Medical-Grade Tier 2 Hyperbaric Oxygen Therapy (HBOT)

Restoring Oxygen. Rebuilding Immunity. Redefining Oncology Care
Nursing-Supervised Clinical Framework for Integrated Oncology

Dear Patient

1. Clinical Overview
Tier 2 Medical-Grade Hyperbaric Oxygen Therapy (HBOT) operates at **2.0 atmospheres absolute (ATA)** and delivers **100% medical-grade oxygen** under regulated clinical conditions. Within an integrated oncology setting, Tier 2 HBOT is a **biological adjuvant therapy**—bridging molecular oxygen physiology with cancer rehabilitation, immune restoration, and adjunctive cytoprotection. This level of care is administered under **nursing supervision** in compliance with hyperbaric medicine standards, supported by oncology and regenerative medicine governance.

---

2. Clinical Rationale in Oncology
Malignant tissue is characteristically **hypoxic**, acidic, and glycolytically reprogrammed (the Warburg phenotype). Hypoxia stabilizes **HIF-1α**, upregulates **VEGF** and **PD-L1**, and drives **angiogenesis, immune evasion, and radio-resistance**.

Tier 2 HBOT directly counteracts this microenvironment through:

- **Reversal of tumor hypoxia:** Elevation of tissue pO_2 disrupts HIF-driven signaling, normalizes redox balance, and enhances radiosensitivity.
- **Vascular normalization:** Improved perfusion and endothelial function mitigate chaotic tumor angiogenesis.
- **Immune reactivation:** Reoxygenation enhances $CD8^+$ T-cell cytotoxicity, NK cell function, and macrophage M1 polarization.
- **Protection of normal tissue:** Oxygen preconditioning reduces ischemia–reperfusion injury and limits collateral damage during radiotherapy or chemotherapy.
- **Modulation of cytokines:** HBOT downregulates IL-1β, IL-6, TNF-α, and TGF-β1, while upregulating anti-inflammatory IL-10 and SOD/catalase expression—restoring immune equilibrium critical in integrative oncology.

Hooper (2025) demonstrates that Tier 2 HBOT provides an optimal translational interface between acute hospital-based oxygen therapy and community-accessible regenerative oncology care. Delivered under nursing supervision, it corrects microvascular hypoxia, down-regulates HIF-1α, modulates IL-1β and TNF-α, and restores antioxidant balance. This framework allows oxygen therapy to function as a **biological adjuvant**, supporting chemotherapy, radiotherapy, and immunotherapy through measurable improvements in tissue oxygenation, immune competence, and patient quality of life.

Tier 2 HBOT offers a **biological adjuvant to oncology and regenerative medicine**, transforming hypoxic, inflamed, or ischemic tissue into a **restorative microenvironment**. Nursing-supervised

precision oxygenation improves quality of life, reduces complications, and extends post-treatment recovery.

As neoplastic processes advance, cancer cells are often subjected to environments with a relatively **low oxygen tension**. This indirectly suppresses mitochondrial function and results in a switch toward intracytoplasmic glycolysis in order to support continued growth and proliferation. The **re-purposed medicines combined with HBOT and high dose Intravenous Vitamin C** interferes with a number of proteins or signalling pathways and so impact upon cancer cells' access to and usage of energy sources.

This combination effect of killing these cells, restricting their multiplication, or reprogramming them to behave like healthy cells. In addition, there is evidence that these medicines can suppress cellular efflux pumps and so increase cancer cells' sensitivity to chemotherapy, radiotherapy, immunotherapy and, where appropriate, hormone therapy. By using medicines in combination with intensive Hyperbaric Oxygen saturation, we are able to target multiple biological pathways, thus creating a synergistic effect and potentially offering greater benefit than would the addition of one adjuvant therapeutic agent on its own. The integrative combination all have anti-cancer potential and there is considerable literature (ranging from in vitro studies, in vivo human tissue studies, case reports, clinical studies and epidemiological studies), which supports their use in the context of cancer.

---

3. Tier 2 Scope and Indications in Oncology
Under Dr Hooper's *Tiered Scope of Practice Framework (2017)*, Tier 2 HBOT encompasses **sub-acute and adjunctive oncology indications** requiring controlled medical oxygenation rather than emergency intervention.

