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BioPak 240R Revolution Training Guide

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Note: It shall be the responsibility of the Biomarine Product Line Manager and the Biomarine Training Manager to periodically review this guide and all associated and referenced documentation to provide improvements and corrects where warranted.

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Statement of Objectives

The BioPak 240R respirator is designed to provide a life-supporting breathing atmosphere to the user in situations that are life-threatening and dangerous. Thus it is paramount that individual users and team users of the device become technically proficient in the use, maintenance, function and support of the device before actually donning such equipment. Biomarine's objective is to provide training to end user individuals and/or teams in order to educate on the proper use, maintenance, function and support of the BioPak 240R.

Training will consist of separate programs for BioPak 240R Users and Benchmen. This guide will present the material to be covered under each training program with specific training objects stated at the beginning of each training session as follows:

Information and Description: *The trainee shall become familiar with the basic components and component functions of the BioPak and shall also become familiar with the technology and terminology associated with breathing respirators.*

BioPak 240R Use: *The trainee shall become familiar with proper procedures for inspection, donning, normal use, emergency use and doffing of the BioPak 240R including the function and meaning of all controls and displays. The trainee shall complete a donning drill, remain under oxygen for a period of no less than one (1) hour and complete a doffing drill.*

BioPak 240R Turn-Around Maintenance: *The trainee shall become familiar with all aspects of turn-around maintenance including disassembly, cleaning and disinfecting, reassembly and inspection.*

BioPak 240R Periodic Long-Term Maintenance: *The trainee shall become familiar with all aspects of long-term maintenance including visual inspections, functional testing and testing validation.*

Benchman Training: *The trainee shall become familiar with all aspects of BioPak maintenance including component replacement, system lubrication, oxygen cylinder lubrication, maintenance procedures, troubleshooting, accessory use and contacting the factory.*

BioPak 240R User's Training Quiz: *The trainee shall demonstrate comprehension and proficiency in the areas of training received pertaining to user certification.*

BioPak 240R Benchman's Training Quiz: *The trainee shall demonstrate comprehension and proficiency in the areas of training received pertaining to user certification.*

The BioPak 240R respirator is designated as life-support equipment and thus shall only be utilized by properly trained users. Biomarine's policy will be one of strictly prohibiting the use of the BioPak 240R unless the user can show evidence of Biomarine approved training on the device.

User Training Requirements

User training can only be administered by a Biomarine certified Benchman or Trainer.

To maintain User Certification, the user is required to recertify through this training program on an annual basis.

The user trainee shall complete the below listed requirements in order to be declared “certified” for BioPak 240R use. Failure of the user to complete all the requirements of User Training will deny User Certification.

1. Completion of Information and Description classroom training.
2. Completion of BioPak 240R Use classroom training.
3. Completion of BioPak 240R Turn-Around Maintenance classroom training,
4. Completion of BioPak 240R Long-Term Maintenance class room training.
5. Completion of practical donning, use and doffing of BioPak 240R. Trainee must complete a minimum of 1-hour under oxygen while wearing the BioPak.
6. Demonstrate training proficiency by achieving a minimum score of 70% on the BioPak 240R User Quiz (document A47D264).

Note: Users that will have a full Benchman team and will not be involved in the activities of Benchmen can omit requirements 3 and 4.

User Training Objectives

- Demonstrate proficiency in ability to inspect, don, wear and doff a BioPak 240R.
- Demonstrate a proficiency of knowledge in the differences between open and closed circuit respirators.
- Demonstrate a proficiency of knowledge concerning various BioPak 240R components and their function.
- Demonstrate a proficiency of knowledge of a positive pressure system.
- Demonstrate a proficiency of knowledge in the “Protection Factor”.
- Demonstrate a proficiency of knowledge in the function and operation of BioPak 240R controls and alarms.
- Demonstrate a proficiency of knowledge concerning carbon dioxide and the importance of absorption.
- Demonstrate a proficiency of knowledge concerning BioPak 240R emergency procedures.
- Demonstrate a proficiency of knowledge concerning user symptoms that require immediate attention or will preclude the user from donning a BioPak 240R.
- Demonstrate a proficiency of User Manual content and structure.

Benchman Training Requirements

Benchman training can only be administered by a Biomarine Authorized Trainer.

To maintain Benchman Certification, the benchman is required to recertify through this training program every two (2) years.

Every BioPak 240R placed into service shall have a minimum of one, but preferable two, certified Benchman. Benchman training is only open to Certified Users. The Benchman trainee shall complete the below listed requirements in order to be declared a Certified BioPak 240R Benchman. Failure of the trainee to complete all the requirements of Benchman Training will deny Benchman Certification.

1. Completion of Information and Description classroom training.
2. Completion of BioPak 240R Use classroom training.
3. Completion of BioPak 240R Turn-Around Maintenance classroom training,
4. Completion of BioPak 240R Long-Term Maintenance class room training.
5. Completion of practical donning, use and doffing of BioPak 240R. Trainee must complete a minimum of 1-hour under oxygen while wearing the BioPak 240R.
6. Completion of Benchman Training classroom activities.
7. Demonstrate training proficiency by achieving a minimum score of 70% on the BioPak 240R Benchman Quiz (document A47D265).

Benchman Training Objectives

- Demonstrate proficiency in all User Training objectives.
- Demonstrate a proficiency of knowledge in the theory of operation of the BioPak 240R.
- Demonstrate a proficiency of knowledge concerning BioPak 240R Turn-Around Maintenance.
- Demonstrate a proficiency of knowledge concerning BioPak 240R Long-Term Maintenance.
- Demonstrate a proficiency of knowledge concerning BioPak 240R troubleshooting.
- Demonstrate a proficiency of knowledge concerning BioPak 240R practical application.
- Demonstrate a proficiency of knowledge concerning carbon dioxide and the importance of absorption.
- Demonstrate a proficiency of knowledge concerning BioPak emergency procedures.
- Demonstrate a proficiency of knowledge concerning user symptoms that require immediate attention or will preclude the user from donning a BioPak.
- Demonstrate a proficiency of Benchman Manual content and structure.

Trainer Training Requirements

Trainer training can only be administered by Biomarine Authorized Personnel.

To maintain Trainer Certification, the trainer is required to recertify through this training program on an as needed basis as determined by the Biomarine Product Line Manager or by the Biomarine Training Manager.

The Trainer shall be considered an extension of Biomarine and shall be capable of presenting the information provided in this guide in a professional and efficient manner to Biomarine customers. The Trainer is not required to be a direct employee of Biomarine but such individuals will agree to submit to the requirements of Biomarine at all times. The Trainer shall meet the requirements listed below that include all User and Benchman training requirements as well as additional requirements.

