

## LE-50 PROSTERILE SPECIFICATIONS

Fluidnatek LE-50 ProSterile	
<b>Chamber internal dimensions (in mm) &amp; cleanliness grade</b>	680x620x550 – ISO 5
<b>Solution dosage</b>	High-pressure syringe pump (2-channel)
<b>Positive HVPS</b>	+30kV
<b>Negative HVPS</b>	-10kV
<b>Rotating collector platform</b>	20 to 2000 rpm
<b>Sterilization systems</b>	Up to 3 combined techniques
<b>Glove box port</b>	<input checked="" type="checkbox"/>
<b>Vacuum antechamber</b>	<input checked="" type="checkbox"/>
<b>Automated linear motion of collector assemble</b>	Y-axis (adjustable both speed and stroke length)
<b>Automated emitter-collector regulation</b>	<input checked="" type="checkbox"/>
<b>Multi-emitter spinning head</b>	5 emitters
<b>Actively regulated exhaust system</b>	<input checked="" type="checkbox"/>
<b>Environmental Control Unit (ECU)</b>	<input checked="" type="checkbox"/>
<b>High-definition Process Data Hub</b>	<input checked="" type="checkbox"/>
<b>Programmable sequential multi-step recipes function</b>	<input checked="" type="checkbox"/>

### Fluidnatek LE-50 ProSterile

The Fluidnatek LE-50 is a compact laboratory benchtop machine as powerful as an advanced research station. Designed with adaptability in mind, the highly modular LE-50 electrospinning device can be easily configured for a variety of electrospinning or electro spraying tasks. Crucially, it is compatible with an AC unit for climate control, which can be added at any time, making it an ideal machine for conducting precise research or development activities. All Fluidnatek electrospinning equipment is compatible all along the range of machines for doing the scale up from lab stage to manufacturing.



## Fluidnatek<sup>®</sup> ProSterile: Electrospinning for In-line Aseptic Bioprocesses

The production of electrospun products in aseptic conditions is a medical application raising more and more interest in clinics and other research labs as well as in biomedical companies. Fluidnatek is not unaware of this demanding request. This is the story which led us to create the range of Fluidnatek ProSterile electrospinning equipment configured to create an aseptic environment for manufacturing sterile products.

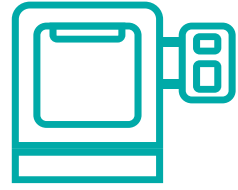


One  
Step  
Ahead



### Ultra-Clean Chamber Design

In collaboration with Mayo Clinic, we have taken electrospinning into a new era of ultra-clean medical device processing. Welded stainless steel inside and out, HEPA filtration to meet ISO 5 cleanliness standards and chamber sterilisation systems enable aseptic conditions for the production of sterile electrospun products for the first time.



### Chamber Sterilisation Systems

Set the challenge of achieving aseptic conditions within the chamber, we developed a combination of complimentary sterilisation measures that eliminate all traces of bacteria, virus and endotoxin before/after processing.



### Precise Solution Dosage

We understand the importance of control and precision when it comes to medical and pharmaceutical devices manufacture. The premium high-accuracy syringe pumps deliver precise solution dosage to ensure a consistent and stable process. An optional second solution feed enables a second material to be deposited simultaneously to combine different material properties, e.g. bioactivity and mechanical strength, within the same device.



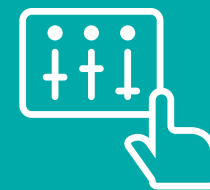
### Glove Port Access with Vacuum Antechamber Pass-through

In order to maintain sterility within the chamber the Fluidnatek LE-50 ProSterile incorporates glove ports to give the operator access to all areas of the spinning chamber, as well as a vacuum antechamber that allows apparatus and materials to be transferred into and out of the chamber without opening the chamber.



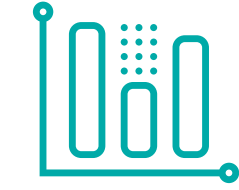
### Environmental Control

Achieving a stable process and consistent product requires tight control of both temperature and humidity within the electrospinning chamber. As one of the first manufacturers to custom-develop climate control systems specifically for electrospinning machines, we have built up many years of expertise in this field. Capable of heating, cooling, drying and humidifying, our powerful ECUs also communicate with the actively regulated extraction from the chamber to ensure the optimum balance of stability and safety.



### Automated Batch-to-Batch Consistency

Product consistency is perhaps the most important aspect of medical and pharmaceutical device manufacture. We have developed a series of automated features to help minimise rejection rate and ensure each batch meets the required quality and specifications. The Fluidnatek LE-50 ProSterile electrospinning machine offers multi-step programming functionality to minimise the risk of operator errors.



### Suitable for GMP and ISO Processing

Manufacture of medical and pharmaceutical devices require a process to be validated and manufacturing runs to be properly recorded. The Fluidnatek LE-50 ProSterile electrospinning machine provides multi-user level access, batch control and high-definition data collection. We can also support your validation by providing an IQ/OQ documentation package and on-site service and even full process development and qualification (PQ) service if required.

