
RESPICIDE* GP DISINFECTING SOLUTION

FIELD TRIAL RESULTS OF A NEW DISINFECTING SOLUTION
FOR TREATMENT OF NON-METAL MEDICAL EQUIPMENT

N. I. Bruckner, Ph.D.
Stephen E. Acker, M.D.
and
Neeraj Khanna, Ph.D.

Bio-Cide International, Inc.
2650 Venture Drive, Norman, OK 73069
July 21, 2003

*Trademark

ABSTRACT

RespiCide GP Disinfecting Solution was evaluated in three sleep labs for 14 weeks. Approximately 12 sleep lab personnel prepared and used the product. One hundred and eighty-two patients (168 from central labs and 14 from remote sites) participated in the study and had exposure to facemasks treated with the test solution.

Most sleep lab personnel liked the product, found it easy to use, mild on equipment and responded favorably to the product's odor. Personnel thought that the product's 5-minute disinfection claim was an important property, they liked the packaging and disinfection container and thought the color change showing proof of activation was a good feature. Nine of nine respondents preferred the RespiCide GP Disinfecting Solution to the products they were currently using.

Patients reported that the odor of their treated facemasks was pleasant or unnoticeable, and that the masks had no effect on their skin or eyes.

RespiCide GP Disinfecting Solution is a preferred alternative to the products currently used by the participating sleep labs to treat their facemasks, tubing, connectors and canisters. All three test sites preferred RespiCide GP Disinfecting Solution to their current product.

INTRODUCTION

RespiCide GP Disinfecting Solution is a single use disinfectant formulated for the disinfection of the rubber and plastic breathing equipment used in the diagnosis and treatment of patients with sleep apnea. The product is bactericidal; fungicidal, virucidal, and tuberculocidal. The product is packaged in two components: a fluid concentrate component consisting of 2% chlorine dioxide precursor and an activator component. Four ounces of RespiCide GP Solution produces one gallon of product. RespiCide GP Disinfecting Solution is effective in 5 minutes at 20°C. Following treatment, equipment is removed from the disinfecting solution, rinsed with water and allowed to air dry before being reused. The disinfecting solution is discarded and fresh solution is prepared for the next disinfection procedure.

RespiCide GP Disinfecting Solution was evaluated in three sleep labs: The Sleep Clinic, Oklahoma City, OK; Norman Regional Hospital, Norman, OK; and the sleep lab at Presbyterian Hospital, Dallas, TX. The fourteen-week study (4 weeks initial plus 10 weeks extended) was reviewed and approved by institutional review boards (IRB). The study began with the sponsor in-servicing each test facility on solution preparation, use procedure, and lab personnel and patient questionnaires. Facilities were contacted periodically by phone; each site was visited once a month during the course of the study.

The objectives of the field test were to obtain the following information:

1. Patients' response to facemasks exposed to product.
2. Sleep lab personnel's perception of the product's packaging, solution preparation, and exposure concerns.
3. Product's compatibility with rubber and plastic treatment equipment.

Information pertaining to items 1 & 2 was obtained from questionnaires completed by patients and healthcare providers at the 3 test sites. One hundred and eighty-two (182) patients, 168 from central locations and 14 from remote sleep labs, participated in the study. There were 42 sleep lab personnel responses, including 4 from remote sleep lab units. Sleep lab personnel also reported on the compatibility of the test solution on equipment (item 3).

RESULTS

Sleep lab patient responses regarding effects of the product on equipment are shown in Table 1 and are summarized below.

1. Ninety-eight percent of the patients reported that the odor of the masks after treatment with RespiCide GP Disinfecting Solution was either pleasant or unnoticeable. The remaining 2% misunderstood the question and reported comments regarding the mask itself.
2. Eighty-nine percent of the patients reported that the treated masks had no negative effect on their facial skin. The balance of the responses, which were recorded as unpleasant, pertained to the effect of the mask itself.
3. Ninety-six percent of the patients reported that the treated masks had no negative effect on their eyes. Again, negative responses were directed to the mask itself.

