Undersea and Hyperbaric Medical Society
631 US Highway 1, Suite 307, North Palm Beach, FL 33408
Phone: 877.533.8467

Testing Facility (or hyperbaric department) Name:

Testing Facility Location:

Testing Facility Contact Name:

Method of Contact (phone/email):

DESCRIPTION OF MEDICAL DEVICE APPROVAL PROCESS – CLASS 'A' MULTIPLACE CHAMBERS

PURPOSE

The following Medical Device Approval Process is a generic process that has been endorsed by the Hyperbaric Oxygen Safety Committee of the Undersea and Hyperbaric Medical Society as a method that may be used to systematically document the evaluation and risk mitigation of medical devices to be connected to or used inside a Class 'A' Multiplace Chamber. This approval process was formatted using the current edition of the National Fire Protection Association (NFPA) 99 Health Care Facilities Code, 2021 Edition, Chapter 14 and other codes invoked by this chapter. This process is intended to serve as an aid in the selection, testing, modification, documentation, and approval of medical devices for use in the Class 'A' Multiplace chamber environment. The user of this document may choose to add other testing as deemed appropriate by their institution.

SCOPE

This document is intended to be used by Safety Directors/Coordinators and Medical Directors of Multiplace Hyperbaric Facilities, working jointly with the facility's Biomedical, Managerial and Administrative Teams.

NOTE: The term Hyperbaric Safety Director is a title used for convenience. This individual may have a different title.

HYPERBARIC MEDICINE MEDICAL DEVICE APPROVAL TEAM

The establishment of a Hyperbaric Medicine Medical Device Approval Team is recommended and may consist of the following members:

Hyperbaric Medicine Safety Director (HSD)

Hyperbaric Medicine Medical Director (HMD)

We also recommend that the following individuals are involved in the process:

Hyperbaric Medicine Manager/Supervisor

Hospital Biomedical Engineering Representative

Hospital Administrative Representative

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All members of the Medical Device Approval Team are expected to review the Medical Device Approval Form for each new or modified medical device. At minimum, the HSD and HMD should indicate their approval by signing the Medical Device Approval Letter prior to use in the hyperbaric chamber. The Medical Device Approval Team may approve the device as presented or with conditions which must be specified on the Letter of Medical Device Approval. The Medical Device Approval Team must determine if each subsequent device of the same make and model must be individually tested and to what extent.

1. No testing required on subsequent devices
2. Each subsequent device receives full functional testing
3. Each subsequent device receives abbreviated testing as determined by the HSD and the Biomedical Engineering Representative.

REFERENCE DOCUMENTS

Access to the reference documents below are needed to complete and verify code requirements:

1. NFPA 99: Health Care Facilities Code (2021)
2. NFPA 70E: National Electrical Code
3. ANSI Z136.3 American National Standard for Safe Use of Lasers in Health Care
4. NFPA 101: Life Safety Code
5. NFPA 53: Recommended Practice on Materials, Equipment, and Systems Used in Oxygen-Enriched Atmospheres
6. CGA Compressed Gas Safety Guidelines
7. ASME PVHO -1 and -2

NOTE: Other electrical engineering Codes and Standards may be required by your institution.

PROCESS

1. Requests for medical device approval should be submitted to the HSD for consideration.
2. The HSD will pass the device, manuals, and approval forms to the Biomedical Engineering representative for visual inspection and schematic review.
3. The device will be disassembled to whatever extent is necessary to complete the examination.
4. Post inspection, the HSD may pass the device approval forms directly to the medical device review board if reasonable data exists from the manufacturer, other facilities, or journal documentation.
5. If inadequate data exists, the HSD will enlist the assistance of appropriate personnel to perform device testing.
6. Upon completion of successful testing, all documentation of the testing process will be forwarded to all medical device review board members for review and approval.
7. All team members are required to sign-off on each device prior to use in the hyperbaric chamber. Any member of the medical device review board may disapprove a device or request further documented evidence or testing at any time prior to approval.
8. All paperwork will be coordinated and maintained by the HSD.

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REQUEST FOR ELECTRICAL MEDICAL DEVICE APPROVAL

Type of device:

Manufacturer:

Model:

NEEDS ANALYSIS

Is this device required for patient care?

What is the reason for the new equipment or modification?

Is the device designed and rated for use with hyperbaric chambers?

Is this device used at any other hyperbaric facilities?

If yes, complete the information below.

Facility:

Contact:

Email/Phone:

If yes, what testing/modification were performed?

Facility:

Contact:

Email/Phone:

If yes, what testing/modification were performed?

Has the device been written about in any journals (insert info)?

Operator's Manual Obtained?

Service Manual Obtained?

