

Infusion Pumps to Consider for Use with Hyperbaric Chambers

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Background

In a March 5, 2014, Important Infusion Pump Discontinuation Notice, Hospira announced that it would be discontinuing the manufacture, sale, leasing, service, and support of the Plum A+ hyperbaric infusion pump after June 30, 2014. This was the only pump with FDA clearance for providing infusions to patients in hyperbaric chambers. Since the pump's dedicated infusion sets were also discontinued, some facilities have reportedly continued to use the pump off-label for hyperbaric infusions with Hospira's standard sets manufactured for the Plum A+ and Plum 360 pumps, which are marketed for conventional hospital infusions.

The market for hyperbaric-compatible infusion pumps is very small, and these pumps have a life expectancy of more than 10 years. Therefore, pump manufacturers cannot justify the regulatory burden and support costs to continue providing them. As a result, there are currently no large-volume or syringe infusion pumps that have FDA clearance for use with hyperbaric chambers. FDA considers clinical chambers to be class II medical devices.

This article describes hyperbaric chambers, explores the issues associated with delivering IV medication to patients receiving therapy in these chambers, and identifies infusion pump models that might be used.

What Is a Hyperbaric Chamber?

Hyperbaric oxygen (HBO₂) chambers are pressure chambers constructed specifically for exposing individuals to pressures greater than 1 atmosphere (14.7 pounds per square inch absolute [psia]) while they breathe near-100% medical-grade oxygen (O₂). Clinical HBO₂ is defined by the Undersea and Hyperbaric Medical Society (UHMS) as an intervention in which a patient breathes medical-grade oxygen while at pressures greater than 1.4 atmospheres absolute (ATA). HBO₂ is indicated for disorders such as decompression sickness, arterial gas embolism, acute

carbon monoxide poisoning, and many others (see the list below).

When the patient breathes HBO₂, both the amount of O₂ per unit volume of arterial and venous blood and the partial pressure of O₂ are increased in blood and tissue. Dissolved O₂ content increases by about 2.3 mL of O₂ per 100 mL of whole blood for each additional atmosphere of pressure, even after the hemoglobin is 100% saturated. The increased partial pressure of O₂ in the arterial blood during hyperbaric oxygenation causes a high O₂ diffusion gradient from blood to tissue. This gradient facilitates delivery of O₂ to hypoxic tissues by diffusion, even when the circulation is impaired. These high partial pressures of O₂ also have wound-healing effects and modulate inflammation.

Conditions Treated with Hyperbaric Oxygen

The UHMS Hyperbaric Oxygen Committee lists clinical conditions for which HBO₂ is indicated:

- ▶ Air or gas embolism
- ▶ Arterial insufficiencies
 - ▷ Central retinal occlusion
 - ▷ Selected problem wounds (to enhance healing)
- ▶ Carbon monoxide poisoning
- ▶ Clostridial myonecrosis (gas gangrene)

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- ▶ Compromised grafts and flaps
- ▶ Crush injuries and skeletal muscle-compartment syndromes
- ▶ Decompression sickness
- ▶ Delayed radiation injuries (soft-tissue and bony necrosis)
- ▶ Idiopathic sudden hearing loss
- ▶ Intracranial abscess
- ▶ Necrotizing soft-tissue infections
- ▶ Refractory osteomyelitis
- ▶ Severe anemia
- ▶ Thermal burns

Most treatments for decompression sickness, carbon monoxide poisoning, and arterial gas embolisms are performed at 3 ATA, whereas most wound care HBO₂ pressures are at 2 to 2.4 ATA.

Types of Hyperbaric Chambers

Monoplace

Monoplace hyperbaric chambers usually consist of a horizontal cylinder made of metal or acrylic, with a metal hatch at one end. A single patient can recline, sit, or lie within the chamber. Through-hull access ports provide for patient support, such as electrical connections for patient monitoring and delivery of IV fluids. Electrical signals in monoplace chambers are limited to patient physiologic leads and communications wiring. Viewports in metal chambers allow observation inside the chamber.

