

CLINICAL

BYOTROL™

CLINICAL EVIDENCE SUMMARY



EVIDENCE



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A CLEAN HOSPITAL ENVIRONMENT NOT ONLY PROVIDES PLEASANT SURROUNDINGS FOR PATIENTS, VISITORS AND HEALTHCARE STAFF BUT ALSO IMPLIES A WELL RUN ORGANISATION WITH GOOD STANDARDS OF CARE.¹ BOTH PATIENTS AND THE PUBLIC CONSISTENTLY RATE A CLEAN HOSPITAL IN THE TOP FIVE THINGS THEY WISH TO SEE IN A MODERN HEALTH SERVICE.¹

There is a large body of clinical evidence available that identifies links between poor environmental hygiene and the transmission of micro-organisms causing Healthcare Associated Infection (HCAI).²

The most common nosocomial pathogens may survive on surfaces for weeks or months and can therefore be a source of direct and indirect transmission unless regular surface disinfection is carried out.³

MRSA	7 days - 7 months
<i>C. difficile</i> (spores)	5 months
VRE	5 days - 4 months
Norovirus	8 hours - 7 days
<i>Acinetobacter</i>	3 days - 5 months

Effective cleaning removes dust and soil, large numbers of micro-organisms (bioburden) and the organic matter (i.e. faeces, blood, urine etc) that may harbour them.⁴ Therefore high standards of cleanliness will help reduce the risk of cross infection⁴ and a clean environment will reduce the number and viability of microbes present thus contributing to the control of infection.

HEALTHCARE ASSOCIATED INFECTION

HCAI is a worldwide problem. At any one time more than 1.4 million people around the world are suffering from infections contracted in healthcare settings. Between 5 -10% of patients admitted to hospital in developed countries acquire infections as a result of their stay and the risk is many times higher in developing countries.⁵ In the European Union approximately 3 million instances of infection and 50,000 deaths occur each year as a result of HCAI.⁶ In the UK at least 300,000 patients develop an HCAI during their stay in hospital with an estimated 5,000 patients dying as a direct result of these infections and a further 15,000 patient deaths reporting HCAI as a major contributory factor.⁷

At a national level, the estimated costs for treating HCAI are US\$ 4.5 - 5.7 billion in the United States and £1 billion in the UK.^{5,7}

The impact of HCAI for patients and organisations are far reaching:

Consequences for the patient	Consequences for the healthcare facility
Complicate their existing medical condition	Increase cost*
Extend their stay in hospital	Impact on bed availability - therefore lost opportunity costs to facility**
Cause discomfort, pain as well as anxiety and stress for both patient and their families	Increase staff workload
Cause loss of earnings	Present a risk to other patients and on occasion staff
Reduce chances of a successful recovery	Increased risk of litigation

* HCAI cost the NHS an estimated £1 billion/year, with each HCAI costing between £4,000 - £10,000.¹

** On average patients length of stay is increased by 10 days for MRSA bacteraemia and 21 days for CDI.¹



LABORATORY TEST RESULTS

SUMMARY

Test	Test conditions	Test organisms	Outcome / Conclusion
Quantitative suspension test for sporicidal activity ⁹ EN13704:2002	Temperature = 20°C Contact time = 5 min 'Dirty conditions'	<i>Bacillus subtilis</i> (ATCC 6633) <i>Bacillus stearothermophilus</i> (NCTC 10339) <i>Clostridium difficile</i> (NCTC 11209)	Log ₁₀ ³ reduction in viability for each test organism PASS ALL CRITERIA
Quantitative suspension test for bactericidal activity ¹⁰ EN1276:1997	Temperature = 20°C Contact time = 1 min 'Dirty conditions'	<i>Pseudomonas aeruginosa</i> (ATCC 15442) <i>Escherichia coli</i> (ATCC 10536) <i>Staphylococcus aureus</i> (ATCC 6538) <i>Enterococcus hirae</i> (ATCC 10541) <i>Staphylococcus aureus</i> (NCTC 12493 MRSA)	Log ₁₀ ⁵ reduction in viability for each test organism PASS ALL CRITERIA
Quantitative suspension test for fungicidal activity ¹¹ EN1650:1998	Temperature = 20°C Contact time = 1 min 'Dirty conditions'	<i>Candida albicans</i> (ATCC 1023) <i>Aspergillus niger</i> (ATCC 16404)	Log ₁₀ ⁴ reduction in viability for each test organism PASS ALL CRITERIA
Virucidal activity test ¹²	Temperature = 20°C Contact time = 5 min 'Clean conditions'	<i>Feline coronavirus</i> (FCoV) (SARS surrogate) <i>Feline calicivirus</i> (FCV) (Human Norovirus surrogate)	Log ₁₀ ³ and Log ₁₀ ⁴ reduction in viability for FCoV and FCV respectively. PASS
Quantitative suspension test for bactericidal activity ¹³	Temperature = 20°C Contact time = 10 min 'Dirty conditions'	<i>Mycobacterium smegmatis</i> (TB simulant)	Log ₁₀ ⁶ reduction in viability PASS
Quantitative suspension test for bactericidal activity ¹⁴ EN1276:1997	Temperature = 10°C Contact time = 5 min 'Dirty conditions'	<i>Listeria monocytogenes</i> <i>Salmonella Typhimurium</i> <i>Escherichia coli</i> O157:H7 (non-toxigenic strain) <i>Yersinia enterocolitica</i>	Log ₁₀ ⁵ reduction in viability for each test organism PASS ALL CRITERIA
Chemical disinfectants and antiseptics. Hygienic hand rub ¹⁵ EN1500:1997	The artificially contaminated hands of laboratory workers	<i>Escherichia coli</i> ATCC10538	PASS ALL CRITERIA

