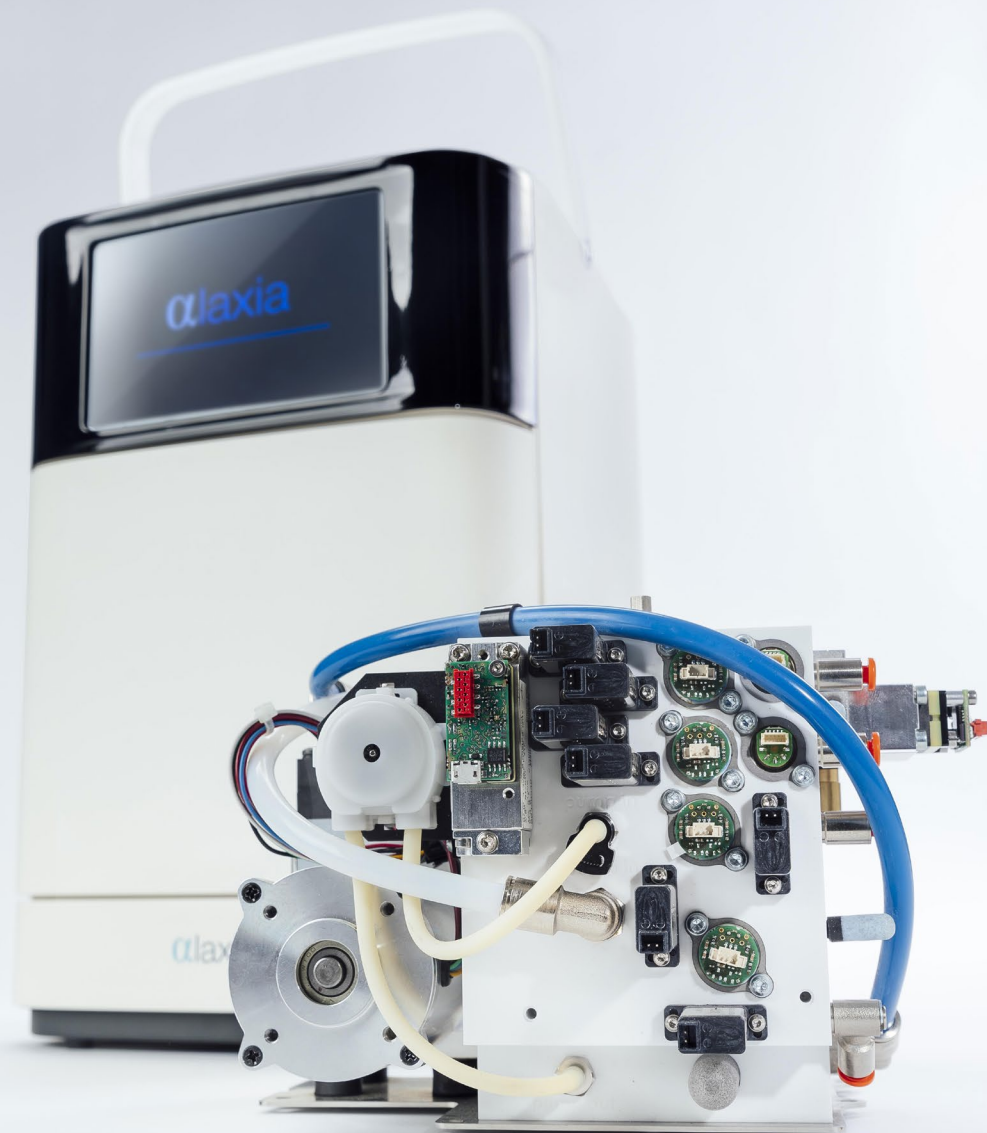


BEST PRACTICE | CREATIVE EURECOM / ALAXIA

## ALX-009

System partnership for the development of a home-use medical device - treatment of cystic fibrosis.



## BÜRKERT FRANCE EQUIPS THE FIRST DEVICE IN THE WORLD TO ENABLE HOME PRODUCTION OF A CANDIDATE DRUG

Creative Eurecom is an R&D company specialising in medical devices based near Angers. Bürkert, which specialises in the design fluid control systems, met Creative Eurecom's needs by developing a custom solution for equipping the first device capable of producing home treatments for combating lung infections in cystic fibrosis patients.



