

**Microbiological Examination of the
Air-Shields® Isolette® C2000 Infant Incubator**

Introduction

The purpose of this study was to determine if the humidification system in the Air Shields® Isolette® C2000 Infant Incubator would introduce bacteria into the air space of the incubator during normal operation at 50% and 85% humidity. In addition to normal operating conditions, "worst-case" conditions were created in which the water in the reservoir was inoculated with high levels of different bacteria that could be contaminating the water. If water-borne bacteria were being introduced into the air of the incubator, these bacteria could pose a health threat to infants in the incubator.

Materials and Methods

Incubator: Air-Shields® Isolette® C2000 Infant Incubator was operated according to manufacturer instructions. The temperature was set at 37° C. Humidity was tested at two different settings, 50% and 85%. Between each test, the humidity reservoir tray was removed and cleaned. In addition, between different bacteria tests, the tubing connecting the humidity reservoir to the evaporator assembly was replaced.

Bacteria

Pseudomonas aeruginosa, *Serratia marcescens*, and *Acinetobacter calcoaceticus* were standard cultures obtained originally from the ATCC culture collection. All bacteria were maintained on Trypticase soy agar (TSA). For each experiment, the bacteria were grown on TSA overnight and washed off of the plate in sterile distilled water. A standard turbidity was achieved such that addition of the 50 ml of bacterial suspension, when added to 950 ml of normal tap distilled water in the humidity reservoir, achieved an initial bacterial concentration of $>1 \times 10^6$ CFU/ml.

For bacterial quantification, samples from the humidity reservoir or swabs were diluted in distilled water and plated on TSA. The TSA air plates were placed directly in to the incubator. The plates were incubated at 37° C for 24 hr and colonies counted for a calculation of the colony forming units (CFU) per ml of sample (or per swab or per m³ of air).

Bacterial identification of *Pseudomonas aeruginosa*, *Serratia marcescens*, and *Acinetobacter calcoaceticus* in the water samples was based on their normal colony appearance. When a different bacterium was the predominant organism, the identity was obtained using the Gram stain morphology and the Biolog Identification System.

Testing Procedures

All testing was performed in triplicate, with four different humidity reservoir conditions (i.e. different bacteria), and at two different humidity settings (50% and 85%). The first reservoir condition used only tap-distilled water, similar to what would be used in a real clinical environment. Any bacteria in the water were naturally occurring, with the predominant bacterial species at the beginning (0 hr) and at the end of each experiment (168 hr) identified and enumerated. The three additional conditions used the tap-distilled water inoculated with one of the three bacteria (*Pseudomonas aeruginosa*, *Serratia marcescens*, or *Acinetobacter calcoaceticus*) inoculated at an initial concentration of $>1 \times 10^6$ CFU/ml.

Samples from the water reservoir were analyzed at the beginning of the experiment (0 hr) and at the end of the 7-day

experiment (168 hr). Air samples were taken inside the incubator at t 0, 24, 48, and 168 hr using a Single Stage N6 Andersen Impaction Sampler using TSA agar media. The equipment was calibrated at 28.3 liters per minute, with a sample time of 20 minutes.

During the experiments at 85% humidity, considerable condensation formed on the inside of the incubator. Thus, at the end of each experiment at this humidity, the inside of the incubator chamber was swabbed (approximately 1 cm²) and cultured to determine if any bacterial biofilms were forming on the interior surfaces.

Results

It should be noted that the interior air of the incubator was not intended to be maintained sterile, but would have the occasional presence of bacteria commonly found in the indoor air. These bacteria would originate from the environment, dust and soil (mostly spore-forming *Bacillus* species and occasionally gram-negative organisms such as *Pseudomonas*) as well as those released from the skin of individuals working in the area (primarily *Staphylococcus* and *Micrococcus* species). The focus of these experiments was to determine if there were additional bacteria being released into the indoor air from the water of the humidification system.

