

Regarding questions surrounding the availability of IV pumps and ventilators used in HBO. My first question is the age-old “Is this intended for Monoplace or Multiplace use?” as the technical needs of either approach will vary. Before we get into further detail, I will point out several keys to remember when approaching this topic:

- The Safety Director and Medical Director of the program should be granted the ultimate authority to make decisions regarding the acceptable use of medical devices in the hyperbaric environment.
- As is the case with other medical devices, each facility will take on some level of risk – regardless of the device manufacturer’s “endorsement” of its capacity to be used in a hyperbaric environment. Therefore, communication with your Legal Administrative personnel and your Biomedical Engineering leadership should be considered at the outset. I encourage the development of a policy /procedure document for this purpose and recommend that your legal team and division administrators endorse it.
- There are two approaches to choosing a product:
 - a. Seek out devices that have been previously tested and endorsed by the FDA to be safe for use in the hyperbaric environment (VERY Limited list – more on this later).
 - b. As most hyperbaric facilities do – consider applying the FDA’s [“Off-label use of Medical Equipment”](#) policy to a device that your institution is already using.
- Regardless of the device, we would advise that the Safety Director performs a risk assessment and tests the devices with assistance from your Biomedical Engineering group. I will provide a document in response to a recent UHMS Safety Committee question that contains a wealth of information about risk assessments that can be applied to any medical device.
- I recommend Tom Workman’s book “Hyperbaric Facility Safety, A Practical Guide,” (2nd Ed., 2020).

Here is a short list of Ventilators and IV Pumps that have been used in hyperbaric environments. Some of the usage data steps from a 2019 survey from one of my Safety Committee colleagues. I have starred the devices that we are using/have used previously and can share first-hand experience. I’ll also direct you to these 2006 papers by Dr. Jacek Kot which offers a lengthier list, but many are older models:

[Medical Equipment for Multiplace Hyperbaric Chambers. Part II: Ventilators](#)

[Medical Equipment for Multiplace Hyperbaric Chambers. Part III: Infusion Pumps and Syringes](#)

***Remember that many of these are designed to be utilized at Sea Level and some risk mitigation measures may have been necessary.**

***This list does not include ALL of the Intravenous Pumps and Ventilators that have been used in Hyperbaric operations.**

***This document is not an endorsement of the use of this equipment by me or the Mayo Clinic.**

***Each Hyperbaric Facility should perform their own risk assessment and testing before considering for patient use under increased atmospheric pressure.**

Ventilators – Click Hyperlinks for more info	Comments
Atlantis by Providence Global Medical Inc	Precursor to the VersalVent V1. No advanced modes. FDA approved hyperbaric ventilator. No longer manufactured/supported. Difficult to find.
Campbell EV S00	Only tested to 4 ATA. No advanced modes.
Draeger OxylogB	No longer supported. Only tested to 3.5 ATA. No advanced modes.
Impact uni-vent Eagle 754	<p>*Used previously at Mayo. Studied extensively by the US Navy. Proven track record – can deliver over 500ml at 2.8 ATA.</p> <p>No longer supported by manufacturer. Very limited parts available, but still in use by many. Consider battery life needs for longer therapy – NFPA does not allow batteries to be charged while under pressure.</p> <p>A handheld respirometer is commonly used along with this device to validate tidal volumes.</p>
Oceanic Magellan	Along with the Sechrist 500A, considered the classic ventilator for Monoplace use. May be difficult to find individual units and parts. Does not offer any advanced modes.
Sechrist 500A	Long-standing history of use in the monoplace. Continued support offered by the manufacturer. Does not offer any advanced modes.
Servo Siemens 900c	Tested up to 2.8 ATA. No longer manufactured/supported. Difficult to find.
Siaretron 1000	Designed for Hyperbaric environments. Offers advanced modes. Italian manufacturer. Not available for sale in the US. CE approved but not FDA-approved. I've heard there is much difficulty in acquiring parts from the manufacturer.
VersalVent Model V1	<p>*Used currently at Mayo. Only FDA-approved hyperbaric ventilator in current production.</p> <p>Pneumatically controlled. No advanced modes. Requires skilled Respiratory Therapists. Can be used for Monoplace or Multiplace</p>
Zoll Z Vent	A promising ventilator currently under evaluation at Duke University Medical Center. Has been tested to 90 FSW. Results of this study should be published next year. Transport Ventilator – significant risk mitigation is required for the Lithium-Ion battery.

