
The mission of AAUS is to facilitate the development of safe and productive scientific divers through education, research, advocacy, and the advancement of standards for scientific diving practices, certifications, and operations.

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Validation of Dive Computers

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Abstract

This paper reviews a workshop on the validation of dive computers that was convened by the Baromedical and Environmental Physiology Group of the Norwegian University of Science and Technology on 24 August 2011 in Gdansk, Poland as part of the European Underwater and Baromedical Society annual scientific meeting. The use of dive computers by working (commercial inshore) divers in Norway to determine decompression status is not currently authorized by the legislative body, the Norwegian Labour Inspection Authority. The objectives of the workshop were to devise recommendations for the process of dive computer validation. Dive table and dive computer validation procedures were considered along with their applicability for commercial diving operations. Current European Union validation standards were reviewed, and the lengthy process of validation of the U.S. Navy dive computer explained involving man-dive testing of algorithms using decompression sickness (DCS) as an endpoint. Results from examinations of dive computer algorithms using a test chamber documented a relative conservatism among those dive computers tested. The use of venous gas emboli as an alternative to DCS as measurable endpoint for validation of dive computers was considered. Data were presented on recreational dive computer use and a dive computer management system for scientific divers was outlined. Discussion of presented data resulted in a set of consensus findings and recommendations that were presented to the Norwegian authorities.

Keywords: algorithm, CE marking, DCS endpoint, dive computer, normatives, personal protective equipment, validation

Introduction

Dive computer 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, through to the 2012 VR3 dive computer that is programmable for air, enriched air nitrox, mixed gas, and rebreather use. 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). Incidence data available for dive computers is drawn from recreational divers usually diving within no-stop limits. However, dive computer effectiveness in providing real-time guidance on decompression status and ascent rate monitoring has been established since 1983.

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The main problem with algorithms in dive computers is in their disability to 'guarantee' safety to their users, and the legislative bodies who have a duty of care to workers. Lang and Angelini (2009) represented that it would not be unreasonable to state that regardless of the number of algorithm variations incorporated in modern dive computers, they all appear to fall within an acceptable window of effectiveness based on the available databases of pressure-related injuries.

Here lies the predicament: there are millions of recreational and scientific dives performed each year that are successful and without incident. Despite this acceptance, the use of dive computers is prohibited in commercial diving operations. The path to commercial acceptance of dive computers is mostly thwarted by economics, i.e., the manufacturers do not want to put their product through the costly and time consuming process of official validation, while governing bodies will not accept their dive computers for a specific purpose until a pertinent validation process has been documented.

The emphasis of this paper is to review and provide considerations for the validation of dive computers for use by working (commercial inshore) divers, with a particular focus on the profiles for 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). 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. 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.

**Methods**

*Dive computer validation procedures*

It is important to differentiate between the terms 'validation' and 'verification', both of which are fundamental in evaluating dive computers. 'Verification' determines that a dive computer functions correctly, i.e., it executes its inbuilt algorithm, while 'validation' confirms that the algorithm performs at the accepted level of risk. 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) and it is implicit that in order to validate a dive computer for use, one must first define its functionality.

The dive computer should allow a diver to perform the chosen dive profile without any adverse effects upon decompression. As it is worn by the diver and therefore exposed to the same depth changes in real time, it should calculate decompression for multi-level pressure exposures and in this way is not tied to the 'square' profiles prescribed by dive tables. It should take into account breathing gas and temperature when calculating decompression and record the time/pressure and gas profiles.

Dive computer validation consists of a number of steps (Hamilton, 2012):

1. **Consideration of ergonomics.**
   Most importantly, the dive computer interface should be clear and provide unambiguous information to the user, particularly if errors occur. It should be intuitive to use and comfortable to wear. It should be rigorously leak tested to avoid malfunction within the battery compartment and circuit board in particular.

2. **Model function and algorithms.**
   Function is dependent on the algorithm that the dive computer uses to calculate the decompression requirements. Therefore, validation may be carried out similarly to that of dive
tables. 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.**
   The dive computer should be put through its paces in simulation mode. The results can then be compared carefully to benchmarked reference tables and judgment applied as to acceptability.

