

Accelerated Age Testing with MicrobeCare with Ohio Medical Push To Set Suction Regulators.

Purpose: To simulate up to 12 years of cleaning the surface on 4 of the 5 plastics used in the Push To Set Suction Regulators. This test will verify the effectiveness of the MicrobeCare solution activated on plastic surfaces and then exposed to various industrial cleaners over a period of time.

Scope: MicrobeCare is a permanent bonded antimicrobial shown to effectively control bacteria, fungi, algae and yeast on a wide variety of treated materials and substrates.

Five main plastics are used in the structure of the Suction Regulator; Polycarbonate (PC), Celcon M90 Acetal, Delrin Acetal, Acrylonitrile butadiene styrene (ABS) and Styrene. Celcon M90 Acetal and Delrin Acetal have very similar mechanical properties and chemical structure so only Celcon M90 Acetal will be used for this test. The results will be very similar and it is unnecessary to test both materials.

Three hospitals were asked how often the Vacuum Regulators were cleaned and what cleaning solutions they used. The three hospitals used to collect this information were 1) RUSH (IL), 2) St. Johns (MO), and 3) Central Dupage (IL).

The gathered results show that the Push To Set Suction Regulators were wiped down 1-2 times per week. To effectively imitate cleaning the surface on the Suction Regulators, the maximum cleaning cycle was used to determine the number of wipes occurring in one year. One year of cleaning was established to be equivalent to 100 wipes.

When the information was collected, the hospitals were each using different but commonly used cleaning/disinfectant solutions. The three cleaning solutions being used were 1) Sani-Cloth AF germicidal disposable cloth, 2) A-456 II disinfectant cleaner and 3) Re-Juv-Nal disinfectant detergent. The three cleaning/disinfectant solutions will be used in this test along with Precise disinfectant cleaner, Super HDQ Neutral One Step Germicidal and Full Strength Bleach. These six cleaning solutions are the most commonly used for cleaning in hospitals. Data Table 1.1 gives a description of the cleaning materials to be used in this test.

62 samples will be use for testing from each resin:

Resin X

Label	Quantity	Treated with MicrobeCare	Tested with Phenol Blue Direct Stain (BPB Test)
Control	1	No	Yes
Control	1	Yes	Yes
Wiped 100 X	6 (1 for each cleaner)	Yes	Yes
Wiped 500 X	6 (1 for each cleaner)	Yes	Yes
Wiped 1000 X	24 (4 for each cleaner)	Yes	*Yes (only 6 of the 24)
Wiped 1200 X	24 (4 for each cleaner)	Yes	*Yes (only 6 of the 24)

**18 of the 24 samples wiped 1000 and 1200 times will be set aside for NAMSA for future testing of the top 4 commonly found pathogens in hospitals. These 18 samples will not be BPB tested.*

1.1

MicrobeCare Cleaning Materials				
Test Solution	Description	Tested Y/N	**Recommended Exposure Time	Active Ingredient
*Cidex	<i>High Level Disinfectant Solution</i>	N	12 minutes	<i>Ortho-Phthalaldehyde (OPA) .55%</i>
Sani-Cloth	Germicidal Disposable Cloth	Y	3 minutes	Dimethyl ethylbenzyl ammonium chloride .14%, dimethyl benzyl ammonium chloride .14%
A-456 II	Disinfectant Cleaner	Y	10 minutes	Octyl decyl dimethyl ammonium chloride 6.510%, Dioctyl dimethyl ammonium chloride 2.604%, Didecyl dimethyl ammonium chloride 3.906%, Alkyldimethyl benzyl ammonium chloride 8.680%
Re-Juv-Nal	Disinfectant Detergent	Y	10 minutes	Octyl decyl dimethyl ammonium chloride 1.62%, Dioctyl dimethyl ammonium chloride .814%, Didecyl dimethyl ammonium chloride .814%, Alkyldimethyl benzyl ammonium chloride 2.17%
Precise	Hospital Cleaner Disinfectant	Y	10 minutes	0-Phenylphenol .37%
Bleach	Household Cleaner	Y	N.A	Sodium Hypochlorite 100%
Super HDQ Neutral	One Step Germicidal Detergent	Y	10 minutes	Didecyl dimethyl ammonium chloride 9.22%, n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%) dimethyl benzyl ammonium chloride 6.14%

**Cidex is known to be used in many hospitals but was not chosen to use for this test because it is not used in the wiping down of surfaces, only in re-processing heat sensitive medical devices. The conditions that Cidex is used in do not correlate with the conditions desired for this test.*

*** The recommended exposure time is used to terminate the unwanted organisms that reside on surfaces. This procedure is to test the wear resistance of the MicrobeCare Solution on the surface of the plastic when wiped over a period of time. This is not a test to check the effectiveness of each cleaning/disinfectant solution.*

Procedure:

A chart has been given (see data table 1.3 on page 6) to record day to day actions. This chart will also act as a checklist to ensure no steps are missed. Be sure to fill out the chart completely after every day.

