Use of Nonmetallic Braid Reinforced Flexible Membrane Multiple Occupancy Vessels under PVHO-1: 2012

Approval date: September 2, 2014
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Inquiry: Under what conditions may non-metallic braid reinforced flexible membrane multiple occupancy cylindrical hyperbaric chamber systems be constructed under the rules of PVHO-1: 2012?

Reply: It is the opinion of the Committee that non-metallic braid reinforced flexible membrane multiple occupancy cylindrical hyperbaric chamber systems may be constructed under the requirements of PVHO-1-2012 and be marked as a PVHO, when the requirements of PVHO-1-2012, with the following exceptions and additions, have been met.

Note: Case 12 relates to similar PVHOs, but of different construction. PVHOs built to Case 12 all have equally spaced multiple clamp plates that enable the flexible tube ends to be deformed for insertion of the circular end door/window assemblies. PVHOs included in Case JJ are designed to have full circumferential clamp rings as part of the end frames. Insertion of the entry door/window assemblies is through oval openings in the end frames.

1. GENERAL

The Case covers similarly designed and constructed cylindrical PVHOs. The PVHOs shall be of single or dual compartment construction. The allowable configurations are shown in Table 1 below. The PVHO systems are not intended to be moved, either with or without occupants, when pressurized.

The PVHOs shall be designed, constructed, inspected, tested, marked and certified to ASME PVHO-1-2012 Sections 1 - 6 with exceptions and additions as detailed in this Case.

The metallic parts shall fully comply with ASME PVHO-1-2012 both in materials and in its design. Each compartment shall have a removable entry door incorporated in a door frame. The entry door shall incorporate an acrylic window to each compartment, sufficiently large for the operator to clearly view the general medical condition of each occupant of the PVHO. The viewport design and construction shall fully comply with Section 2 of PVHO-1-2012. Each entry door shall incorporate a release-able hinge and bracket arrangement to connect it to the entry frame. Ancillary items of equipment that make up the PVHO system shall also meet ASME PVHO-1-2012 requirements. There shall be no welding of structural components of the PVHOs. All detachable sub-assemblies shall be easily identifiable as being a part of each individual PVHO system.

The flexible shell of each PVHO compartment shall comprise a liquid crystal polymer (LCP) braided fiber tube. Rigidly retained on the inner surface of the braid is a double sided polymer coated fabric bladder. The PVHO shall be designed, built and tested to ensure that the bladder is only subjected to radial compressive loads on the braided tube. Both the braided tube and bladders shall be securely attached to the metallic parts at the extremities of each compartment. There shall be no penetrations in the pressure retaining sections of the braided tubes or bladders. Full detailed specifications for the non-metallic parts are defined in Section 2 of this Case.

A reinforced fire retardant double sided polymer coated fabric outer cover shall protect the flexible tube from wear, tear and ultraviolet exposure (sunlight). Important information concerning safety requirements of the PVHO shall be printed on the cover.

A Design Specification shall be developed and provided for each model.

The Design Specification shall meet the requirements of ASME PVHO-1-2012 Section 5 Medical Hyperbaric Systems and/or Section 6 Diving Systems as applicable, but be limited by the following design and performance parameters:

(a) The maximum allowable working pressure (MAWP) shall not exceed 81psig. (0.56MPa).

(b) The internal diameter shall be between 36in (91.5cm) and 72in (183cm).

(c) The maximum overall length shall not exceed 200in (508cm).

(d) The vessels shall have at least one removable entry door per compartment.

(e) The number of pressure cycles for the non-metallic parts is defined in Section 4.1 (b) and shall not exceed 4,000 cycles.

(f) The number of folding and unfolding cycles for the non-metallic parts is defined in Section 4.1 (f) and shall not exceed 3,000 cycles.

(g) The life of the LCP braid and bladder shall expire when the first of the following is reached: (1) 10 years from the date of manufacture, (2) On completion of the allowable number of pressure cycles, (3) On completion of the allowable number of folding cycles for storage.

(h) The design operating temperature range shall be from 0°F to 100°F (-18°C to 38°C).

(i) The design storage temperature shall range from -10°F to +150°F (-23°C to +66°C) using the storage containers supplied with the PVHO.
(j) The maximum number of occupants permitted in each compartment of the PVHO, as well as the total number permitted in the PVHO at any time, shall be clearly defined and be marked on the PVHO.
(k) There shall be one spare breathing gas supply connection in each compartment.
(l) The pressurizing gas shall only be air and a label to this effect shall be suitably displayed.
(m) Breathing gases shall be supplied to the occupants through BIBS masks or hoods with overboard dump facilities. Occupants shall be permitted to breathe chamber air, provided that the quantities of exhaled gases can be maintained at safe levels in each compartment.
(n) The operator shall ensure that sufficient gases are available for the use envisaged, for the number of occupants, for venting the PVHO if necessary, and have sufficient emergency gases to safely complete the proposed task.
(o) The owner/operator shall maintain a detailed log book relating to each PVHO that clearly records the number of pressurizations, the maximum pressure achieved, the duration, the date, location and the reason for each use (i.e. testing, training, therapy etc.) and record whether the PVHO was left assembled or packed in its containers after use.

