

CLEANING, STERILIZATION/DISINFECTION & MAINTENANCE

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A. Intended Use

AFT series facemask two-way non-rebreathing valves are designed for respiratory circuits with spontaneously breathing subjects where the application requires a valve to separate the subject's inspiratory from expiratory flows. These valves have a flexible silicone rubber diaphragm in both the inspiratory and expiratory ports that allow flow in one direction only (functions as a check valve). The mouthpiece is replaced by a facemask assembly. Typical applications are pulmonary function testing. Exercise testing and respiratory research.

- **WARNING:** Do not use these valves in a life support system such as a ventilator circuit.



B. Directions for Use

The facemask two-way non-rebreathing valve has three ports for connection into the breathing circuit. The facemask (mouth port), inhalation and exhalation port. The appropriate sized facemask with adjustable headgear is attached to the mouth port of the two-way valve. Tubing connecting the measurement system to the valve is connected to the inspiratory and expiratory ports. Port diameters are designed to fit snugly with standard tubing systems. Some valve ports are designed with medical tapers, these ports will mate properly with other medical tapered ports. The direction of flow through the valve is indicated with arrows marked on the valve.

For mounting the mask:

1. Attach all four strap and clip assemblies to buttons on mask.
2. Extend the length of the four straps to obtain the maximum distance between the poly net cap and the face piece.
3. Hold the face piece and valve assembly in one hand and use the other hand to seat head cap on crown of head so that it fits snugly around head.
4. Hold head cap in a secure position on head and bring face piece down in front of face, allowing the lower straps to position themselves below the ear lobes.
5. Place and push mask face piece on face holding in a snug position.
6. Hold the strap tab and pull the Velcro straps out away from face to free them from the locked position in the clip.
 - Lift up on the back of the clip for strap to move freely.
7. Pull back on straps, bringing facemask to a snug fit on face.

For dismounting the mask:

1. Pull to detach the four Velcro strap ends.
 - To move the strap freely for loosening, pull the clip top outward 90'.
 - Clips do not have to be removed from buttons on mask.
2. Pull mask up off face and over head removing cap from crown.

Proper use of these valves will ensure their effectiveness. Valves that function ineffectively can cause delays in a procedure and increase the risk of infection and subject injury.

C. Reprocessing Instructions

Scope

This guidance is directed to personnel responsible for decontamination of BIOPAC Systems, Inc. AFT Series facemasks with two-way non-rebreathing valves.

Product Classification

These facemasks with two way non-rebreathing valves are classified as reusable devices.

These mask two-way non-rebreathing valves are supplied clean, non sterile. These mask assemblies fall into the semi-critical device category based on potential risk of infection. This device will come into contact with intact mucous membranes but will not penetrate the body surface. Though sterilization is recommended whenever practical, high level disinfection is acceptable. High level disinfection and sterilization is recommended by using liquid glutaraldehyde disinfectants approved as sterilant/disinfectants by the Environmental Protection Agency and cleared for marketing for use on medical Instruments by the office of Device Evaluation, center for Devices and Radiologic Health, Food and Drug Administration. High level disinfectants are simply sterilants used at a shorter exposure time. The silicone rubber face piece has the option of sterilization by steam.

Precautions

1. Facemasks may become contaminated with subject secretions during use thus, they are cleaned and subjected to high level disinfection or sterilization between uses on different subjects.
2. Thorough cleaning of these valves is required prior to the sterilization or disinfection process.
3. Follow disinfection with appropriate rinsing, drying and packaging, taking care not to contaminate the valves in the process.
4. Use sterile water for rinsing reusable semi-critical devices used on the respiratory tract after they have been chemically disinfected. The introduction of detergents to the disinfectant solution, which can occur if the device is inadequately rinsed after cleaning, can alter the pH of the solution and reduce its effectiveness. Inadvertent dilution of the disinfectant solution by wash or rinse water on wet devices also will lower the disinfectant concentration. Organic matter left on the device can protect microorganisms or inactivate the active chemical agent in the disinfectant.
5. Wash hands before and after contact with mucous membranes, respiratory secretions, or objects contaminated with respiratory secretions, whether or not gloves are worn.
6. The responsibility for handling, cleaning and decontaminating reusable medical devices should be assigned to trained, qualified individuals.
7. Appropriate protective clothing (gloves, masks, eye protection, gowns) will minimize the potential for personal exposure to blood borne and other disease-producing organisms.
8. Immediately separate and contain soiled reusable devices at the point of use and transport to the decontamination area so as to minimize risk of personal contact with contaminants.
9. Liquid chemical disinfectants product label must include information on use-pattern, use-life and storage life of the product.
 - Be sure you understand these terms and follow the manufacturer's instructions. These factors apply to the effectiveness of the disinfectant solution.
10. A disinfectant solution is only effective if it can contact all surfaces of the items to be disinfected or sterilized.
11. Adequate ventilation is required in the disinfection area to evacuate the chemical vapors from glutaraldehyde.
 - Use lidded containers for the disinfectant solution when appropriate.
 - The Inhalation of fumes from disinfectant solutions or skin contact with liquid disinfectants can be hazardous to personnel.