The above table demonstrates that Byotrol™ technology is well proven with a broad spectrum microbiological kill including fungi, viruses, bacteria and bacterial spores. In addition to these laboratory test results the technology has also been proven in the clinical setting by studies undertaken by Professor Curtis Gemmell at Glasgow Royal Infirmary and at the Monroe Hospital in the USA.

THE BYOTROL™ TECHNOLOGY FACTS

MECHANISM OF ACTION

The successful association of **Bronopol**, **Polyhexamethylene Biguanide (PHMB)** and **Quaternary ammonium** compounds (quats) with a nano-polymer backbone ensures Byotrol™ technology has significant broad spectrum biocidal activity and a unique residual kill capacity. Each individual biocide is a lytic agent/membrane disruptor and is recognised as an approved, well understood, effective, broad spectrum biocide within its own right. When used together and sequestered (non-chemically bonded) to the nanopolymer backbone the biocidal effect of Byotrol™ technology is amplified above that of the individual constituent parts.

All effective disinfectants rely on a combination of contact time and toxicity. Combining the three biocides with the nano-polymer backbone significantly increases the contact time and brings about cellular death long after conventional decontamination has ceased to be effective.



A CLEAN HEALTHCARE ENVIRONMENT IS IMPORTANT FOR ALL THOSE USING THE FACILITIES.

NOT ONLY DOES IT PROVIDE PLEASANT SURROUNDINGS FOR PATIENTS, VISITORS AND HEALTHCARE STAFF, IT ALSO IMPLIES A WELL RUN ORGANISATION WITH GOOD STANDARDS OF CARE.

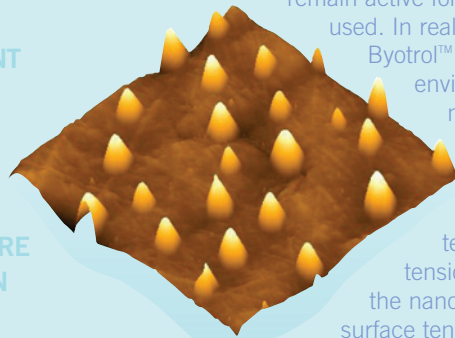


UNIQUE PROPERTIES

The typically hydrophobic nano-polymer backbone is unique and ensures the Byotrol™ technology adheres successfully to any hard surface that it is used upon. This polymer backbone, in combination with the active biocides, dries to create a water resistant biocidal nanolayer which continues to work even after the cleaning process has stopped. The technology behind Byotrol™ ensures that the biocides remain in place and effective for longer which in turn creates an incredibly hostile environment for micro-organisms.

The biocidal nanolayer is responsible for the unique, long lasting, residual efficacy associated with this technology. With ongoing, frequent use the biocidal nanolayer becomes more effective and creates a strong antimicrobial barrier which can remain active for days after the product was last used. In real terms this means that the more the Byotrol™ technology is used, the fewer environmental surfaces are available for microbes to colonise, which in turn will lead to a cleaner environment.

A further benefit of the technology is the variation in surface tension that arises due to the structure of the nano-polymer. These differences in surface tension inhibit microbial attachment to environmental surfaces and help prevent the formation of biofilm in these areas. This again helps reduce the risk of micro-organisms creating colonies within the environment where they may act as reservoirs for infection.



