PVHO-1 Case 21
Use of a Transportable Flexible Coated Aramid Conical Vessel as a PVHO Under PVHO-1–2012

Approval Date: July 17, 2015
Expiration Date: July 17, 2021

Inquiry: Under what conditions may a transportable flexible coated aramid conical vessel be manufactured under the rules of ASME PVHO-1–2012?

Reply: It is the opinion of the Committee that a coated aramid conical vessel may be constructed under the requirements of ASME PVHO-1–2012 and be marked as a PVHO vessel when the requirements of ASME PVHO-1–2012, with the following exceptions and additions, have been met.

1 GENERAL

1.1 Description of the PVHO

This Case covers a designed and constructed conical-shaped PVHO with spherical ends, limited to the main characteristics listed in this Case.

The pressure vessel comprises a flexible impermeable shell made of aramid wound filaments coated with flame-retardant polyurethane resin. The shell holds two spherical rigid glass fiber sandwich composite end caps (Fig. 21-1). The opening of the large end cap allows entrance for the patient. The door, also made of rigid glass fiber sandwich composite, is fixed to the large end cap by an aluminum closing ring equipped with an interlock system. The large end cap (LEC), small end cap (SEC), and the door are the rigid composite parts of the vessel. Only the main shell is flexible.

The door and small end cap both include an acrylic spherical sector window.

(a) A large window (23-in. diameter) is fixed in the door, at the large end of the chamber, allowing light to enter the chamber and facilitating observation of the patient (head, face, chest, and arms).

(b) A small window (11-in. diameter) is fixed in the small end cap, at the small end of the chamber, allowing light to enter the chamber and providing a larger sense of space.

Services (sensors, communication system, etc.) are provided to the vessel through bulkhead penetrators located in the rigid end caps only (Fig. 21-1). The one-piece flexible shell shall not be pierced or cut.

The complete chamber is composed of the pressure vessel mentioned above, a control station, and a transport case (Fig. 21-2). The pressure vessel, control station, and accessories are packed in the custom-made transport case, which is transportable (Fig. 21-3). The transport case is designed to protect the vessel and the control station during transport. The transport case is also convertible into the base of the PVHO during operation.

1.2 General Requirements

The chamber shall be designed, constructed, tested, inspected, and marked according to ASME PVHO-1, Sections 1, 2, 3, 4, and 5, with exceptions and additions as detailed in this Case and IEC 60601-1, third edition.


The PVHO shall comply with the following requirements:

(a) The maximum allowable working pressure (MAWP) shall be 30 psig.

(b) The PVHO shall comprise

1. one conical flexible shell

2. two spherical rigid end caps (LEC and SEC)

3. one spherical door equipped with a closing/locking ring

4. two PVHO acrylic windows, one at each end

(c) The flexible shell shall be made in one piece. No through-hole or penetration shall be made in the shell, and the shell shall contain no cuts or punctures.

(d) The nominal diameter of the large end cap opening shall be 32 in.

(e) The maximum internal diameter shall be 42 in.

(f) The nominal internal diameter at the smallest end shall be 24 in.

(g) The maximum internal length shall be 88 in. (window to window, door closed).

(h) The design temperature limits shall be 32°F to 104°F (0°C to 40°C).

(i) The maximum number of pressure cycles shall not exceed 4,000 cycles.

(j) The rated life shall be no more than 10 yr from the date of manufacture.

(k) The maximum number of occupants shall be one.
Fig. 21-1  Main Parts of the Pressure Vessel

- Closing system
- Large end cap
- Flexible shell and protective cover
- Small end cap
- Pneumatic and electrical bulkhead penetrators

Fig. 21-2  PVHO

- Pressure vessel
- Control station
- Convertible transport case (base model)
The pressurizing gas shall only be breathable air. The chamber inlet port shall be adequately labeled, PRESSURIZE WITH BREATHABLE AIR ONLY.

The chamber shall be equipped with an oxygen sensor with alarm for both low and high oxygen levels. The oxygen level inside the vessel shall be maintained between 18% and 25% at all time during operation.

The breathing gases, pure oxygen or air, shall be supplied to the patient through a hood or a mask equipped with an overboard dump system.

Oxygen and breathable air sources shall comply with local regulations and meet breathable standards for humans.

The chamber atmosphere shall be continuously ventilated. Minimum ventilation shall be indicated in the accompanying documentation.

The PVHO shall be installed on and stored in the transport case supplied with the PVHO.

The owner/operator shall maintain a detailed log book relating to each PVHO that clearly records the number of pressurizations, parameters (operating pressure, duration), location, and date for each use.

The PVHO shall not be transportable while pressurized.

2 MATERIALS

2.1 Material Requirements

Materials shall meet ASME PVHO-1, para. 1-6 and Section 2, with the following exceptions:

(a) The flexible shell materials shall conform to Table 21-1.

(b) The end caps and door materials shall conform to Table 21-2.

(c) All fiber-reinforced plastic (FRP) materials shall conform to the ASME Boiler and Pressure Vessel Code (BPVC), Section X, Part RM. All raw materials used in the manufacture of the vessel shall be supplied with supporting documentation certifying that each lot of materials meets the respective properties listed in this section and Table 21-1. The documentation shall comply with the requirements of the Quality Management System detailed in section 6 of this Case.

All of the materials shall be used in combination to meet the performance requirements of this Case. Process Control Procedures shall be established to determine all the essential steps, parameters, and controls of the fabrication, including how materials are to be used and in what specific quantities.

Manufactured materials shall be tested in accordance with para. 4.6, and test results shall be recorded in accordance with paras. 6.6 and 6.7. Manufactured parts shall have material properties that meet or exceed the values stated in Tables 21-1 and 21-2.

