

Bonaduz, 30th October 2014

Material Compatibility Test Report

Disinfection with hydrogen peroxide

The aim of this test was to examine whether the GLOSAIR™ 400 (H₂O₂) ingredients are compatible with Hamilton Medical ventilator surfaces and the inner electronics.

How GLOSAIR works

The GLOSAIR system diffuses a uniform mist of low concentration hydrogen peroxide solution (5% - 6%) that reduces bio burden levels without leaving toxic residues. The action of the hydrogen peroxide results in mayor reductions in a broad spectrum of pathogens. The mist disinfects all hard nonporous surfaces, and can be used for both small- and large-space decontamination. It is appropriate for use I a variety of environments including ICUs and emergency rooms. The GLOSAIR technology automates hydrogen-peroxide-based decontamination including delivery, contact, and aeration. Once aeration is complete, the room is safe for use for the next patient or procedure.

The GLOSAIR system has also been successfully used in the European market for more than four years, and with more than 650 units currently installed, there have been no reports of material degradation or problems with electromechanical systems used in hospitals.

A variety of studies from Johnson & Johnson show the efficacy of this procedure.

How the test were performed

One unit of each of the Hamilton Medical ventilator product families (HAMILTON-G5, HAMILTON-T1, HAMILTON-C2) underwent 28 GLOSAIR cycles.

Test conditions

- Most of the tests were performed with the ventilation system OFF, without a breathing set or expiratory valve connected.
- Five cycles were executed with the HAMILTON-C2 blower on.

Function tests

- All of the tested devices were subjected to the following tests and inspections before starting the GLOSAIR testing process, and after every 8th cycle through the GLOSAIR system, as specified:
 - Preoperational checks, according to the device operator's
 - General tests, according to the device service manual
 - Electrical safety tests, according to the device service manual
 - Service software run after cycles 9, 18, and 24
 - Visual inspection after every cycle
- Microscopic surface checks were performed after cycle 24
- The testing process was executed according to the information provided in the *GLOSAIR 400 System Quick Guide*.

Test results

There were no visible changes to any of the device surfaces after the compatibility tests were completed. A white layer (hydrogen peroxide stabilizer) was visible on the device after completion of a single test, but this layer could be easily wiped off, leaving no damage to the device. All service-related tests were performed on each of the test devices before the compatibility testing, after each 8th cycle, and after completion of all of the test cycles. These tests were all successful.

The tests with the HAMILTON-C2 showed that all blower-driven devices (HAMILTON-C1/T1/MR1/C2/C3) can be used with the GLOSAIR system will not damage the blower.

Conclusion

As the GLOSAIR 400 did not in any way damage the material of the devices tested, we can conclude that the GLOSAIR 400 can be safely used to decontaminate the surface of Hamilton Medical ventilators and related devices. Confirmation of its efficacy must be requested from Johnson & Johnson, as this did not form part of the compatibility test.

The Department of Hospital Infection at the Ullevål University Hospital in Oslo, Norway published a study¹ in the Journal of Hospital Infection stating that the ventilation of the device could lead to the decontamination of the inner parts of the device. We have not tested the efficacy of this claim, but we can confirm that even with the ventilator blower running, the tests were passed successfully.

With kind regards

Hamilton Medical AG



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