Comments:

Submitted by:

Date of submission:

NOTE: Attach all pertinent documentation

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BIOMEDICAL ENGINEERING VISUAL EXAM & SCHEMATIC REVIEW

Biomedical References Used in the Process of Evaluation:

Device Manufacturer:

Device Manufacturer Representative:

Name:

Email/Phone:

Device Manufacturer Engineer:

Name:

Email/Phone:

In house / Facility Biomedical Engineer:

Name:

Email/Phone:

3rd Party Biomedical Evaluation / Consulting Engineer:

Name:

Email/Phone:

Additional reviewers/experts contacted:

Name:

Email/Phone:

Name:

Email/Phone:

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The following questions will help identify if the medical device meets the code requirements as written in the NFPA 99 (2021) Health Care Facilities Code.

Note: Use the dropdown for each question for “Yes”, “No” OR "NA" if the question is not applicable.

If “No” is answered, the item must be modified or mitigated to satisfy code requirements

For additional comments, reference the NFPA number and add notes to the Biomedical Comments section below.

GENERAL

All electrical equipment connected to or used in conjunction with hyperbaric patients shall comply with the applicable requirements of Chapter 10, Electrical Equipment, and with the applicable paragraphs of 14.2.9.3. (14.2.9.1.5)

All equipment shall be approved before use. (14.3.2.1.1)

Unless approved for use by the safety director and medical director of hyperbaric medicine the following devices shall not be used within the hyperbaric chamber: (14.3.2.1.2)

Portable X-ray devices

Electrocautery equipment

High-energy devices

Photographic equipment with photoflash and/or flood lamps shall not stay in the chamber when pressurized (14.3.2.1.3)

Class 1 or Class 2 lasers defined by ANSI Z136.3, *American National Standard for Safe Use of Lasers in Health Care,* shall be allowed. (14.3.2.1.4)

Class 1: Cannot emit laser radiation at levels that are known to cause eye or skin injury.

Class 2: Average radiant power of 1mW or less. Incapable of emitting laser radiation at levels that are known to cause skin or eye injury within the time period of human eye aversion response (0.25 seconds).

Equipment known to be, or suspected of being, defective shall not be introduced into any hyperbaric chamber or used in conjunction with the operation of such chamber until repaired, tested, and accepted by qualified personnel and approved by the safety director *(see 14.3.1.3.2).* (14.3.2.1.5)

Oxygen containers, valves, fittings, and interconnection equipment shall be metal as much as possible. (14.3.2.2*)

Are the following items compatible to use with oxygen? (14.3.2.3 - 14.3.2.4)

Valve seats

O-rings or Gaskets

Hoses

Lubricants

Fittings

Other _____

Anti-friction bearings that are factory sealed may use standard hydrocarbon if the atmosphere does not have increased oxygen concentration. (14.3.2.4.1)

Equipment containing Cerium, Magnesium and Magnesium alloys are not allowed inside the chamber. (14.3.2.5*)

Does this device contain an integrated motor that is contained within the housing? (14.2.9.3.13)

Note: NFPA 99 does not place restrictions on motors located inside portable medical equipment utilized inside the chamber. This, however, does not mean that there is no risk associated with their use. We strongly recommend that the risk of motors located in portable medical devices be mitigated by utilizing one of the following:

(A) Brushless motors

(B) Inert gas or air purging per the recommendations in Annex B (B14.5).

Is there a surgical version of this device?

(Note: Some manufacturers have produced medical devices that are intended to be used in the surgical setting and contain safety features that may be advantageous for the hyperbaric setting. If the answer is no, this does not necessarily restrict the device. If the answer is yes, you may wish to take advantage of these features.)

Equipment and its components used in the chamber shall not present an explosion or implosion hazard while being used inside the hyperbaric chamber. (14.2.9.3.1)

All equipment shall be rated, or tested and documented, prior to using within the hyperbaric chamber. (14.2.9.3.2)

Only the electrical equipment needed for the safe operation of the chamber and for the required patient care shall be allowed in the chamber. (14.2.9.3.3)

Only portable equipment needed for the logistical and operational support shall be allowed in the chamber during manned pressurization. (14.2.9.3.4)

The requirements of 14.2.9.3.15.1 through14.2.9.3.15.5 is applicable to sensors, signaling, alarm, communication, and remote-control equipment installed or used inside the chamber for the operation of the chamber. (14.2.9.3.15)

Is the equipment isolated from main power by one of the following means? (14.2.9.3.15.1*):

Design of the power supply circuit

Opto-isolation

By other electronic isolation means

Do the circuits such as headset cables, sensor leads, not enclosed as required in 14.2.9.3.6, meet one of the following requirements? (14.2.9.3.15.2):

Are they part of approved intrinsically safe equipment?

Are they limited by circuit design to no more than 28V and 0.5A under normal or circuit fault conditions?