The Design Specification shall also include the following parameters:

1. Pressurization/depressurization rates for each compartment.
2. Method of atmospheric control for each compartment.
3. Pressurization and breathing gas requirements for the PVHO.
4. Temperature and humidity parameters, if any.

The following sections/paragraphs of PVHO-1-2012 are not applicable to PVHO's built under this Case.
Section 1-6, 1-7.1 thru 1-7.3, 1-7.8 and 1-7.11 thru 1-7.16
Section 5-5.7
Section 6-3.1(b)

In the event of a conflict between any provision of PVHO-1-2012 not specifically exempted or excluded by this Case, the requirements of this Case shall govern. In cases where there is no specific requirement, exemption or exclusion in this Case, the provisions of PVHO-1-2012 shall govern.

2. MATERIALS

Materials shall meet PVHO-1-2012, para.1-6 PVHO Materials, with the following exceptions and additions:

2.1.1 The metallic components shall meet the requirements of ASME PVHO-1-2012 in full without exception.

2.1.2 Non-metallic materials of construction used in the manufacture of the LCP braid and bladder shall conform to Table 2 below. Both materials shall be used in combination to meet the performance requirements of this Case. The bladder material, as with all other non-metallic materials used in the PVHO, shall undergo careful selection to ensure that, in addition to its physical properties, resistance to ignition, fire retardancy, fire toxicity levels etc. are optimized through consultation, material selection, testing and risk analysis to ensure safe operation on the entire system throughout the pressure range of the PVHOs. This shall include a comprehensive Oxygen Hazards & Fire Risk Analysis (as per ASTM G63-99).

The intended use of these multiple occupancy PVHOs is for use in remote locations, associated with diving and for the treatment of other acute medical conditions treatable with hyperbaric oxygen. The unit comprises separate lightweight modules, each of which can be connected to the PVHO to produce a comprehensive PVHO system. A process control procedure in accordance with 5.7 shall identify how the materials are to be used and in what specific quantities. All materials used in the manufacture of the LCP braid and bladder shall be supplied with supporting documentation consistent with the requirements of the Quality Management System detailed in Section 5 of this Case. Each length of bladder material used in the manufacture of PVHOs under this Case shall be tested and shall meet or exceed the mechanical properties defined in Table 2. The use of alternative material shall require prototype testing. Material shelf life shall be identified as being suitable for long term storage between uses and shall not exhibit visual or performance deterioration through aging, for the entire life of the PVHO. The PVHO shall be stored in containers that prohibit dust, light and water ingress.

3. DESIGN AND MANUFACTURE

3.1 Design

The PVHO shall be designed in accordance with ASME PVHO-1-2012 and this Case.

3.2 Requirements

The design and manufacture of the PVHO shall be in accordance with the following requirements.

(a) A detailed stress analysis shall be performed by a professional engineer registered in one or more U.S. states, or the provinces of Canada, or licensed by any other country that has equivalent licensing procedures and who is experienced in composite pressure vessel design and construction. The stress analysis shall include full geometric modeling and a detailed finite element analysis of the PVHO to the requirements of ASME PVHO-1-2012. The loads applied by handles, straps and slings, as well as the position and weight of the occupants shall be considered.

(b) The design analysis shall consider the effects of folding, unfolding, and long-term storage of its components. The manner in which the PVHO's non-metallic components fold and unfold is of particular importance in view of the need to avoid scuffing from adjacent components, acute bending or by bending at less than the minimum bend radius of each component. A*cute bending* is defined as a bend in the LCP braid or the flexible membrane at an inside angle of less than 5 degrees. The minimum bend radius for the fiber or flexible membrane shall be no less than 0.05in (1.25mm).
(c) The design and manufacturing process shall produce a flexible shell such that its integrity shall not be compromised by the assembly, pressurization, disassembly, or storage of the PVHO.
(d) The maximum allowable working pressure (MAWP) shall be the lesser of 81psig (0.56MPa) or the MAWP determined by Statistical Analysis, Section D-7 of Appendix D of the Standard following the results of proof pressure testing.
(e) All load bearing handles, straps and slings shall be designed to meet the requirements of ASME B30.9 2010 or BS EN1492-1:2000 + A1:2008 and be labeled.
(f) Any changes to the design, geometry, size, materials or manufacturing procedures of the braid or bladder shall be cause for prototype retesting, unless it can be demonstrated to a Professional Engineer or a qualified independent third party agency, experienced in composite pressure vessel design, that the structural integrity of the PVHO meets or exceeds that of the PVHO which was prototype tested.