4. **Field testing.**
   When testing a dive computer, relatively few or quite a lot of profiles can be used. Judgment at this stage determines how many profiles are required to declare a profile as safe.

What is apparent is that 'judgment' needs to be applied throughout the validation process. Exactly how judgment of what is acceptable is agreed upon is important, because many of these decisions are not simple or obvious. A judgment panel should oversee the validation process, with their principal function determined in the developmental phase. In the later stages, a higher order of control might be beneficial: in the U.S. Navy this is called 'configuration management'. In this way, a broader perspective can be provided, perhaps outlining different goals for the dive computer. If possible, the most beneficial mix of panelists throughout the process will include scientists, business people (if the development is commercial) and independent analysts, in order to focus and authenticate the process. It is imperative that the final distributed product has not been changed from the original, validated version, so the 'configuration management' board should oversee distribution and determine that any changes have been authorized.

The validation process and the integration of judgment principles were outlined by Elliott (1989) at a previous dive table validation workshop and is illustrated by Figure 1.

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."
Dive computer validation considerations
Dive computers are standard pieces of equipment in recreational, scientific, and military diving. 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. In scientific diving, guidelines were established that allow researchers to utilize dive computers in their research (Lang and Hamilton, 1989), and dive computers have been specifically developed for military diving operations (Butler and Southerland, 2001; Gault, 2006; 2008). However, in the commercial diving community dive computers have to date not been utilized to the same extent.

For this type of diving, a dive computer poses a number of benefits over tables. Use of a dive computer makes a dive more flexible: it allows dives of unlimited and arbitrary complexity and still provides a decompression solution (W. Gerth, pers. comm.). Multi-level dive calculations can be produced, without the limitations of the “maximum depth for the entire bottom time” rule that accompanies tables. In addition, the decompression calculations are based on the actual depth of the dive, without the need to round to the next deeper depth, 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 (Huggins, 2012).

However, 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 a safety margin 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 (Huggins, 2012). Additionally, there is the potential for dive computer electrical or mechanical failure and user error.

There has been very limited human subject testing of dive computers, meaning that most support for their use has been due to their operational success in the recreational and scientific diving communities. Yet operational safety does not translate to decompression algorithm safety, since most dives performed do not push the algorithms to their limits, according to recreational diving community records (Huggins, 2012). There is a need for a method to evaluate the associated decompression risk of dive computers for commercial diving use. The simplest method of understanding some of the operational benefits that result from dive computer over table use is to simulate dives using dive computer software and then compare the generated profiles to validated, i.e., known outcome, tables. If the results are very similar, then the risk of DCS should be approximately equal.

Studies at the USC Catalina Hyperbaric Chamber ran dive computers against a group of dive profiles that had been tested with human subjects, or had 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).
Table 1. Risk rating versus dive computer response to profile (from Huggins, 2012).

<table>
<thead>
<tr>
<th>Dive Computer Decompression Requirements</th>
<th>Profile Risk Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>“High” Risk</strong></td>
<td><strong>“Moderate” Risk</strong></td>
</tr>
<tr>
<td>DCS</td>
<td>No DCS</td>
</tr>
<tr>
<td>High VGE</td>
<td>Low to Moderate VGE</td>
</tr>
<tr>
<td><strong>“Low” Risk</strong></td>
<td><strong>Algorithm too Liberal</strong></td>
</tr>
<tr>
<td>No DCS</td>
<td>Moderate Risk</td>
</tr>
<tr>
<td><strong>Less than tested profile</strong></td>
<td>Algorithm risk &lt; profile risk</td>
</tr>
<tr>
<td>Algorithm too Liberal</td>
<td>Unknown Risk</td>
</tr>
<tr>
<td>High Risk</td>
<td>Algorithm risk &lt; profile risk</td>
</tr>
<tr>
<td>Less than tested profile</td>
<td>Algorithm risk &lt; profile risk</td>
</tr>
<tr>
<td>Greater than tested profile</td>
<td>Algorithm Conservative</td>
</tr>
</tbody>
</table>

On the “high risk” decompression dive, none of the computers tested would allow the profile to be performed and, therefore, none received a ‘high risk’ rating. All of the computers 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. 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 because the outcome of following these dive computers to their limits had not been tested. What is unknown is the risk associated with following the dive computer decompression schedules, since those profiles have not been tested.