D. Decontamination

Introduction

These recommended practices provide guidelines to assist the health care personnel in the decontamination, cleaning, maintenance, handling, storage and/or sterilization of BIOPAC Systems, Inc. facemasks two-way non-rebreathing valves. Decontamination is a multi-step process that includes preparation at point of use, thorough cleaning and rinsing, and a microbicidal process.

1. Thorough cleaning and rinsing are the first and most important steps in the reprocessing of any reusable medical device. Without thorough cleaning and rinsing, it might not be possible to achieve high level disinfection or sterilization of the device. The purpose of cleaning and rinsing is to remove all adherent visible soil, to reduce the number of particulates and microorganisms, and to reduce the amount of pyrogenic and antigenic material. Any organic material, lubricants, or residual cleaning agents remaining on a device can inactivate liquid chemical disinfectants/sterilants as well as protect microorganisms from destruction.
2. The second step in decontamination is the microbicidal process, which is defined as a process to provide a particular level of microbial lethality (kill). BIOPAC Systems, Inc. facemask valves are classified as 'semi-critical' items, which are devices that come into contact with intact mucous membranes. Semi-critical devices at a minimum require a high-level disinfection procedure; sterilization is not absolutely essential.

All AFT series facemask valves require complete or partial disassembly for cleaning and disinfection. It is the responsibility of the user (health care personnel) for ensuring that: the cleaning methods recommended by BIOPAC Systems, Inc. can be duplicated in their environment, that appropriate tools and replacement parts are available, and that BIOPAC Systems, Inc. Instructions are followed correctly.

E. Cleaning Agents/Supplies for AFT series facemask components

Cleaning agents

Mild detergents with a neutral pH(7) are recommended for cleaning AFT series facemask assemblies. Grease cutting dishwashing detergent is helpful in removing the silicone lubricant found on many components. Use warm water (22°-43°C) with the mild detergent. To be effective, cleaning agents must assist in the removal of residual organic soil without damaging the device. Cleaning agents should be used in the correct dilution/concentration and at the correct temperature in accordance with the cleaning agents manufacturer's directions. It is ultimately the users responsibility to choose the correct cleaning agent, based on the instructions of the device manufacturer and any recommendations of the cleaning manufacturer. Certain cleaning agents may damage metal or other device materials. Do not use cleaning agents containing bleach or alcohol. Cleaning supplies are very basic, usually consisting of a surgical scrub brush, chenille pipe cleaners, cotton or foam tipped applicators, soft brushes, and soft cloths. Cleaning supplies should be cleaned and disinfected or sterilized daily.

Enzymatic detergents with a neutral pH(7) are recommended when processing difficult-to-clean devices with dried-on matter. Soaking mask and valve components in an enzymatic detergent solution can effectively remove visible debris except for lubricants, thus providing an acceptable alternative to manual cleaning. Rinsing is necessary to remove all traces of detergent and extraneous debris.

Water Quality

Tap water is acceptable for use in cleaning AFT Series reusable facemask valves. AFT Series masks and valves should be soaked, cleaned and rinsed in tap water at 22°-43°C to prevent the coagulation of solid substances onto the device and thus facilitate the removal of debris.

F. Cleaning Methods (High Level Disinfection and Sterilization)

Step 1 Preparation at Point of Use

The cleaning of reusable devices usually begins soon after use. At the point of use, personnel wearing gloves and other protective attire separate disposable items or components from reusable devices and discard them in appropriate receptacles. Soil is wiped from device surfaces with a moist sponge or towel. The soiled/contaminated items are then contained in a manner that will reduce the risk of personal exposure to pathogens. Mask and valve devices are usually placed in a basket, tray or rigid container for transportation to the processing area, usually transported in or on a cart, as hand carrying soiled items is discouraged.

