charged with He-O<sub>2</sub> diluent and one charged with N<sub>2</sub>-O<sub>2</sub> diluent — accompanied the divers for use as an emergency breathing system in the event of a primary UBA failure. Each primary MK 16 MOD 1 UBA was instrumented with a gas sampling block placed in line with the inhalation hose at its junction with the carbon dioxide absorbent canister. The emergency MK 16 MOD 1 UBAs were not fitted with sampling blocks. Each sampling block housed a thermistor and a micro-fuel cell oxygen sensor (PSR-11-75D, Analytic Industries) with the sensing surfaces in contact with but not obstructing the gas flow path. These sensors were connected by cables that penetrated the OSF hull to a computer-based data acquisition system. Prior to the dive trial, the oxygen sensors were tested for a linear response to PO<sub>2</sub> from 0.21 to 2.31 atm. The oxygen sensor mV output was recorded over at least one minute at air pressures from 0 to 330 fsw in steps of 33 fsw (1 atm) and at an air temperature of 30±1 °C. These data were fit by a straight line with  $r^2 > 0.999$  for all fuel cells. Before each dive, the oxygen sensors were calibrated with 100% nitrogen and 100% oxygen at one atm abs. Oxygen sensor mV output, PO<sub>2</sub> calculated from the daily two-point calibration, and temperature of the gas in the sampling block were recorded by the data acquisition system every two seconds throughout each dive.

When divers were in B chamber, diver depth was measured as B chamber pressure in fsw. When the divers were in the wet pot, diver depth was measured as C chamber pressure (which was open to the wet pot) when the divers were seated on the tabletop at the water surface, or as C chamber pressure plus 6 fsw to account for the pressure of the water column when the divers were submerged on the wet pot deck. Depth and wet pot water temperature were digitized and recorded to the data acquisition system every two seconds throughout each dive.



## DIVING

Forty-four qualified U.S. Navy divers gave informed consent under NEDU Institutional Review Board approved protocol 18-14/40093 and participated as subjects. All 44 subjects were male. Anthropomorphic data were missing for two subjects; at the time of their first dive in this study, the remaining 42 subjects had mean (SD) age of 34 (5) years, body weight of 198 (25) pounds or 89.9 (11.4) kg, height of 70 (3) inches or 1.79 (0.07) m, body mass index (BMI) of 28 (3), and body fat percentage estimated from body dimensions<sup>10</sup> of 18 (5). Individual subject details are given in Appendix A. Prior to their enrollment in the study, an Undersea Medical Officer judged all subjects to be physically qualified for diving on the basis of review of medical records and a physical examination. Immediately before each experimental dive, subjects reported any current injury or illness and their amounts of exercise and sleep, any alcohol consumed, and any medications used in the previous 24 hours. On the bases of this self-report and a brief interview, a Undersea Medical Officer either cleared or disqualified subjects for participating in each experimental dive.

Subjects were required to avoid any hyperbaric or hypobaric exposure for 48 hours prior to and 60 hours following any experimental dive. These restrictions were to avoid any cumulative toxic effects of hyperbaric oxygen exposure and to avoid alterations in tissue inert gas partial pressures, gas supersaturation, and bubble growth that could influence P<sub>DCS</sub> of the experimental dive. Subjects were allowed to participate in multiple experimental dives in this trial. Subjects participated in one to 11 experimental dives (median = 2). Steps were taken to minimize confounding by any acclimatization to decompression of subjects who participated in multiple experimental dives. Acclimatization refers to the apparent decrease in susceptibility to DCS, by unknown mechanisms, over successive (or nearly successive) days of hyperbaric exposures.<sup>11-13</sup> Generally, dives were separated by one week, although on a few occasions by the minimum 60 hours. The 60-hour surface interval is considered to minimize acclimatization.<sup>14</sup> In order to minimize confounding by any acclimatization effect persisting longer than 60 hours, all divers participated in a decompression dive 3–10 days prior to each experimental dive. This preceding ‘work-up’ dive was either a previous experimental dive on this protocol or a dry chamber air decompression dive to 130 fsw for a 20-minute bottom time with a 30 fsw/min ascent rate and a 9-minute oxygen decompression stop at 20 fsw.

Subjects were not randomized to different schedules. The diving watch bill was designed to accrue a roughly equal number of man-dives on each schedule and to minimize repeated participation in the same decompression schedule by subjects who participated in more than one dive. The schedule of each subject’s participation in experimental dives is given in Appendix B. The dry chamber work-up dives were typically conducted on Fridays and are not shown in Appendix B.

Twenty-nine days of diving took place in three blocks: 23 July–2 August 2018; 5–27 September 2018; and 23 January–7 February 2019. One experimental dive per day was conducted, Monday through Thursday, at approximately the same time each day.

Typically four subjects — designated Red, Green, Yellow, and Blue divers — participated in each experimental dive. Prior to entering the OSF, divers dressed in full neoprene wet suits (5 mm or thicker), hoods and booties, emergency safety harnesses, and MK 16 MOD 1 UBAs. Divers briefly fitted the MK 24 full face mask and breathed closed-circuit from the MK 16 MOD 1 while completing checks of the UBA, then returned the switchover handle to the open-circuit mode and removed the MK 24. One at a time, divers entered the OSF trunk where the oxygen sensor and thermistor cables were connected to the gas sampling block on the MK 16 MOD 1, then entered the wet pot and stood on the high stand, approximately waist deep in water. Once all divers were in the wet pot, divers simultaneously performed the following procedure to purge excess nitrogen from the lungs and UBA. Divers fitted the MK 24 full face mask with the switchover handle in the open-circuit mode. Divers exhaled fully through the open-circuit exhaust then turned the switchover handle to the closed-circuit mode and inhaled a full breath from the MK 16 MOD 1. Divers repeated this procedure for the next two consecutive breaths. After the third consecutive inhalation, divers remained in closed-circuit mode breathing He-O<sub>2</sub> from the MK 16 MOD 1. Divers then completed leak-checks of the MK 24 and MK 16 MOD 1.

Divers descended to the wet pot deck and stood with mid-chest approximately six feet below the wet pot water surface. Once divers gave OK signals to proceed, the wet pot air space, trunk, and C chamber were compressed by the introduction of compressed air, at a target descent rate of 40 fsw/min, until the pressure at diver mid-chest level (chamber air pressure plus six fsw hydrostatic pressure) was equivalent to maximum dive depth (Table 1). Soon after reaching bottom, divers began walking on the treadmills or lifting kettlebells. Divers worked at their own pace. Divers worked intermittently (10 minutes on / 10 minutes off). During a rest period approximately halfway through the time at bottom, divers switched between treadmill and weightlifting work.

