

RC-40_{Mark 2}

Roller Bottle Systems

Quicker. Easier. Safer. Better.



Semi-Automated Cell Processing Systems

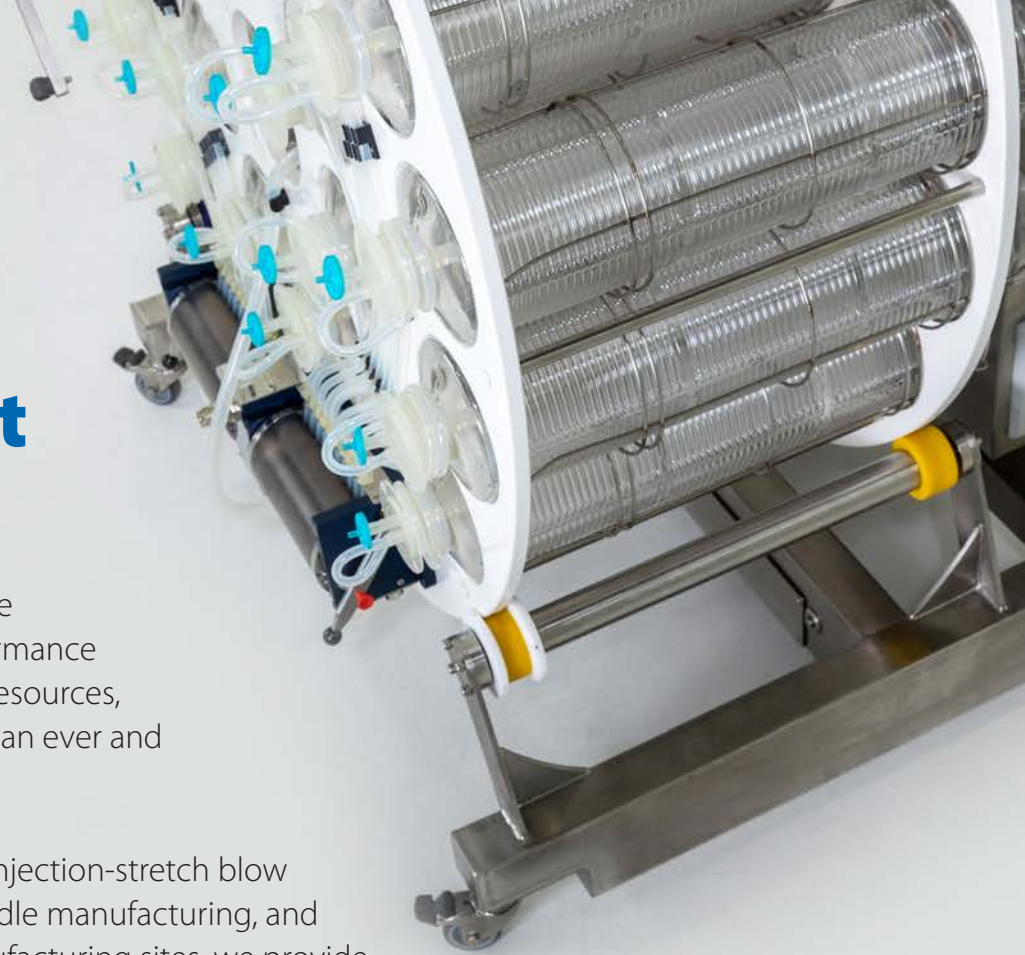


What We Do

Simplifying Single-Use Systems to Build the Best Home a Drug Can Get

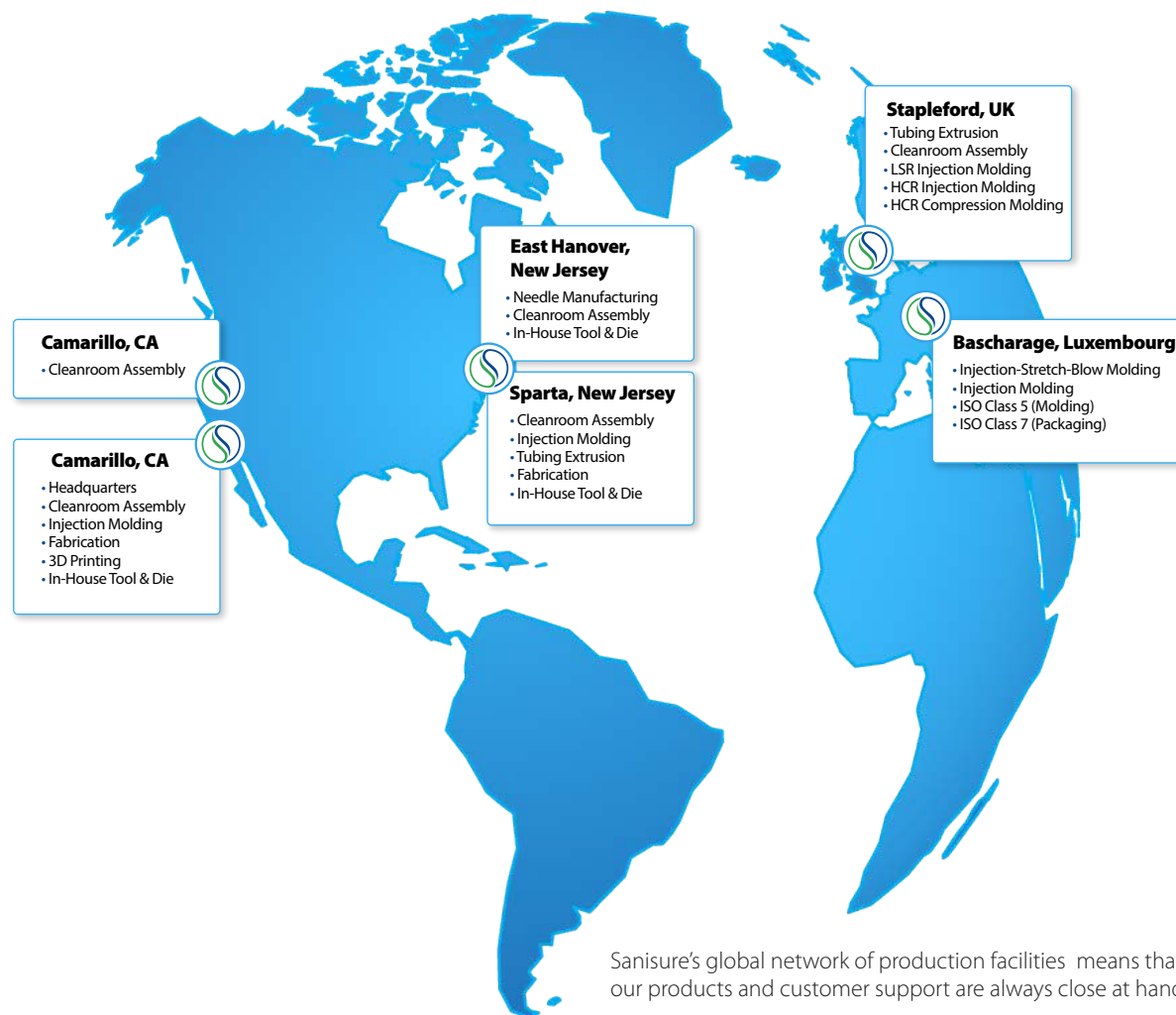
SaniSure is a global leader in simplifying single-use systems for sterile drug and vaccine manufacturing and other biotech applications. With the combination of industry-leading single-use technology (SUT) companies (Cellon, Silicone Altimex, TBL Performance Plastics, GL Engineering and Sani-Tech West) in to SaniSure, our resources, capabilities, and ability to create value for customers is greater than ever and unmatched in the industry.

Our core manufacturing capabilities include injection molding, injection-stretch blow molding, cleanroom assembly, tubing extrusion, fabrication, needle manufacturing, and other proprietary technologies. With a global footprint of 6 manufacturing sites, we provide an unrivaled level of vertical integration and supply-chain security. Our founding companies have been at the forefront of SUT innovation for decades and have supported many clients through all phases of drug and vaccine development and production.



Where We Are

6 Manufacturing Sites Worldwide



Introducing

The Superior **RC-40 Mark 2**

Quicker. Easier. Safer. Better.

Meet the revolutionary RC-40. Once its bottle packs are installed, everything from media exchange to harvesting can be performed automatically in a self-contained environment. This saves time and labor costs while optimizing yields and virtually eliminating contamination.



RC-40 Roller Bottle System

Closed Automated Processing

Unlike robots or traditional roller bottle handling systems, the RC-40 automates all stages of a roller bottle process.



