



## **scale-X™ carbo bioreactor system**

Intensified fixed-bed technology for  
cost-effective & scalable viral production



**UNIVERCELLS**

# scale-X™ [carbo]

Bench-scale automated cell culture system for expression and concentration of viral drug substance, suited for rapid process development and cost-effective clinical production. The scale-X™ carbo system features a modular, scalable, fixed-bed bioreactor designed for enhanced upstream processing of viral products.

## Cost-effectiveness

Low-footprint integrated system delivering high cell densities & viral titers

- » Optimized capital investment & production costs

## Reliability

Homogeneous cell distribution throughout the fixed-bed

- » Provides consistency within & among batches
- » Automated process control

## Scalability

Predictable cell & product behavior

- » Reduced risk in process transfer
- » Simplified process development
- » Seamless scale-up



## Applications

- » Viral vaccines
- » Viral vectors
- » Oncolytic viruses

## Scales

- » 10 m<sup>2</sup> and 30 m<sup>2</sup> of available growth surface
- » Suited from R&D to clinical production

## Automated Process Control

### Controller

Advanced process control functionalities for protocol execution & standard parameter monitoring

### Benchtop system

Ease of use in laminar flow or biosafety cabinet, docking slots for single-use components



### Sensors

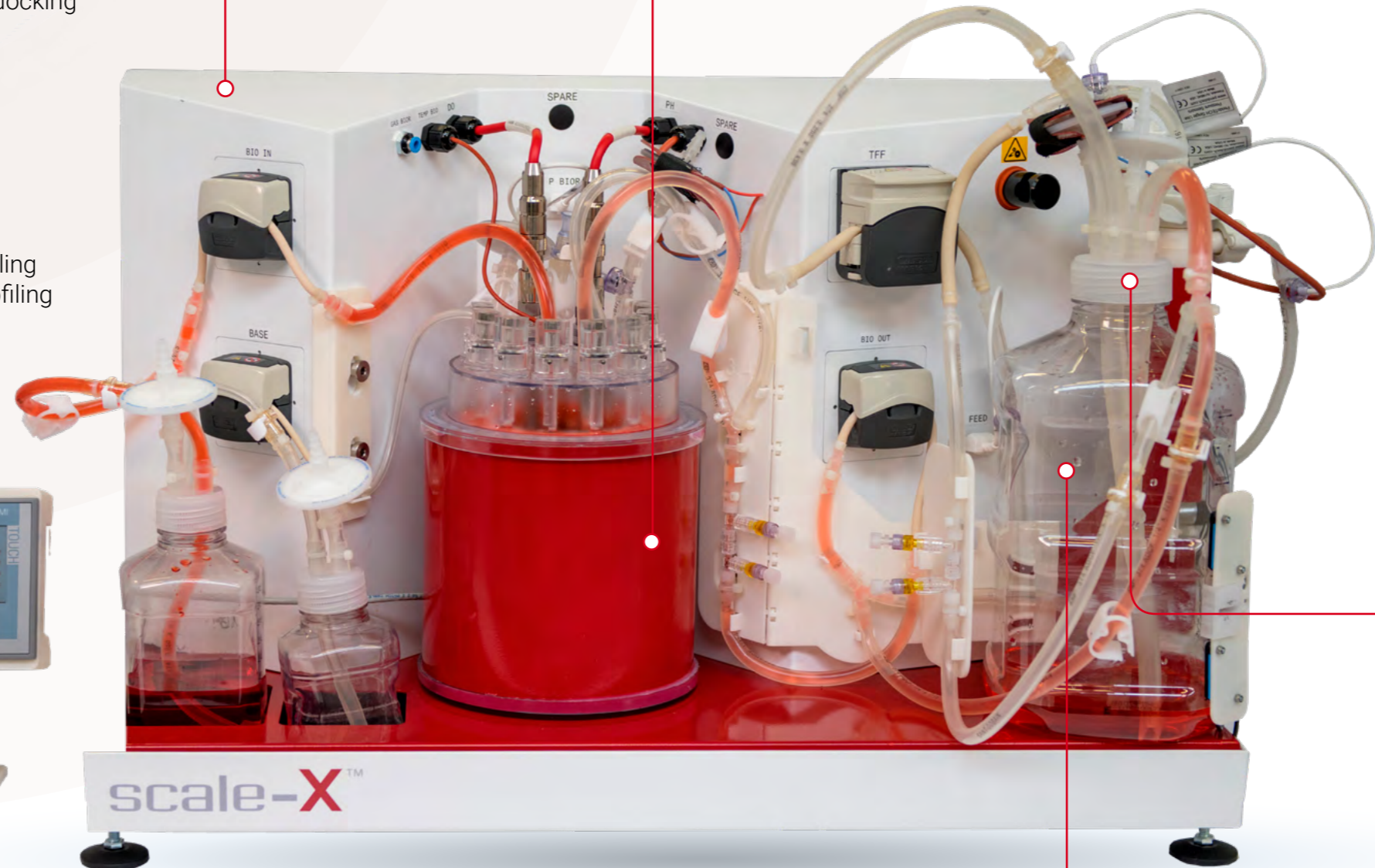
pH, Dissolved Oxygen, temperature, pressure and fluid levels