Divers stopped work before leaving bottom. The wet pot, trunk, and C chamber were decompressed at 30 fsw/min to 100 fsw. The 100 fsw stop time began once all divers had ascended to the wet pot water surface and was completed with divers seated on the tabletop at the wet pot water surface continuing to breathe 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> from the MK 16 MOD 1 UBAs. At the end of the 100 fsw stop, the wet pot, trunk, and C chamber were decompressed at 10 fsw/min, completing any required deeper decompression stops, to the air decompression stop depth (Table 1) and met B chamber which had been compressed to the stop depth with air. At this stop, the divers simultaneously removed the MK 24 full face masks and began breathing chamber air. Stop time began once all divers were breathing chamber air. Divers removed their MK 16 MOD 1 UBAs and one at a time climbed the ladder out of the wet pot into the trunk and then into C chamber. After changing into dry clothes, divers were free to move about B and C chambers and to eat and drink until approximately two minutes before the end of the air stop time. At this time divers assumed a seated position on mattresses along one side of B chamber. Each diver reclined against their decompression MK 16 MOD 1 UBA which was attached upright against the B chamber wall, such that the UBA was positioned approximately as it would if worn. Twenty minutes after beginning breathing chamber air, the divers simultaneously fitted nose

clips and began breathing from the decompression UBA. As soon as the divers were confirmed on gas, B chamber was decompressed to the next stop. Decompression continued with divers breathing 1.3 atm PO<sub>2</sub> N<sub>2</sub>-O<sub>2</sub> from the MK 16 MOD 1 UBA, with 5-minute air breaks every hour. During the air breaks, divers were required to stand and move about the chamber, and could eat and drink. At the end of each 5-minute air break, divers performed the purge procedure to flush any accumulated helium from the breathing loop of the UBA. Travel between stops and to the surface was at 10 fsw/min.

After surfacing, diver-subjects were observed for two hours during which time they generally remained seated and at rest. A Diving Medical Officer interviewed all subjects at 10 minutes and approximately two hours after surfacing, and again the following day (mean 19, range 15–26 hours after surfacing). The principal purpose of these interviews was to establish standard times at which subjects were free of signs and symptoms of DCS; this information is required for incorporating these data into the U.S. Navy decompression database. Subjects were instructed to immediately report any unusual signs and symptoms that occurred outside of these interview times.

## **VENOUS GAS EMBOLI DETECTION**

During the two-hour post-dive observation period, subjects were monitored periodically for venous gas emboli (VGE). Subjects were examined one at a time in the same order as their diver designation (Red, Green, Yellow, Blue). The examinations were at approximately 21 (range 14–34), 50 (range 43–65), 79 (range 70–91), and 109 (range 100–115) minutes post-dive. For each examination, the subject reclined in the left decubital position while the heart chambers were imaged (apical long-axis four-chamber view) with a trans-thoracic two-dimensional echocardiograph (General Electric LOGIQ e R7 with a 3SC-R7 1.7–4.0 MHz phased array cardiac probe). VGE in the right heart chambers (which appear as brightly echogenic spots) were graded according to an ordinal scale adapted from Eftedal and Brubbak<sup>15,16</sup>, and defined in Table 3. The division of grade 4 into 4a and 4b was adopted because it provides better alignment with the VGE grading scale previously used at NEDU.<sup>17</sup> At each examination, VGE in the right heart chambers were graded three times: after the subject had been at rest for approximately one minute and then after forceful limb flexions around the right elbow and the right knee. For the movement conditions, the grade was assigned to the highest signal sustained for four cardiac cycles (grades 1–3) or about 0.5 s (grades 4a–5). Usually this maximum grade was obvious, but in doubtful cases, a video buffer was reviewed. Grades were assigned at the time of measurement and video recording of the measurements were not saved. Measurements were made by the same ultrasound operator throughout the study, one of the investigators (usually DJD or FGM) attended all sessions, and the assigned grades were generally the consensus of the operator and investigator. For each man-dive, the peak grade of all resting examinations and the peak grade of all conditions (rest, arm, and leg) were used for analysis.

Table 3. VGE grading scale

<i>Grade</i>	<i>Definition</i>
0	No observable bubbles
1	Occasional bubbles
2	At least 1 bubble every 4 heart cycles
3	At least 1 bubble every heart cycle
4a	At least 1 bubble per cm <sup>2</sup> in every image
4b	At least 3 bubbles per cm <sup>2</sup> in every image
5	“white-out”, single bubbles cannot be discriminated

## **OXYGEN TOXICITY SYMPTOM SURVEY**

Subjects completed a 10-item self-assessment survey at the times of their pre-dive, two-hour post-dive, and 19-hour post-dive medical assessments. Subjects were asked to grade seven symptoms of oxygen toxicity on an ordinal scale from 0–4 (categories: none, mild, moderate, moderately severe, severe). Two additional items, visual changes and ear problems, requested a grade and a free response describing the changes or problems. A tenth item requested a grade and free response describing any other complaints. Other complaints clearly not related to oxygen exposure (e.g., musculoskeletal pain) were not counted. A count was made of post-dive responses that exceeded the corresponding pre-dive grade.

## **EXPERIMENTAL DESIGN**

The primary outcome measure was the occurrence or not of DCS after diving. Each of the tested decompression schedules have a LEM-he8n25-estimated  $P_{DCS}$  of approximately 4%. Therefore, the outcome (DCS or not) from all decompression schedules was pooled. The experimental unit was the man-dive not the subject. We relaxed the typical definition of independence on the basis that the U.S. Navy has conducted several large-scale dive trials in which the same-diver subject repeatedly dived the same dive profile but with different DCS outcomes<sup>18-20</sup>, which is evidence of day-to-day (intra-subject) variability. The DCS outcomes were treated as independent and identically distributed across all man-dives for the primary goal of validating XVal-He-8\_040 and XVal-He-9\_040 Thalmann Algorithm decompression schedules.

The cumulative incidence of DCS in this study was expected to be about 4%. With a rare binary outcome, it is not practicable to conduct enough man-dives to establish with high confidence that the  $P_{DCS}$  is less than some small value. As is usual for validation of decompression algorithms, the study was designed to reject the decompression algorithm with a high cumulative incidence of DCS, but otherwise accept the algorithm. In this case the specific hypothesis ( $H_0$ ) was that LEM-he8n25-based decompression schedules for extended duration constant 1.3 atm  $PO_2$  He-O<sub>2</sub> dives with accelerated decompression and a helium-to-nitrogen breathing gas switch result in  $P_{DCS}$  not higher than 5% with 95% confidence, as estimated from the observed cumulative incidence of DCS. To limit subject exposure to unnecessary risk, up to 120 man-dives were to be

conducted in a group sequential design. The minimum number of DCS incidents to trigger a stop was four, to avoid stopping due to a cluster of DCS cases early in the trial. Otherwise, the trial was evaluated after each incident of DCS, and the trial stopped with rejection of  $H_0$  if the cumulative incidence of DCS indicated  $P_{DCS}$  greater than 5% with 95% confidence. The trial was also to stop, with acceptance of the schedules, if no DCS occurred in 99 man-dives ( $P_{DCS}$  less than 3% with 95% confidence).

