Introduction

Increasing the level of sanitation and sterility of health-care environments is critical in reducing the transmission of health-care associated infections. The Center for Disease Control estimates that, in the United States, 5% of patients admitted into a hospital are likely to acquire an infection while receiving care, culminating in 1.7 million infections and approximately 99,000 deaths each year as a result of preventable diseases acquired within a healthcare facility[1]. The annual cost burden associated with the treatment of these infections is estimated to be $4.5 billion.

A worldwide study published in the *Journal of the American Medical Association* (JAMA) surveyed the infection status of over 13,000 patients from 1,200 Intensive Care Units (ICUs) in 75 countries. The survey found that more than half of all patients had acquired an infection and those that were infected were more than twice as likely to die as uninfected patients. In addition to increased mortality, it was found that the risk for acquiring an infection increases the longer a patient stays in the ICU. Of those patients that were in the ICU for a day or less, only 32% acquired infections, while of those patients that stayed in the ICU for more than a week 70% developed infections (*JAMA,* 2009*;* 302(21): 2285-2388).

Healthcare facilities present repeated opportunities for the transmission of infectious pathogens from patient-to-patient, via direct and indirect routes including: contaminated devices, equipment, supplies, environmental surfaces, as well as from the hands or gloves of medical personnel. The growing concern of healthcare professionals in regard to antibiotic resistant pathogens is creating an increase in desire for disposable hygienic barriers for commonly used equipment, such as blood pressure cuffs (Dialysis & Transplantation, 2002; 31(5): 337-341).

While healthcare professionals employ strict infection control measures including hand-washing and frequent surface disinfection, these measures are insufficient as the number of

[1] Healthcare Associated Infections in North Carolina, N.C. Department of Health and Human Services, 2012

hospital acquired infections each year continues to rise (*JAMA,* 2009*;* 302(21): 2285-2388). Frequently touched surfaces in ICUs are heavily contaminated with anywhere from several hundred to over ten thousand colony forming units of infectious bacteria. These surfaces are touched by patients, families, doctors, nurses, and cleaning staff and it is exactly here where an added line of defense, specifically in the blood cuff application, has been made available.

Upon admission into a medical facility (i.e. hospital, physician's office) it is common practice to obtain the blood pressure of each individual patient using a sphygmomanometer. The blood pressure cuff is secured around a patient's arm, usually contacting bare skin which can be colonized with a plethora of microorganisms including, but not limited to, *Methicillin Resistant Staphylococcus aureus (MRSa), E. coli*, *P. aeruginosa, and S. aureus.*

The capacity of blood pressure cuffs to act as vehicles of Hospital Acquired Infections (HAIs) has been recognized (International Journal of Medical Sciences, 1991; 160(4):112-3). In an important study, blood pressure cuffs from various inpatient settings were found to have bacterial colonization rates of 81-100%. In addition, 45.7% of the "clean" cuffs were contaminated with organic and/or inorganic substances. The patient contact surfaces of the cuffs were found to be contaminated twice as often as the non-patient sides[2]. In a prior peer-reviewed study , 18 hospital units "revealed" a level of contamination reaching 100 or more colony-forming units per 25 cm^2 on 138 blood pressure cuffs out of 203; 92 were contaminated on the inner sides and 46 on the outer sides of the cuffs. The highest rates of contamination occurred on the patient contact side of BP cuffs kept in intensive care units (ICUs) (20 [83%] of 24) or on nurses' trolleys (27 [77%] of 35). None of the 18 BP cuffs presumed to be clean (i.e., those that had not been used since the last decontamination procedure) had a high level of contamination. Potentially pathogenic microorganisms were isolated from 27 (13%) of the 203 BP cuffs: 20 of these microorganisms were Staphylococcus aureus, including 9 methicillin-resistant strains. The highest rates of contamination with potentially pathogenic microorganisms were observed on cuffs used in ICUs and those kept on nurses' trolleys." (*Infection Control and Hospital Epidemiology*, 2006; 27(9): 889-998). Webb et al. reported a study conducted on blood pressure cuffs before and after use showing the rate of microbial transfer from cuff to patient. Eleven blood pressure cuffs were swabbed before and after use to determine the average bacterial count present on both groups. It was determined that there was a 67% reduction in the number of

