

HOBIT TRIAL - HYPERBARIC - SAFETY PAUSE (Rev. 2)

HOBIT Subject ID: _____ Date: ___ / ___ / ___ Time: _____

HOBIT Treatment Profile: _____ Class A / Class B HBO2 TX: _____ of 10

Operator _____ HBO RN _____ HBO MD _____

ICU RN _____ RT _____ STUDY COOR _____

- | | |
|---|---|
| <input type="checkbox"/> Daily Startup Checklist completed (HBO Tech) | <input type="checkbox"/> Patient identifiers (2) verified (HBO RN) |
| <input type="checkbox"/> Pre-HBO Checklist completed (HBO Tech) | <input type="checkbox"/> Bilat Myringotomies done (MD) |
| <input type="checkbox"/> Critical Care Checklist completed (HBO RN) | <input type="checkbox"/> Mitigations done and Variances recorded (Tech) |
| <input type="checkbox"/> Ventilator Checklist completed (RT) | <input type="checkbox"/> Treatment Logs and timers ready (HBO Tech) |

HBO RN or HBO TECH to complete all variances requiring mitigation procedures prior to HBO treatment

Y	N	ITEM	Mitigations completed by (initial) and comments.
		Jewelry, watches, or other metal objects	
		Dressings or bandages pre-approved for HBO2	
		Removable dentures plates or partials	
		Transdermal medication patches	
		Implanted pacemaker, defibrillator, medication pumps,	
		Cosmetics (makeup, lipstick lip balm, etc.)	
		External Fixation Device(s)	
		Personal clothing of other items	
		See back of this page for additional items.	

- ALL VARIANCES CHECKED "Y" ABOVE**, have proper mitigation procedures completed and approved by chamber operator or HBO supervising MD.
- Variances with equipment or procedures is cleared and documented by the HBO Tech, and the Sup MD.
- Ground strap is secured on patient and verified conductivity with patient to chamber chassis. (Monoplace)
- Wiring, tubing, connectors, etc. are clear of door and ready for patient to be placed in chamber. (Monoplace)
- All above checklists and documentation is cleared for subject's hyperbaric treatment.**

PRE – SAFETY PAUSE CHECKS

SAFETY PAUSE

- Team discussion:** Any variances to discuss? Mitigation orders for the above variances completed.
- Operator:** Verbalize TX Profile. Ground strap tested (monoplace) Chamber & timers ready. Concerns
- HBO & ICU RN's:** Monitoring & IV's ready. Meds for TX and transport Vital signs good Concerns
- RT:** Verbalize Vent settings Cuff NS Alarms set Circuit secure Verbalize BS and suctioning Concerns
- Study Coordinator:** Agrees with Profile. Verbalize Post HBO2 Profile. Concerns
- Supervising MD:** Approve TX Profile, Bilat myringotomies done Concerns Patient cleared for treatment.
- Team: please initial Safety Pause after HBO treatment starts.**

Operator / Tech Initials: _____ HBO Nurse Initials: _____ HBO Supervising MD Initials: _____

ICU RN Initials: _____ RT Initials: _____ Study Coordinator Initials: _____

SAFETY PAUSE INSTRUCTIONS

- 1) It is suggested that the **Safety Pause** be conducted by a hyperbaric staff member, e.g., chamber operator.
- 2) The top half of the page (above the line) includes different team checklists and validations that need to be completed by the RN, the RT and the Chamber Operator prior to starting the Safety Pause.
- 3) The grayed check box is for items that are not normally allowed in the hyperbaric chamber and that have specific pre-approved mitigation orders that need to be completed for each item that is checked on this list. (Note: these items may vary per site.)
- 4) Any items without a pre-approved mitigation order needs to have the HBO Safety Director and the HBO supervising physician's documented approval prior to allowing the subject to be treated in the chamber. This document should be kept and filed for future reference and review.
- 5) Mitigation orders will differ depending on the chamber Class. For example: items that are allowed, with approved mitigation orders, in a Class A chamber may not be allowed in a Class B chamber that is pressurized with 100% oxygen.
- 6) When all checks above line have been completed (Pre-Safety Pause Checks), the Safety Pause is called and team members who are directly involved will gather for a "Team discussion". The chamber operator will address each check box as indicated and ending with the final clearance from the supervising HBO physician.
- 7) Each Safety Pause team member should initial the Safety Pause sometime after the treatment starts.