

SerenaGroup® 2022 Hyperbaric Medicine Therapy (HBOT) Policies and Procedures

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Title: Center Signature Page	Date: 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serena Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Hyperbaric Oxygen Therapy Policy & Procedure Manual

The SerenaGroup® hyperbaric oxygen therapy policies and procedures are intended to support the general, patient care, and other policy and procedures of the hospital. These standards are superseded by hospital standards where applicable.

SerenaGroup® is committed to reviewing and updating every two years or more often when revision is

deemed appropriate. As new policies are received, it is the responsibility of the Program

Director/Nurses Manager to review and implement the new practice.

Print Program Director Name

Print Medical Director Name	Signature of Medical Director	Date

Signature of Program Director

Date

Title: Hospital Signature Page	Date: 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Hospital Approval of Hyperbaric Oxygen Therapy Policy & Procedure Manual

In accordance with accreditation and regulatory requirements, I have reviewed the SerenaGroup® Hyperbaric Oxygen Therapy Policy and Procedure Manual. These policies address the delivery of patie care, treatment and services in the Hyperbaric Chamber Room that is managed by SerenaGroup®.		
These policies and procedures are	approved for use in the Advanced Wound C	are Center.
Print Hospital Liaison Name	Signature of Hospital Liaison	Date
Print Program Director Name	Signature of Program Director	Date

Title: Policy and Procedure Manual	Policy Number: HM.101.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018,1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- HBO Technical Personnel
- Nursing Personnel
- Provider

PURPOSE:

These policies serve as a standard for measuring excellence in the hyperbaric center.

POLICY:

- 1. Each policy and procedure specific to SerenaGroup® is reviewed bi-annually and revised as needed. All revisions will be provided to the center.
- 2. The SerenaGroup® Medical Director has the responsibility of reviewing and approving all policies and procedures.
- 3. The Program Director (PD) has the responsibility to ensure all staff is knowledgeable and compliant.
- 4. The PD will give to the applicable governing body.
- 5. The policies and procedures will be available in print or electronic form.
- 6. SerenaGroup® policies and procedures are proprietary and are valid only during the term of the SerenaGroup® contract.

Title: Medical Record	Policy Number: HM.102.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018,1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Provider

PURPOSE:

To establish a complete medical record for each patient treated at the wound care center.

To establish measures that safeguard medical records against loss, destruction, tampering and unauthorized access or use.

To describe the role of scribes in the center.

POLICY:

- 1. Document all care provided.
- 2. Documentation must meet CMS medical necessity.
- 3. Documentation must be completed per hospital policy and medical staff bylaws.
 - a. In the absence of hospital policy or medical staff bylaws, documentation must be completed within 72 hours of patient encounter.
 - b. Entries should not be made in advance of the service provided to the patient. Predating, pre-timing or backdating an entry is prohibited.
- 4. When the course of treatment is complete, the entire medical record is stored in the electronic health record.
 - a. In the absence of electronic health record, store the record per hospital policy.
- 5. Maintenance of patient records

- a. Must be stored per HIPAA regulation.
- b. In some cases, the medical record may be hybrid, consisting of both electronic and paper documentation and physically exist in separate and multiple locations in both paper and electronic formats.
- 6. Personnel with a "need to know" will have access to the minimally necessary information.
- 7. When the center is closed, the medical records are secured.
- 8. Records will be released in accordance with HIPAA policy.
- 9. Scribing for provider is permitted by SerenaGroup® within the following parameters:
 - a. The scribe records what the provider dictates.
 - b. This individual should not act independent of the provider.
 - c. The provider is accountable for the documentation. Providers must sign the documents after the review of the scribe's entry.
 - d. The scribe will notate any entry made in the medical record.

Title: Guidelines for HBOT	Policy Number: HM.103.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Nursing
- Provider

POLICY:

Guidelines for Hyperbaric Oxygen Therapy (HBOT)

- 1. The hyperbaric unit is maintained and operated as a contracted service by SerenaGroup®.
- 2. A credentialed supervising provider must be on site during HBOT.
- 3. A chamber technician is present in the chamber room during operation.
 - a. Chamber technicians or nurses are required to attend SerenaGroup® training course for HBOT operation or any other certified course approved by SerenaGroup®. Certification is maintained through continuing education requirements monitored by SerenaGroup®.
 - b. Personnel working in the hyperbaric unit are BLS certified.
 - c. A copy of all certifications and in-service records including current primary source verified licensure and BLS are on file.
- 4. Appropriate candidates for hyperbaric therapy are determined by a credentialed HBOT provider. All elements of medical necessity will be documented in the medical record.

- 5. Medication that may cause CNS or respiratory depression while in the chamber for treatment must be reviewed by the hyperbaric provider prior to treatment.
- 6. Diagnoses that do not meet medical necessity for hyperbaric therapy must be approved in advance before treatment is initiated.

Title: HBO Initial Training/Competencies	Policy Number: HM.104.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018,1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- HBO Technical Personnel Clinical Staff
- Provider

PURPOSE:

To ensure the new hyperbaric staff is oriented, trained and can operate the chamber in a safe manner. Such training ensures the trainee understands the basic principles of hyperbaric medicine, creates a consistent and reasonable expectation of skill level, helps build an educated staff, quickly eliminates potential poor performance issues, supports SerenaGroup patient safety efforts, and builds confidence among the physicians as well as center and hospital staff.

The training program is thorough, informative and provides the trainee with the knowledge and tools necessary to pass the exam and skills/competencies assessment on the first attempt. Training includes:

POLICY:

- 1. 40 hours of an approved hyperbaric medicine instruction within the first year of employment
- 2. HBO Technical/Nursing personnel must have all competencies documented in their employee file within 30 days of completing the 40-hour course.

Hyperbaric Technician Competency Assessment Employee Name: Assessment Date: Mode of confirmation of competency: T=Tested, V=Verbalized, D=Demonstrated Mode Fully **Partially** Not The Technician Can Demonstrate the Following: T-V-D Met Met Met Identify 3 beneficial effects of oxygen administered with increased barometric pressure State potential hazards of hyperbaric treatments Manage patient having difficulty equalizing middle ear pressures during hyperbaric treatment Identify procedures for diabetics who have a pre-procedure blood sugar of <100 or >400 Recognize symptoms of hyperbaric CNS toxicity and describe the appropriate actions Demonstrates the operations of a monoplace hyperbaric chamber Name contraindications to hyperbaric treatment Name some indications for hyperbaric treatments State reasons for termination of hyperbaric treatment List some indications to cancel hyperbaric treatment Manage an anxious patient during a hyperbaric treatment Instruct patients and their families about hyperbaric treatments and safety guidelines that must be followed State location of main oxygen valve and demonstrate shutting it off Shows an understanding of display gauge Understands the importance of HIPAA regulations Demonstrates awareness of compliance logs Understands and demonstrates proper maintenance of hyperbaric chamber (chamber cleanliness) Demonstrates emergency removal of a patient to surface pressure Understands the use of emergency venting Demonstrates an understanding of all emergency procedures a patient may encounter, including: fire in and outside of the chamber, as well as all medical emergencies. Demonstrates and awareness of the inner workings of the hyperbaric chamber Demonstrates competency in taking vital signs and blood glucose Demonstrates the ability to work with adults and geriatric populations Demonstrates an understanding of The Joint Commission regulations Understands and complies with universal precautions. CPR Certified: YES NO If YES, Expiration Date: **NOTES:**

Employee Signature:	Date:
Supervisor or Instructor Name:	Date:
Supervisor or Instructor Signature	Date:

Chamber Operation Competency Checklist			
Trainee:	Date:		
Proctor:	Date:		
Trainee has a clear understanding and can demonstrate proper use of the fol	llowing hy	/perbaric	
chamber controls and equipment:			
Control Panel	MET	NOT MET	N/A
Master Valve Function			
Rate Set Control			
Can describe the purpose of rate set control button			
Pressure Set Control			
Chamber Pressure Indicator			
Set Pressure Gauge			
Demonstrates on set pressure gauge 2ATA/14.7PSI			
Chamber Pressure Gauge			
Safety Locking Pin			
Emergency Vent Button			
Emergency Toggle Switch			
Purpose of Green L.E.D. Power Indicator			
Oxygen Conservation Switch			
Audio/Phone Communication System			
Demonstrate proper cleaning maintenance of hyperbaric chamber			
Demonstrates proper use of multimeter ground check			
Identify and demonstrate use of oxygen shut-off value			
Demonstrates use of chamber checklist-start-up/shut down			
Signature of Trainee:		Date:	
Signature of Proctor:		Date:	

Title: Guidelines for Providers	Policy Number: HM.105.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018,1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

Providers

PURPOSE:

Providers are trained and available to work in the Hyperbaric Center.

POLICY:

Training of Hyperbaric Supervising Providers:

Physicians (or NPPs) supervising Hyperbaric Oxygen Therapy should be certified in Hyperbaric Medicine by the American Board of Emergency Medicine (ABEM), the American Board of Preventive Medicine (ABPM) or the American Osteopathic Conjoint Committee of Undersea and Hyperbaric Medicine (AOCUHM) or other entity adopting a Hyperbaric Medicine training protocol by completion of a minimum 40-hour training experience in a nationally recognized program offering AMA Category I CME credits (40 hours) (e.g., American College of Hyperbaric Medicine [ACHM], The Undersea and Hyperbaric Medical Society [UHMS], National Baromedical Services [NBS]).

Hyperbaric Supervising Providers must have completed a 40-hour HBO introductory training course.

Providers must demonstrate a thorough understanding of the indications and contraindications of HBOT, HBOT protocols, the management of HBOT emergencies, the mechanism of HBOT and the ability to work with and manage HBOT technical personnel. They must also have clinical privileges at a contracted hospital. Below are the core privileges provider are typically credentialed for:

Hyperbaric Chamber: Core Privileges

- Initiation and Supervisions of Hyperbaric Oxygen Therapy
- Consultation for Hyperbaric Oxygen Therapy
- Interpretation of all diagnostic equipment such as, skin perfusion pressure/transcutaneous oximetry

Each Hyperbaric credentialed providers should demonstrate completion of a minimum of 12 CME's per two-year period with the content covered pertinent to the practice of hyperbaric medicine or wound care. If the provider has not practiced hyperbaric medicine in the last two years, the 40-hour introductory course is required.

Provider Proctoring:

Each provider supervising hyperbaric treatment will be proctored for a minimum of 5 treatments. The provider proctor will provide clinical oversight in one the following:

- In person observation
- Electronic communication (telephone, email, Skype, or other technologies)
- Chart review
- Informal consultation

The proctor will provide guidance to ensure the safety of the patient and appropriateness of the treatment.

Upon completion of the proctoring, the overseeing provider will attest that the center the provider competent to supervise HBOT.

Title: HBO Admission and Treatment	Policy Number: HM.106.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018,1/1/2020, 1/1/2022
Source: SerenaGroup [®] Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Establish the safe delivery of hyperbaric oxygen treatments.

POLICY:

Provide guidelines and education to the patients receiving hyperbaric oxygen therapy treatments.

- 1. All patients will have a consultation performed by a provider credentialed in hyperbaric medicine.
- 2. Prior to the first hyperbaric treatment, the physician order and HBOT consultation are documented in the medical record.
 - a. The HBOT indication and required documentation is verified in accordance with medical policy.
 - b. A chest x-ray should be completed prior to the first hyperbaric treatment.
 - i. A test completed within 6 months for asymptomatic patients is acceptable.
 - c. An EKG should be completed prior to the first hyperbaric treatment.
 - i. A test completed within 6 months for asymptomatic patients is acceptable.
- 3. A credentialed provider will provide direct supervision during hyperbaric oxygen treatment.
 - a. The HBO technician will verify provider availability prior to start treatment.
- 4. Patient will be assigned a secure location to store valuables during treatment.

- 5. The hyperbaric technician will review the Daily HBOT Patient Safety Checklist prior to each treatment.
 - a. Vital signs and pain will be assessed pre- and post-treatment and documented.
- 6. Focused physical examination will be performed by the provider prior to the first treatment and as needed.
- 7. All diabetic patients will have a blood glucose measurement pre- and post-treatment.
- 8. Patients receiving NPWT must have device disconnected and any tubing unclamped during treatment. The disconnected device cannot go inside the chamber. Once the HBOT treatment is complete, NPWT may be reconnected.
- 9. During HBOT:
 - a. The chamber technician observes and records the patient's response to treatment.
 - b. During the treatment, the patient is continuously evaluated by the chamber technician for the following:
 - i. Signs and symptoms of barotrauma
 - ii. Respiratory rate and effort
 - iii. Level of consciousness
 - iv. Twitches, seizure activity
 - v. Nausea
 - vi. Coughing
 - vii. Sudden chest pain
 - viii. Abnormal chest movement
 - ix. Anxiety/claustrophobia

Title: Missed HBOT Appointments	Policy Number: HM.107.0		
Date Issued: 04/01/2016	Date Revised: 1/1/2018,1/1/2020, 1/1/2022		
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.		
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS		

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Maximize patient adherence to hyperbaric treatments.

POLICY:

The patient will complete the course of treatment as scheduled.

The patient will be provided guidance, support, and encouragement regarding adherence to the prescribed treatment plan.

A standard process will be utilized to resolve missed appointments.