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 subject tests and could provide a rudimentary baseline for dive computer comparisons. Note that in Table 1 half of the cells indicate “unknown risk.” Estimates of these unknown risks could be made without human subject 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. If such risks were established, then 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.

**The need for dive computer validation, normatives and standards**

Although dive computers are now universally accepted for recreational diving, their permissible use in commercial diving varies between countries and industrial sectors. Many countries, such as Norway, legislate against their use because of a lack of information as to how different models compute decompression. The perception of a lack of verifiable safety stems from the absence of standards or normatives specifically for dive computers that would allow assessment of their functional safety.

The topics discussed at the AAUS Dive Computer Workshop (Lang and Hamilton, 1989) included which decompression models should be used, how validation should be carried out, what the acceptable risks were, what limits should be imposed on dive computers, what should happen in the case of a dive computer failure, and operational reliability. Most of these questions are still not answered in 2012 for past or present dive computer models, and continue to form the basis for study. In 1989, the need for standardization of dive computers was recognized and normatives were suggested by Ralph Osterhout (Lang and Hamilton, 1989) 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 dive computer is in a failure mode, incorporating tests of both
   the hardware and software.

Sieber (2012) described functional safety as part of the overall safety relating to the system under
development; 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 dive computer
functional safety, this not only means that the device performs according to the requirements, but also
that in case of a failure, no harm occurs.

Is a dive computer a safety-critical system (Sieber 2012)? A dive computer 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 and scientific divers value the
features of dive computers that provide continuous tracking of tissue tensions and are able to calculate
decompression schedules with wide flexibility. As many divers depend completely on a dive
computer while in the water, it is obvious that if incorrect indications are given, DCS, or in worst
case, even death, can occur. Therefore, the dive computer is a safety-critical system. This conclusion
is also strengthened by a large number of manufacturers categorizing their dive computers as personal
protective equipment (PPE).

Within the European Union, CE marking of products is a key indicator of a product’s compliance
with the EU legislation requiring the protection of the public interest by having safe and reliably
functioning products in the common market. Dive computers are an indispensable means to ensure
the health and the safety of divers. However, as a product, they do not fall into any of the broadly
formulated product groups covered by the Directives that require CE certification, yet certification is
necessary because several of their components have to be CE certified. Herein lies part of the
complex problem in devising 'global' standards and normatives for dive computers (Sieber, 2012).

It is the manufacturer's responsibility to identify the set of standards that the product has to meet and
then assess the conformity of the components. Risk assessment is a key component of this stage and
documentation detailing the checks made has to be compiled. The manufacturer also has to assess
whether a 'Notified Body' has to be involved to achieve certification, but ultimately, it is the
manufacturer that affixes the CE marking to their product, and thus assumes the sole responsibility
for compliance, and therefore also liability in the case of an accident.

Inspection of the dive computers sold in the European Economic Area and their user manuals (Table
2) 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 (Sieber,
2012). The safety of dive computers 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. Second, they fail to perform tests on crucial parts covered by other
Directives. However, manufacturers often wrongly seek compliance with requirements for a product
that they do not integrate in their dive computer.
Several standards are currently applied to dive computers but there is no obligatory standard written specifically for dive computers to meet, nor any suggestions concerning their validation. It is only when a dive computer is integrated with a cylinder pressure gauge that it has to be certified according to EN250 and the PPE Directive become mandatory. A number of the directives and standards that can be applied to dive computers/components are listed below:

1. The **EMC directive** (89/336/EEC): applies to electrical appliances, requires that they neither cause electrical interference, nor are susceptible to it;
2. **EN250:2000**: a standard for respiratory equipment, falling under the PPE directive;
3. **EN13319:2000**: addresses depth gauges and depth/time measuring devices. Decompression obligation is explicitly excluded;
4. **PPE Directive 89/686/EEC**: aims to harmonize products ensuring a high level of protection and safety throughout Europe. Surprisingly, dive computers, 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. 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 dry suits (EN14225-2:2005); and,
5. **ISO9001**: general quality assurance standard; not a specific safety standard.