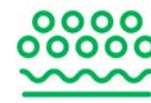
Cell Inoculation



Incubation



Media Exchange



Trypsinisation



Final Harvest

One RC-40 system enables a single operator to complete a full roller bottle tissue culture protocol – seeding, media change, trypsinisation and harvest – for an equivalent of 200 standard roller bottles in less than two hours.

2 Months

Time to convert from lab scale to RC-40 commercial manufacturing.

30 Minutes

Time for operator to perform media exchange of 40 5x roller bottles without opening them

15 Minutes

Time for operator to harvest 40 5x roller bottles without opening them.



Detail Specifics

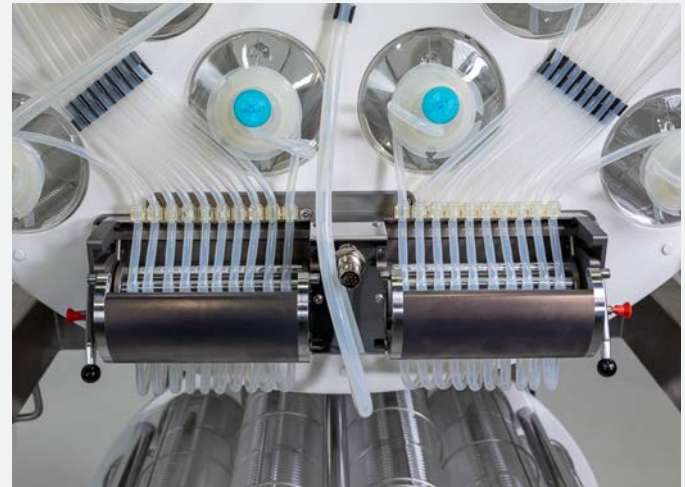
Pump

Consistent Pressure Application

Homogeneous filling is achieved because colinear axis points allow for consistent pressure to be applied on each tube. This results in pump filling accuracy of $\pm 5\%$.



- Easy dismountable cover
- Closing trajectory calculated to have an homogeneous pressure application
- Quick cover locking system with lever
- No mechanical calibration required
- Filling accuracy $\pm 5\%$
- Motor with augmented torque



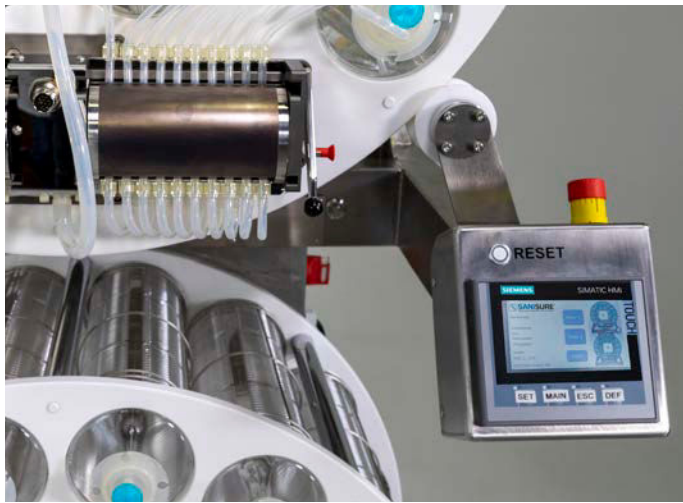
- Same pressure is applied on each tube to provide homogeneous filling
- Colinear to ensure the same pressure application:
 - Positioning pins axis
 - Cam followers axis
 - Center axis of the cover
 - Center axis of the roller assembly

Detail Specifics

HMI

User-Friendly Controls

Modern Siemens HMI KPP 400 Comfort controls include password protection, alarm histories, remote operation and multi-language capabilities.



Screen monitor provides detailed data information.



- Touch panel with different levels of protection through login + password
- Alarm histories
- Easy process configuration
- Monitoring of all important data
- Remote operation / troubleshooting possible through the network
- Multi-language capabilities
- Easily connected
- Multicolor
- Real-time monitoring

Detail Specifics

Frame & Rotors

Automatic Tilt System

Significant improvements to the traditional roller apparatus allows for automation of all tasks previously undertaken manually or by robotic processors.

Frame Overall

- Robust 316 stainless steel frame
- Touch screen multi-color HMI
- Hidden actuators, wires, pulley and belt for improved cleaning & safety
- Profinet (or others on demand) networking available for supervision
- Automatic tilt system
- Improved bottle guidance



The optimized frame features enclosed system components and automatic tilt for an enhanced safe and clean no-touch environment.