### Did you know?

Hidden behind the streamlined design and simplicity of use of this device, there is a complex and sophisticated technology that most notably uses a miniaturised manifold developed specifically to meet the needs of Creative Eurecom by the Bürkert Systemhaus teams in Germany.

## Origin of project ALX-009

At the end of 2016, Alaxia (Stragen Group), a Lyon-based start-up specialising in antimicrobial products, entrusted this development project to the design office of Creative Eurecom to conceive and manufacture a compact and transportable machine that allows a dose of ALX-009 to be produced at home for inhalation by patients affected by cystic fibrosis.

ALX-009 consists of two molecules normally present in the lungs and part of the innate immune system. Cystic fibrosis patients lack these molecules or suffer from a deficiency of them.

Introduced directly to the lungs by inhalation, ALX-009 aims to help the patient's organism better fight bacterial infections.

*Cystic fibrosis is a genetic disease. It is defined by viscous secretions at the level of various organs, principally the lungs and the pancreas. It develops from birth, and advances with progressive episodes. Lung infections are the main cause of mortality among cystic fibrosis patients.*

One of the two components of ALX-009 is special in that it is highly reactive, which prevents conventional approaches to industrial production and distribution in pharmacies or hospitals. To provide relief for this problem, the only alternative was to design a device that would make it possible to produce the solution to be inhaled at home any time.

Several European health agencies have authorised early clinical trials (phase I trials) to evaluate the tolerance of ALX-009. This trial, in which mainly healthy volunteers and cystic fibrosis patients will participate, is currently ongoing. This means that the device will be introduced to various sites participating in this clinical trial in France and the UK very soon. Phase II of the clinical trial is expected to be conducted in Europe and North America.

The objective of project ALX-009 sponsored by Alaxia was to develop a response to antibiotic-resistant infections and thereby to improve the quality of life and life expectancy of patients.



## On-demand production at home

Conceived to be ultra-easy to use from home by the patient and/or their family, the device is fitted with a touchscreen panel and an on/off button.

The device can be used with specific single-use consumables and must be able to reliably, reproducibly and robustly produce each ALX-009 dose.



## A custom solution for regulation and measurement developed by Bürkert

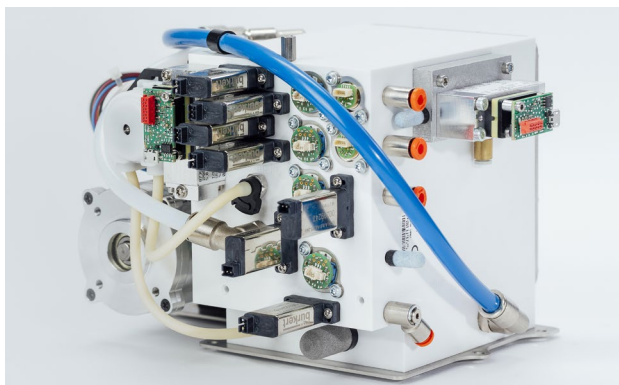
One of the device's key functions lies in regulating air pressure. This was the launching point of the partnership between Creative Eurecom and Bürkert.

Based on the specifications document provided by the client, Bürkert's engineers designed a manifold that integrated several pneumatic components to ensure full functionality.

The system incorporates a compressor, a pump, a filter, solenoid valves, pressure sensors and flowmeters. Fluidic circuits and an air tank are also incorporated directly into

the manifold. This custom system is assembled and fully pre-tested by Bürkert - a reliable turnkey solution to meet the needs of Creative Eurecom.

The WhisperValve Type 6724 is a key element of the system - it is a state-of-the-art solenoid valve fitted with a separating diaphragm. Connected to different sensors, it allows pressure values to be controlled very precisely and reproducibly in order to assure the quality of the final drug.



