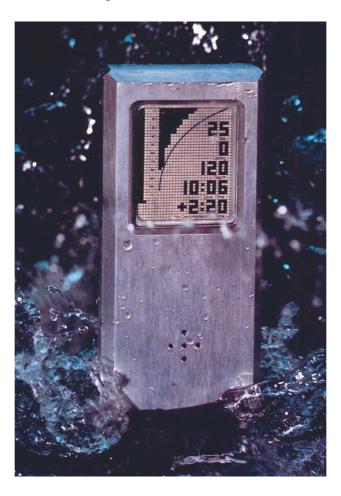


Proceedings of Validation of Dive Computers Workshop

24 August 2011, Gdansk, Poland



S. Lesley Blogg, Michael A. Lang and Andreas Møllerløkken

EDITORS

Sponsorship: Norwegian University of Science and Technology Norwegian Labour Inspection Authority



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Cover image: Electronic Dive Guide (EDGE) computer by ORCA Industries, 1983.

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The workshop organizers would like to extend their appreciation for the financial support of the Norwegian Labour Inspection Authority and sponsorship by the Norwegian University of Science and Technology.

The local host of the 37th Annual Meeting of the European Underwater and Baromedical Society in Gdansk, Dr. Jacek Kot, was most helpful in supporting this workshop.

We thank the workshop presenters and participants for their contributions to the overall success of the discussions on the validation of dive computers.

This workshop was organized and conducted by Andreas Møllerløkken and Lesley Blogg, co-moderated by Michael Lang and Karl Huggins, and co-edited by Lesley Blogg, Michael Lang and Andreas Møllerløkken.

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Dedication



The Proceedings of the EUBS Workshop on Validation of Dive Computers is dedicated to Dr. R.W. 'Bill' Hamilton (1930-2011), whose intellect, compassion, and love of life will not soon be forgotten.

On September 16, 2011, Bill passed away surrounded by his family and close friends, a mere three weeks after he and Kathy participated in this workshop in Gdansk, Poland.

Billy Bob was special. By the way, do you know any other 81-year-olds who still updated their resumes? It's often said that people mellow with age. The exact opposite is true of Billy Bob who productively used every waking minute of every day.

When asked which approach to decompression was the best idea or theory his response represented his sense of humor and operational experience: "It is better to do something, than not."

Born in Midland, Texas, Bill pursued a degree in liberal arts at the University of Texas, followed by a Master's degree in animal reproductive biology at Texas A&M.

The University of Minnesota conferred his doctoral degree in physiology and biophysics in 1964. Along the way Bill joined the U.S. Air Force, earning the rank of Major and serving as a jet fighter pilot during the Korean War and again in Vietnam, where he earned the Distinguished Flying Cross, Air Medal, and other decorations. As a Life Support Officer he helped solve equipment problems on unsuccessful bailouts, which earned him a National Academy of Sciences recommendation to NASA as a Scientist Astronaut. Eventually, Bill left the Air Force with his wife and four children and headed to Buffalo, New York, in 1964, where he met Heinz Schreiner and began his work in the undersea world.

Bill worked as a scientist and director of a leading environmental physiology and diving research lab called Ocean Systems (a division of Union Carbide) based in Tarrytown, NY. He conducted extensive research on the effects of gases both under increased pressure and in hypobaric environments. This work led to the development of decompression modeling tools and operational procedures for divers, astronauts, hyperbaric chambers, and tunnel and caisson workers. In 1965, Bill was both the physiologist and test subject on the first manned laboratory saturation 'dive' to the continental shelf pressure of 12 ATA (200 msw).

Bill met Kathryn Faulkner (aka 'Ruby Lips') on an Eastern Airlines Shuttle, which turned into a 40-year marriage that has created an international family of friends and colleagues. Kathy played a pivotal role in Bill's life, becoming a mother to his children and then grandmother to their children and managed the business aspects of Hamilton Research. It was rare for Bill to be at an event without Kathy close by.

In 1976, Hamilton Research, Ltd. became the premier organization for decompression and hyperbaric research developing procedures and techniques to mitigate the effects of High Pressure Neurological Syndrome and the development of the Diving Computational Analysis Program (DCAP), co-developed with David J. Kenyon. Bill was also the principal investigator of the NOAA Repex Oxygen Exposure tables – the basis for most every oxygen exposure calculation method used today for saturation and repetitive exposures to oxygen in breathing mixtures.

In the late 1980s, Bill stepped out of his traditional role with commercial and military clients and into the world of sport divers by creating project-specific custom decompression tables. He opened up a whole new world of underwater exploration for the free-swimming untethered diver, the birth of 'technical diving.'

Bill was on everyone's invite list for conferences and workshops around the globe. Bill was generous with his time and advice, and he served by volunteering wherever he could. That was his nature.

Bill was recipient of significant honors and awards from many diving and science organizations. His forward thinking of how divers would survive under water is arguably the basis for all extreme-exposure diving today. His modus operandi was to get the job done right and then have a good time with the people around him.

His work with decompression tables, physiological effects of gases, and methods of managing exposure to oxygen were instrumental in the origination and development of the new field of "technical diving."

Bill served on numerous Boards of Directors of diving and medical societies and was a member of many, including Mensa. Hamilton contributed to, and authored, numerous scientific and technical papers, reports, and in particular, diving medical and safety workshop proceedings (http://archive.rubicon-foundation.org).

Billy Bob was predeceased by his first wife Beverly, son Beto and daughter Kitty. He is survived by his wife of nearly 40 years, Kathryn "Ruby Lips," daughters Lucy and Sally, sisters Emily and Ann, grandsons, Felix, Bobby, Zach, Tyler and Truman and an untold number of adoring fans. He is missed.

Billy Bob, thanks for your lasting contributions.

Lesley Blogg, Michael Lang and Andreas Møllerløkken, Editors -

Participants

~			
Surname	Name	Affiliation	E-mail
Angelini	Sergio	Mares, S.p.A	s.angelini@mares.com
Azzopardi	Elaine	NFSD, Oban	elaine.azzopardi@sams.ac.uk
Balestra	Costantino	Haute Ecole Henri Spaak	balestra@daneurope.org
Blogg	S. Lesley	SLB Consulting	lesley@chapelclose20.fsnet.co.uk
Brubakk	Alf	NTNU	alf.o.brubakk@ntnu.no
Buzzacott	Peter	UWA, Perth	peter.buzzacott@uwa.edu.au
Doolette	David	NEDU	david.doolette.as@navy.mil
Egi	Murat	University of Galatasaray	smegi@superonline.com
Fabricius	Christian	Meconett AB	mefaco@algonet.se
Gennser	Mikael	KTH, Stockholm	mikael.gennser@sth.kth.se
Gerth	Wayne	NEDU	wayne.gerth@navy.mil
Guerrero	Francois	University of Brest	francois.guerrero@univ-brest.fr
Gutvik	Christian	Aptomar, Trondheim	christian.gutvik@aptomar.com
Hamilton	RW Bill	Hamilton Research	rubylipshamilton@aol.com
Hamilton	Kathryn	Hamilton Research	rubylipshamilton@aol.com
Huggins	Karl	University of So. Cal.	huggins@usc.edu
Hugon	Julien	BF Systems	hugon.julien@gmail.com
Kot	Jacek	Medical Univ. Gdansk	jkot@gumed.edu.pl
Lang	Michael	Smithsonian Institution	langm@cox.net
Møllerløkken	Andreas	NTNU	andreas.mollerlokken@ntnu.no
Örnhagen	Hans	Hans Ornhagen AB	hans@ornhagen.se
Sieber	Arne	IMEGO, Gothenburg	arne.sieber@seabear-diving.com
Swiergosz	Matthew	ONR	matthew.swiergosz@navy.mil
Wendling	Jürg	DAN Europe	dansuisse@wendling.ch

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The results of the Validation of Dive Computers Workshop, convened by the Baromedical and Environmental Physiology Group of the Norwegian University of Science and Technology on 24 August 2011 in Gdansk, Poland are reported in this volume. The workshop objectives were to discuss the validation of dive computers for use by working (commercial inshore) divers under the control of the Norwegian Labour Inspection Authority. A review of validation procedures of dive tables and dive computers set the stage, followed by consideration of the applicability of dive computers to commercial diving operations. The need for standardization of dive computer technology and their classification as European Union personal protective equipment was discussed. The case was made for welldocumented decompression algorithm testing via man-dives, calibrated against a measurable risk of decompression sickness. The relative conservatism of dive computers was evaluated via test chamber profiles, which could be used to identify a test plan for human trials. The applicability of venous gas emboli as an endpoint in the validation process was debated. The military, scientific and recreational dive community experiences with dive computer use and management was reported. It is worth noting that none of the dive computer manufacturers provide any details as to the inner workings of their models and none have ever performed any substantial human validation. However, in recreational diving, dive computers have been used effectively for over 25 years. The workshop advocated that a validated dive computer would be a useful tool for providing real-time decompression guidance for working divers. It was recommended that a Configuration Control Board be formed to assess conformance with validation requirements, monitor dive computer operational performance, and specify diver education and training.

Keywords: dive computers, algorithm, validation, decompression sickness, endpoints.

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Introduction

Andreas Mollerløkken Norwegian University of Science and Technology Akutten og Hjerte-lunge-senteret Prinsesse Kristinas gt. 3 NO-7491 Trondheim, NORWAY

The European Underwater and Baromedical Society (EUBS) workshop "Validation of Dive Computers" was convened by Professor Alf O. Brubakk and Andreas Møllerløkken with support from the Norwegian Labour Inspection Authority on Wednesday, 24 August 2011 in Gdansk, Poland. The workshop was moderated by Michael A. Lang and Karl E. Huggins, both of whom have specific experience in working with dive computers, both as recreational and scientific tools. The objectives of the workshop were to discuss the validation of dive computers for use by working (commercial inshore) divers and to disseminate the results through a publication. The workshop's focus was not on a discussion of the different models of decompression algorithms that are embedded in dive computers, nor on the history of the different decompression tables, but rather to address the specific goal of describing the mechanism to validate dive computers. One aspect of this effort centered on the different uses of dive computers in order to highlight their efficiency compared to decompression tables.

It has long been recognized that dive computers may enhance both the safety and efficiency of diving. In recreational diving, dive computers have been in use for over 25 years. Different decompression algorithms are implemented in the models of the various brands, and inevitably the results for the same dive profile will be different from computer to computer. Despite this, the diversity of dive computers is still increasing, and there appears to be no trend in existing incident data indicating that some models of dive computers have a higher probability of provoking DCS than others. How then can we determine criteria to consider which dive computers are effective at preventing harm to working divers, for whom the relevant authorities have a duty of care?

The Norwegian Labour Inspection Authority is responsible for the inshore commercial diving community and until now has not allowed the use of dive computers for monitoring decompression status of working divers. In the last couple of years, there has been a proposed revision of the diving regulations and one of the changes was to allow the use of dive computers. What criteria should the Inspection Authority use to select dive computers for approval?

In order to investigate this question, a number of experts within the field of diving research were invited to participate in the workshop. The intent was for each to give a presentation on their specific area of expertise and then help, with the additional aid of the workshop participants, to draw up a list of recommendations for the Norwegian Labour Inspection Authority to consider when compiling their new diving regulations.

This volume contains eight papers and discussions concluding in a final set of consensus recommendations agreed upon by the workshop participants.

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R.W. Bill Hamilton Hamilton Research Ltd. 80 Grove Street Tarrytown, NEW YORK 10591 U.S.A.

"In the beginning God created the heavens and earth. It was not necessary to create the oceans; it was raining at the time. He neglected, however, to devise decompression tables that Adam and his descendants would require. They would need them, so they have been trying ever since to do it themselves." C. J. Lambertsen (1989)

INTRODUCTION

The meaning of the term "validation" is fundamental to the objectives of this 2011 dive computer workshop. A number of efforts have taken place to characterize the functionality and effectiveness of dive computers (Lang and Hamilton, 1989; Hamilton, 1995; Wendling and Schmutz, 1995) and dive tables (Schreiner and Hamilton, 1989; Simpson, 2000). Before the dive computer validation process can take place, a consideration is in order of the function of a dive computer (also see papers by Huggins, Angelini, and Lang, this volume).

DIVE COMPUTER FUNCTIONALITY

The dive computer is supposed to step the diver from a pressure exposure back to the surface without any adverse residual effects, or, if symptoms are present, they should be trivial and easily managed. A wrist-worn, or air-integrated, console-mounted dive computer is exposed to the same pressure and environment as the diver throughout the dive. Therefore it is not limited to the square-wave type dive profiles that dive tables prescribe; it follows the actual multi-level profile of pressure exposure. An acceptable dive computer should also consider the breathing gas, as well as temperature, which is important in dealing with a biological creature. These parameters can be recorded and processed by dive computers. The word 'record' is used here as a verb. The dive computer will perform calculations, but it also records the exposure, the time-pressure profile, the gas profile and the activity of the diver. The ascent rate monitor built into the dive computer provides an accurate speed of pressure reduction, often with a safety stop countdown at approximately 3 msw, and the downloading function of most dive computers allow for a graphic post-dive profile display.

The gas mixtures are an important part of the diver's environment, and most existing dive computers will work with oxygen-enriched air, also known as 'nitrox'. There are also more sophisticated dive computer models that work with helium/oxygen mixtures. Most dive computers allow the diver to control and change the breathing mixture during the course of the dive. The diver may pick up a different breathing gas during the dive but then needs to tell the computer about the change at that time; it is not automatic and has to be done by the diver. Dive computers may incorporate other functions such as navigational tools (electronic compass) or a locating device to help the diver find a boat or perhaps another diver, or a heart rate monitor (Lang and Angelini, 2009).

Many manufacturers use the term 'air integrated,' a fairly straightforward function that records and tracks the gas supply (air or mixed gas) and that also should be able to predict the remaining dive time coupled to a warning system for the diver. Dot matrix displays vary in degrees of sharpness with some showing a high level of detail in either black and white or color, and others in greyscale. The earlier versions had alphanumeric characters that were functional and allowed the diver to tell the computer what to do and then see what it was doing.

Many dive computers can also interface with a desktop or laptop computer, which improves the dive planning function, and affords a chance to print out profiles. The dive computer will simulate the exposure and in that way the diver can walk through the dive without actually entering the water. In some cases 'buddy' monitoring is possible, i.e., the computer can follow more than one transmitter, the sort of thing that a mother might want to do if her kids were all out diving! It's a mechanism to keep track of the dive team.

Several of these dive computer systems will take the individual biological data (i.e., breathing frequency, breathing volume and heart rate) to show the level of activity of the diver and also read environmental temperature. Temperature is a difficult parameter to use; of interest is the temperature of the diver, but the environmental temperature is what is being measured. Even knowing the temperature of the diver does not simplify matters; it is a complex issue that relies on a large database to determine the effects of temperature on the diver. However, if this information is recorded, eventually there will be enough data accumulation to effectively use in model predictions. At least one of the models projects display information into the mask (an aviation term called 'heads-up display') so that the diver can see dive information without having to look down.

DIVE COMPUTER VALIDATION STEPS

What specifically is meant by validation and what steps are taken to do it?

1. Ergonomics.

A term that is used to embrace studies of this type is 'ergonomics.' This concept embraces the interface of dive computer with the diver; what information is displayed to the diver and what controls the diver has over that information. The display must be clear and without ambiguity. Numbers appearing on the display must be discernible as to what they mean. In most cases, the diver has to learn how a particular dive computer works by reading the manual, using the dive computer repeatedly in simulation mode in the dry and then later in dive mode under water. Of primary importance in the evaluation of a dive computer is ensuring that there is no ambiguity, and if any information displayed is unclear, finding out exactly what that information means.

Dive computer controls should be intuitive. Extensive training should not be a requisite to using a particular dive computer. With some experience a diver should be able to select a different model and after a brief review be able to successfully dive it. Comfort and fit is also important, i.e., does it feel good on your arm? If the dive computer is not easily viewed, is too heavy, or there are other accessibility problems, a different model should be selected. When modern electronic, diver-carried computers first appeared in 1983 (Lang and Hamilton, 1989), the divers who used them most successfully were underwater photographers. They had the necessary skills and knew how to seal electronic equipment under water to keep their cameras dry. Therefore, at some point in the dive computer

validation process some leak testing must occur to ensure that the computer does not allow water penetration. The battery compartment must stay dry and salt water intrusion of the circuit board guarantees permanent malfunction.

2. Model function and algorithms.

What is a dive computer supposed to do? Its basic function depends on the model or the computational algorithm with which it calculates the decompression requirements. We are not focused on algorithms as an objective of this workshop, but the algorithm is the business end of the dive computer, the tool that is used to calculate the dive profiles. There are several effective algorithms available, but their treatment is outside the scope of this paper. Schreiner and Hamilton (1989) reviewed the procedures for the validation of decompression tables, the central concept of which also applies to dive computers.

3. Testing dive computer function.

A key consideration that the decompression table validation workshop participants addressed was how to inject 'judgment' into the process of evaluating tables or, in this case, dive computers. How the judgment function of what is acceptable is taken care of is important because many of these decisions are not simple or obvious. At this stage a dive computer is put through its paces and made to do all the functions, such as specific profiles, in simulation mode. The results are carefully compared to reference tables where some judgment is needed. Selected profiles are then physically reproduced and monitored in a dry pressure chamber mode, hoping that the dive computer performs as expected, usually benchmarked to, for example, the U.S. Navy decompression tables.

4. Field testing.

Then comes the fun part: diving the dive computer. When the U.S. Navy first tested their decompression tables, the profile to be tested experienced six exposures and if each one of these six was problem free, it was declared OK and testing proceeded on to the next profile. This protocol was a little optimistic, but that was the way it was done. When testing a dive computer, relatively few profiles can be used or quite a lot. Judgment at this stage determines how many profiles are required to declare a profile as safe?

There is an interesting bit of 'word study' here: the word (diverse) is sometimes pronounced as 'de-verse' and sometimes as 'di-verse', and is essentially the same word as 'divers.' The point being that in order to adequately test a dive computer, its evaluation needs to be done using a variety of different people of all sizes, shapes, ages, weights and skill levels. The broad diversity within the diving community mandates inclusion of this range of divers. That diving community is different from the select group of individuals present today. As I mentioned earlier today, if the bus was driven into the river on its way to this workshop, then it would have set diving technology and decompression research back by a few years! We do need to think about the diversity of exposures when these computers are validated in the field.

CONCLUSION

The judgment component is again emphasized here with reference to the dive computer workshop. During the development of a new decompression table a decompression monitoring board was suggested as the mechanism to be engaged in order to involve an organization with the process. In order to implement a judgment function, there has to exist a committee or board that is charged with this responsibility. The findings of the decompression validation workshop stipulated that it should not be a government body, but preferably an agency of the organization that is doing the development. There are other opinions but the judgment function must enter somewhere in the validation process. I do not purport to have all of the answers, only some of the questions as they relate to validation of dive computers.

ACKNOWLEDGMENTS

R.W. Bill Hamilton was the invited introductory presenter at the Validation of Dive Computers Workshop organized by the Norwegian University of Science and Technology at the annual European Underwater and Baromedical Society Symposium in Gdansk, Poland, August 24, 2011. Bill Hamilton, friend, mentor and colleague passed away on September 16, 2011. This manuscript submission was prepared by Michael A. Lang, Workshop Co-Chair, with appreciation and permission by Kathy Hamilton.

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Dive Computer Considerations

Karl E. Huggins

USC Catalina Hyperbaric Chamber 1 Big Fisherman Cove, P.O. Box 5069 Avalon, CALIFORNIA 90704 U.S.A.

Dive computers are standard pieces of equipment in recreational, scientific, and military diving. However, many commercial diving regulations state that they cannot be used to determine decompression status. The dive computer's ability to continually update decompression status results in more efficient use of dive time. Because few human subject studies have been performed to validate dive computer decompression algorithms, there needs to be a method to evaluate the associated decompression risk for commercial diving use. This evaluation protocol would approve, or reject, specific decompression algorithms. While this protocol could take many forms, this paper focuses on the performance of dive computers exposed to profiles with known human subject results. Approximate risks can be determined by running dive computers against dive profiles with high, moderate, or low risk. Dive computer responses to the same dive profile can vary greatly and decompression algorithms can be assigned levels of risk. For a "high risk" decompression dive, all of the computers went into decompression violation during the decompression (assigned "unknown risk"). If this comparison technique is merged with decompression risk models, different risk estimates could be assigned to the various decompression algorithms over a wide range of dives. The inclusion of dive computers with acceptable decompression algorithms in the commercial diving toolbox would increase the efficiency in multi-level diving operations.

INTRODUCTION

In less than 30 years, commercially viable electronic dive computers have almost completely eclipsed the teaching and use of decompression tables in recreational dive planning and execution. Some recreational training agencies no longer teach the use of decompression tables, training their students from the beginning to rely solely on dive computers. In scientific diving, guidelines (Lang and Hamilton, 1989) were put in place that allow researchers to utilize dive computers in their work, and dive computers have been specifically developed for military diving operations (Butler and Southerland, 2001; Gault, 2006; 2008). However, in commercial diving, dive computers have to date not been utilized to the same extent.

The objective of this workshop is to discuss the validation of dive computers for use by working divers, with an emphasis on inspection and repair dives done in support of Norway's salmon fisheries. Currently these divers must follow the Norwegian Diving and Treatment Tables (Arntzen et al., 2008). The Dive Computer section of this document states:

"Commercial Diving: In principle, a dive computer will work equally well for commercial dives. However, for these dives the diving supervisor is responsible for dive management, depth/time control and decompression supervision according to

prepared procedures. Norwegian regulations require the use of Norwegian Diving and Treatment Tables and these regulations do not allow basing the depth solely on the diver's depth gauge. Further, since most commercial divers spend the entire bottom time at a fixed depth, there is little advantage in using a dive computer. On the contrary, due to the computer's typical extra conservatism, such dive profiles will tend to shorten the bottom time and increase the decompression obligation when using dive computers compared to the use of conventional decompression tables and techniques."

Realistically, dive computers could provide benefits for those divers who do not spend their entire bottom time at a fixed depth. The current diving practice within the salmon pen diving population is some type of multi-level dive with work as they ascend (A. Møllerløkken, pers. comm.) With past estimates of at least 35,000 dives per year on fish farms in Norway (Brubakk, 2001), the ability to use dive computers should have a major impact on improving the efficiency of these dives.

Even though regulations do not permit the use of dive computers in commercial operations at this time, divers have been using computers for years (A. Møllerløkken, pers. comm.) The Norwegian Labor Directorate would like to permit the use of dive computers in their regulations so that workers can improve efficiency in the water when performing multi-level dives, as long as the dives can be as safe as table dives (A. Møllerløkken, pers. comm.) This workshop attempts to answer the question how the safety of decompression algorithms programmed into dive computers can be validated in order to provide reasonable guidance to commercial divers regarding acceptable dive computers and their operational use.

This review addresses how dive computers work, the benefits and risks of dive computer use, potential methods to assess/validate dive computer algorithms, and operational issues that should be considered in determining the efficacy of dive computer use in commercial diving operations.

HOW DIVE COMPUTERS WORK

Dive computers are devices that can be programmed with a variety of decompression models (algorithms) and are able to calculate decompression status on the fly using the actual dive profile, thus freeing divers from the limitations of decompression table formats.

The dive computer senses depth every few seconds and calculates the decompression status from its programmed decompression algorithm. Some dive computers utilize additional variables in their calculations (i.e., temperature, air consumption, heart rate and profile sequence). Once the decompression status is calculated, it is displayed to the diver and the dive computer starts the calculation cycle over again. The diver will then use the calculated decompression status to make decisions about the dive while, hopefully, understanding the limitations of the dive computer. The major benefit of this flexibility is that it allows multilevel dive calculations, without the limitations of the "maximum depth for the entire bottom time" rule that accompany tables. For example, Figure 1 shows a dive to 25 msw for 40 min (the 80 fsw no-decompression limit on the USN 1999 Tables). A dive computer programmed with the table model taken to 25 msw for 35 min would show approximately 5 min of no-decompression time remaining, because the dive performed is the same assumed by the tables. If the computer was taken on the multi-level dive profile shown in Figure 1, then 35 min into the dive it would indicate approximately 135 min of remaining no-decompression

time because it is basing its calculation on the actual dive profile and the depth of the dive computer at that time (13 msw). A diver using the tables on the same multi-level dive would only have 5 min of no-decompression time available since they must assume that their entire bottom time was spent at 25 msw.

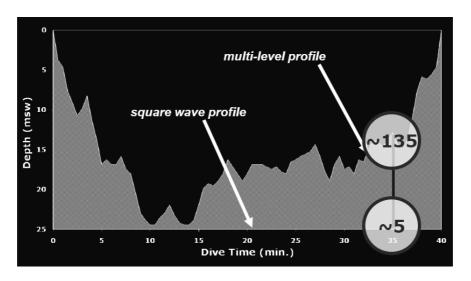


Figure 1. Square-wave (5 min remaining no-deco time) versus actual multi-level profile (135 min remaining no-deco time).

Other benefits include the decompression calculations based on the actual depth of the dive, without the need to round to the next deeper depth calculation, and repetitive dives based on the entirety of the decompression model. Most decompression tables use only one compartment in the model to calculate repetitive dive allowances. Dive computers have accurate depth readings (± 0.5 msw) and provide the diver with information continuously throughout the dive, i.e., decompression status, depth, dive time, maximum depth, ascent rate indication, temperature, and if the computer is air-integrated, cylinder pressure and remaining air time will also be shown. Following the dive, the dive computer maintains a log of the dive and, in most computers, detailed dive profile information. A system set up to collect dive profile information from commercial diving operations would allow for feedback and modification of protocols established for dive computer use.

In order to gain the benefits of dive computer use the diver gives up some of the safety margins built into decompression tables. The assumption that the entire dive was spent at the maximum depth adds some safety to the diver who has performed a multi-level dive. Likewise, entering the table at the next deeper depth and following tested repetitive dive schedules that are based on a single compartment of the underlying decompression model also adds safety. Additionally, there is the potential for dive computer electrical or mechanical failure and user error. But the primary issue addressed by this workshop is the validation of the safety of dive computers. Since there has been very limited human subjects testing, most support for dive computer use has been due to their operational success in the recreational and scientific diving communities. However, operational safety does not translate to decompression algorithm safety since most dives performed do not push the algorithms to their limits.

DIVE PROFILES: COMPUTER VERSUS TABLE

To gain an understanding of some of the operational benefits that result from dive computer use over table use, simulated dives were generated using the decompression software package GAP 2.3 using the ZH-L16C decompression algorithm at its most liberal setting. The ZH-L16C model is a derivation of Bühlmann's (1984) Swiss decompression model, of which variants are used in many dive computers and decompression software packages. The GAP software generated decompression requirements approximately equal to the Norwegian Decompression Tables for a square wave dive to 45 msw for 25 min (Figure 2). Therefore, the risk of decompression sickness, pDCS of these two dive profiles should be approximately equal.

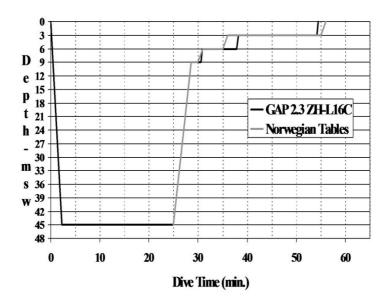


Figure 2. Square-wave dive decompression requirements, Model versus Table. $p(DCS_{model}) \approx p(DCS_{table})$

A simulated inspection dive starting at 45 msw with a continuous slow ascent resulting in the same 25 min of bottom time, could, according to the model, be performed without going into decompression. Using the tables, the diver would be required to assume that the entire bottom time was spent at 45 msw, resulting in 30 min of required decompression upon reaching 9 msw (Figure 3).

In this case the pDCS for the diver following the tables would be less than the diver using a dive computer that allowed the continuous ascent no-decompression dive. What that difference is and whether it is significant is at the heart of the risk/benefit analysis being considered at this workshop.

While the inclusion of the type of continuous ascent dive shown in Figure 3 or some similar multi-level dive with equivalent bottom time seems reasonable, the ability to use dive computers could lead to other types of dive profiles where the difference in risks between model and table could become much greater. Figures 4 and Figure 5 show two types of no-decompression dive profiles that the model would allow.

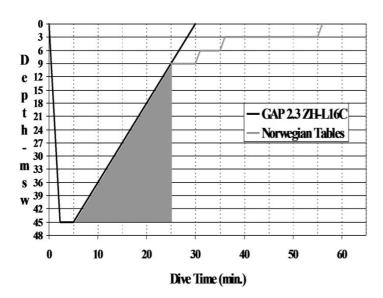


Figure 3. Continuous ascent decompression requirements, Model versus Table p(DCS_{model}) > p(DCS_{table})

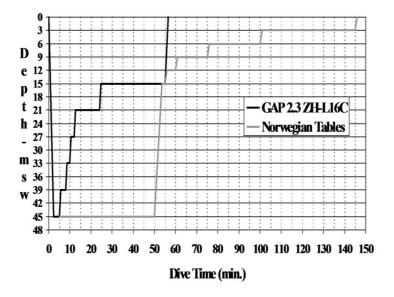


Figure 4. Multi-level no-D dive pushed to model limits, Model versus Table **p(DCS**_{model}) >> **p(DCS**_{table})

Figure 4 is a multi-level dive that runs the no-decompression time at each level (except the last) down to less than 1 min. This technique produces a 45 msw/55 min no-decompression dive. While the model does not require any decompression, the Norwegian tables would require 95 min of decompression. In this case the risk disparity would be much greater than the continuous ascent dive in Figure 3.

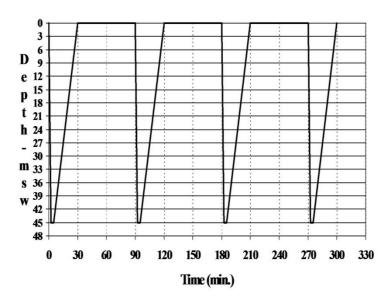


Figure 5. Repetitive deep dives allowed by model.

Other types of no-decompression dives, like the repetitive deep dive series shown in Figure 5 may be allowed by some dive computers. These dives greatly exceed decompression table limits, but do they produce an unacceptable risk of decompression sickness?

There are many ways to assess the risk of the decompression algorithms programmed into dive computers. These include human subjects' tests, monitored pilot programs, comparison to dives with know decompression sickness risk, comparison to risk models, etc. The focus here is on the performance of dive computers when exposed to profiles with known human subject results.

PERFORMANCE OF DCs EXPOSED TO PROFILES WITH KNOWN HUMAN SUBJECT RESULTS

Ongoing studies at the USC Catalina Hyperbaric Chamber ran dive computers against a group of dive profiles that have been tested with human subjects, or have a large number of operational dives (Huggins, 2004). Profiles were rated as "high risk" if they produced cases of DCS or high Doppler bubble scores, "moderate risk" if there was no DCS and moderate Doppler bubble scores, and "low" risk if there was no DCS and no or low Doppler bubbles detected. Dive computer decompression responses to the profiles were compared to the decompression schedules. Conclusions about the decompression algorithm were based on the dive computer's response to the profile (Table 1).

