Efficacy Report Summarization for SoClean 2

April 2018

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Patent No. 9,358,316 | 9,610,373 | 9,616,147 | 9,669,124 | D719,674 | D719,673

TESTING FACILITIES:

Microchem Laboratory

Address: 1304 W. Industrial Blvd. Round Rock, Texas 78681

Phone: (512) 580-1342

Email: contact@microchemlab.com

About: Microchem Laboratory was founded in 1988 by Dr. Norman Miner, a respected microbiologist and talented formulator. Historically Microchem Laboratory focused on the research, development, and testing of high-level disinfectants. In 2014, Dr. Miner's lab was acquired by Dr. Benjamin Tanner, founder of Antimicrobial Test Labs and Cosmetic Test Labs. In 2015, the three laboratories were combined under the Microchem Laboratory name, creating one organization with deep technical expertise across a broad array of testing services. The laboratory offers testing in compliance with current Good Laboratory Practice (GLP) regulations. Clients are welcome to tour the lab, observe studies, and audit the lab's quality system.

Accreditation: ISO 17025, AAMI TIR12, AAMI TIR30, ISO 22196, ISO 11930

Biofocus LADR

Address: Berghäuser Str. 295, 45659 Recklinghausen, Germany

Phone: 023613000-121

Email: wagner@biofocus.de

About: Since its foundation in 1991, Biofocus has been working on the development and practice-oriented application of molecular biology test systems. We establish new diagnostic tests, both on customer request and on the basis of new analytical possibilities in the course of scientific progress.

Accreditation: EN ISO 9001, EN ISO17025

SUMMARY:

Protocols, test method setups, and results are included in the enclosed reports. In addition to the Biofocus 2017 test findings, included for reference is the 2012 Biofocus document.

According to Healthy Facilities Institute (www.healthyfacilitiesinstitute.com) “Log” stands for logarithm, which is the exponent of 10. For example, Log-2 represents 10^2 or 10 x 10 or 100. Log Reduction stands for a 10-fold (one decimal) or 90% reduction in numbers of live bacteria.

Another way to look at it is: 1-Log Reduction would reduce the number of bacteria 90%. This means, for example, that 100 bacteria would be reduced to 10, or 10 reduced to 1.

90%..... 1 Log reduction: Number of germs is 10 times smaller
99%..... 2 Log reduction: Number of germs is 100 times smaller
99.9%..... 3 Log reduction: Number of germs is 1000 times smaller
99.99%..... 4 Log reduction: Number of germs is 10,000 times smaller
99.999%..... 5 Log reduction: Number of germs is 100,000 times smaller
99.9999% ..... 6 Log reduction: Number of germs is 1,000,000 times smaller

Result Summary: Various pathogen species were used for disinfection testing and the SoClean 2 in all testing facilities/species resulted in a minimum average Log 3 reduction (99.9% Disinfection) with many tests performing over a Log 4 reduction (99.99% Disinfection).

Biofocus LADR
2017

Biofocus LADR
Gesellschaft für biologische Analytik mbH

Umwelt / Lebensmittelanalytik

Berghäuser Str. 295, 45659 Recklinghausen

Biofocus LADR - Berghäuser Str. 295 - D-45659 Recklinghausen

SoClean
36 Town Forest Road
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Recklinghausen, 13.07.2017

TEST REPORT B-17-05284

Document number: D-434508

Sample registration: 05.07.2017
End of analysis: 13.07.2017

Customer number: 9110

Setup 1: Desinfection with filter paper and Enterococcus faecalis

Hint:

Attention: System uses comma as decimal separator!

Method setup
A challenge of approximately 10^7 CFU/ml of bacterial spores (Enterococcus faecalis; ATCC 29212) was prepared. 100µl of the suspension was pipetted on filter paper of 1cmx2cm dimension.

6 contaminated filter papers were placed in the device to be tested (two filter papers directly in the nose nozzles of the mask, two filter papers at the front end and two at the back end of the hose.
Another contaminated filter paper served as a control and remained outside.

A Dream Station CPAP unit with mask and hose was connected with the SoClean sanitizing device according to the manufacturer's instruction.
Prior to testing, the mask and the hose were sanitized according the manufacturer's instructions.