- 1. Patient education related to treatment expectations will be discussed and documented.
- 2. If patient is non-adherent to prescribed treatment plan, notify provider.
 - a. A commitment contract may be instituted between the physician and the patient to further reinforce and support the need for compliance to treatment plan.
- 3. Missed appointments will be documented in the medical record.
- 4. Prior to discontinuation of treatment, the case will be reviewed.

Commitment Contract

o: ADD PATIENT NAME HERE	
e: Hyperbaric Medicine Treatment Plan	
o obtain the greatest benefit from Hyperbaric Oxygen Therapy (HBOT), you will need to come in for your eatments as ordered by your provider. Missed hyperbaric treatments will lead to failed healing. For HBO be effective, it must be provided to you five days-a-week. HBOT is much like antibiotic treatment ecause it only works when taken regularly for the time ordered by your provider.	
Ve understand that an unexpected illness or a conflicting doctor appointment can occur, and we will mak every effort to assist you in rearranging the schedule. We understand that coming to the HBOT unit every ay is a huge effort. Inability to comply with this commitment policy will result in your removal from the experbaric therapy schedule.	
ur primary goal is to heal your wound as quickly as possible. If there are any questions regarding this olicy, please do not hesitate to contact our unit at XXX.XXX.XXXX.	
nank you for your cooperation!	
espectfully,	
nter Physician Name & Title Here	
gnature of Patient Date	
☐ I have read this document and understand/accept its terms.	

Title: Staffing Guidelines for HBO	Policy Number: HM.108.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018,1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Provider

PURPOSE:

Provide guidelines for effective staffing of hyperbaric chambers.

DEFINITIONS:

Chamber Technician: Hyperbaric-trained and current competent technologist, therapist, nurse, provider, or other approved allied healthcare professional.

POLICY:

- 1. Chamber technician will be present in the treatment area anytime the patient is in the chamber.
- 2. Chamber technician will have a current annual competency for hyperbaric operation in their employee file.
- 3. One (1) hyperbaric trained staff member can operate a maximum of 2 chambers.

Title: Infection Control Guidelines	Policy Number: HM.110.0		
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022		
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS		

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Provider

PURPOSE:

Establish infection control guidelines for the center.

- 1. Use universal precautions on all patients.
- 2. Patient contact surfaces are cleansed after each use with approved solution.
- 3. All linen will be changed after each patient treatment.
- 4. Isolation linen will be disposed of according to infection control policy.
- 5. Alcohol-based products are prohibited in the hyperbaric chamber room.

Title: Business Hours	Policy Number: HM.111.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Business hours established for the Hyperbaric Center are based on the needs of the center and include an on-call procedure if applicable for managing after hour and holiday emergencies.

PURPOSE:

To meet the routine and emergency needs of the center's patients.

- 1. The center's business hours are provided to patients with instructions on how to obtain assistance outside of business hours.
 - a. Hyperbaric chamber room is recommended to be open 5 days a week to ensure patients receive their hyperbaric treatment daily.
 - b. Closing the hyperbaric chamber room decreases the dose of a limb and life-threatening procedure and can clinically put the patient's life at risk.
- 2. The Program Director establishes a procedure for managing calls received after hours including instructions on how to obtain emergency assistance.

Title: Center Chain of Command	Policy Number: HM.112.0
Date Issued: 04/01/2016	Date Revised: 1/01/2018,1/01/2020
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Provider

POLICY:

The policy is to establish an organizational structure for the center.

- 1. It is the responsibility of the Program Director to prepare and maintain a graphic display of the organizational structure.
- 2. This pictorial display demonstrates the center relationship to the hospital and to SerenaGroup®.
- 3. The center is directed and supervised by the Program Director who has 24-hour accountability and is responsible for staffing the center and communicating directives to all department employees.
- 4. The Program Director reports to the hospital administrator assigned oversight of the center. The Program Director also reports to the Senior VP of Operations or a Regional Manager to which the center is assigned.
- 5. The center operation is assessed, and problem areas identified, using performance improvement monitors and database reports on a routine basis by the Program Director and Medical Director.

Title: Patient Communications via Phone	Policy Number: HM.113.0			
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022			
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS			

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Provider

PURPOSE:

To appropriately document communications and provider orders when a patient calls or communicates with the center staff or providers.

POLICY:

Telecommunication must be documented in the medical record.

- 1. Document all telecommunication with the patient or power of attorney (POA) in the medical record.
- 2. Document all communication with mutual patient providers and ancillary services.
- 3. All information entered in the medical record must be signed by the entering staff member and provider signature.

Title: Prisoners	Policy Number: HM.114.0			
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022			
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.			
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS			

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Providers

POLICY:

Patients under police custody may be evaluated in the Hyperbaric Center. These patients will be guarded on a continuous basis during their hyperbaric treatment. The responsibility of ensuring detention is that of the local, state, or federal law enforcement officer who has accompanied patient to the Hyperbaric Center.

PURPOSE:

Provide a safe environment for patients, visitors, and employees and protect the legal rights of incarcerated patients.

- 1. The law enforcement agency must make prior arrangements for scheduled visits by contacting the Program Director or designee to discuss custodial coverage for the patient prisoner.
- 2. The Program Director or designee will notify hospital security prior to a patient prisoner being seen in the wound care center.
- 3. Custodians of the patient prisoner will report to the security office of the hospital prior to each visit so that the security office can verify the identity of the law enforcement officer and ensure appropriate documentation of education/training is obtained according to hospital policy.
- 4. The hospital security office will communicate appropriate identification of law enforcement officer to the wound center.
- 5. The security office shall instruct the law enforcement officer of his/her responsibilities as it pertains to the hospital.
- 6. The clinical staff will provide the law enforcement officer with any necessary clinical information about the patient prisoner.

- 7. The law enforcement officer will comply with the clinical instructions provided and will not hinder the staff or physicians from conducting normal patient care.
- 8. The law enforcement officer assigned to the patient prisoner is required to control and guard the patient prisoner until the patient is in the chamber and upon completion of treatment.
- 9. The law enforcement officer may stay outside the room when the patient is in the chamber.

Title: Waived Testing	Policy Number: HM.115.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

All Center Staff

POLICY:

Performing waived testing in the wound care center. Staff will follow established policies for orientation, training, and documentation.

PURPOSE:

Standardization of practice in regard to accuracy, reliability, and timeliness of waived testing.

DEFINITION:

- Waived testing Tests that meet the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988) for waived tests and are cleared by the Food and Drug Administration for home use. These tests employ methodologies that are so simple and accurate that the likelihood of erroneous results is negligible, or pose no risk of harm to the patient, resident, or individual served if the test is performed incorrectly.
- Clinical Laboratory Improvement Amendments (CLIA) an amendment passed by Congress in 1988 establishing quality standards for all laboratory testing to ensure accuracy, reliability and timeliness of patient test results regardless of where the test is performed.
- NOTE: Since staff will be conducting capillary blood glucose checks, the center will need to have
 either its own CLIA license or be allowed to operate under the hospital's license. If operating under
 the hospital license, the hospital may need to add the wound care and hyperbaric center's
 location.

- 1. Authorized staff perform waived testing in the center.
- 2. Staff authorized to perform waived testing receive training on instrument use and maintenance.

- 3. Competency in waived testing is assessed annually.
- 4. For instrument-based waived testing, quality control checks are performed each day on each instrument used for patient testing or per manufacturers' instructions. Quality control checks are not required on an instrument when not in use.
- 5. Quality control results are documented in QC log.
- 6. Test results are documented in the patient's medical record.
- 7. Quantitative test results reports in the medical record for waived testing are accompanied by reference interval (normal values) specific to the test method used and the population served. Note: Semi-quantitative results, such as urine macroscopic and urine are not required to comply with this unless it is required by the hospital policies.
- 8. Reference intervals (normal values) not documented on the same page as and adjacent to the waived test result, are located in the permanent record. The result will have a notation identifying the location of the reference intervals.
- 9. Quality control results records, test result records, and instrument records for waived testing are retained for at least two years.

Title: Pain Management in the Wound Patient	Policy Number: 116.0
Date Issued: 8/1/2021	Date Revised: 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup® Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Non-Nursing Staff
- Nursing Staff
- Providers

POLICY:

To assess, document and manage chronic pain associated with wounds in accordance with accepted practice guidelines for chronic wound management. To develop a process for referral of patients to pain specialists when the discomfort associated with the wound cannot be effectively managed in the wound care center.

- 1. Evaluate the degree, severity, location, intensity and exacerbating factors in wound care patients suffering from chronic pain.
- 2. Document the patient's current pain management regimen. This documentation is entered by a Registered Nurse.
- 3. Re-assess all aspects of pain at each clinic visit including any discomfort the patient experienced between visits.
- 4. if the patient continues to complain of pain despite interventions, the Registered Nurse should determine if it is situational or constant.
 - a. In the case of situational-pain, a plan of care is developed to address the reasons for the pain (e.g., dressing removal or a debridement procedure). The RN will assess the adequacy of topical analgesics, the type of dressing used and the dressing change procedure. The RN will review techniques used to control pain during the dressing removal and application as well as during any procedures.
 - b. In the case of constant pain, educate the patient on available options such as referral to a pain management specialist.
- 5. Pain management decisions will be ordered by the provider overseeing the patient's plan of care.
- 6. Opioids are not indicated in the control of chronic pain. If opioids are prescribed for acute pain, the prescription should be written for a total of 3 to 7 days of medication and an opioid contract must be executed and placed in the medical record.

Title: HBO Readiness, Daily & Weekly	Policy Number: HM.201.0			
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022			
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS			

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff

PURPOSE:

Ensure proper equipment functioning and preparedness.

POLICY:

Safely administer HBOT to patients in the HBO chamber.

- 1. Prepare for HBOT by completing the following:
 - a. Daily chamber checklist (according to type of chamber)
 - b. Crash cart checklist (if applicable)
 - c. Environment checklist
 - d. Check functionality of all patient care equipment
 - e. Check medical air tanks for sufficient levels of gas to complete treatments
- 2. Completed checklists are placed in the appropriate log.

Daily Chamber Checklist (Perry-Computer)

Please use a separate checklist for each chamber. Initial each line as completed.	MON	TUE	WED	THU	FRI
Week Of:					
Initials of person completing checklist					
Chamber # Start Up					
Cycle #					
Oxygen zone valves outside & inside the chamber room is on					
Oxygen supply pressure reading @ alarm panel & chamber console: (50-90 psi)					
Air supply pressure reading @ cylinder gauge: (60 psi) if using demand valve, <u>if using free flow system</u> cylinder gauge set at 25 psi					
Chamber covers completely removed and stored in a professional manner					
Chamber ground is connected. Multi meter reading is less than 1 ohm					
Chamber supply/vent hoses without kinks or damage					
Inspect chamber hull for scratches and/or crazing					
Outer ring of the manual override is in the out position					
Electrical Emergency Stop Switch is in the outward position					
Turn the COMMS panel power switch to on and check that the system operates properly					
Flip System START/STOP switch to START . Confirm that indicator eye is showing green. Turn switch off					
Press the (console) main power switch to the depressed position					
and verify that the red "Power On" indicator light is illuminated Press the front panel "Reset" switch and verify the green reset					
indicator is illuminated					
System "ON" Indicator – Glows green when system is switched to the ON position					
Log on to the chamber computer system					
With door open, rotate swing arm lever to closed position and turn master valve on/check air flow and function of intercom					
Inspect chamber door gasket for damage					
Inspect chamber controls for damage or loose knobs					
Inspect chamber interior and exterior for cleanliness					
Air break equipment disinfected					
Air Break cylinder pressure level checked (change below 500psi)					

1. Select the patient			
2. Select the patient's treatment profile			
3. Press the RUN TREATMENT button. This will take you to the next screen RUNNING A TREATMENT			
Observation of the control panel (LC) display visually confirms that the treatment profile is actually transpiring			
Adjust ventilation rates (on Chamber Console) from 125 to 385 liters per minute (lpm). Minimum chamber vent setting is 125 LPM			
SHUTDOWN CHECKLIST			
Turn Oxygen and Air supply to chamber off			
Flip System ON/OFF switch to OFF. Confirm that indicator eye is showing NOT showing green			
Turn the COMMS panel power switch off			
Log off the computer			
Press the power button in for the off position and make sure that the power button light goes out			
Cover chamber to protect the acrylic pressure cylinder			

Person Completing:_____Initials____ Person Completing:_____Initials____

Get a treatment started:

Daily Chamber Checklist (Perry-Pneumatic)