All prototype tests originally conducted shall be considered in the demonstration of structural integrity.

3.3 Design Certification

A Professional Engineer, registered in one or more U.S. states or the provinces of Canada, or licensed by any other country that has equivalent licensing procedures, experienced in composite pressure vessel design, shall certify that the PVHO was designed either by him or under his direct supervision, or that he has thoroughly reviewed a design prepared by others, and that to the best of his knowledge the PVHO complies with PVHO-1-2012 and this Case.

3.4 Manufacture

The braid and bladder shall be manufactured in accordance with detailed process control plans. The process control plans shall clearly define the details of the manufacturing steps necessary to fabricate the flexible components, and shall document the fabrication process. Any anomalies found during the manufacturing process shall be fully documented and may be corrected according to the process control repair plan. Any production testing already completed, shall need to be repeated. The manufacturing processes used for production units shall be identical to those used for the tested prototypes.

4. TESTING

Prototype testing shall be carried out on PVHO pressure boundaries of the same design, size, geometry, materials, methods of construction and pressure rating as production PVHOs. All prototype testing shall be witnessed and verified by a qualified independent third party agency experienced in composite pressure vessel technology. In lieu of the testing requirements of PVHO-1-2012, the following requirements shall apply.

In addition to prototype testing of the entire PVHO system, each individual compartment shall require prototype testing. Dual lock entry compartments shall be designed so that they cannot be subjected to higher pressures than the compartment to which they are attached.

The prototype test pressures required to prove the integrity of PVHO pressure boundaries certified through Cases considerably exceed PVHOs that are built to ASME Section VIII compliant metallic PVHOs. For that reason, certain metallic materials may be substituted by materials having higher tensile strength or increased thickness, so that failure of the PVHO shall not be attributable to the metallic compliant materials.

In order for that to be permitted, the following conditions apply.

1. The substitute metallic materials used are generically the same material with the same modulus of elasticity (e.g., aluminum alloy, steel alloy, etc.) as that used in the production units.
2. Comprehensive analyses of the interface loads and stresses between the metallic and non-metallic portions of the PVHO fully verify the design.
3. The design and dimensions of the metal to non-metal interfaces on both prototype and production units remain unchanged.
4. Analyses of the substitute metallic portions used during prototype testing verify that they are safe for the loads applied and that they transfer the interface loads correctly.

4.1 Prototype Tests

(a) Pressure Proof Test
For each PVHO design, hydrostatic proof tests shall be performed on assembled nonmetallic flexible PVHO pressure boundaries LCP braid and bladder assemblies at their maximum operating temperature. Each complete assembly and each separate compartment thereof, shall be pressurized in accordance with ASME PVHO-1-2012 non-mandatory Appendix D, Paragraph D-7.4 entitled MAWP Determination Based on Non-failure Test Pressure and held without failure for a period of 30 minutes.

Failure of the LCP braid, bladder or its clamping arrangement shall be cause for failure of the prototype design. The outer protective cover, (outside the pressure boundary) shall not constitute part of the pressure proof tests in order to visually record and identify all possible modes of failure.

(b) Cyclic Hydrostatic Test

A cyclic hydrostatic pressure test shall be conducted on one complete PVHO pressure boundary for between 4,000 and 10,000 cycles. Compartments that cannot be individually pressurized shall be tested with the compartment to which they are attached. The test shall comprise pressurization from ambient pressure to the MAWP and back to ambient pressure at ambient temperature. The duration of a cycle shall be determined by adding the times for the two tests described in i) and ii) hereunder.

i) To establish the time for the pressure cycle, a hydrostatic test will be conducted on the LCP braid and bladder to determine the time taken for pressurization from ambient pressure to MAWP, plus the time taken for any changes in volume to subside.

ii) To establish the time for the depressurization cycle, a hydrostatic test will be conducted on the LCP braid and bladder to determine the time taken for depressurization from MAWP to the minimum sealing pressure plus the time taken for any changes in volume to subside.

Digital data, showing pressure against time, shall be used to define the time taken for volume changes to subside.