Normal Tap-distilled Water (50 and 85% humidity)

The predominant bacterium found in the water reservoir in these experiments was *Ralstonia* (formerly *Pseudomonas picketii*). The initial concentrations were always very low (20-50 CFU/ml), with undetected bacteria on one occasion. At the end of the 7-day experiment, the number of these bacteria had always increased significantly, achieving a concentration as high as 150,000/ml on one occasion, but averaged (for the six experiments) approximately 42,000/ml.

The 24 air samples from these experiments were all very clean. No bacteria at all (< 2 CFU/m³) were detected in nearly half (11) of the air samples. The 13 samples that did contain bacteria averaged only 4 CFU/m³. The samples that contained bacteria seemed to be completely random, with no pattern of increasing numbers during the course of the experiments. In addition, no differences were noted between the samples at 50% versus 85% humidity.

An examination of the bacteria found on the air plates showed them to be, as expected, predominantly *Bacillus* (soil/dust) and *Staphylococcus* (skin) species. Other common environmental or skin bacteria noted on a single occasion were *Micrococcus*, *Pseudomonas boreopolis*, and *Proteus* (none of which were detected in the water sample). The predominant bacterium from the water reservoir (*Ralstonia picketii*) was found on one occasion as a single bacterium in the air sample (2 CFU/m³). Since these gram-negative bacteria can be found in the air as well, it cannot be determined whether the single random occurrence of this bacterium originated from the water reservoir or was normal to the air at the time of the sampling from another environmental source.

Finally, the swabs taken from the inside walls of the chambers of the 85% humidity experiments at 168 hr had no bacteria detected.

Pseudomonas aeruginosa (50 and 85% humidity)

While *Pseudomonas aeruginosa* was obviously the predominant organism at 0 hr, it did not establish itself in the water during the course of the experiment and was not detected at the end of the experiment at 168 hr. In each case, the naturally occurring *Ralstonia picketii* had re-established itself as the predominant organism in the water, averaging 32,000 CFU/ml, similar to what was found in the first set of experiments.

The 24 air samples from these experiments were all very clean. No bacteria at all (< 2 CFU/m³) were detected in well over half (15) of the air samples. The 9 samples that did contain bacteria averaged only 3.3 CFU/m³. The samples that contained bacteria seemed to be completely random, with no pattern of increasing numbers during the course of the experiments. In addition, no differences were noted between the samples at 50% versus 85% humidity.

The examination of the bacteria on the air plated showed no *Pseudomonas aeruginosa* or *Ralstonia picketii* detected at any of the time points. The bacteria found on the air plates showed them to be, as expected, predominantly *Bacillus* (soil/dust), *Staphylococcus* (skin) and *Micrococcus* (skin) species. *Sphingobacterium*, a common environmental bacterium, was noted on a single occasion. None of these airborne bacteria were detected in the water sample.

Finally, the swabs taken from the inside walls of the chambers of the 85% humidity experiments at 168 hr had no bacteria detected.

Serratia marcescens (50 and 85% humidity)

While *Serratia marcescens* was obviously the predominant organism at 0 hr, it also did not establish itself well in the water during the course of the experiment and was only detected at the end of the experiment in one case, at a low concentration of 40/ml. In each case, the naturally occurring *Ralstonia picketii* had re-established itself as the predominant organism in the water (except in one experiment that had no detectable bacteria in the water). The final concentration of *Ralstonia picketii* was very high in one of the experiments (600,000/ml), which led to an average concentration to 113,500 CFU/ml.

The 24 air samples from the experiments were all very clean. No bacteria at all (< 2 CFU/m³) were detected in over two-thirds (17) of the air samples. The 7 samples that did not contain bacteria averaged only 4 CFU/m³. The samples that contained bacteria seemed to be completely random, with no pattern of increasing numbers during the course of the experiments. In addition, no differences were noted between the samples at 50 versus 85% humidity.

The examination of the bacteria on the air plates showed no *Serratia marcescens* or *Ralstonia picketii* detected at any of the time points. The bacteria found on the air plates showed them to be, as expected, predominantly *Bacillus* (soil/dust), *Staphylococcus* (skin), and *Micrococcus luteus* (skin) species.