Neck OF: Initials of person completing checklist Chamber # Start Up Cycle #	Please use a separate checklist for each chamber. Initial each line as completed.	MON	TUE	WED	THU	FRI
Chamber #	Week Of:					
Oxygen supply pressure reading @ alarm panel & chamber console (50-90 psi) Air supply pressure reading @ cylinder gauge: (60 psi) if using demand valve, if using free flow system cylinder gauge set at 25 psi Chamber covers completely removed and stored in a professional manner Chamber ground is connected. Multi meter reading is less than 1 ohm Chamber supply/vent hoses without kinks or damage Inspect chamber hull for scratches and/or crazing Inspect both the green oxygen supply and red exhaust bypass indicators to ensure that the lenses are in place and undamaged Flip System ON/OFF switch to ON. Confirm that indicator eye is showing green Turn the communication switch to the on-position Green should be on With door open, rotate swing arm lever to closed position and turn master valve on/check air flow and function of intercom Inspect chamber door gasket for damage Inspect chamber controls for damage or loose knobs Inspect chamber interior and exterior for cleanliness Air Break cylinder pressure level checked (change below 500psi) Air break equipment ready & disinfected (Demand System ONLY) Adjust ventilation rates (on Chamber Console) from 125 to 385 liters per minute (LPM). Minimum chamber vent setting is 125 LPM SHUTDOWN CHECKLIST: Turn Oxygen and Air supply to chamber off Flip System ON/OFF switch to OFF. Confirm that indicator eye is NOT showing green Turn the communication switch to the OFF, on position (green) should go out	Initials of person completing checklist					
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Flip System ON/OFF switch to OFF. Confirm that indicator eye is NOT showing green Turn the communication switch to the OFF, on position (green) should go out	SHUTDOWN CHECKLIST:					
Showing green Turn the communication switch to the OFF , on position (green) should go out	Turn Oxygen and Air supply to chamber off					
Clean chamber interiors, exterior and cover	Turn the communication switch to the OFF , on position (green) should go out					
	Clean chamber interiors, exterior and cover					

Person Completing:Initials Person Completing:Initials	Initials Person Completing:Initials
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Daily Chamber Checklist (Sechrist)

Please use a separate checklist for each chamber. Initial each line as completed

Week Of:	MON	TUE	WED	THU	FRI
Initials of person completing checklist					
Chamber # Start Up Cycle #					
Oxygen supply pressure reading @ alarm panel: (50-90 psi)					
Air supply pressure reading @ cylinder gauge: (60 psi) when using demand valve, if using free flow system cylinder gauge set at 25 psi					
Chamber covers completely removed and stored in a professional manner					
Chamber ground is connected. Multi meter reading is less than 1 ohm (including the grounding bracelet)					
Chamber supply/vent hoses without kinks or damage					
Inspect chamber hull for scratches and/or crazing					
Chamber covers completely removed and stored in a professional manner					
AC power connected and green LED lit					
With door open, rotate swing arm lever to closed position and turn master valve on/check air flow and function of intercom (volume up and pick up handset)					
Inspect chamber door gasket for damage					
Inspect chamber controls for damage or loose knobs					
Inspect chamber interior and exterior for cleanliness					
Air break equipment disinfected					
Air Break cylinder pressure level checked (change below 500psi)					
Flow valve (under chamber) 250-275/I/min. When under pressure If adjusted return to above setting					
SHUTDOWN CHECKLIST					
Turn the master valve to the OFF position					
Turn Oxygen and Air Supply to chamber off					
Clean chamber interiors, exterior and cover					

Person Completing:_____Initials___ Person Completing:_____Initials____

WEEKLY CHAMBER CHECKLIST

Please use a separate checklist for each chamber. Initial each line as completed.

MONTH	MON	TUE	WED	THU	FRI
Week: (circle one) 1 2 3 4 5					
Chamber #					
Clean gurneys with approved disinfectant					
Close and lock chamber and turn master valve on					
Safety locking pins engages at approximately 1 psi					
Idle pressure is 1-1.5 psi					
Pressure the chamber to approximately 10 psi and set the purge flow rate control to minimum per chamber manufacturer recommendations and patient comfort.					
Indicator moves freely when the control is adjusted					
Emergency vent functions properly					
Safely locking pin retracts at less than 1 psi					
Smoke hoods located in center					
Signature	Initial				
Signature	Initial				

Title: Housekeeping and Linens	Policy Number: HM.202.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Provide the housekeeping department and the hyperbaric staff with the necessary information to ensure the hyperbaric chamber room will be kept safe and clean.

POLICY:

Appropriate cleaning of the hyperbaric suite will be coordinated with the designated housekeeping service.

PROCEDURE:

Housekeeping

- 1. All dusting and mopping will be done using a damp mop.
- 2. There will be no use or storage of petroleum products in the hyperbaric chamber room.
- 3. Cleaning of the chambers is the responsibility of the hyperbaric staff and not housekeeping.
- 4. There will be no cleaning of the hyperbaric chamber room while patients are in the chambers.
- 5. Floors in the hyperbaric chamber room may only be waxed with anti-static wax.
- 6. Housekeeping personnel will be provided a formal orientation to the hyperbaric chamber area by the Hyperbaric Safety Director or the Program Director.

Linens

- 1. After each patient the linens will be removed from the stretcher and placed in the soiled linen hamper.
- 2. The stretcher will be cleansed with a nonalcohol based product.
- 3. The stretcher linens will be replaced with a folded sheet which is tucked in at the edges along the sides of the stretcher, a cover blanket or sheet and pillows with pillowcases.
- 4. All hyperbaric linens will be kept separate from general linens.

Title: Emergency Breathing Device	Policy Number: HM.203.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Provide guidance on the use of an emergency breathing device.

POLICY:

The National Fire Protection Agency (NFPA) 99, hyperbaric chapter, suggest that each chamber have emergency breathing devices to support the number of staff in the center.

- 1. Emergency breathing device must be in the chamber room.
- 2. In the event of an emergency where air contamination makes use of a device appropriate, don the device using the directions provided by the manufacturer.
- 3. There will be emergency breathing devices to support the number of staff in the center.
 - a. Hyperbaric personnel are responsible for checking the expiration date of the device and replacing the equipment as necessary.
- 4. Emergency breathing devices are designated for staff use only.

Title: Chamber Cleaning	Policy Number: HM.204.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 10/30/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber technician
- Clinical Staff
- Provider

PURPOSE:

Prevent cross contamination and maintain safe operation of the chambers, all equipment is cleaned and maintained in accordance with manufacturer's specifications. This procedure addresses such infestation as bed bugs, fleas, and lice.

PRECAUTIONS:

- 1. Use chamber manufacturer's approved products on acrylic surfaces.
- 2. Use a soft, damp, cotton cloth or towel to clean the chamber surfaces.
- 3. Use appropriate personnel protection procedures when handling any chemicals.
- 4. Avoid spraying any liquid on exposed electrical circuits, including patient monitoring or grounding leads.

STANDARD:

Clean the exterior of the chamber weekly. Clean the chamber interior daily or immediately after treatment for exposure to the following:

- 1. VRE
- 2. CDIF
- 3. MRSA
- 4. Bed bugs
- 5. Fleas
- 6. Lice

The stretcher mattress is to be cleaned after each treatment. The gurney frame will be cleaned weekly, or after becoming soiled.

Document chamber cleaning.

- 1. Spray the disinfectant solution to cover the chamber interior, beginning at the foot-end and working out through the chamber door. Remove cover plates as needed, to access protected areas. Allow the spray mist to settle.
- 2. Allow the disinfectant to set according to product labeling recommendations.
- 3. Wipe the excess disinfectant with a soft, cotton cloth. Repeat as needed to eliminate streaking.
- 4. Vent the chamber to remove residual odor.
- 5. The non-acrylic chamber exterior can be cleaned with the detergent solution followed by a clean, warm water wipe down.
- 6. All other ancillary hyperbaric equipment will be cleaned after each use with the approved cleaner in accordance with manufacture's recommendations.

Title: Air Breaks	Policy Number: HM.205.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Prevention of oxygen toxicity during the administration of hyperbaric oxygen.

POLICY:

Patients undergoing treatment pressures greater than 2.0 Atmospheres Absolute (ATA) will have air breaks as part of the treatment.

- Air breaks are prescribed by the ordering provider.
- The preferred air break protocol is two 5 minute air breaks. The first air break after 30 minutes at prescribed pressure and the second after 65 minutes at prescribed pressure.

- 1. Free Flow Type Air Break Assembly:
 - a. Ensure USP Medical Grade Air Cylinder is available, has adequate supply (minimum of 75 psi) and external hoses are not kinked or damaged. The cylinder should remain in the OFF position immediately prior to the air break.
 - b. A mask should be assigned to each patient.
 - c. Educate the patient on the importance of air breaks.
 - d. Before closing the chamber door, ensure the internal hose and non-rebreather mask are available and within easy reach of the patient.

- e. Turn on the medical air and confirm the pressure on the regulator is set to 70 psi. Adjust accordingly and close the valve.
- f. Close chamber door and start the treatment as normal, noting the times to begin the air breaks.
- g. At the prescribed time, open the flow meter.
- h. Check that the patient has achieved an effective seal.
- i. Administer air breaks as prescribed.
- j. Turn the medical gas off at the end of the air break.

2. Demand Valve Type Air Break Assembly:

- a. Ensure USP Medical Grade Air Cylinder is available, has adequate supply (minimum of 75 psi) and external hoses are not kinked or damaged. Turn the cylinder ON and confirm the set pressure on the regulator is set to 70 psi. Because this setup has a demand valve, the cylinder can remain on.
- b. A mask and filter should be assigned to each patient and reused by that patient for the course of treatment.
- c. To prevent contamination of the demand valve, utilize a filter between the valve and mask.
- d. Educate the patient on the importance of air breaks.
- e. Before closing the chamber door, ensure the internal hose and mask are available and within easy reach of the patient.
- f. Close chamber door and start the treatment as normal, noting the times to begin the air-breaks on the record.
- g. Ensure the patient is obtaining an effective seal.
- h. Administer the air breaks as prescribed.
- i. Turn the medical gas off at the end of the air break.

Title: Patient Changing Area, Lockers, & HBO Clothing	Policy Number: HM.206.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS
Building the Nation's Leading Wound Care Team	

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

POLICY:

Hyperbaric therapy patients are required to wear center-supplied garments prior to entering the hyperbaric chamber (NFPA 99 HBO Facilities).

A private area will be provided for patients to change into the required garments.

A locker or locked area will be provided for patients to store personal belongings.

PURPOSE:

Establish guidelines for storing personal belongings, wearing appropriate clothing, and for providing privacy while changing for HBOT.

- 1. Patients will be provided with 100% cotton or anti-static blend garments by the hyperbaric staff.
- 2. Footwear must be removed before entering chamber.
- 3. Patients will change garments in the designated area.
- 4. Patients will be provided a secure area to store belongings during treatment. If a key is provided, it is not allowed in the hyperbaric chamber per NFPA 99.
- 5. After hyperbaric therapy, the patient will change garments and place them in the soiled linen hamper provided.

Title: Patient Grounding Strap	Policy Number: HM.207.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
SerendGroup Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Establish a policy on patient grounding requirements.

POLICY:

Patient grounding is an established safety standard by NFPA 99 (2012): 14.3.1.5.3.2 – In class A and class B chambers with atmospheres containing more than 23.5 percent oxygen by volume, electrical grounding of the patient will be met by the use of a high-impedance conductive pathway in contact with the patient's skin.

- 1. Chamber operation requires an acceptable method for grounding.
- 2. Any other method of patient grounding, including ECG pads or electrodes are not supported.

Title: Oxygen Pressure Monitoring	Policy Number: HM.208.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Monitor oxygen pressure at the alarm panel and at the hyperbaric chamber. If a pressure gauge is present on the chamber.

POLICY:

Oxygen pressure will remain in the 45-70 psi range.

PROCEDURE:

Alarm Panel PSI reading and documentation

- 1. Prior to the start of Hyperbaric Oxygen treatments for the day, turn chamber valves to the on position.
- 2. Document the alarm panel pressure reading in the Daily Chamber Checklist.
- 3. If the oxygen pressure is out of range, below 45psi or above 70psi, the alarm will indicate by sounding or lighting.
 - a. Chambers using a dual manifold system may alarm, which may require manually switching from one bank to the other.
 - b. Silence the alarm, proceed to the manifold, and manually switch to the opposite bank. If the system continues to alarm, proceed to step 5.
- 4. Shut down chambers when alarm panel sounds.

- 5. Safely remove patients if not resolved in 5 minutes.
- 6. Notify SerenaGroup National Safety Director if further assistance is needed.

Chamber Pressure PSI reading will remain in the 45-70psi range

- 1. While chambers are in operation at 2 ATA, check psi reading on the chamber pressure gauge and record in the Daily Chamber Checklist.
- 2. If the oxygen pressure falls outside of the acceptable range during operation and the problem cannot be immediately resolved, remove the patient(s) and shut down the chamber(s).
- 3. Notify SerenaGroup® of event.

Title: Safe Handling of Pressurized Gas	Policy Number: HM.209.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

The safe management of compressed gas cylinders.

PURPOSE:

Hyperbaric suite safety.

PROCEDURE:

CYLINDERS:

- 1. Compressed gas cylinders used at the center will be legibly marked by the chemical name on the exterior of the cylinder.
- 2. Compressed gas cylinders intended for medical use containing Oxygen are green in color.
- 3. Compressed gas cylinders intended for medical use containing air are yellow in color.
- 4. Valve protection caps will be hand tightened and in place when compressed gas cylinders are being transported.
- 5. Cylinder valves shall be closed when treatments are finished, empty or transported.
- 6. Cylinders will be secured in an upright position.
- 7. High-pressure gas cylinders are not to be stored in areas where temperatures exceed 125° F or used in areas above 120° F.

- 8. High-pressure gas cylinders will not be stored near flammable substances.
- 9. Used cylinders are labeled "Empty" and are not allowed to drop below 400 PSI.
- 10. Avoid the use or storage of cylinders near an electrical circuit.
- 11. Protect gas cylinders from mechanical shock that may damage the cylinder, valve or relief valve.
- 12. Oxygen and air regulators must be checked prior to use for proper working order.
- 13. Pressure reducing valves are used to reduce the pressure from the cylinder to the supply line.