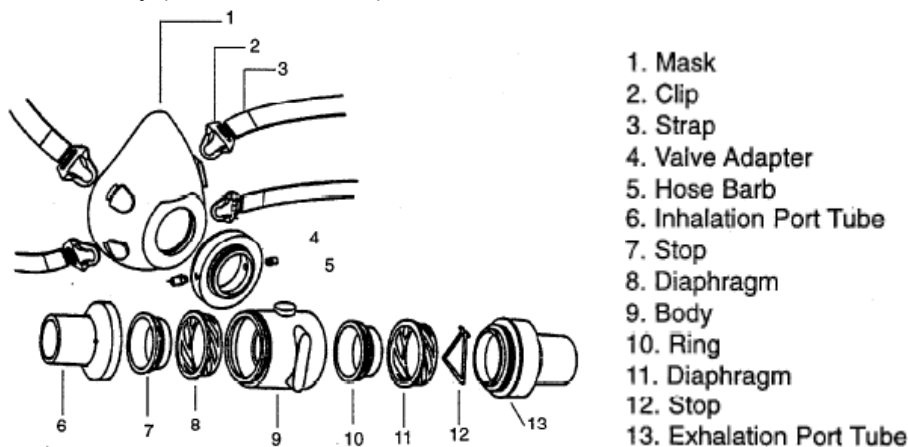
Step 2 Inspection

Inspect the mask components for damage at all stages of handling. If damage is detected on any of the components should be identified and documented. Complete the disinfection/sterilization process and contact BIOPAC Systems, Inc. for guidance on replacement components.

Step 3 Presoak

Protective attire is required of personnel handling contaminated devices. At the processing area soak or rinse the device in tap water 22°-43°C. If an enzyme product is required, soak for one to two minutes. Remove and examine, extend the soak time for components with dried-on matter. Prolonged soaking of components may be detrimental, causing damage to the component surfaces.

Step 4 Disassembly (Mask Assemblies)



Protective attire is required of personnel handling contaminated devices. The person(s) to whom the job of reprocessing mask assemblies is given should have the opportunity to become completely familiar with the mechanical aspects of these assemblies. The mask assemblies must be completely disassembled to expose all surfaces to the cleaning process.

Tools/supplies

1. Philips head screwdriver may be required on assemblies where screws are used.
2. Silicone lubricant may be required on assemblies where orings are used.

Instructions

1. Separate head cap assembly and strap clips from the facemask by sliding the clips off the mask buttons.
2. Separate the valve assembly from the facemask. The flange and groove of the valve adapter mate snugly with the mask groove. To remove the valve and adapter from the mask simply stretch and pull the mask off the valve adapter.
3. Disassemble the two-way non-rebreathing valve and adapter.
 - a. Separate the valve adapter, inhalation port and exhalation port tubes from the valve body (main housing) by unthreading the ports counterclockwise.
 - b. Remove the two rubber diaphragm and ring subassemblies. Observe how these diaphragm/ring subassemblies were mated with the valve body. Separate the diaphragms from the rings by gently pulling them apart. The flange end (open end) of the diaphragm fits into the groove on the ring (see diagram).
 - c. Remove the diaphragm stop from the exhalation port tube groove. This wire stop acts like a spring. Squeeze the legs of the diaphragm stop and it should easily pop out of the groove. Some of the smaller valves do not have diaphragm stops. Refer to the diagrams for details.
 - d. Remove orings from mating components where applicable.
 - e. Installed hose barns should not be disassembled.
 - f. Take care to ensure that all small parts (screws, orings, rings and diaphragms) are contained to prevent loss. Noninterchangeable components of assemblies should be kept together to ensure correct assembly.
 - g. Take care in handling the rubber diaphragms to avoid tearing the legs which connect the sealing face to the open flange end. Always replace damaged components.

Step 5 Manual Cleaning

Protective attire is required for personnel handling contaminated devices. Manual cleaning must be done in a manner that protects personnel handling the devices from aerosolization and splashing of infectious material.