Finally, the swabs taken from the inside walls of the chambers of the 85% humidity experiments at 168 hr had no bacteria detected.

Acinetobacter calcoaceticus 50 and 85% humidity

While *Acinetobacter calcoaceticus* was obviously the predominant organism at 0 hr, it did not establish itself in the

water during the course of the experiment and was not detected at the end of the experiment at 168 hr. In each case, naturally occurring *Ralstonia picketii* organism in the water, averaging 5,500 CFU/ml.

The 24 air samples from these experiments were all very clean. No bacteria at all (< 2 CFU/m³) were detected in half (12) of the air samples. The 12 samples that did contain bacteria averaged only 5.5 CFU/m³. The samples that contained bacteria seemed to be completely random, with no pattern of increasing numbers during the course of the experiments. In addition, no differences were noted between the samples at 50% versus 85% humidity.

The examination of the bacteria on the air plates showed no *Acinetobacter calcoaceticus* or *Ralstonia picketii* detected at any of the time points. The bacteria found on the air plates showed them to be, as expected, predominantly *Bacillus* (soil/dust), *Staphylococcus* (skin) and *Micrococcus* (skin) species. A common environmental bacterium noted on a single occasion was *Flavobacterium flevense* (which was not detected in the water sample).

Conclusions

The purpose of these experiments was to determine if the humidification system of the Air Shields® Isolette® C2000 Infant Incubator could operate normally without introducing bacteria into the air of the incubator. Based on the results of these experiments to date, the air inside of the incubator at all time points and in all conditions of operation was considered safe.

The random occurrence of bacteria in the air, the low numbers of bacteria when detected, and the types of bacteria found, indicated that these bacteria were introduced into the incubator from the indoor air in the room, not from the humidification system. The three challenge bacteria, *Pseudomonas aeruginosa*, *Serratia marcescens*, and *Acinetobacter calcoaceticus*, were present at extremely high concentrations at the beginning of the experiments (>1 million bacteria per ml of water), yet none of them appeared in any of the 60 air samples taken from the incubator in these experiments. Of the naturally occurring bacteria in the water (*Ralstonia picketii*), only a single bacterium was detected on one occasion (out of 96 total samples), and it could not be confirmed whether this bacterium originated in the water reservoir or was naturally occurring in the air from some other environmental source. Thus, this latter finding was interpreted as insignificant. Finally, it should be additionally noted that, despite the large amount of condensation that present during the course of the operation at the high 86% humidity levels, no bacterial growth of any kind was detected on the inside walls of the incubator.

The microbiological evaluation of the C2000 ISOLETTE® infant incubator humidity system detailed in this report was commissioned by Air Shields® and performed by Environmental Safety Technologies, Inc., (Louisville, KY). Environmental Safety Technologies, Inc. certifies that this study was performed using scientifically accepted methods of microbiological analysis and that they believe the information in this report to be true and accurate to the best of their knowledge.

Humidity Condition: 50%
Challenge Organism: NONE – Baseline

RUN 1

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	30	30	<i>Ralstonia picketii</i>
Air Sample	0 hr	2	2	<i>Staphylococcus spp.</i>
Air Sample	24 hr	2	2	<i>Micrococcus spp.</i>
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	4	2	<i>Staphylococcus aureus</i>
			2	<i>Ralstonia picketii</i>
Reservoir Water	168 hr	150,000	150,000	<i>Ralstonia picketii</i>

RUN 2

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	50	50	<i>Ralstonia picketii</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	2	2	<i>Staphylococcus spp.</i>
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	None detected	N/A	N/A
Reservoir Water	168 hr	30,000	30,000	<i>Ralstonia picketii</i>

RUN 3

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	20	20	<i>Ralstonia picketii</i>
Air Sample	0 hr	4	2	<i>Staphylococcus spp.</i>
			2	<i>Staphylococcus spp.</i>
Air Sample	24 hr	16	14	<i>Bacillus spp.</i>
			2	<i>Staphylococcus spp.</i>
Air Sample	48 hr	2	2	<i>Bacillus spp.</i>
Air Sample	168 hr	None detected	N/A	N/A
Reservoir Water	168 hr	18,000	18,000	<i>Ralstonia picketii</i>