## Advantages and benefits of a Bürkert System solution for the client:

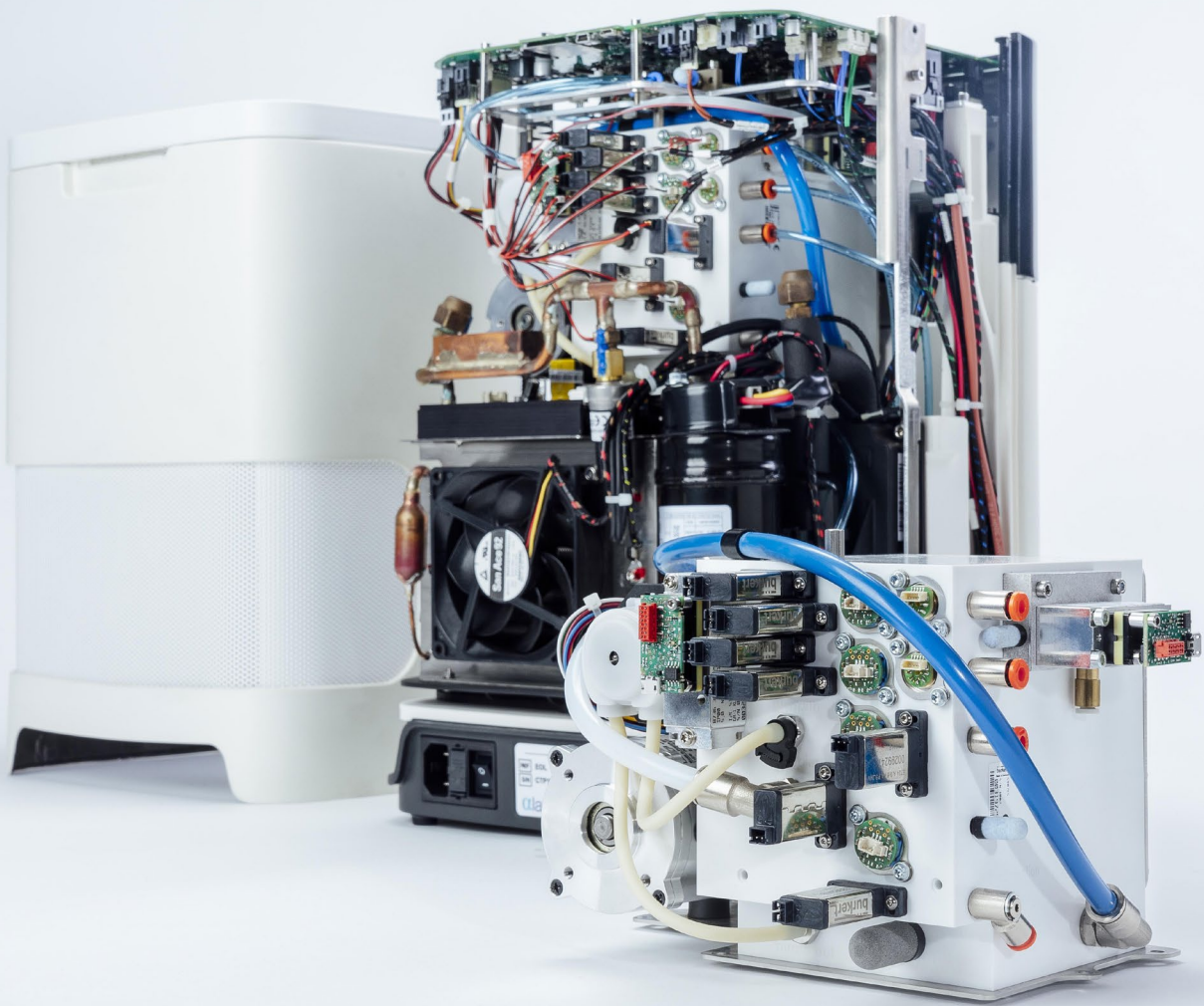
### Time saved in the management of a medical device project:

A development project for a medical device is technically complex and the validation phases are very long, involving technical risks and potential delays.

Working in a close partnership with Bürkert from 2017 in order to create the complete pneumatic module, Creative Eurecom achieved time-savings by benefitting from the experience of the Systemhaus engineers in fluidics and industrialisation. The abilities of each were combined to create a reliable market ready product conform to the specifications.







“Hidden behind the streamlined design and simplicity of use of this device, there is a complex & sophisticated technology that most notably uses a miniaturised manifold developed specifically to meet the needs of Creative Eurecom by the Bürkert Systemhaus teams in Germany.”

## WE KEEP ON LEARNING THANKS TO YOU!

Bürkert today is a valuable partner throughout the world when it comes to working with gases and liquids. Why? Almost certainly because, thanks to our customers, we have been developing our knowledge for 70 years. This always enables us to think ahead when taking decisive action. And where necessary, this sometimes even means leaving our comfort zone.

**We make ideas flow.**

For real added value. Let's talk - we're eager to discover what your challenges are.

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