LIQUID OXYGEN:

- 1. Avoid skin contact with converter piping, or piping that appears to be frozen.
- 2. Do not open or close a valve on a converter unless properly trained.
- 3. Reference the MSDS for Liquid Oxygen.
- 4. Use good, clean, loose fitting gloves and eye protection for handling cryogenic liquids and/or handling the Dewer system.
- 5. Be aware that vapor coming off the converter is dangerously cold.
- 6. Tools used around oxygen are cleaned of all traces of oil and grease.
- 7. Notify SerenaGroup® if there is any problem with the converter.

Title: Fire and Medical Emergency Drills	Policy Number: HM.210.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Center personnel are prepared for a fire emergency in the center or HBO chamber according to NFPA guidelines.

POLICY:

Twice per year, a fire drill is performed.

PROCEDURE:

Fire Drill:

- 1. Safety Director will provide all safety training to staff and other stakeholders.
- 2. Check that fire extinguisher is in the chamber room.
- 3. Two fire drills will be performed annually, of which one will be timed.
- 4. Fire drills are conducted in accordance with NFPA 99.
- 5. Document fire drills.

Clinical Emergencies:

- 1. Select mock scenarios related to potential hyperbaric oxygen complications, complete drills, and document appropriately.
- 2. Sign-in sheet documenting attendance is required for each drill.
- 3. Two clinical drills will be performed annually.

Title: Guidelines for Multi Meter Use	Policy Number: HM.211.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Nursing Staff
- Providers

PURPOSE:

Confirm the chamber ground connection is in operating condition prior to patient treatment.

POLICY:

The HBO Technician will complete a multi meter assessment daily. Multi-meter is a tool used to measure resistance.

- 1. Check each chamber ground prior to first treatment of the day, by using the multi-meter tool.
- 2. Verify proper operation by touching the two leads to each other and verifying a zero reading before conducting the test. Connect the other ends to these plugs into the designated outlets labeled (chamber and wall) located at the lower area of the chambers entrance door. Plug the red one into the outlet port labeled (Chamber) and the black one into outlet port labeled (wall).
- 3. Turn the dial on the multi meter to 200 ohms or auto.
- 4. Meter should read 1 ohm or less, which indicates that chamber ground is working properly. If the multi-meter reading is more than 1 ohm, replace grounding wire and re-test before treating patient.
- 5. After use, and to prolong battery life, turn the multi-meter tool to the OFF position.
- 6. Document test on chamber checklist.
- 7. In lieu of a multi-meter, a continuity pass/fail meter may be utilized.

Title: Disinfecting – Air Break Demand Valve	Policy Number: HM.212.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Nursing Staff

PURPOSE:

Establish procedures for cleaning the interior demand valve regulator for the air break. This procedure is only for Demand Valve version of the air-break system and not needed for the free flow system.

POLICY:

Chamber technician will clean and disinfect the demand valve regulator weekly and document. If no HEPA filter is utilized, the regulator must be disinfected between each patient.

- 1. Fill a container with an approved germicidal solution.
- 2. Remove the Air hose from the regulator.
- 3. Remove the mask from the regulator.
- 4. Twist off the clear end of the regulator and place in the approved germicidal solution.
- 5. Remove the rubber diaphragm from the interior of the regulator and place in the approved germicidal solution.
- 6. Place the entire remainder of the regulator in the approved germicidal solution. The regulator is completely immersed in the solution for complete coverage.
- 7. Allow the regulator and parts to soak for a minimum of 10 minutes.
- 8. Remove, rinse, dry and reassemble the regulator.

Title: Incomplete HBOT Treatments	Policy Number: HM.213.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup® Inc. SerenaGroup® Inc.	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Nursing Staff
- Providers

PURPOSE:

Document in the EMR HBOT patients who are unable to begin treatments.

POLICY:

All patients that come to the center for hyperbaric oxygen therapy and do not enter the chamber, or unable to complete the first 15 minutes of the treatment will be documented in the EMR and seen by the provider.

- 1. The chamber technician or nurse will perform a pre-HBO checklist on the patient. If the patient does not meet criteria to enter the chamber, the visit type will be changed to Wound Care in the EMR and the patient will be seen by the physician.
- 2. Patients receiving less than 16 minutes of HBOT will have their treatment documented as aborted. The provider will be notified.
- 3. Patients receiving more than 16 minutes of HBOT, but not completing the entire prescribed therapy will have their treatment documented as incomplete.

Title: Guidelines for Portable Oxygen System-Dewar's	Policy Number: HM.214.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

• Hyperbaric Oxygen Safety Director

PURPOSE:

To ensure proper and safe function of the portable oxygen system if installed.

POLICY:

Safe and effective operation and maintenance of oxygen system (dewars).

PROCEDURE:

- 1. General maintenance
 - a. Check Dewar body for dents, holes or other damage
 - b. Check the brass fittings for damage
 - c. Open valves slowly and check for any leaks

2. System layout

- a. Left and right bank will be two Dewar's in the piggyback configuration (total of four Dewar's)
- b. The liquid valve will be connected to the vent of the adjacent tank and the liquid oxygen from that tank will flow to the evaporators in the system

3. System checks

- a. Open main oxygen line to chambers located on wall
- b. Turn gas supply on chamber to setting labeled oxygen
- c. Check oxygen panel on wall
- d. Open oxygen manifold flow lines on wall in system area
- e. Check to make sure all valves, pressure builders are open on selected tanks
- f. Check to see if adequate supply of oxygen (order if necessary)

4. High pressure alarm sounds

- a. Decompress patient at rate set of 1
- b. If oxygen system malfunctions, contact SerenaGroup National Safety Director.
- c. Do not treat patient until problem is resolved
 - i. If the pressure alarm sounds when chambers are empty:
 - 1. Turn pressure builders OFF
 - 2. Bleed oxygen tanks by pulling down handle

5. Daily shut down

- a. Turn pressure builders off
- b. Document LOX pressure reading in the oxygen log

6. Weekends and Holidays

a. Shut system down completely by moving all valves into the off position

7. Monday mornings

- a. Open all lines on oxygen tanks
- b. Only open selected tank pressure builders

Title: Patient Orientation to HBO	Policy Number: HM.301.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Nursing Staff
- Providers

POLICY:

Orienting the patient to HBOT.

PURPOSE:

Outline the process for orienting the patient to HBOT before treatments begin.

- The HBO technician, nurse or provider will orient the patient to hyperbaric oxygen therapy.
 Personnel supervising the treatments will assure the orientation is completed before treatment begins.
- 2. Once the provider explains the benefits of HBO as it applies in their case the patient signs the HBO Consent form.
- 3. Each patient receives a unit orientation. The patient is shown the chamber, the treatment is discussed as well as the patient education process.
- 4. Documentation will include:
 - a. Daily HBO Patient Safety checklist
 - b. Education
 - c. Informed consent for hyperbaric medicine and photography
 - d. Insurance information/financial responsibility
 - e. HBO Clearance
 - f. HBO Dive Record
 - g. HBO Orientation (scanned)

- h. Medications/Allergies
- i. Past Medical History
- j. Physical Exam
- k. Physician orders
- I. Review of Systems
- m. Risk Evaluation
- n. Wound Assessment, as applicable
- 5. Minors must have a legal guardian signature for all consents. Those unable to or deemed incapable must have the signature of their legal representative. The patient will receive a copy and the original is placed in the patient chart.
- 6. A "Patient Guide to Hyperbaric Medicine" educational document is given to all patients (Attached).
- 7. Include family members in the patient orientation as applicable, include the following:
 - a. The initial hyperbaric visit with physician/non-physician provider.
 - b. The hyperbaric orientation process as well as a tour of the facility.
 - c. Encouragement to be a "support team" member during the patient's course of treatment.
 - d. In the event of a patient with special needs or problems, consult with Social Services of contracted hospital.

Patient Guide to Hyperbaric Medicine

Welcome to the Wound Care and Hyperbaric Oxygen Therapy Center.

What Is Hyperbaric Oxygen Therapy?

Hyperbaric oxygen therapy (HBO) is a medical treatment in which the entire body is under increased atmospheric pressure and the patient breaths 100% oxygen. This treatment is administered in a pressurized chamber. It is proven effective for several different medical and surgical conditions either as a primary treatment or in addition to other medical treatments such as antibiotics or surgery.

At the Hyperbaric Unit in this Hospital, we use a single person (monoplace) chamber. The chamber is approximately eight feet long and 34 inches or more in diameter. Some facilities use a multi-place chamber and treat more than one person at a time.

How Does It Work?

Normally, our atmosphere is exerting 14.7 pounds per square inch of pressure at sea level. This is equivalent to one atmosphere absolute (1 ATA). In this atmosphere, we breathe approximately 20% oxygen and 80% nitrogen. During HBO, the pressure is increased two or three times more than normal and you breathe 100% oxygen. Most patients are treated at two times the normal atmospheric pressure (2 ATA).

The combinations of high concentrations of oxygen (100%) and increased pressure cause large amounts of oxygen to be dissolved in your blood and other tissue fluids. There can be as much as 10 to 15 times the usual amount of oxygen dissolved in your blood, which gets much more oxygen to the rest of your body.

Many different problems have been shown to benefit from HBO. Some of the most common problems are non-healing wounds (especially in diabetics), osteomyelitis (bone infections), radiation injury to bone or soft tissue burns, decompression illness (bends) and carbon monoxide poisoning.

What Will I Feel During The Treatment?

Once you are in the chamber and the door is closed, you will hear the oxygen begin to circulate, we will then start the gradual increase in pressure. This is called compression. There may be some warmth that you notice, but this is temporary. A nurse/technician will remain with you during the treatment, to adjust the rate of compression according to your tolerance and to coach you in relieving the "full" sensation, which you may feel in your ears. This feeling is like what you may have felt while traveling down a mountain, flying, or scuba diving. We will coach on how to clear your ears, but you

may need to try several ways to find the most effective one for you. Compression generally lasts 7 to 10 minutes, depending on how effectively you clear your ears.

When you have reached the prescribed pressure, fullness in your ears will cease, and you may rest or sleep during the remainder of the treatment. You may also watch TV or listen to music during this time, which will be 1.5 to 2 hours. The temperature in the chamber is similar to room temperature but may be adjusted slightly.

Near the end of your treatment, the nurse/technician will gradually decrease the pressure added at the beginning of the treatment. This is the decompression phase. During decompression, you may experience a "popping" sensation in your ears because of the changing pressure. This popping is a normal adjustment in your ears; like what happens when you are driving up a mountain.

Are There Any Side Effects?

Generally, you will experience no other effect from HBO. However, some patients report a "crackling" sensation in their ears between treatments. This may be relieved in the same manner you clear you ears during compression. If "crackling" should continue, please tell the nurse/technician.

As with all medical procedures and treatments, there are some side effects that may result from the exposure to hyperbaric oxygen. These are rare. The following is a summary of some of the potential risks or side effects of hyperbaric oxygenation:

- Barotraumas or pain in the ears or sinuses: I may experience pain in my ears or sinuses. I also understand that if I am not able to equalize my ears or sinuses that pressurization will be slowed or halted, and suitable remedies will be applied.
- Cerebral Air Embolism and Pneumothorax: Whenever there is a rapid change in ambient
 pressure, there is the possibility of rupture of the lungs with escapes of air into the arteries or
 into the chest cavity outside the lungs. This can only occur if the normal passage of air out of
 the lungs is blocked during decompression. Only slow decompressions are used in hyperbaric
 oxygen treatment to alleviate this possibility.
- Oxygen Toxicity: The risk of oxygen toxicity has been explained to me and will be minimized by never exposing me to greater pressure or longer times than are known to be safe for the body and its organs.
- Risk of Fire: With the use of oxygen in any form, there is an increased risk of fire, but strict
 precautions have been taken to prevent this and all applicable codes have been complied with.
 There has never been a fire involving a patient in a Hospital Based regulated
 Hyperbaric/Wound Center in the United States.

- Risk of Worsening Near-Sightedness: (Myopia) After 20 or more treatments, especially if you are over 40, it is possible that you may experience diminution in your ability to see things far away. Understand that this is believed to be temporary, and that vision usually returns to its pretreatment level about six weeks after the cessation of therapy. Understand that it is not advisable to get a new prescription for your glasses until at least eight (8) weeks have passed after HBO treatment.
- Maturing or Ripening Cataracts: In individuals with cataracts, it has occasionally been demonstrated that there may be a maturing or ripening of the cataracts.
- Temporary Improvement in Far-Sightedness: (Presbyopia) After 20 or more treatments,
 especially if you are over 40, there is a possibility that you may experience an improvement in
 your ability to see objects close by, or to read without reading glasses. However, understand
 this is believed to be temporary and that your vision should return to its previous level of
 acuity in about six weeks following the cessation of therapy.
- Numb Fingers: A small proportion of our patients sometimes notice a numb feeling in the fourth and fifth fingers or the hands after 20 or more treatments. This should not be of concern and should disappear in about six weeks following the cessation of therapy.
- Ear Fluid: Fluid found in the ears sometimes accumulates because of breathing high concentrations of oxygen. It may sometimes feel like a pillow over your ears. This disappears after treatment ceases and often can be eased with decongestants.
- Fatigue: Some people may subjectively feel fatigue following hyperbaric treatment, but this is not a consistent finding.