2.2 Materials Properties

Windows shall be made of acrylic according to ASME PVHO-1, Section 2. The closing ring and the window seats shall be made of aluminum 6061 T651. The closing system bars and shafts shall be made of stainless steel.

1 A “lot” of material is defined as the amount of homogeneous run of material made at the same time, in a predetermined quantity (i.e., yards, meters, pounds, kilograms) and the specific quantity received from such a lot.
### Table 21-1  Required Mechanical Properties of Shell Materials

<table>
<thead>
<tr>
<th>Material</th>
<th>Properties</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>800.001: aramid filament yarn</td>
<td>Linear mass density: 3338 dtex min.</td>
<td>ASTM D885</td>
</tr>
<tr>
<td></td>
<td>Breaking strength: 692 N (155.5 lbf) min.</td>
<td>ASTM D885</td>
</tr>
<tr>
<td></td>
<td>Elongation at break: 2.59% min., 3.21% max</td>
<td>ASTM D885</td>
</tr>
<tr>
<td>800.008: polyurethane flexible resin</td>
<td>Tensile strength at break: 7 MPa (1015 psi) min.</td>
<td>ASTM D412</td>
</tr>
<tr>
<td></td>
<td>Elongation at break: 450% min.</td>
<td>ASTM D412</td>
</tr>
<tr>
<td></td>
<td>Durometer: 25 Shore A min., 35 Shore A max</td>
<td>ASTM D2240</td>
</tr>
<tr>
<td>800.029: internal membrane</td>
<td>Tensile strength at break: 35 MPa (5076 psi) min.</td>
<td>ASTM D412</td>
</tr>
<tr>
<td></td>
<td>Elongation at break: 500% min.</td>
<td>ASTM D412</td>
</tr>
<tr>
<td></td>
<td>Durometer: 75 Shore A min., 85 Shore A max</td>
<td>ASTM D2240</td>
</tr>
</tbody>
</table>

### Table 21-2  Required Mechanical Properties of Rigid Composite Parts Materials

<table>
<thead>
<tr>
<th>Material</th>
<th>Properties</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-glass fiber/vinylester laminate (tested in either 0 deg or 90 deg direction)</td>
<td>Tensile strength: 431 MPa (65,250 psi) min.</td>
<td>ASTM D3039</td>
</tr>
<tr>
<td></td>
<td>Tensile modulus: 22 GPa (3200 ksi) min.</td>
<td>ASTM D3039</td>
</tr>
<tr>
<td></td>
<td>Barcol hardness: 30 min.</td>
<td>ASTM D2583</td>
</tr>
<tr>
<td>800.027: e-glass fiber fabric, weave (0 deg/90 deg)</td>
<td>Linear Weight (tex)</td>
<td>Method 5.2 [Note (1)]</td>
</tr>
<tr>
<td></td>
<td>275 g/km (15.6 oz/mile) min.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tensile:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>warp: 1080 min.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>weft: 1080 min.</td>
<td></td>
</tr>
<tr>
<td>800.025: epoxy vinylester resin (cured properties)</td>
<td>Viscosity at 60 rpm: 40 cPs–60 cPs</td>
<td>Manufacturer test method</td>
</tr>
<tr>
<td></td>
<td>Gel time: 27 min–33 min</td>
<td>ASTM D2471</td>
</tr>
<tr>
<td></td>
<td>Specific gravity: 1.15 g/cm³–1.25 g/cm³ (71.8 lb/ft³–78 lb/ft³)</td>
<td>ASME BPVC, Section X, Appendix 5</td>
</tr>
<tr>
<td>800.037: epoxy foam core</td>
<td>Compression strength: 3.9 MPa (566 psi) min.</td>
<td>ASTM D1621</td>
</tr>
<tr>
<td></td>
<td>Compressive modulus: 160 MPa (23,206 psi) min.</td>
<td>ASTM D1621B</td>
</tr>
<tr>
<td>800.019: vinylester resin</td>
<td>Viscosity at 20 rpm: 600 cPs–700 cPs</td>
<td>Manufacturer test method</td>
</tr>
<tr>
<td></td>
<td>Gel time: 17 min–23 min</td>
<td>ASTM D2471</td>
</tr>
<tr>
<td></td>
<td>Specific gravity: 0.99 g/cm³–1.05 g/cm³ (61.8 lb/ft³–65.6 lb/ft³)</td>
<td>ASME BPVC, Section X, Appendix 5</td>
</tr>
<tr>
<td></td>
<td>Barcol hardness: 28 min.</td>
<td>ASTM D2583</td>
</tr>
<tr>
<td>800.022: structural adhesive</td>
<td>Time to peak exotherm: 25 min–35 min</td>
<td>ASTM D2471</td>
</tr>
<tr>
<td>800.005: aromatic polyether-based thermosetting polyurethane</td>
<td>Gel time: 3 min–7 min.</td>
<td>ASTM D2471</td>
</tr>
<tr>
<td></td>
<td>Hardness: 79 Shore D min.</td>
<td>ASTM D2240</td>
</tr>
</tbody>
</table>

**NOTE:**
(1) CAN/CGSB-4.2: Canadian General Standards Board — Textile Test Methods.
The mechanical properties of materials used in the manufacture of the pressure vessel shall comply with the values listed in Tables 21-1 and 21-2.

### 2.3 Summary of ASTM Test Methods

See Table 21-3 for a summary of ASTM test methods.

### 3 DESIGN

#### 3.1 Applicable Standards

In lieu of ASME BPVC, Section VIII, parts made of FRP materials shall meet the applicable requirements of ASME BPVC, Section X for Class I designs.

