<u>ambient pressure diving</u>



www.apdiving.com info@apdiving.com

Customer Information Notice:

27th November 2008

Rebreather Certification and Marking

We have recently reviewed the Inspiration and Evolution technical documentation with the products' Notified Body, SGS United Kingdom Ltd. The primary role of a Notified Body is to provide services for conformity assessment on the conditions set out in the European New Approach Directives in support of CE marking. This involves assessing the manufacturers conformity to the essential requirements listed in the relevant directives.

The review confirmed that the original decision to certify the Inspiration and Evolution rebreathers under Article 10 (EC Type Examination) of the Personal Equipment (PPE) Directive was correct. EC Type Approval was granted on the APD Manufacturer's Technical Specification and satisfactory user trials. The Technical Specification was based on the "Respiratory equipment-Self-contained re-breathing diving apparatus" standard EN14143:2003 excluding part of clauses 5.6.1.3 and 5.8.8. The products met the Basic Health and Safety Requirements (Annex II) of the PPE Directive 89/686/EEC.

The work of breathing requirements in the rebreather standard are harsher than any other European EN standard including EN250, (regulators) and the EN15333-1 and 2 (umbilical supplied apparatus) in that they test up to 75 litres per minute, as opposed to 62.5, but the same physiological limits are applied.

What are clauses 5.6.1.3 & 5.8.8?

5.6.1.3 Peak Respiratory Pressures

'The peak to peak respiratory pressure shall not exceed 50 mbar. The inspired and expired respiratory pressures shall not exceed 25 mbar each.'

The APD products' peak to peak pressure is less than 50 mbar at all specified breathing rates. However, the inspired and expired pressures exceed 25 mbar at the higher breathing rates, (in excess of 63 lpm)

The inspired and expired limits (b and c, figure 1) are taken straight from the regulator standard because agreement could not be reached during the final drafting of the standard between the experts.

An open circuit breathing loop is always at ambient pressure at end of inhale and end of exhale, so the breathing loop looks similar to that depicted in figure 1. With open circuit it is easy to see how much effort is expended on inhale compared to exhale.

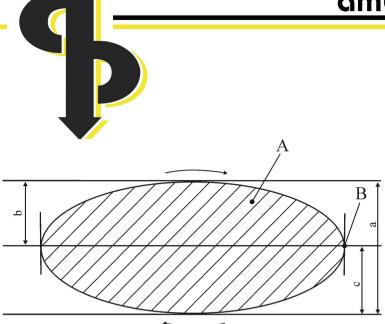
Manufacturers of the Inspiration and Evolution closed circuit rebreathers

Ambient Pressure Diving Ltd Water-ma-Trout Industrial Estate Helston Cornwall TR13 OLW UK Tel: 01326 563 834 Fax: 01326 565 945





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Figure 1 – Analysis of pressure volume loop (open circuit)

However, a rebreather breathing loop always has a slope because you are breathing in and out of a bag and the work of breathing loop will look similar to that depicted in figure 2. While it is easy to see the peak to peak pressure (a) and understand the limit must be 50 mbar, it is still under discussion whether it is realistic for the inspired and expired respiratory pressures to be less than 25 mbar.

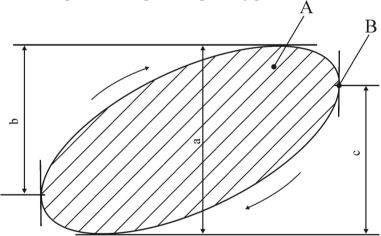


Figure 2 – Analysis of pressure volume loop (closed circuit)

Key

- a) Peak to peak respiratory pressure
- b) Peak expired respiratory pressure (end inhalation to peak exhalation)
- c) Peak inspired respiratory pressure (end exhalation to peak inhalation)
- A) WOB

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B) Reference point of hydrostatic imbalance; end of exhalation ("no flow")

There is also discussion over whether point B is in fact the end of exhale and as a result of this and other discussions EN14143 contains the following statement in the introduction and was put in for immediate review:

'The production of the standard has raised new questions regarding the interpretation of the physiological and equipment acceptance limits for the diving application which have not been fully answered. However, this standard has been published to provide a level of safety for re-breathing diving apparatus.'

Due to committee workload the review of the standard did not start until 2008

Approval was recommended by SGS as peak to peak values and work of breathing comply with the standard at all specified breathing rates, with extremely low hydrostatic imbalance and it is only the Inspired/Expired respiratory pressures which are exceeded at higher breathing rates.

5.8.8 Hose Elongation Test

'The hose shall not collapse and the elongation shall be at least 10 % and not greater than 30 % after applying a force of 10 N to the hose assembly for a period of 5 min.'

Our convoluted hose elongated by 7.1% but due to satisfactory user trials, approval was recommended.

Compliance to EN14143

Under the new approach directives, conformance EN14143:2003 is not mandatory. However, this review identified that the User Instruction Manual included an incorrect statement that the products fully met EN 14143:2003. The rebreather case markings also incorrectly make reference to EN 14143:2003.

In response to the issues raised above we have amended the Rebreather User Instruction Manual and case markings.

- 1. Page 7 in the User Instruction Manual has been amended to exclude full compliance to EN14143. The latest edition of the rebreather manual is available to download from the company's website: http://www.apdiving.com/downloads/manuals/
- 2. Reference to EN14143 has been removed from the Rebreather cases.

Please contact the factory if you have any problems downloading the latest manual or have any questions.

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