

## Microbiology Testing Summary Supporting 99.9% Disinfection Efficacy Claim for the SoClean 2

### Overview:

In order to support the claim “SoClean kills 99.9% of all CPAP germs, bacteria and other pathogens”, SoClean shares below two independent microbiology laboratories which were contracted to conduct microbiological efficacy testing of the SoClean 2 automated PAP disinfecting system.

### SoClean contracted with the following two laboratories to corroborate testing results:

#### Microchem Laboratory - Round Rock, Texas

Microchem Laboratory is a contract testing laboratory built to serve industry with a wide array of testing services. The lab specializes in the testing of environmental surface disinfectants, high-level disinfectants, sanitizers, medical devices, antimicrobial surfaces, personal care products, and antimicrobial devices. Microchem is also an ISO 17025:2015 Accredited and GLP Compliant Laboratory. The scope of accreditation includes the following standards: AAMI TIR12, AAMI TIR30, ISO 11930

#### Biofocus LADR - Recklinghausen, Germany

Since its foundation in 1991, Biofocus has been working on the development and practice-oriented application of molecular biology test systems. Biofocus establishes new diagnostic tests, both on customer request and on the basis of new analytical possibilities in the course of scientific progress. Biofocus is accredited to: DIN EN ISO 17025

Accreditation to ISO 17025, General requirements for the competence of testing and calibration laboratories means that a laboratory's testing procedures are in compliance with this internationally recognized standard.

### Testing Procedures:

The general testing procedure involved inoculating a CPAP mask and hose with generally recognized bacteria and/or fungus as the test organism prior to disinfecting with the SoClean 2. A complete SoClean 2 disinfection cycle (approximately 2 hours and 12 minutes) was conducted. At the end of the disinfection cycle, the mask and/or hose were swabbed and the sample cultured as per standard procedure.

At the end of the culturing period, the samples were observed for bacterial or fungal growth and a log or percent reduction in bacteria or fungus was calculated.

**Log Reduction:**

Represents the reduction in germs as a factor of 10. Examples:

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

**Organisms Tested:**

- Enterococcus faecalis (ATCC 29212) ..... Bacteria
- Staphylococcus haemolyticus (29970) ..... Bacteria
- Staphylococcus hominis (27844) ..... Bacteria
- Staphylococcus epidermidis (12228) .....Bacteria
- Candida Albicans (10231)..... Fungus

**Test Results:**

Various pathogen species were used for disinfection testing and in all cases the SoClean 2 reduced the bacterial load by 99.9% or a 3 Log reduction with many tests resulting in a 4 Log reduction or a 99.99% kill rate.

**Test Summary:**

In summary, testing by the two referenced independent microbiology laboratories confirmed that the SoClean 2 is a highly effective automated PAP disinfecting system reducing bacterial load by at least 99.9% or a 3 Log reduction, in the mask and hose as tested.