[2] Stemicht AL. Significant bacterial colonization of the surface of non-disposable sphygmomanometer cuffs and re-used disposable cuffs. Comet Med. Ctr., New York, NY 10021

bacteria from before use to after, showing that the bacteria were transferred from the cuff to the patients' skin or clothing (Dialysis & Transplantation, 2002; 31(5): 337-341). As one of the most commonly used pieces of equipment within healthcare facilities, the blood pressure cuff has been shown to carry significant risk of pathogen transmission from patient to patient and therefore the methods of disinfecting the cuff are of upmost importance in order to reduce the prevalence of HAIs.

Challenges to Current Sanitation Approach

In an attempt to reduce transmission of health-care associated infections from patient to patient via blood pressure cuffs, few solutions have been tried within the medical industry, but have proven unsuccessful. Single patient, disposable blood pressure cuffs are at this time being utilized within numerous health-care facilities, yet are often not being used as directed due to logistical and coordination issues. The infrequency of changes could be due to the disposable cuffs not being cost-effective enough and having inadequacies when it comes to specific pathogen mitigation on the cuff itself. Hence, in several instances, blood pressure cuffs designed for single patient use, due to high cost, are currently being used for extended periods of time over multiple-patients.

Sanitizing wipes, due to convenient access and ease of use, are the preferred disinfection method of healthcare providers throughout the health-care field. Various wipes have shown efficacy against a broad range of microorganisms, under the proposed indications for use, which typically include a lengthy contact time (up to 10 minutes). For most disinfectants, including combinations of bleach, isopropyl alcohol, quaternary amines, ethanol, and phenol, the required contact time extends beyond the time it takes for the product to dry. Achieving specified levels of disinfection therefore would require continuous application of the disinfectant over an extended period of time. The time necessary for proper sanitation is rarely given and staffing limitations often lead to inappropriate use of disinfectants (Technical Bulletin on Contact Times, Virox). Sanitization through the use of wipes is often omitted at times of elevated patient influx, increasing the patients' risk of contracting an infection.

Disposable blood pressure barriers have been developed for single patient use. The barrier acts as just that between the patient and the blood pressure cuff. In a recent study, heterotrophs, S. *aureus*, and MRSA were reduced in concentration on blood pressure cuffs by 76%, 83%, and 100%, respectively, with the use of a single patient dedicated, single use blood pressure cuff barrier as compared to cuffs without the barrier. The

reduction in bacterial concentration on the cuffs is a direct result of the bacteria being transferred from the cuff to the barrier. If the barrier was not present, the bacteria would then be transferred to the skin or clothes of the patient (Dialysis & Transplantation, 2002; 31(5): 337-341).

Though the barriers have been proven effective, widespread adoption and usage has not occurred since they present a time burden on medical staff and assistants as well as a cost burden on facilities, as they have to be changed between patients.

Biovation's Blood Pressure Cuff Shield

Resultant of the increasing demand from healthcare professionals, Biovation has developed the BioArmour™ Blood Pressure Cuff Shield, an innovative and cost effective global solution to the transmission of pathogens from blood pressure cuffs. The BioArmour™ shield is integrated with an antimicrobial formulation which assists healthcare providers in providing patient safety in a cost-effective and very easy-to-use fashion. The design of the product is a combination of best practices in the healthcare field and augments the current methodologies present.

The shield is designed to be attached to the blood pressure cuff preventing direct contact of the patient's skin with the blood pressure cuff. The durable design will allow for continuous use through inflation and deflation cycles for 24 hours while providing a hygienic antimicrobial barrier between the patient and the cuff. Testing has demonstrated that the BioArmour™ Blood Pressure Cuff Shield will not adversely affect the collection of blood pressure data, allowing for reliable and accurate blood pressure measurement.

The BioArmour™ shield is constructed of patented non-woven technology comprised of biodegradable and biocompostable biopolymer fibers impregnated with non-leaching, FDA and EPA approved antimicrobial agents to mitigate the propagation of pathogens. Contaminant pathogens are mitigated by the blood pressure cuff shield allowing the shield to be used for as many patients as necessary in a 24 hour period, safely and reliably. The shield, prescreened for antimicrobial efficacy in accordance with AATCC100, demonstrated a significant reduction of the pathogenic microorganisms shown in *Table 1* below.