If you have any questions or concerns after your daily hyperbaric treatment, please call the center. If you have concerns or symptoms after hours that cannot wait until the center is open, we recommend you proceed to your nearest Emergency Room.

Call the center as soon as possible if you need to change or cancel your scheduled appointment. However, we strongly encourage you not to miss any treatments.

For HBO therapy to be effective, it must be provided five days a week. Hyperbaric therapy is much like antibiotic treatment because it only works when taken regularly for the time prescribed by your physician. Missed hyperbaric treatment will lead to failed healing and the longer the wound remains open, the greater the risk of amputation.

If there is anything we can do to assist you during this treatment process, please do not hesitate to let us know. Thank you for choosing our center. We look forward to helping you heal.

The Wound Care and Hyperbaric Oxygen Therapy Center Staff

Title: Vital Signs	Policy Number: HM.302.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
SerendGroup Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Nursing Staff
- Providers

PURPOSE:

Evaluate the patient prior to HBOT.

- 1. HBOT staff will provide patient education.
- 2. HBOT staff will perform a basic physical assessment and obtain vital signs for patients prior to treatment.
 - a. **Temperature:** For an oral temperature greater than 101F, notify provider.
 - b. **Blood Pressure:** Contact HBOT provider prior to therapy for:
 - i. Systolic (SBP): < 100 >185.
 - ii. Diastolic (DBP): <60 >105.
 - c. Pulse: Contact HBOT provider for:
 - i. bradycardia (<60 bpm)
 - ii. tachycardia (>100 bpm)
 - iii. irregular heart rate not originally noted during provider consult.
 - d. **Respirations:** Contact HBOT provider for difficulty breathing.

Title: Periodic Wound Assessment of HBOT	Policy Number: HM.303.0
Patients	
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Providers

PURPOSE:

Evaluate wound healing during HBOT.

POLICY:

- 1. Weekly, the wound(s) of each patient will be measured, photographed, and documented.
- 2. The provider will re-evaluate the patient every 30 days and update the goals of HBOT.

Title: Ear Equalization Techniques	Policy Number: HM.305.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Providers

PURPOSE:

Educate the patient in equalizing pressure in the ears and sinuses during chamber pressurization.

- 1. Prior to HBOT, the staff will educate the patient on auto inflation techniques to avoid barotrauma (refer to reference chart).
- 2. The HBOT provider and clinical staff will perform otoscopic examinations prior to HBOT.

Title: Emergency Procedures for Monoplace	Policy Number: HM.401.0
Chamber	
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Providers

PURPOSE:

Provide a quick reference for any emergency that may occur within a mono-place hyperbaric chamber environment once the patient is removed safely from the chamber.

POLICY:

In case of complications, the patient shall be transferred to the Emergency Room for management.

PROCEDURE:

FIRE

Fire in the chamber area (not involving the chamber)

- 1. Using emergency vent Decompress chamber:
 - Turn off oxygen
 - Sound fire alarm
 - Using fire extinguisher, attempt to put out or contain fire
 - If room becomes smoke filled, don emergency breathing device.
 - Remove patient and move to a safe area.

RACE

- Rescue--first, try and remove anyone who is in immediate danger.
- <u>Alarm</u>--second, activate the nearest fire full station. Immediately after activating the fire pull station, go to the nearest phone and call 911. Let the operator know there is a fire and the exact location.
- <u>Contain</u>--third, try to contain the fire by closing all doors and windows in the room or area

where the fire is located. If smoke is observed coming from underneath any of the doors that were closed, dampen towels and place them at the door base.

- Extinguish--finally, try to extinguish the fire. Retrieve the nearest fire extinguisher and use it on the fire.
 - Note: if the fire is out of control, do not attempt to extinguish it. Close the door immediately.

Fire within the chamber

- Using emergency vent
- Decompress chamber:
- Turn off oxygen source
- Remove patient from chamber
- Sound fire alarm of facility
- If room becomes smoke filled, don emergency breathing device
- Evacuate area
- Close doors and await arrival of fire service personnel

SEIZURE

- 1. Symptoms:
 - Vision--tunnel vision
 - Ears--ringing in ears
 - Nausea--sudden nausea and/or vomiting
 - Twitching--facial or extremity twitching
 - Irritability--sudden irritability
 - Dizziness--sudden onset of dizziness
 - Perfuse sweating
- 2. If patient or chamber operator notices any of these symptoms, have the patient use air mask [if available] to breathe.
- 3. Notify the hyperbaric provider immediately.
- 4. Start decompression/depressurization- Call hospital established code.
- 5. If patient is actively seizing, stop decompression.
- 6. Restart decompression when active seizing stops.
- 7. Remove patient.
- 8. Physician evaluates patient.

ANY MEDICAL EMERGENCY (EXCLUDING SEIZURE)

- 1. Symptoms- sudden dyspnea, stabbing chest pain, loss of consciousness, neurological abnormalities, any sign or symptom deemed a medical emergency by supervising physician.
- 2. Start decompression/depressurization (this can be accomplished by raising the rate set).
- 3. Call hospital established code.
- 4. Notify hyperbaric provider.
- 5. Begin CPR if necessary.
- 6. Move patient away from chamber area prior to using defibrillator.
- 7. Await further provider instructions.

LOSS OF OXYGEN SUPPLY

- 1. Turn the Master Valve to the OFF position. The chamber will automatically decompress at a linear rate of approximately 3 to 5 psi per minute depending on the purge flow rate.
- 2. When the Chamber Pressure Gauge reads zero, open door and remove patient.
- 3. Triage patient for transport to the nearest hyperbaric chamber if required for possible treatment.

EMERGENCY DECOMPRESSION

- 1. Turn Master Valve to the Emergency Vent position.
- 2. Press and hold the red (Sechrist) Emergency Vent button OR black (Perry Emergency Exhaust Bypass. The chamber will decompress at a rate of 0.5 psi per second. This button should only be pressed intermittently, not continuously.
 - a. Continuously is used only for FIRE in chamber, fire in immediate area or environmental threat, e.g., tornado, earthquake.
- 3. Keep pressing intermittently until the Chamber Pressure Indicator shows black.
- 4. Open chamber door and remove patient.
- 5. Have hyperbaric physician evaluate patient, call hospital operator to page code.

MANUAL SHUTOFF VALVE OPERATIONS

- 1. The quick operating Manual Shutoff Valve is located between the chamber and the Pressure Relief Valves at each end of the chamber.
- 2. The Manual Shutoff Valve is sealed closed with a soft wire seal with a red tag attached.
- 3. Should a Relief Valve malfunction and cause a rapid decompression, break the seal on the Manual Shutoff Valve and close the valve.
- 4. Evaluate the patient for possible injury from the rapid decompression/depressurization (barotrauma and/or gas embolism).

LOSS OF POWER

- 1. Loss of power causes the unit lights and chamber communications to automatically switch to emergency power.
- 2. Hand held flashlights are located in the unit should emergency power not turn on.
- 3. Try to locate the cause of power loss to determine further course of action and whom to notify.
- 4. Notify the hyperbaric provider of situation and course of action taken.

LOSS OF COMMUNICATION

- 1. Use hand signals for communication with the patient if the communication system fails.
- 2. Abort the treatment dive if communication is not restored.
- 3. Notify the hyperbaric provider of the communication problem prior to aborting

Title: Prohibited & Approved Items in the Hyperbaric Chamber	Policy Number: HM.402.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup® Inc. SerenaGroup® Inc. Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Providers

PURPOSE:

To provide guidelines for materials, items, and devices that are permitted or prohibited from the HBOT chamber.

POLICY:

The only items allowed in the chamber are those found in the approved items list. If an item is not listed on the approved items list, it is considered prohibited unless it has been specifically cleared by the Safety Director in accordance with "Exception to Protocol Policy".

1. PROHIBITED:

- Outside clothing (clothes worn when coming into center whether street or from other healthcare facilities) including, undergarments and socks
- "Velcro" (unless inactivated with tape)
 - o "Inactivated" is defined as wrapping each side of Velcro such that it cannot be connected together. It is not inactivated if wrapped when it is connected together
- Jewelry or Metals (unless covered in tape)
- Hearing aids or ear plugs
- Electronic devices including cell phones, iPad, electronic tablets of any type pagers, etc.
- Dentures or bridge work (Removable ONLY)
- Prostheses (detachable)
- Alcohol pads
- Hair sprays, oils, gels, any hair care products
- Hairpieces or hair pins
- Cologne or deodorant
- Make-up, skin lotions, creams
- Nail polish or products that have been applied within 24 hours

- Food, candy, gum
- Suntan lotion
- Smoking items, including matches and lighters
- Muscle ache patches, warming devices
- Reading material
- Kleenex etc.
- Any battery-operated device
- Transdermal medication patches
- Beverages in a can
- Flammable liquids, gases or vapors
- Non- approved implanted devices
- Sanitary pads with wings
- Glasses (titanium)

PROHIBITED MATERIALS FOUND OR SEEN IN THE CHAMBER ARE JUST CAUSE FOR IMMEDIATE TERMINATION OF THE TREATMENT

2. PERMITTED:

- Linen or hospital gown that are 50% or greater cotton blend
- Approved mattress/wedge/pillow
 - Only those recommended by chamber manufacturer
- Breathable contact lenses
- Glasses (with taped edges) Must not be Titanium
- IV catheters and lines
- Wound Care Dressings
 - Cotton gauze
 - Alginate
 - Hydrocolloid
 - Hydrogel
 - Silver and foam dressings
 - Multi-layer compression wraps
 - Hydrofera blue
 - Transparent film
- Enzymatic debriding agents
 - o Possible HBO inactivation-a fresh dose must be applied after HBO
- All casting materials which have dried for more than 24 hours
- Clean cast (cover with pillowcase to protect chamber)
- Negative pressure dressing, unclamped
- Cellular or tissue products for wound care
- Sutures & Surgical dressing
 - o with supporting letter from Medical & Safety Directors in accordance with NFPA
- Penrose or Peritoneal drains
- Fixation devices (external fixations, metal hardware)-as deemed essential and is wrapped with padding)
- Ostomy appliance

- Ventriculoperitoneal (VP) shunt
- Naso gastric tube
- Plastic water bottle, water
- Approved adult disposable briefs/diaper, plastic urinal/fracture pan
 - Approved are those without Velcro closures
- Tampons and diapers if necessary
- Implanted devices that are supported by the manufacturer for use in hyperbaric environment at the prescribed pressure
- Trachs/Foley Catheters
 - o If air filled cuff-replace air with equivalent volume of liquid and remove post treatment
 - o If dynamic foam filled, no fluid replacement required
- Implanted devices (approved by manufacturer or GAP Analysis performed)
- Feeding tube

Title: Exception to Protocol on Prohibited Items in HBO	Policy Number: HM.403.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Providers

PURPOSE:

Provide guidelines on the approval or prohibition of an item for entry into the hyperbaric chamber.

POLICY:

Establishing a procedure for items allowed into the hyperbaric chamber.

- 1. Identify the item that presents risk prior to treatment.
- 2. Determine if the item is necessary.
- 3. If the item is necessary, complete the Exception to Protocol Form.
- 4. Submit the completed form to the HBO Safety Director and treating provider for review and signature.
- 5. Final approval will be made by SerenaGroup®.
- 6. Keep a copy of the form in the patient's medical record.

Exception to Protocol

Item(s) to be allow: Patient Initials:	
Effective Date:	
Expiration Date:	
Ex	xplanation
Need Assessment	Medical Issue
	Safety Issue
	Comfort Issue
	Other
Additional Safety Measures	Special Patient Training
	Special Staff Training
	Additional Safety Check
	Protective Service In Place
	Other
How Communicated To Staff	Verbal Communication
	Copy Scanned Into Medical Record
	Entered Into Notes
	Written Communication

Approved/Signature

Center HBO Safety Director:	Date:
Program Director:	Date:
Verbal Confirmation w/National Safety Director:	Date/Time:

Title: Prevention & Management of Barotrauma	Policy Number: HM.501.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Provider

POLICY:

Minimize the risk of barotrauma during HBOT. If barotrauma does occur, the degree of barotrauma will be assessed and managed.

- 1. Screen patient for history of ear, sinus, and dental problems and experience with changes in pressure (e.g., flying, diving, etc.).
- 2. Evaluate the external auditory canal and tympanic membrane (TM) on otoscopic examination.
- 3. Develop a plan to remove cerumen if present.
- 4. Instruct patient on autoinflation maneuvers (see table 1).
- 5. Compress patients at 1.5 psi/min or lower.
- 6. Remind patient to equalize middle ear with increasing chamber pressure using autoinflation maneuvers.
- 7. During compression, if patient experiences mild to moderate pain equalizing the pressure in the ears, stop compression and reduce the chamber pressure by at least 1.5 psi. Encourage the patient to autoinflate the ears. Resume compression when the pain subsides.
- 8. If patient cannot tolerate compression 3 times, discontinue therapy and document in medical record.
- 9. During decompression, if mild to moderate pain occurs, stop pressure change to allow an opportunity for the ears to equalize. Resume decompression when the ears have equalized and the pain subsides. If the patient experiences severe pain, stop decompression and recompress the chamber at least 2 psi and hold until pain is relieved, then resume decompression.