1. Manual cleaning of the mask and components should be done under water in cool to lukewarm water (43°C maximum). Use a neutral pH(7) mild detergent. Typical concentration of detergent is one ounce to 3.8 liters of water. Water hardness, temperature and the type of soil affect the effectiveness of the detergents; the detergent manufacturer's instructions should be consumed. Use a small soft brush to scrub all detachable parts. Use a small brush to clean the inner groove at the mask outlet adapter location. Abrasive cleaning compounds and implements can damage these mask and valve components and should not be used. Additional cleaning supplies may be required to clean stubborn stains or hard-to-reach areas.
2. Mask and valve components must be thoroughly rinsed with clean water to remove the detergent residuals and debris from the components. Use a flowing triple rinse cycle at a minimum with tap water.
3. Dry all components thoroughly using soft clean cloths or disposable paper towels. Components should be dry to prevent dilution of the disinfectant used in subsequent steps.
4. Clean the head cap assembly (with strap clips) by hand washing with a mild detergent. Do not use bleach. Remove the head cap from the mask, leaving the strap clips attached to the straps. Machine or line dry. Do not iron the head cap assembly.

Step 6 Manual Disinfection with Liquid Glutaraldehyde Solution

High level disinfection of all mask and valve components must be performed after each use. The disinfectant/sterilization agent must contact all surfaces to ensure disinfection or sterilization. High level disinfection of mask and valve components ensures subject safety and minimizes the risk of infection. Use only liquid glutaraldehyde disinfectant solutions approved as sterilants/disinfectants by the Environmental Protection Agency and cleared for marketing use on medical devices by the Office Device Evaluation, Center for Devices and Radiologic Health, Food and Drug Administration.

When used according to the manufacturer's instructions a high level disinfectant destroys all microorganisms, but not necessarily all bacterial spores. The chemical agent should be sporicidal when used in recommended concentrations, temperatures and contact time. Manufacturer's instructions will include information on monitoring chemical concentration of the disinfection solution for use-life effectiveness. Disinfectants can become diluted with water that is retained in the mask and valve components or accessories.

The fumes of glutaraldehyde can irritate the mucous membranes of eyes, nose and throat. Some people develop allergic reactions to glutaraldehyde that can cause skin rashes, headaches and breathing difficulties. Containers of glutaraldehyde should be kept closed and in a well ventilated area. Gloves made of butyl or

nitile rubber should be worn—do not use latex rubber gloves. The concentration of glutaraldehyde in the air should not exceed 0.2ppm.

1. Determine the required soak temperature and time of the sterilant/disinfectant and assure that these requirements are met.
2. Activate the glutaraldehyde solution by mixing the components per the manufacturer's Instructions. Use the concentration testing devices sold by the manufacture to determine that the solution is above the minimum effective concentration.
3. Pour the activated glutaraldehyde solution into an appropriate sized basin.
4. Completely immerse the mask and valve components in the basin. Assure that all channels and cavities are filled with disinfectant and that no air pockets remain within the components.
5. Cover the disinfectant soaking basin with a tight fitting lid to minimize chemical vapor exposure.
6. Soak the valve components for the time specified by the disinfectant solution manufacturer to achieve high level disinfection. Use a timer to ensure adequate soaking time.

Step 7 Rinse After Manual Disinfection

Adequate rinsing must allow disinfection to remove all traces of the toxic residues of the disinfectant left on the mask and valve components. Sterile water rinse is preferred over tap water. Tap water may contain a variety of micro-organisms which could recontaminate the valve components.

Rinse 1: Fill a basin with 7-8 liters of water (preferably sterile water).

Place the mask and valve components into the basin and thoroughly rinse all the components for a minimum of one minute.

Empty basin.

Rinse 2: Fill a basin with 7-8 liters of water (preferably sterile water).

Place the mask and valve components into the basin and thoroughly rinse all the components for a minimum of one minute.

Empty basin.

Step 8 Drying

To prevent the growth of waterborne organisms, the mask and valve components should be thoroughly dried prior to reassembly and storage.

- Dry thoroughly using a soft cloth (preferably sterile) or disposable paper towels.

Step 9 Inspection

All components should be visually inspected for cleanliness, proper function and freedom of defects. Visual inspection provides evidence at thorough cleaning and proper functioning of all mask and valve components. Mask assemblies in poor working condition are hazardous to personnel and subjects.