- No bacteria were detected in Air Plate Controls run at each sampling time point.
- Limit of sensitivity: water = 10CFU/ml air = 2CFU/m³

Humidity Condition: 85%
Challenge Organism: NONE – Baseline

RUN 1

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	20	20	<i>Ralstonia pickettii</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	None Detected	N/A	N/A
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	2	2	<i>Bacillus spp.</i>
Reservoir Water	168 hr	16,000	16,000	<i>Ralstonia pickettii</i>
Swab – Incubator Wall	168 hr	None Detected	N/A	N/A

RUN 2

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	None Detected	N/A	N/A
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	2	2	<i>Bacillus spp.</i>
Air Sample	48 hr	2	2	<i>Bacillus spp.</i>
Air Sample	168 hr	None Detected	N/A	N/A
Reservoir Water	168 hr	20,000	20,000	<i>Ralstonia pickettii</i>
Swab – Incubator Wall	168 hr	None Detected	N/A	N/A

RUN 3

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	50	50	<i>Ralstonia pickettii</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	12	10 2	<i>Bacillus spp.</i> <i>Pseudomonas boreopolis</i>
Air Sample	48 hr	2	2	<i>Bacillus spp.</i>
Air Sample	168 hr	4	2 2	<i>Proteus spp.</i> Could not isolate from <i>Proteus</i>
Reservoir Water	168 hr	20,000	20,000	<i>Ralstonia pickettii</i>
Swab – Incubator Wall	168 hr	None Detected	N/A	N/A

- No bacteria were detected in Air Plate Controls run at each sampling time point.

- Limit of sensitivity: water = 10CFU/ml air = 2CFU/m³

Humidity Condition: 50%
Challenge Organism: *Pseudomonas aeruginosa*

RUN 1

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	1,500,000	1,500,000	<i>Pseudomonas aeruginosa</i>
Air Sample	0 hr	4	2	<i>Bacillus spp.</i>
			2	<i>Sphingobacterium spp.</i>
Air Sample	24 hr	None Detected	N/A	N/A
Air Sample	48 hr	6	4 2	<i>Micrococcus luteus</i> <i>Staphylococcus aureus</i>
Air Sample	168 hr	None Detected	N/A	N/A
Reservoir Water	168 hr	40,000	40,000	<i>Ralstonia picketii</i>

RUN 2

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	1,800,000	1,800,000	<i>Pseudomonas aeruginosa</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	8	6 2	<i>Staphylococcus spp.</i> <i>Bacillus spp.</i>
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	2	2	<i>Staphylococcus aureus</i>
Reservoir Water	168 hr	20,000	20,000	<i>Ralstonia picketii</i>

RUN 3

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	2,000,000	2,000,000	<i>Pseudomonas aeruginosa</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	None Detected	N/A	N/A
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	None Detected	N/A	N/A
Reservoir Water	168 hr	20,000	20,000	<i>Ralstonia picketii</i>

- No bacteria were detected in Air Plate Controls run at each sampling time point.
- Limit of sensitivity: water = 10CFU/ml air = 2CFU/m³

Humidity Condition: 85%

Challenge Organism: *Pseudomonas aeruginosa*

RUN 1

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	2,500,000	2,500,000	<i>Pseudomonas aeruginosa</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	None Detected	N/A	N/A
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	2	2	<i>Micrococcus luteus</i>
Reservoir Water	168 hr	2,400	2,000 400	<i>Ralstonia pickettii</i> <i>Methylobacterium spp.</i>
Swab – Incubator Wall	168 hr	None Detected	N/A	N/A

RUN 2

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	2,100,000	2,100,000	<i>Pseudomonas aeruginosa</i>
Air Sample	0 hr	2	2	<i>Bacillus spp.</i>
Air Sample	24 hr	2	2	<i>Bacillus spp.</i>
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	2	2	<i>Staphylococcus spp.</i>
Reservoir Water	168 hr	31,000	31,000	<i>Ralstonia pickettii</i>
Swab – Incubator Wall	168 hr	None Detected	N/A	N/A

RUN 3

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	2,000,000	2,000,000	<i>Pseudomonas aeruginosa</i>
Air Sample	0 hr	2	2	<i>Bacillus spp.</i>
Air Sample	24 hr	None Detected	N/A	N/A
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	None Detected	N/A	N/A
Reservoir Water	168 hr	70,000	70,000	<i>Ralstonia pickettii</i>
Swab – Incubator Wall	168 hr	None Detected	N/A	N/A

- No bacteria were detected in Air Plate Controls run at each sampling time point.

