

Airway Medix Closed Suction System 72 Hours Model - Cleaning Chamber Performance

BACKGROUND AND GOAL OF EXPERIMENT

Mechanically ventilated patients treated in intensive care units (ICU) are most commonly ventilated through an endotracheal tube (ETT). During ventilation, secretions accumulate inside the tube and reduce its inner diameter. The Airway Medix Closed Suction System (AMCSS) is a tracheobronchial suction catheter that is used to aspirate liquids or semisolids from a patient's upper airway.

The unique system combines saline jets, suction and balloon wiping to remove biofilm and secretion build up from the internal wall surface of the endotracheal and tracheostomy tubes.

The AMCSS has two versions: a 24 hour model, and a 72 hour model, which incorporates a cleaning chamber. The cleaning chamber serves the function of cleaning the tip of the catheter between suction episodes in order to reduce the contamination level as a result of the long term use.

The purpose of this study is to validate the efficacy of the AMCSS 72 hours cleaning chamber, by proving that the contamination level on the catheter's tip of the 72 hours AMCSS is non-inferior to the contamination level on the catheter tip of the AMCSS intended for 24 hours, without the cleaning chamber.

MATERIALS AND METHODS



In order to simulate real life and common practice conditions a study was designed by Biovo Technologies and performed by MILOUDA&MIGAL laboratories, Israel in winter 2015. Sixteen samples of the AMCSS 12Fr for 24 hours and sixteen samples of AMCSS 12Fr for 72 hours (Figure 1) were tested.

The top 3 cm of the catheter's tip of the 24 hours model was inoculated with a mixture of 1×10^6 CFU's/mL from each of the microorganisms: *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans*. These micro-organisms represent the flora of patient's upper airways in the intensive care units. Following inoculation, a suction procedure was performed during 5 seconds, every 4 hours. Same process was repeated with the AMCSS designed for 72 hours, except that after each suction episode the catheter tip was washed in the cleaning chamber with 10ml sterile saline according to the AMCSS instructions for use. The catheters top 3 cm were cut and tested for bioburden after 24 or 72 hours from the beginning of use.

RESULTS



The comparison between the groups was done using t-test for two independent groups. Figure 2 presents descriptive statistics of total micro-organism colonization on AMCSS catheter's tip, after Log₁₀ transformation was applied. As can be seen, both mean and median of total count in the 24-hours group are greater than those in the 72-hours group (6.61[CFU/ml], 6.59[CFU/ml] and 4.87[CFU/ml], 4.96[CFU/ml], respectively). Figure 3 presents the statistical testing of colonization difference between 72 hours model and 24 hours model. The mean ratio between the total counts is 54.7, meaning that the amount of colonization obtained in the 24-hours group is almost 55 times larger than that in the 72-hours group.

CONCLUSIONS



The aim of this study was to demonstrate non-inferiority of the 72-hours use AMCSS to the 24-hours use AMCSS by comparing the contamination levels on the catheter's tips after standard real life simulated suction procedures. The results showed that not only the 72hr AMCSS is non inferior to the 24hr AMCSS in terms of bacterial colonization, but there is strongly significant difference between the two groups in favor of the 72-hours AMCSS ($P < 0.0001$). The catheter tip lavage performed after each suction episode in the cleaning chamber, reduces significantly the bacterial colonization on the tip of the catheter.

Airway Medix Closed Suction System

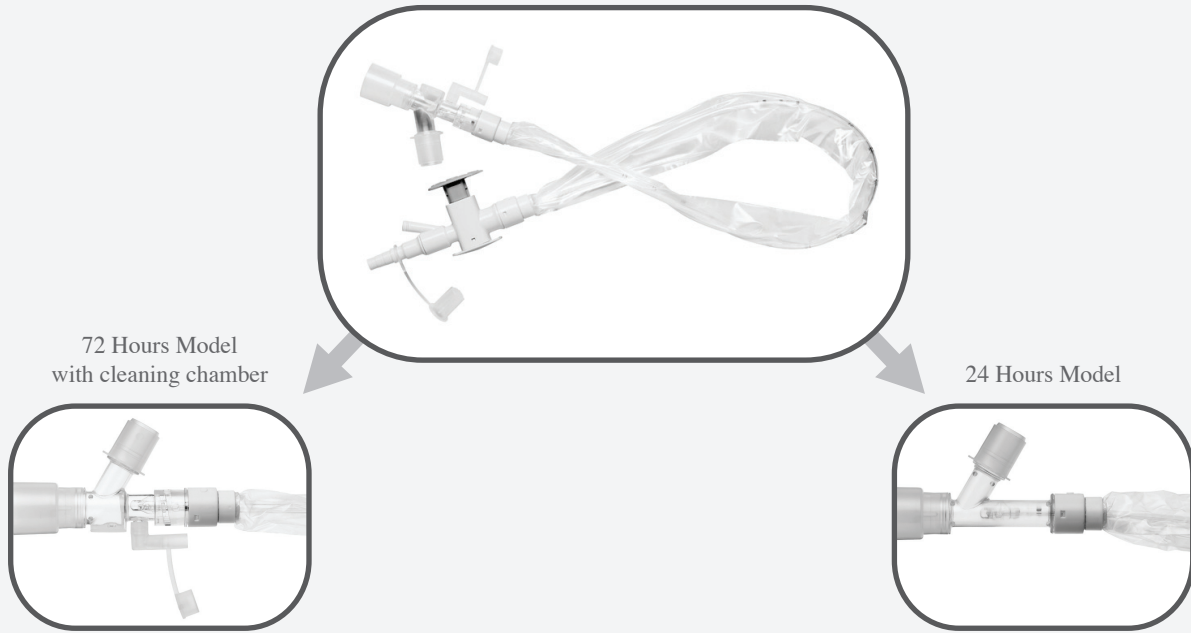


Figure 1: AMCSS 72 hours model and 24 hours model

AMCSS	Log Colonization (CFU/ml)					
	Mean	Std	Min	Median	Max	N
24 Hours AMCSS	6.61	0.17	6.32	6.59	6.90	16
72 Hours AMCSS	4.87	0.48	3.94	4.96	5.82	16

Figure 2: Descriptive Statistics of Log₁₀ Colonization (CFU/mL) by AMCSS Type and Overall

Ratio	Means Ratio	Lower Limit	Upper Limit	P-value
24hr/72hr	54.7	30.1	99.3	<.0001
72hr/24hr	0.018	0.033	0.01	<.0001

Figure 3: Statistical Testing of Colonization (CFU/mL) Difference between AMCSS