- 10. Notify the provider if the patient has difficulty during compression or decompression.
- 11. Compress patient as described in step 5 and stop compression for report of tooth pain. Suspect tooth squeeze if history of dental caries is present.
- 12. Notify provider of patient status.

TABLE 1

Ear and Sinus Cavity Clearing Techniques

Valsalva Maneuver - Pinch your nostrils and blow through your nose

Tonybee Maneuver – With your nostrils pinched, close your mouth and swallow. This will pull open your eustachian tubes while the movement of the tongue with your nose closed, compresses air against them

Lowry Technique - While closing your nostrils, blow and swallow at the same time

Edmonds Technique – While tensing the soft palate and throat muscles and pushing the jaw forward and down, perform a Valsalva Maneuver

Frenzal Manuever – Close your nostrils and close the back of your throat as if straining to life weight, then make the sound of the letter "K", forcing the back of your tongue upward, compressing air against the opening of your eustachian tubes

Voluntary Tubal Opening – Tense the muscles of the soft palate and the throat while pushing the jaw forward and down as if starting to yawn, these muscles pull the eustachian tubes down

Title: Seizure in HBOT	Policy Number: HM.502.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
SerendGroup Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Provider
- Clinical Staff
- Chamber Technician

PURPOSE:

Identify and treat a seizure in the hyperbaric chamber.

POLICY:

Take appropriate measures to identify the signs and symptoms of seizure and manage a seizure in the hyperbaric chamber.

BACKGROUND:

Grand mal seizures may be caused by CNS oxygen toxicity, hypoglycemia, or be the result of a pre-existing seizure disorder. Seizure activity can occur in patients breathing oxygen at pressures of 2.0 ATA or greater. Seizures may occur abruptly and may or may not be preceded by warning signs and symptoms. Signs of oxygen toxicity begin with: sweating, nausea, vomiting, apprehension, shortness of breath, tunnel vision, tinnitus, hallucinations, and muscle twitching.

- 1. Notify the hyperbaric provider if patient experiences the early signs or symptoms of a seizure.
- 2. Give the patient an air break and decrease the pressure of the chamber to 2.0 ATA.
- 3. Continue air breathing for 5 (five) to 10 (ten) minutes until patient improves.
- 4. If the patient is activity seizing, do not decompress the chamber until the seizure activity has ceased.
- 5. When the patient is no longer actively seizing, decompress the chamber at 2.0 psi/min or lower. Emergency venting is not indicated.

- 6. If the patient does not stop seizing, decompress the chamber under provider guidance.
- 7. Following decompression, check the blood glucose in diabetic patients.
- 8. Document the event and patient's response.
- 9. Consult hyperbaric provider for modification of treatment protocol.
- 10. Patients experiencing a seizure will be transported to the emergency department for evaluation.

Title: Cardiac Arrest in the Chamber	Policy Number: HM.503.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Provider
- Clinical Staff
- Chamber Technician

PURPOSE:

Safely remove a patient from the chamber during a cardiac emergency.

POLICY:

Establishing a procedure to safely remove the patient from the chamber during a cardiac emergency.

- 1. In the event of a cardiac emergency, notify the hyperbaric provider and activate the emergency response plan.
- 2. The emergency decompression procedure will be initiated. Decompression rate will depend upon the condition of the patient.
- 3. The patient is removed from chamber once decompression is complete, and the gurney is moved away from the chamber. The patient must be moved a minimum of 10 feet away from the chamber.
- 4. Remove the patient's gown and linen.
- 5. CPR is initiated as indicated until the hospital's emergency team or paramedics arrive.
- 6. If defibrillation is required, the patient must be a minimum of 10 feet away from the chamber.
- 7. Notify SerenaGroup® following the event.

Title: Pediatric/Adolescent Patients	Policy Number: HM.504.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022

Source: SerenaGroup® Inc.



Medical Director SerenaGroup, Inc.

Thomas E. Serena MD FACS



SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- HBO Technician
- All Center Staff
- Providers

POLICY:

Pediatric/adolescent patient may be seen in accordance with hospital policy and the Scope of Services of the outpatient wound care center.

PURPOSE:

To ensure that center staff is knowledgeable about the care of the pediatric/adolescent patient.

- Clinical staff should:
 - Consult with Family Practice/Pediatrics as needed to develop an appropriate plan of care for the pediatric/adolescent wound care patient. Information gathered may include:
 - Growth and developmental needs
 - Emotional, cognitive and social needs
 - Immunization status
 - Family or guardian expectations for and involvement in the continuing care of the patient.
- Clinical staff should:
 - Contact available pediatric/adolescent resources as needed.
 - Develop the patient plan of care for the pediatric/adolescent patient collaboratively with the pediatric/adolescent resource.
 - Consult appropriate resource material (textbooks, journal articles, etc.) as necessary to ensure appropriate treatment plan development and implementation.
 - Participate in any hospital provided and required in-services/training regarding age specific competency and place documentation of such training in the employee's personnel file.
 - A minimum of one clinical staff member must be certified in Pediatric Advanced Life Support (PALS).
 - o Hospital and treating Provider must be credentialed for pediatric patients.

Title: Confinement Anxiety	Policy Number: HM.509.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

POLICY:

Addressing confinement anxiety during HBOT.

Confinement anxiety and claustrophobia are risks to patients receiving HBOT.

- 1. Obtain and document patient history of claustrophobia or confinement anxiety.
- 2. Orient patient to HBOT. The following steps may help prevent confinement anxiety:
 - a. Familiarize patient with chamber unit and other patients receiving treatment. Reassure the patient that they are never alone.
 - b. Demonstrate the two-way communication method.
 - c. Prior to treatment, consider having the patient lie down on the HBOT stretcher for a trial.
 - d. Provide support while the patient is adjusting to the environment.
 - e. Reassure the patient of their control of the situation.
 - f. Inform provider if additional evaluation is needed.
- 3. Use relaxation techniques and diversional activities for patients in the chamber.
- 4. Monitor for the following signs and symptoms of confinement anxiety reaction.
 - a. Hyperventilation
 - b. Clenching of fists
 - c. Sudden complaint of pain or discomfort
 - d. Urgency to empty the bladder
 - e. Feelings of being smothered or suffocated
 - f. Flushed face
 - g. Diaphoresis

- 5. Intervention for a patient experiencing confinement anxiety that cannot be resolved during treatment.
 - a. Start decompression.
 - b. Support the patient during decompression.
 - c. Offer support and understanding to the patient's reaction.
 - i. Encourage the patient to express feelings.
 - ii. Ask patient specific questions regarding anxiety reaction.
- 6. Consult with the HBOT provider for further management of confinement anxiety or claustrophobia.

Title: Implanted Devices	Policy Number: HM.514.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Provide safe and effective treatment of hyperbaric patients with implanted devices.

- 1. Obtain and document the patient's history of implanted devices.
- 2. Request a copy of the patient's device card. If the card is not available, contact SerenaGroup®.
- 3. Chamber technician contacts the manufacturer to determine if the device is rated for hyperbaric pressures.
- 4. Findings are documented in the patient's medical record.

Title: Negative Pressure Wound Therapy (NPWT)	Policy Number: HM.515.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Establish the safe use of negative pressure wound therapy (NPWT) with HBOT.

- 1. Mechanical
 - a. Pre-HBO Treatment:
 - i. Perform hand hygiene and don gloves.
 - ii. Clamp the dressing side of the hose.
 - iii. Turn off the pump.
 - iv. Raise the tube connector above the level of the pump unit.
 - v. Separate canister tube and dressing tubes by disconnecting the connector.
 - vi. Disconnect the tubing and cover ends of the tubing.
 - b. Post HBO Treatment:
 - i. Perform hand hygiene and don gloves.
 - ii. Remove covering from the tube and reconnect tubing.
 - iii. Turn on pump.
 - iv. Patient with NPWT is now ready for discharge post HBOT.
- 2. Non-Mechanical NPWT devices are not cleared for use in HBO Chamber at this time.

Title: Severe Weather During HBOT	Policy Number: HM.518.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
SerendGroup Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

POLICY:

Establish guidelines for early discontinuation of HBOT due to severe weather.

PURPOSE:

Safely remove patients from the chamber during a severe weather event.

PROCEDURE:

In the event of severe weather, chamber technician will:

- 1. Respond appropriately if weather event presents a risk to the hyperbaric center.
- 2. A chamber technician will decompress the patients at a safe rate.
 - a. If danger is imminent, the rate may be increased.
 - b. Remove patients from the chambers.
 - c. Prepare for potential evacuation.
- 3. Chamber room close out:
 - a. Close zone gas valves at the chambers.
 - b. Turn off and unplug all electrical equipment.

Title: Hyperbaric Treatment Table 2.0 ATA	Policy Number: HM.603.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Describes a standard treatment table at 2.0 ATA.

STANDARD:

- 1. Provider prescribes treatment table 2.0 ATA.
- 2. Compress and decompress the chamber at a rate of 1.5 PSI per minute.
- 3. The patient remains at treatment pressure for 90 minutes.
- 4. Documentation of the treatment protocol and a record of events during the treatment will be maintained in the medical record.



Title: Hyperbaric Treatment Table 2.5 ATA	Policy Number: HM.604.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/01/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Serend Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

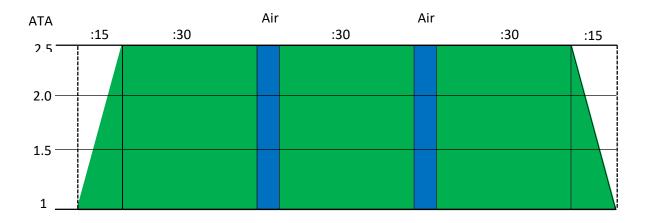
- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Describes a standard treatment table at 2.5 ATA.

STANDARD:

- 5. Provider prescribes treatment table 2.5 ATA.
- 6. Compress and decompress the chamber at a rate of 1.5 PSI per minute.
- 7. The patient remains at treatment pressure for 90 minutes.
- 8. At 30-minute intervals, the patient is instructed to place air-breathing device over nose and mouth to breathe air for five-minute periods.
- 9. Documentation of the treatment protocol and a record of events during the treatment will be maintained in the medical record.



Title: Hyperbaric Treatment Table 3.0 ATA	Policy Number: HM.605.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

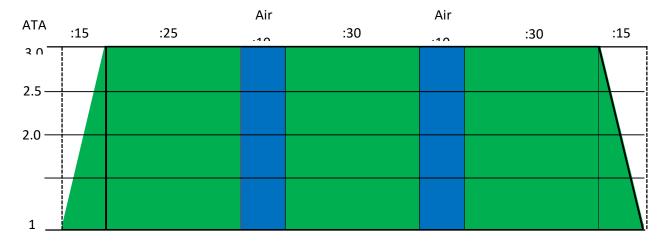
- Chamber Technician
- Clinical Staff
- Provider

PURPOSE:

Describes a treatment table at 3.0 ATA.

STANDARD:

- 10. Provider prescribes treatment table 3.0 ATA.
- 11. Compress and decompress the chamber at a rate of 2.0 PSI per minute.
- 12. The patient remains at treatment pressure for a maximum of 110 minutes.
- 13. At 30-minute intervals, the patient is instructed to place air-breathing device over nose and mouth to breathe air for ten-minute periods.
- 14. Documentation of the treatment protocol and a record of events during the treatment will be maintained in the medical record.



Title: Treatment Room Cleaning COVID-19	Policy Number: 701.0
Date Issued: 04/14/2019	Date Revised: 1/1/2022
Source: SerenaGroup™ Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS

All company facilities, including hospitals and any entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Staff Physicians/Non-Physician Provider

Who are involved in the treatment of COVID-19 positive patients, or patients suspected of COVID-19

PURPOSE:

To prevent cross contamination and maintain safe operation of the Hyperbaric Oxygen Unit, and to ensure that the treatment room and all associated equipment is cleaned and maintained in accordance with manufacturer's specifications.

DEFINITIONS:

<u>COVID-19</u> - novel coronavirus is an infectious disease spread amongst the human population which causes respiratory illness with other flu-like symptoms.

PROCEDURE:

Standard cleaning process of the treatment room will be followed between patients with confirmed or suspected status of COVID-19.

While treating patients with confirmed or suspected status of COVID-19, the treatment room will be terminally cleaned at the end of each business day in accordance with Hospital policy for terminal cleaning.

It is recommended that a UV light source be used during the terminal cleaning process.

Environmental Infection Control:

Dedicated medical equipment should be used when caring for patients with known or suspected COVID-19. It is recommended to use disposable medical equipment wherever possible including but not limited to; stethoscopes, air break masks and grounding wrist straps.

All non-dedicated, non-disposable medical equipment used for patient care should be cleaned and disinfected between each patient according to manufacturer's instructions and facility policies.

Ensure that environmental cleaning and disinfection procedures are followed.

Routine cleaning and disinfection procedures (e.g., using cleaners and water to pre-clean surfaces prior to applying an EPA-registered, hospital-grade disinfectant to frequently touched surfaces or objects for appropriate contact times as indicated on the product's label) are appropriate for COVID-19. Management of laundry, food service and medical waste should also be performed in accordance with routine procedures.

General Precautions:

UV light may damage the acrylic tube of the hyperbaric oxygen therapy treatment chamber.