The disinfection cycle of the SoClean Unit was started

After the waiting time, all filter papers were removed from the test device. One filter of each test position was directly cultivated on agar plates (Sojapeptone-Caseinepeptone-Agar), the other was suspended in 10ml buffered sodium chloride peptone water (pH 7.0) and cultivated in different dilutions.
The residual bacterial count was determined and the disinfection efficacy (log-10 reduction number) was calculated.

The entire process was repeated once with a new mask and hose.

Biofocus LADR
Gesellschaft für biologische Analytik mbH

Umwelt / Lebensmittelanalytik

Berghäuser Str. 295, 45659 Recklinghausen

Order number B-17-05284

Sample number: **B-17-05284-002**
Sample name: Desinfection cycle 2

Results

Parameter	Result	Unit	Test Procedures
Positive control	$5{,}6 \cdot 10^5$	KBE	²
Position sample 1	mask		²
Log-10-Reduction	4,1		²
Position sample 2	hose end		²
Log-10-Reduction	5,8		²
Position sample 3	hose front		²
Log-10-Reduction	5,8		²

Legend: Results in bold show out of limit values. <: value below limit of determination
² = Method not accredited

Assessment:

Legend for results on agar after one day cultivation (bottom picture next side):

middle: positive control from cycle 1 (top) and cycle 2

left: Cycle 1:
hose end (mask side) – top
hose front – bottom left
mask – bottom right

right: Cycle 2:
hose end (mask side) – top
hose front – bottom left
mask – bottom right

Microchem Laboratory
2017

MICROCHEM LABORATORY

STUDY REPORT

Study Title

Medical Device Disinfection Validation

Test Method

AAMI TIR12:2010

Study Identification Number

NG9051

Study Sponsor

SoClean, Inc.
36 Town Forest Road
Oxford, MA 01540

Test Facility

Microchem Laboratory
1304 W. Industrial Blvd
Round Rock, TX 78681
(512) 310-8378

AAMI TIR12: General Information

AAMI, the Association for the Advancement of Medical Instrumentation, is an internationally recognized organization that develops and publishes testing standards. AAMI TIR12 is a quantitative test method designed to evaluate the ability of a reprocessing routine to adequately disinfect a medical device.

Laboratory Qualifications Specific to AAMI TIR12

Microchem Laboratory has performed hundreds of AAMI TIR12 tests on a broad array of medical devices in order to support low, intermediate, and high level disinfection routines. The laboratory is also experienced with regard to modifying the test method as needed in order to accommodate customer needs. Every AAMI TIR12 test at Microchem Laboratory is performed in a manner appropriate for the test substances and test devices submitted by the Study Sponsor, while maintaining the integrity of the method.

Study Timeline

26/27 JUN 2017	28 JUN 2017	28 JUN 2017	30 JUN 2017	05 JUL 2017

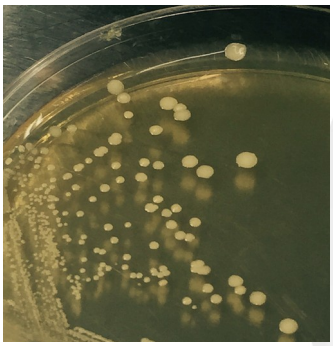
Note: *Staphylococcus* species cultures were initiated on 27 JUN 2017 and *Candida albicans* culture was initiated on 26 JUN 2017.

Test Microorganism Information

The test microorganism(s) selected for this test:

Staphylococcus haemolyticus 29970

This is a Gram-positive, spherical-shaped bacteria commonly found on both the skin of humans and animals. This bacteria is known for being the second most common bacterial isolate from human blood and has been known to cause infections in people with compromised immune systems. Typically not a public health pathogen, recent strains of this microorganism has demonstrated antibiotic resistance.



Staphylococcus hominis 27844

This is a Gram-positive, spherical-shaped bacteria commonly found on both the skin of humans and animals. This bacteria is known for producing compounds that contribute to body odor and has been known to cause infections in people with compromised immune systems. Typically not a public health pathogen, recent strains of this microorganism has demonstrated antibiotic resistance.

