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THE FIRE INDEPENDENT

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FEDERAL AGENCY MISTAKENLY APPROVES BREATHING APPARATUS THAT SHOULD HAVE BEEN REJECTED; FIREMEN PARTICULARLY AFFECTED.

The National Institute for Occupational Safety and Health (NIOSH) apparently violated its own regulations when it approved the BioPak 45 breathing apparatus manufactured by BioMarine Industries, Inc. and now being sold to fire departments throughout the country.

In tests conducted by NIOSH in early 1973 at its Appalachian Center in Morgantown, West Virginia, the BioPak 45 developed exhalation resistances in excess of NIOSH's maximum permitted level. In spite of this, NIOSH issued its Approval No: TC≠13F≠27 for the BioPak 45 on September 7, 1973.

This apparent error by NIOSH was discovered by Mr. Paul A. LaViolette, when he carefully examined test data on closed-loop rebreathers submitted to him by NIOSH in response to a Freedom of Information Act request. LaViolette's findings were reported in the March 1977 issue of "The Fire Independent" magazine.

When the BioPak 45 was tested by NIOSH, it produced an exhalation resistance of 2.4 inches water-column height, a clear violation of the 2.0 inch maximum permitted by NIOSH regulations, but the violation was concealed by the fact that NIOSH engineers made two mistakes in calculating the data, as shown in the accompanying figure.

Excess exhalation resistance in closed-loop systems like the BioPak 45 has

(more)

important and potentially dangerous consequences for firefighters. It means reduced service time, possible difficulty in breathing, and increased danger of an accidental ignition in the oxygen-rich apparatus.

Mr. LaViolette discovered NIOSH's error and reported it to Dr. James A. Merchant, Director of NIOSH's Appalachian Center for Occupational Safety and Health, where the tests were run. Dr. Merchant's reply to Mr. LaViolette stated "We have reviewed the BioMarine breathing resistance data and found an error in the baseline, as you suggested. This has been corrected..." Not satisfied, Mr. LaViolette again wrote to Dr. Merchant, recommending that NIOSH certification of the BioPak 45 be suspended. This time, he received a reply from Mr. Earle P. Shoub, Dr. Merchant's Associate Director, saying "You recently pointed out a probable transposition in the recording of test data in our files for the BioMarine apparatus. Please accept our thanks for noting that discrepancy. However, after a careful review, we found that the BioMarine apparatus did meet the applicable breathing resistance requirements of sections 11.85-5 and 11.85-6 of Part 11." Mr. Shoub failed to amplify this statement nor did he submit any evidence.

Contacted by "The Fire Independent", Mr. Fred A. Parker, Chief Engineer for BioMarine Industries stated, "BioMarine personnel witnessed exhalation resistance tests conducted by NIOSH during 1976 and can attest to the fact from personal observation that exhalation resistances were within NIOSH specifications." However, NIOSH officials told "The Fire Independent" that no additional exhalation resistance tests were run by NIOSH on the BioPak 45.

As a result of these disclosures, "The Fire Independent" is advising fire departments with BioPak 45's in service to suspend their use immediately, pending proper retesting by NIOSH.

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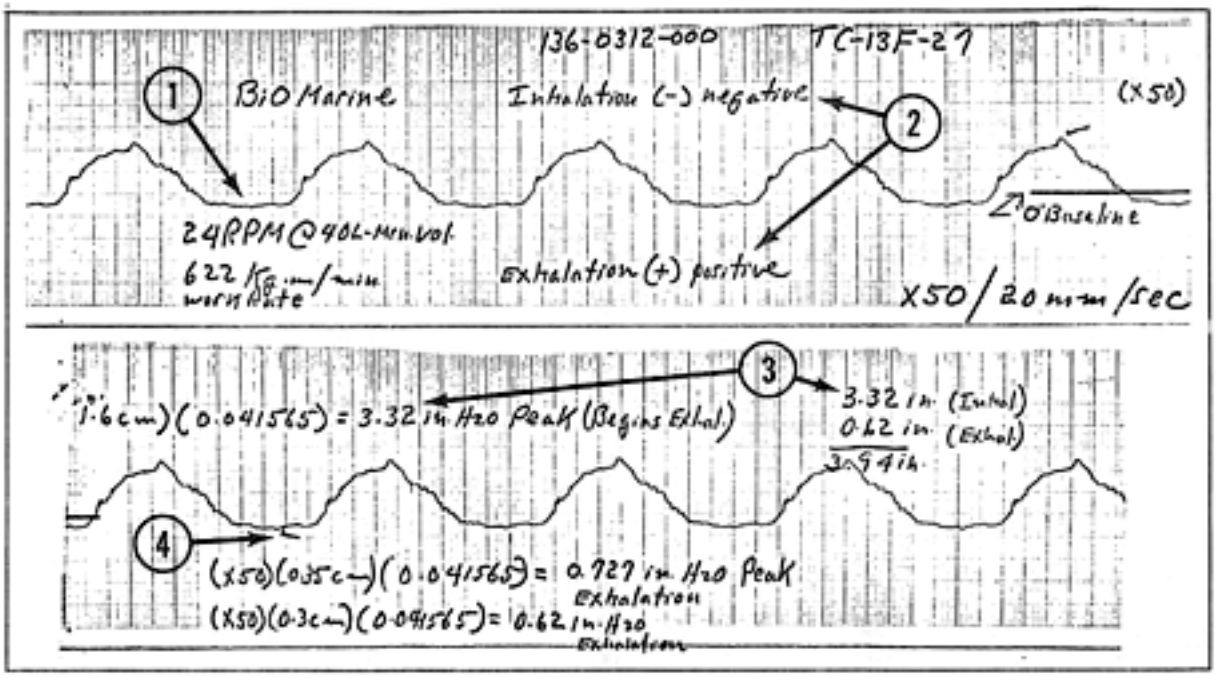

(figure caption)

This xerox copy of one of the pressure vs. time plots made by NIOSH on the BioPak 45 shows the error that led to its improper approval. The wavy line (arrow 1) is the actual strip chart recording of the rise and fall of pressure inside a BioPak 45 facepiece strapped to the head of a dummy while a so-called breathing machine simulated the inhalation and exhalation of the lungs through the dummy's mouth. It seems hard to believe, but NIOSH engineers labeled the chart backwards. What is shown as the "exhalation (+) positive" side of the curve should have been labeled "inhalation (-) negative" and vice versa (arrow 2). As a result, what is calculated in the right lower portion of the chart (arrow 3) as 3.32 inches inhalation resistance is really 3.32 inches exhalation resistance. That is, if it weren't for a second error: the baseline was mistakenly taken as the short mark (arrow 4) instead of the actual baseline, one major division higher on the chart. As a result, the correct value for the exhalation resistance is 2.4 inches, clearly in excess of NIOSH's 2.0 inch maximum. (NOTE: The strip chart was cut by NIOSH prior to xeroxing; the lower segment was originally attached to the left edge of the upper segment.)