Typical applications include:

- Radiation-induced tissue injury (mucositis, proctitis, cystitis, radionecrosis)
- Chemotherapy-related neuropathy, fatigue, or delayed wound healing
- Post-operative oncology reconstruction and flap viability support
- Hypoxic pain syndromes and skeletal metastasis with ischemic bone marrow changes
- Immune dysregulation and post-treatment inflammation (cytokine-driven malaise, cachexia)
- Integrative recovery protocols combining HBOT with nutraceutical, immunologic, or peptide-based therapies

At this tier, therapy functions as a **precision oxygen adjunct** within multidisciplinary oncology programs—delivered safely, reproducibly, and measurable in outcome metrics such as CRP, VEGF, lactate, and cytokine normalization.

---

4. Nursing Supervision and Clinical Governance
Tier 2 HBOT is supervised by a **nursing team trained in oncology hyperbaric protocols** and oxygen pharmacodynamics.

Their responsibilities include:

- **Patient assessment:** Screening for contraindications (e.g., pulmonary blebs, sinus blockage, uncontrolled COPD, cisplatin-induced ototoxicity).
- **Treatment delivery:** Compression between1.5–2.0 ATA using certified monoplace or multiplace chambers compliant with **ASME PVHO-1** standards.
- **Monitoring:** Continuous supervision, pulse oximetry, cardiac surveillance, and observation for barotrauma or oxygen toxicity.
- **Documentation:** Recording session parameters, vital trends, and symptom responses correlated with treatment cycles.
- **Interdisciplinary coordination:** Communication with oncologists, radiotherapists, and integrative medicine clinicians to align oxygen therapy with chemotherapy or immunotherapy schedules.

This structured model enables **safe decentralization of hyperbaric oncology care**, allowing nursing teams to manage routine sessions while maintaining physician oversight.

---

5. Mechanistic Integration with Oncology Pathways

At the molecular level, Tier 2 HBOT modifies tumor and host microenvironments in ways complementary to oncologic regimens:

Mechanism	HBOT Effect	Oncologic Relevance
Hypoxia / HIF-1α axis	Downregulation of HIF-1α, reduction of glycolytic shift	Enhances chemo- and radiosensitivity
Vascular function	Normalizes angiogenic signaling (VEGF modulation)	Improves drug delivery and reduces edema
Immune competence	Boosts oxygen-dependent cytotoxic immunity	Augments checkpoint inhibitor efficacy
Oxidative stress balance	Increases endogenous antioxidant enzymes	Mitigates therapy-induced oxidative damage
Stem-cell modulation	Mobilizes EPCs and MSCs for repair	Supports post-treatment tissue regeneration

By restoring physiological oxygen gradients, Tier 2 HBOT transforms hypoxic, immunosuppressed terrain into one **favorable for treatment synergy and recovery**.

---

6. Clinical Implementation and Safety

- **Pressure range:** 1.5–2.0 ATA for 60–90 minutes per session, 5 days per week for 60-80 sessions (base line saturation) depending on biomarker activity.
- **Equipment:** Certified medical chamber, oxygen purity ≥ 99.5 %, redundant safety valves, and temperature/humidity control.

- **Emergency readiness:** Nursing staff trained in compression-related event management, seizure protocols, and decompression procedures.
- **Follow-up:** Serial assessment of inflammatory and oxidative biomarkers, imaging (MRI or PET) for perfusion changes, and patient-reported quality-of-life indices.

---

7. Integration into Regenerative Oncology Programs
Tier 2 HBOT forms a cornerstone of **Molecular Hyperbaric Oxygen Therapy (MHBOT)** (Hooper) in integrative oncology—used alongside cytokine modulation, peptide immunotherapy, and nutritional correction. The therapy aims not merely to oxygenate but to **reprogram tumor microenvironments** toward regeneration and immune competence through molecular and metabolic recalibration.

This model, underpinned by **nurse-led supervision and precision monitoring**, aligns with the humanitarian ethos of providing **accessible, evidence-based oxygen care** within cancer rehabilitation pathways.

