TECHNICAL NOTE

H2O2 DECONTAMINATION OF THE VIABLE AIR SAMPLER MAS-100 NT®

Figure 1: MAS-100 NT viable air samplers in a PSI (SKAN AG 2019) from SKAN AG (photo courtesy of SKAN AG)

HYDROGEN PEROXIDE DECONTAMINATION

Active microbial air sampling is frequently required for cleanrooms and associated controlled environments. Microbial contamination by the air sampler must be avoided. Thus, they must be decontaminated. The MAS-100 NT/NT Ex viable air sampler is specified for use in ISO 5/GMP Grade A environments. Externally accessible parts are designed for easy cleanability and spray/wiping disinfection. Independent data published by Sandle and Satyada (Sandle und Satyada 2015) have proven effectiveness of external decontamination of the MAS-100 NT using 70% isopropanol.

Vaporised hydrogen peroxide (H_2O_2) is routinely used in critical environments to bio-decontaminate surfaces and equipment. Here we[1] demonstrate that MAS-100 NT can be decontaminated using vaporized H_2O_2 without effect on instrument functionality.

[1] We thank SKAN AG, Allschwil, Switzerland, for executing the experiments.

MBV AG, Industriestrasse 9, CH-8712 Stäfa, T +41 44 928 30 80, welcome@mbv.ch, www.mbv.ch

EFFECTS OF EXPOSURE TO H_2O_2

MBV AG together with the globally leading isolator manufacturer SKAN have performed a detailed evaluation of the portable microbial air sampler MAS-100 NT regarding the decontamination with vaporized hydrogen peroxide. The main functional quality criterium of an impaction-based viable air sampler such as the MAS-100 family instruments is its ability to aspirate a target air volume at a given air flow and impact the air with a constant speed onto an agar filled Petri dish (Figure 2). The physical and biological recovery rate of an air sampler depends on this capability. Key to correct performance is a functioning airflow sensor which controls the air blower. Consequently, the best indicator of performance under stress is testing airflow stability using an alternative measurement method to the differential pressure-based mass-flow sensor integrated into the MAS-100 NT.

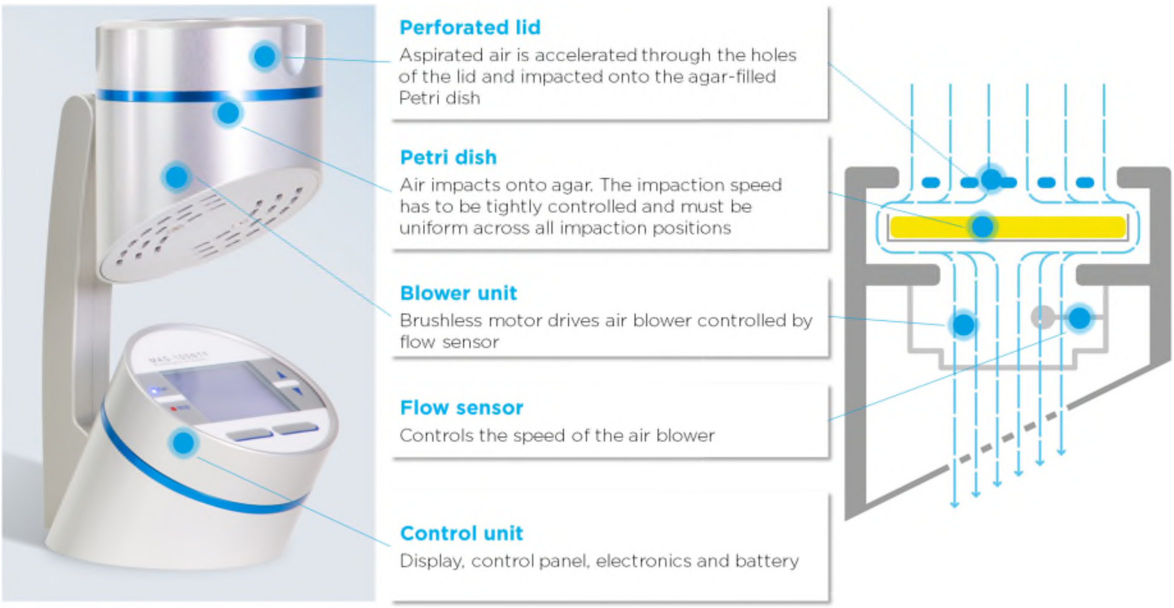

Figure 2: Functioning principle of the impaction-based microbial air sampler MAS-100 NT. On the right schematic cross-section of the sampling head with perforated lid, agar-filled Petri dish and blower unit with airflow sensor.