Maximum operating pressure of monoplace chambers is 3 ATA. Medical-grade oxygen is commonly used to pressurize the chamber; therefore, no O₂ breathing device is necessary. Some monoplace chambers are pressurized with air; in these chambers, a mask or hood must be used for the patient to receive HBO₂. At specialized centers, intubated patients can be treated in monoplace chambers. It is accepted practice for chambers pressurized with oxygen to have a mask or mouthpiece that provides breathing air to the patient. Some treatment protocols call for intermittent air breathing interspersed during HBO₂ to reduce the risk of oxygen toxicity.

Multiplace

Multiplace hyperbaric chambers can accommodate more than one patient and medical staff member at a time. Medical equipment that has been through a comprehensive risk assessment and evaluation may remain inside the chamber to address patients' needs during treatment. Multiplace chambers require a large amount of space and a significant capital investment.

Multiplace chambers are designed to be pressurized with air; maximum operating pressure is 6.8 ATA. If needed, O₂ is delivered to the patient via an O₂ delivery device, such as a mask, hood, or ventilator.

Operating Procedure

For both monoplace and multiplace chambers, after placing the patient in the chamber, the chamber operator closes and seals the hatch, then pressurizes the chamber with air or oxygen. Depending on how quickly the patient can equalize middle-ear pressure, this process takes 4 to 10 minutes or longer. The patient remains in the chamber at a pressure and for a duration determined by the treatment protocol and may undergo HBO₂ in a single session or repeated sessions, depending on the condition being treated.

Use of Infusion Pumps with Hyperbaric Chambers—Key Issues

Although clinical HBO₂ was first used primarily at major medical centers, it is now also performed at many smaller facilities, including non-hospital-based facilities. There are approximately 4,800 hyperbaric chambers in the United States, of which approximately 140 are multiplace chambers.

Very few patients require an IV infusion while receiving hyperbaric therapy, which typically lasts 1.5 to 2 hours, although the need does arise at times:

- ▶ Acute patients (e.g., patients with carbon monoxide poisoning, patients just out of surgery receiving HBO₂ treatment of a compromised flap) often need IV therapy during HBO₂.

- ▶ Critically ill patients may need one or more infusions during HBO₂, such as norepinephrine, vasopressin, or insulin.
- ▶ Some routine patients may be receiving a continuous infusion of an antibiotic that needs to be continued during HBO₂.

Below we discuss the key issues associated with use of infusion pumps for patients in hyperbaric chambers.

Monoplace chamber infusions. For IV infusions delivered to patients in monoplace chambers, the infusion pump is located adjacent to the chamber (see the photo on this page). The infusion pump administration set is connected to a specialized fitting in a port in the chamber hatch, allowing a seal. Inside the chamber, tubing from the specialized fitting is connected to the patient's IV catheter. The infusion pump's occlusion pressure is set to maximum. In order to deliver the IV solution into the pressurized environment, the pump must be able to generate 30 psi or more without alarming and stopping the infusion. An infusion set connector assembly is also required. We are aware of two such assemblies:

1. Argon Medical Devices disposable hyperbaric IV extension set (PN: 041600503A)
2. Sechrist Industries reusable stainless steel pass-through (PN: HB703)

Multiplace chamber infusions. Multiplace chambers are large enough to permit placement of an infusion pump inside the chamber (see the photo on page 4). For a pump that is deployed in this way, there is no need to change the occlusion pressure setting. Chapter 14 of the National Fire Protection Association's NFPA 99, *Health Care Facilities Code*, 2015 edition, applies to hyperbaric facilities. Requirements related to using infusion pumps in multiplace chambers are specified in section 14.2.8.3.17, "Portable Patient Care—Related Electrical Appliances," including 14.2.8.3.17.5, "Battery-Operated Devices." In particular, batteries shall not be damaged by the maximum chamber pressure at which they will be used and they shall not be charged while located in the chamber. Lithium and lithium-ion batteries are prohibited unless the product is listed for use in hyperbaric conditions. The requirements in

section 14.2.8.3.17.6, "Cord-Connected Devices," would apply to infusion pumps in a multiplace chamber with electrical receptacles, although infusion pumps are typically operated on battery power. Also, the infusion pump needs to be able to operate normally at increased pressure.