As a rule, CE marking certifies compliance of a product as a whole unit with the essential safety and health requirements of the Directives that require CE marking. It is beneficial because it boosts confidence in the products circulating within the common market and creates trust that corporate compliance and control procedures are in place and functioning. However, it insinuates that the ‘whole’ dive computer, not just constituent parts, is certified and this may not always be the case. Therefore, there is a need to unify the requirements for safety performance of dive computers as a whole unit. In the case of a diving accident, the CE mark also shifts the burden of proof of non-conformity and non-reliability away from the manufacturer to the consumer, making it difficult for divers to plead their case in court. Thus, a consolidated standard for DC safety should level the playing field between manufacturers and consumers.

<table>
<thead>
<tr>
<th>Manufacturer/Model</th>
<th>CE mark</th>
<th>Air integ.</th>
<th>EN250</th>
<th>EN13319</th>
<th>PPE 89/686/EEC</th>
<th>EMC 89/336/EEC</th>
<th>other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uwatec Galileo Sol</td>
<td>CE0474</td>
<td>wireless</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Uwatec Aladin Tec 2G</td>
<td>CE0474</td>
<td>-</td>
<td>NA</td>
<td>y</td>
<td>Y</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Mares Nemo Escal</td>
<td>CE</td>
<td>NA</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Mares Nemo Air</td>
<td>CE0426</td>
<td>Y</td>
<td>y</td>
<td>no</td>
<td>Y</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Suunto D9</td>
<td>CE0430</td>
<td>wireless</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>ISO 9001</td>
<td></td>
</tr>
<tr>
<td>Suunto D4</td>
<td>CE0430</td>
<td>-</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suunto Cobra 3</td>
<td>CE0430</td>
<td>-</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cressi Sub Archimede 2</td>
<td>-</td>
<td>NA</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Oceanic</td>
<td>CE0120</td>
<td>-</td>
<td>NA</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Apels Quantum</td>
<td>CE</td>
<td>-</td>
<td>NA</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Delta P VRX</td>
<td>CE</td>
<td>-</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>EN14163</td>
<td></td>
</tr>
<tr>
<td>Seeman XPS</td>
<td>CE</td>
<td>-</td>
<td>NA</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Cochran EMAC-20H</td>
<td>-</td>
<td>NA</td>
<td>y</td>
<td>no</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tusa IQ950</td>
<td>CE</td>
<td>wireless</td>
<td>no</td>
<td>y</td>
<td>no</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Tusa IQ900</td>
<td>CE</td>
<td>-</td>
<td>NA</td>
<td>y</td>
<td>no</td>
<td>Y</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Visual inspection of some dive computer models and their manuals for CE mark and normative/directive compliance (NA: not applicable). From Sieber et al., 2012.
CE marking and compliance also impacts on competition between the DC manufacturers. CE self-assessment and verifications by a Notified Body contribute considerable expense 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 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 U.K., for example, depending on the gravity of the violation, imprisonment might be likely.

As a proposed method of consolidation (Sieber et al., 2012) offers two suggestions:

1. Include dive computers in the PPE directive under category III. This would make application of good manufacturing practices mandatory for dive computer 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; and,

2. Draft a normative, specific to dive computers. Rather than being design restrictive by describing a “golden (algorithmic) model for decompression theory” we believe that one should address functional safety. In this regard it would be helpful to reference EN61508, which reduces risk in safety critical systems. Because this is a broad standard, derivation or tailoring would be necessary in order to enable small developers’ teams to fulfill certification requirements.