1. Completion of Information and Description classroom training.
2. Completion of BioPak 240R Use classroom training.
3. Completion of BioPak 240R Turn-Around Maintenance classroom training,
4. Completion of BioPak 240R Long-Term Maintenance class room training.
5. Completion of practical donning, use and doffing of BioPak 240R. Trainee must complete a minimum of 1-hour under oxygen while wearing the BioPak240R.
6. Completion of Benchman Training classroom activities.
7. Demonstrate training proficiency by achieving a minimum score of 95% on the BioPak 240R Benchman Quiz (document A47D265).
8. Demonstrate an ability to communicate clearly and concisely to individuals or large groups. The ability of the trainee to meet this requirement will be judged solely by Biomarine.
9. Demonstrate a professional mannerism that shall include dress, presentation and demeanor. The ability of the trainee to meet this requirement will be judged solely by Biomarine.

The Trainer shall always present himself in a professional manner in front of trainees. Appropriate dress shall be determined by the Trainer based upon the application of the end users. It is preferred that the trainer dress in a Biomarine logo shirt whenever possible. Jeans are permitted providing the end customer is in agreement with such dress.

The Trainer shall have no other responsibility, unless otherwise provided by Biomarine, than to train potential Users and Benchmen. Under no circumstances shall the Trainer move to rule on corporate issues or customer issues.

Training Guide Use

This Training Guide is to be utilized by the Trainer in order to present training data and information to potential Users and Benchmen. The Trainer is free to construct their own presentation style; however, it is required that all information presented in this guide be conveyed to the trainees. Trainers shall provide Biomarine with details of any presentation that will deviate from the information provided within this guide and shall not present such information to any trainee until specific approval is obtained from Biomarine.

The guide will provide outlines for presentation of the topics listed below. Each topic will have a specific objective that will be stated at the beginning of each outline. This object shall be read to the trainees prior to the start of training and again after the completion of training. If a trainee does not feel as if the objectives have been met after completion of training then the Trainer shall retouch on any subject or subjects that the trainee has expressed concern of miscomprehension.

Information and Description: This topic will provide the trainee with a brief history and description of Biomarine and its parent company Neutronics. The trainee will also be provided a description of the basic components of the BioPak 240R and terminology and technology usually associated with breathing respirators.

BioPak Use: The trainee will be instructed on the proper donning, use, and doffing of the BioPak. This will include a review of controls and displays, pre-use inspection, normal use instruction, emergency use instruction and BioPak doffing. The trainee will also actually don the apparatus and stay under oxygen for a minimum of 1-hour followed by BioPak doffing. The BioPak User Manual will be utilized in concert with this training.

BioPak Turn-Around Maintenance: The trainee will be instructed in proper disassembly, cleaning and disinfecting, reassembly and inspection of the BioPak to ready it for another use or mission. The BioPak Benchman Manual will be used in concert with this training.

BioPak Long-Term Maintenance: The trainee will be instructed in the proper procedures concerning additional inspections and testing required for long-term storage of the BioPak. The BioPak Benchman Manual will be used in concert with this training.

Benchman Training: The Benchman trainee will be instructed in BioPak troubleshooting, oxygen cylinder filling procedures and requirements, accessory use and proper lubrication. The BioPak Benchman Manual will be used in concert with this training.

An estimate of time to complete each topic is provided at the beginning of each topic. This is not a hard figure and is intended as a guide to the Trainer.

The Trainer is not required to read verbatim from the text provided in each subject. Written descriptions provided in this guide are for the benefit of the Trainer and the Trainer shall use their own discretion as how best to present the supplied information.

Note that training will consist of covering all of the information presented by this guide as well as the information presented in the User and Benchman manuals while providing visual demonstrations on a functional BioPak 240R apparatus.

Training Session Outlines

The following pages will contain the training outlines for each training subject. These outlines are intended to be utilized as a guide to Trainer and the Trainer is responsible for having a full understanding and knowledge of all information presented in each topic.

Information and Description Outline

Suggested Time: This section will require approximately 60-minutes of presentation and should be presented during the User and Benchman training.

Topic Objectives: The trainee shall become familiar with the basic components and component functions of the BioPak and shall also become familiar with the technology and terminology associated with breathing respirators.

Training Materials: Each trainee shall have a current copy of the BioPak 240R User Manual and a copy of the diagrams provided in Appendix A and B. The Trainer shall have a fully constructed BioPak 240R for visual presentation.

A. Biomarine History and Background

1969

Marine Systems International Company formed by several General Electric Aerospace engineers responsible for the development of life - support systems for NASA. Using their knowledge and experience with advanced life-support and sensor technologies, the company developed, manufactured and marketed various sensor-based products and respirator products.

1970

Company name changed to *Biomarine Industries Incorporated*.

Utilizing closed-circuit, self-contained breathing apparatus technology, the company designed and produced mixed-gas, deep diving units for the special operations groups of the United States Navy, Army and Air Force. The Navy Seals utilized the Mark XV and Mark XVI for dives of long duration and great depth. The most advanced unit is the Mark XVI which featured 100% non-magnetic and non-acoustic characteristics for Navy Explosive Ordinance Disposal (EOD) divers.

The BioPak 240 is developed utilizing the diving technology to provide long-duration, lightweight, self-contained, above-ground breathing protection in the world's first positive-pressure breathing apparatus.

1991

Biomarine Industries, Inc. is acquired by Neutronics Incorporated. The four divisions of Neutronics, Inc. reflect a corporate commitment to safety and environment with industrial analyzer products, high-purity analyzer products, infrared-based refrigerant detection equipment and breathing apparatus products.

2005-2007

With nearly 2-1/2 years of development and testing time and approximately 1-million dollars, Biomarine releases the BioPak 240R. The BioPak 240R provides the world's first rebreather to utilize solid core CO2 scrubbing technology and provides cutting edge technology for the safest available closed-circuit respirator in the market.

B. Technology Review

Closed-Circuit Respirator: Closed-Circuit technology will maintain the majority of respired breathing atmosphere within the respirator itself. Venting to the external atmosphere is kept to a minimum and will only occur whenever the volumetric supply of oxygen by the respirator exceeds the volumetric uptake of the user. The basic components of a closed circuit respirator are provided below.

Facepiece or Mouthpiece: Utilized to separate and isolate the user's mouth and nose from an external respiratory hazard.

Inhalation and Exhalation Check Valves: Directs the flow direction of internal breathing atmosphere to prevent the user from "re-breathing" exhalation air and to prevent exhalation air from contaminating inhalation air.

Absorbent: Carbon dioxide contained within the exhaled air is chemically removed by the absorbent. A number of different types of absorbent are utilized by manufacturers of closed-circuit respirators; however, the safest and least expensive absorbent is calcium hydroxide. Oxides of potassium,

sodium and lithium are also utilized in closed-circuit respirators but their cost and potential hazardous side effects make them less desirable for all but extremely specialized applications. Absorbents can be supplied in granular or solid-core forms. Granular forms can be prone to channeling, dusting, settling and carry a degree of human error during canister filling. Solid-core forms will not channel, dust or settle and carry a lower degree of human error potential.