### Sampling

Fixed-bed and media sampling for cells and metabolite profiling

### Quick access screen

Key parameters display & manual pump control



## High-density fixed-bed bioreactor

Single-use bioreactor with novel structured design for reliable & scalable production

### Growth surface

Treated micro-fabric with alternate spacer netting, assembled as spiral-wound structure

- » Rapid & homogeneous cell entrapment
- » Homogeneous media flow & nutrients availability



### Scalability by design

- » Constant linear velocity of fluids and even distribution through the fixed-bed ensure a smooth scale-up
- » Bubble-free aeration mechanism provides high gas mass transfer coefficient while minimizing stresses

### In-line concentration

Delivering continuously concentrated harvest for simplified purification

### Hollow fiber tangential flow filtration

- » Plug-and-play, 1300 cm<sup>2</sup> cartridge & pre-assembled manifolds
- » Automated process control



### Operations supervision

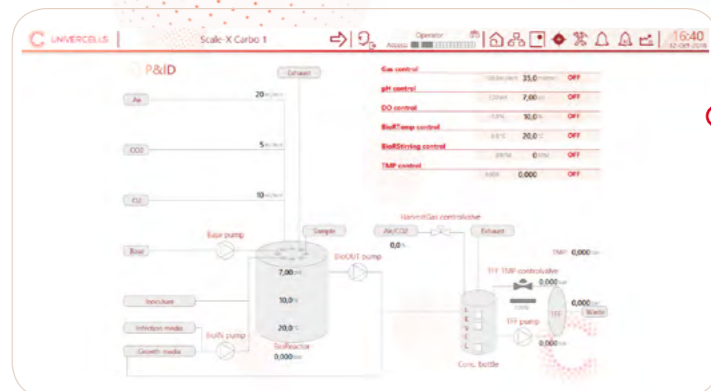
#### Mobile workstation & Wonderware® system platform

- » Process protocol upload
- » Data recording & reporting
- » Operates one or two controllers in parallel

### Manifolds & bottles

Complete set of consumables for media circulation, automated adjustment and sampling

- » Tubing manifolds pre-assembled on bioreactor for easy set-up



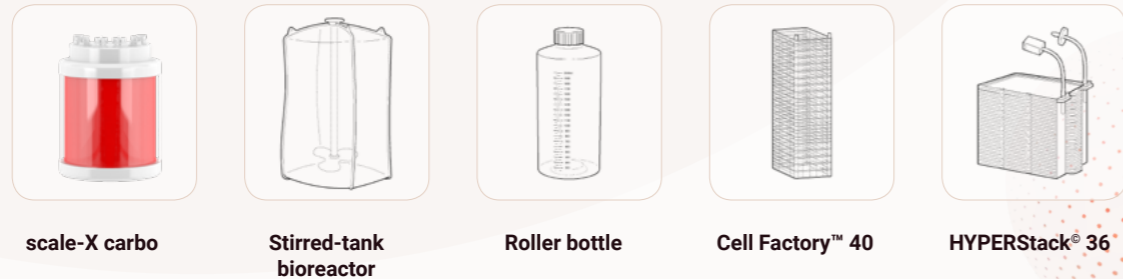
# scale-X™ [carbo]

## Delivering intensified production



The scale-X carbo bioreactor offers a significant increase of the surface/volume ratio compared to conventional technologies:

- » 10 m<sup>2</sup> growth surface in 1.8 L working volume
- » 30 m<sup>2</sup> growth surface in 4.2 L working volume