Monte Carlo simulation of possible trial outcomes errors<sup>21</sup> indicated that the probability of rejecting the hypothesis if the real  $P_{DCS}$  is less than 5% (equivalent to significance) was 2.5% and the probability of failing to reject the hypothesis if the real  $P_{DCS}$  is higher than 5% (equivalent to 1-power) was 3.4%. This latter error was calculated assuming real  $P_{DCS}$  can take on any value from 5% to 100%, and a larger error results from calculations using a more credible upper limit of real  $P_{DCS}$ . For instance, using 24% as the credible upper limit for real  $P_{DCS}$ <sup>22</sup> results in a 16.1% estimate of 1-power.<sup>a</sup> The method of performing these calculations is shown in Appendix C.

There is no gold standard test for DCS and no generally accepted case definition for DCS. For subject safety, and because recompression therapy is safe and effective, a sensitive case definition for treatment decisions is appropriate, and the duty UMO made this diagnosis. For research purposes, a standardized and specific case definition is appropriate. For research purposes the outcome of each man-dive was categorized according to the Weathersby et al. 1988 criteria (reprinted in Appendix A of Temple et al.<sup>23</sup> and reproduced in Appendix C of this report). The categories are A1) definite DCS requiring recompression; A2) Definite DCS not requiring recompression (“marginal DCS” or “niggles”); B) unknown outcome (data cannot be used); C) not DCS.

## RESULTS

### DCS

One hundred and twenty man-dives were completed on five planned schedules and one unplanned schedule (see Table 4). The unplanned schedule occurred because a 160 fsw dive was aborted after 82 minutes time at bottom after one of the divers became unwell (unrelated to the diving exposure). All dives were followed in real-time using the NDP-He with the XVal-He-8\_040 parameter set, and the NDP-He was used to calculate a new schedule for this aborted dive profile. One case of Type I DCS (knee pain) occurred for a cumulative incidence (95% exact binomial confidence limits) of 0.8% (0.02%, 4.6%). This diver was treated with U.S. Navy Treatment Table 6 and had complete resolution of symptoms. There were three suspicious incidents of itching or skin discomfort over the chest and abdomen during decompression in the dry that

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<sup>a</sup> A test comprising 27 man-dives on a schedule with 4.7% LEM-He-25-estimated  $P_{DCS}$  resulted in no treated incidents of DCS, and two incidents of transient symptoms during decompression, not classified as DCS; the upper 99% binomial confidence limit of all incidents (DCS or not) is 24%.<sup>22</sup>

resolved before surfacing. These three incidents did not meet the Weathersby et al. 1988 criteria (Appendix C) for definite or marginal DCS. These four medical incidents are detailed in Appendix E.

Table 4. Number of dives and DCS per schedule

<i>Depth</i>	<i>TB*</i>		
(fsw)	(min)	Dives	DCS
200	115	24	0
190	90	24	0
180	120	24	0
170	90	28	0
160	150	16	1
160	82 <sup>†</sup>	4	0

\*Time at bottom. †Unplanned.

## VGE

VGE measurements were not made following the man-dive that resulted in DCS. For the remaining 119 man-dives, the median of the peak VGE grade of all examination times for the resting condition was 0 (interquartile range: 0–2; range 0–4b). The median of the peak VGE grade of all examination times and for any condition (resting or limb flexion) was 3 (interquartile range: 0–4a; range 0–5). The peak VGE grades of any examination time for each of the five planned schedules are shown in Figure 1. There was no evidence of difference in VGE grades between the five planned schedules (Kruskal-Wallis rank sum test,  $p > 0.05$ ), but this comparison is under-powered.<sup>24</sup>