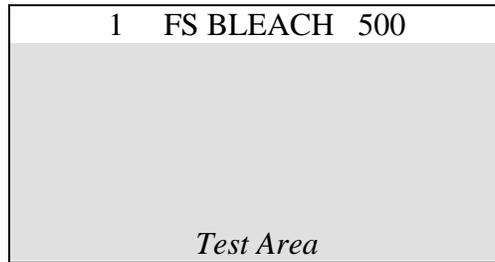
1. Take 61 samples from each resin and label the top of every sample in the following way (using only the number):
 - Polycarbonate- 1
 - Celcon M90- 2
 - ABS- 3
 - Styrene- 4
- *Be sure not to write the label where it will interfere with the test area.**
2. Generously spray both sides of 61 samples from each resin using the MicrobeCare Solution spray. Allow to dry for 24 hours. Generously apply a second coat of then MicrobeCare Solution and allow to set for another 24 hours.
 3. Using a microfiber cloth, buff the surface each sample.
 4. Separate each resin into 6 groups consisting of 10 samples. Each group will represent a different cleaning solution being used. There will be one left over sample from each resin.
 5. For each group, label all the samples next to the numerical material indicator in the following way:
 - Group 1- A-456
 - Group 2- SANI-CLOTH
 - Group 3- RE-JUV-NAL
 - Group 4- PRECISE
 - Group 5- FS BLEACH
 - Group 6-HDQ

FS=Full Strength

6. Take the left over samples and label them: “CONTROL WITH MICROBECARE”. Set aside for future Pass/Fail BPB testing.
7. Label 1 sample from each group 100, label 1 sample from each group 500, label 4 samples from each group 1000, and label the last 4 samples in each group 1200. This number will indicate the number of wipes that will occur on the surface of the sample. (See Example 1.2)

Samples will look like:

1.2



(Polycarbonate, tested with Full Strength Bleach, 500 wipes)

8. Take 1 sample from each resin that **DO NOT** have the MicrobeCare Solution on them and label them “CONTROL”. Identify the material for each sample using the corresponding number. Set aside for future Pass/Fail BPB testing.

Before testing:

- A new Sani-Cloth or rewetting of the microfiber cloth is only required when the cloth no longer leaves a residue on the surface. Be sure the surface remains wet after each wipe.
 - The solution does not need to dry between each wipe.
 - When wiping, apply a small amount of pressure but enough pressure that would remove unwanted buildup on the surface.
 - One wipe is equivalent to a forward and backward motion applied to the surface.
 - Gloves are recommended when testing. Some of the cleaning solutions may be irritating to the skin.
9. Take all of the samples marked with a “1” (Polycarbonate) and make sure there are 60 samples.
 10. Starting with the 10 samples marked “SANI-CLOTH”, wipe the sample with the Sani-Cloth AF. Be sure the sample is wiped the amount of times that is indicated on the top. This should be 100, 500, 1000, or 1200.
 11. Next take the 10 samples marked “A-456”. Spray the A-456 II solution onto a microfiber cloth and wipe each sample the amount of times indicated on the sample. Be sure the cloth remains wet enough to leave a residue. To prepare the A-456 II solution, see IFU.
 12. Now take the 10 samples marked “RE-JUV-NAL”. Spray the Re-Juv-Nal solution onto a microfiber cloth and wipe each sample the amount of times indicated on the sample. Be sure the cloth remains wet enough to leave a residue. To prepare the Re-Juv-Nal solution, see IFU.

