test bed for aerosol drug delivery to neonates.

HIGH-TECH SYSTEMS

CORE COMPETENCIES

1. Fluid dynamics to simulate and minimize deposition of aerosol particles on systems wall
2. Accurate measurement and control of low tidal volumes
3. Airtight, easily exchangeable patient interface and filter system

Development of new products

Medical inhaler technology is increasingly evolving from simple, constant drug administration to intelligent, breathing-controlled systems for inhalation treatment with pharmaceuticals. Compared with other ways of administration (intake of tablets), drug dosing is challenging for inhaled aerosol intake, as it depends on aerosol and breathing parameters and the patient's current health status. Aerosols have become an effective form of drug administration to the lungs and resulted in the development of new, innovative products for aerosol generation. But, before a medical device can be approved for commercialization or clinical application, it has to undergo comprehensive testing to ensure the functionality and safety

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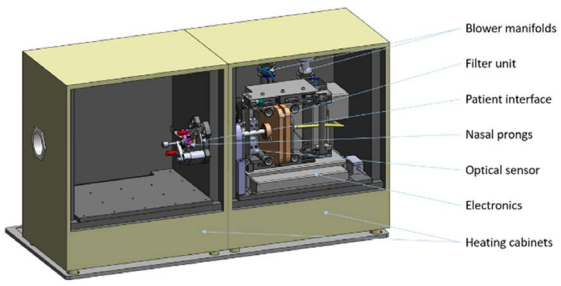
of its use. There is a steep increase in requirements during obligatory conformity assessment, documentation and clinical testing requirements. The introduction of this new level of patient safety through the new Medical Device Regulation places a heavy burden on medical device innovation in Europe. Resulting in a significant number of SMEs in the MedTech field that is now at risk, economically and resource-wise. It threatens value chains and has the potential to affect the sustainability of the entire European medical device sector. With a potential loss of innovation, jobs, economic strength and product diversity.

Joint venture of research institutes, universities and business

In January 2019, Demcon joined 13 partners from 7 European countries in the European Horizon 2020 project MDOT (Medical Device Obligations Taskforce). The goal of MDOT is to establish a 'one-stop-shop' platform for MedTech SMEs – reducing the burden on medical device manufacturers, in the form of a database that will include data on regulatory affairs and testing up to clinical evaluation and clinical studies.

To demonstrate the usability of the platform, it is addressing three technologies as a starting point: inhalers for pre- and early-term neonates, 3D-printed neural implants, and coatings for orthopedic prostheses that reduce the wear of particles in the patient's tissue.

Demcon's task in the project is to develop a test bed for the verification of inhalers for pre- and early-term neonates, under standardized conditions. It fulfills a medical need for a measurement method for aerosol delivery through inhalers, which does not yet exist.



The test section is connected between two copper rings that are connected to the electrode. Because the test section is very high in resistance, the pieces are connected with gold soldering to make sure that there is a durable connection that is also ductile at high temperatures and remains there at these high temperatures. Silver for instance wouldn't work, because it would fuse into the copper.

Simulating breathing patterns of preterm neonates

The test system generates the breathing pattern and integrates the aerosol generator and the measurement device into the ventilation cycle. In addition, for physical characterization of the aerosol at the patient interface the test bed must be suitable for minimal volume flow rates. The system enables the simulation of respiratory parameters of preterm neonates and other parameters affecting aerosol generation, such as temperature. This allows the applied doses to be evaluated.

Combining gravimetric and optical detection

To measure the aerosol delivery the test bed combines gravimetric and optical detection to determine the aerosol output of (triggered) inhalation systems, simulating (preterm) neonate respiratory parameters.

The system has a patient interface where different sizes of nasal prongs, together with the nebulizer and ventilator, can be connected to the test bed. The connection tubes and nasal prongs are heated to the incubator temperature, the breathing generation module is heated to mimic the neonate's body temperature. The test bed itself simulates the neonate breathing pattern (tidal volume, breathing frequency, I:E ratio, CPAP pressure). During the simulated breathing profile, the aerosol is inserted via the patient interface into the test bed. The amount of aerosol inserted into the system by simulating an inhalation is measured by an optical sensor and collected in a filter.

Impact of the system.

The test bed will be used to verify newly designed and/or improved (triggered) inhalation systems by measuring the aerosol output. The fast measurement allows the characterization of inhalation devices and accelerates optimization and development. Fraunhofer ITEM is currently working with Demcon and Poznan University on the development of new administration systems for preterm neonates, this provides patients with the highest drug concentration that is physically possible. The test bed is used to verify the performance.

This new inhalation system allows treatment periods to be reduced to a minimum. The novel technology enables simple adjustment of the dose and dose rate to a patient's specific requirements, without compromising particle quality or quantity.

Fulfilling a medical need

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