The goal was to simulate 10 years regular decontamination of a MAS-100 NT microbial air sampler using vaporized H_2O_2 and test for air flow stability over time. If such airflow calibrations remain within the instrument specification, then performance remains unaffected.

TESTING H_2O_2 RESISTANCE

EQUIPMENT

Testing environment:	Pharmaceutical Safety Isolator from SKAN AG. 840 ppm H_2O_2, controlled by Dräger sensor for high concentration (HC) hydrogen peroxide.
Instruments tested:	2x MAS-100 NT Airflow: 100 Standard liters per min (SLPM) ± 2.5% Instrument 1: SNR: 108400, usage time: 1971 h Instrument 2: SNR 108302, usage time: 1924 h
Calibration instrument:	DA-100 NT digital vane wheel anemometer (±1% reproducibility, temperature and pressure compensated). MBV PC – based software used to perform automated airflow calibration.
Reagents:	50% hydrogen peroxide (Solvay)

MBV AG, Industriestrasse 9, CH-8712 Stäfa, T +41 44 928 30 80, welcome@mbv.ch, www.mbv.ch

PROCEDURE

The MAS-100 NT instruments were positioned inside the PSI isolator (Figure 1). The perforated lids were removed and placed next to the instruments Figure 3.

The instruments were left turned off while exposed to H_2O_2.

The test chamber was filled with 840 ppm H_2O_2. The chamber was vented daily, and the air samplers were checked with the DA-100 NT digital anemometer. The calibration (but no adjustment) was performed automatically, and the resulting calibration protocol was generated and saved.

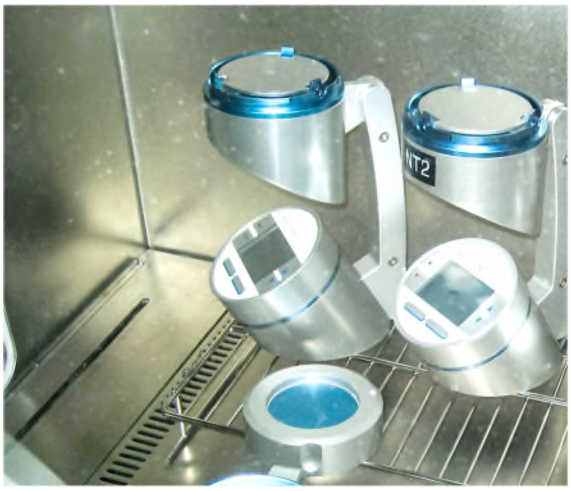

Figure 3: Two MAS-100 NT instruments with removed perforated lids inside the test chamber (photograph courtesy of SKAN AG).

This was repeated for 12 days to simulate approx. 10 years of weekly H_2O_2 decontamination:

- 12 d * 24 h/d = approximately 288 h of H_2O_2 exposure
- 10 y * 50 weeks/y * 1 decontamination cycle/week = 500 decontamination cycles
- 288 h/500 decontamination cycles = 0.58 h/average dwell time