1. Visually inspect all components for cleanliness.
 - If there are signs of residue from the detergent or disinfectant are any signs of remaining stains or organic debris, then repeat the previous steps.
 - If the cleaning and disinfection steps have been repeated with no improvement eliminating residual or stains etc., then dispose of the components and replace.
2. Visually inspect all components for defects and discard and replace any defective parts.
 - Check the rubber parts for tears, nicks, hardening or stiffening, deformation or distortion.
 - Check the plastic parts for crazing, cracking or stripped threads.
3. Visually inspect all metal components for corrosion.
 - Replace any metal components showing rust or chipped plated surfaces.

Step 10 Reassembly

Refer to the previous valve diagrams. Use appropriate personal protective clothing to assure that you do not recontaminate the components.

1. Install rubber diaphragms on the rings. Mating grooves on the diaphragms and rings should fit together. Make sure the diaphragms are completely fitted into the groove on the rings. The flat diaphragm face should contact the ring sealing edge evenly with no visible gaps.
2. Snap the diaphragm stop into the exhalation port groove by collapsing one end of the wire stop while placing the opposing end into the groove.
3. Insert a diaphragm/ring subassembly into the inhalation port of the valve body. Orientation of the diaphragm/ring assembly is very important. Identify the inhalation port by the arrows on the valve body, one arrow points to the mouth port from the inhalation port. The diaphragm should open with air flow into the body. Make sure the flange of the open end of the diaphragm sits squarely in the counter bore of the valve body.
4. With the diaphragm/ring assembly mounted in the valve body thread the inhalation port tube into the valve body. Hand tighten only. Do not over tighten, this could damage the threads.

5. Insert a diaphragm/ring assembly into the exhalation port of the valve body. Orientation of the diaphragm/ring assembly is very important. Identify the exhalation port by the arrows on the valve body. The diaphragm/ring assembly is mounted into the exhalation port of the valve body open flange end first. Make sure the flange of the open end at the diaphragm sits squarely in the counter bore of the valve body. The diaphragm should open with air flow out of the body.
6. With the diaphragm/ring assembly mounted in the valve body thread the exhalation port tube into the exhalation port of the body. Hand tighten only. Do not over tighten, this could damage the threads.
7. Thread the valve adapter into the mouth port of the valve body. Hand tighten only. Do not over tighten.
8. Attach the valve with adapter to the facemask by stretching the rubber facemask groove onto the valve adapter flange.
9. Attach the clips to the mask buttons to assemble head cap with straps and clips on the facemask.

Step 11 Functional test

Confirm that the mask assembly functions as intended before storage.

1. Facemask
A visual test is specified to evaluate the facemask for tears, nicks, deformation, deterioration or discoloration.
2. Two-way Valve
 - a. Attach an appropriate sized volume calibration syringe to the valve mouth port with the piston rod at the mid stroke position.
 - b. Push and pull the syringe piston rod slowly, visually checking the valve function. Air should enter the valve through the inhalation port and exit the valve through the exhalation port. Visually inspect the diaphragm opening and closing functions. The diaphragm should open and close easily without interference.
 - c. Test for the exhalation diaphragm/ring assembly: Block the inhalation port tube with your hand while you easily pull on the calibration syringe piston rod. You should not be able to pull air through the valve into the syringe. If the syringe is filling with air, air leakage is occurring at the exhalation port diaphragm/ring assembly. Inspect the diaphragm/ring assembly if this is suspected and replace if necessary.
 - d. Test the inhalation diaphragm/ring assembly: Block the exhalation port with your hand while you easily push on the syringe piston rod. If you are able to push air through the valve, air leakage is occurring at the inhalation port diaphragm/ring assembly. Inspect the diaphragm/ring assembly and replace if necessary.
3. Subject Functional Test
Leak test—for sealing of mask face piece
 - a. Hold palm of hand over outlet of exhalation valve port tube.
 - b. Create a slight positive pressure inside mask face piece by exhaling gently.
 - It is important to exhale with only a slight positive pressure as this simulates the low pressure of spontaneous breathing common with normal applications of this mask.
 - c. If air leakage occurs around facial seal, readjust face piece and Velcro straps and retest until leakage tight.

Step 12 Storage

Confirm that the mask assembly is completely dry prior to storage. Masks should be stored in a way that prevents recontamination or damage between uses.

1. Place mask assembly in a clean plastic bag and heat seal the end.
 2. Label the bag, documenting that it has been disinfected, date, initials, mask part number and description.

G. Steam Sterilization (Silicone Rubber Facemask only)

Sterilization of the silicone rubber facemasks can be achieved with steam sterilization.