The profiles the dive computers were tested against include two "low risk" multi-level dives (40 msw and 20 msw maximum depths) from the PADI/DSAT RDP test series (Hamilton et al., 1994), a "moderate risk" short 50 msw decompression orientation dive performed at the Catalina Hyperbaric Chamber, and a "high risk" long 36 msw decompression dive from a DCIEM air decompression study (Nishi and Lauchner, 1984).

	Profile Risk Rating					
Dive Computer	"High" Risk "Moderate" Risk		"Low" Risk			
Decompression	DCS	No DCS	No DCS			
Requirements	High VGE	Low to Moderate VGE	No VGE			
Less than tested profile	Algorithm too Liberal High Risk	Algorithm too Liberal Moderate Risk	Algorithm risk greater than profile risk Unknown Risk			
Greater than tested profile	Algorithm risk less than profile risk Unknown Risk	Algorithm risk less than profile risk Unknown Risk	Algorithm Conservative			

Table 1. Risk rating versus dive computer response to profile.

The dive computers were immersed in water inside the chamber and the profile was run. Remaining no-decompression times, or required total decompression times, were recorded from each computer 1 min prior to departure from each depth in the profile. Results from the 20 msw multi-level no-decompression dive showed a range of responses from 20 min of remaining no-decompression time to 19 min of required decompression time just prior to the final ascent. The results for the 40 msw multi-level no-decompression dive were similar, 26 min of no-decompression time remaining to 15 min of required decompression time (Figure 6).

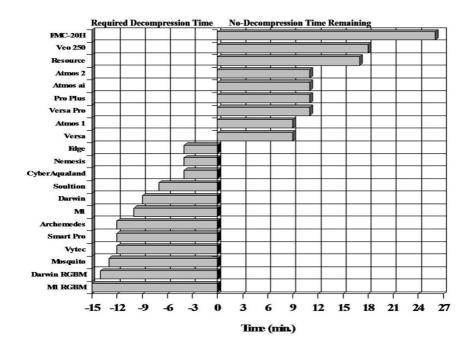


Figure 6. Responses of dive computers to 40 msw no-decompression multi-level dive prior to ascent from 15 msw.

On the "high risk" decompression dive, none of the computers tested would allow the profile to be performed. All of them went into decompression violation at some point while following the profile. On the "moderate risk" decompression dive, all of the computers tested cleared their decompression requirements within 4.5 min of reaching 10 msw. According to the computers, there was no need to continue with the 6 min stop at 10 msw, 7 min stop at 6 msw and 10 min oxygen stop at 3 msw.

For the no-decompression multi-level dives, the dive computers that required additional decompression from the dives were ranked "low risk." For the dive computers that allowed more remaining no-decompression time, no assessment of the risk could be made, since the outcome of following these dive computers to their limits has not been tested.

None of the computers received a "high risk" rating since none of the decompression algorithms allowed the "high risk" decompression dive to be performed. What is unknown is the risk associated with following the dive computer decompression schedules, since those profiles have not been tested. However, all received a "moderate risk" rating when compared to the standard Catalina Hyperbaric Chamber 50 msw orientation dive. Response to the 50 msw dive indicates that more conservative dive computer algorithms would be appropriate for short deep decompression dives. Again, it is unknown what the actual risk would be if the shorter dive computer decompression schedules were followed, because they have not been tested.

COMPARATIVE ASSESSMENT AND VALIDATION

Establishing a battery of previously tested dive profiles against which to run dive computer decompression algorithms would permit evaluation of decompression algorithms without the need of human subjects' tests and could provide a rudimentary baseline for dive computer comparisons. In Table 1 half of the cells indicate "unknown risk". Estimates of these unknown risks could be made without human subjects' tests by analyzing the decompression requirements from the computers with decompression risk models (Nishi and Lauchner, 1984; Gerth and Thalmann, 2000). This would allow general and relative risks to be computed for dive computer responses and the previously tested dive profiles.

The following is a proposed protocol for assessing the risk of dive computer algorithms for use in commercial diving:

- 1. Select profiles that have been tested and have known outcomes (high, moderate, and low risk) similar to operational dives: Inspection dives, cleaning dives, repair dives;
- 2. Select a risk model that estimates pDCS values in line with the dive profile test results;
- 3. Run computers against the test profiles;
- 4. Assess general computer response ("high", "moderate", "low", or unknown risk);
- 5. Use risk model to calculate pDCS of the dive computer decompression schedules; and,
- 6. Determine if the pDCS risks associated with the dive computer for this type of profile are acceptable.

OPERATIONAL CONSIDERATIONS

If the decompression algorithm in a family of dive computers is considered to be acceptable for commercial diving operations, with or without additional usage guidelines, then there are operational issues that need to be considered:

- 1. Is the dive computer simple to operate? If it is too complicated to operate then it will probably not gain acceptance.
- 2. Can the display be easily read in low visibility conditions? If the computer cannot be read on low visibility working dives then it cannot be effectively used.
- 3. Is the display clear and easily understood? Since some dives in the net pens exceed 39 msw on air (A. Møllerløkken, pers. comm.) if the dive computer display is not clear and easy to understand, the result could be confusion while trying to make decisions, especially while suffering from nitrogen narcosis.

- 4. Can the decompression algorithm be adjusted to more conservative settings? Divers may want to add conservatism to their diving practices and many computers allow adjustment.
- 5. Is the dive computer easy to download to collect profile data? If follow-up analysis of dives performed with dive computers is to be done, then the dive computer downloading process should be simple and consistent. Many frustrating hours have been spent trying to download dive computers worn by diving accident victims and their buddies. Often the download is successful after repeated attempts, but sometimes not. To date, the easiest and most consistent download technique is wireless infrared (IR) data transfer. Other wireless techniques like Bluetooth may make profile downloading easier.

CONCLUSIONS

Dive computers are used to safely calculate decompression schedules in recreational, scientific, and military diving operations. There is no reason to assume that they cannot be valuable tools for commercial diving operations, especially on multi-level dives. Comparing dive computer responses to tested dive profiles is one of many ways to assess decompression algorithm risk and validate acceptable safety levels for commercial operations. The inclusion of dive computers with acceptable decompression algorithms in the commercial diving toolbox should greatly increase the efficiency of multi-level dives of the type done on fish farm pens.

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Dive Computers: The Need for Validation and Standards

Arne Sieber

Milena Stoianova IMEGO AB Arvid Hedvalls Backe 4 P.O. Box 53071 SE-40014 Göteborg, SWEDEN

Ewald Jöbstl

QM- Jöbstl Gritzenkogel 6 8052 Graz, AUSTRIA

Elaine Azzopardi Martin D.J. Sayer NERC National Facility for Scientific Diving Dunstaffnage Marine Laboratory Oban, Argyll, SCOTLAND PA37 1QA, UNITED KINGDOM

> *Matthias F. Wagner* Frankfurt University of Applied Sciences Nibelungenplatz 1 D-60318 Frankfurt, GERMANY

Dive computer validation is currently a widely discussed topic for which there is no uniform procedure for testing and validation. Many dive computer manufacturers claim that their products are personal protective equipment. However, dive computers are not listed in the directive for personal protective equipment (PPE Directive 89/686/EEC). EN13319 is one European normative that is frequently applied during CE certification of dive computers. This normative only addresses accuracy and precision of depth sensor and built-in clock/timer – decompression calculations are explicitly excluded from the standard. This overview of normatives and standards suggests those that might be applicable for dive computer validation. The concept of functional safety is discussed. A short market survey is included which presents how dive computer manufacturers certify their CE products. Validation and testing of a dive computer is also of utmost importance for liability considerations, because they are used for decompression planning and, as such, can be classified as personal protective equipment category III. We provide these considerations on dive computer validation for a new tailored normative or standard that will harmonize worldwide dive computer testing and validation procedures and lead to a higher functional safety of these devices.

INTRODUCTION

Over the past two decades dive computers (DCs) have become almost universally accepted in the recreational diving sector for the management of decompression. In fact, many dive

centers now may not accept customers who do not use a dive computer. The permissible use of DCs in commercial diving varies between countries and industry sectors. However, many countries currently legislate against their use for commercial diving possibly because of a present lack of information on many computer models as to how they compute decompression. This, in turn, may promote a perception of a lack of dependable safety. This uncertainty is difficult to counter, mainly because there are no standards or normatives specifically for DCs that would allow an assessment of their functional safety. This paper does not compare different decompression models; instead it reviews the available normatives, standards and directives, their implementation by certain manufacturers, and the functional safety of DCs in general.

DIVE COMPUTER EVOLUTION

During the period of diving where decompression theory became better understood and the first decompression tables were developed (e.g., Boycott et al., 1908), divers were surfacesupplied and their decompression monitored by a surface crew. In the mid-1940s, selfcontained underwater breathing apparatus (scuba) developed and allowed divers to become independent from the surface. Divers then also became responsible for the monitoring and control of their decompression obligations. This introduced new levels of complexity compared to traditional hardhat diving because divers could now move freely in a threedimensional space, frequently resulting in multilevel dives.

Initially divers used tables, depth gauges and bottom timers as tools to monitor their decompression status. Such tables were used for no-decompression diving, where an immediate and safe return to surface was possible. Once the no-decompression times were exceeded, staged decompression stops had to be included during ascent. When it came to repetitive multilevel diving, using tables effectively became impossible because of the inability to calculate accurately the decompression debt for a near infinite number of possible profile combinations. In order to address this, repeat tables tended to base calculations on the maximum depth achieved during the dive series; as a result, the subsequent dives carried heavy time penalties, either resulting in excessively short diving times or requiring a long surface interval in order to return to a single dive decompression schedule.

The early history of DCs was reviewed by Huggins (1989), who described the developmental process from commissioning of the first DC by the U.S. Navy in 1951, through to the 1980s where commercially available units ran on similar hardware and were recognizable with those DCs in use today. Nearly all DCs available today are able to perform calculations with enriched O_2 gas mixtures. Some can be also used with trimix and many modern computers have the facility to program several gas mixtures into the dive plan. More sophisticated DCs include additional features like a compass, an integration of cylinder pressure read out (either by hard connections or, in some cases, wireless), a color display and mixed-gas decompression schedules. A more detailed summary of the dive computer evolution can be found in Bourdelet (2007).

Lang and Angelini (2009) described the future of DCs. A summary of features that they identified as of interest from the diving physiology point of view included the measurement of heart rate, skin temperature, O_2 saturation (Kuch et al., 2010) and inert gas bubble detection. Some recently introduced models are also equipped with color screens, while some are incorporated in the diving mask with heads-up displays (Datamask, Oceanic, US) (Koss

et al., 2011). In the future, navigational aids will include underwater geo-referencing (Kuch et al., 2009; Gamroth et al., 2011; Kuch et al., 2011).

In 1988, a dive computer workshop examined the safety of DCs, their evaluation and the guidelines for their use (Lang and Hamilton, 1989). More specifically, the topics discussed included which decompression models should be used, how validation should be carried out, what are the acceptable risks, what limits should be given for DCs, what should happen in the case of a DC failure and operational reliability. Even 23 years later, most of these questions are still not answered for past or present DC models, and still form the basis for study.

As early as 1988 it was pointed out that standardization of DCs would be ideal (Osterhout, 1989) and suggested for:

- 1. the type of information displayed;
- 2. the manner in which the information is displayed;
- 3. the manner in which information is recalled;
- 4. the decompression models employed; and,
- 5. a uniform means of telling when a computer is in a failure mode.

The testing of the initial analog DCs was relatively straight forward, as there were rather simple means to check for correct function. This could include hyperbaric testing or, for example in the case of an analog pneumatic pure mechanical design, testing for correct gas diffusion rates. In the age of the microcontrollers, the situation became more difficult (Sieber et al., 2010). Hardware testing is a relatively easy task, as simple tests are usually sufficient to prove the correct function, however the critical point is how to standardize software. With the increasing amount of features, the complexity of dive computer software increases exponentially. The first electronic DCs had simple algorithms and data output; the latest ones have many advanced features like graphic color screens, large memory, compass, etc. and current trends are driving towards the development of real-time operating systems running on the microprocessor. In addition, with the increasing use and development of DC features run and controlled by software there comes an increasing risk of failure of one or more of the components so software testing efforts have to increase.

DIVE COMPUTER SAFETY

When considering the best and safest DC, reviewers mainly address its features and implemented decompression model. If one compares different DCs directly, one might expect to witness different readings: for example, one computer might indicate that a diver is still within no-decompression limits and can safely return to the surface without decompression stops, while other computers using a different model to calculate the decompression might show a ceiling warning and require stops (Huggins, 2012). However, given these differences, it then becomes difficult to comprehend that all of the computers on the market could be correct and provide a similar level of decompression protection if, and when, they give such wide-ranging outputs. It is important then to understand that each decompression algorithm carries a certain level of risk for DCS. Therefore, it is too simplistic to say one computer is right and the other wrong; rather the more conservative computer has a lower probability of DCS (pDCS). If one compares the pDCS for a variety of dive profiles, a few minutes more or less on a dive within recreational limits does not change pDCS to a large extent and in some circumstances could be ignored.

In a recent study to compare the features of DCs, they were tested in a hyperbaric chamber and the depth readings (i.e., the computer depth interpretations of the measured pressure) were compared (Azzopardi and Sayer, 2010; 2011), while Denoble (2010) wrote a popular article about DCs and decompression safety.

However, the aim of the present paper, is not to look at different decompression models of DCs and decompression safety, but to examine the functional safety of such devices and describe the normatives and directives that are available to give guidance throughout the development, validation and certification process of a dive computer.

Is a dive computer a safety-critical system?

An important question in this respect is whether a dive computer is a safety-critical system or not. A DC gives information about the dive depth and the dive time but also suggests how to perform a dive, i.e., when to ascend, ascent rate, and the decompression schedule to follow. While technical divers and commercial divers tend to use tables, depth gauges and timers to carry out dives, recreational divers value the advantages of DCs that provide continuous tracking of tissue tensions and are able to calculate decompression schedules with wide flexibility such as for multilevel or repetitive dive profiles. These divers often dive and ascend according to the DC indications. It is obvious that if incorrect indications given to the diver, DCS, or in worst case, even death, can occur.

Therefore, the answer should be that a dive computer is a safety-critical system. This conclusion is also strengthened by a large number of manufacturers categorizing their DCs as personal protective equipment (PPE).

Obvious versus non-obvious failures

One might argue that for redundancy purposes a diver should always carry backup instruments, i.e., a timer, a depth gauge and a table, or a second dive computer, to be able to safely surface in the case of a failure of the primary dive computer. This is a good approach but can only be usefully applied if a failure of a dive computer is recognized by the diver (see Osterhout comments above).

One fundamental point in functional safety is that a failure should be obvious to the diver, so that he/she can take appropriate measures. If a failure remains undetected, the consequences can be serious. An example of a way in which such a non-obvious failure could occur is given thus: if battery life is not sufficient at the start of a dive, then it could cause resetting of the DC so displaying an incorrect total dive time and therefore an incorrect decompression. Another example might be that the DC is programmed to calculate decompression using a different percentage gas to that actually used, which would obviously have a large impact on decompression safety. There are many permutations of DC use/failure that may fall into this category of non-obvious risk unless precautions are taken to make sure it cannot happen.

Functional safety

Functional safety is part of the overall safety relating to the system under development. Safety in general is an emergent property of a system that must not endanger human life. The safety of system components, hardware and software alone is meaningless. In most cases reliability is a necessary prerequisite for safety. Therefore, design methods of reliability engineering are not sufficient for the design of safety critical systems (Leveson, 1995). Applied to DCs functional safety not only means that the device performs according to the requirements, but also that in case of a failure, no harm occurs.

CE certification of DCs

CE marking introduced by European Community legislation is a key indicator of a product's compliance with the EU legislation requiring the protection of the public interest by having safe, healthy and reliably functioning products in the common market. Two types of standardization requirements apply to specific product groups. First, the New Approach Directives set up mandatory basic safety requirements for expressly listed groups of products that need to be CE certified. Where a CE certification is required for a certain product category, the manufacturer is under the legal obligation to carry out assessment of that product with the Directives' requirements. The second set of requirements is found in the so called "harmonized standards" adopted by the European Standards Organization that bear the designation "EN" before the standard number. While the Directives are binding on the manufacturer as to the hazards to be addressed and the outcome to be achieved, the harmonized standards are voluntary but they detail the technical means for verifying compliance with the safety and health requirements of the Directives and therefore are largely complied with by the industry.

In agreement with the preceding argument, DCs are indispensable means to ensure the health and the safety of divers. However, DCs as a product do not fall into any of the broadly formulated product groups covered by the Directives that require CE certification. Certification of DCs is needed because several of their key components need to be CE certified. Therefore, certification of DCs is made according to several Directives and EN standards that will be briefly described below.

The CE certification of a DC occurs in several stages. First, it is the manufacturer's responsibility to correctly identify the set of standards that the product has to meet. Having done that, in a second step, the essential product-specific requirements need to be identified and the assessment of conformity with them planned.

An intrinsic part of the CE marking process is the testing of the DC and the conformity of the parts covered by the Directives with the legal requirements for their safe functioning and use. Risk assessment is a key component of the assessment stage. It is at this stage that the manufacturer has to verify via the Directive whether for compliance certification a "Notified Body" has to be involved or not in order to reach compliance certification. Such certification by a third party is required for certain products that are likely to seriously endanger or affect the public interest from a health and/or safety perspective. However, ultimately the manufacturers affix the CE marking to their products, thereby assuming the sole responsibility for standards compliance. Thus, in case of a diving accident, the manufacturers will be held liable for the faulty performance of their product or component parts thereof.

Performing the tests does not complete the CE certification process. The manufacturer also needs to draw up technical documentation detailing the checks performed and the results obtained. In case of an accident, this documentation will serve as evidence of conformity with the essential safety requirements and will make it possible to identify the cause of the accident to the equipment or to the diver.

A visual inspection of the DCs sold in the European Economic Area and their user manuals (Table 1) shows that only one manufacturer wholly complies with the requirements for CE certification and carries out checks for conformity with all relevant directives and harmonized standards. The safety of DCs is not guaranteed to the full extent because of two types of omissions made on the part of the manufacturers. First, some manufacturers confine

their tests to a number of Directive requirements, then fail to perform tests on crucial parts covered by other Directives.

For example, the EN13319 and the Electromagnetic Capability (EMC) directive, which should be used when certifying a dive computer, are only referenced by a few manufacturers. Some manufacturers categorize their dive computer as PPE, even though this is not mandatory and is only applicable where a cylinder pressure gauge is included within a DC, whereby it then needs to be tested according to EN250 and thus falling under the PPE directive. Most manufacturers of DCs with air integration follow the directive and categorize their devices as PPE. Some of them, however, state explicitly that the directive for PPE is applied solely to the cylinder pressure gauge (e.g., Mares). It is important to note that in the case where a manufacturer declares a DC as PPE, it falls under category III, which means that for CE certification a Notified Body has to be involved.

Manufacturer/ Model	CE mark	Air integ.	EN250	EN13319	PPE 89/686/EEC	EMC 89/336/EEC	other
Uwatec Galileo Sol	CE0474	wireless	v	v	y	no	
Uwatec Aladin Tec 2G	CE 0474	-	NA	'	y Y		
				У		no	
Mares Nemo Excel	CE	-	NA	no	no	no	
Mares Nemo Air	CE0426	Y	У	no	Y	no	
Suunto D9	CE0430	wireless	У	У	У	У	ISO 900
Suunto D4	CE0430	-	Y	У	У	Y	
Suunto Cobra 3	CE0430	Y	У	У	У	Y	
Cressi Sub Archimede 2		-	NA	no	no	no	
Oceanic	CE0120		Y	У	У	У	
Apeks Quantum	CE	-	NA	no	no	no	
Delta P VRX		-	Y	Y	Y	Y	EN1414
Seeman XP5	CE	-	NA	no	no	no	
Cochran EMC-20H		-	NA	У	no	Y	
Tusa IQ950	CE	wireless	no	У	no	Y	
Tusa IQ900	CE	-	NA	v	no	Y	

Table 1. Visual inspection of some DC models and their manuals for CE mark and normative/directive compliance (NA: not applicable).

For example, in the manual of their recently launched DC model IQ-950, the manufacturer TUSA notes that the CE mark is used to identify conformity to the EMC directive 89/336/EEC and is designed to comply with EN13319. However, this dive computer also features air integration and so should also be certified according to EN250; it therefore falls under the PPE directive.

However, manufacturers often wrongly seek compliance with requirements for a product that they do not integrate in their DC. Suunto references EN250 for their D4, even though no cylinder pressure gauge is included and so does not fall under the umbrella of PPE. It is also interesting to note that only a few manufacturers state compliance with EMC directive 89/336/EEC, even though this is mandatory, and in cases where a wireless cylinder transmitter is included, a Notified Body has to be involved. Oceanic does not provide information about CE and normative/directive compliance in the manuals, but do that in a separate document that is valid for all of their DCs.

DIVE COMPUTER CERTIFICATION: STANDARDS AND NORMATIVES

Applied standards

As discussed, there are several standards applied to DCs today, however, there is no standard written specifically for DCs to meet. In general, there are no obligatory guidelines to follow, nor are there any suggestions concerning validation of DCs. As previously noted, it is only when a DC is integrated with a cylinder pressure gauge that it has to be certified according to EN250 and the PPE Directive become mandatory.

The EMC Directive (89/336/EEC)

Like the PPE Directive, the EMC Directive intends to establish a free movement of goods within the EC, hence providing an environment for reliable operation of electrical and electronic equipment. This Directive covers nearly all electrical and electronic appliances and requires that it neither causes excessive electronic interference nor is unduly susceptible to it. It provides for harmonizing legislation to ensure that standards adopted throughout the EC are compatible. Equipment must be manufactured so that it does not generate a level of disturbance that will prevent other equipment from operating properly and does not itself suffer from interference. In cases where radio transmitter/receivers are included, like in a DC with a wireless cylinder pressure transmitter or featuring a Bluetooth-based PC interface, the DC must be subject to an EC-type examination by a Notified Body. The EMC directive also provides that the device be properly CE marked.

EN250:2000

EN250:2000 is a standard for respiratory equipment and includes the use of open-circuit, self-contained, compressed-air diving apparatus. Requirements, testing and CE marking fall under the PPE directive. In general, the standard mainly addresses breathing regulators but it also covers cylinder pressure gauges which, referring to section 5.8.1, are considered to be part of the respiratory equipment. Within section 5.8.2 of that standard, the required accuracy and measurement range of a pressure gauge is addressed.

EN13319:2000

EN13319:2000 addresses depth gauges and combined depth and time measuring devices and as such provides functional and safety requirements and test methods. Chapter 4.1 deals with depth and 4.2 with time measurement. This standard suggests using a gauge factor, where 1 bar pressure correlates to 10 m depth [4.1.1]. Chapter 4.2 addresses accuracy of time measurement and specifies how the dive time is measured by providing a threshold depth of 1.6 m for automatic dive time counting start and stop. Further topics that are within the scope of this standard are, for example, water-tightness, sea water resistance, and operability.

Information on decompression obligations displayed by equipment covered by the standard is explicitly excluded from its scope [EN13319:2000, 1]. This standard also refers to ISO1413: Horology – shock-resistant watches. The standard was prepared by the CEN/TC136 group for "Sports, playground and other recreational equipment." Many manufacturers categorize their DCs as PPE, thus it is interesting to note, that EN13319:2000 is not listed in the official journal of titles and references harmonized standards under Directive 89/686/EEC for PPE.

PPE Directive 89/686/EEC

One main aim of this directive is to harmonize products by ensuring a high level of protection and safety for citizens in specific circumstances and free circulation throughout Europe. The PPE Directive is ratified by each country in Europe. For the CE certification of Category III PPE a Notified Body is mandatory. All Notified Bodies are listed on the European Commission's New Approach Notified and Designated Organizations (NANDO) Information System.

The Directive on PPE aims to harmonize and streamline existing national requirements on PPE and establishes a minimum set of standards to ensure the safe use of equipment. The provisions governing the design and the manufacture of PPE are considered fundamental to the achievement of its aim and they should be distinguished by any national or Community rules that relate to the use of such equipment. Therefore, compliance with the PPE Directive is a stepping stone and absolute prerequisite for safety. The Directive and the related normatives create an obligation for PPE manufacturers to duly test the reliability of their products prior to marketing and sale, and to inform the consumer of having done so by placing correct CE marking on each individual appliance.

Article 8 brings together PPE covered by the Directive into three distinct groups and their relevant conformity assessment procedures: Simple designs (Category I), neither simple nor complex designs (Category II) and complex designs (Category III). For category II and III a Type examination by a Notified Body is required. Further category III products also require a quality control system for the final product and a production-quality monitoring system.

Many parts of diving equipment fall under the PPE directive and need to be tested according to underlying normatives: Examples are respiratory equipment (EN250:2002), buoyancy compensators (EN1809:1999), combined buoyancy and rescue devices (EN12628:2001), respiratory equipment for compressed nitrox and oxygen (EN13949:2004) and rebreathers (EN14143:2004) or drysuits (EN14225-2:2005).

Surprisingly, DCs, which are used by many divers as indicators for decompression obligations and used to perform a decompression schedule or stay within the no-decompression limits, are not listed in the PPE directive under section 3.11 - additional requirements specific to particular risks – safety devices for diving equipment.

<u>ISO9001</u> compliance is often stated by DC manufacturers. ISO9001 is a general quality assurance standard that addresses the control of the quality of general development and production. However, it is not a specific safety standard, nor does it take into account the complexity of software development.

The need for a consolidated DC safety standard

As a rule, CE marking certifies compliance of a product as a whole with the essential safety and health requirements of the Directives that require CE marking. It is beneficial for consumers as it boosts their confidence in the products circulating within the common market and creates trust that corporate compliance and control procedures are in place and functioning. This leads to growth of the markets and to consumer satisfaction.

CE marking of the DCs currently on the market only partially tells the consumer the real story. It creates the wrong impression that the DC as a whole is CE tested and certified but this might not always be the case. Therefore, there is a need to unify the requirements for safety performance of DCs as a whole.

At the same time, CE marking creates the rebuttable presumption that the products on the market satisfy the safety requirements of the Directives and thus, irrespective of incomplete safety checks, in the case of diving accidents the presumption shifts the burden of proof of non-conformity and non-reliability of the DC from the producer to the consumer. As standard compatibility assessment of DCs is rarely described in detail in the user manuals, it might be unreasonably difficult for a non-technically trained diver to successfully plead his case in

court. Thus a consolidated standard for DC safety should level the playing field between manufacturers and consumers.

CE marking and compliance also impacts on competition between the DC manufacturers. CE self-assessment and verifications by a Notified Body account for considerable costs in the value chain of the final product. This results in higher manufacturing costs and higher consumer prices. Non-compliance with CE Directives safety requirements constitutes a competitive advantage in terms of lower costs and better final prices. This, however, comes at the cost of divers' health and safety and is unacceptable.

Protection mechanisms from non-CE certified products

Protection exists against products that do not meet the CE Directives on safety and health requirements. It takes the form of control conducted by the competent national authorities and where non-conformity is found the circulation of the product in the EEA area might be prohibited and the products withdrawn. This can be coupled with fines and in some Member States like the UK, for example, depending on the gravity of the violation, imprisonment might be likely.

DCs AS SAFETY-CRITICAL SYSTEMS

As a DC gives may give an indications as how to handle decompression obligations and, in the case of malfunction, has the potential to endanger human life, it is evident that DCs are typical safety-critical systems (SCS). Some manufacturers seem to share this opinion and already categorize their DCs as PPE.

For most it is accepted that DCs are SCS with typical challenges with respect to their development (Leveson, 1995, 2004; Knight, 2002; Hollnagel et al., 2006). The increasingly important directive that is lacking in terms of DC development is that of comprehensive safety standards.

A dive computer is an active system, subject to functional safety requirements as defined by the IEC61508 standard. This standard had been designed originally as an application-independent standard that could spawn industry-specific derivative standards. One of its major strengths is the focus on safety as a system issue (Herrmann, 1999). The main mechanism through which IEC61508 enhances safety of a system is risk reduction.

IEC61508 is a meta standard and, as such, does not give direct guidelines on testing like EN250 or EN13991, which are very specific in their recommendations. The standard describes a general development life cycle required for building a safe system. The general life cycle defined in the IEC61508 standard covers all major issues of a system composed of hardware and software (Figure 1).

For example, in aviation, space applications or in nuclear power stations, SCS often comply with EN61508. However, they do so by complying with specific standards, which are derived from EN61508. Such a specific interpretation of EN61508 is necessary in order to map the peculiar requirements of a certain field on the development life cycle.

In EN14143:2004, a standard for rebreathers, compliance with EN61508 is required. However, because of the broad nature of this meta standard and the lack of more specific tailoring to the application field, the standard is rarely, if at all, applied. As a consequence,

the CEN/TC79 committee is presently discussing removing EN61508 from EN14143, which makes CE compliance easier to achieve for manufacturers, but is clearly a step back from what concerns mandatory functional safety.

When revisiting consideration of DCs as safety critical systems, EN61508 could work as a tool to accomplish functional safety but, similarly to the example above, a direct application without tailoring is not practical and/or will lead to various interpretations by manufacturers. This is, however, contrary to one of the PPE directives' main aims focusing on harmonized standards. A tailored version of EN61508 addressing DCs should, rather than providing only measures and guidance to test a final product, define a comprehensive life cycle. Further, it has to be taken into account that compared with development teams in the aerospace,

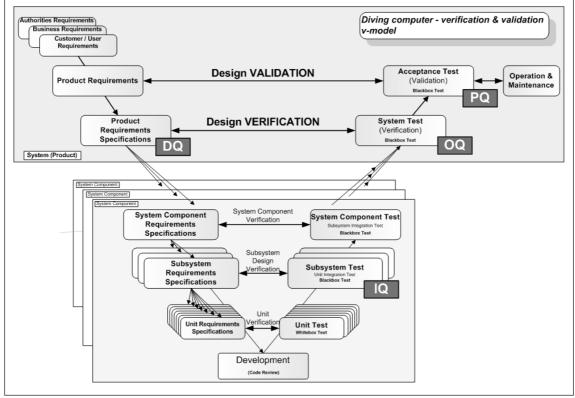


Figure 1. Validation and verification using the V-model.

nuclear or automotive industries, development teams for dive computer systems are comparatively small. Therefore, an adaptation of the IEC61508 towards development efforts of SCS in small groups is essential.