Risk and hazard concerns associated with the use of a device allow the comparison of dive computers to medical devices. Therefore, normatives for medical devices such as IEC62304, ISO14971, and ISO13485 could also be used as a model for drafting a normative specific to dive computers. When it comes to a failure, Sieber et al. (2012) also suggest that the safety status of the dive computer must be displayed, in an unambiguous manner, to the diver. This is not a new suggestion, but has still not been implemented. It would be useful if committees that draft and define these standards have participation not only from manufacturing and legislative bodies, but also from consumer groups and diving medical staff, in order to consider a broad perspective of dive computers and their use.

Validation of dive computer algorithms
Recreational, technical, scientific, commercial and military diving vary in type of exposures and equipment used, but all have in common a low DCS incidence rate and, by and large, rely on decompression schedules evolved from the original compartment model. The safety record of table use by commercial and military divers is very good. Compared to recreational divers, these divers are usually more extensively trained, fit and more focused on a particular task with a reduced chance of making errors. As discussed above, when tables are utilized during dives that are not square in profile, an intrinsic conservatism is automatically introduced. However, the conservatism of tables is often costly in terms of (operational) time.

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 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.

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 \textit{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 a study by Angelini (2012) was to collect a number of relevant computers from the market and analyze their behavior when subjected to a large number of profiles. The computers included:

1. Cochran EMC-20H;
2. Cochran NAVY AIR III;
3. Delta P VRX;
4. Mares Puck;
5. Suunto Vyper Air; and,
6. Uwatec Aladin Prime.

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 attempted to assess the range of options and provide a guideline for future, separate studies, including human trials, from which judgments on safety could be derived. Two hundred thirty four chamber test dives were carried out with profiles ranging from square to triangular, multilevel forward and multilevel reverse, to a maximum depth of 54 msw with air as 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.

The VVAL-18 implemented in the Cochran Navy AIR III is supported by a wealth of documentation describing the validation performed by the U.S. Navy (Doolette et al., 2012). No significant details were provided by any of the other manufacturers about the decompression algorithms incorporated into their dive computers.

Of the very wide offering of dive computers on the market today a representative portion was sampled. Angelini (2012) found that while some computers are more conservative and some are more liberal, there were several in astonishing agreement throughout all tested profiles, especially when it came to the first dive of a series (non-repetitive dive). Furthermore, this agreement was found within the three brands that cover well over 50% of the worldwide market. Given the millions of dives performed every year using these computers, and the very low DCS incidence rate in recreational diving, one might infer that there is such a thing as a standard reference. Most of these dives, however, fall far short from stressing the underlying models, so a conclusion as to the actual conservatism, or lack thereof, cannot be reached in any of these computers. Repetitive dives with short surface intervals (one hour or less) provided less agreement between the various computers, even among the three that otherwise agreed extensively. Angelini (2012) concluded that whereas a relatively standard Haldanean implementation was at the core of these computers, different types of mathematical manipulations were employed to account for residual nitrogen. This indicates that the true impact of residual nitrogen is not fully understood.
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. 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. 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 (Angelini, 2012).

**U.S. Navy dive computer validation**

If on diving under water, gases in the tissue reach a supersaturated state, then upon decompression bubbles may form and there will be potential for DCS to occur (Doolette et al., 2012). In order 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. Practical decompression algorithms balance the probability of DCS ($P_{DCS}$) against the costs of time spent decompressing. Modern, diver-carried dive computers sample ambient pressure 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 it provides decompression profiles with a low incidence of DCS. For the military and commercial communities, decompression should also be efficient, because time spent decompressing is unproductive (costs money) and prolongs exposure to a hostile environment. Requirements will be specific to diving practices and to particular populations of divers because no decompression algorithm is suitable for all types of diving. Validation of a system such as a dive computer is simply a demonstration that it matches its requirements, so it should entail measurement of the incidence of DCS, or estimation of $P_{DCS}$ by some other method, associated with its decompression guidance (Doolette et al., 2012).

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 decompression algorithm by comparison of the dive computer behavior to 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.

The 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 $pO_2$. The history of the development of the original NDC is reviewed in Butler and Southerland (2001).