- Limit of sensitivity: water = 10CFU/ml air = 2CFU/m³

Humidity Condition: 50%

Challenge Organism: *Serratia marcescens*

RUN 1

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	2,000,000	2,000,000	<i>Serratia marcescens</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	None Detected	N/A	N/A
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	12	6 4 2	<i>Micrococcus luteus</i> <i>Staphylococcus spp.</i> <i>Staphylococcus aureus</i>
Reservoir Water	168 hr	600,000	600,000	<i>Ralstonia picketii</i>

RUN 2

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	2,000,000	2,000,000	<i>Serratia marcescens</i>
Air Sample	0 hr	4	2 2	<i>Bacillus spp.</i> <i>Micrococcus spp.</i>
Air Sample	24 hr	None Detected	N/A	N/A
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	None Detected	N/A	N/A
Reservoir Water	168 hr	2,100	2,100	<i>Ralstonia picketii</i>

RUN 3

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	2,000,000	2,000,000	<i>Serratia marcescens</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	2	2	<i>Bacillus spp.</i>
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	None Detected	N/A	N/A
Reservoir Water	168 hr	11,500	11,500	<i>Ralstonia picketii</i>

- No bacteria were detected in Air Plate Controls run at each sampling time point.

- Limit of sensitivity: water = 10CFU/ml air = 2CFU/m³

Humidity Condition: 85%
Challenge Organism: *Serratia marcescens*

RUN 1

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	2,900,000	2,900,000	<i>Serratia marcescens</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	None Detected	N/A	N/A
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	2	2	<i>Staphylococcus aureus</i>
Reservoir Water	168 hr	60,040	60,000 40	<i>Ralstonia pickettii</i> <i>Serratia marcescens</i>
Swab – Incubator Wall	168 hr	None Detected	N/A	N/A

RUN 2

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	4,500,000	4,500,000	<i>Serratia marcescens</i>
Air Sample	0 hr	2	2	<i>Micrococcus luteus</i>
Air Sample	24 hr	None Detected	N/A	N/A
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	2	2	<i>Micrococcus luteus</i>
Reservoir Water	168 hr	7,500	7,500	<i>Ralstonia pickettii</i>
Swab – Incubator Wall	168 hr	None Detected	N/A	N/A

RUN 3

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	2,000,000	2,000,000	<i>Serratia marcescens</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	4	4	<i>Bacillus spp.</i>
Air Sample	48 hr	None Detected	N/A	N/A
Air Sample	168 hr	None Detected	N/A	N/A
Reservoir Water	168 hr	None Detected	N/A	N/A
Swab – Incubator Wall	168 hr	None Detected	N/A	N/A

- No bacteria were detected in Air Plate Controls run at each sampling time point.
- Limit of sensitivity: water = 10CFU/ml air = 2CFU/m³

Humidity Condition: 50%

Challenge Organism: *Acinetobacter calcoaceticus*

RUN 1

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	1,500,000	1,500,000	<i>Acinetobacter calcoaceticus</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	None Detected	N/A	N/A
Air Sample	48 hr	32	30 2	<i>Staphylococcus spp.</i> <i>Micrococcus luteus</i>
Air Sample	168 hr	None detected	N/A	N/A
Reservoir Water	168 hr	600	600	<i>Ralstonia picketii</i>