DCs COMPARED TO MEDICAL DEVICES

Compared with other products on the market, DCs bear a strong resemblance to medical devices. Medical devices are similar to DCs with regards to combinations of hard and software and the high risk involved through influencing life-threatening decisions. In contrast to DCs, medical devices have to fulfill a variety of standards to ensure safety for the patient and the user. Key documents are:

- 21CFR Part 820 Quality System Regulation (Medical Devices);
- EN/ISO13485:2003 Medical devices Quality management systems Requirements for regulatory purposes;
- IEC62304 Medical device software Software life-cycle processes;

- ISO14971:2007 Medical devices Application of risk management to medical devices;
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff January 11, 2002; and,
- GAMP5 Good Automated Manufacturing Practice Supplier Guide for Validation of Automated Systems in Pharmaceutical Manufacture.

Quality-management system regulations: In the EU the international standard EN/ISO13485 applies in particular for regulatory purposes of quality management systems for medical devices and plays a central role. It is one of the essential requirements to fulfill for the CE declaration of conformity to ensure that the products concerned meet the provisions that apply to them. The U.S. laws for current good manufacturing practice (CGMP), in particular 21CFR Part 820 is probably in an adapted version the most suitable for a quality management system for DCs. It is based on the EN/ISO13485 but is clearly structured to fulfill the rules in an easier manner. The requirements within that chapter govern the methods to control development, manufacturing, packaging, labeling, user instructions, other documentation accompanying the product, storage, installation and maintenance of all finished devices intended for human use.

<u>Software development processes:</u> IEC60601-1-4 was the first international standard to deal with programmable electrical systems for medical devices and handles software. However, because of the limitation of active medical devices it was necessary to find a new approach. This was achieved in the IEC62304, which requires preventive measures to be taken during the whole life cycle of the software to reduce its associated risks.

One of the key issues in the development of DCs is reliable software. This can only be achieved if the development of the software follows well-established regulations ensuring that the whole process is under control. IEC62304 starts with the software development planning. The required tasks are related directly to the safety classification of the device under development, dependent on the risk/hazard associated with the device in the case of a malfunction.

This standard does not prescribe any specific life-cycle model but does provides a framework for life-cycle processes with the activities and tasks necessary for the safe design and maintenance of the software. There are several models for the software development process, each describing approaches to a variety of tasks or activities that take place during the development process. One of the most useful models is the V-Model. However, the IEC62304 is too demanding and complicated for DCs. Its enforcement would be a huge burden for a developer and manufacturer, especially for those working on a small scale. But it is essential that the structure of the IEC62304 be used to make the software of DC reliable and safe for the user.

<u>Risk management process</u>: A basic premise of IEC62304 is that the software is developed and maintained within a regulated environment. Therefore, the manufacturer should employ a quality-management system, and a risk-management process complying with ISO14971 Medical Devices - Application of Risk Management to Medical Devices.

Software has to be handled in a separate way. It is not easy to manage common hazards of software errors (bugs) within risk management. A major obstacle is that software errors do not occur randomly. In assessing the likelihood of a risk in software it must be assumed that

probability in the risk analysis of occurrence is 100%. That is where the IEC62304 standard applies by requiring that processes, activities, and tasks are completed to establish and ensure safety by using preventive measures. Those measures should reduce the probability of errors in the code, i.e., wrong bits (8 bits = 1 byte) as well as wrong specifications.

At the beginning of software development, the identification of hazards is a very important step where appropriate measures are needed to reduce the risk by implementing requirements to the software. The IEC62304 software risk-management process is intended to provide those additional requirements for the software during the design and development process when safety, effectiveness and quality of software are established.

The combination of IEC62304 and ISO14971 for risk management of DCs might be very useful, although a direct application might not be possible. Special interpretive tailoring of ISO14971 would be necessary.

<u>From design control to validation</u>: One often used model for the design of software, hardware, or combinations thereof, which shows the relations between design control, requirement specifications, testing, verification and validation is the V-model. As such, it simplifies the understanding of the complex systems associated with their development. The V-model is designed as a guide for planning and execution of development projects, taking into account the complete life cycle including verification and validation. Application of the V-model to a DC might require expansion to an interlaced model of many V-models for each system component and if applicable to the subsystems and units building an overall V-model for the final product.

PROPOSED DC LIFE CYCLE

Typically, a responsible manufacturer has a defined process for system development, usually conforming to a quality normative like ISO9001. For safety-critical systems this process has to be enhanced to fulfill the requirements of the safety life cycle of IEC61508.

In brief, the safety-critical life cycle consists of:

- Overall scope definition: All principal functions of a device are specified here. For a DC, this may include all the parameters displayed (e.g., depth, time, decompression obligations), how they are displayed, mechanical designs, performance parameters, operational ranges (depth, temperature), etc.
- Hazard and risk analysis. All imaginable hazards are listed and the corresponding risk is determined based on the expected probability. In the case of a DC, this list will include operational risks, such as a diver exceeding maximum depth or violation of decompression obligations, but will also system-related risks. These may include battery lifetime, water leakage or malfunction in hardware (such as a defective component). The most complex development part of a DC is software. Typically, a large part of the risk analysis is devoted to software malfunctions. One aim of the risk analysis is to also detect possible failure events.
- Safety requirements allocation: Based on hazard and risk analysis, the overall systems requirements are enhanced by including the safety requirements.
- Design and implementation phase: The hardware and software development takes place here. In parallel, verification and validation plans are established. Verification assures that requirements are preserved from one development phase to the next. Based on the hazard and risk analysis in the design and implementation phases,

measures have to be taken in order to either eliminate or, if not possible, to mediate the impact of a certain hazard. This also includes informing the user about the status of a system – like correctly operating in a failure mode.

- Validation phase: Validation checks the final product against the complete list of requirements, including safety. In the case of validation of a DC, one would not only check if the main functions, for instance, depth and time display are correct, but also what happens in the case of a software reset, hardware failure, or a simple supply voltage drop caused by an empty battery or corroded contacts.

The complete life cycle is documented in the so-called design history file or technical construction file. This file is a prerequisite for CE certification of PPE category III and has to be presented to the Notified Body involved. It is also important to understand that all of the documents are subject to modifications during the development following not only new requirements but also after the appearance of new safety related issues initiated during the design, implementation and validation phase. Guidelines for the implementation of the life cycle can also be found in normatives and regulations for medical systems. Guidelines for the V-model and the more recent V-model XT are one possible method of describing the life cycle. Another alternative was proposed by Fredriksen (2002), who enhanced the widely used Rational Unified Process (RUP) with a safety discipline to incorporate the demands of IEC61508. It is of utmost importance, however, that the life cycle is manageable by the rather small development teams. An ISO working group is currently addressing this topic by working on system engineering life cycles for small development teams. (INCOSE South Africa, pers. comm.)

Another useful document could be the FDA Guidance on General Principles of Software Validation (Final Guidance for Industry and FDA Staff January 11, 2002), which applies to medical device software and to automated process software.

It is clear that design for safety has to start early in the system's life cycle, during system requirements analysis. It is crucial for the safety of the planned system to close the semantic gap between all stakeholders in a development project (Doeben-Henisch and Wagner, 2007). When applied to the development of DCs, this means that all people involved in the DC development have to communicate about the overall requirements.

CONCLUSION

Products within certain groups in the EU require CE certification to be brought to market. It is the manufacturer's obligation to categorize its equipment and apply the corresponding normative to ensure a maximum level of safety. DCs made by several manufacturers have been checked for references to CE certifications. While some manufacturers refer to a variety of normatives, others refer only to a few (Table 1). It is clear that there is no harmonized way of testing and certifying DCs, probably because currently there are no standards or normatives that specifically address them. It is also interesting to note that EN13319, a normative that could be used for certification of a dive computer, is only referenced by a few manufacturers.

A CE mark, even if the dive computer is categorized by the manufacturer as PPE, is no guarantee of safety from a functional safety point of view, even though products developed and certified according to the PPE directive should have been subject to a safety life cycle. This is misleading for the consumer, who is often not aware that there are no standards,

normatives or guidelines specifically for DCs but considers the product to be safe, especially when a manufacturer claims that the device is a PPE and was tested accordingly.

To counter this problem, we have two suggestions: the first is that we suggest including DCs in the PPE directive under category III. This would make application of good manufacturing practices mandatory for DC manufacturers and therefore a safety life cycle for the complete development would have to be followed. This could increase the functional safety to a higher and more uniform level. The second suggestion is that the drafting of a normative, especially for DCs, should be discussed. Rather than being design restrictive by describing a "golden model for decompression theory" we believe that one should address functional safety. Also, it may be helpful to reference EN61508, although this is a broad standard and so derivation or tailoring is necessary in order to enable small developers' teams to fulfill certification requirements.

Risk and hazard concerns associated with the use of a device allows DCs to be compared to medical devices. Therefore, normatives for medical devices like the IEC62304, ISO14971 and ISO13485 could also be used as a model for drafting a normative specific to DCs.

When it comes to a failure, we also suggest that the safety status of the DC must be displayed, in an unambiguous manner, to the diver. This is not a new suggestion, but has still not been delivered.

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- P. Buzzacott: Your last point mentions the judgment panel overseeing the validation process, do you have an opinion on whether the panel should not include the scientists doing the testing, or is it OK for them to be present?
- B. Hamilton: That depends to some extent on the organization that is doing the validation. For example, if it is a scientific organization, you are stuck with the scientists on the panel, but if it is a business-run organization you want to have some business people on it. David Elliott, at the decompression table validation workshop, made a sketch on the board (Fig. 1) showing the process, the judgment points and how feedback is used from the development process and from the field, all of which goes into the model development itself. It is necessary for the organization to include some sort of judgment function in its modeling process.

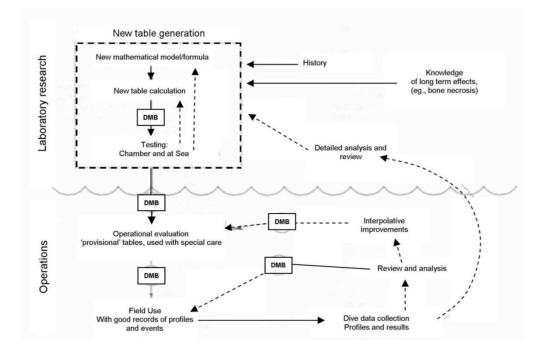


Figure 1. Flow diagram of the decompression table development and validation process by Elliott (1989; reprinted with permission from Schreiner and Hamilton, 1989). The upper part of the diagram is by intent research and subject to "informed consent" procedures. The lower half is operational, and is considered to be within the job description of the divers. Solid arrows show flow of information, dotted arrows show feedback, and those with squares imply some judgmental approval by the Institutional Review Board (IRB) or the "DMB," a competent authority (board or committee) within the organization conducting the dives; it might be called the "Decompression Monitoring Board."

- M. Lang: Independent testing is an often underutilized tool. Manufacturers make claims of their products' capability but obviously until independent testing is carried out, the consumer cannot know if these claims are correct.
- B. Hamilton: This is a sticky question! I have dealt with a situation whereby an organization was getting ready to submit something to the U.S. government to be evaluated. They did not evaluate it themselves first and it was a disaster! At the very least, the

developer has to put together some kind of judgment or evaluation of the product before you can move ahead.

- W. Gerth: The judgment board's principal function is going to be in the developmental phase of the dive computer and I would agree that that would appropriately be handled by the organization that is developing the computer. I think we need yet another higher order of control; we certainly do in the U.S. Navy, which is called configuration management.
- B. Hamilton: This is what M. Lang referred to; more than just the organization itself is needed in the validation process. Somebody else with a broader perspective and different goals needs to have the opportunity to evaluate the dive computer.
- W. Gerth: It is also important that the people who are distributing the product know that it has not been changed, that the manufacturer has not updated any of the systems prior to it reaching the distributors and therefore the product is the version that was validated and that the documentation is still current. Unfortunately, the opposite happens a lot, and people end up distributing a product that was not the one they validated and documented. The configuration management board should oversee the distribution of that product and determine that changes are authorized.
- M. Egi: I prefer use of the word 'verification' instead of 'validation' in certain situations; we should be careful when we use these terms.
- B. Hamilton: This is what the decompression table validation workshop dealt with; the difference between verification and validation is a fine issue, but it is an important point.
- D. Doolette: It is not a fine issue at all; 'verification' and 'validation' are very distinct. 'Validation' measures whether your product meets its requirements, and 'verification' evaluates whether it works or functions.
- M. Egi: It is very clear from an engineering point of view.
- K. Huggins: 'Validation' confirms that a decompression algorithm performs to the level you want in terms of risk. 'Verification' determines that the dive computer does the proper calculations to perform that validated algorithm.
- B. Hamilton: This gives me the opportunity to make the point that I tried for years to convince manufacturers of: they need not be secretive about their algorithm. They should publish it and all they have to do then is show that the computer does what the algorithm says, i.e., verification. However, when they do not share this information, they have to get everything right themselves.
- M. Egi: This may be semantics but I can replace 'dive computers' with 'dive tables' in 80% of K. Huggins' presentation and everything will be the same. Dive tables do not know what is going on inside the human body and so I am very concerned about the wording. The main problem is working out what the difference is between the dive table that you get printed out from V planner or that from the U.S. Navy dive tables. We should focus on this point because a dive table does not mean anything. If I take the dive table produced by V planner and I use gradient factors then I will get 10,000 different decompression schedules, so what is the difference? I would also add that we have a problem with the programming philosophy, as mentioned earlier. We have a problem of open source and intellectual property protection. But the main, basic problem is the documentation of V planner; what is the documentation of the U.S. Navy tables?
- K. Huggins: I agree that for anything that says 'dive computer' you can substitute any one of the software packages. But when you are talking about dive tables, I am primarily

talking about ones that have had some degree of validation, like the U.S. Navy, or the Norwegian tables that have some degree of development over the years and are accepted by the Labor Directorate for example. They are the comparisons I have made.

- M. Egi: If we start with the semantics then we will go in the right direction. What is the problem with open source? We have open source dive computers now.
- W. Gerth: There is no ambiguity about the difference between diving a table and diving on a dive computer, but as K. Huggins pointed out very elegantly, a dive computer allows you to do dives of unlimited and arbitrary complexity and it will give you an answer for that dive, whereas a table will not. The table will give you an answer for a maximum bottom time and that is it. Also, the dive computer will run you to the limits of your algorithm always, whereas a table does not.
- K. Huggins: I do not agree. One of the main successes of dive computers in my opinion is that the vast majority of dive computer diving does not take the algorithm to the limit.
- W. Gerth: They stay in no-decompression?
- K. Huggins: They stay a long way back from the no-decompression limits of the dive computer itself, at least if you look in the recreational diving community records. In these cases the algorithm is not being pushed to the limits and you are not generating these human tests of the algorithm on each dive.
- M. Egi: Regarding the standards and the quality issue, we have software in the dive computers and associated software in the dive planners, so I would also like to see regulated standards for the software.
- A. Sieber: I agree.
- B. Hamilton: Divers use tables as advisory information, but computers are perceived as instructive. However, they are not really any different, I'm just outlining the differences in attitude to using them.
- M. Egi: Human/computer interaction falls into ergonomics; it has to do with perception and is somehow linked to language processing. Further, we need to explain why divers in the U.S. prefer air-integrated computers and why divers in Europe do not.
- A. Brubakk: One of the problems with computers has to do with the endpoint that is going to be used. Regarding the safety of the computer, Karl, you spoke about six dives being used to test a computer. That is such a small number; there were no problems with any of the dives and so it poses a statistical problem, i.e., the results are meaningless. The problem with using dives that have very little incidence of problems (which is normal these days) is that it is very difficult to test the computers in this way. You need something that is measurable so that you can say that this computer does this exactly, rather than saying DCS occurred. DCS is something that we cannot even define, nor can we agree on what to call it. It is not a measurable endpoint for validating dive computers. We need to have something that is measurable, even if it might not be 100 percent correct, it is still useful. The work done in Britain on tunnel workers show that only a very small percentage has symptoms. Looking at more strenuous dives from the 1800s, dives that actually killed people, you will see that over 50 percent of these divers had no symptoms at all. They did horrible things that you would not even think of doing today, with very long bottom times and very short decompressions, but often nothing happened; there were no measurable effects. The results showed that only 5 to 20% of the toughest dives would cause any problems at

all. This, of course, is a challenge to say that this computer is safe and this model is better, this is the key issue.

- K. Huggins: One thing that has to be realized is that dive computers will respond differently to different types of dives. They will produce some responses that are conservative and some not so much. Validating a computer for a specific operation requires an idea of what the dives are and the window of ranges for that dive, to work out if the computer will function in a safe manner within these types of profiles. The same cannot be stated for the entire spectrum of diving operations and diving activities.
- A. Sieber: Maybe we should create some standards or norms for dive computers. We have to think how this should be done in practice, because if we decide what the norm is, then somebody has to make an official document or nothing will change. The general problem in Europe is that the committees that are drafting and deciding on the standards do not have representation from the consumers and diving doctors. The people on the committees are the manufacturers and so the standards are often written giving their ideas, which is perhaps not ideal. The main problem is that the consumers are not there.
- M. Gennser: On the actual committee on personal protective equipment for diving, there are representatives from the official agencies, not only manufacturers. Of course there is a tension between what the manufacturers and the agencies would like to see. You mentioned the IEC61508. This has to be a standard that manufacturers will be able to comply with, because you cannot take something from the aerospace industry and apply it directly to diving.
- A. Sieber: True, but you can use it as a role model, I agree with you.
- D. Doolette: B. Hamilton and K. Huggins said in their talks that the purpose of dive computers, and that of a table or any desktop algorithm, is to decompress with, and I am paraphrasing, some sort of low or acceptable risk or incidence of DCS. I am going to say the same thing in my talk, and I agree with it, but A. Brubakk was disputing that as a purpose of the dive computer.
- B. Hamilton: Never use the word 'safe' in relation to decompression, it just does not apply and is misunderstood by people. Use 'acceptable risk', which gives a different perspective although it really is the same thing.
- D. Doolette: A. Brubakk was suggesting that is not what the issue was; you are saying there is some other endpoint or purpose. We are dancing around this a little, why do we not try and validate what validation is?
- K. Huggins: There are two aspects: one is the validation (whether DCs are reliable pieces of equipment that provide the function that they say they do) and second, whether the function of decompression calculations that DCs say they do, are actually based upon the model. Is that calculation providing, and not exceeding, an acceptable level of risk?
- W. Gerth: D. Doolette's point was: acceptable risk of what? Acceptable risk of VGE grade being high or low? A measure of acceptable risk needs to be defined. That goes right to B. Hamilton's second point, what is the function of this computer? Is it to keep you within a certain level of risk of DCS, or is it something else?
- B. Hamilton: The computer has to get the person to the surface without any residual or long-term effects.
- K. Huggins: The first step in an answer is to look at what is acceptable right now. What does the Norwegian Labour Directorate say? Whatever level they are willing to accept in the established tables should be the starting point.

- J. Wendling: Considering that validation is usually done in the range of normal diving (e.g., PADI recreational diving), that gives an exposure window that is validated by some level of risk that is 'normal,' but what would you like to do for those who dive outside this window, for example yo-yo diving where the risk is higher?
- A. Sieber: The risk is certainly higher. What I argued for is the validation of the system of the hardware and software. Now we focus again on the validation of the algorithm. In order to do this we would have to have a 'gold standard' with which we could compare everything, but I do not know if this is the right way to go.
- J. Wendling: My question was how do you identify this for the consumer, how do you let them know that they are venturing outside of the validated window?
- K. Huggins: That window needs to be defined, which at this point in time doesn't exist because the models, unless viewed operationally, have not been validated with human subject testing.
- A. Sieber: There are now some products that state, for example, "this has been validated for up to one hundred meters, but not beyond." This is perhaps a practical way to do it, but people do not always read the manuals and just use the computers. We found one model that actually stopped giving you decompression data at the point that it deemed the risk was too great. If there were an emergency and the dive had to be aborted, you really need your decompression data. People need to be made aware and appreciate the risks involved in diving, because today they do not. Many divers think 'so long as my dive computer says that I have two or three minutes left of my no-decompression time, then everything is safe'. Divers have to start understanding that this is not the case.
- K. Huggins: Most dive computer manuals will have about five pages of warnings, but many people do not read these or heed them.
- H. Ornhagen: I support A. Brubakk's comment that we are missing the main factor. Using sunburn as an analogy, a standard exposure meter from a camera gives a good correlation with the measured light, but you will not get a correct sun-protection factor until you add the sensitivity of the skin and the ultraviolet filter to the equation. Therefore, we have an imperfect instrument. We do not really know what endpoints to use in diving, and there are so many unknown factors that it is going to be very difficult to say that this is a personal protective device until we know more.
- D. Doolette: The endpoint it is perfectly clear: prevent decompression sickness.
- H. Örnhagen: But what is decompression sickness?
- D. Doolette: Decompression sickness is when the diver gets bent and you have to treat the symptoms. Divers know when they are bent.
- K. Huggins: This is where the terminology issue of decompression sickness and decompression illness comes in, because none of the computers can prevent air embolism, which is decompression illness. Therefore, you need to define what you are talking about and what you are trying to prevent and make sure there is no ambiguity. Otherwise, you will expect the device to protect you from something that it cannot.
- M. Lang: The really interesting slide by K. Huggins shows the computer variations of these different models with red decompression being required and green no-decompression time remaining for the same dive profile. There is such a tremendous range in variability. Looking at the effectiveness of dive computers, are there any that really spike in incidence numbers from the diving accident databases? Is there one model that you really should not buy?

- A. Sieber: Comparing risk calculations of certain profiles with certain bottom times shows that there is not such a big difference in risk. We may say that this profile is bad and that one is good, but in the end, it is a question of risk.
- W. Gerth: There is a big spread and when you do an actual risk of DCS calculation using three models that we use, you find that the risk is between three and eight percent on all of the models despite three hours difference between the two extremes of decompression times.
- H. Örnhagen: Are we talking about the same problem as the speed limits on our roads? We can accept and say that if we have an open speed limit there will be a higher number of people killed or injured on the roads, but at what level is the speed 'safe'? Where do we put limits on dive computers to say that they are safe?
- W. Gerth: In the U.S. Navy in the 'noise' of our risk of DCS estimates we include factors such as what the diver ate for breakfast, body temperature, etc. Then we assert that the model that we use prescribes schedules that are within an acceptable risk of DCS and we say that anybody can dive that profile that will be your mean risk of DCS with such and such an error. We are not going to live long enough to get enough data to parameterize a model to incorporate all of the different factors that have been posited as controlling DCS risk.
- H. Örnhagen: We have to realize that there are people who were treated for DCS who followed a dive computer.
- W. Gerth: True, the risk of DCS on any dive is not zero.
- H. Örnhagen: In addition, there is the problem of the number of divers who were treated for DCS actually having DCS versus those treated due to uncertainty of diagnosis. The classification of the cases that support our statistics may be in question. We have loose ends everywhere.

U.S. Navy Dive Computer Validation

David J. Doolette Keith A. Gault Wayne A. Gerth F. Greg Murphy U.S. Navy Experimental Diving Unit 321 Bullfinch Road Panama City, FLORIDA 32407-7015 U.S.A.

The U.S. Navy Dive Computer (NDC) is a typical diver-carried dive computer that uses a simple decompression algorithm to provide decompression schedules updated in real time. However, unlike many dive computers, the NDC is based on a well-documented decompression algorithm that is the result of extensive manned test-diving and for which the risk of decompression sickness is well defined. Since this Thalmann Algorithm is itself validated, validation of the NDC involved the relatively simple task of verifying a faithful implementation of the Thalmann Algorithm. The U.S. Navy experience in dive computer validation provides a useful framework for validating a commercial off-the-shelf dive computer, but challenges exist for dive computers that do not implement a well-documented decompression algorithm.

INTRODUCTION

Breathing a gas mixture at elevated ambient pressure (p_{amb}) , such as during underwater compressed gas diving, results in tissue uptake of dissolved respired gases. During ascent (or "decompression") to sea level, p_{amb} may decrease to a level less than the sum of the partial pressures of all gases dissolved in tissue, and in this state of gas supersaturation, bubbles can form and potentially cause decompression sickness (DCS). To manage the risk of DCS, dives are conducted according to depth/time/breathing gas decompression schedules derived with decompression algorithms that implicitly or explicitly limit bubble formation by slowing decompression, typically by interrupting ascent with "decompression stops" to allow time for tissue inert gas washout.

Although decompression without tissue gas supersaturation and, therefore, without bubble formation or risk of DCS is possible, such decompression strategies yield schedules that are impractically long. Instead, practical decompression algorithms balance the probability of DCS (P_{DCS}) against the costs of time spent decompressing. Modern, diver-carried dive computers sample p_{amb} at frequent intervals and use this as input to simple decompression algorithms that provide decompression schedules updated in real time.

The principal requirement for a dive computer is that dives following its decompression guidance will have a target (typically low) incidence of DCS. A corollary to this requirement for dive computers used in occupational (military or commercial) diving - the focus of this workshop - is that the decompressions are efficient, because time spent decompressing is unproductive (costs money) and prolongs exposure to a hostile environment. Requirements will be specific to some range of diving practices and to particular populations of divers because no decompression algorithm is suitable for all types of diving and different diving communities have different risk tolerances. Validation of a system such as a dive computer is

simply a demonstration that it matches its requirements. Validation of a dive computer entails measurement of the incidence of DCS, or estimation of P_{DCS} by some other method, associated with its decompression guidance.

Validation could be accomplished by subjecting a dive computer to many different depth/time dive profiles and evaluating the P_{DCS} of resulting decompression guidance. Such validation could be done without knowledge of the underlying decompression algorithm. Alternatively, the decompression algorithm can be validated separately from the dive computer, by measuring P_{DCS} associated with another implementation of the algorithm. The latter would then be the "gold standard" implementation. In this case, validation of the dive computer would follow from verification that it is a faithful implementation of the gold standard implementation. In this approach, understanding of the decompression algorithm can guide the validation process. It is this latter approach that is used by the U.S. Navy.

U.S. NAVY DIVE COMPUTER (NDC)

U.S. Navy Dive Computers (NDCs) are built by Cochran Undersea Technologies (Richardson, TX) but implement the Thalmann Algorithm, a decompression algorithm developed at the U.S. Navy Experimental Diving Unit (NEDU). There are now several configurations of the NDC tailored to the requirements of different diving communities within the U.S. Navy and different diving operations breathing open-circuit air or constant pO_2 from the MK 16 MOD 0 or MK 16 MOD 1 closed-circuit, mixed gas underwater breathing apparatus (UBA). In support of different combinations of these UBAs, the various configurations of the NDC for air and N₂-O₂ diving calculate decompression assuming inspired inert gas partial pressures associated with constant FO₂ = 0.21, constant $pO_2 = 0.7$ atm, and constant $pO_2 = 1.25$ atm, and make depth-dependent changes between these modes.

REQUIREMENT FOR THE NDC

The history of the development of the original NDC is covered in detail elsewhere (Butler and Southerland, 2001). The U.S. Navy requirement for a diver-carried diver computer arose in the 1970s to support Navy SEAL commandos' conduct of multilevel dives breathing air from an open-circuit supply or constant pO_2 -in-nitrogen from the MK 16 MOD 0 UBA (Thalmann et al., 1980). This requirement was the motivation for the development and manned-validation of a new decompression algorithm by CAPT. Ed Thalmann at NEDU (Thalmann et al., 1980; Thalmann, 1984; 1986). Although other options were considered, in 1996 the decision was made to procure and test a modified commercial dive computer for which the principle design requirement was implementation of the Navy-approved VVal-18 Thalmann Algorithm (Butler and Southerland, 2001).

VALIDATION OF THE NDC

1. Development and Validation of the VVal-18 Thalmann Algorithm

The Thalmann Algorithm is a neo-Haldanean decompression algorithm similar to those implemented in many dive computers. Inert gas uptake and washout is modeled for a set of parallel tissue compartments and decompression stops are required to keep the partial pressure of a single inert gas (p_i) in k modeled tissue compartments less than or equal to a depth-dependent maximum permissible value, $p_{i,k} \le M_k = a_k D + M_{0_k}$, where D is p_{amb} at each decompression stop expressed in depth of water, M and M_0 are the maximum permissible

tissue pressures (M-values) at D and at the surface, respectively, and a and M_0 are determined experimentally.

The Thalmann Algorithm differs from earlier such algorithms in several ways. The principal difference is that compartmental inert gas washout can switch from the normal exponential approach to arterial inert gas partial pressure to a much slower linear approach when a compartment is gas supersaturated (Exponential Linear or EL kinetics). This linear rather than exponential gas washout gives appropriately lengthened decompression times, particularly for repetitive dives, without negatively impacting no-stop limits. Another novelty is that the Thalmann Algorithm was developed specifically with a view to implementation in a dive computer, and was originally called the EL-RTA (real-time algorithm). The EL-RTA running on a minicomputer was used to control most man-dives conducted during the development and testing of the algorithm. The version used to calculate decompression tables, (originally the EL-DCM) calculates gas uptake and washout for finite ascent and descent rates, and therefore printed tables exactly match the EL-RTA if the same travel rates are used. Thalmann published the FORTRAN source code of the original EL-DCM (Thalmann, 1983; 1985), and this original code has been further developed at NEDU to support other diving applications. The structure of this enhanced version of the FORTRAN EL-DCM, renamed the Thalmann Algorithm Decompression Table Generation Software, is documented in detail (Gerth, 2010). This implementation was used to calculate the air and MK 16 decompression tables in the U.S. Navy Diving Manual, Revision 6 (Naval Sea Systems Command, 2008a). A Visual Basic implementation of the Thalmann Algorithm developed at NEDU and called the Navy Dive Planner is also documented in detail (Gerth et al., 2011). Users interact with Navy Dive Planner via a graphical user interface to plan dives or to follow dives in real-time and it is intended primarily as a tool for planning multilevel dives that will be conducted using a NDC. Decompression prescriptions generated by the Navy Dive Planner match those of the table generation software (Gerth et al., 2011).

The Thalmann Algorithm is initialized with a parameter set that includes a table of M-values and different parameter sets exist for different applications. The NDCs for air and N₂-O₂ diving use a parameter set called VVal-18, which is the same parameter set used to calculate the constant 0.7 atm pO₂-in-nitrogen (MK 16 MOD 0; Thalmann, 1984) decompression tables and MK 16 MOD 1 N₂-O₂ decompression tables in the U.S. Navy Diving Manual (Johnson et al., 2000). The Air Decompression Tables in the U.S. Navy Diving Manual, Revision 6 (Naval Sea Systems Command, 2008a) are calculated using a modified parameter set proposed by Flynn and designated VVal-18M which results in shorter air decompression times than VVal-18 (Gerth and Doolette, 2007; 2009). The development and testing that lead to the VVal-18 parameter set was simultaneous with development of the Thalmann Algorithm, and was initially in support of constant 0.7 atm pO_2 -in-nitrogen diving with the MK 15 and MK 16 UBAs. This initial development included 1505 air and constant 0.7 atm pO_2 -in-nitrogen man-dives (84 cases of DCS) with the algorithm and parameters being adjusted in response to schedules with high incidences of DCS (Thalmann et al., 1980; Thalmann 1984; 1986). In a recent test of VVal-18 Thalmann Algorithm air decompression, 192 dives to 170 feet sea water (fsw) for 30 minutes bottom time resulted in only three cases of DCS (Doolette et al., 2011).

