LivaNova

Health innovation that matters

Frequently Asked Questions (FAQs) Regarding Use of LivaNova Deutschland GmbH heater coolers in combination with certain oxygenators with polymer heat exchanger designs

1. Which laboratory conducted LivaNova's toxicological assessment?

The toxicological assessment from which LivaNova determined the Allowable Limits for presence of hydrogen peroxide in the patient blood was conducted by IASON Consulting, a specialized laboratory located in Germany (Muehlenstrasse 26A D – 52382 Niederzier / Germany)

2. Was this assessment confirmed by one or more other institutes / experts?

This assessment was confirmed by two other firms: Walker Downey & Associates is a privately-owned, independent consultancy firm and Bibra Toxicology Advice & Consulting Ltd is a large, independent consulting firm that provides a comprehensive range of advisory and consultancy services on all aspects of chemical toxicological hazard and human health risk.

3. Will the LivaNova's toxicological assessment be published or distributed to customers?

The toxicological assessment is part of our Design History File which contains proprietary information related to our design. We are in a regulated industry where products are cleared or approved by Competent Authorities and/or Notified Bodies considering the results of our Verification and Validation activities (V&V). We do not provide the results of the V&V to customers who purchase our products to guarantee that our products are safe and effective but they can rely on our final product certification (CE mark, 510k approvals, … other local approvals) to get this assurance.

4. In the FSN you refer to a category of "*patients with greater susceptibility to hydrogen peroxide*''. Does it mean that there are different ALs for these patients?

Our toxicological assessment has demonstrated that use of the 3T System devices for durations of 6 hours or less remains within Allowable Limits for patients with greater susceptibility to hydrogen peroxide.

5. How can a clinician identify a patient with greater susceptibility to hydrogen peroxide, prior to starting the case?

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Patients with greater sensitivity to H_2O_2 include those with conditions such as Vitamin E deficiency, heritable deficiencies of the enzymes responsible for breakdown of H2O2 and certain types of hemolytic anemia. However, this is not intended to be a complete list of all conditions that could impart greater H_2O_2 susceptibility, but should alert clinicians to general classes of patients who might demonstrate greater susceptibility. Patient monitoring and management should then be based on best clinical practices.

6. As a clinician, what practical options exist to treat patients with greater susceptibility with H_2O_2?

Ensure that the Oxygenators/Heat-Exchangers used to treat these patients are presenting a permeability to hydrogen peroxide that is below the AL specified by LivaNova.

7. In the FSN, you say that LivaNova oxygenators (all brands and models) are compatible with the prescribed Allowable Limits. What conditions were used to evaluate the Inspire family of oxygenators?

LivaNova has performed in vitro testing using water (worst case situation) and bovine blood for the evaluation of hydrogen peroxide diffusion across the Inspire heat exchanger polymer fibers. The conditions used in these tests consisted of circulating water or bovine blood on the patient side of the CPB circuit simulating different patient body weights and H_2O_2 at a concentration of 330 ppm in the 3T heater-cooler water circuit for a duration of 6 hours.

8. What is the H_2O_2 permeability rate of INSPIRE and what is the safety factor vs. the AL?

The quantity of hydrogen peroxide transferred from the water side to the blood circuit an adult patient of 60Kg connected to an Inspire oxygenator was found to be 57 times below the Allowable Limit (AL) for daily systemic exposure to hydrogen peroxide.

9. Why do different oxygenators with polymer heat exchangers have different behaviors in terms of diffusion?

Heat exchanger design, manufacturing process and fiber characteristics may all play a role with respect to diffusion through the HE fibers. We do not have access to these data for competitive device for us to be able to understand the variability observed from in different devices.