Doolette et al. (2012) described the VVal-18 Thalmann algorithm as a neo-Haldanean decompression algorithm, similar to many implemented in dive computers. Inert gas uptake and washout is modeled for a set of parallel tissue compartments, but it differs from earlier algorithms in that washout can switch from a normal exponential approach to a much slower linear approach when a compartment is supersaturated, which provides appropriately extended decompression times.
The development process included testing the algorithm via 1,505 air and nitrox 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 more 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 N2-O2 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 of 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). In carrying out these manned dives, the algorithm was validated under operationally relevant conditions that demonstrated acceptable $P_{DCS}$.

The NDC was then tested to verify that it was operating on a faithful implementation of the Thalmann Algorithm. This was done using functional testing of NDCs, and comparing their behavior to “gold standard” decompression schedules (Doolette et al., 2012). These gold standards exist in two forms: the gold standard printed VVal-18 Thalmann Algorithm decompression tables (Thalmann, 1984) and the 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 NDC and is convenient for generating multilevel dives and decompression schedules of any complexity against which to test the NDC.

Finally, a sample of 10 to 30 of each configuration of the NDC was functionally tested by exposing them to simulated dive profiles in a small, flooded test chamber and comparing the NDC prescription to the gold standard Navy Dive Planner decompression schedules (Southerland, 2000; Gault and Southerland, 2005; Gault, 2006; Southerland et al., 2010). Doolette et al. (2012) describe this type of functional testing as “black box” testing because the tester has no access to internal data structures and computer code. It is essential that black box testing uses a suite of dive profiles that exemplify all expected operational uses of the dive computer. 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.

When using decompression tables, schedules are selected on the maximum depth reached 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, which calculate decompression debt in real time. As a result, dive computer guidance is generally expected to present greater risk of DCS than using printed tables calculated using the same decompression algorithm.

Doolette et al. (2012) reported that the U.S. Navy had not collated data on the incidence of DCS using NDCs; to date, the NDCs have been used principally to keep dives within no-stop limits, with little DCS expected and none 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.
The U.S. Navy experience with validating NDCs can serve as a general guide for validating a commercial-off-the-shelf (COTS) dive computer as illustrated in Figure 2 (from Doolette et al., 2012). For practical purposes, this framework may need to be modified for a COTS dive computer. Validation must occur within a configuration control framework, or via a 'configuration manager' (represented by the diamond in Figure 2), that ensures re-validation if any changes are made to the dive computer software or hardware configuration after it has initially been brought to market.

**The use of venous gas emboli to validate dive computers**

Many decompression models use 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 particularly 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 subjected to. In this way, VGE can be used as a tool to help in the validation process.

The task of validation should be as simple as testing whether the computer provokes DCS or not, and complete enough dives to determine a certain level of risk. However, many dives are necessary primarily as DCS is such a rare event. The U.S. Navy NDC validation process was both lengthy and costly, as such a large number of human dives had to be made to test the algorithm incorporated (Doolette et al., 2012). Gerth and Vann (1996) suggested that a suitable acceptance of DCS incidence was two cases in 142 trials, which would impart a 0.17 - 5% risk of DCS. However, it is very unlikely that the Norwegian Authorities would ever accept a 5% risk of DCS, even in the initial stages of a trial, meaning that the level of risk needs to be reduced even further. To do this, far more dives would be necessary. Gutvik (2011) claims that to achieve a 1% risk at a 95% binomial confidence level, 369 symptom-free dives would have to be made, and if one DCS hit were recorded, the total would rise to 558 dives. If it is accepted that around 500 dives are needed to test one profile in order to bring it to an acceptable level of DCS risk, then it becomes apparent that a huge number of dives are necessary, as more than one profile needs to be tested on the computer.

