

A Report on the Widespread Inadequate Reprocessing of Endoscope Air/Water and Suction Valves by Healthcare Facilities

Nova Biologicals, Inc., August 18, 2011

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## **Abstract**

Reprocessed and patient-ready endoscope valves were submitted to Nova Biologicals, Inc. (Nova) for laboratory testing. Endoscopy facilities located in twenty (20) states throughout the United States sent reprocessed, patient-ready valves directly to Nova for testing. Sixty-four (64) air/water valves and sixty-four (64) suction valves were submitted and tested. Included in this total were air/water and suction valves manufactured by Olympus, Pentax, and Fujinon.

Test results show widespread, inadequate reprocessing of air/water and suction valves by healthcare facilities.

Bacteria, yeast, molds, and/or bacterial spores were detected on seventy-two (72)(56.3%) of the valves tested; endotoxin/pyrogen was detected on twenty-five (25)(19.5%) of the valves tested; and reprocessing chemical residue was detected on ninety-one (91)(71.1%) of the valves tested.

Study results show a significant number of reprocessed and patient-ready valves were contaminated with either pathogenic microorganisms, objectionable microorganisms, endotoxin/pyrogen from gram negative bacteria, or reprocessing chemicals. Results also show that a significant number of reprocessed valves were not reprocessed according to recommended practices for high-level disinfection as described by the U.S. Food and Drug Administration (USFDA) and the American Society for Gastrointestinal Endoscopy (ASGE).(1)(4) Additionally, study results show that a significant number of reprocessed and patient-ready valves were not reprocessed according to the guidelines and procedures published and distributed by endoscope manufacturers i.e. Olympus, Fujinon, and Pentax. (5)(13)(14)

Pathogenic and objectionable microorganisms detected on the reprocessed valves included *Staphylococcus aureus*, *Staphylococcus species, not aureus*, *Escherichia coli*, *Bacillus species*, *Corynebacterium species*, *Pseudomonas species, not aeruginosa*, *Cladosporium species(mold)*, and *Alternaria species(mold)*. The U.S. FDA reports the presence of pathogenic and objectionable microorganisms indicates improper reprocessing and/or improper environmental controls. (4)

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The presence of these types of microorganisms also represents a threat to human health and safety because of either their known pathogenicity (e.g. *Staphylococcus aureus*, *Escherichia coli*) or their known status as opportunistic pathogens (e.g. *Pseudomonas species*, *Staphylococcus species*). (9)  
Objectionable microorganisms (e.g. *Corynebacterium species*, *Alternaria species (mold)*) are indicators of improper reprocessing and demonstrate high-level disinfection has not been achieved. (16)

Objectionable microorganisms and their importance to infection prevention and control in flexible endoscopy are a focus of The Association for Professionals in Infection Control and Epidemiology (APIC). APIC recognizes the role of objectionable microorganisms in healthcare acquired infections and emphasizes the need to use endoscopic accessories (e.g. air/water and suction valves) that have been meticulously cleaned and high-level disinfected. Detection of objectionable microorganisms reinforces the need for endoscopy facilities to strenuously and effectively pursue APIC's focus on preventing and controlling infections in flexible endoscopy. (2)

The presence of endotoxin/pyrogen and reprocessing chemical residue indicates improper valve reprocessing. Properly reprocessed valves should have non-detectable levels of endotoxin/pyrogen and reprocessing chemical residue. Endotoxin/pyrogen is a cell wall component of gram negative bacteria and its presence on reprocessed valves demonstrates the presence of gram negative bacteria and/or gram negative bacterial residue. The presence of reprocessing chemical residues is a direct indication of inadequate reprocessing i.e. inadequate washing and rinsing of the used valves. (7)

### **Study Summary**

Study results show that throughout the U.S. there is widespread use of inadequately reprocessed endoscope air/water and suction valves. Results also show that a significant number of reprocessed, patient-ready air/water and suction valves are either microbiologically, endotoxin/pyrogen, or chemically contaminated and do not meet the high-level disinfection criteria for semi-critical medical devices as established by the U.S. Center for Disease Control and Prevention (CDCP) and the U.S. Food and Drug Administration (U.S. FDA). Use of pathogenic and objectionable microorganism contaminated valves also presents infection prevention and control dilemmas for endoscopy facilities.