To prevent damage to the acrylic surfaces, ensure that the treatment chamber is appropriately covered leaving no areas of exposed acrylic.

The cover should be long enough to lay level with the floor to prevent UV light from entering from underneath the treatment chamber.

Place proper infectious disease signage is placed on the entrance of the treatment room door.

Always wear proper personal protective equipment during cleaning process.

REFERENCES:

Centers for Disease Control and Prevention (CDC). (2020). COVID-19 Infection Prevention and Control in Healthcare Settings: Questions and Answers.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ambulatory-care-settings.html

Title: Chamber Cleaning COVID-19	Policy Number: 702.0
Date Issued: 04/14/2020	Date Revised: 1/1/2022
Source: SerenaGroup™ Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director Serena Group, Inc. Thomas E. Serena MD FACS

All company facilities, including hospitals and any entities operating under the hospital's Medicare Provider Number including, but not limited to, the following;

- Chamber Technicians
- Nursing Staff
- Staff Physicians/Non-Physician Provider

Who are involved in the treatment of patients who have tested positive for or are suspected of COVID-19.

PURPOSE:

To prevent cross contamination and maintain safe operation of the chambers, all equipment is cleaned and maintained in accordance with manufacturer's specifications.

DEFINITIONS:

<u>COVID-19</u> - novel coronavirus is an infectious disease spread amongst the human population which causes respiratory illness with other flu-like symptoms.

<u>N95 Mask/Respirator</u>- a particulate-filtering face piece respirator that meets the N95 standard of the U.S. National Institute for Occupational Safety and Health air filtration rating, meaning that it filters at least 95% of airborne particles.

PROCEDURE:

1. TERMENAL CLEANING:

- a. Frequency
 - **i.** In the event that the previous patient treated in the chamber has <u>not</u> tested positive for COVID-19 terminal cleaning of the chamber is not required.
 - ii. When treating COVID-19 positive patients in succession, the monoplace treatment chamber will be terminally cleaned after every three treatments, or at least once every 8hr
 - 1. All treatment chambers must maintain documented cleaning records.

b. Cleaning Solution

- i. The chamber will only be cleaned with products that have been approved for the use on acrylic surfaces, by the treatment chamber manufacturer (see list below).
- **ii.** Do not use any disinfectant containing alcohol as they initiate crazing and damage to the acrylic cylinder.
- iii. Adhere to manufacturer's instructions for dilution of cleaning solutions
- iv. Correctly diluted cleaners may be used at up to 100°F (38°C) maximum.
- **v.** Avoid spraying any liquid on exposed electrical circuits, including patient monitoring equipment and grounding leads.
- vi. Use a soft, lint free, damp cloth for cleaning. Preferably microfiber
- vii. Do not use cleaners when the chamber is pressurized.
- **viii.** Caution must be exercised when using cleaners containing strong perfumes some of which are known to damage acrylic.

c. Process

- i. Spray the disinfectant solution to thoroughly cover the chamber interior, beginning at the foot- end and working out through to the chamber door. Remove cover plates to access normally hidden areas. Allow the spray mist to settle; if necessary, spray a clean, soft cotton cloth to spread the disinfectant to all exposed surfaces.
- **ii.** Allow disinfectant to set according to product labeling recommendations for contact time.
- **iii.** Wipe the excess disinfectant with a water dampened cloth buff dry with lint free soft cloth Repeat as needed to eliminate streaking.
- iv. Vent the chamber to remove residual odor.
- **v.** Use this same technique for chamber exterior.
- vi. Use this same technique for the mattress/gurney.

d. Ancillary Equipment

- i. The chamber mattress and gurney will be disinfected after all COVID-19 patients.
- **ii.** All other ancillary hyperbaric equipment; pumps, ventilators, and monitors, will be disinfected after each use with the approved cleaner in accordance with manufactures recommendations.
- 2. <u>PERSONAL PROTECTIVE EQUIPMENT</u>- Use of appropriate personnel protection following CDC guidelines for Eye protection, Isolation Gowns, Face mask N95 (Respirators if available) must be worn throughout entire disinfection process.

a. Eye protection

- i. Eye protection should be removed and reprocessed if it becomes visibly soiled or difficult to see through.
- ii. If a face shield is reprocessed, it should be dedicated to one care provider and reprocessed whenever it is visibly soiled or removed (e.g., when leaving the isolation area) prior to putting it back on.
- iii. Eye protection should be discarded if damaged (e.g., face shield can no longer fasten securely to the provider, if visibility is obscured and reprocessing does not restore visibility).
- iv. Take care not to touch eye protection. If you touch or adjust eye protection immediately perform hand hygiene.
- v. Leave patient care area if you need to remove eye protection.

b. Isolation Gowns

i. Reusable (i.e., washable) gowns are typically made of polyester or polyester-cotton fabrics. Gowns made of these fabrics can be safely laundered according to routine procedures and reused. With both disposable or reusable care should be taken to ensure that care providers do not touch outer surfaces of the gown during care.

c. N95 Mask

- i. N95 Masks require proper measurement and fitting before use.
- ii. The facemask should be removed and discarded if soiled, damaged, or hard to breathe through.
- iii. Take care not to touch the facemask. If you touch or adjust the facemask immediately perform hand hygiene.
- iv. Leave the patient care area if they need to remove the facemask.
- v. Follow host hospital policy for disposal or disinfect (in event of multiple use).

d. Gloves

i. Nitrile gloves will be worn during any cleaning process.

3. <u>SPECIAL CONSIDERATIONS:</u>

a. Chamber Ventilation

i. During the treatment of a confirmed COVID-19 patient, set the vent control to full on, 450lpm, for entire treatment. This will provide a constant flush of the chamber.

4. APPROVED CLEANING SOLUTIONS BY BRAND:

a. Perry Treatment Chamber

- i. Tor HB
- ii. Coverage HB
- iii. Hibitane
- iv. Ascend
- v. Asepti-HB Ecolab
- vi. PDI Sani-Cloth Bleach Wipes (MSDS 0010 / EPA Reg. No. 9480-8)
- vii. PDI Sani-Cloth AF Germicidal Wipes (MSDS 0090)
- viii. PDI Sani-Cloth AF3 germicidal wipes (MSDS 0101)
- ix. STERIS LpH® se One Step Germicidal Detergent (product / SDS # 6466 @ dilution ratio of 1:256)
- x. EcoLab #25 HB Quat Disinfectant Cleaner (ready to use Ecolab registration number 61-0000-6316-6)
- xi. EcoLab A-456-N (EPA 42964-31)
- xii. Bleach Up to 15% aqueous Sodium Hypochlorite (NaOCI) [7681-52-9]
- xiii. Aqueous Hydrogen Peroxide 3% to 20% (H2O2) [7722-84-1]
- xiv. Aqueous Chlorine Dioxide up to 2% (ClO2) [10049-04-4]
- xv. Chlorox Healthcare Bleach Germicidal Wipes Clorox Company
- xvi. (Bleach, caustic soda and sodium metasilicate based, lint-free cloths.)
- xvii. Tego 2001 (EUROPE ONLY) Amphoteric Disinfectant Johnson Diversey
- xviii. (Surface active, microbiocidal amphoteric system, with EDTA and IsoPropanol, in small quantity)

- xix. Enviroguard64, Enviroguard64LLC
- xx. (Quaternary Ammonium Surfactants plus Ethanol, in small quantity)
- xxi. Coverage Spray HB Plus Steris
- xxii. (Quaternary Ammonium Surfactants plus Ethanol, in small quantity)
- xxiii. DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach Excolab
- xxiv. (Bleach, caustic soda and sodium metasilicate based, lint-free cloths.)
- xxv. Vital Oxide (formerly EXPEL) Orison Marketing, L.L.C.

b. Sechrist Treatment Chamber

- i. Quik Fill 920 Ecolab Professional Products, Ecolab Inc., St. Paul/MN
- ii. Hi-Tor Plus Ecolab Professional Products, Ecolab Inc., St. Paul/MN
- iii. Tor-HB Ecolab Professional Products, Ecolab Inc., St. Paul/MN
- iv. Stat III TB Ecolab Professional Products, Ecolab Inc., St. Paul/MN
- v. Beaucoup Ecolab Professional Products, Ecolab Inc., St. Paul/MN
- vi. Ascend Ecolab Professional Products, Ecolab Inc., St. Paul/MN
- vii. Matar Ecolab Professional Products, Ecolab Inc., St. Paul/MN
- viii. LpH-se Calgon Vestal Steris Corp., Mentor/OH

REFERENCES:

- 1. Centers for Disease Control and Prevention (CDC). (2020). COVID-19 Infection Prevention and Control in Healthcare Settings: Questions and Answers.
- 2. Occupational Safety and Health Administration (OSHA). (2020). Respirator Types.
- 3. https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html
- 4. https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
- 5. https://perrybaromedical.com/hyperbaric-oxygen-therapy-info/
- 6. https://sechristusa.com/

Title: Patient HBOT Clothing COVID-19	Policy Number: 703.0
Date Issued: 04/14/2020	Date Revised: 1/1/2022
Source: SerenaGroup™ Inc.	Medical Director SerenaGroup, Inc.
Sereng Group Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Entities operating under the hospital's Medicare Provider Number including, but not limited to, thefollowing;

- Chamber Technician
- Clinical Staff
- Provider

Who are involved in the treatment of a COVID-19 positive patient.

PURPOSE:

To establish guidelines for storing patient personal belongings and for providing privacy for patients while changing clothing for hyperbaric oxygen treatment. Also to provide understanding of approved clothing for hyperbaric treatments.

POLICY:

Patients undergoing hyperbaric therapy will be required to dress in center supplied garments of 100% cotton or >50% cotton/polyester blends with no snaps or pockets a prior to entering the hyperbaric chamber. No garment with greater than a 50% polyester blend will be permitted into the treatment chamber.

PROCEDURE:

When treating an inpatient who has tested positive for COVID-19, the following steps will be taken to ensure that exposure between Hyperbaric Oxygen staff and patient is limited, while ensuring that the proper clothing material requirements are met.

- 1. Hyperbaric Oxygen staff will provide the appropriate garments to the patient floor prior to treatment.
- 2. The patient will change into the provided garments before being transported to the Hyperbaric Oxygen Unit.
- 3. Personal belongings will not be permitted in the Hyperbaric Unit. All personal belongings will remain properly secured in the patient room.
- 4. Any socks or footwear required for transportation will be removed prior to entering the treatment chamber.

5.	After the Hyperbaric Oxygen treatment, the patient will be transported back to their room in the HBO
	specific garments.

6	The natient will change	ge out of the HBO garments	upon being returned	to their room

REFERENCES:

1. NFPA 99 Healthcare Facilities Code. Code numbers 14.3.1.6.4.1, 14.3.1.6.4.2. (2018). https://www.nfpa.org

Title: Patient Grounding Wrist Straps COVID-19	Policy Number: 705.0	
Date Issued: 04/14/2020	Date Revised: 1/1/2022	
Source: SerenaGroup™ Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director Serena Group, Inc. Thomas E. Serena MD FACS	

PATIENT GROUNDING STRAP

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- HBO Technical Staff
- Clinical Staff
- Provider

Who are involved in the treatment of patients who have tested positive for COVID-19.

PURPOSE:

To implement a policy on minimum patient grounding requirements and establish approved methods of attaining safe patient grounding.

DEFINITIONS:

1. Ground- the reference point in an electrical circuit from which voltages are measured, a common return path for electric current, or a direct physical connection to the earth.

POLICY:

Patient grounding is an established safety standard by NFPA 99 (2012): 14.3.1.5.3.2 – In class A and class B chambers with atmospheres containing more than 23.5 percent oxygen by volume, electrical grounding of the patient achieved by a high-impedance conductive pathway in contact with the patient's skin.

- 1. Chamber manufacturers provided versions of acceptable methods of grounding during chamber delivery and setup. For example, Sechrist Industries provides a metal wrist strap and grounding wire. Perry Baromedical provides an elastic strap with a metallic pad and wire.
 - Regardless of manufacturer, these methods of patient grounding are interchangeable and acceptable.
- Any other method of patient grounding, including ECG pads or electrodes are not supported due to lack of
 documentation of provision of adequate patient grounding. Additionally, the chamber manufacturers as
 well as the ECG pad manufacturers do not support their use for this purpose.

- 3. Storing between use- Hospitals may choose one of three options for handling grounding straps after treatment.
 - Straps may be disinfected, labeled for that specific patient and stored in a plastic container to be used for that patient's next treatment.
 - Straps may be sent with the patient back to their room. That strap will then be worn to each subsequent treatment.
 - Straps may be treated as disposable and discarded after each treatment.

REFERENCES:

1. NFPA 99 Healthcare Facilities Code. Codes: 14.3.1.5.3.2 (2012). https://www.nfpa.org

Title: Patient Orientation to HBO COVID-19	Policy Number: 706.0	
Date Issued: 04/14/2020	Date Revised: 1/1/2022	
Source: SerenaGroup™ Inc. SerenaGroup™ Inc. Building the Nation's Leading Wound Care Team	Medical Director Serena Group, Inc. Thomas E. Serena MD FACS	

Entities operating under the hospital's Medicare Provider Number including, but not limited to, thefollowing:

- Hyperbaric Technician
- Clinical Staff
- Provider

Who are involved in the treatment of patients who have tested positive for COVID-19

PURPOSE:

To outline the process for orienting the patient to HBO Therapy before treatments begin, while minimizing staff exposure to COVID-19.