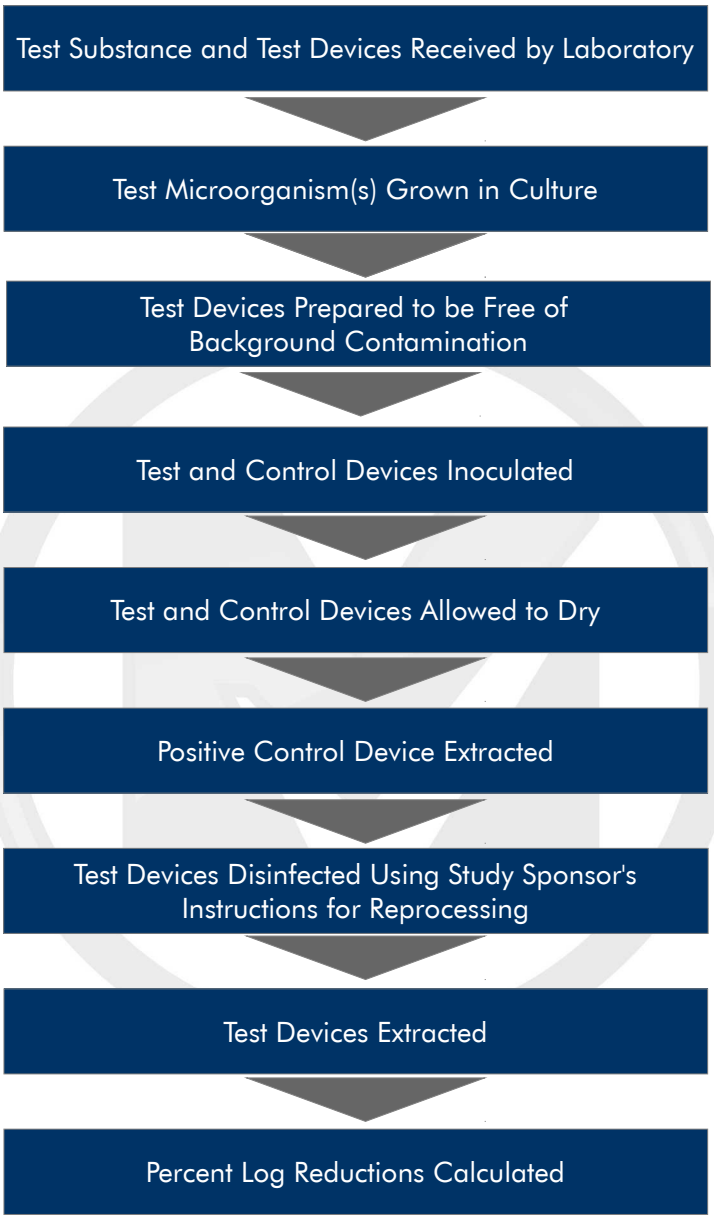
Staphylococcus epidermidis 12228

This bacteria is a Gram-positive, cocci-shaped, facultative anaerobe. *S. epidermidis* is part of the human bacterial flora, mostly located on skin. It is not usually pathogenic, however, antibiotic resistant strains have evolved. Most *Staphylococcus* species are a hardy microorganisms capable of surviving on surfaces and under dry conditions. This bacteria, specifically, is regularly used in quality control, media testing, and pharmacuetical/personal care products testing.

Candida albicans 10231

This fungi is facultatively aerobic and can grow both as a yeast and as a filamentous fungus. *Candida albicans* is a commensal microorganism meaning it normally inhabits the human mouth and gastrointestinal tract but is opportunistic and can cause candidiasis or thrush. *Candida albicans* can survive for long periods of time without nutrients and is known to form biofilms on medical devices, therefore, disinfection to kill these fungi is very important.

Diagram of the Procedure



Summary of the Procedure

- The test microorganism is prepared, usually by growth in liquid culture medium.
- The test culture may be supplemented with an artificial soil load, such as horse or fetal bovine serum.
- Received test devices are prepared such that they are free of background contamination prior
- to the test.