Detail Specifics

Frame & Rotors

Automatic Tilt System

The RC40 Mark 2 Roller Bottle processing system has been designed for improved operator handling and post-production cleaning operations.

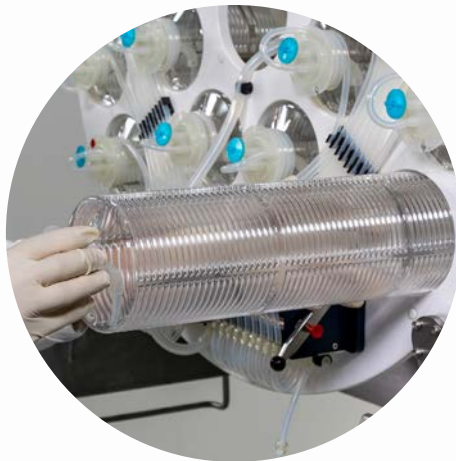


Rotors

- Design reduces the number of screws and enhance cleanability
- Rotor unit easy to handle with the help of a semi- automatic lift (coming soon)
- Good bottle positioning ensured with guide and spring concept for easy bottle load/unload
- 2 rotors operate independently allowing processing of one while the other continues incubation

Ready-Assembled **Bottle Packs**

The gamma irradiated RC-40 Bottle Packs consist of 20 bottles ready-assembled with tubings, manifolds, and filters providing access to the cell culture area via a aseptic connection. One Bottle Pack is required per rotor and once placed in the rotor, RC-40 Bottle Packs enable all further processing to be performed without additional bottle handling by the system operator. These unique Bottle Packs provide a closed production environment, virtually eliminating handling related contaminations.



Gamma-Irradiated Bottles

Guide and spring concept assures easy initial bottle load, and unload upon processing completion, by operator.



20 Bottle Ready-Assembled Packs

PETG and polystyrene bottle formats provide an extended surface area of approximately 84,000 cm²



Single Aseptic Connection

Tubings, manifolds, and filters provide access of up to 84,000 cm² of cell culture area via one aseptic connector per bottle pack.

RC-40 Roller Bottle System Specifications

Dimensions

- 1.98m High
- 0.95m Wide
- 0.71m Deep

Weight

- Machine only — 76Kg
- With packs loaded and 40L media — 132Kg
- With 40L media and Battery Backup — 144Kg
- Shipping weight — 110Kg

