



MONOGRAPH

SANIDOSE[®]

**AUTOMATED ENDOSCOPE
REPROCESSOR
WATERLINE TREATMENT
AND DELIVERY SYSTEM**

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SANIDOSE[®] DELIVERY SYSTEM (SDS)

The Sanidose Delivery System is an effective method for providing safe rinse water to an Automated Endoscope Reprocessor (AER). While delivering a low dose of peracetic acid (PAA) at approximately 50 parts per million (ppm), the system provides a three log reduction on incoming bacteria counts. Levels as high as 1000cfu/100ml are reduced below the safety level of 10cfu/100ml. The testing was performed using common water contaminating organisms such as *Pseudomonas aeruginosa* (ATCC 15442). Continuous use of SANIDOSE, when used as directed can aide in the reduction of the need for daily disinfection of automated endoscope reprocessors when used as part of a validated water quality program.

Using the Sanidose water treatment in conjunction with the SDS is safe for both patient and health care worker. Testing data on representative scopes of the most difficult to rinse show PAA and hydrogen peroxide (H₂O₂) levels to be well below the maximum residuals allowed. The established limits are 7050 mg PAA and 5950 mg H₂O₂, while the detected levels are 0.39 mg PAA and 1.95 mg H₂O₂ after routine scope disinfection. Results show worst case scenario and are on file, and was performed using a 24 hour exhaustive extraction under FDA guidelines.

The biocompatibility effects of PAA are well documented and show that skin will not be penetrated at levels as high as 8000 ppm (0.8%) PAA (Kruger and Jancke, 1976). Skin sensitization did not occur with levels of PAA at 2000 ppm (0.2%) on long-term use of hand wash solutions (Pazdiora and Kubicek, 1967). Drinking water containing 1000 ppm (0.1%) PAA administered to rats for seven weeks had no toxicological change (Juhr et al, 1978). The 1000 ppm (0.1%) PAA level did not show any ocular irritation in humans that had the solution applied to eyelids for 5 – 10 minutes to check for eye irritation (Kretzschmar, 1972).

The Sanidose Delivery System provides safe rinse water by controlling microbial levels with a 50 ppm PAA dose. When used in conjunction with the AER, residual levels of peracetic acid and hydrogen peroxide are well below established limits. Biocompatibility studies confirm that PAA at much higher levels than 50 ppm are not toxic to humans. This ensures a high level of safety to health care workers and patients using the SDS.

ANTIMICROBIAL EFFICACY OF SANIDOSE[®] WATERLINE TREATMENT FOR CONTROLLING BACTERIA IN ENDOSCOPE REPROCESSOR RINSE WATER

Summary:

The Sanidose[®] Delivery System (SDS) was connected to the incoming water line of a Mediators' Advantage[®] Automated Endoscope Reprocessor (AER) and the efficacy of Sanidose Waterline Treatment against *Pseudomonas aeruginosa* was evaluated. Testing has shown that at 31ppm PAA, Sanidose Waterline Treatment produced a three (3) log reduction in this organism. Therefore, if the incoming waterline (bacterial concentration should be less than 1000 CFU/100mL) to an AER is connected to the Sanidose[®] Delivery System, (which is set to deliver 50ppm PAA), rinse water with a bacteria concentrations of <10 CFU/100 ml will be produced.

Test Methods:

A culture of *Pseudomonas aeruginosa* (ATCC 15442) with concentration of 10⁶ CFU/100ml was prepared according to standard procedures.

Pseudomonas aeruginosa at the concentrations in Table 1 were introduced into SDS. The surviving organisms in the rinse water were monitored. The numbers of surviving organism are displayed in Table 1: The log reduction of the test organism was calculated from this data and is also found in Table 1.

Results:

Table 1: Antimicrobial Efficacy of Rinse Water Treated with Sanidose Waterline Treatment

Sample #	PAA Concentration (ppm) *	Survivors in Rinse Water (CFU/100 ml)	Log Reduction
1**	0	1.4 x 10 ⁶	NA
2	10	TNTC	NA
3	10	TNTC	NA
4	16	TNTC	NA
5	16	TNTC	NA
6	31	1000	3.1

* Concentration of PAA is given as the average of three samples of rinse water.

** Sample collected and diluted using serial dilutions to determine the initial bioburden of the rinse water.

Conclusions:

The use of the Sanidose Delivery System with Sanidose Waterline Treatment will control bacteria in the rinse water of an AER. If the incoming water to the SDS is less than 10³ CFU/100ml, the rinse water in the AER will contain less than 10 CFU/100 ml of microorganisms.