13. Take the 10 samples marked "PRECISE". Spray the Precise solution onto a microfiber cloth and wipe each sample the amount of times indicated on the sample. Be sure the cloth remains wet enough to leave a residue. To prepare the Precise solution, see IFU.
14. Take the 10 samples marked "FS BLEACH". Spray the Bleach onto a microfiber cloth and wipe each sample the amount of times indicated on the sample. Be sure the cloth remains wet enough to leave a residue.
15. There should be 10 samples left marked "HDQ". Spray the HDQ onto a microfiber cloth and wipe each sample the amount of times indicated on the sample. Be sure the cloth remains wet enough to leave a residue.
16. Repeat steps 9-14 for the remaining 3 resins. Be sure to record all information.

Bromophenol Blue Direct Stain (BPB Test):

17. Prepare 0.025% stock solution of Bromophenol Blue Sodium Salts (2 grams per 8 liters of dH₂O). A wetting agent such as Dow Corning Q2-5211 may be added at 0.01% for hydrophobic substrates. Store in sealed amber bottle; material will photo degrade.
18. Soak the bottom 2 inches of the sample directly in BPB solution for 5-15 minutes.
19. Rinse with copious amounts of tap water
20. Observe for blue stain. Compare to pre-determined BPB color standard.

Data/Results:

1.3

DATE/INITIAL	ACTION	COMMENTS/OBSERVATIONS
06/24/11 JK	<i>Labeled 51 samples from each resin to indicate material and sprayed with MicrobeCare Solution.</i>	<i>Day 1</i>
06/27/11 JK	Labeled all resin samples with cleaner, material and number of wipes required.	I am only testing with A-456 II and Re-Juv-Nal cleaners on all four resins.
06/29/11 JK	Sprayed the first coat of MicrobeCare.	Sprayed both sides of each sample generously at approximately 9:30 am. Let set for 24 hours.
06/30/11 JK	Sprayed the second coat of MicrobeCare.	Sprayed both sides of each resin generously at approximately 9:40 am. Let set for 24 hours.
07/01/11 JK	Buffed the surface of both sides for each sample. Started wiping for 100X and 500X wipe test.	Finished wiping the samples marked 100X and 500X using the A-456 and Re-Juv-Nal solution. I finished all 4 of the resin samples.
07/06/11 JK	Began wiping the resin samples 1000X	Only wiped with A-456 II cleaning solution
07/07/11 JK	Continued wiping samples 1000X	Finished wiping 1000X using A-456 II cleaning solution
07/08/11 JK	Wiped 1 sample from each resin 1000X or 1200X	1000X used Re-Juv-Nal, 1200X used Re-Juv-Nal and A-456 II cleaning solution.
07/11/11 JK	Wiped a second sample from each resin 1000X or 1200X	1000X used Re-Juv-Nal, 1200X used Re-Juv-Nal and A-456 II cleaning solution.
07/12/11 JK	Wiped the 3 rd set of samples from each resin type 1000X or 1200X	Only got half way through the 3 rd set due to time. 1000X used Re-Juv-Nal, 1200X used Re-Juv-Nal and A-456 II cleaning solution.
07/13/11 JK	Finished wiping the 3 rd set of samples from each resin type 1000X or 1200X	1000X used Re-Juv-Nal, 1200X used Re-Juv-Nal and A-456 II cleaning solution.
07/14/11 JK	Wiped the last set of samples from each resin type 1000X or 1200X	1000X used Re-Juv-Nal, 1200X used Re-Juv-Nal and A-456 II cleaning solution.
07/15/11 JK	Started testing with Phenol Blue	Tested controls, 100X, and 500X. Kept in Phenol Blue for 10 min each.
07/18/11 JK	Continued testing with Phenol Blue	Only one sample from each resin was tested.
07/19/11 JK	Finished testing with Phenol Blue	All samples are tested except those that will be sent into NAMSA.

Chemical Phenol Blue Results:

Four of the five plastic materials used in the Push to Set Vacuum Regulator were treated with MicrobeCare antimicrobial spray solution. For each material, the samples went through an accelerated aging process that involved wiping the samples 100 to 1200 times. Five different cleaners that are regularly used in hospitals were chosen to use when wiping the samples in the aging process. The samples were dipped in a prepared solution of Bromophenol Blue Sodium Salts for 10 minutes each.

The samples were compared to a pre-determined BPB color standard and evaluated for a pass or fail result. The results showed that all the samples passed the phenol blue test for the maximum cleaning cycle completed, 1200 wipes. This is equivalent to 12 years of cleaning at a hospital.

Next, the samples will be sent to NAMSA for further biological testing to ensure the maximum time the antimicrobial will be effective.