heat and moisture exchanger booster.

LIFE SCIENCES & HEALTH

CORE COMPETENCIES

1. Redesign
2. Compatibility
3. Certification
4. Production

When a patient needs artificial respiration, dehydration of the patient is an important concern. It is vital that the supplied air is sufficiently humidified and heated, while preventing condensation in the respiratory tubes. To improve the humidification performance Medisize has developed an active Heat and Moisture Exchanger (HME) booster element for use in combination with their disposable respiratory tubes. The original design of this HME booster was susceptible for water intrusion and failure. Medisize therefore had a clear need for a next generation HME booster, which was more robust but had a comparable price level.

DEMCON | ADVANCED MECHATRONICS

What were our challenges?

The redesign faced several challenges. Firstly, there are strict requirements on the materials that could be used. As parts of the exterior of the HME booster are in contact with the air that go to the patient, biocompatible materials needed to be used. Also the product is positioned quite near the head of the patient. This means that very high temperature and voltage safety requirements are applicable.

For the HME booster to function properly, a watertight seal with the disposable tubing slot is required. As it turned out, the shape and size variations of this slot were quite extensive. Combined with the required lifetime, the design of a seal was very challenging.

Besides a good seal, also the enclosure of the HME booster needed to be tolerant for water intrusion. This means that the product required a rather high IP class. At the same time, internal air still needed to be able to escape from the HME booster interior for cooling.

Finally, very strict requirements were set on the target cost price of the product, limiting the technical solutions that were possible. In addition, the product is intended for use in different parts of the world, meaning that the design procedure should be compatible with the different certification procedures in these countries.

How does the HME booster work?

In order to ensure biocompatibility while keeping the development effort within bounds, the same plastic exterior material as used for the original booster was applied. This material had already proven its worth and, although newer plastic compounds with better injection molding properties were available, no new elaborate biocompatibility tests would be required.

By applying a specific membrane, allowing air to pass but blocking liquid, a high IP class of the product could be realized, while still allowing warm air to escape. In this way, rather simple components could be used and not stringent temperature demands were needed for the interior components. In turn, this ensured a lower cost price.

A thorough analysis of the mechanical tolerances of the disposable booster slot and the HME booster exterior size was setup. In close cooperation with suppliers, it was chosen to employ an X-ring seal instead of an O-ring seal. This improved robustness, lowered insertion forces and had no significant impact on price level.

Our role developing this system

By thoroughly analyzing the problems with the original booster, we could draft a set of requirements for the redesign. An experienced multidisciplinary team of engineers worked closely together with application engineers and regulatory affairs officers from Medisize. Also the ever important documentation was setup in such a way that it aligned with both our Quality Management System and the one of Medisize.

The technical design and tests were carried out by us. Medisize provided their input via regular review sessions and update meetings. Selection of suppliers was done in a joint effort.

Because the serial production of the HME booster is also performed by us, a smooth transition of the design phase to the serial production phase was ensure, in which challenges could swiftly be resolved. Currently the HME booster is being produced in larger quantities at Demcon production, which includes the assembly, testing, clean packaging and shipping of the products.

Contact at Demcon

Demcon advanced mechatronics • 31 (0)88 115 20 00 • info@demcon.com • www.demcon.com/mechatronics