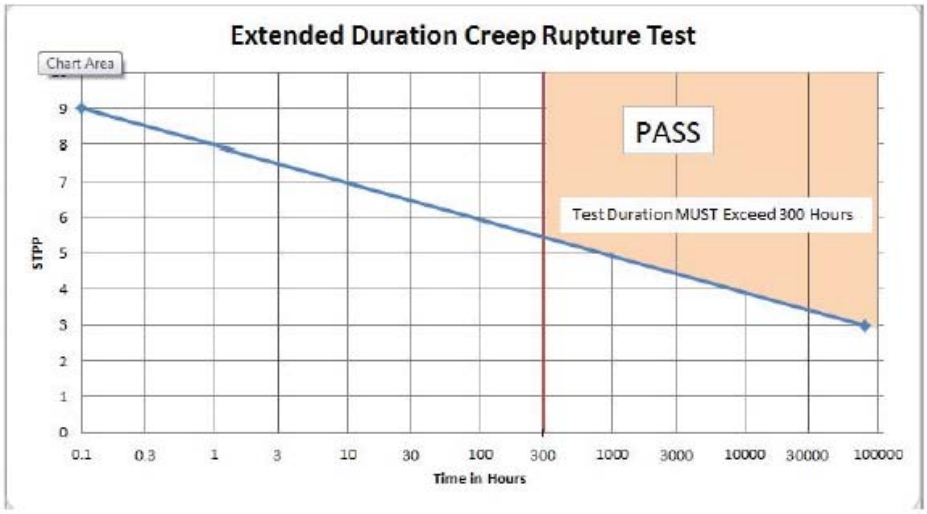
To establish the maximum number of pressure cycles satisfactorily completed on the unit under test, the pressure retention properties of the vessel shall be checked every 2000 cycles for leakage or any damage to the PVHO pressure boundary. Should leakage occur during cyclic testing, or at a cyclic level, then the maximum number of cycles achieved at the previous cyclic level shall be defined as [CT] and be used to determine the number of approved operational cycles [CA] for the PVHO pressure boundary using the following calculation:

$$CA = [CT/2] - 1000$$

(c) Extended Duration (Creep Rupture) Test

The non-metallic load bearing materials of the PVHO pressure boundary shall be subjected to proof pressure testing at a pressure of five times the MAWP of the PVHO at maximum operating temperature for a period of at least 300 hours duration. If at the completion of testing, the following criteria are met, the PVHO shall be considered to have acceptable creep behavior.

A straight line shall be plotted using semi log coordinates with pressure on the linear scale (Y) and time on the logarithmic scale (X). The beginning coordinate of the line shall be the pressure at 0.1 hour and the MAWP multiplied by 9. The end coordinate on the line shall be three times the MAWP at 80,000 hours. A straight line shall be drawn through these two coordinates. This line represents the minimum pressure-time acceptance line. Failure to the left and below the pressure-time acceptance line is disallowed.



(d) **Cold Storage Test**
A test shall be conducted at least twice, demonstrating that the pressure retaining parts of the PVHO pressure boundary can be assembled and inflated at minimum operating temperature. The PVHO shall be folded and stored for a minimum of 8 hours at minimum operating temperature immediately prior to the commencement of the tests. No leakage, damage, or permanent distortion of the PVHO is permissible.

(e) **Off-gassing Test**
An off-gassing toxicity test shall be carried out that meets the requirements of Section 1-10 of ASME PVHO-1-2012.

(f) **Cyclic Folding Test**
A folding and unfolding test shall be carried out on one fully assembled PVHO pressure boundary. One cycle comprises the packing of the PVHO from assembled (at ambient pressure), placed in its storage case(s), followed by reassembly to its fully assembled state, ready for pressurization. The required number of folding test cycles is related to the PVHO's rated number of folding cycles and shall meet the following criteria:

(1) PVHOs rated for 100 cycles or less: 150 percent of the PVHO's rated number of folding cycles
(2) PVHOs rated for 101 to 1,000 cycles: 125 percent of the PVHO's rated number of folding cycles
(3) PVHOs rated for 1,000 cycles or more: 110 percent of the PVHO's rated number of folding cycles.

Upon completion of the folding and unfolding test cycles, the PVHO pressure boundary shall be pressurized to 1.5 times the MAWP and held for 30 minutes at room temperature. The PVHO shall deem to have failed the test if the resultant pressure loss exceeds 2% per hour, or if there is delamination or other visible defects to the LCP braid and bladder tube assembly of the PVHO.

4.2 Production Test

Every completely assembled compartment of the PVHO pressure boundary shall be subjected to a pneumatic test at a pressure of 1.5 times the MAWP and held for a period of 1 hour with a permissible leakage rate not greater than 2% of the chamber pressure per hour. Compartments that cannot be independently pressurized, shall be tested with the compartment to which they are attached. Internal and external air temperatures shall be measured and recorded at the beginning and end of each test so that compensation may be made for any temperature differences.
Every PVHO will be examined visually and dimensionally for damage following each test. Any signs of cracks, permanent deformation or other signs of damage will be grounds for rejection of the PVHO. Any changes to production PVHOs built to this Case shall require prototype re-testing as defined in Para. 3.2(f) above.

4.3 In Process Tests

Each PVHO that has undergone repair or maintenance to any of the non-metallic components, (such as a repair patch to the inner surface of the internal bladder) shall undergo full production re-testing as per 4.2 above and full details of which shall be recorded in the PVHO log.