IV Pumps – Click Hyperlinks for more info	Comments
Abbott Hospira Plum A+	*Used previously at Mayo. Compatible with Monoplace and Multiplace. These are no longer manufactured or supported. Tubing sets are no longer available. Some centers have continued use without Baxter ‘hyperbaric’ tubing sets. Battery life was an issue. FDA-approved and designed for the hyperbaric environment. Wireless connections caused battery drain. Loop-back cat-5 connectors required.
Alaris CareFusion 8015 PC	*Currently testing at Mayo. Very popular pump nationally. Used in many hyperbaric facilities. Multiplace applications only. Technical Report.
Alaris Med System III	*Currently used at Mayo. Also a very popular pump among hyperbaric facilities. Drug Library is difficult to update – uses old software, manual-only updates. Tubing sets are no longer manufactured. Some expiring sets still available. Flow settings lack a rate in mcg/min, requiring the use of a “drug library calculator” to convert mcg/min to ml/hr. Users enter this rate manually for some infusions (usually norepinephrine).
B Braun Infusomat Space	OEM states “Do not use in a hyperbaric oxygen chamber.” At least one center has tested and used this pump successfully in the multiplace hyperbaric environment. No published documentation is available.
Baxter Flo-Guard 6201	No longer manufactured or supported. Parts will be in limited supply. Pump is available online. Has been tested in Monoplace and Multiplace chambers.
Baxter Sigma Spectrum	OEM states: Warning - The SIGMA Spectrum Infusion System has not been tested or evaluated for use in a hyperbaric chamber. At least one center has tested and used this pump successfully in the multiplace hyperbaric environment. No published documentation is available.
Braun Outlook 400es Series	One reported use in the multiplace hyperbaric environment. No published documentation is available.
Haux Model	Syringe pump (external?) Website says “Available Soon” but there are reports of this pump being used in the multiplace setting. Needs further investigation.
ZYNO Z-800F	This pump is on the market and supported by the manufacturer. Notably, this pump has a user-configurable occlusion setting.

Evaluated for the Monoplace and Multiplace environment (See attachments).

This is a “tip-of-the-iceberg” topic, and there are many other important risk factors to consider. I am happy to discuss any of the above with the Hyperbaric Safety Director for your program. If you have someone that would be appropriate for me to connect with, I welcome the introduction.

Many Thanks,

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ADDITIONAL RESOURCES:

- <https://www.uhms.org/resources/medfaqs-frequently-asked-questions-faq/search/1-%20Search.html?yrfagsearch=Apex%Pro%FH>
- Poster: [Performance of the Z-800F, Body Guard 323 Color Vision™ & Flo-Gard® 6201 infusion pumps for monoplace chamber use](#)
- Abstract: [Performance of the Zyno Medical Z-800F, CME Body Guard 323 Color Vision™ and Baxter Flo-Gard® 6201 infusion pumps for monoplace chamber use.](#)
- Presentation Slides: [Performance of the Zyno Medical Z-800F, CME Body Guard 323 Color Vision™ and Baxter Flo-Gard® 6201 infusion pumps for monoplace chamber use.](#)
- [Evaluation Of Intravenous Therapy Devices In The Hyperbaric Chamber](#)
- [Performance of three large-volume infusion pumps with the monoplace hyperbaric chamber](#)
- Poster: [Preliminary evaluation of the Zyno Z-800F, CME 323 Color Vision, and Alaris Med System III infusion pumps for use in the multiplace chamber](#)