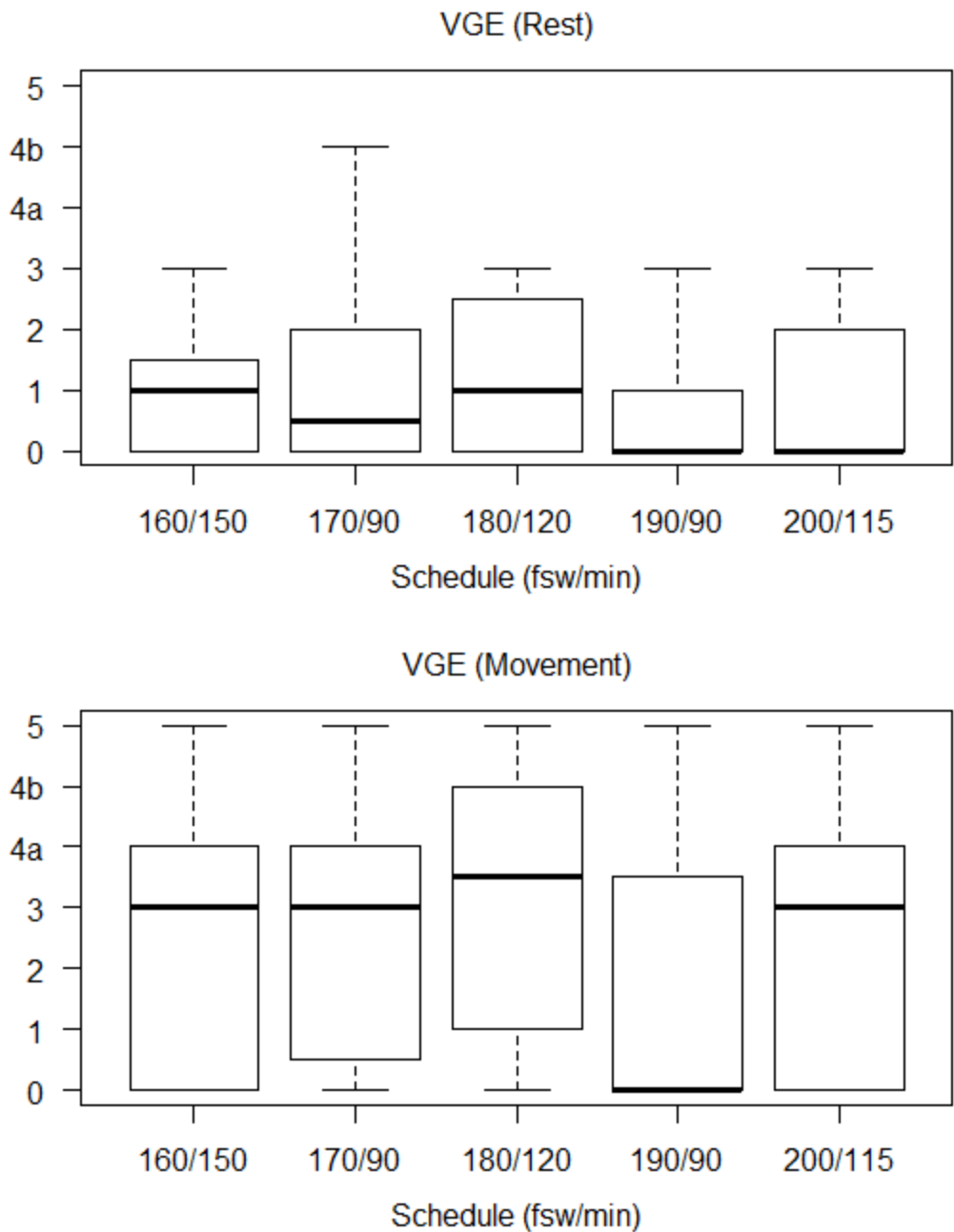


Figure 1. Peak VGE grade of any examination time for the resting condition (top panel) and the peak grade of any examination for any condition (resting or limb flexion [movement], bottom panel), for the five planned schedules. Box and whisker plots indicate median, interquartile range, and range.

## OXYGEN SYMPTOMS

Oxygen symptom data were excluded from analysis for the one subject who received hyperbaric oxygen for treatment of DCS prior to the post-dive surveys. Symptom surveys were missing for an additional three man-dives. Of the remaining 116 man-

dives, 14 resulted in symptoms attributable to the hyperoxic exposure. Symptoms were all graded as mild or moderate and are summarized in Table 5.

Table 5. Oxygen symptoms

Symptoms*	# man-dives	(%)
Pulmonary Inspiratory burning, chest pain, cough	7	(6.0%)
Other Draeger ear, dry eyes	7	(6.0%)

\*Symptoms were scored as either mild or moderate.

## UBA OXYGEN CONTROL

It was common for sampling block oxygen sensor signals to decline steadily during the long decompression, whereas there was no corresponding decline in the PO<sub>2</sub> readings on the MK 16 MOD 1 secondary display of the UBA control system oxygen sensors. This mismatch could arise from an increase in the UBA control system oxygen sensors' response to PO<sub>2</sub> (and resulting decrease in UBA PO<sub>2</sub>) due to increasing gas temperature and imperfect oxygen sensor temperature compensation. However, this mechanism is unlikely because the apparent drift in inspired PO<sub>2</sub> did not reflect the time course of inspired gas temperature (see Figure 2). The decline in the sampling block oxygen sensor signal was attributed to an artifact of moisture accumulation on the sensing surface rather than a true decline in UBA PO<sub>2</sub>. The protocol as initially written required that the divers be directed to manually add oxygen if the sampling block oxygen sensors indicated a PO<sub>2</sub> below 1.15 atm for 15 consecutive minutes, a provision written for the possibility of UBA malfunction. This provision was followed for the first block of diving (23 July–2 August 2018, 28 man-dives). Although the decline in sampling block oxygen sensor signal was common, it only reached 1.15 atm and prompted manual oxygen addition in eight man-dives, typically in UBAs with a lower initial measured PO<sub>2</sub>.<sup>b</sup> The number of manual oxygen additions in an individual man-dive ranged from one to five. Figure 2 is an example of a dive with five manual oxygen additions. After this first block of diving, the protocol was modified to eliminate this routine manual addition of oxygen, both because the decline in PO<sub>2</sub> was considered to be artifact, and because in actual diving operations there would be no similar indication of PO<sub>2</sub> decline to motivate manual addition of oxygen.

<sup>b</sup> Although the MK 16 MOD 1 UBA has a nominal PO<sub>2</sub> set point of 1.3 atm, the actual PO<sub>2</sub> at set point varies slightly owing to the limited precision of the calibration procedure.



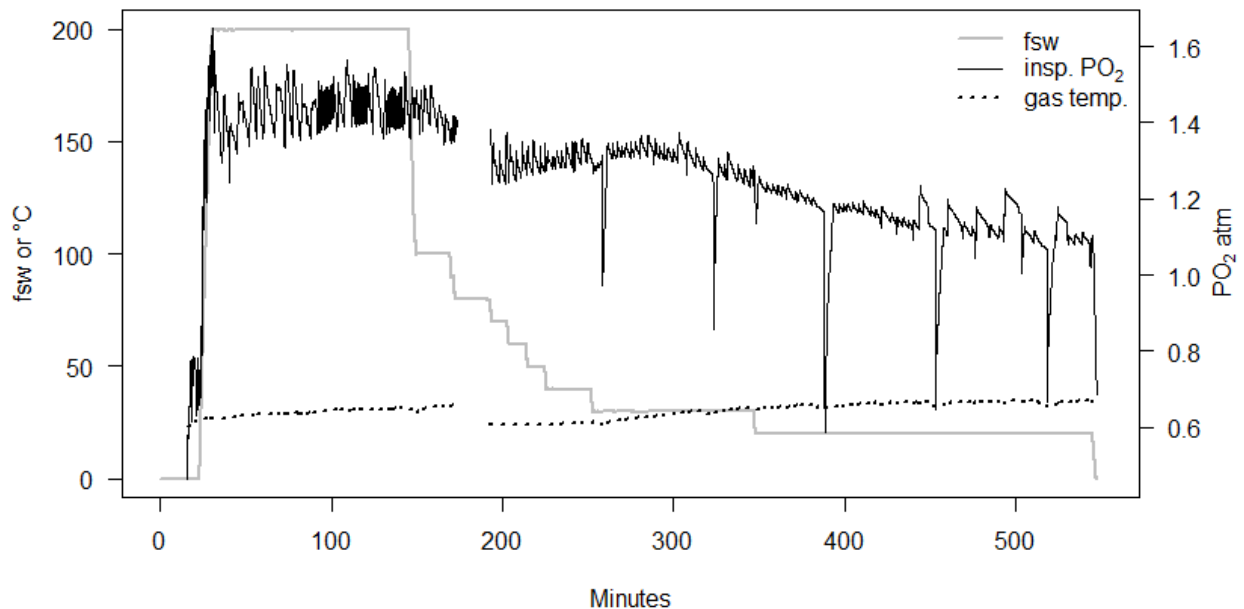


Figure 2. Oxygen control in a dive with manual oxygen addition. The inspired  $PO_2$  (solid thin line) and inspired gas temperature (dotted line) before and after the 80 fsw air stop are readings from diving and decompression UBAs, respectively. The large downward spikes in the decompression UBA  $PO_2$  trace are the result of the purge procedure conducted after every 5-minute air break. Starting at approximately 450 minutes, five manual additions of oxygen are each evident as a step up in the  $PO_2$  trace.

