

# Product Advisory

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## Acrylic Window Aging - Maintenance & Inspections

We at Perry Baromedical would like to thank you for your purchase of a Perry Baromedical Hyperbaric Chamber. Whether you're a first time customer or a long-term member of the Perry family, we truly hope your facility is enjoying a successful operating program and that you have been able to treat your patients in a manner that has helped them through difficult recoveries.

As the end-user of a PVHO chamber (Pressure Vessel for Human Occupancy), and according to the requirements contained within the Operator's Manual, ASME/PVHO-2 (Clause 1-2.1, Clause 1-6.1), NFPA 99 (National Fire Protection Association Clause 14.3.1.3.2), and the FDA (US Food and Drug Administration - implicit operators responsibilities pursuant to the manufacturers statement of specified servicing under FDA 21CFR Part 820, Subpart N, Section 820.200), your facility is responsible for developing and implementing a maintenance program that will specifically address and satisfy the requirements for the proper inspection of the acrylic window (in addition to the general chamber maintenance requirements). The purpose of this memo is to alert you of these and additional requirements specifically in regards to the acrylic window as the window nears the end of the 10-year design life. It is strongly suggested that you obtain copies of the above referenced documents and read them thoroughly.

These controlling standards, and in particular, PVHO-2, Section 2 (Viewports), Clause 2-4.1, calls for (1) an operational acrylic window inspection based on daily usage, and (2) a more comprehensive maintenance inspection based on design life. Prior to end of design life, in addition to daily inspections, the acrylic window would also be inspected annually, based on the maintenance schedule listed in the Operators Manual. As the acrylic window reaches 10 years of age (or 10,000 cycles, whichever comes first), the inspection requirements become much more stringent and expand to include the need for additional specific documentation. The need and frequency of this inspection schedule is outlined in PVHO-2, Clause 2-4.3, and is specified at a maximum interval of 24 months after the end of the design life (PVHO-2, Table 2-4.3-1).

Under normal conditions a 10-year inspection results in a satisfactory review and the chamber is certified to remain in service for an additional (1) year period, with a scheduled re-inspection each year thereafter for a total possible life span of 20 years (or 20,000 cycles, whichever comes first). However it's important to know that acrylics do age and eventually require replacement. And because of the costs involved, knowing this well before you face the need to do such a replacement will assist you in accurately costing your treatment profiles over the long term.

Please keep in mind that at any time during the annual inspection process (prior to end of design life), if a determination is made that the acrylic has failed the (above referenced) PVHO requirements, and cannot be repaired, or it is in need of replacement based on the applicable standards, the inspecting firm **is required to red tag** the machine and prohibit its continued use for human treatments. Fortunately, outside of cases of specific trauma to the acrylic window, the aging process is usually gradual and windows can be monitored monthly or quarterly should an anomaly be found during an inspection.

We realize that this inspection and possible "red tag" may severely impact your facilities operating capabilities, but the first priority is patient safety and the requirements under which these devices are built, manufactured, and maintained.

Should you like additional information on the requirements of the referenced code specifications, information on possible inspection programs, or just wish to discuss the general aspects of the chamber servicing requirements, please contact either Perry Baromedical's Engineering or Customer Service departments at your earliest convenience.

Thank you again for your business. Everyone at Perry is committed to your long-term success.

Sincerely,  
Perry Baromedical Engineering