Consumables					
Growth surface/unit	30 m <sup>2</sup>	4,400 cm <sup>2</sup> /g	850 cm <sup>2</sup> /RB	25,280 cm <sup>2</sup> /CF40	18,000 cm <sup>2</sup> /HS36
# units	1 bioreactor	68 g microcarriers	350 RB	12 CF40	16 HS36
Hardware					
Required equipment (W x D x H)	Controller 0.8 x 0.3 x 0.5 m	50 L Bioreactor 0.6 x 0.9 x 2.0 m Control tower 0.8 x 0.9 x 1.7 m	Incubator (for 55 RB) 1.0 x 0.9 x 2.2 m	Incubator (for 16 CF40) 1.9 x 1.2 x 1.7 m	Incubator (for 8 HS36) 1.4 x 1.2 x 1.8 m
# units	1 controller	1 bioreactor	7 incubators	1 incubator	2 incubators
<b>Total footprint</b>	<b>0.24 m<sup>2</sup></b>	<b>1.26 m<sup>2</sup></b>	<b>6.3 m<sup>2</sup></b>	<b>2.28 m<sup>2</sup></b>	<b>3.36 m<sup>2</sup></b>

Consumables (# units)		scale-X carbo <sup>30</sup>	
		1	
	RB	350	
	HS36	16	
	CF40	12	
	STR	1	
Equipment footprint (m <sup>2</sup> )		scale-X carbo <sup>30</sup>	
		0.25	
	RB	6.3	
	HS36	3.36	
	CF40	2.28	
	STR	1.26	

### Cost-efficient & reliable operations

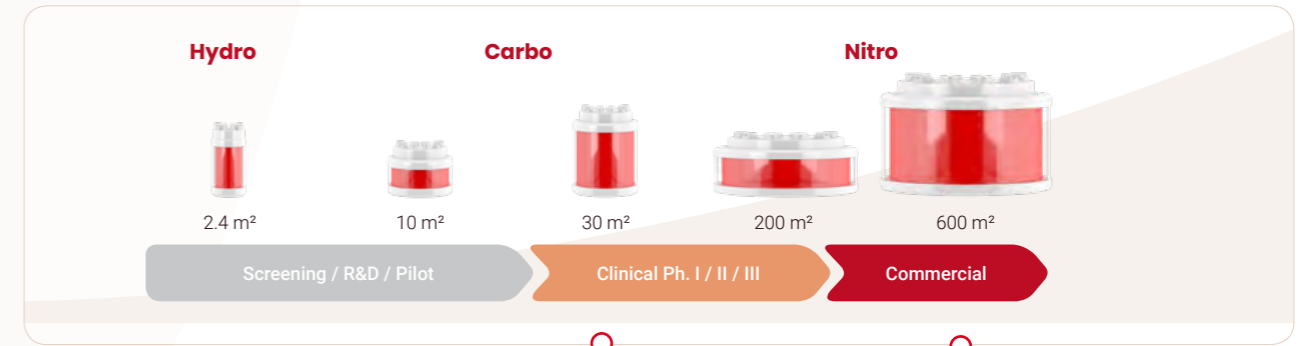
- » Reduced consumables, media & utilities consumption
- » Simplified manual operations

### Optimized capital investment

- » Simplified equipment & infrastructure

## A broad range of solutions from discovery to commercial stage

The scale-X family is designed to ensure seamless scalability from early process development to commercial manufacturing. The fixed-bed structure provides a high surface area available for cell culture in a very low footprint, while delivering similar fluid conditions at all scales, thus ensuring predictable cell & product behavior.



## scale-X carbo is the perfect tool for R&D activities and clinical material production

Benefiting from a low footprint, the scale-X carbo system can be used in a laminar flow or biosafety cabinet, providing production capacity for R&D to clinical applications.

- » 800 x 300 x 500 mm for a total 0.24 m<sup>2</sup> footprint

## Chaining scale-X nitro to downstream processing

in the NevoLine™ biomanufacturing platform, delivering concentrated bulk product for clinical and commercial manufacturing.

- » Process intensification and chaining enable containment in 10 m<sup>2</sup> isolators or biosafety cabinets, for rapid deployment of low-CAPEX facilities