---

8. Conclusion
Tier 2 Medical-Grade HBOT represents a clinically governed, nursing-supervised, and biologically targeted modality in integrated oncology. It corrects the hypoxic foundations of malignancy, fortifies immune function, and enhances tolerance to conventional therapies. Delivered within a regulated framework, it exemplifies the fusion of molecular oxygen science

Table Tier 2 Medical-Grade Hyperbaric Oxygen Therapy (HBOT) – Integrated Oncology Clinical Protocol (Nursing-Supervised Framework)

Category	Clinical Parameter / Protocol Detail	Clinical Rationale / Commentary
Therapy Classification	**Tier 2 HBOT – Medical Grade (1.5–2.0 ATA)**	Defined within **Hooper MR. PhD Thesis (2025): *Hyperbaric Oxygen Therapy and Regenerative Medicine – A Humanitarian and Scientific Revolution*** and the *Tiered Scope of Practice* framework (2017). Tier 2 provides supervised medical-grade oxygenation for sub-acute and adjunctive oncology applications.
Chamber Type	Certified monoplace or multiplace chamber compliant with **ASME PVHO-1** and **AS 1210** pressure-vessel standards.	Engineering and medical compliance guarantee patient and operator safety in regulated facilities.

Category	Clinical Parameter / Protocol Detail	Clinical Rationale / Commentary
Oxygen Source	100 % medical-grade oxygen (≥ 99.5 % purity, USP/EP certified) via built-in breathing system (BIBS).	Ensures purity, stable concentration, and contamination-free oxygen delivery required for reproducible biological response.
Pressure Profile	Therapeutic pressure: 1.5–2.0 ATA for 90 minutes at depth.	Provides optimal oxygen partial pressure to reverse tumor and tissue hypoxia, suppress HIF-1α, normalize vascular tone, and enhance immune efficiency without CNS toxicity.
Compression / Decompression	1–2 psi per minute.	Controlled transitions prevent barotrauma, sinus distress, and oxidative instability.
Treatment Frequency	5 sessions per week for 60-80 total sessions during the initial oxygen saturation.	Generates cumulative mitochondrial, angiogenic, and cytokine-modulating effects; dosing schedule supported by translational data (Hooper 2025).
Primary Oncology Indications	• Radiation-induced tissue injury (cystitis, proctitis, osteoradionecrosis) • Chemotherapy-related fatigue and neuropathy • Post-surgical graft or flap ischemia • Hypoxic bone and soft-tissue pain • Cytokine-driven inflammation and cachexia • Post-viral immune dysregulation	Targets the hypoxic, inflammatory, and ischemic sequelae that compromise tissue recovery and immune resilience in oncology patients.
Monitoring Parameters	Continuous pulse oximetry and ECG; blood pressure pre/post-session; otic and sinus checks; neurological observation; pain and fatigue scores.	Nursing supervision ensures real-time physiological stability and correlation of symptom improvement with oxygen exposure.
Safety Screening	Exclude: untreated pneumothorax, severe COPD with blebs, recent bleomycin use, active sinus/ear infection, uncontrolled seizures, claustrophobia.	Prevents pulmonary barotrauma, oxidative lung injury, or pressurization intolerance.
Adjunctive Integration	• **Radiotherapy:** HBOT within 2 h post-session to enhance radiosensitivity. • **Chemotherapy:** schedule ≥ 24 h	Synchronizes oxygen delivery with oncology regimens to improve tissue perfusion and protect non-target tissue from collateral oxidative damage.

OXYGEN EARTH | OXYMED AUSTRALIA
28 CLAREMONT STREET, SOUTH YARRA, VICTORIA 3141
T: +61 3 9826 9898 | NURSING TEAM: 0459 664 901