TABLE 1
SLEEP LAB PATIENTS

Performance Properties	Patient Responses			
	Pleasant	Unnoticeable	Unpleasant (see comments)	Comments
Odor of facemask	31 [2]*	133 [12]	4	stale air scent plastic scent
Effect of facemask on skin	15 [2]	134 [10]	19 [2]	not used to on face constricting too tight pressure mask itches a little sweaty uncomfortable hurt - removed
Effect of facemask on eyes	11	149 [14]	8	too tight slightly drying reading difficult prefer glasses irritates below eyes tears in eyes

*Number in bracket indicates patients receiving treatment by the Sleep Clinic at remote locations

Sleep lab personnel comments regarding the product's performance properties are shown in Table 2 and are summarized below.

1. The size and shape of the one-gallon container used to store product was easy to handle. Remote sites preferred a quart container.

2. The appearance and size of the 3-gallon disinfection container was acceptable. Some lab personnel preferred the container without the attached lid and available in several sizes.
3. Over 83% of the sleep lab personnel reported that the RespiCide GP Disinfecting Solution was easy to prepare.
4. All lab personnel reported product labeling easily understood.
5. Ninety-eight percent of responses indicated no concern or only moderate concern regarding the safety of exposure to the test solution.
6. Eighty-eight percent of respondents reported the odor of the test solution acceptable. However, when the solution was allowed to remain in a covered container overnight, the odor was strong and unpleasant due to the buildup of active ingredient.
7. The color change showing proof of solution activation was considered a good feature; and the color did not obscure the visibility of equipment in the disinfection container.
8. The 5-minute product disinfection claim was considered by almost everyone (98%) to be an important or very important property.

Sleep lab personnel comments regarding the effect of the product on equipment are shown in Table 3 and are summarized below.

1. Thirty-one percent of lab personnel reported no change in appearance of facemasks. However, 69% of the lab personnel reported slight discoloration to two types of facemasks manufactured by RespiCide. The silicone material on the Comfort Select mask became slightly yellow and the polyurethane nose cover on the Profile Lite mask became slightly pink. In all situations, the color changes did not appear to intensify with repeated treatments. Unlike masks treated with aldehyde disinfectants, masks treated with RespiCide GP Disinfecting Solution did not become opaque.
2. Ninety-three percent of the lab personnel reported that after treatment the facemasks had either a pleasant, unnoticeable, or acceptable odor.
3. The flexibility, hardness, and tactile properties of the facemasks remained unchanged after repeated treatments in RespiCide GP Disinfecting Solution.
4. Tubing, connectors, and canisters remained unchanged in appearance and functionality after repeated treatments in RespiCide GP Disinfecting Solution.

SUMMARY

The overall sleep lab personnel assessment of RespiCide GP Disinfecting Solution is summarized below and presented in Table 4.

1. Eighty-nine percent of sleep lab personnel (8/9) rated the appearance of their rubber and plastic equipment treated with RespiCide GP Disinfecting Solution better than or the same as equipment treated with their current product.
2. All respondents (100%) rated the performance of RespiCide GP Disinfecting Solution better than their current product and wanted to replace their current product with RespiCide GP Disinfecting Solution.
3. The most prominent features of RespiCide GP Disinfecting Solution perceived by sleep lab personnel were: lack of odor, ease of use, quickness of kill, and non-staining.

CONCLUSION

RespiCide GP Disinfecting Solution was perceived by sleep lab personnel as being a safe, pleasant-smelling, non-staining, user friendly, fast acting, easy on equipment disinfecting solution. RespiCide GP Disinfecting Solution was rated better than the current product used by each sleep laboratory.