POLICY:

A patient-centered focus is essential to a successful patient outcome. It is the policy of the Hyperbaric Center to involve immediate family members as much as possible in the program and interact with them in a kind and caring manner.

Each new hyperbaric patient will receive orientation via telephone or video conference, prior to his/her first treatment

- 1. The HBO technician, nurse or provider will orient the patient to hyperbaric oxygen therapy. Personnel supervising the treatments will assure the orientation is completed before treatment begins
- 2. Once the provider explains the risks and benefits of HBO and the patient is given ample time for questions, the patient will provide a verbal consent and understanding which will be documented in the patient medical record
- 3. Documentation will include:
 - Daily HBO Patient Safety checklist

- Education
- Informed consent for hyperbaric medicine and photography
- Insurance information/financial responsibility
- HBO Clearance
- HBO Dive Record
- HBO Orientation (scanned)
- Medications/Allergies
- Past Medical History
- Physical Exam
- Physician orders
- Review of Systems
- Risk Evaluation
- Wound Assessment, as applicable
- 4. Minors must have a legal guardian's signature for all consents. Those unable to or deemed incapable must have the signature of their legal representative. The patient will receive a copy and the original is placed in the patientchart
- 5. A "Patient Guide to Hyperbaric Medicine" educational document is given to all patients (Attached)
 - The printed Patient Guide to Hyperbaric Medicine, will be provided to the inpatient unit to be delivered to the patient prior to their first treatment
- 6. Include family members in the patient orientation as applicable, including the following:
 - The initial hyperbaric visit with physician/non-physicianprovider
 - The hyperbaric orientation process as well as a tour of the facility
 - Encouragement to be a "support team" member during the patient's course oftreatment
 - In the event of a patient with special needs or problems, consult with the hospital Social Services department

Patient Guide to Hyperbaric Medicine

Welcome to the Wound Care and Hyperbaric Oxygen Therapy Center.

What Is Hyperbaric Oxygen Therapy?

Hyperbaric oxygen therapy (HBO) is a medical treatment in which the entire body is under increased atmospheric pressure and the patient breaths 100% oxygen. This treatment is administered in a pressurized chamber. It has proven effective for a number of different medical and surgical conditions either as a primary treatment or in addition to other medical treatments such as antibiotics or surgery.

At the Hyperbaric Unit in this Hospital, we use a single person (monoplace) chamber. The chamber is approximately eight feet long and 34 inches or more in diameter. Some facilities use a multi-place chamber and treat more than one person at a time.

How Does It Work?

Normally, our atmosphere is exerting 14.7 pounds per square inch of pressure at sea level. This is equivalent to one atmosphere absolute (1 ATA). In this atmosphere, we breathe approximately 20% oxygen and 80% nitrogen. During HBO, the pressure is increased two or three times more than normal and you breathe 100% oxygen. Most patients are treated at twice the normal atmospheric pressure (2 ATA).

The combinations of high concentrations of oxygen (100%) and increased pressure cause large amounts of oxygen to be dissolved in your blood and other tissue fluids. There can be as much as 10 to 15 times the usual amount of oxygen dissolved in your blood, which supplies much more oxygen to the rest of your body.

Many different problems have been shown to benefit from HBO. Some of the most common problems are non-healing wounds (especially in diabetics), osteomyelitis (bone infections), radiation injury to bone or soft tissue burns, decompression illness (bends) and carbon monoxide poisoning.

What Will I Feel During Treatment?

Once you are in the chamber and the door is closed, you will hear the oxygen begin to circulate, we will then start a gradual increase in pressure. This is called compression. There may be some warmth that you notice, but this is temporary. A nurse/technician will remain with you during the treatment to adjust the rate of compression according to your tolerance and to coach you in relieving the "full" sensation, which you may feel in your ears. This feeling is similar to what you may have felt while traveling down a mountain, flying, or scuba diving. We will coach you on how to clear your ears, but you may need to try several ways in order to find the most effective one for you. Compression generally lasts 7 to 10 minutes, depending on how effectively you clear your ears.

When you have reached the prescribed pressure, the fullness in your ears will cease, and you may rest or sleep during the remainder of the treatment. You may also watch TV or listen to music during this time, which will be 1.5 to 2 hours. The temperature in the chamber is similar to room temperature, but may be adjusted slightly.

Near the end of your treatment, the nurse/technician will gradually decrease the pressure added at the beginning of the treatment. This is the decompression phase. During decompression, you may experience a "popping" sensation in your ears as a result of the changing pressure. This popping is a normal adjustment in your ears, similar to what happens when you are driving up a mountain.

Are There Any Side Effects?

Generally, you will experience no other effect from HBO. However, some patients report a "crackling" sensation in their ears between treatments. This may be relieved in the same manner you clear you ears during compression. If "crackling" should continue, please tell the nurse/technician.

As with all medical procedures and treatments, there are some side effects that may result from the exposure to hyperbaric oxygen. These are rare. The following is a summary of some of the potential risks or side effects of hyperbaric oxygenation:

- Barotraumas or pain in the ears or sinuses: I may experience pain in my ears or sinuses. I also understand that if I am not able to equalize my ears or sinuses that pressurization will be slowed or halted and suitable remedies will be applied.
- Cerebral Air Embolism and Pneumothorax: Whenever there is a rapid change in ambient pressure, there is the possibility of rupture of the lungs with air escaping into the arteries or into the chest cavity outside the lungs. This can only occur if the normal passage of air out of the lungs is blocked during decompression. Only slow decompressions are used in hyperbaric oxygen treatment to alleviate this possibility.
- Oxygen Toxicity: The risk of oxygen toxicity has been explained to me and will be minimized by never exposing me to greater pressure or longer times than are known to be safe for the body and its organs.
- **Risk of Fire:** With the use of oxygen in any form, there is an increased risk of fire, but strict precautions have been taken to prevent this and all applicable codes have been complied with. There has never been a fire involving a patient in a Hospital Based regulated Hyperbaric/Wound Center in the United States.
- Risk of Worsening Near-Sightedness: (Myopia) After 20 or more treatments, especially if you are over 40, it is
 possible that you may experience diminution in your ability to see things far away. Understand that this is
 believed to be temporary and that vision usually returns to its pretreatment level about six weeks after the
 cessation of therapy. Understand that it is not advisable to get a new prescription for your glasses until at least
 eight (8) weeks have passed after HBOtreatment.

- Maturing or Ripening Cataracts: In individuals with cataracts, it has occasionally been demonstrated that there may be a maturing or ripening of the cataracts.
- Temporary Improvement in Far-Sightedness: (Presbyopia) After 20 or more treatments, especially if you are over 40, there is a possibility that you may experience an improvement in your ability to see objects close by, or to read without reading glasses. However, understand this is believed to be temporary and that your vision should return to its previous level of acuity in about six weeks following the cessation of therapy.
- **Numb Fingers:** A small proportion of our patients sometimes notice a numb feeling in the fourth and fifth fingers or the hands after 20 or more treatments. This should not be a concern and should disappear in about six weeks following the cessation of therapy.
- Ear Fluid: Fluid found in the ears sometimes accumulates as a result of breathing high concentrations of oxygen. It may sometimes feel like a pillow over your ears. This disappears after treatment ceases and often can be eased with decongestants.
- **Fatigue:** Some people may subjectively feel fatigue following hyperbaric treatment but this is not a consistent finding.

If you have any questions or concerns after your daily hyperbaric treatment, please call the center. If you have concerns or symptoms *after hours* that cannot wait until the center is open, we recommend you proceed to your nearest EmergencyRoom.

Call the center as soon as possible if you need to change or cancel your scheduled appointment. However, we strongly encourage you not to miss anytreatments.

For HBO therapy to be effective, it must be provided five days a week. Hyperbaric therapy is much like antibiotic treatment because it only works when taken regularly for the time prescribed by your physician. Missed hyperbaric treatment will lead to failed healing and the longer the wound remains open, the greater the risk of amputation.

If there is anything we can do to assist you during this treatment process, please don't hesitate to let us know. Thank you for choosing our center. We look forward to helping youheal.

The Wound Care and Hyperbaric Oxygen Therapy Center Staff

Title: Air Breaks COVID-19	Policy Number: 710.0	
Date Issued: 04/16/2020	Date Revised: 1/1/2022	
Source: SerenaGroup™ Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS	

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Chamber Technician
- Personnel Clinical Staff
- Provider

Who are involved in the treatment of patients who have tested positive for or are suspected of COVID-19.

PURPOSE:

Prevention of oxygen toxicity during the administration of hyperbaric oxygen.

POLICY:

Patients undergoing treatment 1.7 Atmospheres Absolute (ATA) will have air breaks administered as part of the treatment.

• The preferred air break protocol is 2.5-30-5-30-2.5 minutes schedule.

- 1. Free Flow Type Air Break Assembly:
 - a. Ensure USP Medical Grade Air Cylinder is available, has adequate supply (minimum of 75 psi) and external hoses are not kinked or damaged. The cylinder should remain in the OFF position immediately prior to administering the air break.
 - b. A disposable mask should be assigned to each patient.
 - c. Instruct the patient on the need for air breaks as well as importance of compliance for their own safety.
 - d. Before closing the chamber door, ensure the internal hose and non-rebreather mask are available and within easy reach of the patient.
 - e. Turn on the medical air cylinder and confirm the set pressure on the regulator is set to 70 psi. Adjust accordingly and close the valve.

- f. Close chamber door and start the treatment as normal, noting the times to begin the air-breaks on the record.
- g. At the prescribed time, open the flow meter.
- h. Ensuring the patient is obtaining an effective seal.
- i. Administer the air breaks per the provider as ordered.
- j. A disposable mask and should be assigned to each patient and disinfected for reused by that patient for entire course of treatment or discard and replace as necessary. Or discarded after treatment.

2. Demand Valve Type Air Break Assembly:

- a. Ensure USP Medical Grade Air Cylinder is available, has adequate supply (minimum of 80 psi) and external hoses are not kinked or damaged. Turn the cylinder ON and confirm the set pressure on the regulator is set to 70 psi. Because this setup has a demand valve, the cylinder can remain on.
- b. A disposable Tru-Fit mask and filter should be assigned to each patient and reused by that patient for a course of treatment. Discard and replace as necessary.
- c. To prevent contamination of the demand valve, utilize a filter between the valve and mask. If a filter in all cases disinfecting the internal parts of the demand valve is necessary as part of the chamber disinfection.
- d. Instruct the patient on the importance of compliance with the air breaks as well as the need for an effective seal.
- e. Before closing the chamber door, ensure the internal hose and mask are available and within easy reach of the patient.
- f. Close chamber door and start the treatment as normal, noting the times to begin the air-breaks on the record.
- g. Administer the air breaks per the provider as ordered.
- h. Ensure the patient is obtaining an effective seal.
- i. Turn off the air cylinder once the final air break is completed.
- j. Clean and disinfect the internal demand valve weekly.

Title: Abbreviations	
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
·	Medical Director SerenaGroup, Inc.
SerendGroup Building the Nation's Leading Wound Care Team	Thomas E. Serena MD FACS

Abbreviation	Definition
ABN	Advanced Beneficiary Notice
AKA	Above Knee Amputation
ATA	Atmospheres absolute
ВКА	Below Knee Amputation
BLS	Basic life support
ВР	Blood pressure
BPM	Beats Per Minute
CDIF	Clostridioides Difficile
CEU	Continuing Education Unit
CLIA	Clinical Laboratory Improvement Amendment
CMS	Center for Medicare Services
CME	Continued Medical Education Credits
CNS	Central Nervous System
CCO	Chief Clinical Officer
СТР	Cellular and/or Tissue-based Products for Wound Care
CXR	Chest X-Ray
DBP	Diastolic Blood Pressure
ECG	Electrocardiagram
EMR	Electronic Medical Record
ENT	Ear Nose& Throat
FDA	Federal Drug Administration
H&P	History and Physical
НВОТ	Hyperbaric Oxygen Therapy
HEPA	High Efficiency Particulate Air
HIPAA	Health Insurance and Portability Accountability Act
HR	Human Resources
ICD	Implantable Cardioverter defibrillator
IM	Intramuscular
IRB	Institutional Review Board
IV	Intravenous
LCD	Local Coverage Determination
LOX	Liquid Oxygen
LPN	Licensed Practical Nurse
LVN	Licensed Vocational Nurse
MIN	Minute

MRSA	Methicillin-resistant Staphylococcus aureus
MSDS	Material Safety Data Sheet
NCD	National Coverage Determination
NFPA	National Fire Protection Agency
NPWT	Negative Pressure Wound Therapy
02	Oxygen
OSHA	Occupational Safety and Health Administration
P&P	Policies and Procedures
PD	Program Director
PE	Pulmonary Embolism
PPE	Personal protective equipment
PHI	Protected Health Information
POA	Power of Attorney
QC	Quality Control
PSI	Pound per Square Inch
R	Respiration
RN	Register Nurse
SBP	Spontaneous bacterial peritonitis
STAT	Immediately (statim)
TCOM	Transcutaneous oxygen measurement
TM	Tympanic Membrane
UHMS	Undersea and Hyperbaric Medical Society
USP	United States Pharmacopeia
VRE	Vancomycin resistance