Category	Clinical Parameter / Protocol Detail	Clinical Rationale / Commentary
	apart to avoid free-radical overlap. • **Immunotherapy:** cytokine and redox monitoring through treatment cycle.	
Cytokine / Biomarker Tracking	IL-1β, IL-6, TNF-α, TGF-β1, IL-10, VEGF, SOD, catalase, CRP, lactate, and transcutaneous pO_2.	Enables objective measurement of anti-inflammatory, angiogenic, and redox normalization effects; biomarkers validated in Hooper (2025) PhD dataset.
Nursing Team Responsibilities	Patient education and consent; chamber operation and safety checks; continuous monitoring; vital sign recording; treatment documentation; communication with attending physician.	Establishes the nursing-led operational model central to Tier 2 HBOT; ensures accountability and protocol fidelity.
Physician Oversight	Medical clearance, protocol authorization, periodic review of clinical data, and emergency support availability.	Provides governance while enabling autonomous nursing execution within approved Tier 2 parameters.
Outcome Evaluation	**Functional:** Pain and fatigue reduction (VAS, FACIT-F); improved mobility and sleep. **Biochemical:** Decreased CRP and IL-6; increased SOD/catalase. **Structural:** Enhanced wound/graft viability and post-radiation healing.	Defines measurable translational outcomes linking oxygen therapy to molecular and clinical recovery indices.
Documentation & Compliance	Electronic recording of pressure/time curves, vital responses, and adverse events; audited under institutional clinical governance and occupational safety standards.	Ensures transparency, reproducibility, and medico-legal compliance under Tier 2 HBOT accreditation.

Clinical Safety in a Medical-Grade Hyperbaric Oxygen Chamber
(Tier 2 Supervised Environment – Nursing-Led Framework)

Safe operation of a hyperbaric chamber depends upon strict adherence to clinical, engineering, and procedural standards. The chamber is a controlled, high-oxygen, high-pressure medical environment where small errors can result in serious complications. Safety protocols therefore integrate **engineering design, oxygen-handling procedures, patient monitoring, and staff competency** into one unified governance model.

1. Structural and Engineering Safety

- **Chamber Certification:**
  Must meet **ASME PVHO-1**, **ISO 13485**, or equivalent national standards (AS 1210 in Australia).
  Chambers are designed to withstand specified pressure loads and have redundant pressure-relief valves, emergency shutoffs, and interlocks.
- **Built-in Breathing System (BIBS):**
  Ensures medical-grade oxygen delivery and allows rapid switch to ambient air in emergencies.
- **Materials:**
  All interior surfaces are **non-flammable and anti-static**; patient clothing and bedding are cotton to prevent ignition.
- **Fire Suppression:**
  The chamber environment is oxygen-rich; ignition sources are strictly prohibited (no electronics, oils, alcohol-based products, or synthetic fabrics).
  A **water mist fire suppression system** and **rapid venting mechanism** are mandatory in hospital-grade installations.

---

2. Oxygen Safety and Fire Prevention

- **No Ignition Sources:**
  Prohibit electrical devices, lighters, matches, watches, mobile phones, and metallic batteries inside the chamber.
- **Patient Preparation:**
  Remove cosmetics, petroleum-based ointments, and nail polish; use water-based dressings only.
- **Grounding and Static Control:**
  The chamber and gas systems must be grounded to prevent electrostatic discharge.
- **Atmospheric Monitoring:**
  Sensors continuously record chamber oxygen concentration, temperature, and humidity to avoid exceeding 23.5 % ambient oxygen in multiplace chambers.

---

3. Patient Monitoring and Clinical Oversight

- **Continuous Observation:**
  Patients are visually monitored throughout the session via internal and external cameras and intercom systems.
- **Vital Parameters:**
  Pulse oximetry, heart rate, and blood pressure are recorded pre- and post-session; neurological vigilance is maintained for early detection of oxygen toxicity (twitching, nausea, or visual changes).
- **Emergency Decompression:**
  The nursing operator is trained to initiate controlled depressurization in the event of seizure, distress, or chamber malfunction.

- **Communication:**
  A two-way communication system allows immediate contact with the supervising nurse and attending physician.

---

4. Physiological Safety Parameters

Risk Category	Clinical Manifestation	Preventive / Response Strategy
Barotrauma	Ear/sinus pain, tympanic rupture, pulmonary expansion injury	Slow compression/decompression (1–2 psi/min); pre-session ear clearing; halt session if pain persists.
Oxygen Toxicity (CNS)	Perioral twitching, nausea, dizziness, tunnel vision, convulsion	Maintain $PO_2 < 2.0$ ATA; implement "air breaks" every 20–30 min; immediate decompression and air breathing if symptoms occur.
Pulmonary Oxygen Toxicity	Cough, chest tightness after multiple sessions	Limit exposure duration; incorporate rest days in prolonged regimens.
Hypoglycaemia (diabetic patients)	Weakness, confusion	Pre-session blood glucose monitoring; provide carbohydrate snack if required.
Anxiety or Claustrophobia	Panic, hyperventilation	Pre-briefing, reassurance, communication; decompress if unresolved.