5. QUALITY ASSURANCE

5.1 General

PVHO's built to this Case shall be built by manufacturers whose Quality Management System is approved and certified by a Notified Body as meeting the requirements of ISO 13485:2003 and European Directive 93/42/EEC Annex II (excluding Section 4) for Medical Devices. In addition, the requirements of Section 3 of ASME PVHO-1-2012 shall be met in full.
A documented Quality Assurance Plan (QAP) shall be developed for the design and manufacture of the PVHO. This section describes the requirements of the content of the QAP.

5.2 Organization

The QAP shall describe the organizational structure, with responsibilities, authorities, and lines of communication clearly delineated. Persons shown in the QAP to be responsible for verifying the PVHO quality shall have the authority and organizational freedom to:

(a) Identify problems affecting quality
(b) Initiate, recommend or provide solutions to quality problems, through designated channels
(c) Verify implementation of solution
(d) Control further processing, delivery or assembly of a non-conforming item, deficiency or unsatisfactory condition until proper corrective action has been taken

5.3 Design Control

A methodical process shall be used to develop and control the PVHO design, which includes:

(a) A process for design inputs and review
(b) A requirement for formal design review
(c) A process for product configuration management and change control

5.4 Document Control

The QAP shall describe the manufacturer's measures for assuring that design output documents are translated correctly into manufacturing specifications, drawings, procedures and shop/lab instructions. Considerations shall be made for reviews and approvals, including those of the purchaser. The manufacturer shall include the procedure for assuring distribution of appropriate documents to the working areas in a timely fashion and the process for assuring non-use of obsolete documents.

5.5 Procurement Control

The QAP shall include the controls necessary to assure that applicable requirements are included in procurement documents. The manufacturer shall describe the basis for source evaluation and selection and the method of objective evaluation of the quality of furnished materials, items and services upon receipt.

5.6 Material Control

The QAP shall describe the identification applied to material and items upon receipt and shall show that this identification shall remain until the material or item is incorporated into the PVHO. Identification shall be such that the manufacturer's personnel can easily determine quality status, material or item type, specification, lot or part as appropriate and job number. At least five (5) test samples, taken at random, from the length of LCP braid and bladder used in the manufacture of each flexible shell on both prototype and production PVHOs, shall be obtained and tested for the key strength parameters. The upper value of the 90% Confidence interval of the production material shall be at least as great as the lower value of the 90% confidence interval of the material that were used in the prototype units that were tested.

5.7 Process Control

The QAP shall include a Process Control Procedure that will record the identification of materials and items incorporated into the PVHO and each chronological step in its manufacture, including inspection and test steps. The Process Control Procedure shall contain periodic operator and inspector signature points so that product status can be readily determined. The manufacturer shall identify critical manufacturing activities and assure that they are accomplished by appropriately trained and qualified personnel. Inspection points shall follow the activities in the process control plan.

5.8 Inspection Control

The QAP shall include the measures used by the manufacturer to assure that inspections are reliable.
These measures shall include:

(a) Proper qualification of inspection personnel
(b) Calibration of inspection instrumentation
(c) Incorporation of acceptance criteria into inspection points in the Process Control Plan
(d) Assurance that inspections are performed by persons other than those performing or supervising work
(e) Documentation of all inspections.

5.9 Test Control

The QAP shall describe the measures used to assure that tests (including lab tests) are performed consistently and reliably. The following requirements shall be met:

(a) Tests shall be performed in accordance with written instructions stipulating acceptance criteria
(b) Test results shall be documented
(c) Examination, measurement and testing equipment used for activities affecting quality shall be controlled, calibrated and adjusted at specified periods to maintain required accuracy
(d) Tests shall be performed by trained & qualified personnel
(e) Tests shall be verified by persons other than those performing or supervising the test.

5.10 Control of Measuring Test & Inspection Equipment

The QAP shall describe the equipment used in inspections and tests and the measures used to assure appropriate accuracy. Appropriate equipment shall be calibrated and the calibration shall be traceable to standards where they exist. Where such standards do not exist, the equipment manufacturer's recommendations shall be followed.

5.11 Control of Non-Conforming Items/Materials

The QAP shall describe the measures used by the manufacturer to control materials or items that are found to be discrepant to prevent their use. Nonconforming materials/items shall be identified and not used. The discrepant condition(s) shall be documented. The process for determining, documenting and verifying corrective action shall be described, including the involvement of the purchaser.

5.12 Quality Assurance Records

The QAP shall provide for quality assurance records:

(a) Records shall be specified, compiled and maintained to furnish documentary evidence that services, materials and completed PVHOs meet this and applicable referenced standards
(b) Records shall be legible, identifiable and retrievable
(c) Records shall be protected against damage, deterioration or loss

(d) Requirements and responsibilities for record transmittal, distribution, retention, maintenance and disposition shall be established and documented
(e) Records required for traceability shall be retained for a minimum of 12 years

5.13 Standard Repair Planning

The QAP shall describe methods for repairing discrepancies that occur during the PVHO manufacture. The QAP shall further ensure that all repair methods must be tested in a manner similar to the requirements of prototype testing, to prove that the integrity of any repair does not compromise the integrity of the PVHO itself.