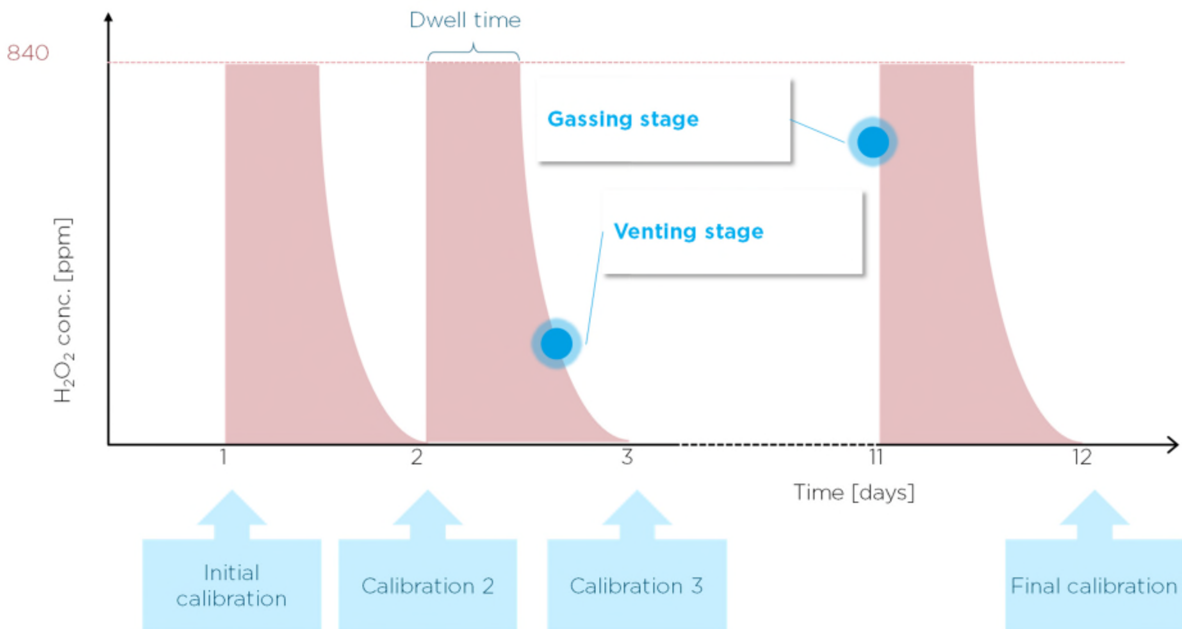

Figure 4: Schematic of H_2O_2 exposure, calibration and decontamination cycle. The time required for the gassing and venting stages are exaggerated in comparison to the dwell time.

PROVEN RESISTANCE TO H2O2 EXPOSURE

The results of the daily airflow calibration of the two MAS-100 NT are presented in Figure 5. Throughout the 12 days exposure of the air samplers to H_2O_2 the airflow remained within the specification of ±2.5% of the target air flow 100 SLPM. As the pneumatic performance of the air sampler during the simulated time frame of 10 years remained unaffected, we concluded that the instrument can withstand at least the simulated 500 calibration cycles.

MBV AG, Industriestrasse 9, CH-8712 Stäfa, T +41 44 928 30 80, welcome@mbv.ch, www.mbv.ch