Breathing Bag/Chamber: A flexible breathing gas reservoir or “counter-lung” is employed to capture exhaled breath and provide a breathing “tidal volume” for reuse. The BioPak 240R utilizes a hardened chamber with a flexible diaphragm as the gas reservoir.

Oxygen Supply: Oxygen is added to the breathing gas loop to maintain an oxygen concentration of at least 21% by volume. Compressed oxygen is the typical oxygen supply; however, some systems employ the use of chemically generated oxygen with the use of potassium compounds or “candles” or with liquid oxygen that must be gasified before breathing. Oxygen additions to the breathing loop are made through one or a combination of constant and/or demand adds.

Pneumatics: The pneumatic system serves to deliver regulated pressure oxygen into the breathing chamber via the various add devices and mechanisms and includes the oxygen regulator, manifold assembly, plumbing lines, emergency bypass valve, demand add valve and remote pressure gauge. All pneumatic components of the BioPak 240R are designed to withstand a minimum of twice the unregulated pressure of oxygen in the oxygen cylinder.

Show trainees BioPak 240R Flow Diagram of Appendix A.

Open-Circuit Respirator: Open-Circuit technology will function in a similar manner as closed circuit and will have many common components. An open-circuit respirator will not have a breathing bag or a carbon dioxide absorbent since breathing atmosphere is utilized only one time by the user and is not recycled for additional use. The oxygen cylinder of closed-circuit system is usually replaced by a compressed air cylinder in an open-circuit system and this cylinder usually contains a far greater amount of gas and is physically larger than oxygen cylinders of closed-circuit systems of the same duration. This is due to fact that the breathing gas is presented to the user one time for inspiration so a large volume of gas must be carried. Gas inhaled by the user will subsequently be exhaled through an exhalation check valve and exhausted external to the system.

Positive Pressure versus Negative Pressure: The BioPak 240R system will deliver a breathable oxygen atmosphere to the user under positive pressure. A positive pressure system will maintain internal respirator pressure, **including the facepiece**, at a level higher than external pressures. Internal respirator pressure will run approximately 1.5 to 2.5 inches of water column higher than external pressure depending upon the breathing rate of the user. Conversely a negative pressure system will maintain internal pressures lower than the external pressures. Thus positive pressure systems will provide advantages over negative pressure systems as the potential for external atmospheric toxins to penetrate into the respirator atmosphere is reduced. The use of positive pressure requires that facepiece fit and sealing is maximized as any leak in the respirator breathing loop will result in increased pressure demand adds and will serve to reduce respirator duration.

Show trainees Positive Pressure versus negative Pressure Diagram of Appendix B and stress difference between the two technologies.

Protection Factor: A measure of how well a facepiece protects the user is referred to as a “**Quantitative Fit Test**”. This test will yield a figure known as the “**Protection Factor**”. The higher the protection factor value the higher the degree of protection is provided against inhaling airborne contaminants. The protection factor is calculated using the formula provided below using test data. **The BioPak 240R will provide the user with a protection Factor of 20,000.**

Protection Factor (PF) =
$$\frac{\text{Concentration of Particles Outside Facepiece}}{\text{Concentration of Particles Inside Facepiece}}$$

Example:
$$PF = \frac{1000 \text{ ppm Outside Facepiece}}{10 \text{ ppm Inside Facepiece}}$$

$$PF = 100$$

C. BioPak 240R Detailed Description/Breakdown

Point out each component on an actual BioPak 240R to the trainees as it is being discussed.

Outer Housing: Constructed of an injection-molded polycarbonate-stainless steel alloy that provides fire resistance and static dissipative characteristics. Housings will provide flame protection to approximately 950°C (as tested by NFPA 1981 standards) and a surface resistance under 10^9 ohms. There are no materials of aluminum, magnesium, titanium or alloys or metals containing such proportions of these metals as, on impact, can give rise to frictional sparks capable of igniting flammable gas mixtures.

Breathing Hoses: Manufactured from flame-resistant EPDM rubber. Large flow diameter to provide low pressure drop and low breathing pressures.

Facepiece: Scott Health and Safety AV3000 design. Comes standard with flame-resistant materials of polycarbonate, EPDM rubber and Kevlar head harness in three sizes. EN145 version contains an internal nose cup while NIOSH versions include an internal nose cup with foam inserts. Options include a magnetic wiper system, neck strap, lens mounting kits and voice projection units.

Harness: Thermo-formed manufacturing provides a standard non-flame rated version and flame-rated version of the harness. Standard version is manufactured from Nylon and Acetal materials while flame-rated version is manufactured from Kevlar, Nomex and metal materials. Harness provides multiple adjustments to allow positioning of respirator weight on the hips or shoulders of the user. Options include chest and waist strap extensions for large users.

Oxygen Cylinder: Lightweight, carbon fiber wrapped aluminum lined construction. Certified to DOT, TC and European PED standards and regulations. Cylinder supplied with oxygen compatible valve, pressure gauge, over-pressure protection and particulate filtration. Cylinder assembly is required by certification to be hydrostatically tested every 5-years with a maximum cylinder life of 15 years. Cylinder is color-coded for oxygen according country of destination and exterior of all cylinders are protected by a static dissipative coating.

Regulator Assembly: Manufactured by Sherwood and design to fail in an open position. Two ports are provided, one for regulated pressure and another for unregulated pressure. Regulated pressure of approximately 148-158 psig (10-11 bar) will supply the oxygen demands of the BioPak system. Unregulated pressure will be routed to a remote pressure gauge for viewing by the user.

Remote Pressure Gauge: The remote pressure gauge will provide a real time display of remaining oxygen cylinder pressures via a luminescent dial face in both psi and bar measurements. The gauge attaches to the shoulder of the BioPak harness via a snap strap and magnetic catch. The whip leading to the remote gauge is protected against oxygen loss in the event of severing via a flow restrictor and shut off valve. The flow restrictor will keep oxygen loss flows under 3.5 lpm while the shut off valve will provide for 0 lpm oxygen loss flow.

TRIM Housing: The TRIM housing is permanently attached to the remote pressure gauge and will provide the user with alarm and status indicators during BioPak use. Light is fed through the armored light guide to the housing to provide light indications of: GREEN system okay, BLUE check coolant and RED system fault or alarm.

Monitoring System: An electrical-based system that is independently operated from the remote pressure gauge to provide real time status monitoring of the BioPak during use to provide redundant monitoring and alarming. The monitor is certified as intrinsically safe for use in methane-oxygen atmospheres. Powered by a 9VDC battery the monitor will provide approximately 200-hours of life on a single battery. The TRIM housing function is controlled by the monitoring device as well as an audible alarm horn.

