



RPC Position Statement: Use of 100 Percent Peroxyacetic Acid in Dialyzer Reprocessing Equipment

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What is 100 percent peroxyacetic acid?

One hundred percent peroxyacetic acid (PAA) is defined here as the non-diluted, full strength PAA dialyzer reprocessing germicides such as Micro-X (RPC), Peracidin (HDC Medical), and Renalin (Minntech), in 100 percent concentrated form. Renalin 100 (Minntech Corp) is equivalent to 100 percent concentrated Renalin.

What is RPC's position on the direct use/uptake of 100 percent PAA in reprocessing equipment?

RPC is opposed to the direct use/uptake of 100 percent PAA in dialyzer reprocessing equipment and recommends against it.

Why does RPC oppose and recommend against direct use/uptake of 100 percent PAA in reprocessing equipment?

There are two reasons RPC opposes and recommends against direct use/uptake of 100 percent PAA in reprocessing equipment:

1) When 100 percent PAA is used without prior dilution and thorough pre-mixing a potential exists for the reprocessing equipment to deliver a non-homogenous (not adequately mixed) solution of PAA to the dialyzer during the reprocessing cycle. RPC believes a non-homogenous PAA solution may result in variable concentrations (“hot spots”/“weak spots”) of PAA within the dialyzer. Variable concentrations of PAA within the dialyzer may have an adverse impact on dialyzer performance and possibly compromise patient safety.

Reprocessing equipment typically does not employ internal mechanical mixers and relies largely on incoming water pressure and flow turbulence for internal mixing of the concentrated chemical uptake. Water pressure and subsequent water flow may be sufficient to operate the equipment but insufficient to thoroughly mix the internal diluted solution of PAA.

RPC believes each reprocessing equipment manufacturer, that supports the use of 100 percent PAA in their equipment, should have studies validating that dialyzers reprocessed with 100 percent PAA on their equipment, are cleaned and filled with thoroughly mixed PAA solutions under all normal equipment operating parameters and varying water supply conditions. These studies should show that no variable concentrations or PAA “hot spots”/“weak spots” are present within the internal PAA solution to be delivered to the dialyzer by the reprocessing equipment. In addition, the studies should be made public to facilitate peer review.

2) An increase in replacement parts cost, equipment downtime, and staff response/repair time can be expected as reprocessing equipment fluid pathway materials are very likely to fail at a greater rate when using 100 percent PAA. Manifold plastics, uptake tubing, valves, and other components are all subjected to a much more aggressive oxidizing chemical with a very low pH when 100 percent PAA is used. Any warranty from the equipment manufacturer is not likely to cover all costs associated with equipment downtime or staff response/repair time.

Note: Vernon S. Taaffe is the author of this opinion paper. Mr. Taaffe is a dialysis technical specialist with 25 years of experience and is a member of the NANT and AAMI. As President of Reprocessing Products Corp. (RPC) and as former Director of Technical Services at Renal Systems, he has developed and presented at more than 30 domestic and international dialyzer reprocessing and dialysis-related workshops. He was directly involved in the development, manufacturing, evolution, and technical support of three automated reprocessing systems and a portable water treatment system. He holds patents for his research and development work on dialysis-related devices. Mr. Taaffe has written several publications on dialysis-related devices and dialyzer reprocessing.