Oxygen and diluent usage during these dives were estimated from the UBA flask pressures before and after diving, read from the UBA pressure gauges. The MK 16 MOD 1 UBA flasks have a floodable volume of 0.101 cubic feet (2.9 L), from which the volumetric gas usage was calculated. Mean (SD) and maximum gas usage during the diving operations in the wet pot and during decompression in B chamber for each of the planned schedules is given in Table 6 and Table 7. Some large values of gas usage result from leak of gas from the UBA breathing loop; for instance, burping of the overpressure relief valve during the weightlifting, and illustrate the importance of maintaining good breathing loop discipline.

Table 6. UBA gas usage, psi

	Wet Pot			B Chamber		
	Mean	SD	Max	Mean	SD	Max
<b>Oxygen</b>						
200/115	935	128	1200	1492	333	2100
190/90	785	115	950	1219	234	1750
180/120	977	446	2900	1262	260	1900
170/90	898	214	1800	1080	234	1650
160/150	1075	159	1300	1255	218	1500
<b>Diluent</b>						
200/115	916	436	2400	408	213	1000
190/90	600	142	950	454	346	1400
180/120	823	320	1550	315	122	600
170/90	812	347	1900	364	262	1250
160/150	759	262	1200	306	121	500

Table 7. UBA gas usage, cubic feet

	Wet Pot			B Chamber		
	Mean	SD	Max	Mean	SD	Max
<b>Oxygen</b>						
200/115	6.4	0.9	8.2	10.2	2.3	14.4
190/90	5.4	0.8	6.5	8.4	1.6	12.0
180/120	6.7	3.2	19.9	8.7	1.8	13.1
170/90	6.2	1.5	12.4	7.4	1.6	11.3
160/150	7.4	1.1	8.9	8.4	1.5	10.3
<b>Diluent</b>						
200/115	6.3	3.0	16.5	2.8	1.5	6.9
190/90	4.1	1.0	6.5	3.1	2.4	9.6
180/120	5.6	2.2	10.6	2.2	0.8	4.1
170/90	5.6	2.4	13.1	2.5	1.8	8.6
160/150	5.2	1.8	8.2	2.1	0.8	3.4

## DISCUSSION

The present dives serve as manned-validation of both XVal-He-8\_040 and XVal-He-9\_040 Thalmann Algorithm for long bottom times with decompression in the dry. XVal-He-9\_040 is the preferred of the two parameter sets because it provides more appropriate schedules at or near the no-stop limits. This validation resulted in a low cumulative incidence of DCS. The upper 95% confidence limit (4.6%) of the observed cumulative incidence is below the maximum 5% estimated  $P_{DCS}$  accepted for normal exposure U.S. Navy diving.<sup>5</sup>

Adoption of XVal-He-9\_040 for diving operations should be done considering that the validation was limited in scope in several ways. A presumption of the present result is that testing relatively few different schedules is sufficient for validation because XVal-He-9\_040 Thalmann Algorithm is designed to compute decompression schedules with near-uniform LEM-he8n25-estimated  $P_{DCS}$ . The study was under-powered to conclusively establish that all the schedules tested had similar  $P_{DCS}$ , but there was no evidence to the contrary from the cumulative incidence of DCS and VGE grades on the individual schedules. The present data together with previous trials represent relatively varied applications of LEM-he8n25 and provide increasing confidence in LEM-he8n25  $P_{DCS}$  estimates. The majority of previous man-dives are of single and repetitive schedules, to depths of 80–300 fsw, computed to have  $P_{DCS}$  near 2.3%.<sup>2</sup> A small number of man-dives were completed on a single schedule to 220 fsw computed to have  $P_{DCS}$  of 4.7%.<sup>22</sup> All trials resulted in relatively low cumulative incidences of DCS consistent with LEM-he8n25 estimates.

The present test dives spanned a relatively narrow range of maximum depths (160 –200 fsw) and focused on long times at bottom (82–150 minutes). Results motivate confidence that XVal-He-9\_040 Thalmann Algorithm is applicable across the depth and time domain tested. The XVal-He-9\_040 Thalmann Algorithm could also be useful outside of the depth and time domain tested in this study, but such dives have not been man-validated.

The present test dives were conducted with divers dry and warm during decompression, conditions that may have reduced the  $P_{DCS}$  compared to dives with decompression conducted cold and immersed. Comparison of chamber dives conducted entirely dry to dives conducted entirely immersed failed to identify an important difference in  $P_{DCS}$ .<sup>25</sup> However, divers without thermal protection decompressed in warm water (97 °F, 36.1 °C) have a substantially reduced decompression requirement (or reduced  $P_{DCS}$ ) compared to decompression in cold water (80 °F, 26.7°C).<sup>26</sup> Such extreme thermal conditions were not used in the present study, but divers were dry and dressed for comfort during decompression, and potentially warmer than divers conducting decompression immersed in cold water with only passive insulation.

Some decompression algorithms track uptake and washout of both helium and nitrogen and assign faster half-times to helium than to nitrogen in the same compartments. In such algorithms, slower uptake of nitrogen than washout of helium in modelled compartments can result in less prescribed decompression obligation for a He-O<sub>2</sub> dive

with a helium-to-nitrogen gas switch for decompression compared to dives conducted breathing He-O<sub>2</sub> throughout.<sup>27</sup> The Thalmann algorithm is a single inert gas algorithm and does not accommodate differences between helium and nitrogen with a single parameter set or in the same dive. If a helium-to-nitrogen gas switch does accelerate decompression, the gas switch in the present dives (dives computed for He-O<sub>2</sub> throughout) would have reduced the P<sub>DCS</sub>.

Nitrogen washes out more slowly than helium from body tissues with slow gas exchange,<sup>28-30</sup> and this probably underlies the slower required rate of decompression from N<sub>2</sub>-O<sub>2</sub> saturation dives than from He-O<sub>2</sub> saturation dives<sup>31,32</sup> (a saturation dive is one of sufficient duration for all the body tissues to completely equilibrate with inspired inert gas partial pressures). However, direct measurement of helium and nitrogen exchange in tissues with faster gas exchange (of the same magnitudes that control decompression from bounce dives) indicate no difference in the half-times for nitrogen and helium.<sup>33</sup> Indeed, U.S. Navy experiments have not been able to identify a decompression advantage of helium-to-nitrogen gas switches for moderate duration bounce dives.<sup>34</sup> Even though the present dives were of extended duration, such that the slow gas exchange tissues where nitrogen exchanges more slowly than helium may control some decompression stops, nitrogen uptake into modelled compartments only occurred during air breaks, otherwise both helium and nitrogen washed out of tissues throughout decompression because of the low inspired PN<sub>2</sub> with constant 1.3 atm PO<sub>2</sub> N<sub>2</sub>-O<sub>2</sub> breathing.