5.14 Quality Assurance Overview by an Independent Third Party

A qualified independent third party agency (a member of the Independent International Organization for Certification (IIOC) shall be employed to ensure that all PVHOs under this Case are designed, manufactured and tested to the requirements of PVHO-1-2012 and this Case.
That includes, but is not restricted to the following:

(a) The PVHO is designed in accordance with PVHO-1-2012 and this Case
(b) The manufacturer is working to the requirements of the quality control system
(c) The materials used in construction of the PVHO comply with Table 2 as required by PVHO-1-2012 and this Case
(d) The manufacturing operations are conducted in accordance with approved procedures by qualified operators, as required in PVHO-1-2012 and this Case
(e) All defective components are removed, tagged and shall not be used on the PVHO
(f) All prototype and production testing has been performed and witnessed as required by PVHO-1-2012 and this Case
(g) The PVHO is marked in accordance with PVHO-1-2012 and this Case
(h) A visual inspection of the PVHO is conducted to confirm that there are no material or dimensional defects

The manufacturer shall arrange and give the third party agency free access to all facilities associated with the manufacture of the PVHO. The manufacturer shall keep the third party agency informed of the progress of the work and shall notify them reasonably in advance when PVHOs will be ready for any required tests or inspections.

6. MARKING

(a) In lieu of PVHO-1-2012, Section 1-9, Marking, a label shall be permanently and rigidly attached to the outside surface of the braid and bladder assembly and shall be permanently marked, close to one end, with the data required in PVHO-1-2012, para. 1-9(a). and the following designation:

EXAMPLE

PVHO-1-2012 (Case 18)
Certified by …… (Name of Manufacturer) ……/…… psi/MPa internal (Maximum Allowable Working Pressure)
……°F …… °C

(Design Temperature Range)	
…….. (Manufacturer's serial number)	…… (Year built)
PVHO-1-2012 Case 18 (Design Criteria)	Section …… Section 5 [Medical] and/or Section 6 [Diving]
Multiple Occupancy PVHO	…….. (Total Number of occupants)
Main Lock	…….. (Max. Number of occupants)
Transfer Lock	…….. (Max. Number of occupants)

In addition to the above, the PVHO shall prominently be marked with the following instructions:

Overall chamber length	…….inches	……centimeters
Compartment lengths	Main lock .....in.……cm	Transfer lock.……in……cm
Allowable No. of Pressure Cycles:	(As defined following prototype testing)	
Allowable No. of Folding for Storage Cycles:	(As defined following prototype testing)	
Flexible Tube Expiration Date	(DD/MM/YYYY)	
Storage Temperature (min/max):	-10°F/+150°F -23°C/+66°C	
PRESSURIZED WITH AIR ONLY		
NOT TO BE MOVED WHEN PRESSURIZED - WITH OR WITHOUT OCCUPANTS		
CONTINUOUS MONITORING REQUIRED WHEN PRESSURIZED WHILE OCCUPIED		
DO NOT EXPOSE PVHO TO DIRECT SUNLIGHT OR UV LIGHT SOURCES FOR EXTENDED PERIODS		

(b) Form PVHO Case 18, Manufacturer's Data Report for Pressure Vessels for Human Occupancy, shall be completed to certify that each PVHO meets the requirements of PVHO-1-2012 and this Case.

TABLE 1- PLAN VIEW
Configurations covered under this Case

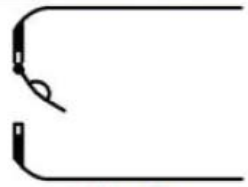
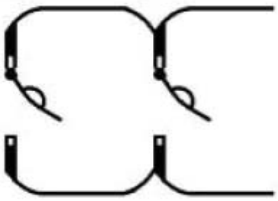
Chamber Type	Main Entry (Plan View)	Opposite End Options (Plan View)		
		1	2	3
Single Lock	 Entry Door	 Closed End	 Closed End with Window	 Entry Door
Double Lock	 Dual Lock Entries			

TABLE 2 – STRUCTURAL NON-METALLIC MATERIALS OF CONSTRUCTION

PVHO-1-2012 Case 18 Structural Non-Metallic Materials of Construction – Flexible Shell Assembly