The MK 16 MOD 1 N_2 - O_2 VVal-18 Thalmann Algorithm decompression tables were validated with 515 man-dives that resulted in seven cases of DCS (Johnson et al., 2000; Southerland, 1998). All these man dives were conducted in the wet pot of the Ocean Simulation Facility at NEDU under conditions relevant to occupational divers: divers worked

on the bottom and were at rest and cold during decompression - conditions shown to increase the risk of DCS (Van der Aue et al., 1945; Gerth et al., 2007). There has not been extensive manned-testing of air decompression tables calculated using the VVal-18M parameterization of the Thalmann Algorithm, but the P_{DCS} of the each schedule in both VVal-18 and VVal-18M air decompression tables have been estimated using NMRI98 (Parker et al., 1998) and BVM(3) (Gerth and Vann, 1997) probabilistic decompression models (Gerth and Doolette, 2007; 2009).

2. Verification of the NDC and configuration control

As outlined in the preceding paragraphs, the VVal-18 Thalmann Algorithm was already validated with manned diving trials under operationally relevant conditions that demonstrated acceptable P_{DCS} . Testing of the NDC was therefore simply to verify that it was a faithful implementation of the Thalmann Algorithm. This could be done by functional testing of NDCs comparing their behavior to "gold standard" decompression schedules and these gold standards exist in two forms. The gold standard printed VVal-18 Thalmann Algorithm decompression tables are the constant 0.7 atm pO_2 -in-nitrogen (MK 16 MOD 0) (Thalmann, 1984) decompression tables and MK 16 Mod 1 N₂-O₂ decompression tables (Johnson et al., 2000) that have appeared in several revisions of the U.S. Navy Diving Manual. The gold standard software implementations are the Thalmann Algorithm Decompression Table Generation Software and the Navy Dive Planner. The latter software package is designed specifically to complement the NDCs and is convenient for generating multilevel dives and decompression schedules of any complexity against which to test the NDC.

A sample of 10 to 30 of each configuration of the NDC has been functionally tested by exposing them to simulated dive profiles in a small, flooded test chamber and comparing NDC prescription to gold standard Navy Dive Planner decompression schedules (Southerland, 2000; Gault and Southerland, 2005; Gault, 2006; Southerland et al., 2010). Schedules differ by no more than can be accounted for by the specified pressure sensor tolerance (maximum ± 2 fsw (0.61 msw) deviation at maximum operating depth). This type of functional testing is called "black box" testing because the tester has no access to internal data structures and computer code to guide testing. The agreement between the Cochran Undersea Technologies and the U.S. Navy does not extend to sharing such proprietary information. The outcome of dive computer testing only remains valid while the system remains unchanged and by agreement with the manufacturer, no hardware or software changes are made to any configuration of the NDC after it has passed validation testing at NEDU. Every NDC unit undergoes a simple functional test of pressure sensor accuracy at purchase and subsequently every 18 months.

3. Pitfalls and lessons learned from U.S. Navy experience

Black box testing assumes that the suite of test dive profiles adequately exercise the algorithm so that any errors in the NDC implementation are revealed. Neo-Haldanean decompression algorithms, such as the Thalmann Algorithm, are well behaved and predictable, so that a relatively small test suite of dive profiles would be expected to adequately exercise the algorithm and suffice for verification. An example would be a test of no-stop limits across the range of operational depths, dives requiring decompression stops governed by all relevant compartments, dives to at least the maximum required operating depth and dive duration, and repetitive dives.

However, there are pitfalls in assuming the dive computer implementation is well-behaved, even for a simple algorithm. For example, the U.S. Navy is currently procuring a new

configuration of the NDC for use in a new operational scenario. This new configuration passed a relatively small suite of black box verification test profiles, of similar scope as described above, focused on exercising the relevant configuration changes. Subsequently, the NDCs were tested with a simulation of the new operational scenario, a dive profile not considered necessary for the original test suite. On this profile NDCs produced decompression schedules substantially different than those of the gold standard NEDU implementations, a difference that required revision of the NDC algorithm. This test revealed a simplification in the NDC implementation of the Thalmann Algorithm that only manifested substantively following an unusual type of multilevel dive.

The preceding anecdote illustrates that individual dive computer implementations, even of simple neo-Haldanean algorithms, can manifest unanticipated behavior. It is therefore essential that black box testing uses a suite of dive profiles that exemplify all expected operational uses of the dive computer. This requirement is increasingly important if validating dive computers that implement algorithms that are not well-documented, are more complex that neo-Haldanean algorithms, or are unknown.

VALIDATION OF COMMERCIAL-OFF-THE-SHELF DIVE COMPUTERS

The U.S. Navy experience with validating NDCs can serve as general guide for validating a commercial-off-the-shelf (COTS) dive computer as illustrated in Figure 1.

The steps taken by the U.S. Navy were: 1) define requirements; 2) develop and validate the decompression algorithm; and 3) verify the NDC computer implementation of decompression algorithm. For practical purposes argued below, this framework may need to be modified for a COTS dive computer. Validation must occur within a configuration control framework (represented by the diamond in Figure 1) that ensures re-validation if any changes are made to the dive computer software or hardware configuration. In the discussion that follows, "configuration manager" will be used loosely to mean an entity that has oversight of dive computer requirements, validation, and configuration control for a diving community.

1. Requirements for a COTS dive computer

The first step in the selection and validation of a dive computer is to define the requirements. This definition should include the scope of diving applications for which the dive computer must be applicable, for instance: no-stop diving, repetitive diving, multilevel diving, and decompression diving with or without gas switching. This scope will help to define the suite of test dive profiles for validation. The scope of diving application will also suggest specifications, such as depth range, support for multiple breathing gases, and availability of desktop planning software, that may be used to narrow the field of candidate dive computers. Requirements should also include the intended user communities, for instance: scientific, commercial, or military divers. These requirements inform setting of an acceptable range of P_{DCS} for diving operations.¹ The principal requirement for a dive computer is that it provides efficient decompression schedules that meet the target P_{DCS} .

¹ The U.S. Navy decompression schedules that require no or brief total decompression stop time, which are the dives conducted most frequently, have a low estimated P_{DCS} ; risk increases with total decompression stop time.^{12,13}

U. S. Navy Dive Computer

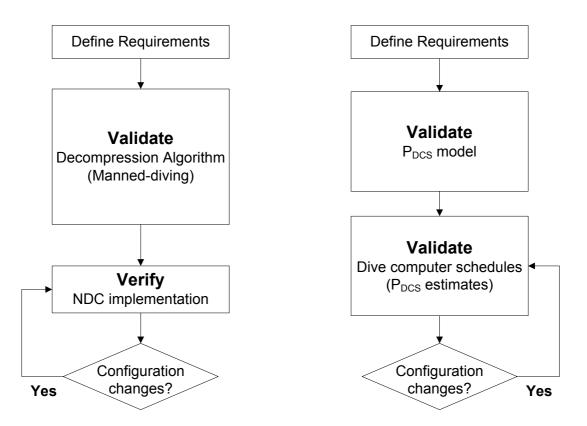


Figure 1. Outline of validation of the U.S. Navy Dive Computer and a proposed framework for validation of a COTS dive computer. The size of the boxes is intended to indicate the level of effort. Development, validation, and documentation of the Navy VVal-18 Thalmann Algorithm was a large effort. Consequently, verification of the NDC implementation of the algorithm can be a substantially smaller effort. Development and validation of a probabilistic decompression model (P_{DCS} model) is a substantial effort, but many already exist. Many dive profiles would need to be generated with an undocumented COTS dive computer decompression model.

2. Validating a COTS dive computer

After defining the requirements, there are two paths for validating a COTS dive computer. One path, similar to that used by the U.S. Navy, is to choose a dive computer that implements a well-documented, validated decompression algorithm that the configuration manager considers acceptable, and verify that the dive computer is a faithful implementation of that algorithm. The second path is to demonstrate that decompression guidance provided by the dive computer is acceptable, by some measure, without reference to the underlying algorithm. Each of these will be discussed in turn.

3. Verifying a dive computer implementation of a validated algorithm

If a dive computer implementation of a well-documented, validated decompression algorithm can be identified, a substantial portion of the validation effort is complete at no further cost to the configuration manager. A difficulty with this approach is that, often, scant detail of the decompression algorithms implemented in COTS dive computers is available (Huggins, 2006). Some dive computer implement variants of the "ZH" family of decompression algorithms, is probably the decompression algorithm with the best documentation available in the public

COTS Dive Computer

domain. It is not the purpose of this paper to recommend any particular decompression algorithm, that is a policy decision for the configuration manager, but we will use the ZH algorithm as an example of the challenges in validating a COTS dive computer implementation of an algorithm.

The development of the ZH algorithm is described in several scientific papers and most recently summarized in a monograph (Bühlmann, 1995). In addition to many mixed-gas dives, 813 dry, chamber air dives were conducted in the development of the algorithm (Bühlmann, 1995). This is a substantial number of man-dives, but any validation of the algorithm under the immersed, working conditions relevant to occupational divers appear to be open-water dives that are less well characterized than laboratory dives. In its most recent form, the ZH algorithm comprises 16 compartments with different half times for nitrogen uptake and washout and different pairs of coefficients equivalent to the a and M_0 parameters used to generate M-values. Two different parameter sets are proposed: ZH-L16B for calculation of printed decompression tables and ZH-L16C for use real-time applications. Although the conceptual model is described, there is no documentation of a gold standard ZH decompression algorithm implementation against which a dive computer could be verified. Desktop dive planning software provided with a COTS dive computer, without documented provenance, structure, and verification, is not a gold standard. Published schedules against which a dive computer might be validated exist, but these present challenges. First, the most recently published schedules are of the 1986 ZH-86 tables (Bühlmann, 1995) which appear to be calculated using the ZH-L16B parameter set. On the other hand, most dive computers purport to use the ZH-L16C parameter set, often use a reduced number of compartments (e.g., ZH-L8C), use an "adaptive" variant of the algorithm that adjusts values of the parameters under certain conditions, or use undocumented, proprietary modifications. Second, the methods by which the ZH-86 tables were produced are not clearly documented, but they appear to be calculated using inert gas kinetic equations that handle only instantaneous ascent and descent rates, something that cannot be replicated in dive computer testing. Therefore, no real-time implementation of ZH-L16 will exactly replicate the published schedules.

4. Validating a dive computer implementation of an unvalidated algorithm

Since there are substantial challenges to verifying the implementation of an algorithm in a COTS dive computer, a more practical approach would be to validate such a dive computer without reference to the underlying algorithm. This is illustrated on the right-hand side of Figure 1. This procedure involves generating a large number of validation dive profiles representing a range of depth/time combinations and decompression according to the dive computer prescriptions. The P_{DCS} associated with these validation dive profiles would then be evaluated. This decompression algorithm may be unknown and cannot be assumed to be well-behaved. Many dive profiles would be required to characterize the entire expected operational range of depths, bottom times, and decompression stop depths, as well as multilevel and repetitive diving. It may be possible, by negotiation with the manufacturer, to obtain access to simulation software that executes the exact source code as the dive computer. This simulation software could be run on a larger computer and automated to generate the large number of dive profiles required for validation. In this case the dive computer implementation could be verified in a test chamber with a smaller test suite as described for the NDC. Otherwise, all the validation dive profiles would need to be generated manually. Candidate dive computers would be subjected to the validation range of depth/time combinations in a test chamber. The decompression prescriptions indicated on the dive computers would be recorded as they evolve during the bottom time and during manual

decompression of the test chamber according to these prescriptions to verify consistency with the displayed prescriptions and actual behavior. The P_{DCS} of manually generated dive profiles would be evaluated.

It would be expensive to evaluate all the resulting dive profiles with man-dives. Instead, the dive profiles could be evaluated with decompression models that themselves have been validated as providing accurate estimates of P_{DCS} . For instance, the P_{DCS} of each dive profile could be estimated using probabilistic decompression models such as NMRI98 (Parker et al., 1998) and BVM(3) (Gerth and Vann, 1997). The parameters of these models were found by fit to data comprising thousands of carefully controlled and documented experimental air and N_2 -O₂ dives with known depth/time/breathing gas history and time of onset of any DCS. These models therefore embody the experience contained in these large data sets. These models were then validated by their ability to predict the incidence of DCS in data sets of dives not used for calibration but conducted under similar conditions (Parker et al., 1998; Gerth and Vann, 1997). In these probabilistic decompression models, instantaneous risk of DCS is a function of either modeled compartmental supersaturation or bubble volumes and P_{DCS} is the time integral of instantaneous risk during and following the dive. Such models can therefore be used to evaluate dive profiles of arbitrary complexity, as would be required to evaluate dive profiles produced in black box validation of dive computers.

A recently published model of ultrasonically detectable venous gas bubbles (Gutvik et al., 2010) can also be used to evaluate dive profiles of arbitrary complexity, and assign each profile a peak bubble score. Peak venous gas bubble scores are weakly associated with incidence of DCS and are used as a surrogate measure of decompression stress (Sawatzky, 1991; Eftedal et al., 2007). Although this model has yet to be validated, once it has, it could be used to evaluate dive computer prescriptions. Care is needed with this approach to evaluating decompression procedures to choose target bubbles scores based on their association with a target P_{DCS} and not seek to minimize venous gas bubbles *per se*, as the latter results in inefficient decompression schedules.

RISK OF DCS USING THE NDC

Conducting dives using printed decompression tables requires that schedules are selected on the maximum depth obtained at any time during the dive and may require round-up to the next deeper depth and longer bottom time. Avoiding this costly round-up procedure is a principal motivation for using dive computers. As a result, however, diving to the no-stop limits or conducting decompression dives using dive computer guidance are expected to generally present greater risk of DCS than divers using printed tables calculated using the same decompression algorithm.

The U.S. Navy has not collated data on the incidence of DCS using NDCs. Indeed, to date, the NDCs have been used principally to keep dives within no-stop limits, and little DCS is expected and none has been reported. Going forward, NDCs will be used to conduct dives to no-stop limits and to conduct decompression dives. Recently, 92 decompression dives were conducted in open water using NDC guidance and no DCS was reported. However, this is a small sample and the U.S. Navy relies on probabilistic model estimates and the outcome of laboratory trials of the VVal-18 Thalmann Algorithm to quantify the expected incidence of DCS when NDCs are used to conduct dives to no-stop limits and to conduct decompression dives.

1. Air no-stop diving

The U.S. Navy Dive Computer (NDC) used for air scuba diving is designated the AIR III. Only no-stop diving is conducted using air scuba in the U.S. Navy. The AIR III is functionally equivalent to the original NSW III configuration of the NDC and assumes air breathing shallower than 78 fsw and constant 0.7 atm pO_2 -in-nitrogen at 78 fsw and deeper. The NSW III is used for operations where both MK 16 MOD 0 UBA (constant $pO_2 = 0.75$ atm) and open-circuit air may be breathed, since a constant $pO_2 = 0.7$ atm results in a lower pN_2 than air shallower than 78 fsw and a higher pN_2 than air at 78 fsw or deeper. This same configuration was chosen for the AIR III to shorten the no-stop limits deeper than 78 fsw compared to those calculated for air (Doolette et al., 2009; Naval Sea Systems Command, 2008b).

The no-stop limits obtained using the AIR III are close to the no-stop limits printed in the U.S. Navy Air Decompression Table in the U.S. Navy Diving Manual, Revision 6 (Naval Sea Systems Command, 2008a). The discrepancies arise due to different assumptions in the calculations but also to substitution of the no-stop limits in the printed Air Decompression Table with no-stop limits from the Standard Air Decompression Tables that appeared in all earlier versions of the U.S. Navy Diving Manual since 1959, where these latter are shorter (Gerth and Doolette, 2009). The motivation for these substitutions and for the choice of AIR III configuration is that a laboratory test of no-stop limits longer than the those of the Standard Air Decompression Tables resulted in a lower than predicted incidence of DCS, but all the DCS that occurred manifested as unacceptably severe symptoms involving the central nervous system (Doolette et al., 2009).

Table 1 shows that the AIR III no-stop limits for the range 30-190 fsw have a mean estimated P_{DCS} of 2.02% (range 1.32–4.96%) according to the NMRI98 probabilistic model, slightly higher than the U.S. Navy Diving Manual, Revision 6 air no-stop limits which have a mean estimated P_{DCS} of 1.83% (range 1.01–4.96%). Table 1 also shows the probability of severe central nervous system DCS (P_{CNSDCS}) estimated using a logistic model calibrated with 1629 laboratory no-stop man-dives (Doolette et al., 2009). AIR III no-stop limits have a mean estimated P_{CNSDCS} of 0.24% (range 0.11–0.36%), slightly higher than the U.S. Navy Diving Manual, Revision 6 air no-stop limits which have a mean estimated P_{CNSDCS} of 0.13% (range 0.01–0.36%).

2. MK 16 MOD 1 decompression diving

There are several NDC configurations used to support diving with the MK 16 MOD 1 UBA, which makes depth-dependent transitions between constant pO_2 s of 0.75 and 1.30 atm. The EOD III configuration of the NDC begins with constant $pO_2 = 0.7$ atm at the surface, transitions to constant $pO_2 = 1.25$ atm upon any descent to 34 fsw or deeper and subsequently transitions back constant $pO_2 = 0.7$ atm on ascent to 12 fsw or shallower. The EOD III is an alternative to the MK 16 MOD 1 N₂-O₂ decompression tables in the U.S. Navy Diving Manual, which were developed for Explosive Ordinance Disposal (EOD) diving which involves repetitive dives to the no-stop limits and repetitive decompression dives (Johnson et al., 2000).

Like all neo-Haldanean decompression algorithms, VVal-18 Thalmann Algorithm schedules are not iso-risk. The MK 16 MOD 1 N₂-O₂ no-stop limits have probabilistic model estimated P_{DCS} in the vicinity of 2% and the estimated P_{DCS} increases with increasing total decompression time (Johnson et al., 2000). In the U.S. Navy Diving Manual, Revision 6, routine risk of DCS is capped by limit lines that make all schedules with estimated P_{DCS}

greater than 5% exceptional exposure dives (Navy Experimental Diving Unit, 2007). Conduct of exceptional exposure dives is prohibited for routine diving and requires permission of the Chief of Naval Operations. Dives conducted using NDCs are planned using the Navy Dive Planner. The Navy Dive Planner has a risk monitor that displays red when dives are planned with estimated P_{DCS} of 5% or greater, indicating the dive should not be conducted and serving the same purpose as the limit lines in the printed tables (Gerth et al., 2011). Laboratory validation of the MK 16 MOD 1 N₂-O₂ decompression tables consisted of dives relevant to EOD operations and with repetitive dives calculated in real-time mode, analogous to the operation of an NDC, and resulted in 3 DCS in 325 dives (95% C.L. 0.2%, 2.7%) (Johnson et al., 2000). Since NDCs enable diving to the limits of the decompression algorithm, it is expected that routine MK 16 MOD 1 N₂-O₂ dives conducted using the EOD III will have similar incidence of DCS as the laboratory trials.

Table 1. Air no-stop bottom time (BT) limits and estimated P _{DCS} and P _{CNSDCS}
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fsw	U.S.N. I	.S.N. Diving Manual, Rev 6			AIR III	AIR III	
	BT	P _{DCS} %	P_{cnsDCS} %	BT*	P_{DCS} %	P_{CNSDCS} %	
30	371	4.96	0.36	371	4.96	0.36	
40	163	2.95	0.35	164	2.95	0.17	
50	92	2.20	0.16	92	2.20	0.11	
60	60	1.96	0.10	63	2.06	0.12	
70	48	2.05	0.17	48	2.05	0.15	
80	39	2.06	0.22	39	2.06	0.20	
90	30	1.86	0.19	32	2.01	0.24	
100	25	1.80	0.23	27	1.97	0.30	
110	20	1.63	0.21	23	1.91	0.36	
120	15	2.17	0.14	19	1.82	0.35	
130	10	1.12	0.06	16	1.75	0.35	
140	10	1.25	0.11	13	1.60	0.29	
150	5	0.88	0.01	11	1.53	0.27	
160	5	0.94	0.02	9	1.41	0.21	
170	5	1.01	0.04	8	1.40	0.22	
180	5	1.08	0.06	7	1.37	0.21	
190	5	1.16	0.09	6	1.32	0.18	

*BT assuming 60 fsw/min descent rate and 30 fsw/min ascent rate

CONCLUSION

The principal requirement of the NDC is implementation of the U.S. Navy-approved VVal-18 Thalmann Algorithm. The U.S. Navy maintains gold standard software implementations of the Thalmann Algorithm. VVal-18 Thalmann Algorithm decompression schedules produced by these gold standard implementations have acceptable P_{DCS} as demonstrated in manned dive trials and estimation of P_{DCS} using probabilistic models. The NDCs are validated by faithful replication of gold standard decompression schedules when exposed to simulated dives.

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Validation of Dive Computer Algorithms

Sergio A. Angelini Angelini Consulting Egg 28 CH-5444 Künten, SWITZERLAND

Results of a comprehensive effort to analyze commercially available dive computers and PC-based dive planners are reviewed. For this study 234 chamber test dives were carried out with profiles ranging from square to triangular, multilevel forward and multilevel reverse, to a maximum depth of 54 m. Air was the breathing medium for all dives. A first phase considered only no decompression dives, a second phase considered decompression dives at two levels of PRT (pressure root time) and a third phase considered repetitive dives with various surface intervals.

INTRODUCTION

Boycott, Damant and Haldane (Boycott et al., 1908) developed their rather crude decompression model in 1908. The body was divided in 5 compartments, with half times of 5, 10, 20, 40 and 75 minutes, and a decompression schedule was calculated such that the nitrogen pressure in each compartment was never more than twice the nitrogen partial pressure in the inhaled gas (air). More than 100 years later much has changed: the compartments have grown in number (up to 20), a much wider spectrum of half times (from 2.5 to 640 minutes) is considered and the tolerated supersaturation ratio is not constant but rather varies with half time (from 4 for short halftimes to little over 1 for long ones). There are claims of bubble size, volume calculations, adaptations to workload, water temperature and much more being taken into consideration. Indeed, considering the complexity of human physiology and the banality of asymptotic compartment ongasing and offgasing, it is both desirable and optimal to incorporate more physiological parameters into present day decompression models than the three English gentlemen did in 1908.

Diving can be grouped into five categories:

- recreational (dives mostly shallower than 40-50 m, within the no-decompression limits, primarily using the same breathing mix from beginning to end);
- technical (dives pushing depths beyond 100 m and/or dive times to 20 and more hours, using highly dedicated equipment and a multitude of breathing mixes tailored for each part of the dive);
- scientific (dives shallower than 60 m, usually within no-decompression limits, with air or N_2O_2 as breathing mix and computer-controlled dive profiles)
- commercial (dives with a specific goal, e.g., maintenance or inspection of underwater facilities); and,
- military.

The five categories vary in type of exposures and equipment used, but they have in common a rather low decompression illness (DCI) incidence rate and the fact that, by and large, they all rely on decompression schedules evolved from the original compartment model.

In commercial and military diving in particular the use of dive tables is still widespread, and the safety record there is very good. The community of divers relying on tables is, compared to recreational divers, usually more trained and fit and more focused on a particular task with less chance of making errors. Furthermore, when tables are utilized during dives that are not square an intrinsic conservatism is automatically introduced; for the purpose of calculating the decompression, the maximum depth is rounded off to the next value in the table and then applied to the entire duration of the dive.

The alternative to dive tables is dive computers. They track the profile of the dive very closely, but there is no inherent additional conservatism when performing non-square dives. Further, the target market for these instruments are divers who are not always fit people and are less mission-oriented. Therefore, the dive computer models employed are a detuned, more conservative version of the tables (primarily achieved by reducing the tolerated supersaturation levels). Despite the additional conservatism in the algorithms themselves, for most practical uses dive computers will allow for more bottom time because profiles are hardly ever square and only a fraction of the time is spent at the maximum depth.

Dive computers present other very clear and definite advantages. In addition to being able to display a continuously updated decompression schedule, they can warn the diver of unsafe procedures (such as a fast ascent or excessive ppO_2) and also provide a log of the dive itself. This can be useful for monitoring of activities, accident analysis and, ultimately, can represent a database to be used to further our understanding of decompression physiology.

Blind faith in dive computers can certainly be dangerous. Simply because they keep track of pressure over time does not imply that they can be applied to any profile. At the heart of the dive computer there is a mathematical model that wants to mimic human physiology under hyperbaric conditions and any such model has a limited range of applicability. Using a model outside of the validated range carries obvious risk, but even its use within the validated range needs to be addressed with caution. We cannot assume a priori that a multilevel dive computed as an extension of the multi-compartment theory validated via square dives is going to follow the same rules.

The aim of this study was to collect a number of relevant computers from the market and analyze their behavior when subjected to a large number of profiles. Each profile was then also "dived" using two commercially available PC-based dive planners. The profiles ranged from square, no-decompression dives to multilevel long decompression dives. This analysis does not include a judgment about the safety of each product, but rather attempts to assess the range of options and provide a guideline for a separate study including human trials, from which such judgment could be derived.

MATERIALS AND METHODS

Dive computers and PC-based dive planners used in the study

All major manufacturers were asked to participate by submitting the model of their own choosing. We focused on one product per decompression model employed. For example, since all Uwatec computers utilize the same algorithm, one Uwatec product was sufficient for our study. Likewise we used one Suunto and one Mares dive computer.

We contacted, in alphabetical order, Cochran, Delta P Technologies, Oceanic, Mares, Suunto, Uemis, Uwatec. Oceanic and Uemis declined to participate. Suunto did not formally decline

but also did not respond affirmatively to our query and did not submit a product; given the wide distribution of Suunto computers we deemed it necessary to purchase one. Cochran, Delta P Technologies, Mares and Uwatec kindly submitted two samples of the same computer: having two allowed us to verify that they were behaving as expected, and in case of a failure we could continue the study without disruption. None of the computers failed during the study.

Our test field comprised the following dive computers:

- Cochran EMC-20H
- Cochran NAVY AIR III
- Delta P VRX
- Mares Puck
- Suunto Vyper Air
- Uwatec Aladin Prime

All dive computers were delivered with PC-interfacing hardware and software, which was used to download and archive all dives. For this purpose we used an HP COMPAQ 6820s running Windows Vista Business SP2.

All computers allowed for some level of conservatism. We only tested the baseline algorithm, i.e. the least conservative setting. Some allowed for salinity setting, typically between fresh water and salt water (Mares, Uwatec). The Cochran computers adjust the salinity automatically by measuring the conductivity between two metal contacts. Delta P and Suunto are calibrated to salt water and this setting cannot be changed.

We intentionally stayed away from special conditions like fast ascent, yoyo diving, cold water or other aspects which, although interesting, should be relegated to a later study when the initial understanding is sound. With enough parameters to deal with, it was important to not introduce additional complexity.

Aside for the VVAL-18 implemented in the Cochran Navy AIR III, which is supported by a wealth of documentation describing the validation performed by the US Navy (Doolette et al., 2012) no real details are provided by any manufacturer about the decompression models. The following is what we were able to gather from manuals, websites and other sources:

- Cochran EMC-20H: 20-tissue Haldanean model.
- Cochran VVAL-18: nine-tissue Haldanean model with exponential ongasing and linear offgasing.
- Delta P: 16-tissue Haldanean model with VGM (variable gradient model, i.e., the tolerated supersaturation levels change during the dive as a function of the profile, but no details are provided as to how this is done).
- Mares: 10-tissue Haldanean model with RGBM; what the RGBM part of the model does is not described in detail anywhere and is not available to the public.
- Suunto: nine-tissue Haldanean model with RGBM; what the RGBM part of the model does is not described in detail anywhere and is not available to the public.
- Uwatec: eight-tissue Haldanean model.

On the PC used for downloading and analyzing all dive computers we also installed V-Planner (version 3.87) by HHS Software Corp. and GAP (version 2.3, build 1665) by Gap Software. V-Planner runs the Variable Permeability Model (VPM; Yount et al., 2000) and allows the choice of VPM-B and VPM-B/E. We chose to use VPM-B/E and for each dive we

ran the calculation for all six conservatism levels (baseline plus five incrementally more conservative ones).

GAP allows the user to choose between a multitude of Bühlmann-based algorithms and the full RGBM (Wienke, 2001) in its five conservatism levels (base line, two incrementally more liberal and two incrementally more conservative). For each dive we ran GAP using RGBM in all five conservatism levels. For some dives we also ran the 16-tissue Bühlmann model in GAP for comparison.

Description of the dive profiles and equipment utilized

All dives were carried out in the chamber depicted in Figure 1. The chamber has a usable volume of 30 cm length, 19 cm width and 12 cm height. Effectively, the usable space is the surface of 19x30 cm since we wanted to observe the computers during the dive and thus could not stack them. This area was sufficient for our purposes.

The chamber is fed by the low pressure line off of a scuba tank as can be seen in Figure 2. Maximum pressurization of the chamber is 70 msw, controlled by an overpressure relief valve. In all profiles, a descent speed of 20 m/min and an ascent speed of 10 m/min (unless otherwise specified) was applied.



Figure 1. Dive chamber utilized to generate dive profiles.



Figure 2. Dive chamber and source of pressurization.

During a dive, at fixed time intervals, the information displayed by each computer was recorded by hand on a log sheet. This was also done right before and right after each depth change. All computers were also downloaded to PC for archival purposes and for analysis of the dives with the respective PC software packages.

The study itself comprised three main phases:

Phase one: No-decompression dives with no considerations for repetitive diving effects.

- Phase two: Decompression dives with no considerations for repetitive diving effects. This is split into two ranges of PRT values (PRT: Pressure Root Time is an indicator of the severity of a dive). For square dives, this is the result of multiplying the absolute pressure in bar by the square root of the time at depth. Hence a 40 msw dive for 25 min has a PRT of 5x5=25.
 - a. Low to moderate exposures (PRT<25)
 - b. Extended exposures (25<PRT<30)
- Phase three: Repetitive dives, covering both no decompression and decompression dives.

Phase 1: No-decompression dives

<u>Phase 1a</u>: SQUARE no-decompression dives. During this first phase, we compared the dive computers and the PC-based dive planners simulating dives to the limit of decompression, for depths between 18 msw and 51 msw, in 3 msw increments.

<u>Phase 1b</u>: TRIANGULAR no-decompression dives. A triangular dive is one in which, after an initial bottom time at maximum depth, the diver maintains a constant, slow ascent to the surface (e.g. 1 m/min). A sample profile is depicted in Figure 3.

<u>Phase 1c</u>: MULTILEVEL no-decompression dives. Here things start to get complex, because of the various possible shapes of a multilevel dive and the multiplying effect of wanting to test various residence times at the various levels. Sample profiles are depicted in Figures 4 and 5.

For these profiles we need to define the depth and the duration of each level. Maximum depth was either 40 or 50 msw, and the other levels were between 15 and 35 msw. For simplicity sake, and because we are still within the realm on no-stop diving, we spent approximately half of the available no-stop time at the first level, then carried the second level to 1 minute of no-decompression time remaining, and then residing at the third level to the limit of the available no-decompression time.