SHORT SUMMARY OF STUDIES

Skin Penetration:

Experiments with pig skin (Kruger and Jancke, 1976): Solution of 0.8% (8000 ppm) incubated with pig skin in diffusion cell resulted in no PAA penetration with intact skin. Some penetration was observed with damaged skin.

Dermal toxicity:

Busch and Warner (1974): pigs exposed to 1.5% PAA solution (=15000 ppm) showed hyperkeratosis, hair loss, and inflammation after 20 days.

Skin Sensitization:

Freeman, 1991: Guinea pigs exposed to 1:33 dilution of 5-6% PAA (therefore about 1764 ppm PAA max) showed no irritation or sensitization.

Kuhn et al. (1996): short-haired albino Guinea pigs exposed to 10% of 5% PAA solution (therefore 5000 ppm PAA) did not elicit a sensitizing reaction.

Minntech data: (19??), quoted in Minncare Research Data, document # 50090-129: Skin sensitivity testing (Burckhardt Test) in human volunteers, using 3% Renalin, did not produce any visible effects.

Pazdiora and Kubicek (1967): Long-term use of hand wash solutions with 0.2% PAA (equivalent to 4% Renalin) has been reported to result in no irritation to the skin, except in exposure to small wounds (cuts, abrasions). Concentrations of 0.5% (5000 ppm) PAA caused skin irritation in humans.

French (1993): Exposure of eczema-prone patients to 0.1% PAA (1000 pm) or less was not associated with skin irritation.

Oral toxicity:

Benes (1966): Drinking water containing 0.1% PAA (=1000 ppm PAA) administered to rats for 7 weeks did not result in toxicological change.

Juhr et al (1978): Exposed rats to PAA in drinking water. Reportedly 200 ppm was without effects, but degradation of PAA in water may have occurred.

Eye irritation:

Kretzschmar (1972): A solution of 0.1% (1000 ppm) PAA applied to eyelids for 5-10 minutes (human volunteers) did not show ocular irritation.

Freeman (1991): A solution of 0.15% (1500 ppm) PAA evaluated in rabbit eyes found to be mildly irritating.

Duprat (1974): A solution of 0.034% (340 ppm) PAA caused no effects in rabbit eyes during 24 hours of exposure.

EVALUATION OF 50 & 100 PPM EXPOSURE

Given the above studies, exposures to concentrations of PAA up to 200 ppm have not been shown to cause skin or oral toxicity, and concentrations up to 1000 ppm do not show skin sensitization. Exposures of up to 340 ppm directly on rabbit eyes (the closest analogy to exposed mucous membranes tested) did not show irritation. Therefore exposure to 50 or 100 ppm PAA is not expected to cause any irritation or toxicity. Lastly, the EPA has assigned an NOEL of 100 ppm to peroxyacetic acid (Federal Register, May 6, 1998, Vol. 63, Number 87, pg 24949-24955). Given that PAA will degrade fairly quickly after application to the filters, it is not expected that the concentrations of PAA will be close to the minimum toxicity levels reported in the literature.

BIOCOMPATIBILITY OF ENDOSCOPE REPROCESSED WITH ADASPOR SINGLE SHOT GERMICIDE IN COMBINATION WITH SANIDOSE

Purpose

The purpose of this study was to demonstrate that endoscopes subjected to disinfection with Adaspor Single Shot HLD and rinsing with Sanidose treated water will have germicide residues at levels which make the disinfected endoscopes safe for both patient and health care staff.

Background

The Sanidose waterline antimicrobial treatment is a device for pretreating the incoming water to 50 ppm of PAA in order to maintain low background levels of bacteria within the AER filters and lines, so that rinsing at the end of the disinfection treatment will not recontaminate the scopes. This study determined that the residual PAA was well below safe levels.

Definitions

PAA: peracetic acid

AER: automatic endoscope reprocessor

Justification

Sample size

Three disinfection/extraction cycles were completed for each of two Advantage AER systems-the 17L single shot and the 10L single shot, both set up with software consistent with running Adaspor Single Shot chemistry.

Models chosen

The models chosen for this study are:

- Fujinon EC 250 HL5
- Fujinon EC 410 HL
- Olympus XCF H160 A4L

The endoscopes chosen are representative of those most difficult to rinse.