Fire risks. A clinical hyperbaric chamber combines the use of a pressurized atmosphere with the use of oxygen, which creates an increased risk of fire. NFPA requires that chambers be electrically grounded; additionally, if the atmosphere contains more than 23.5% O₂ by volume, patients also must be electrically grounded. A fire-suppression system is required for multiplace chambers. NFPA classifies multiplace and monoplace chambers as Class A and Class B chambers, respectively. NFPA 99 section 14.3.2.4 specifies that equipment used in the chamber be lubricated with oxygen-compatible material, if lubrication is required.



A Zyno Medical Z-800F pump infusing to a patient in a monoplace chamber. The pump's infusion set is attached to the proximal connector of a hyperbaric extension set that is sealed in the wall of the chamber (see arrow). Pumps must be able to generate 30 psi or more to deliver fluid into a pressurized chamber. Although it is depicted being used for a hyperbaric infusion, this model has not been FDA-cleared for such use. (Photo courtesy of Lindell Weaver, MD, Intermountain Healthcare, Salt Lake City, Utah)

Equipment safety evaluation. NFPA 99 requires the safety director of the hyperbaric facility to be responsible for all equipment used in the hyperbaric environment. A comprehensive evaluation and risk assessment of any portable medical equipment must be completed and documented under various hyperbaric conditions to ensure that the equipment is safe for use with or within a chamber.



An Alaris MedSystem III pump set up for use on battery power in a multi-place chamber. Although it is depicted being used for a hyperbaric infusion, this model has not been FDA-cleared for such use. (Photo courtesy of Lindell Weaver, MD, Intermountain Healthcare, Salt Lake City, Utah)

Infusion Pumps That May Be Considered for Use with Hyperbaric Chambers

Listed alphabetically below are the models that appear in studies of pump operation during use within, and/or during delivery into, pressurized hyperbaric chambers. (See the bibliography for the list of studies.) Also included are pumps whose specifications indicate that they could meet the requirements for hyperbaric use.

These studies of standard infusion pumps (some of which are no longer commercially available) demonstrate the extent of variations in performance when operating during hyperbaric conditions. Hyperbaric facility staff should be guided by these studies in testing any infusion pump that they want to use with their chamber(s) to ensure proper operation and to anticipate possible deviations in flow accuracy.

Large-Volume Pumps

For Use with Monoplace Chambers

1. Baxter Flo-Gard 6201—This pump is discontinued but is readily available; it operates with Baxter s-series infusion sets. [Hyperbaric Clearinghouse](#) supplies a modified version of the Flo-Gard 6201 pumps for use with monoplace chambers.
2. CME Body Guard 323 Color Vision—This pump has not been FDA-cleared to be marketed in the United States for any clinical application.
3. Zyno Medical Corp. Z-800F—See our [Evaluation](#) of this pump (available to members of specific ECRI Institute programs).

For Use in Multiplace Chambers

1. CareFusion (formerly Alaris) MedSystem III—In addition to CareFusion, infusion sets are available from Medline and Moore Medical.

2. CareFusion Alaris System 8015 Large-Volume Pump—See our [Evaluation](#) of this pump. The service manual states that the Alaris System (with the exclusion of the EtCO₂ module) “has been verified to operate with no malfunction alarms due to the hyperbaric chamber environment or unintentional key presses when used in a hyperbaric chamber”; it is not certified for use in oxygen-enriched environments.
3. Imed/Alaris Gemini PC1 and PC2—These pump models are discontinued but readily available; they operate with CareFusion infusion sets marketed for the Alaris System 8015 LVP module.
4. Medical Technology Products MTP.

Syringe Pumps

1. Atom Medical Corp. 235—This pump is discontinued and was not FDA-cleared to be marketed in the United States for any clinical application.

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3. Fresenius Vial Infusion Technology PILOTE Hyperbaric—Although this pump is specified for operation with both types of hyperbaric chambers, it has not been FDA-cleared for marketing in the United States for any clinical application.

Pump manufacturer information can be obtained from the ECRI Institute’s *Healthcare Product Comparison System [HPCS]* reports for [large-volume infusion pumps](#) and [syringe infusion pumps](#). (HPCS is available to members of the Health Devices Gold and SELECTplus programs.)

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