For each of the profiles, we also wanted to test what happens if the first two levels were combined into one level of the same duration and at a depth corresponding to the weighted average of the first two. In other words, we wanted to establish whether, so long as the depth is increasing, a profile can be reasonably approximated with a square dive with the same area.

Phase 2: Decompression dives

Phase 2 covers decompression dives. These are divided into two categories (low to moderate exposure, and high exposure) as defined by the PRT parameter. For each we perform square and multilevel dives as seen in Phase 1, but extended the dive times accordingly. For non-square dives the PRT is less meaningful so we extended the residence times at each level with respect to Phase 1 in order to arrive at total ascent times comparable to the square dives.

Phase 3: Repetitive dives

The complexity grows even more when we attempt to study the effect of repetitive diving. Because a single session is constituted not just by two independent dives but also by the interval of time in between them, the number of possible combinations grows very rapidly. Thus, we chose to limit ourselves to square dives only, repeating the same dive after a given surface interval or performing a different one (for instance, an 18 msw for 62 min followed

by a 42 msw for 18 min and vice versa) in order to gain some insight into the effect of the shape and sequence of the dives in a repetitive series. Surface intervals of 30, 60, 90 and 120 min are used for no-decompression and low-PRT decompression dives, whereas longer surface intervals are used for high-PRT decompression dives (up to five hours).

RESULTS

Phase 1

During this phase, 118 dives were carried out in the pressure chamber. These dives were split in three categories as follows: Square dives (n=34), Triangular dives (n=9), and Multilevel dives (n=75 total, of which 24 forward and 51 reverse).

Not all computers yield the same results, and because all were tested simultaneously in the same chamber, it is obvious that some computers would have some decompression requirement at the end of the dive while some stayed within the limits of no decompression. The results are then expressed in the following terms:

- for square dives: no-decompression limits. If a computer went into decompression, the bottom time that would have allowed a direct ascent is observed and recorded manually during the dive and then confirmed with the downloaded logbook on the PC;
- for triangular dives: we performed several dives with different residence times at the maximum depth, trying to get some residual decompression at 6 m in order to stress the various models;
- for multilevel dives: we drove the profile so as to get to the limit of decompression on at least some computers, but this would invariably imply that some others would have a decompression obligation while others would still be within the no-decompression limits. Hence in this case we simply reported the status at the beginning of the final ascent.

Square dives

Square dives were carried out in the depth range from 18 msw to 51 msw, in 3 msw increments. Figure 6 summarizes the no decompression times observed during these dives, and also the corresponding results from the GAP and V-Planner PC simulations in their baseline setting.

The two Cochran computers have the longest no-decompression times, with the two models alternating as to which one is the most liberal: the EMC-20H is more liberal at 18 m and 21 m, whereas the NAVY AIR III is more liberal at 24 m and deeper. Mares, Uwatec and Suunto are, in their standard setting, almost identical, whereas the Delta P VRX is a bit more conservative.

Triangular dives

These dives involve a descent at 20 m/min to a target depth, a certain amount of time spent at that depth, then an ascent at 1 m/min, either continuous or discretized in 1 or 2 msw steps. We also performed some dives in which the ascent speed was further reduced, to 0.5 m/min, from a depth of 16 msw to the surface.

Such dives are not very practical for recreational diving, since a great deal of attention has to be paid to maintaining a constant ascent rate. However, they could prove to be very useful in commercial activities such as fish tank cleaning. Primarily, however, these profiles have been

introduced in this study because they would represent the greatest challenge for empirical models fitted to square dives. During a slow ascent, the transition from ongasing to offgasing for the various tissues could easily lead to discrepancies between models and might possibly misrepresent the actual human physiology.

In the PC simulations the ascent rate is a user-defined parameter, but for the chamber simulations the ascent is controlled by the operator via an exhaust valve, and hence is very difficult to control to a given speed with certain accuracy. Therefore, in chamber dives we have always applied a discretized ascent in 1 or 2 m steps, performed every 1 or 2 minutes with a quick transition from one depth to the next.

PC Simulations - constant, discretized and variable ascent rates

For a maximum depth of 40 msw, we have run several simulations to determine the longest allowed bottom time which, when followed by the slow ascent, would result in no residual decompression obligation at three msw or six msw ("residual" in the sense that the very slow ascent in itself already represents a very long decompression, so that by the time one reaches six msw, there is no decompression obligation left). The simulations were performed with a continuous straight-line 1 m/min ascent, in 1 msw steps performed each minute, in 2 msw steps performed every 2 min and in 2 msw steps performed every 2 min up to 16 msw, then 1 msw steps every 2 min from 16 msw to the surface.

The findings are as follows:

- RGBM (at setting 0) allows longer bottom times at 40 msw when a discretized ascent in 2 msw steps is used (9 min) with respect to 1 msw steps (6 min) and a continuous ascent (1 min). The allowed bottom time grows to 18 min when a 2 m/2 min ascent rate is employed up to 16 msw, then 1 m/2min from there.
- For ZH-L16 it is the opposite, allowing 19 min for a continuous ascent, 6 min for 1 msw steps and none for 2 msw steps, even when the speed is reduced further from 16 msw onwards.
- V-Planner yields the same results regardless of the ascent method used (2 min at nominal setting), but for the variable ascent rate (1 msw every 2 min from 16 msw to the surface) the allowed bottom time is longer (4 min).

This means that:

- in RGBM offgasing prevails over ongasing when following a discretized ascent rate, the coarser the better. A slower ascent rate in the shallower portion of the profile is very beneficial;
- in ZH-L16 offgasing prevails over ongasing when following a continuous ascent rate;
- V-Planner behaves the same way as long as the overall ascent is similar. A slower ascent rate in the shallower portion is beneficial.

Chamber simulations with dive computers

For a maximum depth of 40 msw, we have performed four dives:

- Dive 16: 6 min at depth followed by an ascent of 2 msw every 2 min;
- Dive 17: 5 min at depth followed by an ascent of 2 msw every 2 min;
- Dive 18: 4 min at depth followed by an ascent of 2 msw every 2 min;
- Dive 21: 6 min at depth followed by a variable ascent rate: 2 msw every 2 min up to a depth of 16 msw, and then 1 msw every 2 min from 16 msw to the surface.

A direct comparison between dives 16 and 21 is very interesting because it shows the effect of slowing down the ascent rate in the shallower part of the profile. The two profiles are depicted in Figure 7. The Mares, Uwatec and Suunto dive computers (Cochran and VRX were not tested in these profiles) show a slight advantage for the split ascent rate, resulting in less remaining decompression obligation at 3 msw (from 8 to 4, 10 to 7 and 8 to 4 min, respectively). RGBM (1 and 0 min remaining decompression time, respectively) and V-Planner (5 and 2 min remaining decompression time, respectively) yield the same trend, whereas ZH-L16 gives the same result for both ascents (1 min remaining decompression at 3 msw).

For a maximum depth of 50 msw, we have performed two dives, each with a two min stay at the bottom, in one case with a 2 msw ascent every 2 min (dive 19), and one employing a variable ascent rate: 2 msw every 2 min up to a depth of 16 msw, and then 1 msw every 2 min from 16 msw to the surface (dive 22). Curiously, RGBM behaves the opposite way than on the 40 m dive: now the slower ascent rate from 16 m to the surface yields longer decompression obligations (20 instead of 9 min), whereas V-Planner still shows an advantage in employing a slower ascent rate in the shallower portion (9 instead of 16 min). The dive computers also show a marked advantage for the implementation of a slower ascent rate (Cochran EMC-20H: 6 instead of 11 min; Cochran Navy: 57 instead of 67 min; Mares: 33 instead of 40 min; Suunto: 24 instead of 35 min; Uwatec: 22 instead of 34 min; VRX: not tested). The wide spread in the results obtained by Gap, V-Planner and the various dive computers shows that these dives are very challenging for the decompression algorithms, especially in light of the otherwise close agreement between some of the computers.

Multilevel profiles

All dives were performed so as to produce near zero decompression obligations on the dive computers, at least on those that are giving very similar results in their nominal setting (Mares, Suunto and Uwatec). We have performed a multitude of dives, with profiles ranging from deepest level first, to deepest level in the middle, to deepest level at the end of the dive. For most dives, we have also repeated the equivalent dive at the average depth of the regular profile at the beginning of the final ascent. All of these permeations were carried out in pursuit of anomalies in order to uncover discrepancies between models, or at least peculiar aspects for specific circumstances.

So as to be able to compare the various decompression calculations in some unbiased way, and highlight things that appear interesting, we have assigned a score to each profile for the two PC-based dive planners, according to the Table 1.

Model/ Score	0	1	2	3	4
RGBM	only most conservative setting has decompression	only 3 most conservative settings (of 5) have decompression	least conservative setting has 1min of decompression or less	least conservative setting has between 2 and 4 minutes decompression	least conservative setting has 5 minutes or more decompression
V- Planner	least conservative setting has 5 minutes or more decompression	only 4 most conservative settings (of 6) have decompression	least conservative setting has 1min of decompression or less	least conservative setting has between 2 and 4 minutes decompression	least conservative setting has 5 minutes or more decompression

On the table describing the dives, we have included a column for the difference in the score between RGBM and V-Planner: when the difference was 3 or 4, it means that the two models are painting a completely different picture for the dive and they are worth looking into

further: for example one computer might say that there is hardly any decompression required, while the other requires a lot of decompression.

Similarly, we wanted to look at dives for which both PC-based dive planners predict very high decompression, since the controlling force of each dive is a no-decompression condition in the dive computers at their nominal setting. It is therefore worth trying to understand what is causing these discrepancies.

Forward profiles

Forward profiles are those in which the maximum depth is reached towards the beginning of the dive, after which the profile gradually evolves towards shallower depths. All profiles are broken into three main sections at constant depths, for instance, 50-35-15 meaning that the chamber is pressurized to 50 msw for some time, then the pressure is reduced to the equivalent of 30 msw and eventually to the equivalent of 15 msw before starting the final ascent to the surface. Figure 8 depicts an example of a forward profile.

For the deepest level we have employed depths of 50 and 40 msw, for the intermediate level 35, 30, 25 and 20 msw, and for the shallowest portion 25, 20 and 15 msw. In all dives to 50 msw, 2 min was spent at depth, hence ascending at 4 min 30 sec dive time. For the dives to 40 msw, 5 min was spent at depth, hence ascending at 7 min dive time.

Table 2 gives the complete overview for these forward profiles in terms of the scoring system described at the beginning of this section.

Dive no.	Dive descriptor	RGBM	V-Planner	Diff.
23	50-35-20	1	4	3
24	50-35-15	0	3	3
25	50-35-25	2	2	0
26	50-30-15	0	3	3
27	50-30-20	1	4	3
28	50-30-25	2	2	0
29	50-25-25	2	2	0
30	50-25-15	0	3	3
31	50-25-20	1	1	0
32	40-30-15	0	4	4
33	40-25-20	1	1	0
34	40-25-15	0	4	4
35	40-30-20	1	4	3
36	40-20-20	1	1	0
37	40-20-15	0	0	0
45	40-25-20 2step	1	2	1
46	40-25-15 2step	1	4	3
48	50-25-25 1step	2	4	2
49	40-20-20 1step	2	3	1
50	50-35-15 2step	0	4	4
51	50-35-25 2step	2	1	-1
52	50-30-15 2step	0	4	4

Table 2. Multilevel forward dives.

What immediately jumps out is the agreement between RGBM and V-Planner for the dives in which the third level is relatively deep, yet a large discrepancy in results when the last level is relatively shallow (24 and 25, 27 and 28, 32 and 33 etc). In other words, RGBM starts to give credit at a deeper depth than V-Planner and hence there are high decompression requirements for those dives in V-Planner and little or none with RGBM. It was also noted that combining the first two levels in one of the cumulative duration and at the average depth, yields, if not the same decompression requirements of the original profile (40-25-20, 40-25-15, 50-35-15), then only a small difference (50-25-25). Only the 40-20-20 profile, when reduced to a unique depth of 23.8 m for the entire duration of the dive, gave appreciable differences in decompression schedule for all models.

Reverse profiles

These are divided into 3 profile types:

- dives in which the deepest portion of the dive is reached at the beginning of the dive, but then a shallower portion follows before a deeper one. An example is shown in Figure 9. A peculiar aspect of these dives is that there is offgasing of some tissues before ongasing starts again;
- dives in which the deepest portion of the dive is in the middle of the dive, as depicted in Figure 10. In these dives, all tissues are ongasing during the first two levels while some may switch to offgasing during the third level;
- dives in which the depth was gradually increasing and the final ascent made from the deepest point (Figure 11). In these dives, all tissues are ongasing until the final ascent.

A summary of all dives is shown in Table 3, in which the score for each is listed. We again find big discrepancies between RGBM and V-Planner when a 15 msw step is at the end of the dive: one model gives credit (RGBM) while another one does not (V-Planner).

As part of these dives we also experimented with profiles in which the sequence of the depth levels were changed without changing the duration at each level, to see what effect this would have on the resulting decompression profile (5 min at 40 msw, 5 min at 30 msw and 14 min at 20 msw). The dive computers showed limited influence (from a minimum of 2 to a maximum of 6 min decompression for the Mares, Suunto and Uwatec; the others were not tested), whereas the V-Planner (minimum of 7, maximum of 18) and RGBM (minimum of 2, maximum of 12) showed bigger changes (dives 35, 91-95, 99).

Dive no.	Dive descriptor	RGBM	VPLAN	Delta (R-V)
53	50-15-30	1	0	1
54	50-15-35	2	1	-1
55	50-20-30	2	1	-1
56	40-15-30	1	1	0
57	40-15-35	2	1	-1
58	40-20-30	2	1	-1
59	50-15-30 2step	2	3	1
60	50-15-35 2step	3	4	1
61	50-20-30 2step	2	4	2
62	50-15-30 1step	1	2	1
63	50-15-35 1step	1	2	1

Table 3. Multilevel reverse dives.

30 $30-0-50-14kp$ 2 3 4 1 66 $50-15-35-2step$ 3 4 1 68 $20-50-20$ 2 4 2 69 $20-50-25$ 2 4 2 70 $20-50-25$ 2 4 2 71 $25-50-25$ 2 4 2 73 $25-50-25$ 2 4 2 74 $25-50-25$ 2 4 2 74 $25-50-25$ 2 4 2 76 $30-50-20$ 2 4 2 78 $30-50-30$ 3 4 1 79 $20-40-15$ 1 4 3 80 $20-40-25$ 2 2 0 81 $20-40-25$ 2 2 0 82 $20-40-30$ 3 3 1 84 $25-40-25$	64	50-20-30 1step	2	3	1
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69 20-50-25 2 4 2 70 20-50-30 3 4 1 71 25-50-15 1 4 3 72 25-50-20 2 4 2 73 25-50-20 2 4 2 74 25-50-30 3 4 1 75 30-50-15 0 4 4 76 30-50-20 2 4 2 78 30-50-30 3 4 1 79 20-40-15 1 4 3 80 20-40-25 2 2 0 81 20-40-25 2 2 0 82 20-40-30 3 3 0 85 25-40-25 2 2 0 85 25-40-25 2 2 0 90 30-40-20 1 4 3 89 30-40-25 2 2 <td></td> <td></td> <td>1</td> <td></td> <td></td>			1		
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94 30-20-40 4 4 0 95 30-40-20 2 4 2 96 20-50-15 2step 0 3 3 97 20-50-15 1step 1 3 2 98 20-50-20 2step 1 1 0 99 40-30-20 1step 2 4 2 100 20-50-20 1step 2 3 1 101 20-50-25 2step 2 3 1 102 20-50-25 1step 2 3 1 103 20-50-30 2step 2 3 1 104 20-50-30 2 3 1 105 25-50-15 2step 0 3 3 106 25-50-20 2step 1 1 0 107 25-50-20 1step 2 3 1 108 25-50-25 2step 2 1 -1	92	20-40-30	3	4	1
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96 20-50-15 2step 0 3 3 97 20-50-15 1step 1 3 2 98 20-50-20 2step 1 1 0 99 40-30-20 1step 2 4 2 100 20-50-20 1step 2 3 1 101 20-50-25 2step 2 2 0 102 20-50-25 1step 2 3 1 103 20-50-30 2step 2 4 2 104 20-50-30 2step 2 3 1 105 25-50-15 2step 0 3 3 106 25-50-20 2step 1 1 0 107 25-50-20 1step 2 3 1 108 25-50-25 2step 2 1 -1	94	30-20-40	4	4	0
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102 20-50-25 1 step 2 3 1 103 20-50-30 2 step 2 4 2 104 20-50-30 2 3 1 105 25-50-15 2 step 0 3 3 106 25-50-20 2 step 1 1 0 107 25-50-20 1 step 2 3 1 108 25-50-25 2 step 2 1 -1	100	20-50-20 1step	2	3	1
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105 25-50-15 2step 0 3 3 106 25-50-20 2step 1 1 0 107 25-50-20 1step 2 3 1 108 25-50-25 2step 2 1 -1	103	20-50-30 2step	2	4	2
106 25-50-20 2step 1 1 0 107 25-50-20 1step 2 3 1 108 25-50-25 2step 2 1 -1	104	20-50-30	2	3	1
106 25-50-20 2step 1 1 0 107 25-50-20 1step 2 3 1 108 25-50-25 2step 2 1 -1	105	25-50-15 2step	0	3	3
108 25-50-25 2step 2 1 -1	106		1	1	0
108 25-50-25 2step 2 1 -1	107	25-50-20 1step	2	3	1
			2		-1
	109		2	4	2

1	Í.		1	
110	25-50-30 2step	2	3	1
111	25-50-30 1step	2	3	1
112	30-50-15	0	3	3
113	30-50-15 1step	1	3	2
114	30-50-20 2step	1	1	0
115	30-50-20	2	4	2
116	30-50-25 2step	2	2	0
117	30-50-25 1step	3	4	1
118	30-50-30 2step	2	2	0
119	30-50-30 1step	2	4	2
120	20m for 50min	1	3	2

Summary of Phase 1

Computers manufactured by Mares, Suunto and Uwatec all produced very similar results. With 118 dives in this first phase and a plethora of profiles and shapes, no-decompression limits or decompression times necessary to complete the dive where always within +/-1 min, at the most, but very rarely, 2 min. One should note the relevance of this finding, given that these three manufacturers cover more than 50% of the worldwide market.

If one were to expand this study to include human trials, the cost and time required to perform each profile to a statistically relevant extent, makes it paramount to focus on few dives with the most significant impact on our learning and understanding. Table 4 summarizes those dives from which human trials should be picked and the reasoning behind the choices.

Dive	Ref.	Description	Profile	Reasoning, notes and comments		
no.	dive	_		-		
1	16	Triangular	40m 1m/min discretized ascent	Effect of ascent rate, trend inversion by		
2	21	Triangular	40m split ascent	RGBM.		
3	19	Triangular	50m 1m/min discretized ascent			
4	22	Triangular	50m split ascent			
5	26	ML forward	50-30-15	Large discrepancy between RGBM and V-		
6	27	ML forward	50-30-20	Planner for 26 and 27, trend inversion in 28,		
7	28	ML forward	50-30-25	validity testing of 2-in-1 in dive 52.		
8	52	ML forward	50-30-15 2step			
9	33	ML forward	40-25-20	33 yields low decompression in both PC		
10	34	ML forward	40-25-15	simulations, 34 yields big discrepancy, 45		
11	45	ML forward	40-25-20 2step	tests the 2-in-1.		
12	54	ML reverse	50-15-35	Test 3-step vs 2-step vs 1-step, for which		
13	60	ML reverse	50-15-35 2step	RGBM (2, 3, 1) and V-Planner (1, 4, 3) don't		
14	63	ML reverse	50-15-35 1step	agree.		
15	75	ML reverse	30-50-15	75 has big discrepancy, 78 has both high, 114		
16	78	ML reverse	30-50-30	both low and 117 both high scores,		
17	114	ML reverse	30-50-20 2step			
18	117	ML reverse	30-50-25 1step			
19	35	ML forward	40-30-20	Effect of changing sequence when times at		
20	93	ML reverse	20-30-40	depth are left unchanged		

Table 4	Relevant	dives	from	Phase	1
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Phase 2

Phase 2 was further broken down into three parts: square dives between 18 and 51 msw corresponding to a PRT of 22, square dives between 18 and 54 msw corresponding to a PRT of 28, and multilevel dives that were a repetition of those considered the most interesting in phase 1 in which the residence time at the various levels was lengthened. For the square

profiles, the depths were chosen to have some difference from one dive to the next, though in some cases the depth was chosen because data existed from human trials for that profile (Ljubkovic et al., 2011; Møllerløkken et al., 2011). For example, the 54 msw for 20 min at a PRT 28 dive was selected instead of a 51 msw dive). Table 5 summarizes the dives performed.

Depth [m]	Dive time [min]	Descriptor
18	62	Square PRT 22
24	40	Square PRT 22
30	30	Square PRT 22
33	26	Square PRT 22
42	18	Square PRT 22
45	16	Square PRT 22
51	13	Square PRT 22
18	100	Square PRT 28
24	70	Square PRT 28
30	49	Square PRT 28
33	42	Square PRT 28
42	29	Square PRT 28
54	20	Square PRT 28
50-30-15		Multilevel
50-30-20		Multilevel
50-30-25		Multilevel
37.7-15		Multilevel
40-25-20		Multilevel
40-25-15		Multilevel
50-15-35		Multilevel
30-50-15		Multilevel
30-50-30		Multilevel
40-30-20		Multilevel
20-30-40		Multilevel

Table	5	Dives	in	Phase	2
1 auto	υ.	DIVUS	111	1 mase	4.

The analysis is performed on graphs depicting the behavior of the computers and the PCbased dive planners for the given profiles. Due to the desire to keep things clear and understandable, we split the results into two groups so to avoid data overload in each plot. In the first group we compare the two PC-based dive planners at the most liberal and most conservative level (RGBM -2, RGBM +2, V-Planner 0 and V-Planner +5), in addition to the Uwatec standard algorithm L0. In the second, we compare all dive computers at their base setting. The choice of the Uwatec L0 as a main reference was due to the fact that, in absence of yoyo dives, workload and cold water effects, it represents the cleanest Haldanean implementation between the three computers that are in strongest agreement (Mares, Suunto, Uwatec).

Square dives

Figures 12 and 13 show the total ascent time as a function of maximum depth calculated for the square dives between 18 and 51 msw for a PRT of 22. We observe that:

RGBM -2 shows the shortest total ascent times, the 18 msw dive for 62 min and also the 24 msw for 40 min are even considered no-decompression dives. From 30 msw onwards the trend is for increasing total ascent time as the depth increases until 45 msw, at which point it seems to stabilize.

- RGBM +2 shows total ascent times always longer than the Uwatec computer, save for the 18 msw dive for 62 min. The trend is for increasing total ascent times as the depth increases up to 42 msw, and a decrease after that.
- V-Planner 0 behaves very similarly to RGBM +2.
- V-Planner +5 shows the longest total ascent times, with an increasing trend for depth up to 33 msw and a decrease thereafter.
- The Uwatec computer shows rather constant total ascent times, in a way indicating that for a pure Haldanean model PRT is possibly a good indicator of severity of the dive.
- The Mares, Suunto and Uwatec computers yield practically the same results.
- The VRX is much more conservative for shallow dives but less so at 33 msw and deeper.
- The Cochran EMC-20H is even more aggressive than RGBM -2.
- The Cochran VVAL 18 changes from being the most liberal to being the most conservative computer as depth increases.

Figures 14 and 15 depict the results for the dives between 18 and 54 msw corresponding to a PRT of 28. We observe that:

- RGBM -2 is very liberal, giving the absolute shortest total ascent times. The 18 msw for 100 min dive is considered a no-decompression dive and the trend is for increasing total ascent times with depth throughout the depth range.
- RGBM +2 is always more liberal than the Uwatec computer, save for the 42 msw dive which yields about the same result for the two. The trend is for increasing total ascent time with depth with a slight dip at 54 msw.
- V-Planner 0 is behaving almost identical to RGBM +2, though the trend of increasing total ascent time with depth is more marked.
- V-Planner +5 is giving the longest total ascent times, with a trend of increasing total ascent times with depth, though this appears to be reaching an asymptotic limit.
- The Uwatec computer is also in this case showing that the results are more or less constant when the PRT is kept constant.
- Mares, Suunto and Uwatec behave the same way, the only discrepancy is at 18 and 24 msw where the Suunto is more conservative yet follows the same trend.
- The VRX is also more conservative on shallow dives but approaches the behavior of the other computers as the depth increases.
- The Cochran EMC-20H is showing approximately half the total ascent time of the Uwatec computer and, unlike the case of PRT 22, is now a bit more conservative than RGBM -2.
- The Cochran VVAL18 requires up to three times the total ascent time of the Uwatec computer.
- The PC-based dive planners, claiming a bubble-type model, yield results that are nonlinear as the depth increases (in light of a constant PRT), whereas the Haldanean implementation seems to behave in a linear way.
- The most conservative implementation of RGBM behaves rather similarly to the most aggressive implementation of VPM.

Multilevel dives

The dives in this sub-phase do not possess a characteristic that allows a clear order between dives, hence the horizontal axis in the graphs simply represents the sequential dive number. Figure 16 shows that:

- RGBM -2 gives the shortest total ascent times, with six of the dives actually being considered no-decompression dives.
- RGBM +2 is always more conservative than the Uwatec computer.
- V-Planner 0 behaves again very similarly to RGBM +2.
- V-Planner 5 is always more conservative than the Uwatec computer.

From Figure 17 we see that, even with the randomness introduced by these profiles, the Mares, Suunto and Uwatec computers yield once again practically the same results. The VRX gives the same result on most dives and is more conservative on others, while the Cochran duo is once again at the two opposite ends of the spectrum.

The Suunto computer displayed an odd behavior in most dives: it did not credit decompression time at a 1:1 ratio even when the decompression stop depth was perfectly matched (dives 217, 219, 223. In the latter it took 63 min for the Suunto to clear 44 min of decompression while at 3.1 msw).

Phase 3

PRT 22

In the first set of plots we present the total ascent time for an 18 msw dive for 62 min following the same dive and following a 42 msw for 18 min dive. Surface intervals were 30, 60, 90 and 120 min. For the sake of illustration, we placed the data for the desaturated dive at six hours. We observe that:

- RGBM +2 yields the same result regardless of whether the first dive is performed to 18 msw or 42 msw.
- Conversely, V-Planner 0 yields different results, giving longer total ascent times when the first dive was the shallow 18 msw instead of the deep 42 msw dive.
- V-Planner +5 shows a smaller difference between the two, but the trend remains the same, i.e., the 18 msw dive is more punishing than the 42 msw.
- The Uwatec computer shows little difference but also gives longer total ascent times when the first dive was the shallow one.
- Mares and Uwatec behave the same way and are hardly affected by the profile of the first dive.
- Suunto has a stronger repetitive dive effect (probably one of the aspects of their version of RGBM, as emphasized by a warning triangle on the display for surface intervals under one hour) which is affected by the shape of the first dive.
- VRX behaves similarly to the Suunto although the desaturated dive is a lot more conservative.
- The Cochran EMC-20H recovers extremely quickly from the repetitive dive effect.
- The VVAL18 on the other hand has very penalizing repetitive dive effect, more so in light of a first dive that is a no decompression dive.

In the second set of plots, we investigate the results for a 42 msw dive for 18 min with surface intervals of 30, 60, 90 and 120 min when the first dive is the same or when it is an 18 msw for 62 min dive. We observe that:

- RGBM -2 yields the lowest total ascent times, rather constant and thus apparently unaffected by surface interval and the shape of the first dive.
- RGBM +2 is more conservative than the Uwatec computer when desaturated, more liberal when it comes to repetitive dive effect. It also does not distinguish between the shape of the initial dive, but surface interval does play a role.

- V-Planner 0 yields total ascent times that are shorter when the first dive is at 42 msw for 18 min and longer total ascent times when the first dive is to 18 msw for 62 min.
- V-Planner 5 yields the longest total ascent time, with not much differentiation due to the shape of the first dive.
- The Cochran EMC-20H is extremely liberal and does not distinguish between the shape of the initial dive.
- The Cochran VVAL-18 shows a very strong repetitive dive effect.
- The VRX, though a bit more conservative on the desaturated dive, shows less repetitive dive effect than the Uwatec computer and shows no dependence on the shape of the first dive.
- The Mares shows no dependence on the shape of the dive profile and is slightly more conservative than the Uwatec computer.
- The Suunto shows the strongest repetitive dive effect (other than VVAL-18) and a slight dependence on the profile shape.

However, aside from the two Cochran products overall the dive computers once again show a rather good agreement. The two computers that claim an RGBM algorithm seem to show more conservative calculations for repetitive dives.

The next graphs show the results for 18, 30 and 42 msw dives, all for a PRT of 22. The increased amount of data makes the plots more difficult to read, but we can see that the PC-based dive planners do not give consistent results with PRT, whereas the Uwatec computer does. When looking at the same data for computers, we see the following:

- The VRX yields the same results for 18 msw and 30 msw, but is more conservative at 42 msw. This is probably due to the use of profile-dependent gradient factors.
- The Suunto shows the opposite trend, being more liberal as the depth increases.
- Mares and Uwatec show some variation, but much smaller.

<u>PRT of 28</u>

In the first set of plots we present the total ascent time for an 18 msw dive for 100 min following the same dive and following a 42 msw for 29 min dive. Surface intervals were one, two and four hours. For the sake of illustration, we place the data for the desaturated dive at 12 hours. We see that the Uwatec computer is now closer to V-Planner 5 than V-Planner 0, though in absolute terms the differences are quite considerable, going for instance from 85 min ascent of the Uwatec computer to the 110 min of V-Planner 5. Interestingly, V-Planner 0 still agrees with RGBM +2, whereas RGBM -2 considers this a no-decompression dive even after a 30-min surface interval.

When compared to the desaturated case, total ascent times can more than double for short surface intervals (1 hour) and be 50% higher for a two-hour surface interval. In the case of the computers, Cochran again owns the two ends of the spectrum, Mares and Uwatec yield similar results, VRX is more conservative and Suunto even more so.

For the 42 msw dive for 29 min when dived after the same dive and after an 18 msw for 100 min dive, the behavior is repeated, though what is immediately obvious is that the shape of the first dive plays much less of a role, and the same is true for PC-based dive planners and for computers.

When comparing 18 msw, 30 msw and 42 msw dives repeated after the same dive, the first striking evidence is that RGBM loses any recollection of a prior dive at both extremes after a

surface interval of three hours. As always, RGBM -2 is the most liberal, V-Planner 0 behaves similar at times very similarly to RGBM +2 and V-Planner 5 is the most conservative. The Uwatec computer once again falls somewhere in between.