For the reasons outlined above, the helium-to-nitrogen gas switch was not expected to reduce the overall P<sub>DCS</sub> compared to breathing He-O<sub>2</sub> throughout the present dives. Rather, the helium-to-nitrogen breathing gas switch for decompression was used because there is some evidence that a helium-to-nitrogen breathing gas switch may reduce the probability of Type II DCS relative to Type I DCS.<sup>8</sup> In other words, even if a helium-to-nitrogen breathing gas switch does not change the overall P<sub>DCS</sub>, DCS occurrence after such a switch is likely to manifest as Type I signs and symptoms only. The present trial was not a test of this notion, but the only DCS that occurred was Type I.

## CONCLUSIONS

XVal-He-9\_040 Thalmann Algorithm can compute decompression schedules with near-uniform estimated P<sub>DCS</sub> for depths up to 300 fsw and can be implemented in the NDP-He, NDC, or other currently available dive computer hardware.<sup>4</sup>

Manned-validation of dives from 160 fsw to 200 fsw for long times at bottom resulted in low cumulative incidence of DCS.

XVal-He-9\_040 Thalmann Algorithm is suitable for planning and conducting extended duration 1.3 atm PO<sub>2</sub> He-O<sub>2</sub> dives with decompression in the dry.

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## Appendix A DIVER CHARACTERISTICS

Diver ID	Age	Height (inch)	Height (m)	Weight (lb)	Weight (kg)	Waist (inch)	Waist (m)	Neck (inch)	Neck (m)	BMI	Body Fat (%)
1	31	71	1.80	200	90.7	38	0.97	15	0.38	28	24
2	30	69	1.75	175	79.4	33	0.84	14.5	0.37	26	17
3	32	72	1.83	180	81.6	34	0.86	15	0.38	24	16
4	30	71	1.80	194	88.0	36	0.91	14.5	0.37	27	21
5	37	72	1.83	203	92.1	35	0.89	15	0.38	28	19
7	33	71	1.80	182	82.6	32	0.81	15	0.38	25	13
8	37	75	1.9	267	121.1	42	1.07	16.5	0.42	34	26
9	39	72	1.83	200	90.7	36	0.91	15	0.38	27	20
10	41	70	1.78	234	106.1	41	1.04	16	0.41	33	27
11	31	76	1.93	235	106.6	34	0.86	16.5	0.42	29	12
12	27	69	1.75	165	74.8	32	0.81	14	0.36	24	15
13	32	70	1.78	185	83.9	32	0.81	15.5	0.39	26	12
14	28	68	1.73	179	81.2	33	0.84	15	0.38	27	16
15	44	72	1.83	235	106.6	39	0.99	16.5	0.42	32	23
16	29	71	1.80	175	79.4	32	0.81	15	0.38	25	13
17	36	70	1.78	210	95.3	38	0.97	15	0.38	30	25
18	36	67	1.70	188	85.3	36	0.91	16	0.41	30	20
19	37	73	1.85	168	76.2	30	0.76	14	0.36	22	9
20	34	72	1.83	195	88.5	36	0.91	15	0.38	26	20
22	34	75	1.90	240	108.9	35	0.89	17	0.43	30	14
23	51	71	1.80	205	93.0	39	0.99	16	0.41	29	24
24	35	71	1.80	196	88.9	38	0.97	16.5	0.42	27	22
25	34	70	1.78	236	107.0	42	1.07	16.5	0.42	34	28
28	33	74	1.88	245	111.1	38	0.97	18	0.46	31	18
31											
32	31	68	1.73	180	81.6	32	0.81	15	0.38	27	14
35	28	72	1.83	206	93.4	35	0.89	15	0.38	28	19
36	27	68	1.73	170	77.1	31	0.79	14.5	0.37	26	13
38	46	67	1.70	208	94.3	43	1.09	19	0.48	33	27
39	31	69	1.75	205	93.0	40	1.02	16	0.41	30	27
40	31	73	1.85	210	95.3	38	0.97	17	0.43	28	20
41											
42	35	70	1.78	200	90.7	34	0.86	16	0.41	29	15
43	40	67	1.70	165	74.8	30	0.76	15	0.38	26	10
44	39	70	1.78	210	95.3	34	0.86	17	0.43	30	13
45	40	59	1.50	195	88.5	37	0.94	16.5	0.42	39	25
46	41	70	1.78	190	86.2	34	0.86	15	0.38	27	17
47	37	66	1.68	164	74.4	33	0.84	15	0.38	26	17
48	34	68	1.73	165	74.8	34	0.86	15	0.38	25	18
49	29	71	1.80	178	80.7	32	0.81	15	0.38	25	13
50	35	70	1.78	175	79.4	33	0.84	15	0.38	25	16
52	33	74	1.88	232	105.2	37	0.94	16	0.41	30	19
53	27	71	1.80	182	82.6	30	0.76	15	0.38	25	8
54	29	70	1.78	200	90.7	37	0.94	15	0.38	29	23

## Appendix B DIVING INTENSITY

### BLOCK A

DiverID	2018-07-23	2018-07-24	2018-07-25	2018-07-30	2018-07-31	2018-08-01	2018-08-02
1							
2	190						180
3	190						
4				200			
5		170					180
7			180				
8	190				160*		
9							
10							
11		170			160		
12	190					190	
13							
14						190	
15							
16			180				
17			180			190	
18							
19							180
20			180			190	
22		170		200			
23							180
24		170			160		
25							
28							
31							
32				200			
35				200			
36					160		
38							
39							
40							
41							
42							
43							
44							
45							
46							
47							
48							
49							
50							
52							
53							
54							

Numbers in table indicate the schedule by maximum depth; \*DCS

**BLOCK B**

DiverID	2018-09-04	2018-09-05	2018-09-06	2018-09-10	2018-09-11	2018-09-12	2018-09-13	2018-09-17	2018-09-18	2018-09-19	2018-09-20	2018-09-24	2018-09-25	2018-09-26	2018-09-27
1	180														
2				200											
3		200													
4															
5															
7		200		200			170	180			170	160			170
8															
9						160								190	
10	180														
11	180				Mod									190	
12															
13															
14															
15	180				Mod										170
16															
17			170	200										190	
18		200													
19															
20													200		
22			170	200				180			170	160			170
23		200				160									
24			170				170			190		160			
25											170			190	
28															
31															
32							170		200						
35															
36									200						
38			170												
39								180							170
40						160									
41								180							
42					Mod				200						
43						160									
44					Mod				200						
45							170								
46										190		160			
47											170				
48										190			200		
49													200		
50										190			200		
52															
53															
54															

Numbers in table indicate the schedule by maximum depth. "Mod" indicates the 160/82 schedule.