Many dive profiles would need to be tested, including shallow long exposures, deeper shorter exposures and multilevel dives, but a conservative estimate of the number of bottom time/depth exposures that need to be tested might come to approximately 10 permutations (Gutvik, 2011). Workload and where the work is performed (bottom phase/deco phase), water temperature and insulation, repetitive exposures and type of gas all need to be taken into consideration. Gutvik (2011) suggested that if five different values for each of these parameters were tested, then the total number of dives that should be performed could be calculated as 500 (dives to test one profile) x 10 (profiles) x 5 (workloads) x 5 (temperatures) x 5 (gas types) x 5 (repetitive exposures) = 3,125,000 total dives to be made. After this, multilevel exposures should also be taken into account, including triangular dives, recompression spikes, yo-yo diving and the like. There are so many variations that would need to be tested on the computers that it is simply impossible, so a different approach is necessary. Blogg and Møllerløkken (2012) suggest that perhaps measuring VGE would help resolve the problem.
U. S. Navy Dive Computer

1. Define Requirements
2. Validate Decompression Algorithm (Manned-diving)
3. Verify NDC implementation

Yes
Configuration changes?

COTS Dive Computer

1. Define Requirements
2. Validate P_{DCS} model
3. Validate Dive computer schedules (P_{DCS} estimates)

Yes
Configuration changes?

Figure 2. Outline of validation of the U.S. Navy Dive Computer and a proposed framework for validation of a COTS dive computer (from Doolette et al., 2012). 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 algorithm and then evaluated using the probabilistic decompression model.

Historically there has been dispute over the relationship between VGE and DCS, but it can be summed up by saying that ultrasonic measurement of VGE has a higher sensitivity with a very low specificity. Efthdal et al. (2007) opined that the data strongly suggest that for some saturation diving the absence of detectable bubbles is a good indicator of decompression safety, but the occurrence of bubbles, even higher grades, is a poor predictor of decompression sickness. Gutvik (2011) argues that in order to exploit the characteristics of the VGE, a method based on Bayesian statistics be used. It essentially uses a priori statistics on VGE and DCS to analyse VGE-only data for DCS risk, greatly reducing the number of test dives that have to be made. It should be noted that when carrying out trials using this method there is often no occurrence of DCS, so if validation were to be made from the point of view of DCS, then obviously nothing would be learned at all. Previously established relationships can be used to determine point risk estimates of the exposures and also credibility intervals that are narrower than looking for DCS exclusively (Gutvik, 2011). In this way, the higher sensitivity of the VGE measurement can be exploited. The point of the Bayesian method is to gain an accurate prediction with as low a sample size as possible. Success does depend to some extent on drawing a fortuitous subset from pre-existing data, but it seems that far less exposures are necessary to draw the same conclusions.
If the number of dives that have to be made to validate this method were reduced significantly, a huge number of dives would still have to be made. Weathersby et al. (1984) worked with probabilistic modeling. Instead of specifically validating a procedure, computer or schedule, this method attempted to predict the behavior of a model and it is now used by the U.S. Navy to predict risk of DCS, P(DCS). There are several obvious advantages: the first is that any type of dive can and should be included for calibration. Historical data can be used, while a predictive model also provides a better risk assessment and gives a more consistent risk of control because optimal procedures can be used (Gutvik, 2011). The disadvantages include that a significant amount of DCS data must be present in order to make the predictions valid, because if there is no DCS, even huge amounts of data will not reveal anything. Another disadvantage is the lack of diversity in the historical data that is available, which makes it difficult to assess entirely new decompression profiles.

Gutvik (2011) hypothesized that the high sensitivity of VGE could be exploited in a probabilistic model to better effect than DCS occurrence. This is the reasoning behind the Copernicus model, which, instead of predicting the risk of DCS, predicts the amount of VGE produced after any dive exposure. The problem is viewed via a physiological approach and a model produced to predict VGE load using parameter estimation. The set of parameters to be defined by the model are identified, the model is excited with a specific exposure, a measure is made and the outcome can then be estimated. In the case of Copernicus, the endpoints of this exposure are VGE. The model estimation of VGE can then be compared with actual measurements and a large range of exposures used to calibrate the model. The aim is to draw a map comparing the real world outcome and the model. The crucial factor with this kind of predictive modeling approach is that for best results, the model should be excited with as much diversity as possible. If the model is not excited enough, then it will give a perfect fit to the limited data it is tested against, but will start to fail the moment that it is extrapolated.