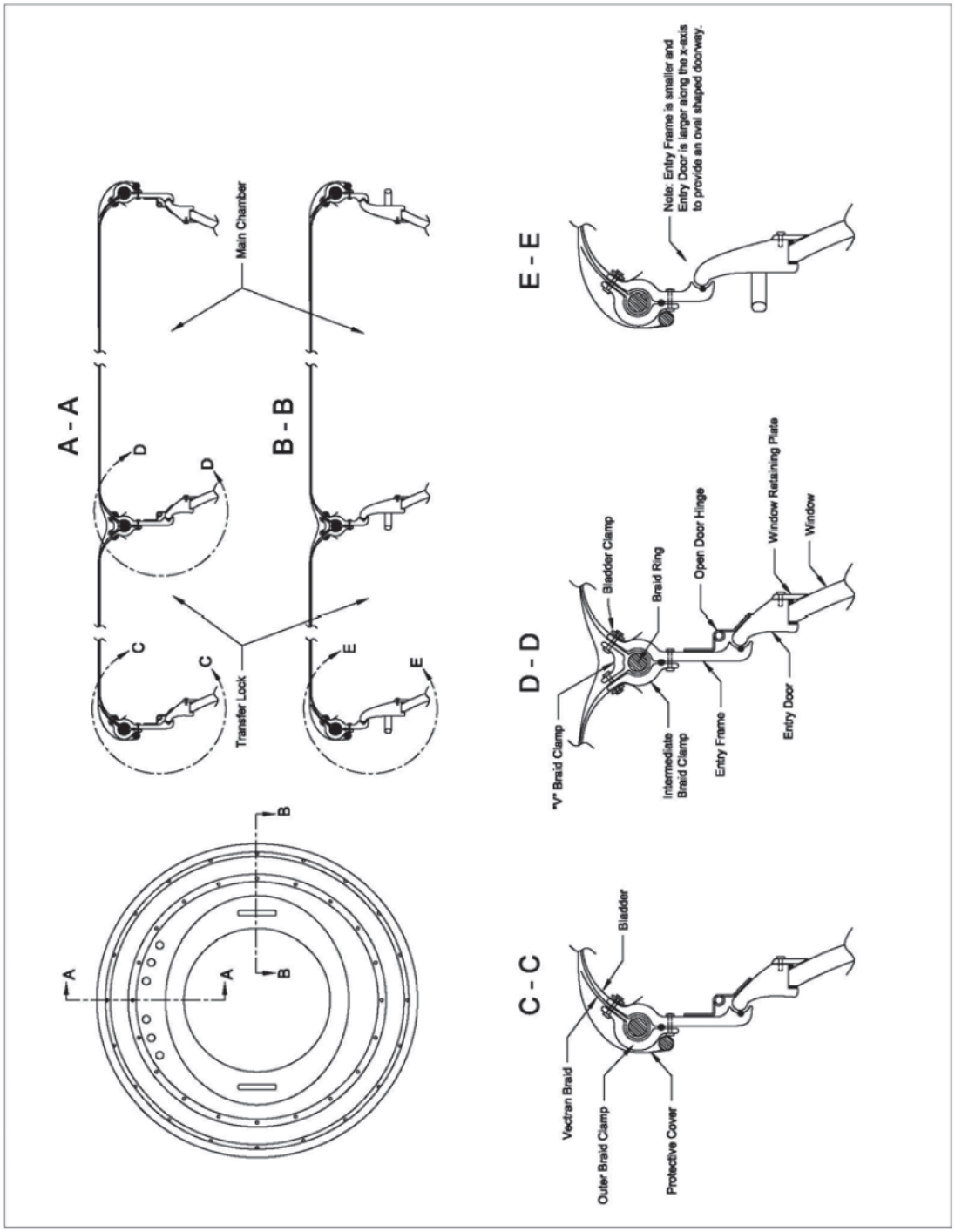
An asterisk (*) denotes the key properties that determine whether batches of material are considered identical for continuity of quality and performance

Component	Material/Material Properties	Minimum Values or as stated	Test Procedure or Specification
Membrane (Bladder)	Spun Meta-Aramid Fiber Fabric with double sided fire retardant polyurethane coating	Fabric: Weight: 122g/m² (± 5%) Weave: Plain Density: 1.38 Threads per dm: 118 (+/-0.2) Warp,* 120 (+/-0.2) Weft * Construction: Yarn Linear Density 40/2 (Warp/Weft) Tensile Strength (N/50mm) Warp: >700 Weft: >750 Elongation (%) Warp: <20 Weft: <23 Finished Material: Coating/side: 0.5mm* Total thickness: 1.2mm* ±0.1mm Total weight: 1.3 kg/m² ±0.1 Tensile Strength: N/5cm Warp: >1200 Weft: 900 Elongation at Break: Warp: <15 Weft: <30 Tear resistance: Warp min. 1600 N* (Middle cut) Weft min. 900 N* (Tongue test) Tear strength:* Weft min. 1400 N/5cm* Adhesion: > 250 N/5cm* Conforms to Flame Test Cold Resistance: -30°C ±5*	BS EN 12127:1998 BS EN 1049-2:1994 ISO 2060:1995 ISO 13934:2013 ISO 13934:2013 ISO 3801 ISO 1421 ISO 1421 ISO 4674 ISO 4674 ISO 2411 UL94 HB
Braid	Liquid Crystal Polymer (LCP) Fiber Filament Yarn	1500 Denier* 300 filaments/yarn* Density: 1.4 g/cm³ Break Strength* [±10%] 3206 MPa/25.9 g/denier/465 ksi Initial Modulus*: 75000MP/ 600g/denier/10,760 ksi Elongation at break: 3.8% Equilibrium Moisture Regain < 0.1% Limiting Oxygen Index: 28	ASTM D885-07
Outer Cover	PU coated woven polyester fabric cover	Base fabric: Mass 180g/m² Threads 17/cm warp, 13/cm weft. Coated Fabric: Total Mass 240 +/-10 g/m² Tearing Strength: ≥75N Across Warp* ≥85N Across Weft*, Tensile Strength*: ≥1800 N/50mm,Warp, ≥1200 N/50mm Weft	 ISO 4674-1:2003 Method A2 ISO 13934-1
Handle Straps & Slings	Nylon Webbing with Aluminium or Stainless Steel Fittings	Structural items – not pressure boundary items	ASME B30.9 2006 or EN1492-1:2000 +A1:2008

TABLE 3 – TEST PROCEDURES AND/OR SPECIFICATIONS

Test Procedures and/or Specifications listed in Table 2or referred to in Case 18	
ASTM D751-06(11)	Standard test methods for Coated Fabrics
ASTM D885-07	Standard test methods for tire cords, tire cord fabrics and industrial filament yarns made from man-made organic-base fibers.
ASTM G63-99(2007)	Standard guide for evaluating nonmetallic materials for oxygen service
ASTM 2863-13	Standard Test Method for Measuring the Minimum Oxygen Concentration to Support Candle-Like Combustion of Plastics (Oxygen Index)
ASME B30.9 2010	Slings
BS EN 12127:1998	Textiles. Fabrics. Determination of mass per unit area using small samples
EN1492-1:2000 +A1: 2008	Textile slings. Safety. Flat woven webbing slings, made of man-made fibers, for general purpose use
ISO 1049-2:1994	Textiles. Woven fabrics. Construction. Methods of analysis. Determination of number of threads per unit length
ISO 1421:1998	Rubber or plastic coated fabrics for determination of tensile strength & elongation at break.
ISO 2060:1995	Textiles. Yarn from packages. Determination of linear density (mass per unit length) by the skein method
ISO 2411:2000(en)	Rubber - or plastics - coated fabrics - Determination of coating adhesion
ISO 3801:1977	Textiles - Woven fabrics - Determination of mass per unit length and mass per unit area
ISO 4674-1:2003	Rubber or plastic coated fabrics. Determination of tear resistance - Part 1: Constant rate of tear methods.
ISO 13934-1:1999	Textiles. Tensile properties of fabrics. Determination of maximum force & elongation at maximum force using the strip method.
ISO 13485:2003	Medical devices - Quality management systems - Requirements for regulatory purposes
UL94:2013	Flammability of Plastic Materials for Parts in Devices and Appliances testing (Issue 6)
93/42/EEC	European Council Directive concerning Medical Devices

FIGURE 1 Typical Configuration



PVHO Case 18 Form Manufacturer's Data Report for Pressure Vessels for Human Occupancy

1. Design criteria _____

2. Manufactured and certified by_____

3. Manufactured for _____

4. Vessel identification_____
(Manufacturer's serial no.) (Year built)

5. The design, construction, workmanship, and chemical and physical properties of all parts meet the applicable material specifications of PVHO-1-2012 and Case No 18

6. Manufactured for a maximum allowable working pressure of _____psig _____barg _____fsw

_____msw, a maximum working temperature of _____°F _____°C and

a pneumatic internal test pressure of _____psig _____barg _____fsw _____msw

7. Design analysis conducted by _____

8. Designed for a maximum of _____occupants in the PVHO, with a max. of _____ in the main compartment

and _____ in the transfer lock

9. Windows: Certification reports, properly identified and signed by the window fabricator, are attached for the following items:

No.	Location	Type	Diameter	Nominal Thickness	How Attached

CERTIFICATION OF DESIGN

Design specification on file at _____

Manufacturer's design report on file at _____

Design specification certified by _____State _____ Reg. no. _____

Manufacturer's design specification certified by _____State_____ Reg. no. _____

Prototype test program attested by _____

Quality assurance program reviewed by _____

Manufacturer's documentation reviewed by_____
(name and date)

Post production functional testing witnessed by_____
(name and date)

CERTIFICATE OF CONFORMITY

We certify that the statements made in this report are correct and that all details of the design, material, construction and workmanship conform to the ASME Safety Standard for Pressure Vessels for Human Occupancy (PVHO-1-2012) and PVHO Case 18

Date _____ Company Name _____ Signed _____