Coolant: All systems contain dual ice canisters that are to be inserted into the coolant shells of the BioPak in a frozen state. The canisters are reusable and are to be frozen in the forms provided with each BioPak. Some systems may also employ the Phase Change Module or PCM. This is a wedge-shaped canister that will sit internal to the breathing chamber and will use a phase change material for additional

heat pick up and cooling of breathing gasses. The PCM is also reusable and is regenerated by maintaining it in a temperature below 80°F (27°C) until it re-solidifies.

Breathing Chamber: The breathing chamber will contain the counter-lung or diaphragm, the absorbent, moisture absorber and coolant. The hardened outer form and the flexible diaphragm form what is referred to as the breathing chamber. All oxygen additions and system venting is conducted within this chamber.

Oxygen Pressure Demand Add: When a user consumes oxygen in the respirator the internal volume of the breathable gas internal to the unit will decrease. This decrease in volume will result in the breathing chamber diaphragm springs pushing the flexible diaphragm further up into the chamber. If the volume is reduced enough the diaphragm will trigger the release of oxygen at 40-80 lpm through actuation of a mechanical demand valve located within the breathing chamber. Pressure demand adds of oxygen will occur in short bursts and will serve to maintain positive pressure in the respirator and replenish oxygen volumes.

Relief Valve Function: Should the internal volume of the breathing chamber expand beyond the normal operating volume the diaphragm will be forced against the rear housing. A mechanical relief valve will be actuated via contact with the rear housing to momentarily vent excess gas. This valve serves to maintain internal breathing pressures to a comfortable level.

Constant Oxygen Add: A constant flow of approximately 1.8 lpm is continually fed into the breathing chamber at all times during BioPak use. This flow is designed to support the oxygen needs of a user at a moderate work rate. Oxygen is metered through a stainless steel flow restrictor plug located within the manifold assembly of the pneumatics. Flow is injected into the breathing chamber through one of the side gas ports.

Emergency Bypass: The emergency bypass push button will provide oxygen additions into the breathing up to 100 lpm while the button is depressed. This feature is only intended for use in real emergencies and should never be utilized in attempts to clear facepiece fogging or cool breathing gas temperatures.

Moisture Containment: Moisture will be generated by the carbon dioxide absorption reaction and will accumulate within the breathing loop. If left unchecked this accumulated moisture could run into the facepiece should the user place himself in a head-down position. The breathing chamber contains three moisture absorbent sponge sections sized to absorb and retain all expected generation of moisture that will accumulate during a 4-hour mission. These sponge sections are located in the breathing chamber directly underneath the coolant shells. The sponges are reusable and require cleaning and disinfection after each use.

END

Restate topic objectives with trainees and address any questions or issues stated by the trainees.

BioPak 240R Use Outline

Suggested Time: This section will require approximately 60-minutes of classroom presentation and should be presented during the User and Benchman training. Practical use of BioPak will require a minimum of 1-hour.

Topic Objectives: The trainee shall become familiar with proper procedures for inspection, donning, normal use, emergency use and doffing of the BioPak 240R including the function and meaning of all controls and displays. The trainee shall complete a donning drill, remain under oxygen for a period of no less than one (1) hour and complete a doffing drill.

Training Materials: Each trainee shall have a current copy of the BioPak 240R User Manual and a fully charged and functional BioPak. The Trainer shall have a copy of the BioPak 240R User Manual and a fully constructed BioPak 240R.

A. Introduction

The previous section was designed to allow students to understand the BioPak 240R components and functions and to become familiar and comfortable with its operation. This section of the training is designed to show the trainee how to actually use the BioPak 240R.

B. Controls and Displays

Review the function and operation of the controls and displays while having the students follow discussion referencing their BioPak 240R User Manual.

Oxygen Cylinder Valve: The oxygen cylinder valve will provide control of the release of oxygen stored within the oxygen cylinder. This valve shall be kept in the closed position at all times when the BioPak is not being used or serviced. The valve is a green knob located on the lower right side of the housing. Turning the valve counterclockwise will open the valve and turning the clockwise will close the valve. The valve will require a full two turns to fully open.

Remote Pressure Gauge: This gauge, located on the left side of the harness, will convey the pressure of oxygen remaining in the oxygen cylinder when the oxygen cylinder valve is open. The gauge will convey pressure in both psi and bar units. Red color coding is provided on the gauge dial in the 0-750 psi (0-51.7 bar) range to indicate when oxygen stores are below 25% of full service life. The user should frequently check this gauge during BioPak use to verify that there is enough oxygen remaining for escape from a specific situation. **The user should immediately exit the area to a safe location for BioPak doffing whenever the pressure gauge indicator is in the red colored area of the gauge.** Upon initial opening of the oxygen cylinder valve the pressure gauge shall read a minimum of 3000 psig in order to achieve full duration of the respirator.

Remote Gauge Shut Off: The remote gauge feed plumbing is provided with two protection devices to guard against rapid oxygen loss in the event the external gauge line become severed. A sintered stainless steel flow restrictor is located at the inlet of the pressure feed line connected to the pressure regulator. This restrictor will serve to limit oxygen losses to under a 3.5 lpm flow rate if the external line is severed. The gauge shut off valve is located on the lower left side of the housing and will serve to completely shut off oxygen flow should the external feed line become severed. In the event the external feed line is severed, the user shall pop off the black plastic lock out clip from the gauge valve then pull up on the quick disconnect flange of the valve to disengage the external feed line. The valve will automatically seal and prevent further losses of oxygen. **The user should then immediately exit the area to a safe location for BioPak doffing whenever the remote gauge line has become severed.**

TRIM Housing Display: The TRIM housing is permanently attached to the remote pressure gauge and will work in tandem with the alarm horn of the monitoring system. The display will provide respirator status signals to the user and will automatically become activated whenever the oxygen cylinder valve is opened and pressure remains in the oxygen cylinder. The user should frequently check this display, as with the remote pressure gauge, during use to keep informed as to the status of the respirator at all times. The following alarms are provided by both the TRIM housing and the monitoring system alarm horn and the function of these alarms are independently activated from the function of the remote pressure gauge thus providing the user with a redundant alarming system. **The user should immediately exit the area to a safe location for BioPak doffing whenever a RED alarm or a HORN sounding is detected.** Alarming states of the system are provided below.

Initial Start Up;	Cycling of Red, Green, Blue of light and horn sounding This situation is not an exit alarm state.
Low Monitor Battery:	Red, Green, Blue flashing light with chirping horn This is an exit alarm state.
Check Ice Alarm:	Blue flashing light within initial 5-10 minutes This is an exit alarm state.
System Fault	Red flashing light with horn sounding This is an exit alarm state
Low Oxygen	Red flashing light with horn sounding This is an exit alarm state
Normal Function	Green flashing light This is not an exit alarm state.

