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Date: 3/24/23
From: UHMS HBO_2 Safety Committee
RE: **MEDFAQ Response**

MEDFAQ Category: Item Approval

MEDFAQ Question: Can a home infusion system be used in a monoplace chamber? Patient has implanted port.

Thank you for your question. The UHMS HBO_2 Safety Committee can provide information to assist you in answering your question, but the ultimate responsibility for these types of questions rests with the Hyperbaric Medical Director (HMD) and Hyperbaric Safety Director (HSD) of your facility.

Discovery
Upon further review, the device your patient has is an elastomeric pump – an AVANOS C-Series (C100020) Homepump. Upon reaching out to the manufacturer, it was discovered that the company tested a device of the same design many years ago (On-Q Pain infusion device). AVANOS identified that the design of the flow restrictor has not changed. The testing suggested that that the pump would behave as designed while under hyperbaric conditions. Regardless of this finding, the Safety Committee recommends that your Medical Director and Safety Director assess the safety of this device for your particular setting and decide whether or not to add the device to an "approved" or "approved with mitigation" list developed by your program.

Elastomeric Pumps in Hyperbaric Settings
We are aware of several published reports of the performance of other elastomeric pumps in hyperbaric settings. Some results show a safe delivery of the medications with no adverse outcomes. Other reports with a separate make and model show a slight decrease in delivery rate. The UHMS HBO_2 Safety Committee has responded to a similar question about the Braun Easypump several years ago. In your case, the information received by that manufacturer should provide some assurance that the pump will function as it was designed.

Response and General Approach to Equipment Evaluation
We would encourage you to first determine the necessity of the item for the time duration required to complete the therapy. Oftentimes, antibiotics may be delayed or briefly interrupted without negative outcomes. If it is possible and safe to delay either the HBO Therapy or the infusion, we would recommend this approach.

If you are considering the option to test this device for safe use within the hyperbaric environment, we can provide you with specific resources that may assist you in your evaluation process. This information not an endorsement by the UHMS HBO2 Safety Committee for the use of this device in the hyperbaric environment. Rather, we hope that you will consider these suggestions in your individual approach:

- We strongly encourage a formal risk assessment of the device, with assistance from your hospital biomedical engineering group and perhaps your hospital safety or legal teams.

- If you discover that the device has been tested previously under hyperbaric conditions, we suggest that this may be utilized as validation of your final assessment, but we do not recommend that this is the entirety of device approval. Simply put, we recommend a formal risk assessment regardless of testing methods. (Exception: Modern ICD's and Pacemakers are commonly tested by the manufacturer for function under pressure. Therefore, use under increased atmospheric conditions does not constitute an off-label use of those devices.)
- Consider reaching out to the manufacturer to learn more about the device, especially if there are limited performance details/specifications in the product manual.
- Try to gain an understanding of what types of stress the device was subjected to during the manufacturing and testing phase.
- You may wish to make the manufacturer aware of your intentions or you may remain anonymous.
- Regardless of the manufacturer's response, there may be good reason for you to proceed with the evaluation, as this device may be vital to the continuum of care to the patient.
- It should be noted that any modifications to the device or use other than as recommended by the manufacturer risks voiding any warranty on the product.
- If evaluating a medical device, it is understood that few are intended to be used in the Multiplace hyperbaric environment. Therefore, consider that such use will likely fall into the FDA category of "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices ". You may also wish to review FDA.gov: Frequently Asked Questions about Medical Devices for more information.

NOTE: Regarding medical device evaluation, at least one major academic institution's legal team with experience in medical device modification has approached the current FDA regulations in the following fashion:

> *"The program (modification and testing of medical devices for safe use in the hyperbaric environment) is not subject to FDA regulation. FDA regulates manufacturers and not the practice of medicine. Physicians are able to use FDA approved products other than under the labeled indications as long as the physician meets certain criteria. FDA's statement on this off-label use is as follows:*
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> *"Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB)."*

We hope that this response will assist you in determining the best course of action for your program. Please do not hesitate to reach out to the UHMS HBO_2 Safety Committee if you have any follow-up questions.

Respectfully,

The UHMS HBO_2 Safety Committee

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