



REBREATHERS



BIOMARINE INC., A WHOLLY OWNED SUBSIDIARY OF NEUTRONICS INC.

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AV3500 Series Facemask

PRODUCT NOTICE

You are being informed of a BioPak 240R alert involving the AV3500 Series Facemask Assembly. You MUST act immediately according to the procedures provided in this notice.

Date: February 2016

ISSUE:

It has come to the attention of Biomarine that a small number of fielded AV3500 Series Facemask Assemblies have suffered cracking and/or breakage in the location of the BioPak 240R facepiece lens interface connection. This issue requires prompt inspection and correction to avoid possible injury to any BioPak 240R user caused by the sudden disconnection of the BioPak from the facemask.

This issue has been reported to NIOSH by Biomarine and you are instructed to conduct an inspection of your facemasks as directed by this notice. Biomarine will repair or replace affected facemasks either on site or at our factory.

Biomarine is taking an overly cautious and extremely proactive approach to correct this issue and your involvement is paramount to providing a quick and efficient resolution.

CAUSE:

Biomarine has determined the cause of the cracking to be a concentration of stress in sharp molded corners of the raw mask front opening as depicted below. The sharp corners serve to concentrate stress and promote possible cracking in the mask.

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REMEDY:

Biomarine has no control over the formation of the sharp corners in the mask as it is a third party supplied component; however, Biomarine can provide a remedy to the cracking issue. Biomarine will remove the front adapter pieces of the mask and remove the silicone gasket material from the front adapter piece. A solid polycarbonate gasket will be solvent-welded directly to the raw mask and the front adapter will be solvent welded directly to the solid polycarbonate gasket creating a gas-tight seal of the adapter to the mask.

The remedy will increase the bearing surface of the raw mask to external forces by a factor of sixteen (16) times. This will equate to an increase of force resistance of 6.5. In the current design a 1-pound force applied to the top or bottom of the plug-in hose adapter would impart a 2.5-pound force on the raw mask bearing surface. With the remedied design it would take a minimum force of 16.3-pounds applied to the top or bottom of the plug-in hose adapter to impart the same stresses on the raw mask.

IMPACT TO USER OF NEW DESIGN

The new design will not alter the appearance of the mask, the protection provided by the mask or the method of utilizing the mask. The internal front adapter piece will be permanently welded to the mask and will no longer be removable.

OWNERSHIP RESPONSIBILITY

All BioPak 240R AV3500 facemask assemblies **must be immediately** inspected by the user/owner of the fielded sets.

1. Use a Phillips-drive screwdriver to remove the three screws from the front of the cowling.
2. Remove the front cowling, yellow push button and spring form from the assembly.
3. Remove the internal interface piece by rotating it 90-degrees to allow disengagement of the piece from the mask.

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4. Inspect the front mask surface, bearing surface and corners as depicted below for cracks or breakage.



The damage that is occurring is a long-term effect of the mask design. If masks are not seen to be cracking it is not expected that sudden breakage of the mask will occur and continued use of the mask is safe. It is still advised to have the modification completed on masks with no cracking detected to prevent possible cracking in the future.

Contact the Biomarine Service Manager, Jack Derfler, as directed below for assistance in scheduling a Biomarine field visit or for returning masks to Biomarine. **DO NOT RETURN ANY MASKS TO BIOMARINE WITHOUT FIRST CONTACTING THE BIOMARINE SERVICE MANAGER.**

Telephone: (610) 524-8800, extension 146
Email: Jack.Derfler@NeutronicsInc.com

Should you have questions concerning this notice or this issue, contact the Biomarine Service Manager as listed above.