Voltage: **Amps:**

DOES THE DEVICE HAVE A FLEXIBLE ELECTRICAL CORD?

Do the flexible cords used to connect portable utilization equipment to the fixed electrical supply circuit meet all the following requirements? (14.2.9.3.8):

Are these cords approved for extra-hard use in accordance with Table 400.4 of NFPA 70, National Electrical Code?

Are the electrically conductive casings of all portable equipment for use inside the chamber grounded?

Do these meet the requirements of Article 501.140 of NFPA 70, National Electrical Code?

If using the device's supplied cord, is the portable device rated at less than 2 A and the cord positioned out of traffic and protected from physical abuse? (14.2.9.3.8.1)

Amp Rating:

Does the device have an on–off power switch? (14.2.9.3.16.5(1), 14.2.9.3.16.5(3))

Does the electrical rating of the device exceed 120V and 2A? (14.2.9.3.16.5(2))

Are the electrical portions of the device purged with inert gas or air other than from the chamber environment? (14.2.9.3.16.5(2), 14.2.9.3.17, A.14.2.9.3.17, B.14.5)

Voltage: **Amps:**

Comments on FLEXIBLE CORDS

Do the receptacles provide for connection to the ground conductor of the flexible cord? (14.2.9.3.9.2)

Do receptacles supplied from isolated power circuits meet the requirements of 14.2.9.4.2? (14.2.9.3.9.3)

Ensure the design of the receptacle(s) is such that sparks cannot be discharged into chamber environment when plug inserted or withdrawal under electrical load. (14.2.9.3.9.4)

One of the following must be satisfied to protect against inadvertent withdrawal of the plug under electrical load (14.2.9.3.9.5):

The receptacle-plug combination must be of the locking type.

The receptacle must be affixed with a label warning against unplugging under load, and the power cord must not present a trip hazard for personnel moving in the chamber.

Switches used in the fixed wiring installation must be of waterproof type. (14.2.9.3.10)

Make and break contacts of the switches must be housed in the electrical enclosure so that no sparks from arcing contacts can reach the chamber environment. (14.2.9.3.10.1*)

Note: 14.2.9.3.16.5 (1) allows on/off power switches for portable, cord-connected devices. 14.2.9.3.16.5 (3) identifies that the plug shall not be used to interrupt power to the device.

Comments on SWITCHES

TEMPERATURE RATING?

Does electrical equipment installed or used in the chamber have an operating surface temperature less than 85°C (185°F) (14.2.9.3.11*)

Surface Temperature:

Comments on TEMPERATURE RATING

ANY EXPOSED LIVE ELECTRICAL PARTS?

Exposed Live Electrical Parts. Exposed live electrical parts must not be permitted, except as specified in sections 14.2.9.3.12.1 and 14.2.9.3.12.2 of NFPA 99, Chapter 14 (2021 edition). (14.2.9.3.12)

Are the exposed live electrical parts intrinsically safe? (14.2.9.3.12.1)

Exposed live electrical parts that constitute patient monitoring leads, which are part of electromedical equipment are permitted if they meet the requirements of 14.2.9.3.16. (14.2.9.3.12.2)

Comments on EXPOSED LIVE ELECTRICAL PARTS

IS THIS EQUIPMENT PORTABLE PATIENT CARE-RELATED?

Is the appliance designed, constructed, inspected, and maintained in accordance with NFPA 99, Chapter 10? (14.2.9.3.16.1)

Is there an ongoing maintenance program as required in NFPA 99 Chapter 10, that verifies and documents the electrical and mechanical integrity of the appliance? (14.2.9.3.16.2)

Oxygen does not accumulate in the electrical portions of the equipment under normal and abnormal conditions? (14.2.9.3.16.3)

Comments on PORTABLE PATIENT CARE EQUIPMENT

IS THE DEVICE BATTERY OPERATED OR CONTAIN BATTERIES?

Is the device battery operated?

Does the device contain batteries?

Are the batteries fully enclosed and secured within the device? (14.2.9.3.16.4(1))

Will the batteries be damaged by the maximum chamber pressure they are exposed to? (14.2.9.3.16.4(2))

Are the batteries of a sealed type that does not off-gas during normal use? (14.2.9.3.16.4.(3))

The batteries or battery-operated equipment are not charged while located in the chamber? (14.2.9.3.16.4(4))

The batteries are not changed on in-chamber equipment while the chamber is in use? (14.2.9.3.16.4(5))

Is the electrical rating of the device less than 12V and 48W? (14.2.9.3.16.4(6))

Voltage: **Watts:**

What is the expected life of the battery (in months or charge cycles)?

How long will the device run on a fully charged battery (in hours)?