The PVHO and associated systems shall be designed in accordance with ASME PVHO-1 with the exclusions and requirements detailed in this Case, particularly

(a) In lieu of ASME PVHO-1, paras. 1-7.12 through 1-7.15, the design requirements of this section shall apply.

(b) Viewports shall meet the requirements of Section 2 of ASME PVHO-1.

(c) Piping systems shall meet the requirements of Section 4 of ASME PVHO-1.

(d) The PVHO shall meet the requirements of Section 5 of ASME PVHO-1.

A complete list of design exclusions is provided in Table 21-4.

The PVHO and associated systems shall be considered an electrical medical device. They shall be designed in accordance with IEC 60601-1, third edition and other applicable medical device regulations and standards.

#### 3.2 Design Analysis

A stress analysis shall be performed by a Professional Engineer (PE) registered in one or more of the states of the United States or the provinces of Canada, or licensed by any other country that has equivalent licensing procedures, who is experienced in composite pressure vessel design and construction.

The stress analysis shall include a detailed finite element analysis of the PVHO under varying pressures up to a minimum of 6 times the rated pressure (e.g., 180 psig, 12.4 bar).

#### 3.3 Design Requirements

(a) The MAWP shall not exceed 30 psig (2.1 bar) at 104°F (40°C).

(b) The design temperature range shall be between 32°F and 104°F (0°C to 40°C).

(c) The design temperature of the windows shall be 150°F (66°C).

(d) The rated pressure shall be based on tests in accordance with section 5.1 of this Case.

(e) The rated cyclic life shall be determined by test in accordance with section 5.1 of this Case.

(f) Any changes to the design, materials, or manufacturing procedures of the PVHO shall be cause for full prototype retesting and consideration for resubmittal as a new Case.

(g) All penetrators shall be located in the rigid end caps of the PVHO (Fig. 21-1).

(h) The flexible shell shall not be pierced by penetrators or other items.

(i) The windows shall be located in the door and small rigid end caps of the PVHO (Figs. 21-4 and 21-5).

(j) If material supplier data is not available, the manufacturer shall conduct tests to verify that the materials are compatible with the pressurizing medium. Material safety datasheets and/or other test documentation shall be part of the Manufacturer’s Data Report.

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### Table 21-3 ASTM Test Methods

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASTM D412</td>
<td>Standard test methods for vulcanized rubber and thermoplastic elastomers, tension</td>
</tr>
<tr>
<td>ASTM D792</td>
<td>Standard test methods for density and specific gravity (relative density) of plastics by displacement</td>
</tr>
<tr>
<td>ASTM D885</td>
<td>Standard test methods for tire cords, tire cord fabrics, and industrial filament yarns made from manufactured organic-base fibers</td>
</tr>
<tr>
<td>ASTM D1621</td>
<td>Standard test method for compressive properties of rigid cellular plastics</td>
</tr>
<tr>
<td>ASTM D2240</td>
<td>Standard test method for rubber property, durometer hardness</td>
</tr>
<tr>
<td>ASTM D2471</td>
<td>Standard test method for gel time and peak exothermic temperature of reacting thermosetting resins</td>
</tr>
<tr>
<td>ASTM D2583</td>
<td>Standard test method for indentation hardness of rigid plastics by means of a Barcol impression</td>
</tr>
<tr>
<td>ASTM D3039</td>
<td>Standard test method for tensile properties of polymer matrix composite materials</td>
</tr>
</tbody>
</table>
### Table 21-4  ASME PVHO-1 Design Exclusions

<table>
<thead>
<tr>
<th>Clause</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-1 Introduction</td>
<td>ASME PVHO-1 with exclusions including in this Case ASME BPVC, Section VIII shall be replaced by ASME BPVC Section X.</td>
</tr>
<tr>
<td>1-6 Materials</td>
<td>The nonstandard materials are the main exclusion of this Case. In lieu of the requirements of ASME PVHO-1, section 1-6, requirements of this Case shall be considered regarding the use of nonmetallic FRP composite materials. In lieu of ASME BPVC, Section VIII, requirements of ASME BPVC, Section X shall apply.</td>
</tr>
<tr>
<td>1-7.1 Joint Design</td>
<td>In lieu of ASME BPVC, Section VIII requirements, ASME BPVC, Section X requirements shall apply.</td>
</tr>
<tr>
<td>1-7.2 Welding</td>
<td>Not applicable to the design presented in this Case since there are no metallic welding parts in the pressure vessel boundary.</td>
</tr>
<tr>
<td>1-7.3 NDT</td>
<td>NDT shall conform to ASME BPVC, Section V according to ASME BPVC, Section X requirements in lieu of ASME BPVC, Section VIII.</td>
</tr>
<tr>
<td>1-7.6(g)</td>
<td>In lieu of ASME BPVC, Section VIII requirements, ASME BPVC, Section X requirements shall apply.</td>
</tr>
<tr>
<td>1-7.8 Testing</td>
<td>In lieu of ASME BPVC, Section VIII, requirements of ASME BPVC, Section X and this Case shall apply.</td>
</tr>
<tr>
<td>1-7.9 Documentation</td>
<td>In lieu of Forms U-1 and U-2, Forms of ASME BPVC, Section X and this Case shall be used.</td>
</tr>
<tr>
<td>1-7.12</td>
<td>This clause is not applicable for the following reasons:</td>
</tr>
<tr>
<td>1-7.13</td>
<td>(a) no brazed or riveted construction</td>
</tr>
<tr>
<td>1-7.14</td>
<td>(b) design is based on prototype qualification as detailed in this Case as permitted in ASME BPVC, Section X for Class I vessels</td>
</tr>
<tr>
<td>1-7.15</td>
<td>(c) no rectangular door</td>
</tr>
<tr>
<td>1-9 Marking</td>
<td>Requirements of section 7 of this Case shall apply.</td>
</tr>
</tbody>
</table>

#### Fig. 21-4  Closing System and Large Window Assembly Details

![Closing System and Large Window Assembly Details](image)
(k) The quick-actuating closing system shall meet or exceed the requirements of ASME BPVC, Section X, Article RD-8 (Fig. 21-6).