- Prepared devices are inoculated with the test culture. Inoculated devices are allowed to dry under ambient conditions. To evaluate low or intermediate level disinfection routines, test devices are allowed to dry for <1 hour. To evaluate high level disinfection routines, test devices are allowed to dry for a minimum of 1 hour.
- The positive control device is extracted after the dry time to determine the baseline concentration of the test microorganism of test devices following the dry time.
- Test devices are disinfected using the reprocessing routine specified by the Study Sponsor.
- At the conclusion of the contact time, test devices are neutralized and extracted.
- Dilutions of the extraction fluid are evaluated using an appropriate growth media to determine the surviving microorganisms present on test devices after the disinfection regimen.
- The number of surviving microorganisms present on test devices after observing the disinfection routine is compared to the number of microorganisms recovered from the positive control device to determine microbial reductions.

Results of the Study

Microorganisms Recovered from Test and Control Devices.				
Device	Replicate	CFU/Device	Percent Reduction Relative to Positive Control Device	Log_{10} Reduction Relative to Positive Control Device
Negative Device Control		0.00E+00	NA	
Positive Device Control		6.90E+05		
Positive Device Control (Long)		2.50E+04		
Test Device	1	5.00E+02	99.93%	3.14
	2	< 1.00E+1	> 99.998	> 4.83
	3	< 1.00E+1	> 99.998	> 4.83
Note: The limit of detection for the above table is 10.0 CFU/Device				

Test and Control Device Dry Times.		
Device	Replicate	Elapsed Dry Time
Positive Device Control (Dry time only)		12 Minutes 28 Seconds
Positive Device Control (Dry time + Contact time)		01 Hour 29 Minutes
Test	1	11 Minutes 20 Seconds
	2	11 Minutes 20 Seconds
	3	09 Minutes 27 Seconds

The results of this study apply to the tested substances(s) only. Extrapolation of findings to related materials is the responsibility of the Sponsor.

Biofocus
2012

Report – Disinfection efficiency of SoClean

Analysis was performed from Dezember 11th 2012 to January 31st 2013
by

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1) Disinfection of used CPAP equipment

Setup:
A used “Mojo Vented Full Face Mask” (Sleepnet Corp.) was examined by swab sampling before and after sanitizing the mask with one standard cycle of the SoClean system (15min Ozone generation, wait time 2 hours).

Results:
The swab-test showed slight contamination of the mask with aerobic sporulating bacteria. Fungi could not be detected.
After one sanitizing cycle no bacteria and fungi could be detected (Fig. 1).