At any time a red light is flashing in one of the above alarm exit states or the green light is not flashing the user should exit the area to a safe location for BioPak doffing.

Emergency Bypass Valve: The emergency bypass valve is a red push button located on the left rear side of the housing below the level of the oxygen cylinder valve. Up to 100 lpm of oxygen will be bled into the breathing chamber whenever this button is depressed. Releasing the valve button will automatically halt the flow the oxygen into the breathing chamber. This valve should only be utilized in times of emergency and should not be utilized in attempts to clear the facepiece or cool breathing gas. Actuation of this valve will release large volumes of gas that will directly reduce respirator duration.

C. Pre-Use Inspection

Review each inspection criterion on a BioPak while having the students follow discussion referencing their BioPak 240R User Manual.

Prior to donning the BioPak the user should perform the following inspections to verify that the BioPak is in ready condition. This type of inspection is much like that a pilot would conduct before flying an airplane.

General Inspection: Visually inspect the BioPak to verify that no obvious signs of degradation are present. This would include broken components, missing components or any other signs of damage.

Turn Around Maintenance Tag: Verify that the BioPak has a COMPLETED turn-around maintenance tag tied to the two buckles of the harness waist belt. This tag **MUST BE FULLY COMPLETED** as described in the user manual before the BioPak is ready for use. **Do not utilize any BioPak that does not have a fully completed turn-around maintenance tag!**

Sponges/Scrubber: Remove the upper housing and the breathing chamber lid. Remove the sponges sections and moisten. Wring out the moistened sections and replace into the breathing chamber. Note that use of totally dry sponges will result in warmer than usual breathing temperatures due to a lack of seal around the coolant shell baffle bottom. Inspect the expiration date on the scrubber can and verify that the scrubbers within have passed the expiration date. Install the fresh scrubber gaskets and scrubbers into the breathing chamber as detailed by the User Manual.

Facepiece: Visually inspect the facepiece for worn or damaged parts. Visually inspect the seal around the perimeter of the anti-fog lens and insure there are no gaps or broken sections in the adhesive band. Apply Anti-Fog spray to the interior of the lens as directed by the User Manual. If using a wiper soak the chamois of both wiper pieces with anti-fog or water.

Alarm Check: Open the oxygen cylinder valve and allow the pressure gauge to come to full reading. Verify a reading of at least 3000 psig for full BioPak duration. This will take approximately 60-seconds. Verify that the monitor system has automatically powered up and that it has run through its light color sequencing and horn sounding as described in the User Manual. Close the oxygen cylinder valve.

Coolant: Retrieve and install two frozen ice canisters into the coolant shells of the BioPak as described in the User Manual.

D. Donning the BioPak

Review each procedure on a BioPak while having the students follow discussion referencing their BioPak 240R User Manual. Trainer shall actually don the BioPak in front of trainees to demonstrate proper technique.

Facepiece: Don facepiece as described in the User Manual. **USER CAN NOT HAVE ANY FACIAL HAIR IN ORDER TO ACHIEVE AN ADEQUATE FACEPIECE SEAL.** *Emphasize proper positioning of head harness and the need to be clean shaven. Also emphasize that facepiece seal is the most important aspect of user protection.*

BioPak: Don BioPak as described in the User Manual. *Emphasize proper positioning of BioPak on user and demonstrate various adjustment possibilities in order to gain maximum comfort.*

Check Valve Testing: Test check valve function as described in the User Manual.

Connect Facepiece/Open Oxygen Cylinder: Connect BioPak to facepiece and lock facepiece adapter into position. Note that the facepiece may be connected to the facepiece adapter PRIOR to donning the facepiece if the user is more comfortable with this procedure.

Gauge/TRIM Inspection: Inspect gauge and verify 3000 psi pressure for full BioPak duration. Inspect TRIM housing for light and horn sequence as described in User Manual.

Emergency Bypass Valve Functional Test: Depress and release bypass valve button. User should hear sound of flowing gas while button is depressed. Flow sounds shall cease when button is released.

E. BioPak Operation

Review each point on a BioPak while having the students follow discussion referencing their BioPak 240R user Manual. Trainer can demonstrate points with or without BioPak actually donned and operational.

Normal Breathing: *Stress there is no need to breathe in any other manner as one would normally breathe. Rapid breathing will only serve to activate demand add and system venting thus wasting oxygen and shortening duration.*

Speaking: *Stress speech should be made in a slow and loud manner placing emphasis on clear annunciation of words.*

Emergency Bypass: *Stress this is ONLY to be utilized in times of emergency and should be utilized in attempts to clear the facepiece of fog or cool the breathing gas. Use of this valve will shorten duration.*

TRIM Display and Pressure Gauge: *Stress periodic inspection of these devices during use to gain knowledge of BioPak status. Emphasis should be placed upon exiting the area whenever an alarm condition is present in these devices.*

Facepiece Wiper: *Stress application of wiper will clear facepiece of fogging but will also serve to wipe away anti-fogging agent. Wiper should not be used unless absolutely necessary.*

Emergency Operation: Review procedures stated in User Manual for Equipment Failure, Gauge Line Severing, Pressure Gauge or TRIM failure, Facepiece Pressure, Demand Valve Failure, and Regulator Failure.

Duration: Review factors that can affect duration of BioPak such as work load, temperature, facepiece seal and user fitness.

User Health Symptoms: Review all symptoms of user health that are listed in User Manual. Stress negative impact of any of these symptoms.

Cooling: Demonstrate replacement of coolant canisters during use. Indicate use of optional PCM canister as an optional extra cooling device.

Facepiece: **STRONGLY** stress presence of any hair (facial and head hair) contained within the seal **WILL** cause leakage and reduced duration. Discuss optional accessories for the facepiece including magnetic wiper, eyeglass supports, voice projection units and neck straps. Stress that best eyeglass support is to utilize contacts instead of eyeglasses.

Carbon Dioxide Poisoning: Review symptoms of poisoning as provided in User Manual.

Accessories: Review all of the listed accessories in the User Manual and explain their use and function.

F. Doffing the BioPak

Review each procedure on a BioPak while having the students follow discussion referencing their BioPak 240R User Manual. Trainer shall actually doff the BioPak in front of trainees to demonstrate proper technique.

Doffing Area: Stress that BioPak should only be removed in an area known to be safe (free of atmospheric toxins, containing minimum oxygen concentration of 19.5% and generally non-hazardous).

Close Cylinder Valve: Show clockwise rotation to full close and show resultant response of TRIM display and pressure gauge.

Harness: Demonstrate unbuckling of harness and removal of BioPak. Stress importance of not simply dropping BioPak to ground as this is where the majority of abuse and neglect to a BioPak will occur.

Turn-Around Maintenance: Stress importance of immediate turn-around maintenance to prevent bacteria and mold growth.