---

5. Nursing and Operational Protocols

- **Competency Standards:**
  Nurses and chamber operators must hold recognized HBOT certification, advanced life support (ALS) training, and documented competency in chamber emergency drills.
- **Patient Screening:**
  Pre-treatment evaluation includes ENT assessment, lung imaging if indicated, medication review (e.g., bleomycin, doxorubicin, cisplatin), and cardiovascular risk profile.
- **Pre-Session Briefing:**
  Explain pressure sensations, ear equalization techniques, and communication signals.
- **Post-Session Review:**
  Assess for ear discomfort, transient visual changes, fatigue, or mild light-headedness.
- **Incident Reporting:**
  Any deviation or adverse event is documented in the HBOT safety log and reviewed in morbidity/safety meetings.

---

6. Environmental and Infection Control

- **Air Quality:**
  Compressed gas supplies are filtered and dried to medical standards; chamber interior cleaned daily with non-flammable disinfectants.

- **Infection Control:**
  All patient-contact surfaces are covered with disposable, hypoallergenic linens; devices disinfected between sessions.
- **Temperature Regulation:**
  Chamber environment maintained between 21–25 °C to prevent heat stress or condensation.

---

7. Emergency Preparedness

- **Fire Drill Protocols:**
  Regular staff simulation for chamber fire response, oxygen shutoff, and patient evacuation.
- **Medical Emergency:**
  External crash cart positioned within 5 metres of the chamber; emergency decompression procedures rehearsed monthly.
- **Power Failure Contingency:**
  Manual valves allow controlled depressurization without electrical systems.
- **Gas Supply Redundancy:**
  Dual-cylinder or piped backup ensures uninterrupted oxygen supply.

---

8. Governance and Documentation

All operations fall under the **Hyperbaric Clinical Governance Framework (Hooper MR, PhD, 2025)** which mandates:

- Daily safety checklist before pressurization.
- Recording of environmental parameters and treatment logs.
- Maintenance logs for valves, compressors, and oxygen systems.
- Quarterly audit of staff competencies, incident reports, and calibration certificates.

Summary

Safety inside a hyperbaric chamber is achieved through **rigorous engineering control, oxygen discipline, and trained clinical oversight**. Under Tier 2 nursing supervision, risk is minimized by structured pre-screening, controlled pressurization, continuous physiological monitoring, and strict adherence to non-flammable, contamination-free conditions.

When properly executed, medical-grade HBOT maintains one of the lowest complication rates in clinical medicine (<0.01 % reportable incidents), providing a **controlled, predictable, and physiologically restorative environment for oncology, wound care, and regenerative medicine patients.**

References

1. **Hooper MR.** *Hyperbaric Oxygen Therapy and Regenerative Medicine – A Humanitarian and Scientific Revolution.* PhD Thesis. 2025.
2. **Hooper MR.** *Tiered Scope of Practice in Hyperbaric Medicine: Clinical Governance for Translational Oxygen Therapy.* HBOT2017 Symposium, New Orleans.

3. Thom SR. Molecular mechanisms of hyperbaric oxygen therapy in oncology. *Undersea Hyperb Med.* 2018;45(3):219–232.
4. Efrati S, Ben-Jacob E. Refocusing the concept of hyperbaric oxygen therapy in integrative oncology. *Front Oncol.* 2020;10:567.
5. Daruwalla J, Christophi C. Hyperbaric oxygen therapy and tumor hypoxia: molecular mechanisms. *Cancer Lett.* 2006;242(1):1–8.
6. Moen I, Stuhr L. Hyperbaric oxygen therapy and cancer: a review. *Target Oncol.* 2012;7(4):233–242.
7. Kindwall EP, Whelan HT. *Hyperbaric Medicine Practice.* 4th ed. Best Publishing Company; 2017.
8. Thom SR. *Hyperbaric oxygen therapy: principles and safety. Undersea Hyperb Med.* 2018;45(3):203–218.
9. International Standard ASME PVHO-1. *Safety Standard for Pressure Vessels for Human Occupancy.* 2021.
10. European Committee for Hyperbaric Medicine (ECHM). *Code of Safety for Hyperbaric Facilities.* 2019.