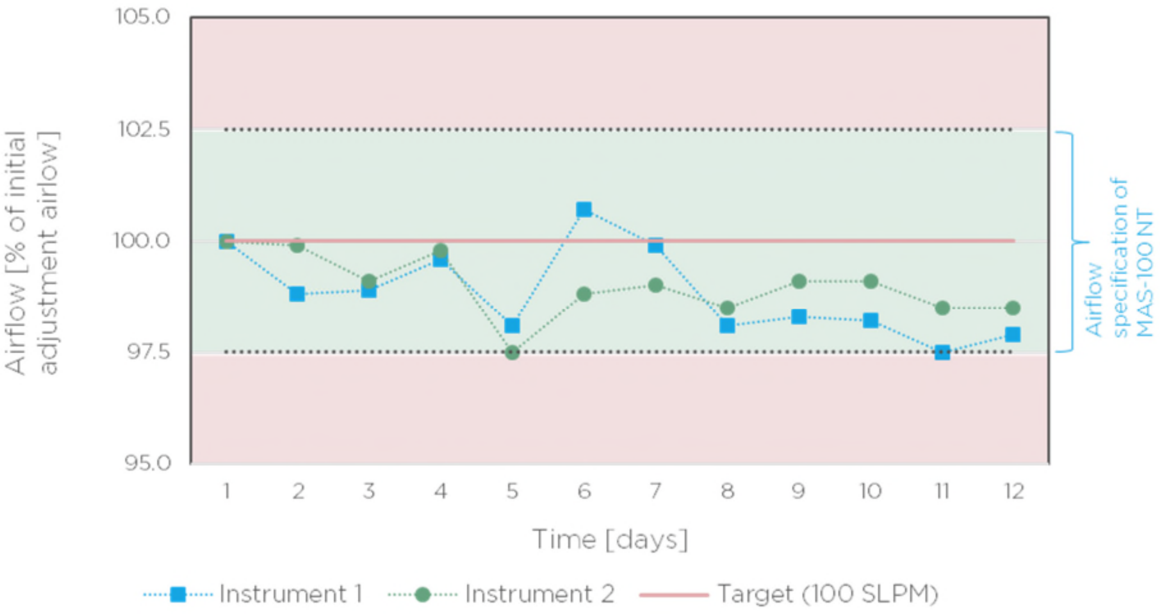

Figure 5: Airflow calibration of two MAS-100 NT exposed to H_2O_2 over 12 days.

Apart from testing the airflow calibration we separately tested individual electronic and mechanical components. These were placed inside the same test chamber and assessed optically after 12 days exposure.

The electronic components were visibly affected but not damaged. To protect flow sensor and electronics H_2O_2 decontamination must be performed with the blower inactive.

Decolorization of the blue anodized aluminium parts (perforated lid 300 x 0.6 and rings) was apparent (Figure 6). The decolorization is only a cosmetic degradation and has no effect on the functioning of the air sampler.

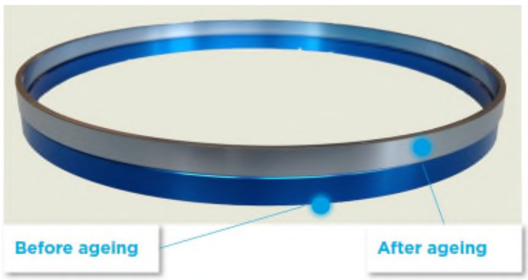

Figure 6: Blue ring (see Figure 2) before and after long-term exposure to vaporized hydrogen peroxide. The decolorization has no influence on function and may also occur when an instrument is frequently cleaned or disinfected with solvents or detergents.

The [MAS-100 NT Ex] is the explosion proofed version of the MAS-100 NT and the results described above can be extended to that product.

MBV AG, Industriestrasse 9, CH-8712 Stäfa, T +41 44 928 30 80, welcome@mbv.ch, www.mbv.ch

RESTRICTIONS AND RECOMMENDATIONS

- The results and conclusions of this technical note are only applicable to decontamination with vaporized H_2O_2. No conclusions for the use of other decontamination media can be made.
- It is mandatory, that throughout the whole H_2O_2 decontamination process the instrument must be switched off and the blower must remain inactive.
- It is not permitted to decontaminate the instrument or perforated lid with a liquid medium and then dry the perforated lid by running the blower.
- The blue anodized parts may experience decolorization due to H_2O_2 exposure.
- The perforated lid shall be unmounted during the H_2O_2 decontamination. The perforated lid and the dust cover can be autoclaved for 20 minutes at 121°C.
  Alternatively, the perforated lid and the dust cover can be dry-decontaminated at 180°C for 60 minutes.
  In case of dirt / blocked holes of the perforated lid: Clean them with a needle, or by using an ultrasonic bath. Do not wash aluminium parts in dishwashers.

REFERENCES

Sandle, Tim, and Ravikrishna Satyada. "Assessment of the disinfection of impaction air sampler heads using 70% IPA, as part of cleanroom environmental monitoring." *European Journal of Parenteral & Pharmaceutical Sciences.* Vol. 20. no. 3. 2015.

SKAN AG. *Modular Working Isolator PSI-M.* 04 12, 2019. https://skan.ch/en/products-view/44-modular-working-isolator-psi-m (accessed 4 12, 2019).

MBV AG, Industriestrasse 9, CH-8712 Stäfa, T +41 44 928 30 80, welcome@mbv.ch, www.mbv.ch