(l) Vessel lighting shall consist of low-power, light-emitting diodes (LED) only. The lighting shall not expose the windows to radiation in the UV portion of the light spectrum that is known to be harmful to acrylic.

(m) Lighting shall be located outside of the vessel. LED shall not be in direct contact with acrylic windows.

(n) LED lighting shall be placed such that the window is not heated above 150°F (66°C).

(o) Fire prevention and protection measures shall include the following:

1. The PVHO shall be electrically safe according to IEC 60601-1, third edition and NFPA 99:2012.
2. All electrical applied parts shall be protected by at least two means of patient protection.
3. No electrical part shall be in contact with oxygen-enriched gases in normal use.
4. Prevention of electrostatic discharges shall be considered as the use of antistatic materials inside the PVHO and proper grounding of the patient and accessories according to IEC 60601-1, third edition and NFPA 99:2012.
5. Materials used inside the PVHO shall be compatible with oxygen-enriched gases.
6. Pressure boundary parts of the PVHO shall be fire resistant according to the requirements of section 5.1.7 of this Case.

(7) Fire-related risks shall be identified and evaluated in the risk analysis. Standard guides ASTM G63 and ASTM G128 give recommendations on the evaluation of nonmetallic materials for oxygen service and control of hazards and risks in oxygen-enriched systems.

3.4 Design Certification

Conformance of the design of the PVHO to the requirements of ASME PVHO-1 and this Case shall be established by one of the two following procedures:

(a) A PE registered in one or more states of the United States or the provinces of Canada, or licensed by any other country that has equivalent licensing procedures, who is experienced in composite pressure vessel design, shall certify that the PVHO was designed either by the PE or under the PE’s direct supervision, or that the PE has thoroughly reviewed a design prepared by others, and that the PVHO complies with ASME PVHO-1 and this Case.

(b) The design of the PVHO shall be reviewed by an independent third-party agency that is a member of the International Association of Classification Societies (IACS) and experienced in composite pressure vessel design. Such organization shall provide a certificate that the PVHO complies with ASME PVHO-1 and this Case.

The design and manufacturing processes shall produce a conical shell that is resistant to damage by the assembly, pressurization, and storage of the PVHO.
The design of the viewports and frames shall be conducted as a part of the stress analysis as indicated in para. 3.2 of this Case. Acrylic windows and window seats shall be designed using the criteria of ASME PVHO-1, Section 2. The stress analysis of these items shall be used only as a reference for verification of the overall design.

4 MANUFACTURING

4.1 Qualification

The manufacturer of the PVHO shall have a quality management system compliant with all the requirements of section 6 of this Case.

The PVHO shall be manufactured in accordance with a detailed process control plan. The process control plan shall clearly define the details of each manufacturing step necessary to fabricate the PVHO, and shall document the fabrication processes. The process control plan shall apply to both the PVHOs used in the prototype testing and the PVHOs produced for commercial purpose. Each production unit and prototype unit shall be provided with test records, traceability records, manufacturing records, and other certificates required in this Case.

The process control plan shall meet or exceed the requirements of ASME PVHO-1, Section 3; ASME BPVC, Section X, Part RF; 21 CFR Chapter I, Subchapter H, Part 820—Quality System Regulation; and para. 6.7 of this Case. Controls shall be applied to both processes and parts.

4.2 Methods of Fabrication

As mentioned in section 1 of this Case, the PVHO is composed of three rigid composite parts and a flexible shell. Each rigid composite part is composed of two FRP laminate skins and a lightweight core.

All methods of fabrication used for the flexible shell and FRP components shall comply with ASME BPVC, Section X, Article RG-4.

The flexible shell shall be produced using filament winding techniques (winding of a continuous band of reinforcements) in accordance with detailed manufacturing processes documented in the quality management system of the manufacturer. The flexible shell shall be manufactured using a computer numerically controlled (CNC) winding machine. The machine shall be regularly calibrated, and regular maintenance shall be performed according to the equipment maintenance plan documented in the quality management system of the manufacturer.

FRP laminate skins of rigid composite parts (large end cap, small end cap, and door) shall be produced using vacuum infusion molding in accordance with
manufacturing processes documented in the quality management system of the manufacturer. Infusion equipment shall be regularly calibrated, and maintenance shall be performed according to the equipment maintenance plan documented in the quality management system of the manufacturer.

FRP laminate skins shall be bonded using adhesive resins identified in Table 21-1 and in accordance with manufacturing processes documented in the quality management system of the manufacturer. Tooling used shall be regularly calibrated, and maintenance shall be performed according to the equipment maintenance plan documented in the quality management system of the manufacturer.

4.3 Manufacturing Procedures

Manufacturing procedures for the flexible shell and FRP components shall be qualified in accordance with ASME BPVC, Section X, Part RQ. In particular, they shall specify all the essential variables of the processes indicated in Articles RQ-4 and RQ-5 of ASME BPVC, Section X.

Manufacturing procedures used to manufacture the prototypes for certification testing shall be clearly identified and recorded in the quality assurance system and shall become the manufacturing procedures used for all production units. Any essential variation from the manufacturing procedures shall be cause for full retesting of the PVHO and submission as a new Case. Any deviation from an essential variable, as determined by ASME BPVC, Section X, shall be considered an essential variation.