CLASSROOM END

Restate topic objectives with trainees and address any questions or issues stated by the trainees.

G. BioPak Practical Instruction

After completion of the classroom instruction the trainees shall now demonstrate donning, use and doffing of fully charged and functional BioPak 240R units. Time under oxygen by each trainee shall be no less than one (1) hour but may extend the entire four (4) hour duration of the BioPak as per the trainer's discretion.

Observe the trainees to verify that each is donning the BioPak in the proper manner. For large groups it is suggested that the Trainer call out each step and observe the entire group completing each step.

When donning is complete instruct each trainee to turn on the oxygen supply. The trainer should record the starting pressure of the trainee's cylinder and listen for excessive demand additions. Excessive demand additions at the onset of going under oxygen will signal a poor facepiece fit. After the initial 20 minutes of being under oxygen inspect each trainee's oxygen pressure and compare to the initial pressure reading. If a trainee consumes more than 250 psig (17 bar) in the initial 20 minutes of use the facepiece fit and seal is poor and leaking.

Have the trainees walk about, jog, turn their heads into different positions and activate the emergency bypass valve. In short have the trainees do a variety of activities in order to familiarize themselves with the feel and sounds of the BioPak during use. Stress periodic inspection of the pressure gauge and TRIM display.

After a minimum of one (1) hour, lead the trainees through the doffing procedure.

PRACTICAL END

Restate topic objectives with trainees and address any questions or issues stated by the trainees.

BioPak 240R Turn-Around Maintenance Outline

Suggested Time: This section will require approximately 60-minutes of classroom presentation and should be presented during the User and Benchman training.

Topic Objectives: The trainee shall become familiar with all aspects of turn-around maintenance including disassembly, cleaning and disinfecting, reassembly and inspection.

Training Materials: Each trainee shall have a current copy of the BioPak 240R Benchman Manual. The Trainer shall have a copy of the BioPak 240R User Manual, a Test Kit and a fully functional BioPak 240R. It is suggested to utilize the BioPak 240R units that the trainees used under the BioPak practical instruction.

BioPak Disassembly: Demonstrate proper disassembly as detailed in Benchman Manual. Stress retention of loose parts and proper discarding of spent carbon dioxide scrubbers. Also stress importance of installing washing plug of test kit to center section pneumatic ports so as not to loose port o-rings; and, proper removal of center section lid to avoid rim stress cracking.

Washing and Disinfecting: Stress importance of proper washing and disinfecting to avoid transmission of disease to other or same user. Point out parts that should be simply wiped down (housing shells and oxygen cylinder) and parts that require full wash down (breathing loop parts). Emphasize that all full wash down parts need to be wetted for a minimum of ten (10) minutes for full disinfection.

Oxygen Cylinder Charging: Discuss fill level and how to get cylinder filled. Review oxygen quality requirements as specified in the Benchman Manual.

Ice Canisters: Stress that canisters must be free of exterior moisture before being placed into freeze forms or they may stick when frozen. Emphasize careful handling of freeze forms and to avoid denting of can. Review freezing conditions as stated in the Benchman Manual and inform trainees that placing large volumes of ice canisters into a single freezer will require a longer freeze time.

Facepiece: Review inspection of mask, anti-fog lens and wiper as detailed in Benchman Manual.

Reassembly and Testing: Review and demonstrate the reassembly and testing of the BioPak as detailed in the Benchman Manual. This is also a good time to review the contents of the test kit. Stress the importance of the Turn-Around Maintenance Tag and its proper use. Demonstrate the use of Maintenance Log Sheet provided in the Benchman Manual.

Practical Instruction: It is suggested that the Trainer walk the trainee through the process of Turn-Around Maintenance in a step by step fashion so as to familiarize the trainee with all procedures and techniques.

END

Restate topic objectives with trainees and address any questions or issues stated by the trainees.

BioPak 240R Periodic Long-Term Maintenance Outline

Suggested Time: This section will require approximately 60-minutes of classroom presentation and should be presented during the User and Benchman training.

Topic Objectives: The trainee shall become familiar with all aspects of long-term maintenance including visual inspections, functional testing and testing validation.

Training Materials: Each trainee shall have a current copy of the BioPak 240R Benchman Manual. The Trainer shall have a copy of the BioPak 240R User Manual, a Test Kit and a fully functional BioPak 240R.

Visual Inspection: Demonstrate inspection on BioPak as detailed by Benchman Manual.

Functional Testing: Demonstrate functional testing of Demand Valve, Vent Valve, Emergency Bypass Valve and Low Pressure Alarm Function as detailed by Benchman Manual.

High Pressure Leak and Cylinder Gauge Testing: Demonstrate testing as detailed by Benchman Manual.

Turn-Around Maintenance Validation: Emphasize importance of verifying that the Turn-Around Maintenance Tag is fully complete and properly positioned on the BioPak as described in the Benchman Manual. Stress verification of carbon dioxide scrubber expiration date.

END

Restate topic objectives with trainees and address any questions or issues stated by the trainees.

Administer BioPak 240R User's Quiz to trainees. Trainees shall be given a maximum of 30 minutes to complete the test from memory.

Benchman Training

Suggested Time: This section will require approximately 120-minutes of classroom presentation and should be presented during the Benchman training.

Topic Objectives: The trainee shall become familiar with all aspects of BioPak maintenance including component replacement, system lubrication, oxygen cylinder lubrication, maintenance procedures, troubleshooting, accessory use and contacting the factory.

Training Materials: Each trainee shall have a current copy of the BioPak 240R Benchman Manual. The Trainer shall have a copy of the BioPak 240R User Manual, a Test Kit and a fully functional BioPak 240R.

Scheduled Component Replacement: Review scheduled component replacement as presented in the Benchman Manual. Stress that this listing is **RECOMMENDED** and is not **MANDATORY**. If the components are functioning fine and do not appear to be visually stressed or fatigued there is no reason to replacement them. Note that it will be expected that trainees that might have been past Drager users will argue the point that Drager stipulates mandatory replacement of some components. The Trainer's response shall be one of recognition of Drager's requirements but should point out that the BioPak is a device of high reliability and does not require mandatory replacement of any component other than the oxygen cylinder. The oxygen cylinder will carry a federally mandated life of 15 years maximum.

System Lubrication: Review lubrication requirements as presented in the Benchman Manual. Stress proper removal and handling of o-rings as improper removal and handling is the number one cause of seal failure in the BioPak.

