CHI Advisory Bulletin:

Portable Chambers or Soft sided chambers being Marketed for Home Use

Within the past two years it is has come to our attention that there is a rigorous marketing campaign to target parents of children with special needs in Quebec. Parents having marketing efforts that are characterized by misrepresentation and aggressive sales tactics have reported this. This bulletin has been prepared in an attempt to correctly represent the facts that currently are associated with the use of this device.

1. The units currently marketed under the label names Oxyhealth- are the models Solace (21 inch diameter), Respiro (27inch diameter), Vitaeris (32 inch)
    a. The 21 inch model had received pre-market approval by the US FDA (510k) for use with ambient air in the condition of acute mountain sickness. Cautionary labeling is attached to the device against using or pressurizing with anything greater than ambient air or 21% oxygen. Given the substantial modifications and the deliberate marketing of the device by representatives of the manufacturer with oxygen to be used in direct contravention with cautionary labeling.

    b. None of these devices has the approval or clearance from HEALTH CANADA for sale or use in Canada.

    c. Neither the Respiro (27 inch diameter) nor the Vitaeris (32 inch) have received pre-market approval for marketing in the US.

2. None of the soft-sided chambers complies with safety guidelines set up to define minimum standards for pressure vessels for human occupancy. These guidelines are recognized as the industry standards to ensured the safety of those using the device.
3. None of the paperwork suggest that its installations should comply with the requirements of the CSA standards or NFPA guidelines.
4. The use of this device in the an enclosed area with the augmentation of greater than atmospheric oxygen (use of oxygen concentrator) can could result injury to occupants and attendants of treatment with the portable chamber
5. The use of high pressure cylinders to augment the FiO2 past 21% violates Cautionary labeling and the absence of environmental monitoring and safety devices may result in over pressurization, which has the capability to compromise the pressure boundary.
6. Two instances of boundary compromise have been reported with substantial damage to the structure housing the device.
7. Damages to a structure through the use of device non compliant to industry safety standards may not be reimbursable by insurance.
8. Inability to ensure proper device grounding of the device to assure prevention of static build up with device usage. This is further complicated by the extensive use of synthetic materials in its construction.

9. The manufacturer of the device has not submitted to destructive testing by an independent agency to allow the customer to anticipate specific modes of failure.
10. A valid lifecycle of the device in not been determined
11. Common failures reported:
    a. Compromise of the 1 of 2 zipper closures rending bag unusable
    b. Delamination of dissimilar material that may compromise pressure boundary making the device unusable
        1. PVC pass-thrus and the flexible bag material
        2. Plastic window and bag material
    c. In the fall of 2007 a failure of the mild system resulted in smoke entering the chamber. Child was treated in traditional chamber for smoke inhalation. To date no explanation has been made by the distributor.
12. CEO of Oxyhealth Corporation reports the widespread use of PVC in the construction of the device. Heavy metals are used to keep PVC flexible or pliable. This is of particular importance considering that this device is marketed to treat autistic children who often are being treated to remove heavy metals. The device on pressure change will experience changes in temperature. Because of the nature of the material it is unlikely that this can be eliminated over the life of the product.

13. Air sampling provided by Oxyhealth is not serial number or model specific so the sample submitted for testing could be from any source.

14. Often in marketing of the device for use with children of special needs it is stated that the parent and the children can go in at the same time. If this is done, the device is likely to experience “fogging” as seen in the movie Medicine under Influence. The presence of fogging may be indicative of buildup of CO2 and inadequate flow.

15. The use of pressures less than 1.5ATA has been demonstrated to foster the growth of certain bacteria which respond to minimal hyperoxia. These bacteria will respond to these elevations in oxygen until their oxidative defenses have been compromised. (Kindwall 1999, Hyperbaric Medicine Practice)