4.4 Control of Raw Materials

All raw materials shall be purchased, tested, and provided with documentation in accordance with section 2 of this Case. A traceability report shall be issued for each part manufactured and shall include traceability information on all materials used in the manufacture of the part.

4.4.1 Resin Systems. Resin systems shall be provided with documentation ascertaining that properties meet or exceed the requirements of Tables 21-1 and 21-2 of this Case.

Resin systems shall be tested in accordance with ASME BPVC, Section X, RM-121 to ensure characteristics of the resin remain within the ranges of values permitted by the procedure specifications. Resin testing shall be done at first usage and at subsequent intervals of not more than one-fourth of its shelf life.

Resin systems shall be stored in accordance with supplier recommendations.

4.4.2 Fiber Systems. Fiber systems shall be provided with documentation ascertaining that properties meet or exceed the requirements of Tables 21-1 and 21-2 of this Case. Fiber shall be stored in accordance with supplier recommendations.

4.4.3 Core Materials. Core materials shall be provided with documentation ascertaining that properties meet or exceed the requirements of Table 21-1 of this Case.

Core materials shall be stored in accordance with supplier recommendations.

4.5 In-Process Controls

All manufacturing operations shall be controlled according to the process control plan detailed in the quality management system of the manufacturer. Nominal values and acceptable tolerances/limits shall be defined in the manufacturing procedures.

4.5.1 Winding. The manufacturer shall measure and report the essential parameters defined in ASME BPVC, Section X, RF-410 to ensure repeatability and quality during the filament winding of the shell.

4.5.2 Infusion Molding (Contact Molding). The manufacturer shall measure and report the essential parameters determined in ASME BPVC, Section X, RF-510 to ensure repeatability and quality during the infusion of the FRP laminates.

4.5.3 Adhesive Bonding and Casting. For all bonding and casting operations, the manufacturer shall check and document the following, as a minimum:

(a) surface preparation
(b) adhesive mixes (resin/catalyst ratio)
(c) temperature and duration of the cure

4.6 Parts Inspections

All manufactured and bonded parts shall be controlled according to the process control plan detailed in the quality management system of the manufacturer. Nominal values and acceptable tolerances/limits shall be defined in the manufacturing procedures.

Nondestructive test methods shall meet or exceed the requirements of ASME BPVC, Section V and Section X, Article RT-4 for Class I vessels.

4.6.1 Resin Cure. All manufacturing operations involving resins (shell winding, FRP laminate fabrication, laminate bonding, castings, etc.) shall be subjected to a polymerization test in accordance with ASME BPVC, Section X, RM-123 and this section of the Case to check if the part is properly cured.

The polymerization of the rigid resins shall be tested using Standard Test Method for Indentation Hardness of Rigid Plastics by Means of a Barcol Impressor (ASTM D2583).

The resin of the shell is very flexible, and its polymerization cannot be tested using ASTM D2583. Standard Test Method for Rubber Property—Durometer Hardness
(ASTM D2240) shall be used. The fabricator shall establish durometer specifications that have been documented by independent third-party testing that such durometer readings are indicative of complete resin cure. For each manufactured flexible shell, a minimum of three resin pucks shall be produced and tested in accordance with ASTM D2240.

4.6.2 Laminate Mechanical Properties. For each lot of manufactured materials used in the production of rigid composite parts (e.g., large end cap, small end cap, and door), a representative sample of composite laminate (E-Glass Fabric 800.027/Vinylester resin 800.025) shall be produced and tested in accordance with ASTM D3039. A Barcol test shall be performed on the representative sample to validate proper cure of the laminate before testing.

4.6.3 Weight and Fiber-Resin Ratio. For each manufactured part, the reinforcement weight, resin weight, and fiber-resin ratio shall be measured and documented. Part weight and fiber-resin ratio shall comply with the requirements of ASME BPVC, Section X, RF-400, RF-500, and RT-430.

4.6.4 Visual Inspection. Each molded or wound part shall be visually examined, using a suitable light source, to determine whether there are any imperfections of the type specified in ASME BPVC, Section X, Table 6-100.1. Acceptance criteria of Table 6-100.1 shall be applied.

4.6.5 Secondary Bonding. Secondary bonding shall only consist of cured laminate parts assembled using adhesive resins. The cure of resins and adhesives used for secondary bonding shall be tested in accordance with section 4.6.1. Secondary bonding shall be visually examined, using a suitable light source, to determine whether there are any imperfections of the type specified in Table 6-100.1 of ASME BPVC, Section X (i.e., voids, cracks, or foreign inclusions). Where visual examination is inappropriate, additional nondestructive methods of examination shall be used.

4.6.6 Wall Thickness Checks. The thickness of each molded or wound part shall be determined in compliance with ASME BPVC, Section X, RT-211 at a minimum of three points along its length on each of its four quadrants. The thickness determination shall be made with mechanical gauges or other devices having an accuracy of ±2% of true thickness. The wall thickness is governed by the number of layers of wound strands of filaments or fiber fabric specified in the manufacturing procedure. Thickness shall not be less than that set forth in the manufacturing procedures.

5 TESTING

In lieu of the requirements of ASME PVHO-1 and ASME BPVC, Section X regarding prototype qualification testing, the following requirements shall apply.

The prototype vessels used for testing shall be full size and of identical construction to the end item, with all fabrication completed (i.e., all options affecting the integrity of the vessel shall be done on the prototypes).

5.1 Prototype Testing

PVHOs used for prototype testing shall not be used other than for testing. Prototypes that have undergone testing without failure may be used for additional tests different from those already performed on the prototype.