**BLOCK C**

DiverID	2019-01-23	2019-01-24	2019-01-28	2019-01-29	2019-01-31	2019-02-04	2019-02-06	2019-02-07
1								
2						190		
3	170							
4								
5								170
7		200			180	190		
8								
9								
10								
11	170							170
12				160			190	
13	170				180		190	
14								
15								170
16								
17								
18								
19								
20			180					
22						190		
23								
24						190		
25								
28				160				
31		200		160				
32								
35								
36								
38								
39							190	
40								170
41								
42			180					
43		200			180			
44								
45								
46								
47								
48								
49			180		180			
50								
52			180					
53		200						
54	170			160			190	

Numbers in table indicate the schedule by maximum depth

## Appendix C ACCURACY OF GROUP SEQUENTIAL TRIAL

To limit subject exposure to unnecessary risk, up to 120 man-dives were to be conducted in a group sequential design. The trial was to stop, and the decompression algorithm prescriptions rejected if the cumulative incidence of DCS indicated  $P_{DCS}$  greater than 5% with 95% confidence, according to the stopping rules Table C-1. The trial was also to stop, and the schedules accepted, if no DCS occurred in 99 man-dives, which would indicate  $P_{DCS}$  less than 3% with 95% confidence (stop-low, accept).

Table C-1. Stop-high (reject) rules

Stop with 95% confidence $> 5\% P_{DCS}$	
# DCS (or more)	in # man-dives (or fewer)
4	28
5	40
6	53
7	67
8	81
9	95
10	110

Monte Carlo simulation of possible trial outcomes errors<sup>21</sup> indicates that the probability of rejecting the hypothesis if the real  $P_{DCS}$  is less than 5% (equivalent to significance) is 2.5% and the probability of failing to reject the hypothesis if the real  $P_{DCS}$  is higher than 5% (equivalent to 1-power) is 3.4%. This latter error is larger (and the power lower) if a more credible upper limit of real  $P_{DCS}$  is used. For instance, using 24% as the upper limit for real  $P_{DCS}$  results in an estimate of 1-power of 16.1%. The method of performing these power calculations is illustrated in Figure C-1 and C-2.

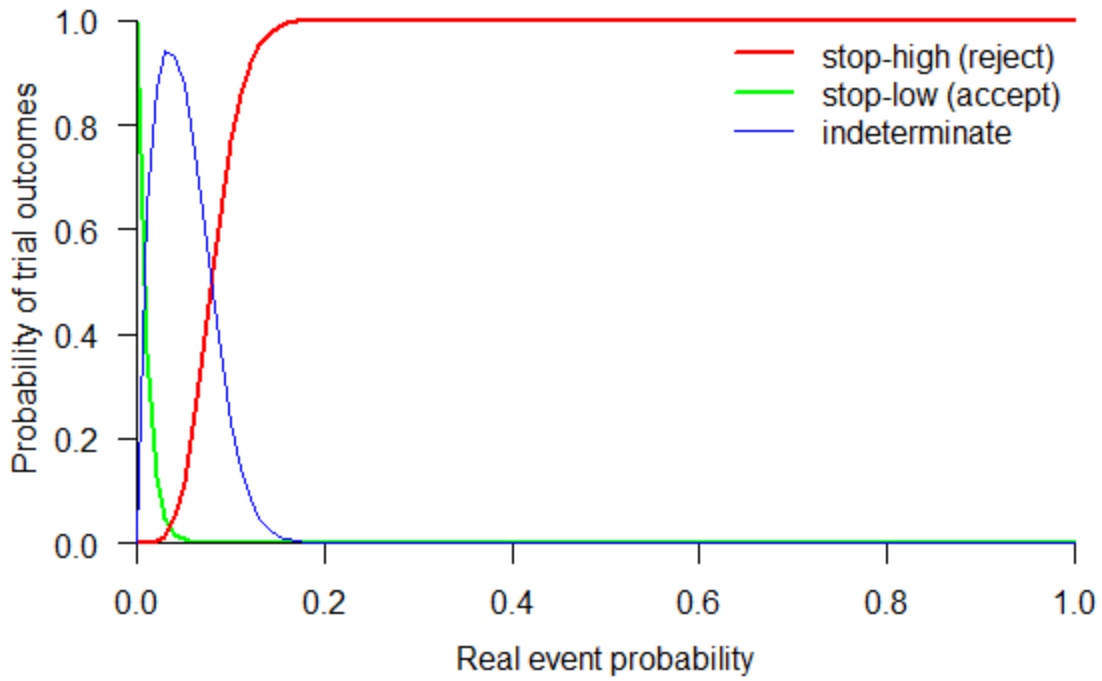


Figure C-1. Monte Carlo simulation of the proposed trial showing the probability of trial outcomes (y-axis) for different actual  $P_{DCS}$  of the experimental schedules (x-axis). Stop-high is the outcome of stopping with a high incidence of DCS, stop-low is the outcome of stopping with a low incidence of DCS, and indeterminate is continuing to 120 man-dives. The simulation assumes the trial is evaluated each time four man-dives are accumulated.