Table 1: Antimicrobial Efficacy of the BioArmour™ Blood Pressure Cuff Shield

Test Article Identification	Organism Count (CFU/mL) Zero Time	Organism Count (CFU/mL) 24 Hour	Log Reduction	Percent Reduction
TP02102013– MRSA (Methicillin-resistant *Staphylococcus aureus*)	2.30 x 105	$<1.00x10^2$	5.48	>99.999%
Control - MRSA	2.88 x 105	$>3.00x10^7$		
TP02102013 – Klebsiella pneumoniae (Kp)	1.02 x 105	$<1.00x10^2$	5.48	>99.999%
Control – Kp	1.03 x 10^5	$>3.00x10^7$		
TP02102013 – Pseudomonas *aeruginosa* (Pa)	2.73 x 10^5	$<1.00x10^2$	5.48	>99.999%
Control- Pa	$2.23x10^5$	$>3.00x10^7$		
TP02102013 – VRE (Vancomycin resistant Enterococcus)	$3.30x10^5$	$<1.00x10^2$	5.48	>99.999%
Control – VRE	4.30 x 10^5	$>3.00x10^7$		
TP02102013 – Acinetobacter *baumannii* (Ab)	3.00 x 10^5	$<1.00x10^2$	5.48	>99.999%
Control- Ab	2.90 x 10^5	$>3.00x10^7$		
TP02102013 – Candida *albicans* (Ca)	2.53 x 10^5	$<1.00x10^2$	5.38	>99.999%
Control- Ca	3.56 x 10^5	$>3.00x10^7$		
Clostridium *difficile (*Cd)	$1.15x10^7$	$1.69x10^5$	1.83	98.3%
Control- Cd	$1.23x10^7$	$4.27x10^5$		

The Blood Pressure Cuff Shield is currently undergoing testing in accordance with the FDA (Class II) and CE (Class I) guidelines and regulations to ensure that the product is both safe and effective. The device is being assessed for biocompatibility including, cytotoxicity, sensitization, and irritation, per ISO 10993 to validate that the product is innocuous for skin contact. A human factors and usability validation study will ensure that the instructions and warnings are effective and easy to follow. Antimicrobial efficacy tests for the Blood Pressure Cuff Shield are inclusive of a Minimum Effective Concentration study, to determine the minimum amount of chemistry needed within the product to achieve the a 99.99% reduction

of pathogens; and Antimicrobial Textile Tests (AATCC 100) to validate the products capacity to mitigate infectious microbes transferred from the skin to the shield in the worst case (soiled) scenario. The microorganisms to be tested are those found to be prevalent on surfaces and equipment and are known to be detrimental when transferred from patient to patient, inclusive of: *MRSA*, *VRE*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa, Candida albicans*, *Acinetobacter baumannii,* and *Clostridium difficile.* Additionally, the material is being assessed through a leachability study to ensure that the antimicrobial particles will not leach from the product.

The easy to use and cost effective BioArmour™ Blood Pressure Cuff Shield will allow hospitals and healthcare facilities to continue to implement and demonstrate proactive measures for infectious disease reduction and control. Once FDA and CE clearance have been achieved, projected to be by Oct 2015, this product will be made available in US, EU and international markets allowing healthcare professionals to heighten the level of patient safety, globally.

BioArmour™ Blood Pressure Cuff Shield Benefits:

- Mitigates risk of infectious pathogen transmission from the blood pressure cuff.
- Manufactured for multiple patient use through a 24 hour period.
- Compostable and green technology.
- The anti-fray shield is durable and will withstand continual use.
- Robust through to multiple inflation-deflation cycles.
- Does not adversely affect the collection of blood pressure data.
- Allows hospitals and healthcare facilities to implement and demonstrate proactive measures for infectious disease reduction and control.

Contact Us

Biovation's expertise is in product solutions in the healthcare markets, specifically infection control and advanced wound care, and we look forward to partnering up with you. We invite you to contact us **solutions@biovation.com** to discuss how Biovation can help you with our portfolio of technologies and solutions.

Revision Level: A, July 23, 2014