5.1.1 Proof Pressure Test. The MAWP shall be determined as follows:

(a) Hydrostatic pressure tests shall be conducted on a minimum of three completely assembled PVHOs.
(b) The three prototypes shall be tested to at least 180 psi. The test pressure shall be held for 30 min as a minimum.
(c) The MAWP shall be based on a minimum 6:1 ratio of the test pressure determined by this test.
(d) Proof pressure tests shall be performed in warm water at the maximum operating temperature. The pressurizing medium shall be water.
(e) Rupture in the flexible shell, acrylic window, end caps, door, or closing system shall be cause for failure of the prototype.

5.1.2 Cyclic Hydrostatic Pressure Test. The maximum permissible number of operational pressurizations shall be determined by cyclic testing of a full-scale PVHO.

(a) A cyclic hydrostatic pressure test shall be conducted on one full-scale prototype chamber.
(b) The cyclic hydrostatic pressure test shall be from 1 atm ambient (0 psig) to MAWP and back to ambient.
(c) After 4,000 cycles, and then after every 2,000 cycles and at completion of testing, the PVHO shall be visually inspected for damage. The requirement for acceptance of the cyclic pressure test is that no crack (or other damage) shall be visibly detectable, using methods that are normally used for visual inspection of the applicable PVHO material. If cracks are detected during inspection, the previous number of cycles completed shall be defined as the total number of test cycles performed, CT.
(d) The number of approved operational cycles, CA, shall be computed as:

\[ CA = (CT/2) - 1,000 \]

The chamber shall be cycled for a minimum of 10,000 cycles.
(e) The cyclic hydrostatic pressure test shall be performed at the maximum operating temperature. The pressurizing medium shall be water.

5.1.3 Extended-Duration (Creep-Rupture) Test. A creep test shall be conducted on full-scale prototype chambers according to the graph in Fig. 21-7.
Fig. 21-7 Creep-Rupture Test Acceptance Criteria

![Graph showing creep test acceptance criteria]

GENERAL NOTE: Test duration shall exceed 300 hr.

<table>
<thead>
<tr>
<th>Number of Prototypes Tested</th>
<th>Minimum Test Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>$5.46 \times \text{MAWP}$</td>
</tr>
<tr>
<td>3</td>
<td>$4.87 \times \text{MAWP}$</td>
</tr>
<tr>
<td>5</td>
<td>$3.64 \times \text{MAWP}$</td>
</tr>
</tbody>
</table>

GENERAL NOTE: Minimum test duration shall be 300 hr.

(a) The creep test shall be conducted on one, three, or five prototypes.

(b) In all three cases, the test temperature shall be the maximum operating temperature and the pressurizing medium shall be water.

(c) In all three cases, the test duration shall be 300 hr as a minimum.

(d) Acceptance criteria are related to the number of prototypes tested. They are represented in Fig. 21-7. The lines in Fig. 21-7 represent the minimum pressure-time acceptance lines for each of the three test options. If all prototype test pressures and durations exceed the pressure and time defined by the respective acceptance line and the test duration for each prototype is 300 hr as a minimum, the design meets the creep test requirements.

Rupture of the PVHO below the pressure-time acceptance line or before a test duration of 300 hr is cause for failure of the test. Table 21-5 illustrates the minimum test pressures according to minimum test duration (300 hr) of the three test options.

**5.1.4 Cold Storage Test.** A cold storage test demonstrating that the chamber can be inflated at minimum operating temperature shall be conducted. One chamber shall be folded and stored for a minimum of 8 hr at $32^\circ F$ ($0^\circ C$), and then inflated to operating pressure (MAWP) within 15 min. The cold storage test shall be repeated twice.

After completion of each cold storage test, the chamber shall be visually inspected for damage and leakage. Leakage shall be measured at MAWP for at least 1 hr with the supply pressure isolated. The maximum pressure loss shall not exceed 10% of the rated pressure per hour, plus initial leakage if the prototype used was already tested.

**5.1.5 Cyclic Folding Test.** A folding and unfolding test for a minimum of 1,000 cycles shall be conducted on one PVHO. The chamber shall be folded by approaching both solid frames together while remaining parallel. When completely folded, the two end caps shall not be more distant than when stored in the transport case. After this is completed, the PVHO shall be unfolded to the stretched-out position. Folding cycles may be performed with the door removed.

Upon completion of 1,000 cycles, the chamber shall be inspected for damage and leakage. Leakage shall be measured at MAWP for at least 1 hr with the supply pressure isolated. The maximum pressure loss shall not exceed 10% of the rated pressure per hour, plus initial leakage if the prototype used was already tested.
5.1.6 Off-Gassing Toxicity Test. The chamber is continuously ventilated with breathable air, and oxygen is delivered to the patient by means of a hood. Therefore, off-gassed volatiles are continuously removed and the chamber complies with ASME PVHO-1, para. 1-10(b). An off-gassing toxicity test according to ASTM D5116-06 (Standard Guide for Small-Scale Environmental Chamber Determinations of Organic Emissions From Indoor Materials/Products) shall be performed. The concentration level of volatile compounds shall not exceed one-third of the threshold limit values (TLV) set forth in the current edition of Threshold Limit Values for Chemical Substances [American Conference of Governmental Industrial Hygienists (ACGIH)].

5.1.7 Flammability Tests. Flexible shell material shall meet or exceed the requirements of NFPA 701, Method 2—Fire Tests for Flame Propagation of Textiles and Films. Rigid composite parts shall meet the flammability requirements of 49 CFR 238.103—Fire Safety for wall and ceiling panels.

5.1.8 Puncture Test. A puncture test using a 3/8-in. cylindrical flat-end plunger shall be performed on one PVHO under a pressure equal to or greater than MAWP. The force to puncture the flexible shell shall be 400 lb (180 kg) as a minimum. After the plunger punctures the PVHO body, there shall be no tearing or rapid decompression.