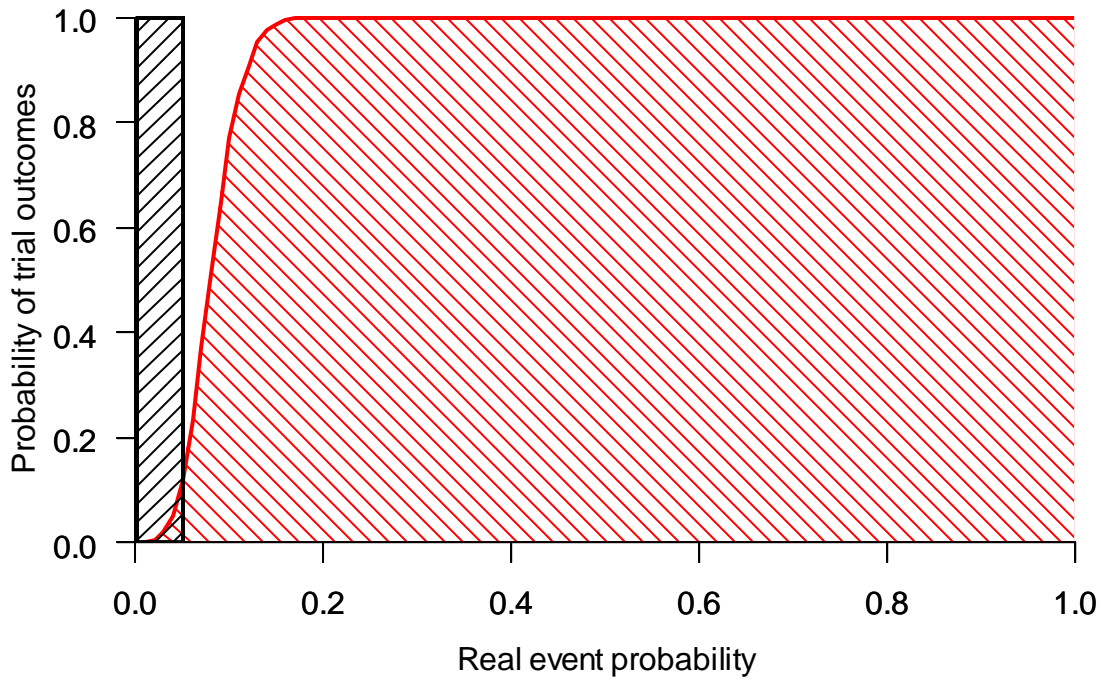


Figure C-2. Example power calculation: probability of rejecting  $H_0$  if  $H_{01}$  is true. Determination of the conditional probability of rejecting given real  $P_{DCS}$  of the experimental schedules  $\leq 0.05$  (5%). The curve shows the stop-high trial outcome from the simulation given in Figure C-1. The area under this distribution is the probability of a failing to reject for all real probabilities of DCS [ $P(B)$ ]. The area inside the rectangle is the probability of all possible trial outcomes for real  $P_{DCS} \leq 0.05$  [ $P(A)$ ]. The intersection of these two areas (cross-hatched area) is the probability of a reject trial outcome for real  $P_{DCS} \leq 0.05$  [ $P(A \cap B)$ ]. The conditional probability of a fail to reject trial outcome given real  $P_{DCS} \geq 0.05$  [ $P(B|A)$ ] is the cross-hatched area divided by the rectangular hatched area [ $P(A \cap B)/P(A)$ ], which is 2.5%.

## Appendix D CRITERIA FOR DCS AS AN EXPERIMENTAL OUTCOME<sup>c</sup>

### A1: DCS requiring recompression

Joint pain persisting at least as long as tabulated below (whether recompressed or not)

Severity	One joint	Multiple joints
Mild	60 min	30 min
Moderate	30 min	15 min
Severe	15 min	8 min

Skin rash or mottling in combination with joint pain of any duration

Dyspnea, unless clearly from barotrauma or anxiety hyperventilation syndrome

Any spinal neurological symptoms supported by signs

Any brain symptoms<sup>d</sup>

Any inner ear symptoms,<sup>e</sup> unless clearly from barotrauma

Any suspicious symptom leading to and relieved by recompression

### A2: Marginal DCS (DCS not requiring recompression)<sup>f</sup>

Joint pain not persisting as long as tabulated above

Moderate or severe fatigue

Skin itch in water-immersed divers breathing air or N<sub>2</sub>-O<sub>2</sub>

Skin rash or mottling as only symptom

Symptoms reported as “DCS not requiring recompression” not fitting other criteria

### B: Unknown outcome (data should not be used)

Headache, typical and common for this diver

Vague abdominal or chest pain, not related to trauma or barotrauma

Vague symptoms of any kind not responding to recompression or oxygen therapy attempted <18 hours after dive<sup>g</sup>

### C: Not DCS

No signs or symptoms reported

Signs or symptoms reported 24 hours after surfacing

Mild joint pain or fatigue consistent with recent exercise

Sharp pain consistent with joint sprain or impact injury

Vague symptoms similar to Marginal DCS not responding to recompression therapy attempted >18 hours after dive<sup>h</sup>

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<sup>c</sup> Weathersby et al. 1988 criteria<sup>23</sup>; language reflects development for retrospective data review; not used for treatment decisions

<sup>d</sup>e.g., visual blurring, “mental sluggishness”

<sup>e</sup> e.g., unsteadiness, vertigo, hearing loss

<sup>f</sup> Based on perception that lack of treatment will not result in morbidity

<sup>g</sup> Diver may have gone on to develop DCS if not treated

<sup>h</sup> At which time any DCS should have occurred



## **Appendix E MEDICAL INCIDENTS**

### **DCS: DIVER ID 8, 31 JULY 2018, 160/150 SCHEDULE**

Eight minutes after surfacing, the diver had a vaso-vagal (fainting) episode. There was no loss of consciousness or injury secondary to the fainting episode. The diver admitted to right leg pain during ascent from the 20 fsw last stop to the surface. The diver later described the pain as moderate to severe in his right leg and which soon localized to the right knee. The diver was diagnosed with Type 1 DCS affecting his right knee. A neurological exam showed no other abnormalities. Eighteen minutes after surfacing, the diver was recompressed. He had resolution of symptoms during descent past 20 fsw, and reported complete resolution of symptoms on assessment at reaching 60 fsw. The diver completed treatment on a Treatment Table 6 without recurrence of symptoms. The diver experienced mild inspiratory burning (rated as a 3-4/10) on the third oxygen period, consistent with pulmonary oxygen toxicity. The inspiratory pain improved after surfacing. At his follow-up medical appointment, the next day, the diver denied recurrence of DCS symptoms and reported improvement in symptoms of pulmonary oxygen toxicity.

### **DIVER ID 15, 27 SEPTEMBER 2018, 170/90 SCHEDULE**

Soon after surfacing the diver, complained of skin "pain" under right breast, onset at the 50 fsw stop. The sensation migrated to left lower quadrant. Symptoms resolved completely before surfacing.

### **DIVER ID 15, 4 SEPTEMBER 2018, 180/120 SCHEDULE**

Following the incident described above, the same admitted to similar symptoms during this earlier dive. Transient "pain" on skin over right pectoral, migrating to stomach, onset during decompression. Symptoms resolved before surfacing.

### **DIVER ID 23, 12 SEPTEMBER 2018, 160/150 SCHEDULE**

At the 18–24-hour post-dive medical follow up, the diver reported abdominal itching had onset at the first decompression stop. Itching completely resolved during 20 fsw stop. No return of itching, but woke the day after the dive with abdominal sensitivity "like I had a good ab workout". No rash, discoloration, fullness etc. Not DCS.