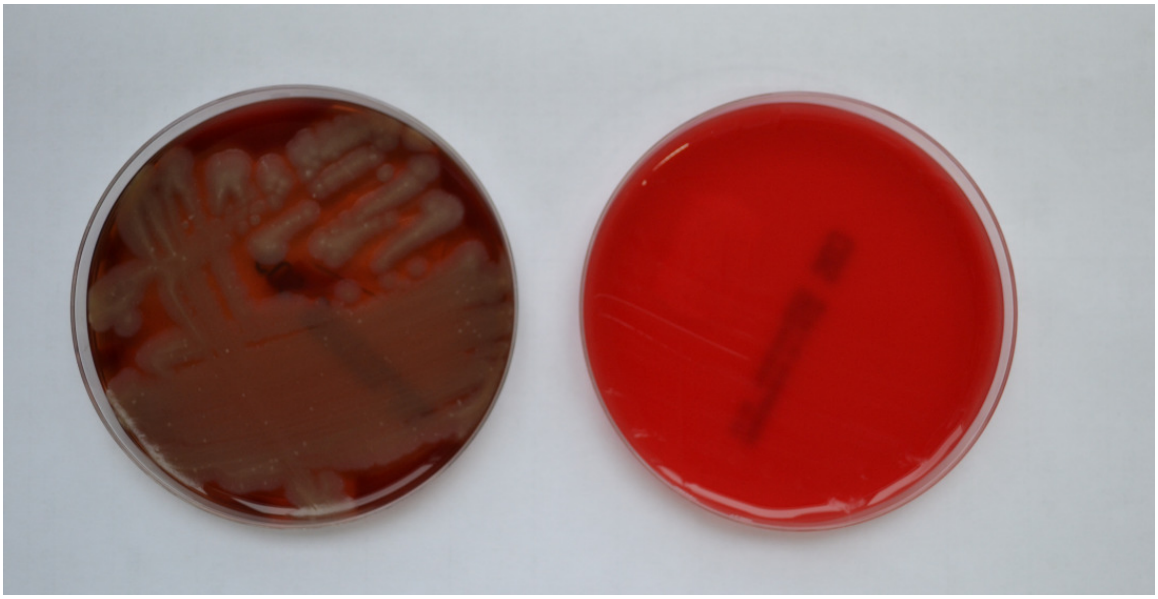

***Figure 1**: Result of the swab-test before (left) and after (right) one sanitizing cycle with SoClean.*

2) Inactivation of Enterococcus faecalis immobilized on filter paper

Setup:
A reference cell culture of Enterococcus faecalis (ATCC 29212) was diluted 1/10 with sterile water. A membrane filter paper (0.45µm, Whatman, ME25) was contaminated with the bacteria by normal filtering. Each filter was separated into two parts. One part was positioned within the CPAP-mask (Fig.2), the other part was used as reference and was stored outside the incubation camber during the sanitizing process. After one standard cycle the filter was directly placed on a culture medium (Slanetz and Burtley, Oxoid, P05018A) and incubated for 60h at 37°C.

***Figure 2**: Positioning of the contaminated filter papers in the mask.*

Results:
Enterococcus faecalis was completely inactivated on all filter papers subjected to the sanitizing process. The part of the filter not placed in the ozone chamber showed almost the same bacterial activity as a freshly prepared filter.

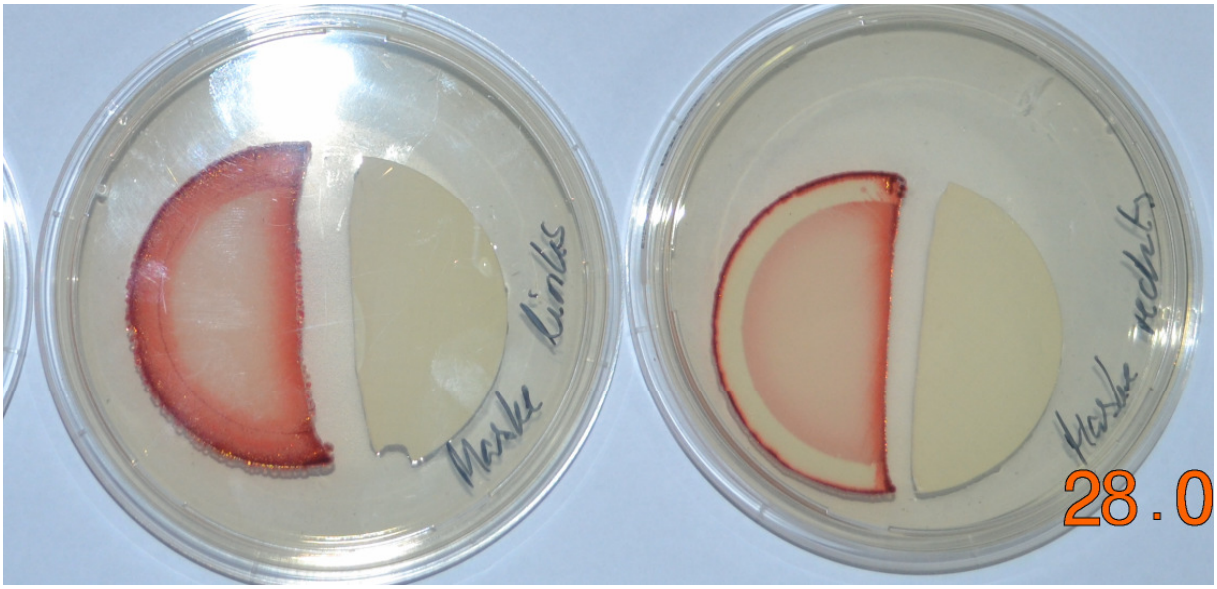

***Figure 3**: Result of the filter incubation form the left and right side of the mask. The red colour of the reference filters (left side of each plate) indicates the presence of bacteria. The white colour indicates complete elimination of the bacteria.*

3) Sanitizing a mask, directly incubated with Enterococcus faecalis

Setup:
The mask and the hose were contaminated by an Enterococcus faecalis (ATCC 29212) cell culture solution (Fig. 4). The contaminated surfaces of the mask were examined by swab testing after one sanitizing cycle within the SoClean. A directly contaminated swab was used as reference.