Among the computers, the Mares and the Uwatec once again yield remarkably similar results, more so considering that we are in the range of almost 100 min of total ascent time. The VRX is mostly more conservative whereas the Suunto goes out of range (indicating simply more than 99 min of total ascent time). The desaturated total ascent times of the Suunto, however, are very much in line with those of Mares and Uwatec for 30 and 42 msw and much longer at 18 msw.

CONCLUSIONS

There is a very wide offering of dive computers on the market today. We sampled a representative portion and found that whereas some computers are more conservative and some are more liberal, there are several that are in astonishing agreement throughout all tested profiles, especially when it comes to the first dive of a series (non-repetitive dive). Furthermore, the agreement is among the three brands that cover well over 50% of the worldwide market. Most of these dives, however, are very far from stressing the underlying models, so we cannot reach any conclusion as to the actual conservatism, or lack thereof, in any of these computers.

When one considers repetitive dives with short surface intervals (one hour or less), there is less agreement between the various computers, even among the three that otherwise agreed very extensively. One concludes that, whereas a relatively standard Haldanean implementation is at the core of these computers, different types of mathematical manipulations are employed to account for residual nitrogen. This is indicative that the true impact of residual nitrogen is not fully understood. Indeed, repetitive diving has not been researched and validated to an extent that would allow a firm footing in its characterization, in part due to the complexity of approaching a variety of dive profiles combined with a variety of surface intervals, and in part due to the increased complexity of the physiology involved (endothelial damage, pre-existing bubble population at the start of the dive, etc.)

It is worth noting that none of the dive computer manufacturers provide any details as to the inner workings of their models and none have ever performed any substantial validation. It is beyond their means and field of expertise. Rather, they have built upon the experience, published or not, of others (Bühlmann, 1995; Wienke, 2001). The only documentation available comes from the U.S. Navy for the VVAL-18 implemented in the Cochran NAVY AIR III (Doolette et al., 2012). This model was extensively validated, probably more so than any other. Interestingly enough, the VVAL-18 has the most liberal behavior in no-decompression diving, but quickly becomes the most conservative when decompression stops are required. This may indicate that the range of applicability of all other computers on the market is narrower than assumed. The non-linear behavior of the PC-based dive planners for high PRT dives points in the same direction, though until tests are performed, this remains speculation.

The range of applicability may indeed be the key question when assessing dive computers. Since dive tables are of limited range, one cannot extrapolate beyond them. So as long as the tabulated dives have been validated (or at least tested with some measured outcome), using tables should produce a safe or at least known outcome. A dive computer on the other hand continues to calculate and may be well out of its area of competence before an out-of-range message, if any, is displayed.

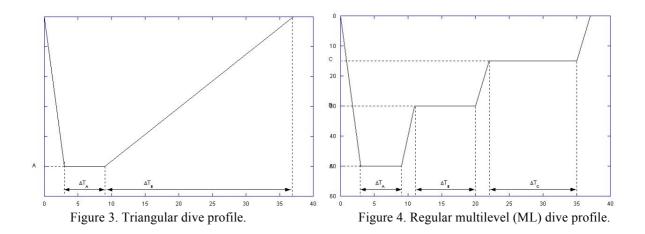
The final conclusion is that we can only comment on the relative conservatism of dive computers and PC-based dive planners. To go beyond this, one would need to devise a test plan with human trials, possibly drawing from this study when trying to identify which profiles to test.

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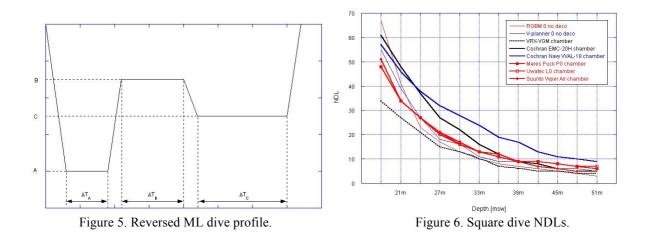
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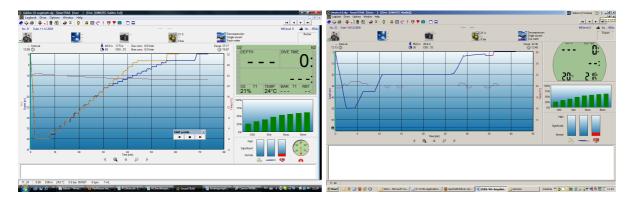
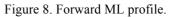


Figure 7. Standard/split ascent rate in triangular dive profile.



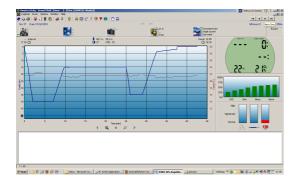


Figure 9. Reverse ML dive, shallowest level in middle.

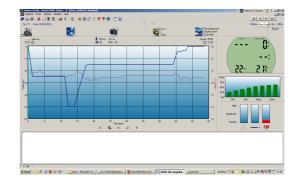


Figure 10. Reverse ML dive, deepest level in middle.

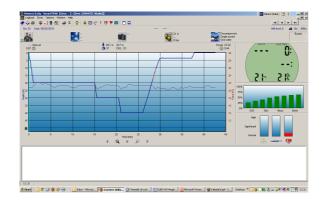


Figure 11. Reverse ML dive with deepest level at the end.

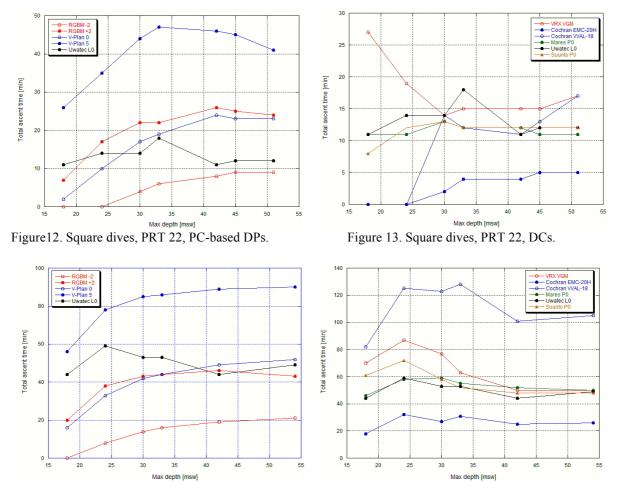
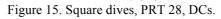
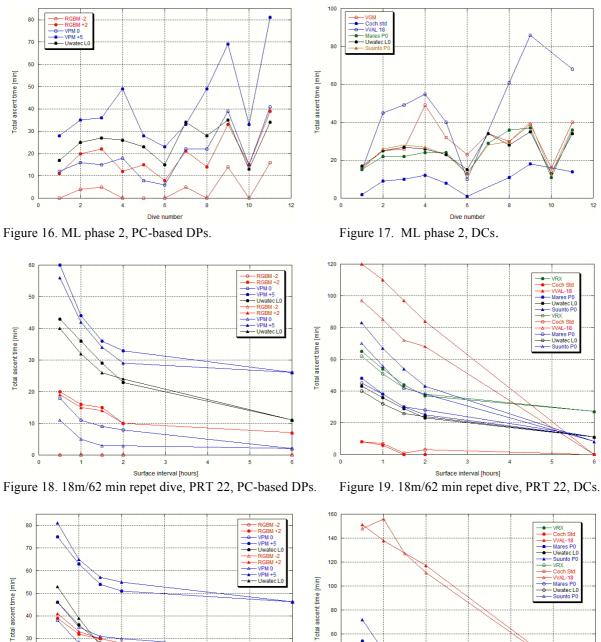


Figure 14. Square dives, PRT 28, PC-based DPs.





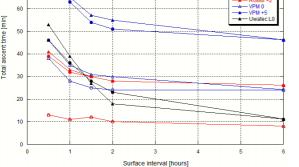
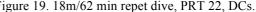
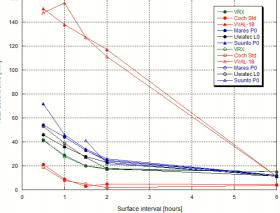
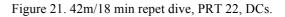


Figure 20. 42m/18min repet dive, PRT 22, PC-based DPs.



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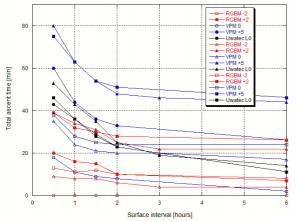


Figure 22. PRT 22 square dives to 18, 30 and 42m, PC-based DPs.

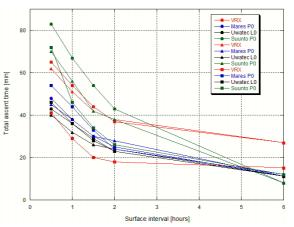


Figure 23. PRT 22 square dives to 18, 30, and 42m, DCs.

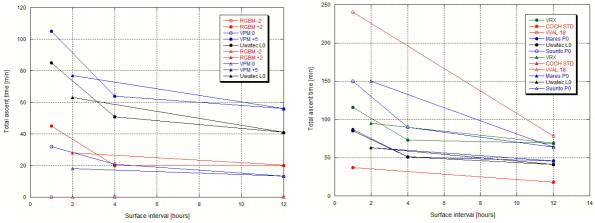


Figure 24. 18m/100 min repet dive, PRT 28, PC-based DPs. Figure 25. 18m/100 min repet dive, PRT 28, DCs

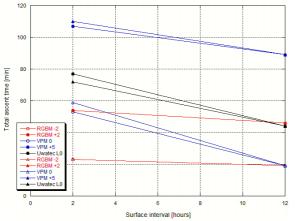


Figure 26. 42m/29 min repet dive, PRT 28, PC-based DPs.

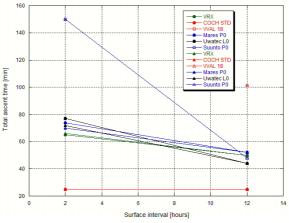


Figure 27. 42m/29 min repet dive, PRT 28, DCs.

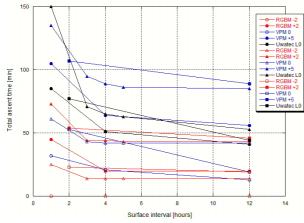


Figure 28. PRT 28, square dives to 18, 30 and 42m, PC-based DPs.

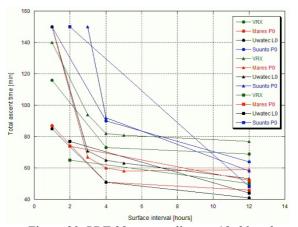


Figure 29. PRT 28, square dives to 18, 30 and 42m, DCs.

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- M. Gennser: Were the manned validation dives all square dives?
- D. Doolette: Yes, we use very traditional table development.
- M. Egi: We recently analyzed the DAN accident database, and found out that statistically we had four types of decompression sickness (DCS). You have two different models and two different probability functions, one is for central nervous system DCS and the other one is for type I DCS.
- D. Doolette: The probabilistic models do not distinguish between the types of DCS. The CNS model was a logistic model, looking at the 1600 no-stop dives that we had in our database. We do not believe that we have enough data to try and tease out the categories of DCS. We have about 10,000 laboratory dives that have only around a 2% incidence of DCS, which is too low to categorize. People at Duke are trying to do that at the moment and we will be very interested to see if they can, as it will be invaluable work.
- K. Huggins: Is the desktop model still just for Navy use?
- D. Doolette: It is at the moment. You would have to speak to the Supervisor of Diving about whether it will be available outside of the Navy.
- W. Gerth: There is no such thing as a right or a wrong way to decompress. There are an infinite number of ways of decompressing from any dive safely, however you define that, or unsafely, however you define that. There is no correct or incorrect way. All you are talking about is comparing one schedule against another; that first schedule being prescribed by one algorithm or dive computer and the other one being prescribed by another algorithm or dive computer. Is the risk of DCS or whatever you are trying to prevent from those two prescriptions different? We should not spread the fallacy that comes about if somebody has a family of computers and they give you a disparate set of prescriptions for a given dive that one has to be right and all the rest are wrong. That is incorrect. Regarding the Cochran VVal18 computer, one of the things that distinguishes the Thalmann algorithm from the Bühlmann algorithm is that it does not assume that the gas uptake kinetics are the same as the gas elimination kinetics; it is called the EL algorithm. You uptake a gas exponentially and if you are offgasing, you have a sufficient supersaturation that triggers a so-called linear offgasing. You turn from exponential to linear rates and wash out slower. That is why you saw a difference between the 10-foot stop, where the guys go to the linear offgasing phase in comparison to when they stayed at the 20-foot stop, where they stayed exponential and washed out faster. It is all well documented in reports, and we have particularly talked about the situation when you apply that algorithm to air dives, as I think that is what you were doing. What we recommended was that you use a 20foot last stop on the tables, but in the Cochran computers, we allowed a 10-foot final stop, so that is why you saw the difference.
- P. Buzzacott: It is a very interesting procedure comparing the dive computers across a range of different profiles that are quite common in recreational diving: multi-level, repetitive, reverse etc. You mentioned that you had the potential to run these tests at altitude. In the results that you presented, you ranked the computers in order of conservatism so that we could see clearly which computers were the most liberal for any given profile. Did you do that at altitude?

- S. Angelini: No, I mentioned it to describe the portability of the system.
- M. Egi: Altitude diving produces huge differences between the algorithms, because of discrepancies in the way they extrapolate to altitude. One will say five minutes and one will say 25 minutes. This discrepancy exists even within one algorithm. For example, Bühlmann has changed the algorithm so much from its initial inception to produce a five-fold difference between it and current versions. This is a good way to test the algorithms, as at the end of the day, the models are dependent on differential equations, which are dependent on initial conditions. If you go to altitude and change the initial conditions you will see which one is right.
- A. Brubakk: One of the good points made here is that once you are inside the envelope, everything behaves in the same way. We know quite a bit about that from human testing with a large number of professional dives, around 1000, carried out in the North Sea. Analysis showed that the most important factor in the risk of decompression sickness was the relationship between depth and time (Hennessy equation). That is the only thing that they found definitively. They used something like 25 different models for decompression. We found a similar result on a much smaller scale study in Norway on air dives. On dives that were deeper than 30 meters and longer than 30 minutes they had a significantly increased risk of DCS. This is important for commercial fish farm divers in Norway. Water temperatures are rising and the salmon do not like that and go deeper. The fish traps are now very deep, on the order of 60 meters, and we have a limit for air diving in Norway of 50 meters, so what do you do? All of the salmon traps have to be tested manually to make sure that they are problem free, so we are going into an area where we have very little experience. We know from previously collected data using DCS as an endpoint that we will probably get a significant increase in clinical symptoms. Another point concerns a study that I did 10 years ago showing that people lie. I do not think Navy divers lie as much as other divers, but other professional divers tend to not tell people what they have done and what has happened to them. We produced a questionnaire with specific questions on the symptoms that these divers had during their diving career, and over 70 percent of these experienced offshore divers had experienced quite serious symptoms without telling anybody. This makes it very difficult to predict what is going to happen.
- M. Lang: That is one of the drawbacks of the empirical accumulation of experience, because if you have a penalty as a commercial diver, for example, you have to stop diving for a period of time if you report a symptom of DCS, you are less likely to make a report and so the data collected will be skewed (under reported).
- C. Balestra: We had this kind of problem with PFO issues. In France they could not declare they had a PFO and still continue to dive professionally.
- C. Gutvik: I want to echo W. Gerth's point that there is no right or wrong decompression schedule. It is important to distinguish between the model itself or the model fundamentals and the profile calculations. It is possible to fit the wrong model fundamentals to a set of data, and so produce the wrong schedule for the job.
- S. Angelini: My interest is in getting people to buy computers, to come back happy and then perhaps at some point come back and buy another one. The only thing that matters to me is whether we have a computer that does that, and how it gets there is less important.
- W. Gerth: P. Weathersby said what Christian said, that model fitting success does not imply model truth.

- S. Angelini: Absolutely. Please note that I am taking out the one line about spread awareness from my presentation based on W. Gerth's comments.
- M. Egi: The Suunto Zoop computers that you use have the possibility of converting the logs to DL7 format that DAN uses, a quite common format.
- M. Lang: We considered the Divers Alert Network, National Science Foundation and National Oceanic and Atmospheric Administration programs. After over six months of trial and error, we decided to throw them out and start with a blank sheet. These programs were too clunky and did not meet our needs. We also spoke with Keith Gault at NEDU where they are developing a dive computer management program but I do not believe it is ready for implementation yet.
- W. Gerth: NEDU is nowhere near as far along with that program as you are. We have issues with the government in that we cannot just connect any computer to our Internet system, which is causing us a lot of trouble. The bottom line is that you are much farther ahead than we are. Kudos to you for getting to the point you are at!
- P. Buzzacott: How many dives have you collected in your database so far?
- M. Lang: In January 2010, we mandated that Smithsonian-issued Zoop computers be used to monitor decompression status by all divers and be downloaded into the database, there are approximately 7,000 dives. Since 1990, we have around 82,000 dives total recorded in our database.
- P. Buzacott: With all of these dives, presumably from lots of different profiles, do you have plans to use the data to look at occupational risk assessment?
- M. Lang: We have requirements as an Organizational Member program of the American Academy of Underwater Sciences to report our annual dive accident and exposure records and also any pressure-related incidents (or lost days at work) to the Occupational Safety and Health Administration. But with regards to managing decompression sickness (DCS) hits, if you don't have any, then that is hard to do!
- W. Gerth: I want to clarify that statement, because it is true that you have no DCS, but if you have no hits, then the worth of the data is easily misunderstood. If you have 10,000 dives with no DCS, it is not that you have not learned anything at all, rather, you have learned that those 10,000 dives are all safe! But you have not learned anything about how far away you are from DCS.
- C. Gutvik: You have learned something about the safety of the procedure, but you cannot calibrate the behavior of the model.
- W. Gerth: Roughly between 10 and 30 DCS hits are needed for each parameter you are trying to estimate. If your model incorporates 10 parameters you need at least 100 hits in that database to start to get confidence about those parameters. This is why I marvel how people can claim to know how temperature, dehydration, diet and everything else affects DCS. They need to show me the data where they have that much information available on that many dives with DCS for each of those different factors.
- D. Doolette: Regarding VGE as an endpoint I was really interested to see your analysis of the study that Gerth, Gault and I did on deep stops and particularly the work you did on 20 dives where you said you could have got a result comparing two schedules with VGE. That seems to be where using VGE is quite useful, in comparing different procedures. However, that is often not what we are doing and certainly not what we are doing when we are trying to validate dive computers where we are trying to validate individual schedules. In that respect, I am interested that in using Bayesian statistics as you suggest, you would have rejected our shallow stops schedule under your Norwegian requirements, as the credible interval was 3% to 6% according to

your estimates. However, it is a patently acceptable schedule where we did 200 dives and we got three DCS hits. Two guys had 'one out of ten' grade knee pain and one had slightly more serious symptoms. On that schedule, we had around 1% incidence of DCS, mainly of the kind that you would not worry about. Yet using VGE as an endpoint, you would have had to exclude that dive. To put it into perspective, it has about triple the decompression time of the Norwegian tables for that dive, so where are we going if we are going to try and validate using VGE as an endpoint? Your divers are not going to make that extra \$2000 a day, they are going to be losing that amount!

- C. Gutvik: You are right. I wanted to make a point on how the VGE method worked and how it is more sensitive. I would not use Bayesian statistics to reject dive computers, exactly for the reason you described, as it is not very accurate with a low percentage of DCS hits. Rather, the sensitivity of VGE can be exploited to make model-based calibrations or calculation.
- D. Doolette: You would still find the same thing, that you will drive yourself towards very conservative schedules, which may not be acceptable to an occupational diving group.
- W. Gerth: Another way of saying the same thing is that David Sawatsky's data is the gold standard compilation of VGE and DCS information, and we would all agree with that. But if you use that data and take 100 divers from it, all who have grade IV VGE, you can only predict that 12% of them would have bends. The highest incidence of DCS that Sawatzky's data can show is 12%, so it is likely to underestimate DCS incidence with very high grade VGE and similarly, probably overestimate (just like our probabilistic models do), the incidence of very low risk DCS. I really need to know what the higher risk is for certain situations and not be limited at 12%, as that is probably not a true indicator and is limited by the data set. The thing that Olav Eftedal's Bayesian method is good at is comparing two schedules; otherwise it is not useful in the way that you are intimating.
- K. Huggins: With your download software, do you have the ability to look at what percent loading of the model occurred?
- M. Lang: Not currently, but I cannot see why it could not be added on as a functionality.
- M. Swiergosz: You ended up writing your own software. In your experience with other dive computers do they tend to have proprietary output that is almost useless? Should it not be standardized more?
- M. Lang: K. Huggins showed a great slide with perhaps 38 different download programs for computers that have as many different attachments! At the Dive Computer Workshop in 1988 we recommended that standardization was needed. Ralph Osterhout (former CEO of Tekna and Head of DEMA) made the argument that the competitive nature of selling dive computers to the public had more to do with the user interface and how the information was displayed, but that the algorithm, whatever was ultimately decided upon, should be the same for all computers but it's still a mess!
- W. Gerth: When I was working with Richard Vann at DAN we got most of the dive computer manufacturers to record internally the algorithmic memory format for recording the depth, time and gas used in different profiles, a fixed format that can also record extra fields for each dive, but the problem occurs in the format that the computer downloads the data. It is highly proprietary and the problem is the companies will not release the dynamic link libraries (DLL) to let you download.
- A. Sieber: There is now a program that you can use to download data from a range of manufacturers' computers.
- W. Gerth: Does it handle Cochran's format?

- K. Huggins: It does, I have looked at this program that but not in great depth. The main problem is that you have to have a suitable cable. Most computer software is available for free from the Internet, but the main problem is getting the link from the computer to the PC to download the information.
- C. Balestra: That is exactly what the Italian DAN software does, it is available on the net for free.
- M. Lang: Regarding the discharge rates of the batteries, we tested a number of different dive computers for ice diving. The ones that we use are all gel encased so it takes some time for them to get really cold. We found that you go in with a fully charged battery on a computer, but the discharge rate is precipitous, going from being fully charged to discharged in no time at all.
- S. Angelini: Be careful though, as not all batteries are the same.
- A. Sieber: It all depends on the battery type, Ni-Cd or Li-Ion, etc.
- J. Wendling: How do you find the LCD displays perform in polar diving, as sometimes they just seem to shut off?
- M. Lang: Sometimes you get a bit of a flicker or a wave going through the displays, but other than that we have not had any problems. It seems it is a battery problem, no longer a display problem as in the past. We dive mostly out of heated dive huts, so the computers are not exposed to the ambient air temperature of -40°C, and the water temperature is only -1.8 °C, so they don't really get that cold and they work.
- W. Gerth: This is another example of having to define your requirements, i.e., the range of temperatures that this computer has to work within, in addition to its other requirements.
- A. Sieber: You are using the Suunto Zoop computers, but if I remember correctly I thought that the computers were not to be used for commercial diving and scientific diving?
- M. Lang: We have used computers for scientific diving since 1990, but I am not sure about commercial diving. I suppose as a recording function in surface-supplied commercial diving computers would work, but everything is controlled from the surface, so why would you need a dive computer anyway? Operationally, there does not appear to be a value, given that the diver is talking to the surface and everything is controlled from topside, gas switches and deco stops, so why would you need one?
- A. Sieber: They just exclude everything apart from recreational diving.
- A. Brubakk: One point about diving, particularly in Norway, is that for fish farming for example, the computers give you an enormous advantage.
- M. Lang: That is not surface-supplied diving though, is it?
- A. Brubakk: No, but even if it was, the point is that the computer is on your arm and it can use the same algorithm as topside. To use a computer means that you do not have to perform square dives where you have to go down, stay for a number of minutes, come back and then go back again. Square dives do not allow you to do the type of diving that needs to be done for example in fish farming, where you want to go gradually up the net as you check it. If you use a dive computer you can do this; it gives you a lot more dive time and that is the obvious benefit. There was a discussion as to why that was not allowed. Without the use of a computer, the diver has to do many more square dives and they are probably more risky than triangular dives.
- W. Gerth: As part of the U.S. Navy's dive computer program we do have exactly the kind of tool that you were talking about for supporting surface-supplied diving, we call it the topside decompression monitor (TDM). It is inter-operable with our NDCs, so you can do a surface-supplied dive controlled from the surface. The TDM runs on a laptop at the surface and the advantage is that in running it on a PC, you can see different

options for decompression in real time. It gives you all three different schedules available, so you can make decisions on the fly in the surface-supplied situation.

- M. Lang: Does your surface-supplied divers wear a unit on their arm?
- W. Gerth: No. There is a transducer on the diver. Anyway, A. Brubakk is absolutely right, the computer runs the same algorithm, but in running the TDM on the laptop topside we are not space constrained or CPU constrained.

The Use of Venous Gas Emboli to Validate Dive Computers

S. Lesley Blogg SLB Consulting c/o The Barn, Winton, Cumbria, CA17 4HL, UNITED KINGDOM

Andreas Møllerløkken

Norwegian University of Science and Technology Akutten og Hjerte-lunge-senteret, NO-7491 Trondheim, NORWAY

Many decompression models use decompression sickness (DCS) as a measurable endpoint, but often it is not practical to commit the time or money to the large number of dives necessary for validation, nor is it always ethical to provoke DCS. Venous gas emboli (VGE) nearly always accompany DCS, although their presence does not have a direct relationship with clinical symptoms. However, VGE are an accepted indicator of the level of decompression stress that a diver is subject to. There are benefits in using VGE as a predictor for decompression stress. Unlike DCS, which may be misdiagnosed or underreported, the presence of bubbles is an objective measure. As VGE load may be graded, a smaller sample size can be used, as opposed to the endpoint of DCS or no-DCS. Further, the ethical limits of human studies do not have to be reached, as DCS is not the measurable endpoint. This increased sensitivity of measuring VGE allows us to use statistical methods such as the Bayesian approach, a method that employs a priori information, i.e., takes a known outcome sample and combines it with new observations, to produce a risk estimate for DCS. However, the number of dive profiles needed for validation of a dive computer (DC) is infinite. Therefore, a more simple approach is to tailor test to an envelope of the most common profiles used by the target diving population. This method may be used in order to find the optimal DC model for adoption. DCs can be tested against one another, and the DC producing the lowest decompression stress (in terms of VGE produced), then chosen. The DC could then be further validated across a range of other profiles using predictive modeling.

INTRODUCTION

Although the world-wide incidence of decompression sickness (DCS) is remarkably low at around 0.03% in the recreational diving community (Pollock et al., 2008) and the risk of DCS in U.S. commercial divers was approximately 0.1% (Brubakk et al., 1993), there still remains a duty of care for employers to ensure that the risk of DCS remains at the lowest possible level For the Norwegian Labour Inspection Authority, this means that "the use of dive computers (DCs) should be as safe, or safer, than use of the Norwegian Tables". To validate DCs for commercial inshore diving use, we are guided by the methods of testing and validating dive tables and algorithms.

There are numerous decompression models that are used to attempt to determine or predict the outcome of dive profiles, using DCS as a measurable endpoint. The U.S. Navy has

rigorously tested and verified their tables with manned dives in this way (Doolette, et al., 2012). They used the outcomes to derive a probability of DCS that is contained in the Thalmann algorithm that drives the U.S. Navy DC (Thalmann et al., 1980; Thalmann, 1984). Testing tables or algorithms in this way is a very lengthy and expensive process, requiring many hundreds of dives. Therefore, it is often not realistic to carry out such testing and it may also be seen as unethical to push human subjects to the point at which DCS occurs.

RELATIONSHIP OF VGE TO DCS

The presence of a large load of venous gas emboli (VGE) in the body following decompression, as investigated with ultrasound techniques, is recognized to be associated with an increased risk of DCS, with a large VGE load increasing the risk (Spencer and Johanson, 1974). In extensive studies carried out by Sawatzky (1991) of 3234 human exposures to either air or heliox dives, in one case only was DCS not accompanied by the presence of VGE in either the pre-cordial or sub-clavian sites.

However, a close relationship between the number or load of VGE present and DCS cannot be derived. One might expect that the highest measurable bubble loads would guarantee the occurrence of DCS, but this is not the case. The Sawatzky (1991) data, which reports fairly conservative profiles, shows an incidence rate of 11% DCS associated with a relatively high, but still sub-maximal Kisman Masurel (KM) grade of III. Only three measurements reaching the highest grades on the scale (KM IV) were noted and none of these were associated with DCS. Herein lies the problem: in order to obtain grades at the highest level to determine the true relationship between the maximal bubbles loads and DCS, the test profiles need to be far more provocative.

When profiles do push towards limits of safety, then a greater incidence of DCS is seen with higher grades. In two such studies (Spencer and Johanson, 1974; Neuman et al., 1976) a DCS incidence rate of 80% and 32% respectively was associated with the highest grade of KM IV. Therefore, although the relationship between bubble grade and DCS occurrence cannot be said to be completely defined, it is clear that there is an increased risk of DCS with increasing bubble load. Although the occurrence of VGE might be a relatively poor predictor of DCS, the absence of VGE is a good indicator of decompression safety, and can be used to estimate a level of decompression stress.

PHYSIOLOGICAL ENDPOINTS

Using DCS as an endpoint might seem straightforward, but in reality, this is not always the case. To quote Ed Thalmann (1989) on the validation of decompression tables, "Careful clinical observation is the best method of evaluating decompression table adequacy as long as all symptoms, no matter how minor or trivial, are recorded and evaluated first hand by trained and experienced medical personnel. Minor symptoms such as fatigue or transient niggles must be considered as they probably indicate a higher level of decompression stress than completely asymptomatic tables". It is very likely that in past and present studies DCS has been underreported and misdiagnosed, given that divers often do not report symptoms. In light of this observation, the presence of VGE is a far more objective measure of decompression stress, provided that well-trained operators record ultrasound data.

Most importantly, using VGE as a physiological measure of decompression stress meets our modern ethical constraints. Gaining approval for human experimental diving that uses DCS

as an endpoint is increasingly difficult and ethically questionable. Although it cannot be guaranteed that in the process of testing even conservative profiles subjects will not present with DCS, it is far preferable that a measure be used whereby DCS does not have to be provoked to get a meaningful result.

In addition, a smaller sample size for testing may be used when measuring VGE, as the range of grades available by which to rate the bubble load gives a greater level of sensitivity. In contrast, the binomial nature of a DCS or no-DCS endpoints means that a far greater number of comparisons have to be made. For example, more than 300 exposures with no DCS are needed to confirm an incidence below 1% with a 95% confidence interval (Eftedal et al., 2007), while if only one DCS 'hit' occurs, then the figure will rise to more than 500 dives. It should be noted that even in the simplest terms, this would only take care of one depth/time combination. In reality, multiple combinations and types of profile would need to be tested in order to validate a model/algorithm/DC (Angelini, 2012).