5.1.9 Lighting Heat Test. Where LED lighting elements may cause heating of the acrylic window, the temperature rise of the window shall be measured. The test shall be conducted on one PVHO.

(a) LED lighting shall be powered at full capacity during the whole duration of the test.

(b) The temperature of the closer surface of the window from the LED lighting shall be measured at a minimum of three points regularly distributed until the steady-state condition is achieved.

(c) The initial temperature of the window shall be recorded prior to testing.

(d) The test shall be performed at the maximum operating temperature. Ambient temperature shall also be measured throughout the test.

Acceptance Criteria: temperature of the window shall not exceed 150°F (66°C)

5.1.10 Cyclic Closing System Wear Test. A cyclic wear test shall be conducted on a fully assembled closing system, including the large end cap and door. The flexible shell and small end cap can be removed during this test.

(a) A number of closing cycles equal to or greater than the total number of approved operational cycles, CA, derived from the cyclic hydrostatic pressure test defined in para. 5.1.2 above shall be performed.

(b) A “closing cycle” is defined as the full closing and full opening of the closing system, including removal and reinsertion of the door.

(c) After completion of the test, the closing system parts, the large end cap and door, shall be subjected to a hydrostatic pressure test to at least 180 psig (12.4 bar). The door gasket may be replaced prior to the hydrostatic pressure test.

(d) The hydrostatic pressure test shall be performed with warm water at the maximum operating temperature. The pressurization rate shall not exceed 30 psig/min (2.1 bar/min).

(e) Rupture in the closing system parts, the large end cap or door, at a pressure lower than 180 psig (12.4 bar) shall be cause for failure of the prototype.

5.2 Production Testing of Assembled Vessel

(a) All production units shall be subjected to a minimum of five pressure cycles between atmospheric pressure and MAWP.

(b) All production units shall be subjected to a pneumatic pressure test of 1.5 times the MAWP to be held for 60 min with the supply pressure isolated.

1 Internal and external temperatures shall be measured and recorded at the beginning and end of each test so that compensation can be made for any temperature differences.

2 The maximum allowable pressure loss after 60 min shall not exceed 5% of the rated pressure.

Every PVHO shall be examined visually and dimensionally for damage following each test, both pressurized and nonpressurized. Any signs of cracks, permanent deformation, or other damage according to ASME BPVC, Section X, Table 6-100.1 shall be cause for rejection of the PVHO.

Following testing, the PVHO shall be pressurized at the maximum operating pressure, inspected for damage to the sealing areas, and subjected to a soapy water spray leak test.

6 QUALITY ASSURANCE PROGRAM

6.1 General

A Quality Assurance Program shall be developed and applied for the design and manufacture of the PVHO. This Quality Assurance Program shall be reviewed, approved, and certified by an independent third-party inspection agency as meeting, as a minimum, the requirements of 21 CFR Chapter I, Subchapter H, Part 820—Quality System Regulation and ISO 13485 (current edition). Requirements of Section 3 of ASME PVH-1 shall be met in full.

This is a medical device subject to all safety requirements per the user manual. The chamber is intended to be used, installed, and operated only by qualified professional hyperbaric personnel.
This section describes the requirements of the content of the Quality Assurance Program (QAP).

6.2 Organization

The QAP shall describe the organizational structure, with responsibilities, authorities, and lines of communication clearly delineated. Persons indicated in the QAP to be responsible for verifying the PVHO quality shall have the authority 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 nonconforming items, deficiencies, or unsatisfactory conditions until proper corrective action has been taken

6.3 Design Control

A documented 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

6.4 Document Control

The QAP shall describe the manufacturer’s measures for ensuring that design output documents are correctly translated into manufacturing specifications, drawings, procedures, and shop/laboratory instructions. Considerations shall be made for reviews and approvals, including those of the purchaser.

The manufacturer shall include the procedure for ensuring distribution of appropriate documents to the working areas in a timely fashion and the process for ensuring nonuse of obsolete documents.

The manufacturing procedures used for the fabrication of the qualified prototypes shall be clearly identified and recorded in the manufacturer’s QAP. These procedures shall be used for the manufacturing of all PVHOS in accordance with this Case.

6.5 Procurement Control

The QAP shall include the controls necessary to ensure that applicable requirements are included and verified 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.

6.6 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. Properties of all materials used in production units shall meet or exceed the properties of materials used in prototype construction and testing. Materials shall be provided with certificates to attest conformity with this Case. Supplier agreements shall be signed with material suppliers to clearly monitor and control the quality of materials used in the PVHO fabrication.

Any change in raw material shall be cause for full retesting of the PVHO and submission as a new Case. The manufacturer shall provide and maintain raw material specifications including minimum properties.

6.7 Process Control

As the manufacturing process may influence the finalized material properties, stringent Process Control Procedures (PCP) shall be established.

The QAP shall include a PCP 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 PCP shall contain periodic operator and inspector signature points so that product status can be readily determined.

The manufacturer shall identify critical manufacturing activities and ensure that they are accomplished by appropriately trained and qualified personnel. Inspection points shall follow the activities in the process control plan. Tests shall be performed on finalized material samples for all pressure-bearing parts to ensure that properties of Tables 21-1 and 21-2 are met or exceeded. Records of these tests shall be kept in accordance with section 6.12.

6.8 Inspection Control

The QAP shall include the measures used by the manufacturer to ensure 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
(c) documentation of all inspections

6.9 Test Control

The QAP shall describe the measures used to ensure that tests, including laboratory 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.
Tests shall be performed by trained and qualified personnel.

Tests shall be verified by persons other than those performing or supervising the test.

6.10 Control of Measuring Test and Inspection Equipment

The QAP shall describe the equipment used in inspections and tests and the measures used to ensure 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.

6.11 Control of Nonconforming Items and 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 inadvertent use. Nonconforming materials and items shall be identified. 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.

Where discrepancies are such that a repair is allowed, the repair method, documentation of repair, and appropriate inspection documentation shall be provided.

6.12 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 Case 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 yr.

6.13 Quality Assurance Overview by an Independent Third Party

An independent third-party agency shall be employed to ensure that all PVHOs intended to be classified under this Case are designed and manufactured to the requirements of ASME PVHO-1 and this Case. This includes, but is not restricted to, the following:

(a) The PVHO is designed in accordance with ASME PVHO-1 and this Case.

(b) The manufacturer is working to the requirements of the quality control system.

(c) The materials used in the fabrication of the PVHO comply with the approved procedure by qualified operators, as required by ASME PVHO-1 and this Case.

(d) All manufacturing operations are conducted in accordance with approved procedures by qualified operators, as required by ASME PVHO-1 and this Case.

(e) All defects are acceptably repaired.

(f) All prototype and production testing has been performed and witnessed as required by ASME PVHO-1 and this Case.

(g) The PVHO is marked in accordance with ASME PVHO-1 and this Case.

(h) A final 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 inspection agency free access to all facilities associated with the manufacture of the PVHO. The manufacturer shall keep the third-party inspection 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.

6.14 Risk Analysis

An established procedure for evaluating and mitigating potential risks associated with the PVHO and associated systems shall be developed and applied for the design and manufacture of the PVHO. This procedure shall meet or exceed the prescriptions of ISO 14971 (Medical Devices—Application of Risk Management to Medical Devices). Requirements of para. 1.11 of ASME PVHO-1 shall also be met.


Risk analysis shall identify compounds, cleaning agents, and/or surface contaminants that may degrade or attack the pressure vessel and identify corrective actions and/or indications of damage. The operations manual and pressure vessel markings shall caution the user to stop operations should surface changes be noted (e.g., orange peel or blisters) and contact the manufacturer for further action if detected.

7 MARKING AND REPORT

7.1 Marking

In lieu of ASME PVHO-1, section 1-9, the external surface of the conical shell shall be permanently marked, close to one end, with the data required in ASME PVHO-1, para. 1-9(a) and the following (sample) designation:

30-24-42-88-PVHO-1 (CC21)-GMG-0001-20xx
where

- $30 = \text{rated pressure, psig}$
- $24 = \text{smallest inside diameter, in.}$
- $42 = \text{largest inside diameter, in.}$
- $88 = \text{length of the vessel, in.}$

$\text{PVHO-1 (CC21)} = \text{PVHO designator and Case number}$

- $\text{GMG = manufacturer’s initials}$
- $0001 = \text{manufacturer’s unique identification for the PVHO}$
- $20xx = \text{year of manufacture}$

*Maximum allowable working pressure: 30 psig (0.207 MPa)*

*Operating temperature: 32°F (0°C)/104°F (40°C)*

*Allowable cyclic life: 4,000 cycles*

*Conical shell expiration date: DD/MM/YYYY*

The shell shall also display the following notice:

DO NOT EXPOSE TO DIRECT SUNLIGHT OR UV LIGHT SOURCES FOR EXTENDED PERIODS.

The vessel shall also display the following notices:

THIS IS A MEDICAL DEVICE SUBJECT TO ALL SAFETY REQUIREMENTS OUTLINED IN THE USER MANUAL.

THE CHAMBER SHALL ONLY BE OPERATED BY QUALIFIED PERSONNEL WHO MUST BE IN ATTENDANCE AT ALL TIMES DURING USE.

ITEMS THAT CAN BE DANGEROUS INSIDE A CHAMBER (SUCH AS FLAMMABLE ITEMS, OPEN FLAME, HAND WARMERS, AND ELECTRONIC DEVICES) ARE PROHIBITED.

7.2 Report

PVHO Case 21 Form, Manufacturer’s Data Report for Pressure Vessels for Human Occupancy, shall be completed to certify that each PVHO meets the requirements of ASME PVHO-1 and this Case.
1. Manufactured and certified by

2. Manufactured for

3. Location of installation

4. Vessel identification __________________________ (drawing no.) (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 ________ (year) and Case No. 21.

6. Manufactured for a maximum allowable working pressure of 30 psig, at a maximum working temperature of 104°F and a pneumatic test pressure of 45 psig (internal).

7. Windows: Certification Reports, properly identified and signed by the window manufacturer, are attached for the following items:

<table>
<thead>
<tr>
<th>Nos.</th>
<th>Location</th>
<th>Type</th>
<th>Diameter or Size</th>
<th>Nominal Thickness</th>
<th>How Attached</th>
</tr>
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</table>

8. Manufacturer’s Data Reports/Partial Data Reports, completed in accordance with the ASME BPVC, Section X, and properly identified and signed by Commissioned Inspectors, are attached for the following items:

<table>
<thead>
<tr>
<th>Data Report</th>
<th>Remarks (Name of Part, Manufacturer’s Name, and Identifying Stamp)</th>
</tr>
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CERTIFICATION OF DESIGN

User’s Design Specification on file at ____________________________

Manufacturer’s Design Report on file at ____________________________

Prototype test program attested by ____________________________ (name and date)

Quality Assurance Program reviewed by ____________________________ (name and date)

Fabrication documentation reviewed by ____________________________ (name and date)

Production testing witnessed by ____________________________ (name and date)

CERTIFICATION OF COMPLIANCE

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) and PVHO Case 21.

Date __________________ Company name __________________ Signed __________________