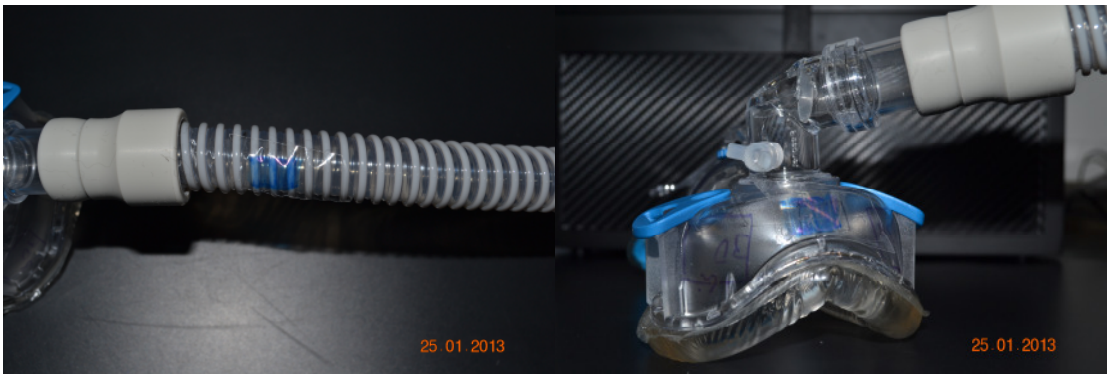

***Figure 4**: Contaminated surfaces (marked blue) in the hose (left) and the mask (right).*

Results:
On the contaminated surfaces all bacteria were inactivated (Fig. 5).

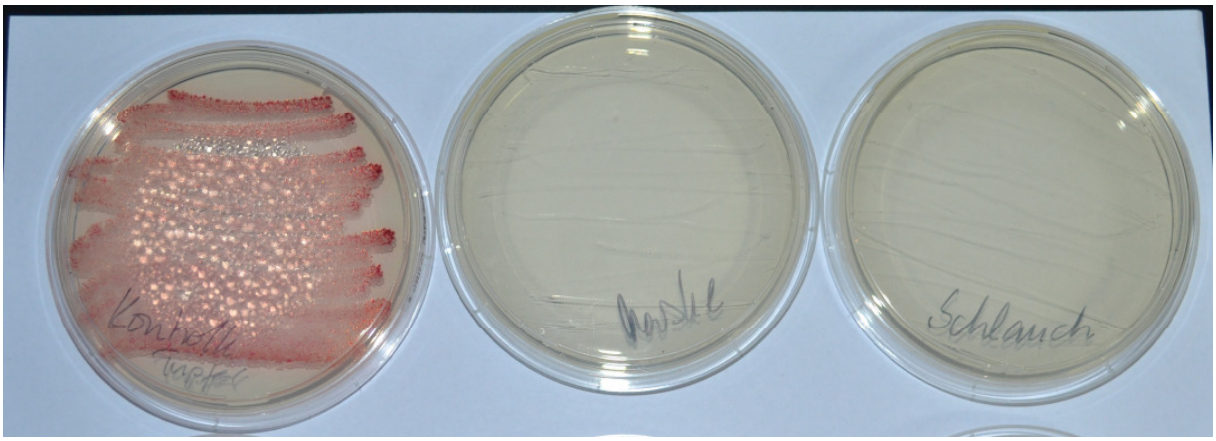

***Figure 5**: Result of the swab-test. Reference (left), mask (middle) hose (right). The red colour indicates the presence of bacteria. The white colour indicates complete elimination of the bacteria.*