It is apparent that a deterministic approach to validating dive computers is not feasible. Instead, an approach to test against a stress predictor model, such as Copernicus, may be helpful, and experimental efforts should be focused on the scientific consolidation of such a model (Gutvik, 2011). The use of VGE data is necessary for exciting the model through a wide diversity of exposures, with historical datasets describing DCS from a probabilistic view being of great use. The high sensitivity of VGE can most likely be exploited in a probabilistic model to better effect than DCS occurrence. This is the reasoning behind the Copernicus model that, instead of predicting the risk of DCS, predicts the amount of VGE produced after any dive exposure. The problem is viewed from a physiological approach and a model designed to predict VGE load.

AN ACCEPTABLE LEVEL OF RISK: STATISTICAL CONSIDERATIONS

Consideration has to be made as to what the acceptable level of risk of DCS is. If the physiological endpoint to be used is not DCS but VGE load (i.e., decompression stress), then despite the highly non-linear relationship between VGE and risk of DCS, a decision still has to be made as to where to draw the line. Defence Research and Development Canada (formerly DCIEM) has selected a limit of KM grade II or greater in 50% of subjects to discriminate between stressful and acceptable procedures (Nishi and Eatock, 1989). Eftedal et al. (2007) have previously suggested that by designing decompression procedures so that less than 50% of the subjects have bubble scores of III and IV, the DCS risk should be less than 5%. Pollock (2008) suggested that "VGE data should be interpreted conservatively, with an analytical focus on the most meaningful Doppler grades – III or higher – on standard scales". However, there is a danger that in defining VGE limits for decompression profiles, too high a level of conservatism may be reached, and meaningful diving will not be able to proceed. This limitation must be considered and weighted up when attempting to use VGE to validate DCs, particularly as the occurrence of DCS across dive populations, and therefore the projected risk to divers, is statistically low.

The higher sensitivity of VGE measurement versus the DCS endpoint may be exploited by using statistical techniques such as the Bayesian method to validate profiles. This technique uses *a priori* information, i.e., takes a known outcome sample (for example the Sawatzky data) and combines it with new observations, reducing the necessary sample size. The higher sensitivity of VGE data also produces narrower confidence intervals than looking exclusively for DCS. It should be noted that because the sample size is considerably reduced when

designing trials using this methodology (for example, n < 50) it is unlikely that there would be any incidence of DCS, so it would not be possible to use DCS as an endpoint in studies deigned in this way.

However, even if the number of dives that have to be made are reduced substantially by the use of techniques like the Bayesian method during the validation process, a huge amount would still have to be made to encompass all of the combinations of profiles and dive types that a DC could compute (Angelini, 2012). Therefore, a more simple methodology would be to use the VGE approach, but test only profiles that are commonly used by the target population. This approach reduces the complexity of the validation process to a manageable process in terms of time and economics

CONCLUSION

Once the target population has identified their need for a dive computer, then ideally their most commonly used dive profiles could be used to test different models against one another to find the optimal DC for the populations' use. It is necessary to test individual DC models, because each is driven by a specific, but usually unidentifiable, algorithm. Although this might not be ideal, it is a cost-effective approach and with objective endpoints, an eminently testable approach to take. This method obviously could not be employed if using DCS as an endpoint. Using VGE measurement, the algorithms in each DC for each specific profile can be rated for decompression stress, then paired comparisons can be made and the optimal DC (producing the lowest amount of VGE across the test population over selected profiles) chosen for use in that specific population.

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Dive Computer Use in Recreational Diving: Insights from the DAN-DSL Database

Costantino Balestra

Haute Ecole Paul Henri Spaak Environmental and Occupational Physiology Laboratory 91 Avenue C. Schaller 1160 Auderghem, BELGIUM

Data from the DAN Europe Diving Safety Laboratory (DSL) suggest that approximately 95% of recreational diving is carried out today using a dive computer. The most widely dived computers/algorithms, irrespective of brand, use the Bühlmann ZHL-16 or the Wienke RGBM algorithm, with roughly a 50/50 distribution across the DSL population. The vast majority of the 167 recorded decompression sickness (DCS) cases occurred without any significant violation of the respective algorithm's limits, i.e., most occurred while using gradient factors that were well below the maximum allowed by the algorithm. The DSL database and field research also show that many other physiological variables may be involved in the pathogenesis of DCS, even within computed "safe" limits, causing a variable individual response despite similar inert gas supersaturation levels. We conclude that the current computer validation modalities, although important and useful as a basic benchmark, still allow a probability of DCS beyond ideal levels in a recreational setting. In order to limit unexpected DCS a more aggressive "biological" approach is recommended that is able to identify and then control the most significant physiological variables involved in the pathogenesis of DCS, in addition to the inert gas supersaturation levels.

INTRODUCTION

Recreational diving is mostly done with the use of dive computers (DCs) that divers tend to trust with absolute "faith." Not many individuals realize that the validation protocols underlying the marketing of such computers and the algorithms that they use are far from perfect. It is apparent that the validation of DCs is both an expensive and lengthy process, and one that most manufacturers cannot afford to carry out to the necessary level. In most cases manufacturers do not have sufficient data to make the claim that their product functions to a certain level of risk or degree of risk reduction, which is an important issue for the end user, the diver. Even the most reliable DCs still accept a probability of DCS ranging from 2 to 5%, with a probability of neurological DCS in the range of 0.2 - 0.5%. (Divers Alert Network, 2000; 2001; Egi and Gurmen, 2000; Andric et al., 2003; Wienke, 2010).

It seems that divers are generally unaware of these facts, believing that their dive computer is infallible and that accidents will not happen if they follow the information given by their computer. However, those who work in the diving medical field know that this is not the case and that accidents do happen, albeit rarely.

Data gathering is essential to draw useful safety limit conclusions, especially now that technology allows us to readily do so. Scuba diving data collection in the field has also been

carried out to some extent by the commercial, scientific, and military diving communities. The DAN DSL database contains records of 39,944 dives from 15,908 dive events, with data from DAN Europe and America in the process of being merged. Most of these dives were made using DCs implementing the Bühlmann ZHL-16 (compartmental model; 44%) or the Wienke RGBM (bubble model; 47%) algorithms. The remaining 9% of divers used their computer in 'gauge' mode, or referred to other decompression software or tables. A total of 181 cases of DCS were reported within this database (0.45% rate of incidence).

ALGORITHM CONSERVATISM AND ASSESSMENT OF SAFETY

When assessing the causes of these 181 cases of DCS, it is important to investigate how the individual divers used their computers, i.e., how far was the algorithm pushed towards the limits of safety?

Gradient factors can be used by divers to choose how fast and close to let the tissue compartments approach the 'M' value (e.g., the Bühlmann ZHL-16 algorithm). The M-value is a 'maximum pressure value' applicable for the respective depth and tissue compartment which, if exceeded, Bühlmann (2002) believed would greatly increase the risk of DCS. If focusing on the computed gradient factor for a hypothetical tissue with a half time of 12.5 minutes, it can be observed that of the 14,000 (of the recorded 39,944) dives analyzed, 95% were well below 80% of the maximum allowed supersaturation, with only a minor portion getting close to the 100% maximum value.

However, exposure factors (EF), or critical volumes, as derived by Hennessy and Hempleman (1977), can be used similarly to assess the risk of no-decompression dives using dissolved gas and safe ascent pressure as measures. If the value for PRT (Pressure Root Time is an indicator of the severity of the dive exposure where P = pressure in bar, T = dive time in minutes) exceeds 25, then the risk of DCS incidence is believed to sharply increase. Dives should therefore be planned to remain below this level, a strategy that has been implemented by the U.K. Health and Safety Executive. When analyzing the calculated EF of dives in the DAN database, it was observed that 60% of the dives were within an EF of 20, another 18% reached an EF of 25, and surprisingly, 32% of dives produced an EF greater than 25.

A further analysis of the 14,000 dives from the DAN DSL database showed that 99.9% were performed without violation of the computer algorithm, and less than 1% had M-values marginally above 100% for only the fastest tissue, yet the proportion of dives with an EF exceeding 25 was unusually high at 32%. However, the incidence of DCS was less than 0.5%, indicating that both the algorithms and the EF calculations are not capable of accurately predicting DCS risk.

DCS INCIDENCE AND TYPE OF DIVE COMPUTER USED

The DSL collection system was initially only compatible with some compartmental model dive computers, only allowing a direct comparison of DCS incidence between compartmental and bubble models with some level of bias. However, a short while after the DAN dive data collection program was implemented, collection from virtually all types of dive computers on the market was made possible and direct comparison between both level of use and DCS incidence with compartmental and bubble models began. From a sample of 10,738 dives, dived with Bühlmann ZHL-16 or Wienke RGBM algorithms, 165 DCS cases were recorded, almost equally distributed between the two (1.35% vs. 1.75%).

This incidence is higher than the overall incidence of DCS from the entire sample of dives we analyzed (0.45%), but this could be due to the relatively small sample size and may equilibrate towards more "normal" percentages with the increase of the number of recorded dives. However, it is interesting to note that only 10% of these DCS cases approached the maximum allowed inert gas supersaturation according to the selected algorithm (between 90% and 99% of the M-value) while another 10% occurred with supersaturation levels between 80% and 90% of the M-value. Unexpectedly, 80% of these DCS cases occurred with supersaturation levels lower than 80% of the maximum allowed by the specific algorithm, with an average supersaturation level of 75% of the M-value (median = 0.8 (80%); SD = 0.25).

This surprising finding suggests that the level of supersaturation upon decompression alone may not be responsible for the occurrence of DCS. Instead, other contributing factors should be considered when evaluating risk and validating optimal decompression procedures. The DAN Europe DSL's goal is to identify the non-mathematical, physiological variables associated with decompression that can allow for better recreational diving decompression safety.

PHYSIOLOGICAL MEASUREMENTS: VENOUS GAS EMBOLI (VGE)

Although VGE may be detected in divers in the absence of DCS, it is established that the higher the venous bubble load in the body, the more likely DCS is to occur (Francis and Mitchell, 2003). Therefore, measurement of VGE can be used in place of DCS as endpoint to aid in validation of decompression safety.

DAN has performed a total of 1,181 Doppler measurement analyses have to date and a further 2,100 await evaluation. The data distribution shows that the mean depth of the dives performed is roughly 28.5 m (min. 5 m; max. 192 m) and as noted previously, 95% of the documented dives are below maximal saturation of medium half-time tissues. Accordingly, the Doppler data show a low occurrence of high bubble grades.

Nevertheless, even if bubble scores are low, this does not totally prevent DCS. We are now focusing on gathering data on other physiological parameters, such as the importance of hydration on bubble production, with the aim of optimizing the reduction of bubble production.

CONCLUSIONS

Dive computers have come a long way since the 'Deco Brain' and the first black and yellow Uwatec model. Many recreational divers now trust and rely on DCs completely to calculate their dive profiles and decompression obligations. The fact that present day decompression models allow the diver to change the level of conservatism is a major step forward towards "personalizing" the dive computer. However, some elemental facts are overlooked and it is often forgotten that the implemented algorithms do not interact directly with the human body. For example, a dive computer does not take into account behavioral and environmental factors that influence the diver, such as how much alcohol has been consumed or what medication has been taken. The algorithm does not calculate the dive differently because the diver is dehydrated or suffering from electrolyte imbalance due to illness.

The limitations of dive computers need to be stressed and acknowledged. Some diving educational organizations tend to skip teaching the use of the diving tables because of reliance on computers, but this is a mistake because computers can fail or break.

DCS events are rare and thus it can be stated that the current use of dive computers is generally safe. However, analysis of the DAN DSL database shows that despite low bubble grades and the low supersaturation levels attained, some DCS incidents are still observed. DCS occurrence can thus be considered partially dependent on other (physiological) factors, which need further investigation.

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Dive Computer Program Management in Scientific Diving

Michael A. Lang Smithsonian Institution Office of the Under Secretary for Science PO Box 37012 Washington, DISTRICT OF COLUMBIA 20013-7012 U.S.A.

The Smithsonian Institution Scientific Diving Program is a large civilian scientific diving program in the United States through which, since 1990, approximately 140 active scientists have logged over 3,400 dives annually in a multitude of locations around the world. In 2005, the decision was made to develop a management tool to assist in streamlining and monitoring Smithsonian diving activities: a web-based virtual dive office. Launched in 2007, DECOSTOP has provided an efficient mechanism to submit diver applications and dive plans, maintain diver medical, equipment, training and certification records, enter dive log information and review and authorize diving projects. Besides providing the benefit of paperless-database functionality, since 2010, all Smithsonian-authorized diving requires the use of a Smithsonian-issued dive computer from which all dive profiles are now directly uploaded to a database in DECOSTOP for review and collation. This web-based virtual office has dramatically improved the efficiency of the management of the Smithsonian Scientific Diving Program and monitoring of occupational dive profile exposures.

INTRODUCTION

Dive computer (DC) evolution has taken place at a rapid rate since the first modern-day, diver-carried electronic dive computer (the ORCA Industries' EDGE) became commercially available in 1983 housing a 12-compartment model based on Spencer et al.'s Doppler studies and reduced no-decompression limits (Huggins, 1989) through to the 2011 VR3 dive computer that is programmable for air, enriched air nitrox, mixed gas, and rebreather use that comes with a web site proclamation stating "...we have all the answers..." Looking forward, Lang and Angelini (2009) presented the future of dive computer development with benefits from advances in consumer electronics technology (high resolution color display, rechargeable battery, GPS receiver, underwater communication and navigation and EPIRB-Emergency Position Indicating Radio Beacon), monitoring technology integrated into the algorithm (heart rate monitoring, skin temperature measurements, oxygen saturation measurements, and inert gas bubble detection) and advances in decompression physiology research.

The emergence of dive computers has raised a number of questions regarding their safety, evaluation procedures and guidelines for use in the scientific and recreational diving communities (Lang and Hamilton, 1989; Wendling and Schmutz, 1995), and for this particular project, the Norwegian commercial diving community. Uncertainty was indicated regarding the dive computer's ability to manage multiple deep repetitive dives, which was reconfirmed when it was noted that little data existed on repetitive diving in general (Lang and Vann, 1992). However, dive computer effectiveness in providing real-time guidance on

decompression status and ascent rate monitoring has been established since 1983. Guidelines for dive computers have provided a framework for their operational use but the issue of how to validate a dive computer remains unresolved, other than with reference to the analogous validation of decompression tables (Schreiner and Hamilton, 1989).

A significant problem of testing the efficiency of dive computers is the disagreement over, or poor definition of, a valid end point to measure. Clinical symptoms of decompression sickness (DCS) may be totally inadequate in this regard, but recording the amount of gas produced by a profile also has its drawbacks with respect to timing and exact location of measurements. Accepting this argument, for this particular discussion it appears reasonable to assume that once a diver reports a problem, the diving emergency system is activated and the emergency oxygen kit is deployed, then that dive profile on that particular day for that individual diver perhaps cannot be recorded as "safe." Follow-up neurological examination and chamber treatment would be the determinant of whether DCS was appropriately diagnosed as the symptom.

DIVE COMPUTER EVALUATION CRITERIA

The process of determining which dive computer to approve should include knowledge of the effectiveness of the decompression model being used, i.e., 'what's in the box' and is it an acceptable model? An algorithm is simply a means by which one can extrapolate limited experience to new circumstances and is only as reliable as the database upon which it was tested. Determination of an acceptable independent validation process of dive computers would appear to include knowing what type of test profiles were performed. Some would argue that human subjects testing with Doppler monitoring should be part of this consideration. An acceptable level of DCS risk should also be prescribed and operational reliability data examined. A final consideration would be to determine how applicable to a specific diving community's mission a dive computer is in addressing, for example, long shallow and short deep dives, staged decompression dives, multi-level dives, repetitive multi-day dives, reverse dive profiles, ascent rates, altitude diving, and parameters for flying after diving.

There are four ways, in ascending order of practical value, to decide if a computer is physiologically acceptable (Edmonds, 1989):

- Testimonials and personal experiences by using satisfied customers as spokespersons, but the repeated diving of the computer to the limit is often lacking;
- Compliance with decompression theories if there were unanimity of opinion on a single theory of decompression and no empirical modifications to tables;
- Compliance with established diving tables, although progressive table modification has deleted unsafe profiles, and if decompression for same single and repetitive fixed-level profiles were comparable; and,
- Comparison with hazardous diving profiles recognizing that there exists minimal information on safety limits of multi-level diving and even less information on decompression and repetitive deep dives.

The safety of divers could be enhanced by ensuring that: DCs are tested to confirm a reliability at least equal to the US Navy tables and specifically towards the extremes of recommended depths, dive durations and surface intervals; DCs are sequentially demonstrated to be relatively safe for square-wave and repetitive dives before extrapolating to multi-level dives; written recommendations be incorporated into the DC function

identifying their safe use; and, the DC be demonstrated to be valid physiologically, mechanically and electronically reliable through the same validation procedures as a new diving table would need to be (Edmonds, 1995).

A relatively new mechanism to ethically meet some testing requirements with a minimal need to actually expose subjects in a pressure chamber was described by Peterson (1995). Guidelines to use past experience and field exposures as part of the validation process were provided by Schreiner and Hamilton (1989) and may be applicable in this consideration of which dive computers might be best suited to meet the needs of Norwegian commercial divers.

Validation protocol suggestions have been difficult to make with the vast number of past and current commercially available dive computers being used. Further, many dive computers are really multiple computers (10) in one with a number of user-selectable settings, as for example the SUUNTO Vytec set with RGBM 100% (P0/A0, P0/A1 or P1/A0, P0/A2, P1/A1 or P2/A0, P1/A2 or P2/A1, P2/A2) or RGBM 50% (P0/A0, P0/A1 or P1/A0, P0/A2, P1/A1 or P2/A0, P1/A2 or P2/A1, P2/A2). A comparison of 30 msw no-stop limits among different dive computers reveals a range of 19 to 7 minutes depending on the aforementioned DC settings. Further, if the factors influencing DCS susceptibility (e.g., depth, time, ascent rate, temperature, profile sequence, breathing mixture, exertion level, physical condition, limb positioning, hydration level, age, body composition) are programmed into the DC, it becomes infinitely variable and forms an impossible task to test all combinations and validate their efficiency. Therefore, the Smithsonian Scientific Diving Program decided to select a common dive computer through its Standardized Equipment Program for training, operational and safety purposes.

SMITHSONIAN SCIENTIFIC DIVING PROGRAM

The Smithsonian Scientific Diving Program (SDP) is a large U.S. civilian scientific diving program. Since 1990, approximately 140 active scientists log over 3,400 dives annually in a multitude of locations around the world. SDP Unit Diving Officers (DOs) are stationed at laboratories across the latitudinal gradient of the western Atlantic (Maryland, Florida, Belize and Panama) and in the Washington DC area. In 2005, the need was identified to develop a management tool to assist in streamlining and monitoring tasks among scientific divers, DOs and the Scientific Diving Officer (SDO): A proprietary web-based virtual dive office. Launched in 2007, DECOSTOP has provided an efficient mechanism to submit diver applications and dive plans, maintain diver medical, equipment, training and certification records, enter dive log information, and review and authorize diving projects under Smithsonian auspices. Earlier attempts at modifying existing more complex programs to meet our specific needs were abandoned and DECOSTOP was structured using some elements from a dive log program provided by the National Oceanic and Atmospheric Administration. Besides the benefit of paperless-database functionality, dive profile information collected through the dive log upload function has proven superior to previously collected data. Since 2010, all Smithsonian-authorized diving requires the use of a Smithsonian-issued dive computer from which all dive profiles are now directly uploaded to a database in DECOSTOP for review and collation. Former dive log information submitted as "shells" (i.e., maximum depth and time) provided no measure of the physiological stress level of a particular dive nor any abnormalities considered to be triggers for DCS such as rapid or multiple ascents, violation of ceilings, or inadequate decompression.

1. Diving safety regulations

The SDP diving safety regulations pertaining to dive computers have been continuously updated since 1990 and were derived primarily from the output of diving safety research projects conducted specifically for the scientific diving community by the SDP (Lang and Hamilton, 1989; Lang and Egstrom, 1990; Lang and Vann, 1992; Lang and Lehner, 2000; Lang, 2001). The SDP has long maintained that the ultimate responsibility for safety rests with the individual scientific diver, with buoyancy control being a critical skill in slowing ascent rates and fundamental to safe diving practices. Only those makes and models of dive computers specifically approved by the program's Scientific Diving Control Board (SDCB) may be used. Since 1990, the program has approved SUUNTO, UWATEC, and Orca Industries models and since 2010 has implemented the SUUNTO ZOOP as the standard required dive computer to be worn on all Smithsonian scientific dives. Each diver relying on a dive computer to plan dives and indicate or determine decompression status must wear his/her own unit and be proficient in its use and it is strongly recommended that each diver also dive with a back-up dive computer. A diver should not dive for 18 hours before activating a dive computer to use it to control his/her diving. Once the dive computer is in use, it must not be switched off until it indicates complete offgasing has occurred or 18 hours have elapsed, whichever comes first. Only one dive in which the no-decompression limit of the dive computer has been exceeded may be made in any 18-hour period. On any given dive, both divers in the buddy pair must follow the most conservative dive computer. If the dive computer fails at any time during the dive, the dive must be terminated and appropriate surfacing procedures initiated immediately. In an emergency situation breathing 100% oxygen above water is preferred to in-water air procedures for omitted decompression.

Ascent rates are controlled at 10 m/min from 20 m and do not exceed 20 m/min from depth. A stop in the 3-10 msw zone for 3 to 5 minutes is required on every dive and multi-day repetitive diving requires that a non-diving day be scheduled after multiple consecutive diving days. Reverse dive profiles for no-decompression dives less than 40 msw with depth differentials less than 12 msw do not lead to a measurable increase in DCS risk. A PO₂ of 1.6 atm is the maximum limit for enriched air nitrox for which standard scuba equipment is approved for up to 40% oxygen content.

Scientific divers are further cautioned about exceeding model and/or tested DC limits, blindly trusting the dive computer (i.e., the brain still needs to be turned on to make decisions from the DC numbers being displayed), ignoring decompression requirements, continuing to dive with a DC that malfunctioned on a previous dive or switching dive computers during a day of diving, and that repetitive multi-level, multi-day diving needs allowances to adequately offgas slow tissue half-times.

2. Dive computer selection criteria

Much consideration was given to the selection criteria of a dive computer that would meet our needs. REEF NET SENSUS PRO dive recorders were ruled out in favor of the provision of real-time dive information from a similarly priced dive computer. Both puck-type and air integrated computers were considered from SUUNTO and UWATEC. Dive computer operation should be effortless through easy-to-use push buttons, wet switch activation and a straightforward menu-based user interface. A DC with metric/imperial unit option, date and watch function of 12/24 hours, water resistance to 100 m and light weight were prioritized features. A bright phosphorescent LCD display and an option of wrist unit or consolemounted dive computer assist in ease of reading displayed data. Multi-mode versatility should include a programmable function for enriched air nitrox (EANx) mixtures of 21% to 50% O_2 and adjustability for partial pressures of oxygen (pp O_2) between 1.2 - 1.6 bar, CNS% and OTUs (oxygen toxicity units).

Further considerations included the type of algorithm and documented experience with it (the SUUNTO RGBM algorithm in SDP's case). Ascent rate and available no-deco time need to be displayed graphically with clear color-coded indicators and the availability of visual and audible alarms when necessary was also a desirable feature. The DC had to be powered by a user-replaceable 3V lithium battery, and have a power indicator and low battery warning. Because of the SDP's polar and tropical diving work, DC operating temperatures should range between $0^{\circ}C - 40^{\circ}C$, and have a storage temperature between $-20^{\circ}C - 50^{\circ}C$. Other functions had to include altitude adjustability, ascent rate monitor, dive planner, decompression data, log book memory, maximum depth of 100 meters, 3-30 sec sampling rate option, safety stop countdown, and temperature recording.

The implementation logistics started with the establishment of policy that required use of SDP-issued ZOOP dive computers. A dive computer training module was developed and the SUUNTO ZOOP user guide was made available on the SDP web site. An online dive computer exam tests the theoretical knowledge of the diver on dive computer function and use. The SDP Unit Diving Officers download dive profiles into the database by a cross-referenced entry by dive plan authorization number.

The resources required to implement this program include sufficient dive computer acquisition, management, shipping, and tracking of the dive computers, dive computer batteries and supplies, PC-interface cables and downloading, and a diver training program for dive computer use.

3. Database integration of dive profiles

Scientific divers are required to log all dives via DC download on DECOSTOP, using web browser interfaces to interact with an SQL database through a relational database management system provided by the Smithsonian Office of Information Technology. The major goals of implementing a dive computer monitoring program are to streamline the dive logging process for increased accuracy in data collection and providing enhanced dive log information. Dive log data is retrieved directly from the dive computer that each individual diver wears by uploading log files into DECOSTOP. The final step automatically extracts dive log files from the dive computer .SDE file (Steganos Disk Encryption), populates the dive log table with dive log data, and creates a graph from the data per dive.

To enhance the 'Upload Dive Profile' function all .XML files (Extensible Markup Language) are extracted from the .SDE files. Each .XML file, along with data entered within the upload form, is inserted into the database as a separate dive log record. To create a graph from the uploaded .XML files, the function of the icon on the dive log list was changed to a graphical representation of the data contained in a dive .XML file similar to graphs currently displayed in the SUUNTO Dive Manager 2 (DMS2). The diver is able to see dive depths and times at points within the graphical display.

The development strategy for this program included scripting an add-on ColdFusion program function to automatically extract .XML files from the .SDE file as it is uploaded into the DMS2 database. This function then automatically inserts the .XML files into the database as BLOB (Binary Language Object) fields. Finally, using an .XSL (XML Style Sheet) transform, a web-based graphing system was built using .HTML (Hypertext Markup

Language) and .CSS (Cascading Style Sheets). The DECOSTOP virtual office is accessed through https://www.si.edu/dive.

CONCLUSIONS

The overall issue with dive computers remains the mechanism of repetitive dive control. On balance, the 28-year operational experience with dive computers has demonstrated that their advantages over table use outweigh the disadvantages. The large range of dive computer variability demands that the establishment of their selection criteria meets a particular diving community's specific needs. An important element of this approach is the characterization of a community-specific universe of 'safe' dive profiles for which the computer is effective through use of a dive computer monitoring program. Dive computer validation to the specific model's limits, as has been traditionally tested with dive tables via human subjects testing, is not likely to occur because of the time and expense involved and the infinite combination of dive computers and settings.

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Plenary Discussion

Michael A. Lang and Karl E. Huggins, Moderators

- W. Gerth: Do you acknowledge or accept that associated with the kind of diving that we do today, recreational diving or commercial diving or whatever, is a relatively large incidence of VGE with grades higher than a Kisman Masurel grade III or so? In other words, do we have a lot of VGE associated with the dives that we do today? We have people screaming that the diving we are doing is unsafe because of all of the VGE produced, but we have relatively few cases of DCS.
- C. Balestra: We have been thinking about this for a few years but do not know exactly how we behave with bubbles. We know that acute phase reactants, for example microparticles, may be one of the clues. We are looking at how we behave with bubbles, not just the outcome in terms of DCS.
- W. Gerth: I just do not hear a screaming cacophony of people out there saying that the type of diving we all do today is causing them trouble.
- C. Balestra: I understand that.
- W. Gerth: Because the VGE we produce do not seem to be giving us problems, we should not be looking at how we get rid of them, we should be looking at how we tolerate them.
- C. Balestra: That is what I said; we are now trying to understand how we cope with VGE and not just why we have DCS.
- B. Hamilton: Can you mention what happens when a computer fails and whether that happens very much?
- M. Lang: The short answer is that they do occasionally fail. Battery compartments used to be sealed with an o-ring of rubber and you would not know sea water had penetrated until enough corrosion had occurred for the screen to go blank. With the new computers that we are using, many are gel-encased and we have not had that many problems. We also always dive with a second back-up computer that will give you ascent and deco information should the primary fail.
- A. Brubakk: I would like to address the question of what we are trying to validate in this session. What is the endpoint? Is it DCS, or DCI, what is a measure of what is going on, in particular in those divers who have clinical symptoms and those who have clinical symptoms but do not tell anybody. It is very difficult and we have to look at it in a totally different way. There are data that support a very simple statement, which is that decompression sickness is an inflammatory disease. It seems that inflammation, particularly in the vascular tissue, forms a very important part of the whole decompression problem. We have a lot of tools to treat inflammatory problems and also to investigate them. There are many ways, genetic studies and experimental studies and I feel this is a good way to proceed. What I would like to hear at the end of this session is that we have to focus on the problem of how to define what we want the computers to do.
- M. Swiergosz: That would depend on your requirement. I have endpoints for my undersea medicine program because we are interested in discovering the aetiology of DCS or DCI, or nitrogen narcosis. The simple fact that matters is that the divers want to know that if they perform a certain profile they are likely to get DCS. That is what they are

concerned with and perhaps you need to take your scientist cap off for a little while to see this.

- A. Brubakk: I agree, everybody who uses DCs says that they want to have a practical answer. But the paradox is that there are people who follow all of the rules of diving and end up having problems, and there are a lot of people who do crazy dives and have no problems at all.
- M. Lang: The first point is that decompression sickness is an inflammatory disease and the second is the request for a recommendation that there should be further investigation as to the correct endpoint.
- D. Doolette: What does that have to do with validating DCs?
- K. Huggins: The point I would draw from A. Brubakk's comment is that we are looking at a risk management process. Number one, we want to define the risk, and what the concept of that risk is, DCS or DCI. The second question is how does one monitor or measure that risk, whether it is symptomatic DCS or VGE, or other information.
- J. Wendling: I like that aspect because it includes risk of DCS, and risk of diving accidents as it would also include failure of the hardware or software while diving.
- A. Sieber: We should further divide this into validation of the algorithm, which I think should be done by physicians or a medical group, and validation by the manufacturer. The manufacturer will focus more on the hardware and software and whether the algorithm is implemented correctly and doing what it should do.
- M. Lang: We can include this information in this document; however, information on this topic was not discussed in the program today.
- B. Hamilton: It was covered in the previous workshop and was called the 'chemical cascade.'
- W. Gerth: In terms of level of risk, I would reiterate that it differs with what the risk is. For example, I would not accept a very high level of the risk of death, but accept a high risk of scratching my toe!
- A. Sieber: Perhaps we should actually look at this in terms of risk analysis?
- W. Gerth: We need to look at what is acceptable.
- D. Doolette: In fact, what is acceptable in what situation? What do we mean by risk and the definition of the risk, a bad outcome?
- K. Huggins: What outcome are we looking at, i.e., the negative outcome is the risk.
- D. Doolette: The word outcome is a better word than risk, because 'level of risk' has no real meaning, it should be the probability of risk.
- W. Gerth: We should say what level of risk of that outcome is acceptable.
- A. Sieber: We are talking about what level of risk is accepted today. For the Norwegians for example, at present they take a table to see the risk of a particular profile, or they take data from real dives and from that they see what the risk is.
- A. Brubakk: How can you define the risk, when you do not even know exactly what you are looking for?
- W. Gerth: Do we think that most diving today is safe? Within acceptable levels of risk or whatever you want to call it? There are no screams from the community out there in the real world that they are getting hurt, so do we think that what we are doing now is relatively safe?
- M. Lang: There is also a need to define acceptable risk for a specific community: military, commercial, scientific, recreational.
- K. Huggins: The Norwegian tables are used by the Norwegian Society of Underwater Contractors. From the decade 1993 to 2003, 220,000 diving hours have been logged and DCI/DCS incidence reached 0.05% per hour, so one case of DCI per 20,000

hours. Therefore, the Norwegian community tables are safe and are based on the old U.S. Navy tables. This is the incidence right now and is what they are saying would be acceptable. I am not sure if they would accept a greater incidence or not?