Oxygen Cylinder: Review all requirements of the oxygen cylinder as presented in the Benchman Manual. Stress the danger of handling 100% pure oxygen. It is strongly suggested to present the following statement to the trainees: "Materials that normally burn in atmospheric oxygen pressures will burn more readily and with more vigor and may spontaneously combust in the presence of oxygen pressures in excess of atmospheric conditions. Materials that do not burn in atmospheric oxygen pressures may burn in the presence of oxygen pressures in excess of atmospheric conditions". Explain the requirement of hydrostatic testing (every 5-years by a qualified inspection vendor) and maximum service life (15 years). Also explain that cylinder can be filled by a local vendor, filled at the user's site with a proper booster pump or returned to Biomarine for filling. Each user will be responsible for adhering to local requirements concerning oxygen cylinder handling, filling and maintenance.

Maintenance Procedures: Review each procedure presented in the Benchman Manual.

Factory Service and Training: Review the information provided in the Benchman Manual concerning factory contacts. Stress the importance of providing as much information as possible when contacting the factory or local service representative. The Trainer should make available the contact information of the trainee's local service representative.

Troubleshooting: Review the troubleshooting guide in the Benchman Manual.

Accessories: Describe the accessories, their function and how they are to be utilized on the BioPak as listed in the Benchman Manual.

END

Restate topic objectives with trainees and address any questions or issues stated by the trainees.

Administer BioPak 240R Benchman's Quiz to trainees. Trainees shall be given a maximum of 45 minutes to complete the test from memory.

User Training Quiz Answer Sheet

The Trainer shall utilize the answer key to grade the trainee's BioPak 240R User's Quiz. In order to pass the written examination the trainee shall answer a minimum of 28 questions correctly. Trainers can also use the results of this test to track their own effectiveness at training potential users.

Trainers are also asked to track answers of trainees to determine if any of the quiz questions are misleading, wrong or poorly stated. This would be indicated by a large majority of trainees getting the same question wrong. Please indicate such instances if they should arise to the Biomarine Product Line Manager.

- | | |
|-----------|-----------|
| 1. A | 21. FALSE |
| 2. A | 22. FALSE |
| 3. D | 23. FALSE |
| 4. D | 24. FALSE |
| 5. A | 25. FALSE |
| 6. B | 26. FALSE |
| 7. D | 27. FALSE |
| 8. D | 28. FALSE |
| 9. B | 29. TRUE |
| 10. E | 30. F |
| 11. A | 31. E |
| 12. D | 32. C |
| 13. D | 33. E |
| 14. C | 34. C |
| 15. B | 35. B |
| 16. FALSE | 36. A |
| 17. FALSE | 37. D |
| 18. TRUE | 38. E |
| 19. FALSE | 39. C |
| 20. TRUE | 40. E |

Benchman Training Quiz Answer Sheet

The Trainer shall utilize the answer key to grade the trainee's BioPak 240R Benchman's Quiz. In order to pass the written examination the trainee shall answer a minimum of 43 questions correctly. Trainers can also use the results of this test to track their own effectiveness at training potential users.

Trainers are also asked to track answers of trainees to determine if any of the quiz questions are misleading, wrong or poorly stated. This would be indicated by a large majority of trainees getting the same question wrong. Please indicate such instances if they should arise to the Biomarine Product Line Manager.

Note: Question 35 is a three-part question. Each part of the question will be treated as a separate question in terms of scoring.

- | | | | |
|-----------|------------|-----------|-----------|
| 1. FALSE | 21. B | 39. D | 59. TRUE |
| 2. FALSE | 22. A | 40. C | 60. FALSE |
| 3. TRUE | 23. D | 41. B | |
| 4. FALSE | 24. G | 42. D | |
| 5. FALSE | 25. D | 43. B | |
| 6. TRUE | 26. C | 44. C | |
| 7. TRUE | 27. D | 45. E | |
| 8. FALSE | 28. B | 46. C | |
| 9. FALSE | 29. C | 47. C | |
| 10. FALSE | 30. A | 48. D | |
| 11. FALSE | 31. B | 49. C | |
| 12. FALSE | 32. A | 50. B | |
| 13. FALSE | 33. C | 51. FALSE | |
| 14. TRUE | 34. E | 52. TRUE | |
| 15. FALSE | 35A. 2 & 5 | 53. FALSE | |
| 16. C | 35B. 3 & 4 | 54. TRUE | |
| 17. D | 35C. 1 | 55. FALSE | |
| 18. D | 36. D | 56. TRUE | |
| 19. F | 37. D | 57. FALSE | |
| 20. D | 38. A | 58. TRUE | |

Training Completion

At the conclusion of training the Trainer shall provide Biomarine with a listing consisting of the following information.

1. Trainee Name
2. Trainee Employer and Contact Name
3. Trainee Employer Address
4. Trainee BioPak Application (mining, tunneling, fire-fighting, etc.)
5. Trainee Training Results (quiz scores, training sections completed)
6. Date of Trainee Training Completion

Once the above material is received, Biomarine will review the information and issue certificates of achievement to each trainee representative of the level of training passed. These certificates will be mailed directly to the trainee's employer contact for distribution to the trainee(s). Biomarine will issue the initial certificate to each trainee. The trainee's employer will then be responsible for creating and issuing any other desired certificates for recertification.

Factory Contacts

Should the Trainer encounter errors in any of the training materials, feels additional material is needed in the training materials or simply has questions, the Trainer is welcome to contact Biomarine directly or contact the locally Biomarine authorized representative. Biomarine authorized representatives will directly answer questions, if possible, or forward requests to Biomarine directly.

Biomarine-Ntron Incorporated

456 Creamery Way
Exton, Pennsylvania 19380
United States of America

Phone: (610) 524-8800 (9AM-5PM Eastern US Time, Monday through Friday)