## scale-X™ carbo > Specification

### Control unit

<b>Controller</b>	Description	PLC-based Siemens® TIA S7-1200 control system with a local HMI control
	Automation design	Developed and tested according to Gamp5 standard
	Dimensions (W x D x H)	800 x 300 x 500 mm
	Net weight (empty)	30 kg
	Net weight (including largest consumable liquid filled)	40 kg
	Material	Painted stainless steel
	Heating	Heating docking station Bioreactor heating range: room temperature to 37°C
	Agitation	Magnetic agitation plate (0-1500 RPM)
	Pumps & flow rate range	<ul style="list-style-type: none"> <li>• Bioreactor IN: Watson-Marlow™ 114; 0-141 mL/min</li> <li>• Bioreactor OUT: Watson-Marlow 114; 0-141 mL/min</li> <li>• Base, Watson-Marlow 114; 0-42 mL/min</li> <li>• TFF: Watson-Marlow 313; 0-900 mL/min</li> </ul>
	<b>Probes &amp; sensors</b>	Dissolved oxygen
pH		1 x Hamilton EasyFerm® plus HB Arc probe (autoclavable) 120 mm (carbo 10 m <sup>2</sup> ); 225 mm (carbo 30 m <sup>2</sup> )
Temperature		1 x PT-100 Temperature probe (0-50°C)
<b>Quick access screen (HMI)</b>	Description	4" color touch screen HMI (Human Machine Interface) for parameters visualization & sampling command
	Communication	Ethernet port RJ45 connected to the controller
<b>Power, data &amp; gas management box</b>	Location	Outside of BSC/LAF, within a 2-meter distance
	Materials of construction	Painted steel
	Dimensions (W x D x H)	300 x 160 x 600 mm
	Weight	15 kg
	Gas	Gas Process air, CO <sub>2</sub> and O <sub>2</sub> (up to 200 mL/min)
<b>Utility requirements</b>	Electrical supply	110 to 230 V
	Power consumption	650 W
<b>Mobile workstation (SCADA)</b>	Description	Mobile workstation with Wonderware SCADA software interface; PLC-based control system Siemens S7 Tia Portal
	Automation design	Developed and tested according to Gamp5 standard
	Network compatibility	Network connection available for Company network
	Data export	SQL-based structure, CSV format data export

### Single-use components

		carbo 10	carbo 30
<b>Fixed-bed bioreactor</b>	<b>Vessel</b>		
	Available growth surface (m <sup>2</sup> )	10	30
	Dimensions (D x H)	209 x 166 mm	209 x 341 mm
	Vessel total volume (L)	1.8	4.2
	Vessel working volume (L)	1.6	3.3
	Materials	Disposable single-use casing	
	Sterilization	Autoclavable	
<b>Agitation</b>	Impeller	Magnetically-driven impeller	
	Recommended agitation speed	250 rpm	450 rpm
	<b>Ports</b>	Liquid and gas connections	
	Monitoring	<ul style="list-style-type: none"> <li>• 1 x Liquid IN (1/4")</li> <li>• 1 x Alkali (1/8")</li> <li>• 1 x Liquid OUT (1/4")</li> <li>• 1 x Gas IN (1/4")</li> <li>• 1 x Gas OUT with pressure sensor (1/4")</li> </ul>	
<b>Monitoring</b>	Fixed-bed sampling	8 x single-use fixed-bed samples, non-aseptic sampling method	
	Liquid sampling	Via syringe on media OUT line	
<b>Manifolds</b>	Tubing manifolds pre-fitted with vessel	Allowing liquid inlet & outlet, base addition, gas vents	

### Concentration via Tangential Flow Filtration – Optional

<b>Cartridge</b>	Description	1300 cm <sup>2</sup> Hollow Fiber Tangential Flow Filtration cartridge
	Materials	Cartridge: modified polyethersulfone; Cartridge housing: polysulfone
<b>Manifolds</b>	Description	Tubing, connectors and single-use pressure sensors for automated process control, 5L bottle
	Materials	Manifolds: C-Flex® tubing; Connectors: PC, PVDF and polysulfone; Bottle: PET

### Manifolds & bottles

<b>Bottles</b>	1* Bottle kit (readily sterilized)	<ul style="list-style-type: none"> <li>• 1 x Inoculation bottle (1 L)</li> <li>• 1 x Harvest bottle (5 L)</li> <li>• 1 x Alkali bottle (500 mL)</li> </ul>
	1* Set of bottle caps pre-fitted with the required tubing, connectors and filters	<ul style="list-style-type: none"> <li>• 1 x Inoculation bottle cap manifold</li> <li>• 1 x Harvest bottle cap manifold</li> <li>• 1 x Alkali bottle cap manifold</li> </ul>
<b>Manifolds</b>	Base manifold	1/8" C-Flex, CPC connector
	Media IN manifold	1/4" C-Flex, sterile connector
	Media OUT manifold	1/4" C-Flex, sterile connector with filter vents (0.22 µm) 1 x foam trap bottle 2 x in-line liquid sampling ports with closed system transfer device
	Bioreactor vents	1/4" C-Flex, PendoTECH™ pressure sensor, 0.22 µm filters
	<b>Cell counting kit</b>	Lysis solutions