Type of Cycle: Gravity Displacement

Temperature: 132°-135°c

Type Of Load: Wrapped Method

Cycle Time: 10-15 minutes

Special Notes:

- a. Follow cleaning procedures as instructed prior to steam sterilization. Since the degree of sterility assurance depends on the amount of contamination of item to be sterilized, thorough cleaning procedures are essential.
- b. Remove all lubricants from components because they will interfere with steam contact.
- c. Dry devices (components) reduce the potential for wet device packs after sterilization.
- d. Sterilization container systems should be cleaned after each use.

1. Package Material Requirements
 - Allow adequate air removal from and steam penetration of the package
 - Provide adequate barrier to microorganisms
 - Resist tearing or puncturing
 - Have proven seal integrity
 - Be free of toxic ingredients
 - Be low linting
 - Maintain sterility of the contents until the package is opened
 - Provide for removal of the contents without contamination
2. Preparation of Devices

All devices should be disassembled into component parts. Mask face pieces should be individually packaged in an acceptable packaging material and sterilized in a position that ensures adequate steam contact with all surfaces.
3. Loading the Sterilizer

Allow for free circulation of steam around each pack and each item. Position devices in the sterilizer to allow for adequate air elimination and drainage of condensate without wetting of other items in the load. Sterilizers differ in their design and operating characteristics, so it's important that the manufacturer's written instructions be carefully followed.
4. Sterilization Cycle for Wrapped Items

Gravity displacement cycle: 10.15 minutes
Exposure time at 132°.135°c
5. Unloading the sterilizer

All items removed from the sterilizer after sterilization must remain in the sterilizer cart until adequately cooled. They should not be touched during the cooling process, because hot packs absorb moisture, hence bacteria from hands.
Visually Inspect all packs for torn packaging, compressed packaging or with packaging that appears to be wet, such items should be returned to the decontamination area for reprocessing.
6. Storage
 - Gloves should be worn to prevent contamination of sterile packages.
 - Plastic dust covers should be applied soon after sterilization but only to packages that are thoroughly cool and dry.
 - Placing a dust cover on a wet item may result in condensation inside the dust cover, causing contamination of the package contents.
 - The dust cover should be sealed using a heat sealer or similar method to be an effective barrier to moisture.
 - The cover should be clearly designated as a dust cover to prevent it being mistaken for a sterile wrap. Label the package (dust cover) with the appropriate identity and traceability information.
 - Sterile items should be stored away from floors, ceilings or outside walls. They should be positioned so that the packaging is not crushed, bent, compressed or punctured. Closed or covered cabinets are recommended for storage of sterile packages.

H. Reuse Life

BIOPAC Systems, Inc. AFT Series facemasks and valves, when maintained properly and reprocessed per these instructions, should function within specifications for 100 reuses. Visual inspection of all the components during each reprocessing cycle will identify any defects. The functional test as described in Section F, Step 11 will determine if the mask is functioning properly.

I. Warnings

1. Do not use these valves in a life support system such as a ventilator circuit.
2. Do not ethylene oxide, steam sterilize or pasteurize the valves, outlet adapters or head cap components.
3. Do not expose the valves, outlet adapters or head caps to heat at or above a temperature of 45°c (113°F).
4. Use only approved liquid glutaraldehydes (see Section F, Step 6). Do not use alcohol or bleach solutions.
5. Glutaraldehyde solutions are hazardous to humans.
 - a. Do not get into eyes, on skin or on clothing.
 - b. Use In well ventilated area in closed containers.
 - c. For emergency, safety or technical information about the glutaraldehyde solution contact the manufacturer.
6. Appropriate personal protective clothing should be worn when cleaning and sterilizing/disinfecting soiled devices.

7. Contaminated, reusable devices must be thoroughly cleaned prior to disinfection or sterilization, since residual contamination will decrease effectiveness of the glutaraldehyde solution.
8. It is the user's responsibility to validate any deviations from this recommended method of processing.
9. Federal (USA) law restricts this device to sale by or on the order of a physician.

J. Safety Information

Safety or technical information regarding BIOPAC Systems, Inc. AFT Series facemask assemblies can be obtained from BIOPAC Systems, Inc., 42 Aero Camino, Goleta CA 93117 USA 805-685-0066, Fax 805-685-0067, or by contacting your BIOPAC Systems, Inc. representative.

K. References

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