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## **Introduction**

With studies showing medical errors, including healthcare-associated infections (HAI), responsible for 44,000 to 98,000 deaths in the United States annually, infection control practitioners are intensifying their efforts to identify problem areas within healthcare facilities [Centers for Disease Control and Prevention (CDC), 2011].

Endoscopy suites are being assessed and evaluated as potential reservoirs for pathogenic and objectionable microorganisms. Infection control practitioners are finding that detailed manufacturer's guidelines for equipment reprocessing and disinfection are not being followed and that approximately 1 out of every 20 patients will contract an HAI. (7) While the complete burden of HAIs cannot be uniformly attributable to improper endoscope valve reprocessing, failure to follow established guidelines for reprocessing has resulted in the transmission of infectious agents causing serious patient injury and/or death. (3)

The design of re-useable endoscope air/water and suction valves make them difficult to clean and disinfect i.e. reprocess. These difficulties are manifested by the presence of intricately designed valve components that impede or prevent proper cleaning prior to high-level disinfection. (1)

With this in mind, laboratory studies were initiated with the intent of accomplishing the following:

1. Isolate and identify bacteria, yeast, and fungi present on sixty-four (64) air/water valves and sixty-four (64) suction valves that had been reprocessed and deemed patient-ready by endoscopy practitioners.
2. Determine the level of pyrogen/endotoxin in eluates (extracts) collected from these valves following rinsing with pyrogen-free sterile water.
3. Determine the pH level of eluates (extracts) collected from these valves following rinsing with pyrogen-free sterile water.

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## **Methods and Materials**

### *Sources of Air/Water and Suction Valves*

A total of sixty-four (64) re-useable air/water valves and sixty-four (64) suction valves were tested. Upon the request of the author and with the approval and cooperation of supervisory personnel from each participant endoscopy service, all valves were shipped via overnight courier service to Nova Biologicals, Inc. Nova conducted all of the testing reported in this paper using U.S. Food and Drug Administration-recognized Good Laboratory Practices (GLP). All valves were received for testing between December, 2010 and April, 2011. Testing of each valve was instituted within 18 hours of receipt of each valve at Nova. Each valve was submitted in an individual sterile plastic bag and each valve was tested separately. Participant endoscopy services were selected based on the availability of valves for testing and their desire to participate in the study.

94.8% of the valves tested were submitted by endoscopy facilities using Olympus equipment, 3.5% by facilities using Fujinon equipment, and 1.7% by facilities using Pentax equipment. Endoscopy services submitting valves for testing were located in various areas of the U.S., including Kentucky, Virginia, Pennsylvania, Missouri, Colorado, Arizona, Indiana, Louisiana, Mississippi, California, Washington, Wisconsin, Oregon, Ohio, Texas, Illinois, Florida, Alabama, Kansas, Arkansas, and Washington, D.C.

### *Isolation and identification of bacteria, yeasts, and fungi*

Bacteria, yeast, and fungi (microorganism) isolation and identification was conducted according to methods found in U.S. Pharmacopeia/National Formulary 32/27, 2009, Chapter <61> and Manual of Clinical Microbiology, American Society for Microbiology, 9<sup>th</sup> Edition, 2007.

### *Pyrogen/Endotoxin Determinations*

Endotoxin testing was conducted according to U.S. Pharmacopeia/National Formulary 32/27, 2009, Chapter <85>.

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## *pH Determinations*

pH determinations were conducted according to U.S. Pharmacopeia/National Formulary 32/27, 2009, Chapter <791>.

## **Results – See Appendix**

### Table 1: Microorganisms Detected and Identified From Air/Water Valves

Test results show that 56.3% (36 of 64) air/water valves were contaminated with either pathogenic microorganisms, objectionable microorganisms, or molds.