Variation in surface tension due to the structure of the nano-polymer

ADVANTAGES

KEY FEATURES	BENEFITS
■ Residual, durable long-lasting activity	Effective days to months even after it dries. Unlike other disinfectants it keeps working between episodes of cleaning
■ Broadband efficacy including antibiotic resistant bacteria	Effective against a multitude of micro-organisms including (but not limited to) MRSA, VRE, <i>C. difficile</i> , norovirus
■ Developed resistance extremely unlikely	The technology affects all microscopic organisms, physically damaging them and rendering all vulnerable to the biocides
■ Safe to use with low toxicity	The physical effect is targeted at microscopic levels and weakens the micro-organisms so the required biocide doses are kept to a minimum. Not considered poisonous to humans, animals or plants
■ Easy to use	Simple application via wipes, sprays, hand mousse etc
■ Environmentally friendly	Fully biodegradable - breaks down when in landfill or waste water
■ Does not contain any antibiotics	Bacteria will not develop antibiotic resistance as a result of being exposed to Byotrol™ technology
■ Does not contain heavy metals such as mercury or lead	No heavy metals will be discharged into the environment as a result of using Byotrol™ technology

CLINICAL STUDIES

CLINICAL STUDY 1 High contact sites in wards as sources of MRSA contamination

METHOD: A six month study in a single ward using a control area (one six-bed open unit + one single room) and an experimental area (one six-bed open unit + two single rooms). All areas were cleaned according to normal hospital cleaning procedures. In addition, all high contact areas in the experimental area were cleaned daily with wipes containing Byotrol™ technology.

Each week 74 high contact environmental sites were sampled and cultured for MRSA. After four months cleaning regimes were switched over with the wipes containing Byotrol™ technology being used in what was previously the control area and standard cleaning practices taking place in what was previously the experimental area.

RESULTS: At the four month time point MRSA had been identified from 48 sites (7.0%) in the experimental (Byotrol™) area and 69 sites (12.3%) in the control area. Using Byotrol™ technology on only one-fifth of surfaces in the relevant ward area significantly reduced the number of sites contaminated with MRSA. After the switchover there was a reduction in environmental MRSA in the former 'control' area and a delayed return to higher levels in the former 'experimental' area. Ten cases of nosocomial MRSA infection occurred in the first four-month period of this study, of which six were in the control area.

CONCLUSION: This study demonstrates that it was possible to reduce MRSA infection rates by the addition of a single intervention (regular use of Byotrol™ technology on high-contact sites) to the ongoing infection control practices of the hospital. The study results showed significantly reduced levels of environmental contamination in the Byotrol™-treated areas and a delayed return to the control area levels of MRSA after the four month switch-over, therefore indicating a residual efficacy when using Byotrol™ technology.¹⁶

CLINICAL STUDY 2 A weapon against superbugs

METHOD: A hard, non-porous, environmental surface (3" x 3") was used to evaluate the residual efficacy of Byotrol™ against VRE and MRSA over three consecutive days. Surfaces were treated with Byotrol™ technology as per the manufacturer's specifications. An identical surface moistened with sterile water and no disinfectant was used as a control. Surfaces were inoculated with MRSA or VRE. For three consecutive days, these surfaces were streaked with sterile swabs and then inoculated to blood agar plates to check for growth.

RESULTS: The results from the study are given in the table below.

Cleaning Agent + Innocumum	Bacterial Growth/No Growth DAY 1	DAY 2	DAY 3
No disinfectant (control) - MRSA	Growth - light and sporadic at 24 hours	Growth - moderate over test area at 48 hours	Growth - almost covers test area at 72 hours
No disinfectant (control) - VRE	Growth - sporadic at 24 hours	Growth - moderate over test area at 48 hours	Growth - full coverage of area at 72 hours
Byotrol™ - MRSA	Very sparse - could be considered no growth	No advance in growth at 48 hours	No advance in growth at 72 hours - could be considered no growth
Byotrol™ - VRE	No growth	No growth	No growth

CONCLUSION: Byotrol™ technology demonstrates residual efficacy for up to three days on environmental surfaces. Residual biocidal efficacy will prove a valuable weapon against antibiotic resistant bacteria such as MRSA and VRE. Along with appropriate antibiotic usage, effective hand washing and isolation precautions, residual disinfectants can additionally increase a facility's chance of decreasing the transmission of MRSA and VRE respectively.¹⁷

CLINICAL STUDY 3 Hospital stays superbug free for two years thanks to revolutionary British technology

Byotrol™ technology has helped create a hospital in the United States that has been free of hospital acquired MRSA, VRE and *C. difficile* for two years. Monroe hospital treats 13,000 patients every year, including 3,000 orthopaedic operations. James Ballard, Director of Infection Prevention at Monroe, puts much of this remarkable success story down to Byotrol™ technology.

Ballard undertook an initial evaluation which demonstrated the residual efficacy of Byotrol™ against VRE and MRSA over a three day period. Following this successful evaluation, Byotrol™ has been used across the hospital on a daily basis to clean hard surfaces, high contact surfaces, from patient call buttons to wheelchair handles, and extensively for hand hygiene (including visitors and staff).

Fred Price, President and Chief Executive Officer of Monroe Hospital in Bloomington, said; *"Monroe Hospital partnering with Byotrol™ has maintained an environment of zero infections since we opened our doors 24 months ago. I cannot understand why every healthcare entity that comes in contact with patients doesn't use Byotrol™? Our patients depend upon us to be "bug" free".*¹⁸



OUR WORK PROTECTS YOUR WORLD™

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