RUN 2

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	6,000,000	6,000,000	<i>Acinetobacter calcoaceticus</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	None Detected	N/A	N/A
Air Sample	48 hr	None detected	N/A	N/A
Air Sample	168 hr	4	2 2	<i>Micrococcus luteus</i> <i>Bacillus spp.</i>
Reservoir Water	168 hr	20,000	20,000	<i>Ralstonia picketii</i>

RUN 3

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	1,050,000	1,050,000	<i>Acinetobacter calcoaceticus</i>
Air Sample	0 hr	4	4	<i>Staphylococcus spp.</i>
Air Sample	24 hr	2	2	<i>Flavobacterium flevense</i>
Air Sample	48 hr	6	2 2 2	<i>Bacillus spp.</i> <i>Micrococcus luteus</i> <i>Staphylococcus spp.</i>
Air Sample	168 hr	4	2 2	<i>Bacillus spp.</i> <i>Micrococcus luteus</i>
Reservoir Water	168 hr	6,000	6,000	<i>Ralstonia picketii</i>

- No bacteria were detected in Air Plate Controls run at each sampling time point.

- Limit of sensitivity: water = 10CFU/ml air = 2CFU/m³

Humidity Condition: 85%

Challenge Organism: *Acinetobacter calcoaceticus*

RUN 1

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	2,000,000	2,000,000	<i>Acinetobacter calcoaceticus</i>
Air Sample	0 hr	None Detected	N/A	N/A
Air Sample	24 hr	2	2	<i>Micrococcus spp.</i>
Air Sample	48 hr	None detected	N/A	N/A
Air Sample	168 hr	2	2	<i>Micrococcus spp.</i>
Reservoir Water	168 hr	2,200	2,200	<i>Ralstonia pickettii</i>
Swab – Incubator Wall	168 hr	None Detected	N/A	N/A

RUN 2

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	3,500,000	3,500,000	<i>Acinetobacter calcoaceticus</i>
Air Sample	0 hr	2	2	N/A
Air Sample	24 hr	2	2	<i>Bacillus spp.</i>
Air Sample	48 hr	4	4	<i>Bacillus spp.</i>
Air Sample	168 hr	2	2	<i>Bacillus spp.</i>
Reservoir Water	168 hr	None detected	N/A	N/A
Swab – Incubator Wall	168 hr	None Detected	N/A	N/A

RUN 3

Sample Type	Time Sample Taken	Total Bacterial Count	Count of Different Types of Bacteria	Identification
Reservoir Water	0 hr	4,000,000	4,000,000	<i>Acinetobacter calcoaceticus</i>
Air Sample	0 hr	None detected	N/A	N/A
Air Sample	24 hr	2	2	<i>Bacillus spp.</i>
Air Sample	48 hr	None detected	N/A	N/A
Air Sample	168 hr	None detected	N/A	N/A
Reservoir Water	168 hr	4,000	4,000	<i>Ralstonia pickettii</i>
Swab – Incubator Wall	168 hr	None Detected	N/A	N/A

- No bacteria were detected in Air Plate Controls run at each sampling time point.

- Limit of sensitivity: water = 10CFU/ml air = 2CFU/m³

Europe, Middle East, Africa, Latin America,
Asia, Pacific:

Dräger Medical AG & Co. KG

Moislinger Allee 53-55
23542 Lübeck

GERMANY

Tel: +49-1805-3 72 34 37
+49-451-882-822

Fax: +49-451-882-37 79

E-mail: Business.Support@draeger.com

USA:

Draeger Medical, Inc.

3135 Quarry Road
Telford, PA 18969

USA

Tel: +1-215-721-5400

Toll-free: +1-800-437-2437

Fax: +1-215-723-5935

E-mail: info@draegermed.com

Canada:

Draeger Medical Canada Inc.

120 East Beaver Creek Road Suite 104

Richmond Hill Ontario L4B 4V1

CANADA

Tel: +1-905-763-3702

Toll-free: +1-866-343-2273

Fax: +1-905-763-1890

E-mail: Canada.Support@draeger.com

www.draeger-medical.com

Manufacturer:

Draeger Medical Systems, Inc.

Telford, PA 18969, USA

The quality management system at
Draeger Medical Systems, Inc. is certified
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