### Table 2: Microorganisms Detected and Identified From Suction Valves

Test results show that 56.3% (36 of 64) suction valves were contaminated with either pathogenic microorganisms, objectionable microorganisms, or molds.

### Table 3: Pyrogen/Endotoxin Levels Detected From Air/Water Valves

Test results show that 10.9% (7 of 64) air/water valves were contaminated with pyrogen/endotoxin.

### Table 4: Pyrogen/Endotoxin Levels Detected From Suction Valves

Test results show that 28.1% (18 of 64) air/water valves were contaminated with pyrogen/endotoxin.

### Table 5: pH Values Detected From Air/Water Valves

Test results show that 73.4% (47 of 64) air/water valves were contaminated with reprocessing chemicals.

### Table 6: pH Values Detected From Suction Valves

Test results show that 68.8% (44 of 64) air/water valves were contaminated with reprocessing chemicals.

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*Brief Description of Detected and Identified Microorganisms(9)*

Microorganism	Description
<u>Bacillus</u> species	Commonly found in the general environment including soil, air, dust, water, and decaying matter. It is rarely associated with infectious disease.
<u>Staphylococcus</u> species, not aureus <i>S. capitis</i> , <i>S. ureolyticus</i> , <i>S. caprae</i> , , <i>S. cohnii</i> , <i>S. epidermidis</i> , <i>S. equorum</i> , <i>S. gallinarum</i> , <i>S. haemolyticus</i> , <i>S. hominis</i> , <i>S. novobioceticus</i> , <i>S. hyicus</i> , <i>S. intermedius</i> , <i>S. lugdunensis</i> , <i>S. pasteurii</i> , <i>S. saccharolyticus</i> , <i>S. saprophyticus</i> , <i>S. schleiferi</i> , <i>S. coagulans</i> , <i>S. sciuri</i> , <i>S. simulans</i> , <i>S. warneri</i> , <i>S. xylosus</i>	Common members of the normal flora of skin and mucous membranes. Its large numbers and ubiquitous distribution make it one of the most commonly isolated organisms in the clinical laboratory. While at one time the appearance of <u>Staphylococcus</u> species, not aureus in clinical material could be dismissed as contamination, it is now one of the most important agents of healthcare associated infections. Immunosuppressed or neutropenic patients are particularly at risk, as are individuals with indwelling catheters or prosthetic devices. It can also cause endocarditis in individuals with previous heart valve damage. The hydrophobic nature of the organism's cell surface facilitates its adherence to synthetic devices as well as damaged heart valves. Following initial colonization, a copious amount of extracellular polysaccharide or slime is synthesized, forming a protective biofilm around the colony. Because many isolates are multiple antibiotic resistant, these infections are very serious and can even be fatal.

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Staphylococcus aureus	Often simply called "staph" (pronounced "staff") bacteria. Staph bacteria can live harmlessly on many skin surfaces, especially around the nose, mouth, genitals, and rectum. But when the skin is punctured or broken for any reason, staph bacteria can enter the wound and cause an infection. Staph bacteria can cause folliculitis, boils, scalded skin syndrome, <u>impetigo</u> , <u>toxic shock syndrome</u> , <u>cellulitis</u> , and other types of infections.
Molds (fungus)	Commonly found in the soil and environment.
<u>Corynebacterium</u> species	In general, <u>Corynebacterium</u> species are bacteria commonly found on the skin and mucous membranes and in the gastrointestinal tracts of humans, mammals, and some other animals.
<u>Escherichia coli</u>	<u>E. coli</u> is a Gram negative bacillus and normal inhabitant of the human intestinal tract. It is frequently associated with urinary tract infections and other infectious processes.
<u>Cladosporium</u> species	<u>Cladosporium</u> is a fungus commonly found in the general environment including soil, air, dust, water, and decaying matter. It is rarely associated with infectious disease. <u>Cladosporium</u> is an indicator of fungal contamination.
<u>Gaffkya tetragena</u>	<u>Gaffkya</u> is a Gram positive cocci that has been implicated in endocarditis and other infectious processes.