Experimental Design

The endoscopes were put through standard Advantage AER cycles using Adaspor Single Shot High Level Disinfectant in the machine and hooked up to a waterline treated with Sanidose. Following the FDA guidelines, the endoscopes were immediately exhaustively extracted for 24 hours to remove residues. Approximately 24 hours after the completion of the first extraction, the extraction was repeated for a shorter time (4 hour extraction). The total rinse volume was kept as low as possible (in order to keep any residuals as concentrated as possible). The rinse volumes were recorded for the calculation of the total mg load of PAA. The eluents were analyzed first by testing the eluents for PAA by using Minntech PAA Residual strips (catalog#78258), which are sensitive in the 1 ppm to 500 ppm range. No amounts equal to or greater than 50 ppm were detected, therefore no titration was performed, as indicated in the original protocol.

Adaspor Single Shot Part A lot 19907 and Adaspor Single Shot Part B lot 19907 were used in the systems during the study. Renalin 100 lot 200363 was used for the Sanidose system. Renalin 100 has the same chemical formulation as Sanidose chemistry.

Experimental Procedure

The experimental procedure documented in the original protocol QP 201921 was followed without modification. Baseline extractions were performed on each endoscope prior to running a cycle in the system to confirm the absence of PAA prior to experimental exposure to chemical.

Results

The detected levels of hydrogen peroxide are listed in the table below. Hydrogen peroxide concentrations in the Adaspor Single Shot chemistry are five times higher than the PAA concentrations. Taking the total volume of extraction fluid for each endoscope and then dividing the peroxide number

by five, generates the PAA value. The volumes of extraction fluid for each endoscope were as follows: Fujinon EC 250 HL5-450 ml (0.45L); Olympus XCF H160 AYL-650 ml (0.65L); Fujinon EC 410 HL-625 ml (0.625L). Total mg area calculated by ppm concentration multiplied by volume in liters (ppm=mg/L).

Table 1: 17L Advantage System Results

Endoscope	Condition	Detected H ₂ O ₂ (ppm)	Total mg H ₂ O ₂	Equivalent Total mg PAA
Fujinon EC 250 HL5	Baseline	0	0	0
Olympus XCF H160 AYL	Baseline	0	0	0
Fujinon EC 410 HL	Baseline	0	0	0
Fujinon EC 250 HL5	24 hr post-exposure	3	1.35	0.27
Olympus XCF H160 AYL	24 hr post-exposure	3	1.95	0.39
Fujinon EC 410 HL	24 hr post-exposure	3	1.875	0.38
Fujinon EC 250 HL5	4 hr post-exposure	0	0	0
Olympus XCF H160 AYL	4 hr post-exposure	0	0	0
Fujinon EC 410 HL	4 hr post-exposure	0	0	0

Table 2: 10L Advantage System Results

Endoscope	Condition	Detected H ₂ O ₂ (ppm)	Total mg H ₂ O ₂	Equivalent Total mg PAA
Fujinon EC 250 HL5	Baseline	0	0	0
Olympus XCF H160 AYL	Baseline	0	0	0
Fujinon EC 410 HL	Baseline	0	0	0
Fujinon EC 250 HL5	24 hr post-exposure	3	1.35	0.27
Olympus XCF H160 AYL	24 hr post-exposure	1	0.65	0.13
Fujinon EC 410 HL	24 hr post-exposure	3	1.875	0.38
Fujinon EC 250 HL5	4 hr post-exposure	0	0	0
Olympus XCF H160 AYL	4 hr post-exposure	0	0	0
Fujinon EC 410 HL	4 hr post-exposure	0	0	0

Conclusion

The maximum allowable PAA residue on the endoscope was set to 7050 mg total and the maximum allowable hydrogen peroxide residue on the endoscope was set to 5950 mg total in the original protocol based on a review of toxicological data. The highest hydrogen peroxide value detected in this study was 1.95 mg. The highest PAA value detected in this study was 0.39 mg. Both of these values are substantially below the acceptable limits. This indicates that endoscopes reprocessed with Adaspor Single Shot HLD in systems using Sanidose treated waterlines area safe for both patient and health care worker.

Protocol Changes

There were no changes to this protocol.

Records

All raw data, documentation, protocols, interim and final reports will be retained in the archives at Minntech Corporation, 14605 28th Avenue North, Minneapolis, Minnesota 55447.

For additional information on Sanidose please see the following documents:

- Sanidose Delivery System Installation Instructions (50096-838)
- Sanidose Directions for Use (50096-821)
- Sanidose Test Strips Directions for Use (50096-822)
- Sanidose Material Data Safety Sheet (MSDS) (50095-050)