TABLE 2: SLEEP LAB PERSONNEL – PERFORMANCE PROPERTIES

Assessment	Size/shape of 1 gal cont.	Solution preparation	Solution activation	Labeling	Exposure to solution	Odor of solution	Vis. of equip in solution	Proof of act [soln color]	Disinfection container appearance	Disinfection container size	Disinf. Time 5-minutes
Easy to handle Moderate Tedious Difficult	33 of 42 (3/4)* 6 of 42 (1/4) 3 of 42	35 of 42 (3/4) 5 of 42 (1/4) 2 of 42	38 of 42 (2/4) 3 of 42 (2/4) 1 of 42 (2/4)								
Easily understood Not easily understood				42 of 42 (4/4)							
No concern Mod concern Concern					17 of 42 (3/4) 24 of 42 (1/4) 1 of 42**						
Pleasant Acceptable Unpleasant						6 of 42 (1/4) 31 of 42 (1/4) 5 of 42***					
Very visible Visible Mod visible Not visible							14 of 42 (1/4) 24 of 42 (2/4) 4 of 42 (1/4)				
Good feature Not important Don't like								41 of 42 (4/4) 1 of 42			
Like Dislike Not important									28 of 42 (2/4) 14 of 42 (2/4)		
Good Too small Too large										35 of 42**** (3/4) 3 of 42***** 4 of 42 (1/4)	
Very important Important Moderately important Not important											30 of 42 (2/4) 11 of 42 (2/4) 1 of 42

*() Responses from personnel serving remote locations

** Mixed solution and let sit overnight while covered. Exposure caused irritation to nose—needs ventilation

*** Strong odor if let stand for long period

**** Better if lid not attached. Lid interferes with rinsing and concerned about durability.

***** Good for 1 room, too small for 2 rooms

TABLE 3: MATERIALS COMPATIBILITY

Assessment	Facemask				Tubing			Connectors/Canisters		
	Appearance (color)	Odor	Flexibility / hardness	Tactile [sticky to the touch]	Appearance (color)	Flexibility / hardness	Tactile [sticky to the touch]	Appearance (color)	Flexibility / hardness	Tactile [sticky to the touch]
No change Slight change Moderate change Change*	13 of 42 (1/4) 15 of 42* (2/4) 8 of 42* 6 of 42**(***)(1/4)		42 of 42 (4/4)	42 of 42 (4/4)	30 of 30 (4/4)	30 of 30 (4/4)	30 of 30 (4/4)	23 of 23 (4/4)	23 of 23 (4/4)	23 of 23 (4/4)
Pleasant Unnoticeable Acceptable Unpleasant		5 of 42 32 of 42 (4/4) 2 of 42 3 of 42								

* Slight yellowing, which does not increase in intensity over time. Respironics Comfort Select mask. Literature says no bleach or chlorine. Colored belts and head gear lightened (bleached) yellow tint

** Nose part on blue mask turned slightly pink; intensity doesn't increase over time

(***)Masks did not become cloudy. Previously, masks treated with a dialdehyde product became cloudy

(/) Data from technicals using product at remote facilities. The Sleep Clinic

TABLE 4

RESPICIDE GP DISINFECTING SOLUTION
FIELD TRIAL CLOSE OUT QUESTIONNAIRE SUMMARY

How would you rate the appearance of your equipment after treatment in RespiCide GP Disinfecting Solution?

	Responses	Comments
Like new:	1/10	none
Unchanged:	3/10	minor discoloration
Slightly changed:	5/10	slight discoloration
Changed:	1/10	slight pink ¹ , slight yellow ²

1. RespiCide Profile Elite
2. Simplicity Comfort Select

How would you rate the appearance of your equipment after treatment in RespiCide GP Disinfecting Solution compared to your current product?

Better:	5/9	
Same:	3/9	slight color change
Worse:	1/9	equipment color change

Current products:	Control [®] III Elite ³	Sleep Clinic
	Cidex [®] Plus ⁴	Norman Regional Hospital
	Cidex [®] OPA ⁴	Presbyterian Hospital

3. Registered trademark of Meril Products, Inc.
4. Registered trademark of Johnson & Johnson

How would you rate the overall performance of RespiCide GP Disinfecting Solution to your current product?

Better:	9/9
Same:	-
Worse:	-

What feature(s), if any, did you like best about RespiCide GP Disinfecting Solution?

- Kills everything; can totally submerge masks (Sleep Clinic)
- Easy to mix; works fast (Sleep Clinic)
- Odor was not unpleasant (Norman Regional Hospital)
- Fast acting; easy to use; no smell (Norman Regional Hospital)
- Fast acting; no smell; did not smell like glutaraldehyde (Norman Regional Hospital)
- Easy to prepare; less volatile in smell; doesn't stain skin (Presbyterian Hospital)
- Disposable; doesn't discolor masks (Presbyterian Hospital)
- Better smell than current dialdehyde product; Not so hard on the technicians using solution. (Presbyterian Hospital)