It must be noted that the use of VGE could lead to excessive conservatism within a model. If the ultimate goal is to dive to a certain level of DCS risk, bubble loads are indicative of decompression stress, but there exists no definable linear relationship with DCS occurrence. A consensus agreement on endpoints, whether they are occurrence of DCS or degree of VGE load, remains elusive. For models such as Copernicus, at some point a bubble grade will have to be agreed upon as an endpoint, so that a level of conservatism will be implicit that is not binary in nature (Gutvik, 2011). For example, Defence Research and Development Canada (formerly DCIEM) has selected a limit of Kisman Masurel (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%, while 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. Therefore, in some cases it is anticipated that decompression profiles may be discarded when using a VGE endpoint that otherwise might have been accepted if using DCS, albeit having had to perform many more dives to reach that outcome. However, if the aim is to test different algorithms or dive computers against one another, to find the one that provokes the least physiological decompression stress for a particular depth/bottom time combination, then this approach would be ideal (Gutvik, 2011).

**Dive computer program management**

Dive computer validation procedures, normatives and standards, and algorithm validation provide the foundation that allows Diving Control Boards to consider approval of dive computer use by scientific divers. There is an operational need for an ongoing, systematic, methodical monitoring of dive computer use by scientific divers. An exemplar of dive computer program management by a scientific diving program is provided here.
Lang (2012) described the Smithsonian Scientific Diving Program (SDP) as a large U.S. civilian scientific diving program through which, since 1990, approximately 140 active scientists logged over 3,400 dives annually in a multitude of locations around the world. In 2005, the need was identified to develop a management tool to assist in compiling and monitoring diving activities: a web-based virtual dive office, DECOSTOP. Launched in 2007, it 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. 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. In the future, it may be beneficial to look at the percentage loading of the model (i.e., how far a dive profile pushes the algorithm towards its limits) and add this functionality to the software.

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. 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. It is strongly recommended that each diver also dive with a back-up dive computer, because they do occasionally fail. 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 msw 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 PO\textsubscript{2} 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 dive computer limits, blindly trusting the dive computer (i.e., the brain still needs to be turned on to make decisions from the dive computer numbers being displayed), ignoring decompression requirements, continuing to dive with a dive computer 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.
Much consideration was given to the selection criteria of a dive computer that would meet scientific diving needs. Dive computer operation should be effortless through easy-to-use push buttons, wet switch activation and a straightforward menu-based user interface. A dive computer with metric/imperial unit option, date and watch function of 12/24 hours, water resistance to 100 msw and light weight were prioritized features. A bright phosphorescent LCD display and an option of wrist unit or console-mount 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% O₂ and adjustability for partial pressures of oxygen (pp O₂) 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 dive computer 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, dive computer operating temperatures should range between 0°C to 40°C, and have a storage temperature between -20°C to 50°C. Other functions had to include altitude adjustability, ascent rate monitor, dive planner, decompression data, log book memory, maximum depth of 100 msw, 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. Scientific divers are required to log all dives via dive computer 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. It is recognized that it would be preferential if dive computer manufacturers standardized their dive profile download software for all dive computer types.

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.

Discussion

The EUBS Validation of Dive Computer Workshop (Blogg et al., 2012) involved discussion leading to a set of consensus findings and recommendations that were delivered to the Norwegian Labour Inspection Authority. General community-specific requirements were outlined as follows: acceptance that at present decompression sickness is the measurable negative outcome; specification of an acceptable level of DCS risk and how it is measured; definition of a window of applicability for the dive computer; requirement of the support of a dive planner for the dive computer; and, the need for documentation and verification of equipment functionality/functional safety.
The Workshop agreed on specific findings applicable to commercial diving: A dive computer 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 because the dive computers are not pushed to their model or algorithm limits. There is no evidence that multi-level dives with dive computers are more risky than square dives following the same algorithm; documentation of theory (i.e., logic and equations) is required to answer what’s in the box?; this documentation must include methods to test the implementation of the theory in the dive computer; use a DCS-risk indicator model to validate the algorithm, or manufacturers may produce a dive computer with a validated and documented algorithm; specify platform technical requirements; and, develop and implement a configuration control plan.

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

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