FAX: (610) 524-8807

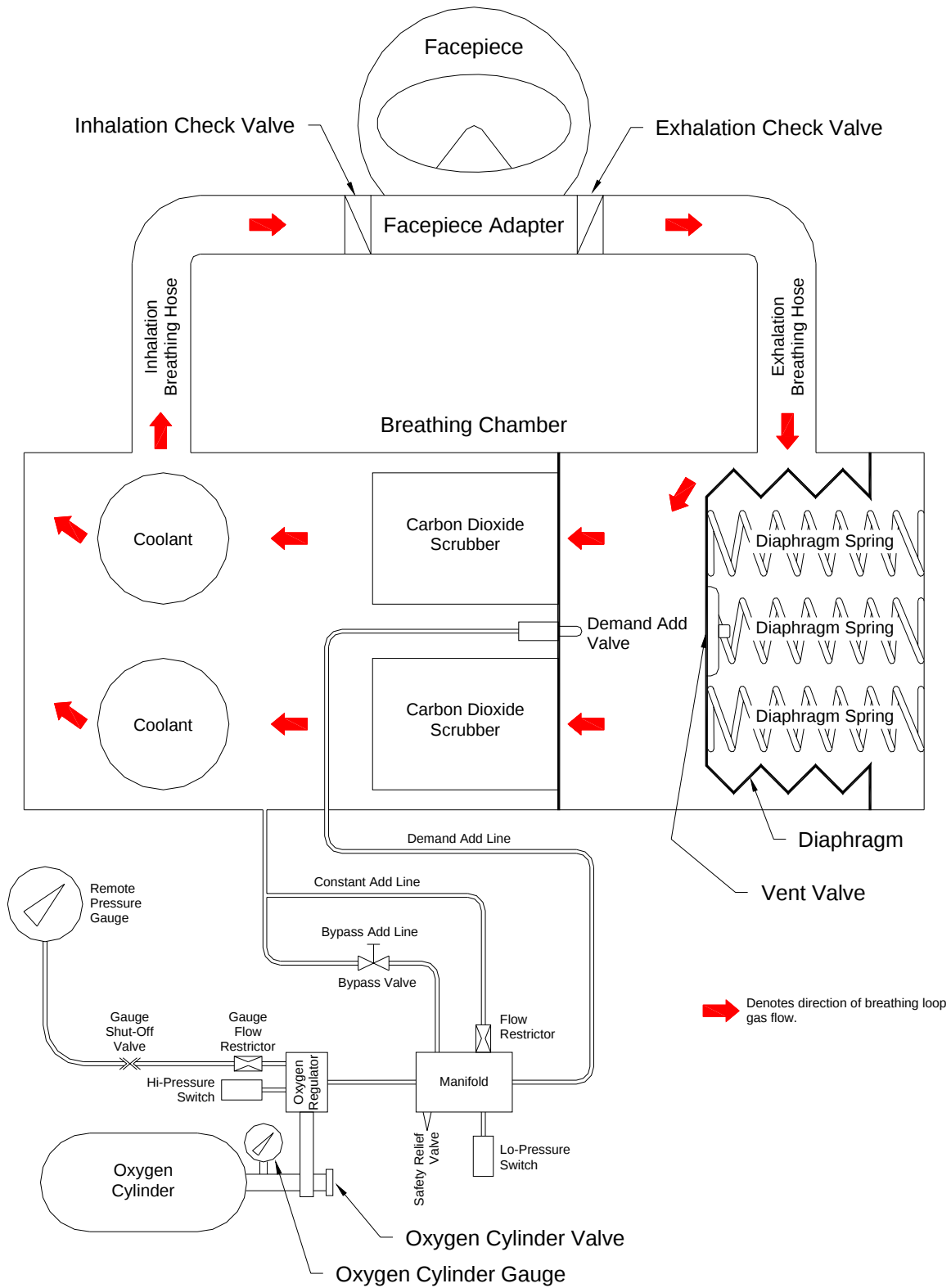
WEB: <http://biopak240r.com>

Direct Contacts:

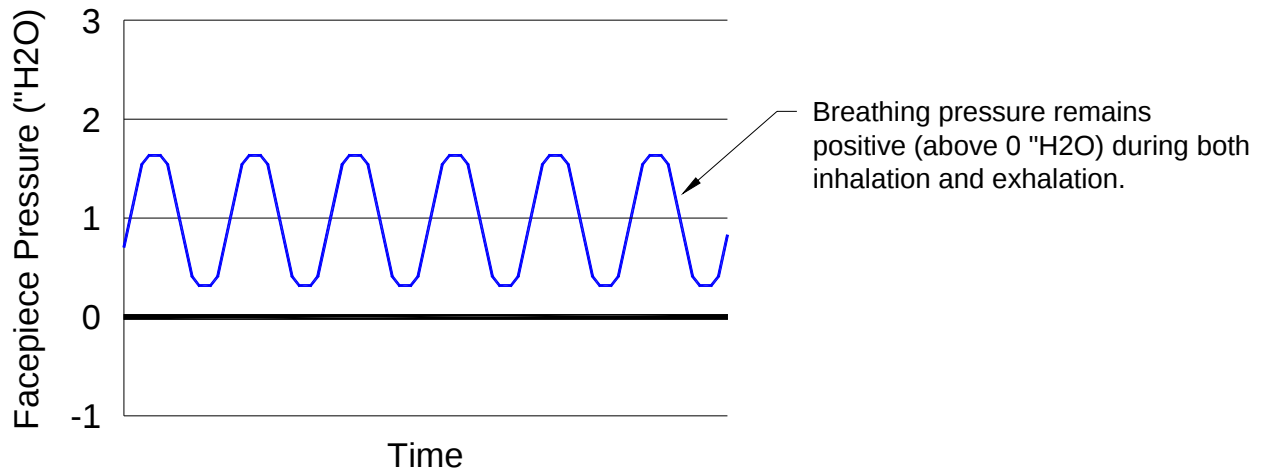
Biomarine Product Line Manager: Doug Anderson, phone extension 150

Biomarine Training Manager: Ted Beck, phone extension 121

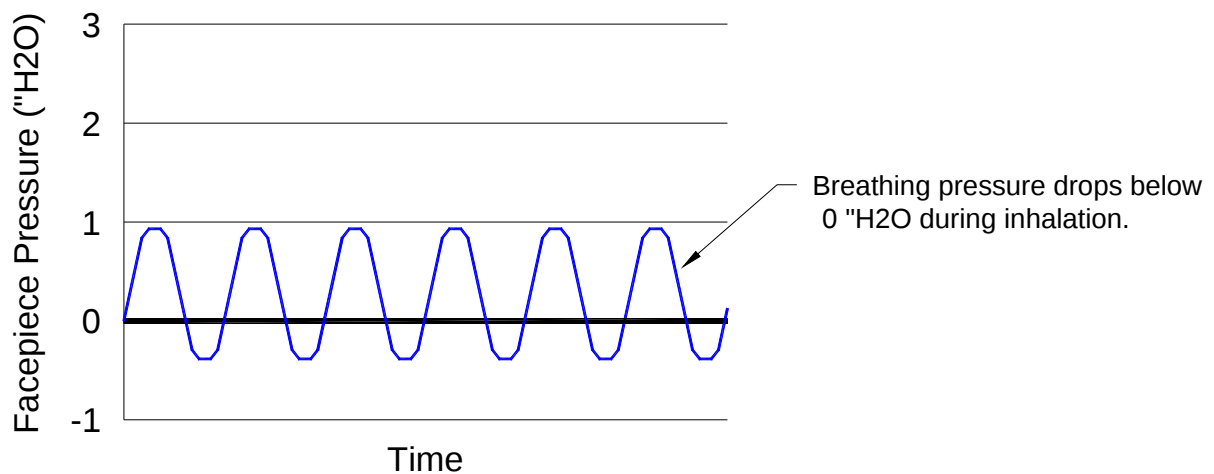
Appendix A: BioPak 240R Flow Diagram



Appendix B: Positive Pressure Versus Negative Pressure Diagram



Positive Pressure Breathing Trace



Negative Pressure Breathing Trace