Rotor Speed

- 0.1 rpm to 12 rpm

Delivery Accuracy

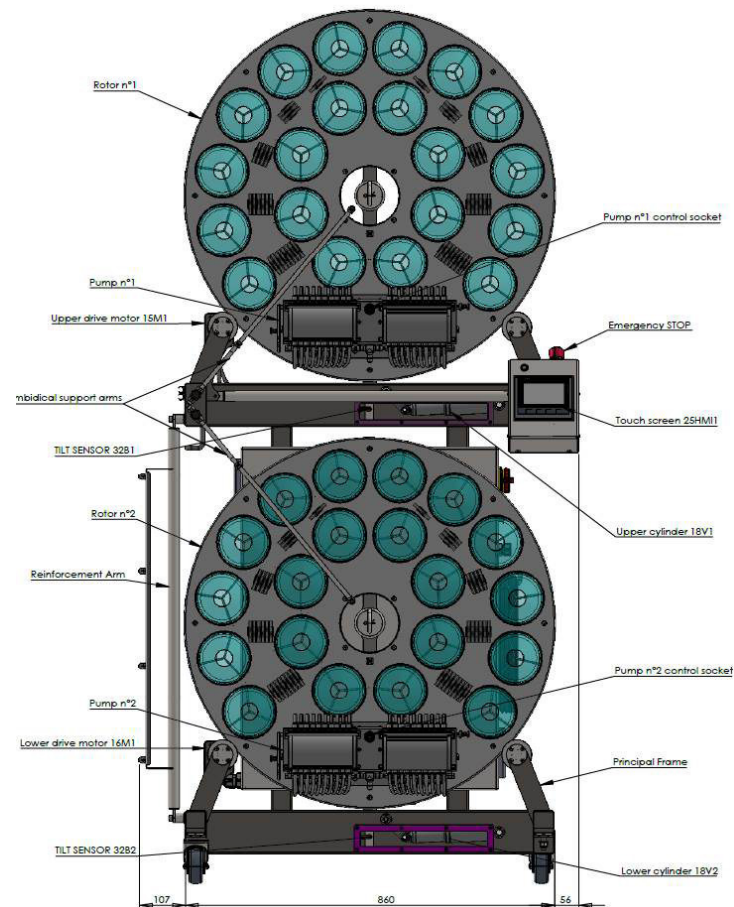
- $- < 0 + 5\%$

Power Supply

- Voltage - 90 to 264V ac
- Frequency - 47 to 63Hz
- Current - 5A

Environment

- Temperature — 0 to 40 deg _C
- Humidity — 0 to 95% RH, non-condensing

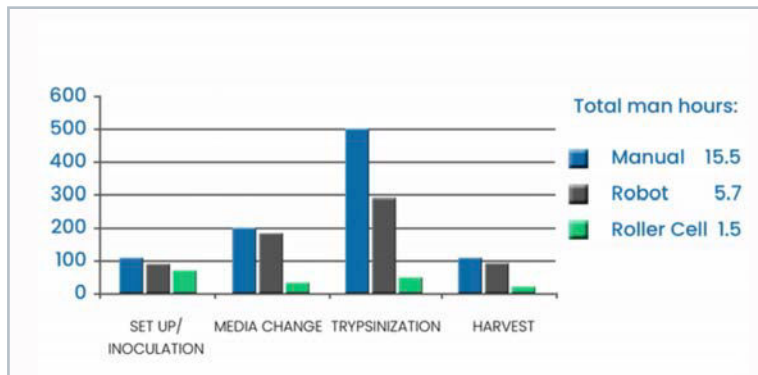


RC-40 Front View

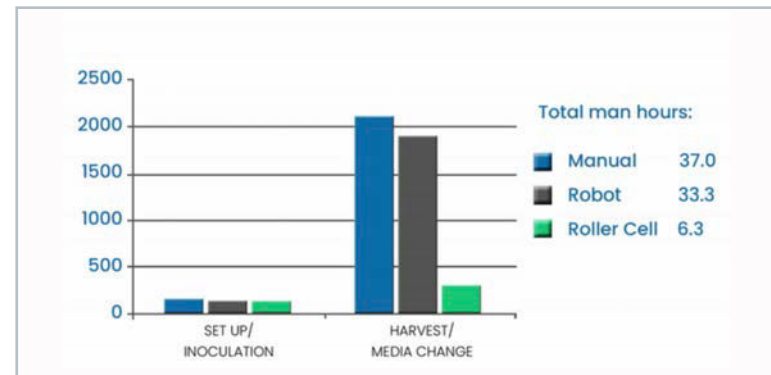
Manual or Robotic System Operaton vs. RC-40 Automated System

Production Protocol Comparison

Comparing the time taken to process the equivalent of 200 standard bottles manually or with a robotic automated system, the RC-40 shows a major positive impact on labor cost and total cost of production.



Simple (Cell Harvest) Culture Protocol



Multi-Harvest (10x Harvest/ Refeed) Protocol



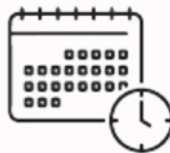
RC-40 Roller Bottle System

Additional Information



Applications

Roller bottles offer an established, reliable method and a relatively inexpensive way to set up flexible biopharmaceutical operations. They are especially well suited to all adherent based vaccines and viral vector processes (MDCK, VERO, PERC6, HEK-293) for fermenter cultures and recombinant proteins.



Time to Market

It takes less than two months to convert from lab scale to commercial manufacturing with the RC-40.



Automation and Control

Automation is inexpensive with the RC-40 system. Optional pH and DO wireless sensors (coming soon) provide additional control.

RC-40 Mark 2

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IMPORTANT: It is the user's responsibility to ensure the suitability and safety of SaniSure products for all intended uses.

For a period of 90 days from the date of delivery, SaniSure warrants this product to be free from defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our discretion, refund the purchase price thereof. User assumes all other risk, if any, including the risk of injury, loss or damage, direct or consequential, arising out of the use, misuse or inability to use this product. THIS LIMITED WARRANTY IS IN LIEU OF THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. No deviation is authorized. SaniSure assumes no obligations or liability for any advice furnished by it or for results obtained with respect to those products. All such advice is given and accepted at the user's risk. All specifications contained within this document are subject to change without notice. Please contact our quality department for the most up to date validation and information related to product-qualification.



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