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## **Discussion**

Test results show that 56.3% of the air/water and suction valves tested were contaminated with various microorganisms. Contaminants included known human pathogens, documented opportunistic pathogens, objectionable microorganisms, and microorganisms commonly found in soil, dust, and water. Test results demonstrate that a high percentage of the valves tested failed to meet CDC and U.S. FDA criteria for high level disinfection (6). Test results also support the report of Gorse and Messner (6) that showed compliance with various aspects of endoscope reprocessing guidelines ranged from 67% to 93%; demonstrating that compliance with reprocessing guidelines can be improved. Additionally, the data reported herein indicates that the level of non-compliance with various aspects of valve reprocessing may be significantly greater than previously reported.

Failure to comply with accepted guidelines for the reprocessing of air/water and suction valves results in the use of microbiologically contaminated equipment for patient care. The use of such equipment establishes a known pathway for the transfer of potentially pathogenic microorganisms from one patient to another with the distinct possibility of initiating an infectious disease in an otherwise healthy patient. (3)

Pyrogen/endotoxin testing was used to detect and quantify bacterial endotoxins that may be present on air/water and suction valves. Endotoxin/pyrogen is a cell wall component of gram negative bacteria and its presence on reprocessed valves demonstrates the presence of gram negative bacteria and/or gram negative bacterial residue. Endotoxins are gram negative bacterial toxins with the capability to elicit a febrile reaction in a patient. The Method Detection Limit was 0.06 Endotoxin Units per milliliter of eluate/extract. Test results show that 19.5% of the valves tested had pyrogen/endotoxin levels greater than the Method Detection Limit.

The presence of pyrogens/endotoxins on valves creates the potential for introducing these agents into a patient, resulting in a febrile reaction. Febrile reactions may occur naturally following an endoscopic procedure and are a recognized side effect of these procedures. However, the use of pyrogen/endotoxin contaminated valves enhances the possibility of a febrile reaction by increasing the patient's exposure to pyrogen/endotoxin. The use of endotoxin contaminated valves establishes a known and deliberate pathway for the transfer of

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endotoxins to a patient, potentially resulting in a febrile reaction. Additional research is needed to determine the link between the incidence of febrile reactions in patients and the use of endotoxin-contaminated valves.

pH testing of valve eluate/extract was used to determine the presence of alkaline or acid chemicals on the valves. Results that are  $\pm 0.2$  pH units of the pH control indicate reprocessing chemicals (e.g. enzymes, detergents, and disinfectants) have not been completely removed from the valves. Test results show that 71.1% of the valves tested had pH values that were outside the acceptable range of  $\pm 0.2$  pH units as compared to the pH control, indicating the presence of reprocessing chemicals on the valves. These findings support the position that showed compliance with various aspects of endoscope reprocessing guidelines ranged from 67% to 93% (6). Additionally, chemical colitis can occur as a result of accidental contamination of endoscopes. Most cases of chemical colitis have occurred after contamination with glutaraldehyde and/or hydrogen peroxide. (15)

### **Conclusion**

Results suggest microbiologically contaminated, endotoxin contaminated, and improperly re-processed endoscope air/water and suction valves are routinely used in the United States by practitioners conducting endoscopic examinations. Test results demonstrate that the majority of patient-ready, re-usable endoscope air/water and suction valves do not meet the high-level disinfection criteria for semi-critical medical devices as established by the U.S. Center for Disease Control and Prevention (CDCP) and the U.S. Food and Drug Administration (U.S. FDA). Additional research is indicated to determine the reasons and causes for the observed levels of microbiological, pyrogen/endotoxin, and chemical contamination of endoscope air/water and suction valves.

Given the intrinsic complexity of endoscope air/water and suction valves and the demonstrated difficulties associated with re-processing the valves it is prudent and in the best interest of the patient to use single-use/disposable air/water and suction valves.



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## **Appendix**

### Table 1: Microorganisms Detected and Identified From Air/Water Valves

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