- H. Örnhagen: I think the vast majority of recreational divers today are diving according to safe procedures. We are seeing a reduction in the numbers of decompression incidents in many countries around the world, not necessarily because of DCs, but because of the limitation of ascent speed and the safety stop. These are two important measures that have been taken and have reduced the number of cases of divers who post-dive, experience something abnormal. As A. Brubakk says, we do not really know what we are talking about in terms of definable endpoint, and many others and I agree that it is an inflammatory disease and there must be a trigger for it. We believe that trigger may be bubbles, but we know it cannot be bubbles alone, so what is the risk? If we take an experienced diver who has an inappropriate fatigue for two or three hours after a dive, and decides not to dive again, do we say he or she had a decompression incident? Put this in contrast with the novice diver who was rushed to the hospital with a funny feeling in their hand, who is then examined by an inexperienced doctor and who decides to treat for decompression sickness as a precaution. All of a sudden we have a decompression illness incident, when in fact that may not be the case. All of this makes it difficult to define the risk and hence makes this discussion very difficult.
- S. Angelini: We are talking about risk or safety. We think that DCs are being used in a safe way but perhaps the most important thing that we need to do as manufacturers is to define the window of applicability of these computers. If something that has been sold as safe is then pushed to and beyond untested limits by the consumer, then we do not know what is going to happen. This is the first and easiest thing that should be done and then perhaps we can look at how to expand this window of applicability.
- K. Huggins: One also has to define the operational window that commercial divers will be using these computers in. What kind of depth ranges and dive profiles will fish-farm divers be performing? These are probably not going to be standard, multiple, multiday dives. In other words not the type of dives that recreational divers do.
- A. Sieber: The DCs that we have now all more or less give the same readings and produce quite consistent data and we do not see many bends. The big question is, do we need a validation of the algorithms at present?
- D. Doolette: Absolutely we do. As has been said over and over, the incidence data that we have for DCs is from recreational divers diving within the no-stop limits. We are now talking about taking these computers and applying them to working divers, which is a completely different situation and the computers need to be validated for that diving community. They must decide what their acceptable level of risk is or whatever it is they are trying to avoid, then go about validating the computer in the appropriate way. The incidence data that we have now is useless for the working diver.
- M. Lang: We should perhaps preface this part of the document to say that what we have been discussing so far is in reference to the recreational diving community, not commercial diving.
- W. Gerth: For the purposes of this outline, we need to make a statement that how we define the negative outcome is going to be community specific and dependent on the requirements of the community using a computer. There will not be one answer to the question
- S. Angelini: Are we going to make a computer for each community, or are we going to try and make one that fits all?

- E. Azzopardi: Regarding the window of applicability, a lot of computers say not to dive outside the limits, not to go below 30 meters, etc., because this is not what that computer is designed for. Do you think manufacturers would be willing to push that a little?
- S. Angelini: The manufacturers do that only for liability, not because they do not trust their computers.
- E. Azzopardi: How is the window of applicability, as decided by the manufacturers, going to change to allow us to apply that to professional or recreational diving? Would the manufacturer be able to do this?
- S. Angelini: This is where a standard should be brought in that takes away the liability from the manufacturers.
- W. Gerth: There are no clashes here at all. The issue is that at present we are letting the manufacturers define what they think the requirements are for the market that they are serving. If they want to go after the recreational DC market, the kinds of requirements they will have to meet there will be different from the military market for example. In our experience we have found when we have expressed all of the requirements for military DCs and put it out to tender, we have had very few respondents. The manufacturers are free to choose not to address our market, but we should not leave it up to them to define our requirements, the diving communities should do that and then pass them on to the manufacturers.
- A. Brubakk: Can we make a requirement that the manufacturers who sell DCs have to publish their algorithms? Or perhaps we make a recommendation that people do not use computers where the algorithms are not published?
- M. Lang: It would appear that your Labor directorate in Norway is certainly going to want to know this information as one of their validation criteria.
- A. Brubakk: Yes, they are going to want to know what is in the box.
- K. Huggins: Not only because you want to have that information, but also if in your validation process you are comparing the algorithm to different profiles, it is much easier to use the actual algorithm rather than having the computer run the program in real time.
- A. Brubakk: I suggest that we have a documented requirement that the manufacturers tell us what the algorithm in the box is.
- A. Sieber: One of the ways to force the manufacturers to do this is to put DCs on the list of PPE. Because then the manufacturer is liable, so they should be very happy to publish the algorithm.
- S. Angelini: I wish that it was like that, that we had one standard that everybody is using and that the algorithm was published. The variation causes confusion and harms the market. But although I agree with you, the Vice President for Marketing at Mares might think differently.
- C. Fabricius: Is it the wording that is the problem? Perhaps we could look at diving as some kind of drug and use pharmaceutical terminology, for example, 'adverse effects, 'side effects' etc., otherwise it confuses people by inventing our own wording for this. Within medicine there is also common knowledge that you can use a set percentage of acceptability of adverse effects and serious adverse effects. Use that terminology and accepted knowledge.
- D. Doolette: No. Decompression sickness is not a side effect; it is the main thing you are trying to control.

- K. Huggins: The closest thing would be the use of anaesthetics, because a procedure is done and you are looking at the side effects of that, but not to a specific drug to treat a specific condition.
- C. Fabricius: No, I am just talking about using the system, the terminology, to evaluate side effects on the human body.
- D. Doolette: No, the wording would be confusing because DCS is not a side effect. We are all dancing around here, trying not to define the negative outcome because no one wants to offend each other, but these algorithms and these computers control DCS. If you want to dive a computer sometime in the next decade for occupational diving, you are going to have to accept that DCS is the negative outcome that we have at the moment. We have to validate from that, or some surrogate measure of that, such as VGE if you believe that they can be used that way. We are not going to have DCs that do anything else but that in the short term.
- M. Lang: Does everyone agree that we will define DCS as the negative outcome in this document? (General consensus yes)
- C. Gutvik: One concern is with reference to long-term effects of diving, do we have any models that can predict this?
- D. Doolette: If we could model long-term effects that would be very interesting, but this is a relatively short-term exercise we are trying to do here.
- B. Hamilton: They do have a great interest in long-term diving effects in Norway.
- W. Gerth: We do not have a large group of people screaming about long-term effects from the diving we do today and have been doing for a large number of years.
- C. Gutvik: To say that long-term effects are not pertinent here is not true, because in Norway the Labor Directorate is facing one of the biggest lawsuits in history due to long-term effects, where several hundred divers are saying they have been affected.
- W. Gerth: I understood that there were only around 15 divers who had complained of long-term adverse affects?
- A. Brubakk: The data from nearly all of these divers involved in the lawsuit show that they have had decompression sickness. I agree that the long-term effects should not really be discussed here today, but of course it all depends on whether the mechanism is the same as for short-term DCS as to how pertinent the question is.
- M. Lang: We need to focus the discussion on the material that was presented here today in Gdansk. Are there any other topics that we think should be carried forward into the document?
- M. Egi: Dive planners are also part of the discussion, because dive planner methodology is always the same. Everyone has the same problem in terms of trying to combat the occurrence of DCS. If we try to focus on the software side, then we have open source software and open source DCs and they describe exactly what is in the box. Why does nobody mention these open source DCs? Why is the research so far away from the dive communities, particularly the technical divers, which is something that I do not understand.
- M. Swiergosz: The dive planning goes hand in hand, it is just as much a part as the dive itself.
- M. Egi: An open source DC means that every single electronic element, not only the software, is described so that you can validate the whole thing.
- K. Huggins: There are now two or three DCs out there that are open source, but the PC software planners can be utilized in the same way that DCs can be utilized. The planning is done ahead of time; they should have the same validation process in this type of situation.

- A. Sieber: We had a similar discussion about open source software when we were developing rebreather software. One of the problems was with the documentation, but the other thing is validation. The equipment is well documented and you can start with the validation, but if I want to develop a new product and I have to start with validation of all of these parts, I will never finish.
- M. Egi: No, the computer engineering is all described and you have compliance, so you can just document everything as part of the auditing.
- A. Sieber: Yes, but who is doing the auditing?
- M. Egi: I am just saying that there are solutions that we are ignoring.
- S. Angelini: From the perspective of a computer manufacturer who sells between 50,000 to 100,000 units a year, what does open source do for us? The guy who goes diving once a year does not want to fiddle with half-times and M values. We would risk generating algorithms that get us completely confused. I do not think that open source brings us much other than perhaps specialists would like to discuss it and come up with a standard for use.
- A. Brubakk: I want to go back to the point in the document where we state that we accept decompression sickness as an endpoint. The U.S. Navy also recognizes the problem with using such a broad term as DCS. E. Thalmann of the Navy said that in order to evaluate the decompression procedures you had to take into consideration all kinds of negative symptoms, adverse effects of decompression as it was called. I think that we have to be careful when using DCS as the measurable negative outcome because it is so diverse. It can limit the ability to evaluate one procedure against another. We have to consider at least another definition or part of that statement.
- M. Lang: But this is a historical statement, from the beginning to the present time. DCS is the accepted measurable negative outcome, which is a true statement.
- K. Huggins: The question is, how do you measure that risk? We could look at VGE, or inflammatory markers.
- W. Gerth: To talk about software and open source software brings us to another level of discussion that we have not reached in this outline at all at present. Software that runs the computers is a manifestation of some theory, some logic and equations that can be implemented in a variety of different ways. One implementation of a given algorithm that is well documented is not the same as another implementation, but which of them are you going to have as open source? For example, in our NDCs, the software that runs in the computer is an implementation of the Thalmann algorithm. It is different from the implementation of the Thalmann algorithm in the dive planner that we use, compared to our gold standard tables. Which of those are you going to have as an open source software? It is not of much interest to have open source code, unless you decide where it is that it is going to be used. What I want to know is how can I establish, in the documentation, that this implementation and that implementation give me a valid representation of that theory? That is all I want to know. How you go about doing it, once I have made sure that the implementation is valid.
- M. Egi: I still think it gets rid of the problems described by S. Angelini.
- W. Gerth: How many software code packages have you written? Open source is not a simple thing. For example, one of the implementations of our Thalmann algorithm has been compiled in old compact FORTRAN. I cannot compile it with the new Intel version of FORTRAN. Which version shall I have as open source? The theory is the same; the code is a little different.
- M. Egi: You can at least know what is in the box.

- W. Gerth: It is not that simple. The second thing we have to think about is how to test an implementation of that theory. Whether it be the real time version that you are running in your computer, or one that is prescriptive that you are running in your dive planner. They will almost inevitably be different, one might be written in binary code, one in FORTRAN, and one in C. This is the point I am trying to make; it can be highly variable. In the end, all I really need to know is the theory behind it.
- M. Egi: Yes, but at least you have a traceable format.
- W. Gerth: The traceability is in the documentation of the implementation testing. To do this I publish the software test documents. In the U.S. Navy this is about 180 pages long. It is a line by line test of all of the features in the implementation, once you get through that successfully then you can validate that the software meets the requirements.
- A. Sieber: When we look at creating such a standard we also need to know that the manufacturers are willing to fulfill it. If something like open source is required then it will mean that not only is the code public, but also the schematics of the electronics and I do not think a diving manufacturer such as Mares will do that.
- M. Egi: There is a company in Germany (Heinrichs Weikamp) that will do that.
- A. Sieber: They provide for a niche market.
- S. Angelini: They are certainly not living off of that. We are talking about supplying the recreational market, because it is the one that generates the profit that allows the other small niche products to be made. If you only focus on niche products, you will find that most companies will not head down this route because there is no financial benefit. This was the case for tenders for the U.S. Navy DC where manufacturers did not come forward. What we look to when developing a product is catering for Joe Diver, who goes diving once a year for a week to the Caribbean. We need to make this work for other markets and this is probably the toughest part, but it is not impossible, especially if the liability is taken away from the manufacturers for the algorithm. My idea would be to get the manufacturers to tone down the marketing and even better, do so in the sense that they all have the same algorithm; at that point why not give them an algorithm that they can use, then claim that the big three manufacturers use it to get the others to do so, and then have scientists develop it over time.
- W. Gerth: Somewhere in here we have to talk about defining the requirements, and as we have said, these requirements are different in the different markets. The markets must take it upon themselves to define what they want. The manufacturers should remember that our market (military) is growing and that commercial divers will probably end up needing the same requirements as us, particularly with regard to the documentation process. Any government agency is going to require this.
- M. Lang: The Norwegian Labor Directorate is going to require it, is that correct?
- A. Møllerløkken: Correct.
- W. Gerth: We need to establish here today, in this workshop, that the requirements for the different communities are going to be different. I do not think we are going to have time to do all of that today.
- M. Lang: There was not enough information presented here today to do that.
- B. Hamilton: We already have a community in focus, the Norwegian commercial diving community.
- M. Lang: That is correct, so what else do we need in the document to allow the Norwegian Labour Directorate to assess the use of DCs for their commercial diving community?
- D. Doolette: They need a method of validating the algorithm. There are two paths available to take that I put them up in my presentation. S. Angelini just agreed with the Navy

path. He is saying give the manufacturers a validated algorithm to put in the computer, and that that might be a path that manufacturers would like. The other path is to take the algorithm that the manufacturer wants to use and test it yourself. That is going to have to be by the method I described, as did C. Gutvik. K. Huggins also talked about the way you generate profiles on the computer and evaluate them with a validated model.

- K. Huggins: I have a simple solution. I am recommending that you use the U.S. Navy DC.
- D. Doolette: That is the obvious conclusion. A lot of work has been done and probably nobody else currently meets that, so that is an option, but perhaps not very palatable.
- M. Lang: Would that simplify the Labour Directorate's decision-making process?
- A. Brubakk: It is the general principles here that are important, not the details, not specific products.
- P. Buzzacott: Does the diving to which this is going to be applied differ much from the U.S. Navy diving, is it unique?
- A. Brubakk: The major shore-based diving industry is in connection with fish farming. A lot of it is maintenance work and inspection, so it is not hard work in that sense, but of course there are a lot of other activities that will benefit from it. The problem is that everyone has used DCs recreationally, but they are not allowed to do so while working. If the Norwegian Labour Directorate decides to implement DC use, then there will be a set of requirements put in place and if that happens then there will be large implications for sports diving across the rest of Europe.
- David Doolette: The diving is probably not that different, but as C. Gutvik said, the requirements are different. The U.S. Navy for example will accept a 2% incidence of decompression sickness, but apparently that would be unacceptable for the Norwegians.
- A. Brubakk: That was pointed out before. We do not have enough data to say that the real risk is 1%, which is preferable in Norway, or even 2%; that is the major problem. Mortality is too infrequent to be a measurable endpoint and symptomatic DCS is also low, so the paucity of pertinent data is a problem.
- P. Buzzacott: Would it not be fair for the recommendations that came from this discussion to say that one of the first priorities would be to define the operational needs and then secondly to define what is accepted, is that where we are headed?
- D. Doolette: That has already been established. We have accepted that the requirements will be community specific and we do have a method. With some sort of probabilistic model you could say that it has to generate schedules that are all less than 1% DCS. What else are you going to do, you are certainly not going to go out and man-dive these computers?
- W. Gerth: R. Vann and others at DAN and Duke have done a great deal to make estimates as to how the probabilistic models used in the Navy map to actual recreational dives by using them to estimate risk on recreational dives that have been recorded. I think there are about 140,000 dives in that PDE database, so we do have a tool to do that.
- K. Huggins: Which protocol can be used to evaluate current DC model software? That is one of the big questions. We are not designing a DC; we are not putting out an algorithm for DCs to implement. What we do want to know is what tool or method can be utilized to evaluate what is out there. D. Doolette's suggestion to use a tuned probabilistic model to assess the risk of various profiles within this window of commercial divers' activities is one way of looking at it.
- D. Doolette: That is the way we do it in the Navy. You would use some sort of probabilistic stress indicator model.

- W. Gerth: The word 'stress' needs caution, because we are witnessing here a subtle, or not so subtle, attempt to redefine what decompression stress is. Is it VGE, or is it DCS risk? We should write use of a DCS indicator model, to be clear. I need to see the probability of DCS occurring, or else it is just a number and has no meaning to me. For example, if we recorded the area of red skin after a dive, how is that of use to me since we do not know how it is quantifiably linked to DCS? As D. Doolette said, you could take a model that fits your VGE data to DCS for example, it could be done, but it is not being done yet.
- C. Balestra: If you state 'stress or DCS indicator?' Maybe you can add some other stress indicators, I don't know but we keep coming back to the same point.
- W. Gerth: I do not think we are designing DCs to reduce the risk of 'athlete's foot' in divers!
- C. Balestra: I understand, but it could say 'to reduce the risk of bubble-related risk, not just DCS.'
- D. Doolette: Bubbles are an indicator of DCS risk, according to some.
- A. Brubakk: There is no doubt that there is data that shows that if there are no detectable gas bubbles then the risk of serious DCS is very, very low, so that is a way to say that this procedure is reasonably good.
- D. Doolette: The Norwegian inshore occupational diving industry will go out of business if that is the goal or criterion.
- W. Gerth: I agree. Certainly by controlling VGE to grade one or less, you will end up prescribing schedules for decompression that will be conservative for DCS. They will also be very long, and you will get laughed out of the room when they get presented in front of real divers. You have to consider the issue that D. Doolette pointed out in his presentation, you have to get divers out in the shortest possible time and in such a fashion that they reach, but do not exceed, this negative outcome that you have decided to accept.
- M. Lang: That is exactly the goal of what the commercial divers do. Time is money, and it is a competitive advantage for the company if you can decompress more efficiently and faster than your competitor.
- W. Gerth: Assessing VGE is not a practical criterion.
- M. Lang: Let us table the VGE discussion for now and ask if there are any other speakers who still would like to include a take home message in the document?
- D. Doolette: It is absolutely essential to include configuration control for occupational diving computers. There is no point validating it if the diver wakes up the next morning and on a whim changes the settings in some way. It is easier to do with open source, but we have to make sure that there is configuration control and the computers are not changed in any way.
- C. Balestra: We should perhaps consider DCS as the major negative outcome but not the only one. Maybe we should not be so single-minded about this.
- M. Lang: We have to be. DCs are a tool. What you use it for and are trying to avoid is the necessity to have to treat a diver with DCS in a chamber. We are not looking at long-term health effects at this stage.
- C. Balestra: I can see that is the direction that this workshop is taking, but maybe others want to hear other ideas.
- W. Gerth: We are not talking about future research; we are talking about DCs as they exist right now and an applied focus for them. We do not have to assuage people on the business of dive research. We should make it very clear in the introduction to this

document that we are not trying to do that. We are trying to direct what DCs are trying to do today,

- M. Lang: I appreciate C. Balestra's concern and we should include some words in the document to say as much.
- A. Brubakk: We should also clearly state that we are not only talking about algorithms. Other factors discussed here today are also important, for example, making sure that DCs are measuring the pressure they say they are measuring and that they do the technical things they are supposed to do.
- K. Huggins: We should say that equipment functionality must be documented.
- W. Gerth: A. Sieber had a great outline of how to do this in his presentation. The buyer going to the manufacturer has to specify what he wants, in an explicit document.
- A. Sieber: My take-home message is that we have to look at the functional safety of the whole thing and that one has to understand that the computer should be looked upon as PPE.
- M. Lang: With a focus on DC as PPE concept, is there an issue from the manufacturers' perspective?
- S. Angelini: If a DC were classified as PPE, then we would need to have a 'norm' for the algorithm, which does not exist and therefore it cannot presently be a PPE. We would need to have a common algorithm.
- K. Huggins: That would be a good thing to put down as a recommendation for the future, but right now, how do we recommend the validation process as the situation stands currently? What you are looking at is something that would take years to first establish and then implement.
- S. Angelini: What we can do right now should be based on the history that we have, 20 years of DC use. We can select the window of applicability and say that the validation for this window is done, we just need to define the window. The 20 years of experience means that we have data to use and most of it is not pushing the limits.
- W. Gerth: Should we not ask the Norwegian Labour Directorate what the requirements are? The manufacturers have been dictating to us and now we need to tell them what our requirements are.
- S. Angelini: You told Cochran to make a computer for you and told them what you wanted in terms of algorithms.
- W. Gerth: They need to tell you what their window of requirement is.
- M. Lang: It is time to talk about the requirements of the Norwegian Labour Directorate now.
- A. Møllerløkken: When we started the whole project the one thing that Norway prioritized, given that its diving history comes from dive tables, was that they would like to look into DCs but they needed to be at least as efficient as the tables. We know that the Labour Directorate would like computers that will meet the requirements of the existing tables.
- D. Doolette: What do you mean by 'efficient'?
- A. Møllerløkken: Giving the same results, or the same risk of DCS.
- D. Doolette: Do they mean divers forced to dive those tables to the limit, as you would in a laboratory test, or their historical experience of the tables?
- A. Møllerløkken: When we started to work on this project, we told them that we were working with VGE as a stress indicator - sorry to bring VGE back into focus - and we found in recent studies that acceptable dive table profiles were giving high levels of VGE, but there was no incidence of DCS. We said that all of the DCs that we have tested would be fine for the commercial industry but we did not feel that all of the

computers were the same. How then would we set up a system to pick the correct DC equipment for the commercial industry? When we specify the list to the Labour Directorate and they then produce their list of requirements, perhaps the big manufacturers (Mares, Suunto and Uwatec) might just say that they do not want to deal with this very small market. We do not know that, but this is what we are trying to learn from this discussion.

- S. Angelini: Maybe what would have helped is if a set of dives that the Norwegian Labour Directorate expects to be doing are defined, in order to focus on those rather than picking out profiles randomly.
- K. Huggins: That would be very helpful. The other issue is to look at the risk of the tables as currently implemented. How many of the dive supervisors are bouncing up tables or adding time for cold, arduous dives? Are the tables pushed to the limit?
- B. Hamilton: That is a state-of-the-art practice that is not going to change.
- D. Doolette: It does not matter if we have an incidence number and not per hour number, as I do not believe that is particularly useful. If we look at what has historically been found in terms of DCS incidence in Norwegian onshore diving, then we ask can the DC guys give us the same risk or better. In reality, I suspect they cannot. It is going to be difficult to find a computer that gives any benefit in terms of time in water, as historically these tables have incidences of something like one in 10,000 in the Navy. It is an extraordinarily low number anyway, and this is what the Norwegian tables are based on.
- W. Gerth: As was pointed out, they do not dive the table to its limit.
- K. Huggins: In particular on inspection dives, they are diving a table but certainly not taking it to its limit.
- D. Doolette: Therefore, to meet that historical incidence of DCS, you probably are not going to need a DC, you are going to have to dive the same very inefficient way of diving.
- K. Huggins: The other way to look at it is if they are willing to accept the same risk as their tables have, then they are willing to accept the same risk of the table if they had been taken out to their limits. We can run a risk model against them and get a distribution of the risk associated with those tables, and say we have a DC that falls within the same range; theoretically, the risk of the computer use versus table use will be equal. We need to differentiate between actual risk incidents and risk of the tables, and know which they are concerned with.
- C. Gutvik: That is spot on, but the problem is that the authorities are not capable of taking that line.
- D. Doolette: If they want to match the historical incidence, do not recommend a DC because there will be none that can do it. If they want to just meet diving the Norwegian tables to the limit, probably any DC will match that, because the tables are based on the old U.S. Navy tables which, dived to the limit, are fairly risky. They are two very divergent paths. If as C. Gutvik says, they do not know which way to go, then they are going to have to consider some advice.
- W. Gerth: The risks in the old Navy tables are certainly defined. The new tables are better than the old ones, though not always by much.
- D. Doolette: Those numbers range from two, to five, to ten percent risk of DCS, and that is not going to be socially acceptable.
- B. Hamilton: There needs to be some sort of method for exerting judgment on the system.
- A. Brubakk: A question that has come up a number of times in this discussion is that we know that the tables are based on the old U.S. Navy tables, but we do not know how the results are applicable if you start diving on computers. Is that a reasonable

objection for using computers at all? You cannot use the data from the dive tables because you dive them differently? For example, you do not use a square dive, but you do a gradual ascent instead. Is there any data to support that one is better than the other? We have bubble measurements, but as we have said, that is not DCS, so is there any other data?

- D. Doolette: There is not.
- A. Brubakk: How do we handle this then?
- K. Huggins: The U.S. Navy probably has the closest match in terms of utilizing a model that is then implemented in a computer and the profile is generated inside the table limits. The validation of that is an entire system to come up with a good outcome. But with DCs out in the recreational community, there are no studies looking at the results of running a computer to the limit of its algorithm, or what the risk is. This is one of the main questions, because if you give somebody a tool, and the whole point of this tool is to be more efficient in the water, they are probably going to run it out to its limit.
- A. Brubakk: We will probably need to say as a group that diving with DCs is or is not more risky than table diving. Can we say that?
- M. Lang: No, we cannot.
- K. Huggins: What we can say is that the way DCs are used today by the recreational and scientific diving communities gives a comparable or maybe even lower risk of DCS than diving tables to the limits.
- A. Brubakk: It would be very useful for us to be able to say that.
- D. Doolette: We would have to qualify that and say that it stands for sub-saturation, nodecompression diving.
- W. Gerth: If the Norwegian Labour Directorate wants computers that describe safe dives, in the context of that statement, i.e., for no-decompression situations, then fine, but the statement becomes irrelevant in the situation whereby a dive becomes a decompression dive. We do know that the risk of those dives is going to be operationally higher than when we use tables, because at that point the computer is always going to be running at its limits of risk.
- D. Doolette: What was questioned was whether we can evaluate the Norwegian tables with a probabilistic model and say the schedules have, for example, a 4% risk. If we evaluate a net inspection decompression dive that is unusual looking and that comes out at 4% risk, are we really confident in that number?
- W. Gerth: That is true, there is a lot of uncertainty.
- D. Doolette: We cannot say with 100% certainty that the computer schedules will be no riskier than the tables.
- A. Brubakk: That is not the point. We have been attacked by people who said that computers are like a product of the devil or snake oil. They are saying that it is much riskier to dive with a computer than it is to dive a table, regardless of the fact that with a table, to achieve the same end, you have to make many more dives. A simple statement to say that there is no data to show that it is significantly more risky will be very useful, if we feel we can say that.
- C. Gutvik: Could we say confidently that the operational risk is less with a computer than diving a table to its limits?
- W. Gerth: No, it should be the same. The point of an algorithm running in real time is that it will always push you towards that acceptable risk limit.
- K. Huggins: Only if you are pushing it towards that limit or if you are in a decompression situation.
- W. Gerth: A. Brubakk's question is a good one. We do not have evidence either way to say what the risk would be on these more complex profiles. From our best guesstimate, in

those cases where we have been able to test algorithmic prescriptions based on square dives, things have worked out OK. We do not have any evidence that we are getting bad estimates using our models.

- A. Brubakk: That is good to know.
- D. Doolette: We need a statement to that effect.
- S. Angelini: One thing that we can consider is that most computers have no-decompression limits that are shorter than tables. A direct comparison of square computer dives versus square table dives results in the computer dive being the safer of the two.
- K. Huggins: At least for the first dive, not necessarily for repetitive dives.
- S. Angelini: If you use them on non-square dives, this reduction in the no-decompression limit times in the computers might help you make a statement like that. This is why knowing whether the Norwegians only want to make square dives, or only triangular dives or a mix of everything would be very useful.
- M. Lang: Exactly right. When this project first came up I said that the first thing that needed to be done was to go out and buy several dozen of the Sensus Pro dive recorders and find out exactly what the divers were doing so that we can then characterize the window of dive requirements.
- S. Angelini: One of the main differences between the decompression schedules for the recreational market and that of the Navy and professional diving, is that for the latter, the aim is to get your diver out of the water as fast as possible because time is money. The recreational diver does not want that. He does not want to have to sit there and work out a table, he just wants to get out there and look at fish and coral. The foundations of these two ways of thinking about making up the DC are completely different and therefore to find one that works for all is very difficult.
- A. Brubakk: Looking at the section of the document where we talk about communities and their requirements, we should also consider that environmental requirements might be different.
- W. Gerth: The community sets the kind of environment it is going to be diving in.
- D. Doolette: The community can be as narrow or wide as you like, for example, it could encompass polar divers.
- A. Brubakk: The reason I suggested this point is that we are moving into areas further north than we have been to before, so we need to be able to make sure that equipment will cope with depth and extreme temperatures.
- M. Lang: That is one of my take-home points, we will need monitoring and feedback of the hardware's performance.
- M. Lang: With 30 minutes of workshop time remaining, before we go through everything and try and fine tune it for agreement, are there any additional salient points?
- W. Gerth: There is nothing that talks about hardware as of yet in the document.
- D. Doolette: Is that not encompassed by the section on functionality?
- W. Gerth: We need to specify the platform, the mechanical specifications.
- M. Lang: Any other points for inclusion?
- W. Gerth: With regard to the statement referring to the operational risk of DCS, are we recommending that DCs be adopted for real-time decompression guidance by Norwegian commercial divers?
- M. Lang: Is the take-home message from this workshop whether we advocate this recommendation? The consensus was complete agreement.
- K. Huggins: The workshop advocates that a validated DC would be a useful tool for providing real-time decompression guidance for working divers.

124 VALIDATION OF DIVE COMPUTERS

The Validation of Dive Computers Workshop concluded by promulgating consensus Findings and Recommendations.

General community-specific requirements:

- Accept that at present decompression sickness (DCS) is the measurable negative outcome;
- Specify acceptable level of DCS risk and how it is measured;
- Define window of applicability for the dive computer (DC);
- A dive planner to support the DC is required; and,
- Equipment functionality/functional safety must be documented and verified.

Findings applicable to commercial diving:

- A DC is a risk management tool. The operational risk of DCS in the recreational and scientific diving communities is no worse than previous experience with sub-no-decompression diving compared to table use, primarily as the DCs are not pushed to their model or algorithm limits. There is no evidence that multi-level dives with DCs are more risky than square dives following the same algorithm;
- Documentation of theory (i.e., logic and equations) is required what's in the box;
- This documentation must include methods to test the implementation of the theory in the DC;
- Use a DCS-risk indicator model to validate the algorithm, or manufacturers may produce a DC with a validated and documented algorithm;
- Specify platform technical requirements; and,
- Develop and implement a configuration control plan.

Recommendations

- The workshop advocates that a validated dive computer would be a useful tool for providing real-time decompression guidance for working divers;
- A mechanism for making judgment should be part of the system; and,
- Institute a Configuration Control Board to assess conformance with validation requirements, monitor DC operational performance, and specify diver education and training.