Battery type (chemistry)? (i.e. Alkaline, Lead Acid, Lithium-Ion, Lithium-Polymer, Nickel Cadmium (NiCd), Nickel Metal Hydride (NiMH))

DOES THIS DEVICE HAVE OR CONTAIN SPEAKERS?

Is the electrical circuitry and wiring for chamber speakers completely enclosed? (14.2.9.3.15.3)

Does the electrical rating of the speakers exceed 28V rms and 25W? (14.2.9.3.15.4)

Voltage: **Watts:**

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SIGNATURE OF BIOMEDICAL EVALUATOR(S):

Biomedical Engineer: Date:

Comments:

Biomedical Engineer: Date:

Comments:

Biomedical Engineer: Date:

Comments:

Biomedical Director: Date:

Comments:

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HYPERBARIC FUNCTION TESTING

As described in the Handbook under section 14.3.2.1.1 of NFPA 99 (2021), chamber equipment should be assessed for compliance to NFPA Chapter 14 requirements, to include the potential release of energy into the chamber environment, potential release of toxic gases into the chamber environment, damage from exposure to maximum chamber pressure, and functional performance at different chamber pressures.

- The device to be tested should be prominently labeled "HBO_2 TEST DEVICE- NOT APPROVED FOR PATIENT USE" prior to testing.
- If approved for chamber use the "HBO_2 TEST DEVICE- NOT APPROVED FOR PATIENT USE" label should be replaced with a "HYPERBARIC MEDICINE ONLY" label.
- If the device receives approval "with conditions", the device must be clearly labeled with the specifics of the conditions and a hyperbaric Policy/Procedure will be created to address the use of the device in the chamber and the nature of the conditions.
- When approved for use and where appropriate, the electrical plug should be changed to a chamber compatible plug.
- Refer to the operation manual to establish a list of functions which must be verified for function and accuracy at all pressures for which the device will be utilized.
- Accuracy for the purpose of hyperbaric testing is defined as the amount of tolerance as specified in the device operation manual. (Ex. ±5%)
- When a function has a useful range, the device will be tested at 15, 50, & 85 percent of the range unless specified by the safety director.
- Function testing will be conducted at 45, 66, & 165 FSW (feet of seawater) unless specified by the safety director.
- After completion of testing, the Function Test Log will be filed by the Safety Director. A copy of the Function Test Log is to accompany the Request for Medical Device Approval for all team members to review.
- Rapid Med lock testing Implosion/Explosion testing will be performed on all devices unless this requirement is waived by a joint decision of the Safety Director and the Biomedical Engineer. (Implosion/Explosion testing will consist of a rapid compression from surface pressure to 6 ATA (165 FSW) with a bottom time of 30 minutes, immediately followed by a rapid decompression to surface. The device will be visually inspected and function tested at surface pressure. This cycle is repeated 3 times.)
- If the device fails function testing, it may be retested after modifications are made. All modifications must be clearly documented and presented with the request for approval to the Medical Device Approval Team for evaluation.
- If the device fails to pass the testing process it must be checked out by the biomedical engineering department prior to removing the "HBO_2 TEST DEVICE- NOT APPROVED FOR PATIENT USE" label.
- Devices that have failed function testing will be returned to the vendor, placed back in circulation for patient use, or rendered inoperable and discarded so it cannot be used for patient care.

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FUNCTIONAL TEST LOG

33 FSW (Indicate PASS or FAIL) Depending upon the treatment protocols used at your facility, you may wish to consider testing the device at other appropriate depths (i.e. 30 fsw, 60 fsw)

Function Test Description:

45 FSW (Indicate PASS or FAIL)

Function Test Description:

66 FSW (Indicate PASS or FAIL)

Function Test Description:

165 FSW (Indicate PASS or FAIL)

Function Test Description:

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Letter of Medical Device Approval

Device Manufacturer:

Device Model:

Device Name:

Name of Facility:

Location of Facility:

We, the undersigned members of the Hyperbaric Medicine Medical Device Approval Team have reviewed the Medical Device Approval Form and have determined that this device is (choose one):

☐ APPROVED

☐ APPROVED With the following limitations (See comments below)

☐ APPROVED With the following modification (See comments below)

☐ NOT APPROVED

Subsequent devices of the same make and model will require (Choose One):

☐ No testing

☐ Full function testing

☐ Abbreviated testing as identified by the HBO_2 Safety Director and Biomedical Engineering Representative

Electronic signature indicating the above is true to the best of your knowledge (Check Box indicates electronic signature):

Hyperbaric Safety Director: Date:

Hyperbaric Medical Director: Date:

Hyperbaric Manager: Date:

Biomedical Representative: Date:

Administrative Representative: Date:

Comments/Limitations/Modifications:

Nitrogen Purge Testing/Results/Recommendation:

Other modifications for use: