The scale-X™ hydro structured fixed-bed bioreactor

Small-scale production for early stage process development

scale-X™ [hydro]

UNIVERCELLS Technologies

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A RANGE OF SCALABLE SINGLE-USE BIOREACTORS

Our manufacturing technologies have been designed to achieve cost-effective, high- performance viral production in a compact footprint. The scale-X™ range features single-use, structured fixed-bed bioreactors designed to ensure a seamless transition through process development, clinical validation and commercial manufacture.

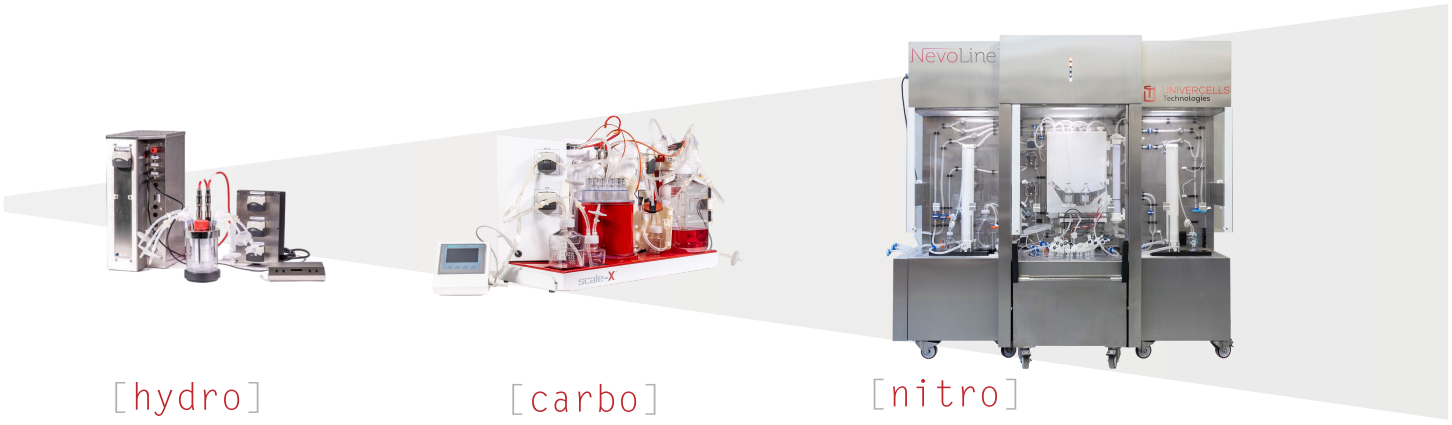
High productivity
Homogeneous cell growth and increased viral yield in a reduced footprint

Reliability
Batch-to-batch consistency and reproducibility across scales achieved via automation and constant physical parameters

Cost-effectiveness
Significant costs savings across the different stages of the product development

scale-X™

NevoLine™ Upstream

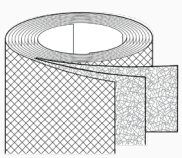


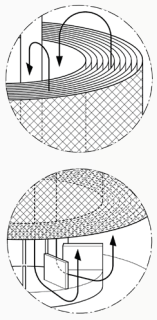
[hydro]
[2.4 m²]

[carbo]
[10 & 30 m²]

[nitro]
[200 & 600 m²]

R&D	Clinical	Commercial





An intensified process

A structured fixed-bed consisting of alternating sheets of non-woven PET fabric and spacer netting spiral wound. This unique design densifies the area available for cell growth in a small volume.

- Rapid & homogeneous cell entrapment
- Consistent media flow & nutrient availability
- Reproducible high-productivity

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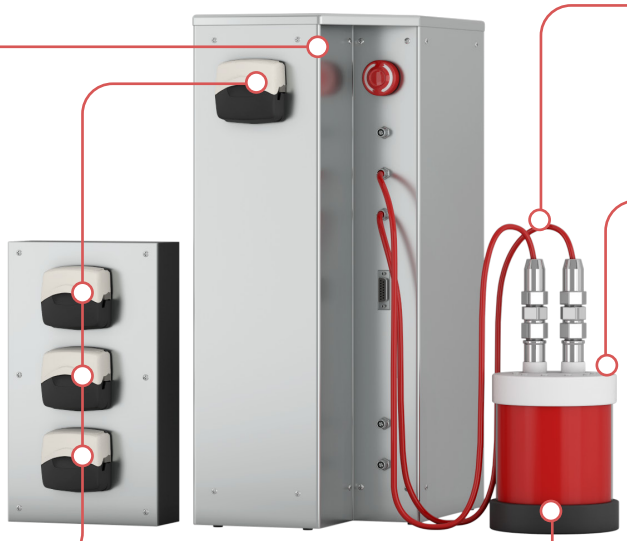
A SOLUTION FOR EARLY PROCESS DEVELOPMENT

The scale-X hydro bioreactor is a small-scale, single-use, structured fixed-bed bioreactor enabling direct process transfer from existing processing technologies for rapid proof of concept studies within a reduced footprint.

Automated process control

Controller with an integrated software interface for automated process execution and cell culture parameter monitoring and adjustment (pH, DO, temperature & agitation)



In-line monitoring

RedOx pH, optical DO & temperature sensors

Easy manifolds set-up

Pre-assembled tubing manifolds available

Fluid management

Built-in peristaltic pumps

High density cell culture and viral production*

- Structured fixed-bed bioreactor with 2.4 m^2 cell growth surface
- 12 fixed-bed samples for cell counting

Low footprint system to be used in laminar flow or biosafety cabinet.

*Can be used on selected third party controllers (ask our sales representatives for more information)

Ease of process transfer

Rapid transfer from 2D technologies or alternative fixed-bed bioreactors.

Selected proven success

Cell lines

- Vero
- HEK293
- EB66
- CHO
- MRC-5

Applications

- Viral vectors for cell & gene therapy
- Viral vaccines (human & veterinary)
- Oncolytic viruses
- Other biological products (e.g. exosomes)

Viral products

- Adenovirus
- VSV
- AAV
- sIPV
- Lentivirus

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scale-X hydro > Specifications

scale-X hydro controller

Component	scale-X hydro controller External pump box	Outside BSC/LAF Inside and/or outside BSC/LAF
Characteristics	Weight Dimension (W x D x H) Material of construction Compliance	15 kg 275 x 350 x 790 mm (11 x 14 x 31 inch) Stainless steel CE mark
Utilities	Electrical supply	Universal input 110 V or 230 V, 50/60 Hz with safety cut-off switch
	Power consumption (W)	500 W (maximum)
	Gas supply	Filtered*, 0.6-1.5 bar supply, medical grade (filtration with cut-off 0.22 µm), dry, oil-free **Note: Only use filters suitable with a pressure of 0.6-1.5 bar.*
	Integrated software interface	Ethernet laptop connectivity to end user's laptop for control of process parameters through web interface
	Environment	Operating: T= 5-40°C (41-104°F), non-condensing conditions Storage: T= 20-50°C (68-122°F), non-condensing conditions
Magnetic driver controller	Mixing	Agitation range: 540 – 840 rpm
Heating system	Heating	Temperature range: 31 – 39 °C (88 - 102 °F)
Sensors	pH Delivered oxygen Temperature	1 * Hamilton EasyFerm Plus HB Arc 120, autoclavable 1 * Hamilton VisiFerm DO Arc 120 H0, autoclavable 1 * Jumo PT-100 resistance temperature detector
Pumps	4 x Watson Marlow 114 pumps (3 in the external pump box, 1 on scale-X controller)	Base pump: 0 – 41 mL/min Recirculation In pump: 0 – 141 mL/min Recirculation Out pump: 0 – 141 mL/min Media In/Sampling pump: 0 – 255 mL/min
Mass Flow Controller	Flow rate range: 5-250 mL/min Air, CO^2 and oxygen control in overlay	

scale-X hydro bioreactor

Material of construction	Casing: Non-woven fabric: Spacer netting:	Polycarbonate PET Polypropylene
Vessel	Dimensions (D x H) Growth surface Volume (total) Sterilization	11.4 x 15.5 (with lid) cm (4.5 x 6.1 inch) 2.4 m^2 Min 500mL, Max 900mL; recommended 750mL (process dependent Autoclavable
Sampling	Fixed-bed sampling Liquid sampling	12 pre-cut fixed-bed sample carriers that require aseptic extraction from the bioreactor using sterilized tweezers. Operation in a LAF/SBC. Sampling manifold or from the lid cap
Ports	Liquid and gas connections	1 * Recirculation IN 1 * Recirculation OUT 1 * Base IN 1 * Media IN/Sampling 1 * Gas IN 1 * Gas OUT with foam trap
	Monitoring	1 * port for pH probe 1 * port for DO probe 1 * port for T probe

Manifolds assemblies and cell counting

Bottles	1 * Bottles kit	Pre-sterilized bottles: 1L Pharmatainer, 5L Pharmatainer and 125 mL Pharmatainer
	1 * Set of bottles caps pre-fitted with the required tubing, connectors and filters	Lid connection manifold Sampling manifold Foam Trap manifold Base manifold Recirculation loop manifold
Manifolds	Base IN Recirculation IN Recirculation OUT Sampling/Media IN	Silicon, MPC connectors, L/S14 Silicon, MPC connectors, L/S16 Silicon, MPC connectors, L/S16 Silicon, MPC connectors, L/S25
Cell counting kit	Lysis solution	500 mL of lysis solution A 500 mL of lysis solution B

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