Reprocessing Products Corp (RPC)
Rabrenco Scientific - Division of RPC

Use of Full-Strength Micro-X™ Cold Sterilant in a Dialyzer Reuse Machine
- Application Note -

Introduction

In a position statement dated October 4, 2001, RPC expressed concern regarding the use of non-diluted, full-strength Micro-X™ in reprocessing equipment. A potential for inadequately mixed final peroxyacetic acid (PAA) solution delivered to the dialyzer and a potential for a greater equipment part failure rate were cited as reasons for concern. In addition, RPC stated a belief that studies should be performed to validate that dialyzers are filled with thoroughly mixed PAA solution under varying water supply conditions, for each type of reprocessing equipment, when full-strength Micro-X™ is used. Consistent with the position statement recommendation, RPC has completed a comprehensive study of this type, for a specific reuse machine. A summary of the study results, and subsequent recommendations applicable to Micro-X™, are presented here.

Summary of Study Purpose and Format

The purpose of this study was to determine whether or not peroxyacetic acid (PAA) based end solutions, diluted and delivered to dialyzers by a dialyzer reuse machine (Renatron II station), were stratified (non-homogeneous) when the reuse machine was operated with AAMI quality water having a pressure of 20-psig (step 04) and temperature of 59° F (worst-case condition for normal range of operation). Each end solution tested originated from different starting germicides. The starting germicides - connected at different times to the reuse machine - included externally mixed Micro-X™ 21%, Micro-X™ 100% concentrate, and another PAA based germicide also at 21% and 100%. Before the Micro-X™ 100% or the other 100% germicides were connected, the reuse machine was adapted for use with Renalin 100. AAMI quality water was used for all external dilutions and to operate the reuse machine. The reuse machine was thoroughly rinsed before connecting each different starting germicide. Titrations were used to determine concentrations of hydrogen peroxide and peroxyacetic acid in peroxyacetic acid concentrates as well as dilutions from the reuse machine. More than 200 total titration tests were performed. A second phase of the study looked at the role increased water pressure (30-psig) might play in the mixing of the germicide solution. An independent lab professional, holding a PhD in organic chemistry, performed all titrations and data analyses.

Summary of Study Results

In the final analysis to determine if stratification was occurring in the reuse machine, the percent relative standard deviation of hydrogen peroxide and peroxyacetic acid values were considered. Titration test values for each reuse machine cycle were compared to obtain a percent relative standard deviation (% RSD). The %RSD values appear in **Table 1**.

Deviations	% RSD H_2O_2	% RSD AcOOH
Micro-X™ 21% Cycle-00	2.80%	6.57%
Micro-X™ 21% Cycle-CH	7.88%	2.74%
Micro-X™ 21% Cycle-HF	0.65%	3.34%
Micro-X™ 100% Cycle-00	4.51%	2.90%
Micro-X™ 100% Cycle-CH	4.50%	5.81%
Micro-X™ 100% Cycle-HF	1.30%	5.17%
Other Germicide 21% Cycle-00	2.02%	5.02%
Other Germicide 21% Cycle-CH	2.90%	4.60%
Other Germicide 21% Cycle-HF	1.63%	1.59%
Other Germicide 100% Cycle-00	1.87%	4.89%
Other Germicide 100% Cycle-CH	3.52%	4.11%
Other Germicide 100% Cycle-HF	3.39%	2.55%
Micro-X™ 100% Cycle-00 30psi	3.14%	5.55%
Micro-X™ 100% Cycle-CH 30psi	3.08%	3.75%
Micro-X™ 100% Cycle-HF 30psi	0.64%	4.07%

Table 1 - % RSD of H_2O_2 and AcOOH values.

In comparing %RSD of titration samples for either Micro-X™ 21% with Micro-X™ 100%, or the "other germicide 21%" with the "other germicide 100%", we see that seven out of twelve times there is higher variability in the use of 100% full-strength starting germicide. A more distinct trend is seen in comparing HF samples to their counterparts. Independent of water pressure, HF cycles should have more mixing due to extra reuse machine fill/dilute time, yet four in five results demonstrate less variability in the HF values when the 21% germicides are used.

Comparing the average low and average high values obtained with both 21% externally mixed and 100% solutions we see that 21% mixed solutions have an average range of 93% - 110% and the 100% solutions have an average range of 91% - 114% which represents a 6% increase in the variability range.

Greater mixing appears to occur with higher water pressure as variability drops in five out of six values between Micro-X™ 100% concentrate at 20-psig and Micro-X™ 100% concentrate at 30-psig.

Titration values for samples from the reuse machine when connected to 100% full-strength starting germicides, were consistently higher - by an average of approximately 21% - than the values for the reuse machine samples when connected to the externally diluted/mixed germicides. Test measurements were taken of the reuse machine germicide uptake amounts before and after the machine was adapted for Renalin 100 use. These tests confirmed that the adapted reuse machine would consistently uptake a greater amount of germicide concentrate and dilute it to the same internal water dilution level present prior to the machine adaptation. The amount of the resulting concentration increase, in the final germicide delivered to the dialyzer, varied depending on the reuse machine cycle.

Discussion and RPC Recommendations

RPC cannot say conclusively that the increased variability - present when the reuse machine is operated at 20-psig with full-strength PAA germicide - poses additional risk to the patient; however, what is evident from the study is that this increased variability is not present with the 21% (mixed outside the machine) germicide (PAA).

Variability decreased in five out of six values when the Renatron II 100 was operated at 30-psig (vs. 20-psig) with Micro-X™ 100% concentrate. It is reasonable to assume this decrease in variability happens as a result of increased water turbulence, in the reuse machine internal mixing vessel, which delivers a greater agitative force - for more thorough mixing.

In consideration of the RPC study results, RPC recommends the following action items for dialysis professionals who choose to use non-diluted, full-strength Micro-X™ direct with a Renatron II 100 (Renalin 100 adapted) dialyzer reuse machine. In addition, continue to follow all other relative procedures, warnings and cautions.

Action Item	Rationale
1) Operate each reuse machine station at a minimum of 30-psig-water pressure (in Step 04). Do not exceed the reuse machine manufacturer's specification for maximum water pressure.	1) To remove the extra germicide variability which can be present when the reuse machine is operated at 20 psig.
2) Monitor the dialyzer pre-dialysis rinse procedure, carefully. Use K100-0100 Micro-X™ Residual Test Strips to be certain germicide is properly removed and no rebound occurs.	2) To ensure the stronger concentration of germicide, delivered by the adapted reuse machine, is properly rinsed from the dialyzer, without rebound.
3) Inspect reuse machine components carefully during routine preventive maintenance. If components show signs of wear or erosion, replace the components and increase the frequency of preventive maintenance.	3) To set a maintenance schedule that ensures reuse machine components are replaced before by-products, of the components breaking down, can be released to the fluid pathway.
4) Use only externally diluted and mixed, Micro-X™ with all automated and manual reuse systems other than the Renatron II 100 (Renalin 100 adapted).	4) At this time, RPC has no Micro-X™ study for other reuse machines that may be adapted to use non-diluted, full-strength PAA germicides.

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