

DOMINIQUE DUTSCHER SAS

Sterisart® Universal | Gen 4

Where Convenience Meets Compliance

Simplifying Progress

SARTORIUS

Sterility Testing for a Connected Era

Sterility is a non-negotiable requirement in pharmaceuticals and biotechnology, where products intended for patient use must meet stringent quality and safety requirements. The right tools not only streamline the testing process, but also enhance product integrity.

Barrier technologies, such as isolators and cleanrooms are essential for preventing contamination in sterile environments, where the margin of error is small. Consequently, there is a heightened demand for solutions that improve the user experience, support compliant data recording, and offer adaptable connectivity for easy integration with existing systems.

The **Sterisart® Universal | Gen 4 pump** is built for seamless operation within barrier technology environments, offering precise and contamination-free transfer of samples and media into Sterisart® canisters for sterility testing. The integration of cutting-edge hardware with advanced user-friendly software facilitates compliant, paper-less documentation and reporting, addressing the needs of modern, connected labs.



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A Universal Pump for Any Space

The Sterisart® Gen 4 Pump features a compact, universal design that easily fits into various workspaces, including benchtops in laminar airflow cabinets, RABS, and sterility testing isolators. Select the model that meets your needs with the convenience of built-in upgradability.

Basic Model

Provides essential functions without the added cost of a digital display

Essential Model

Includes a user-friendly digital display for real-time data visualization

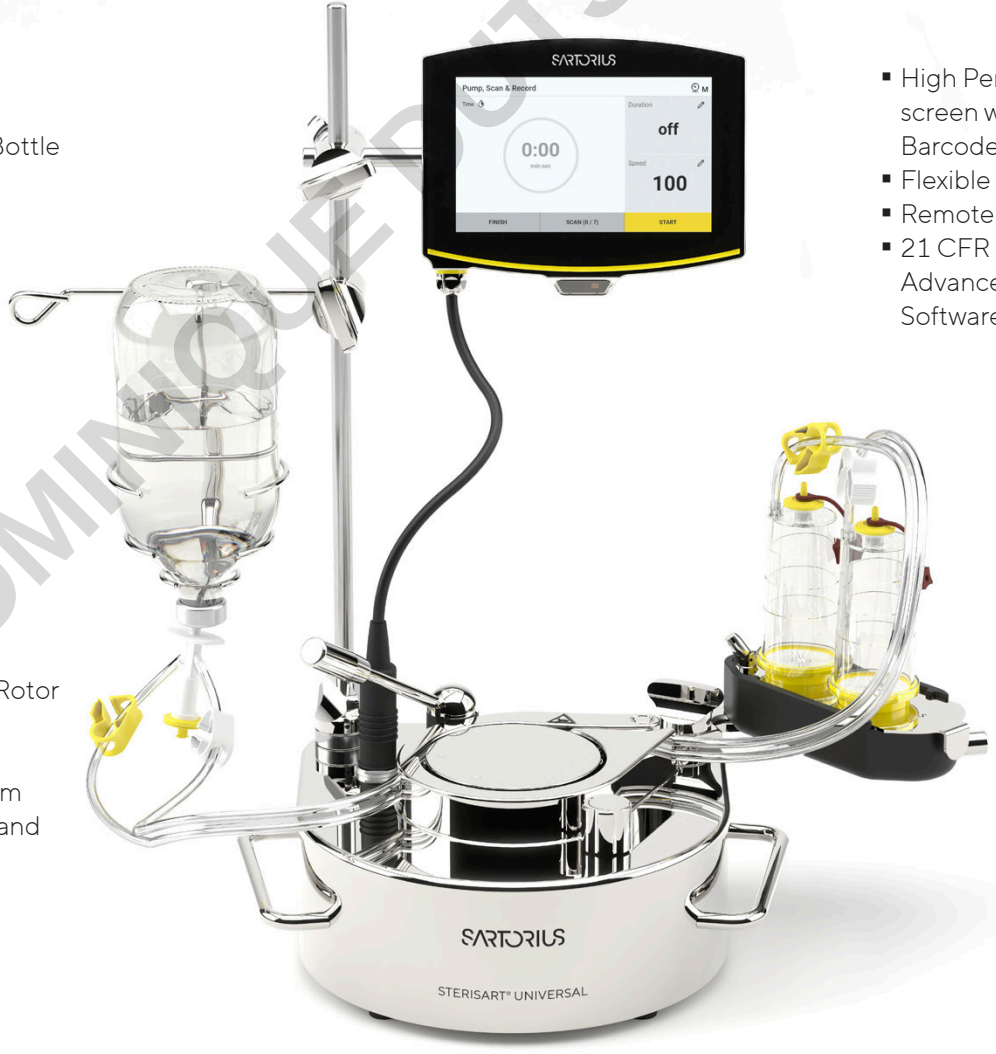
Advanced Model

Integrates 21 CFR Part 11 compliant software for enhanced traceability

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Key Features

- Multi-Functional Bottle Holder
- State-Of-The-Art Rotor Head
- Fail-Safe Tube Locking Mechanism
- Easy Disassembly and Cleaning



- High Performance Touch-screen with Integrated Barcode Scanner
- Flexible Connectivity
- Remote Operation
- 21 CFR Part 11 Compliant Advanced Reporting Software

High-Performance Touchscreen

An intuitive 7-inch digital display provides clear visualization of real-time data and menu functions.

The touchscreen is designed for use with isolator gloves and is complemented by a tactile control knob as a second option for navigation.



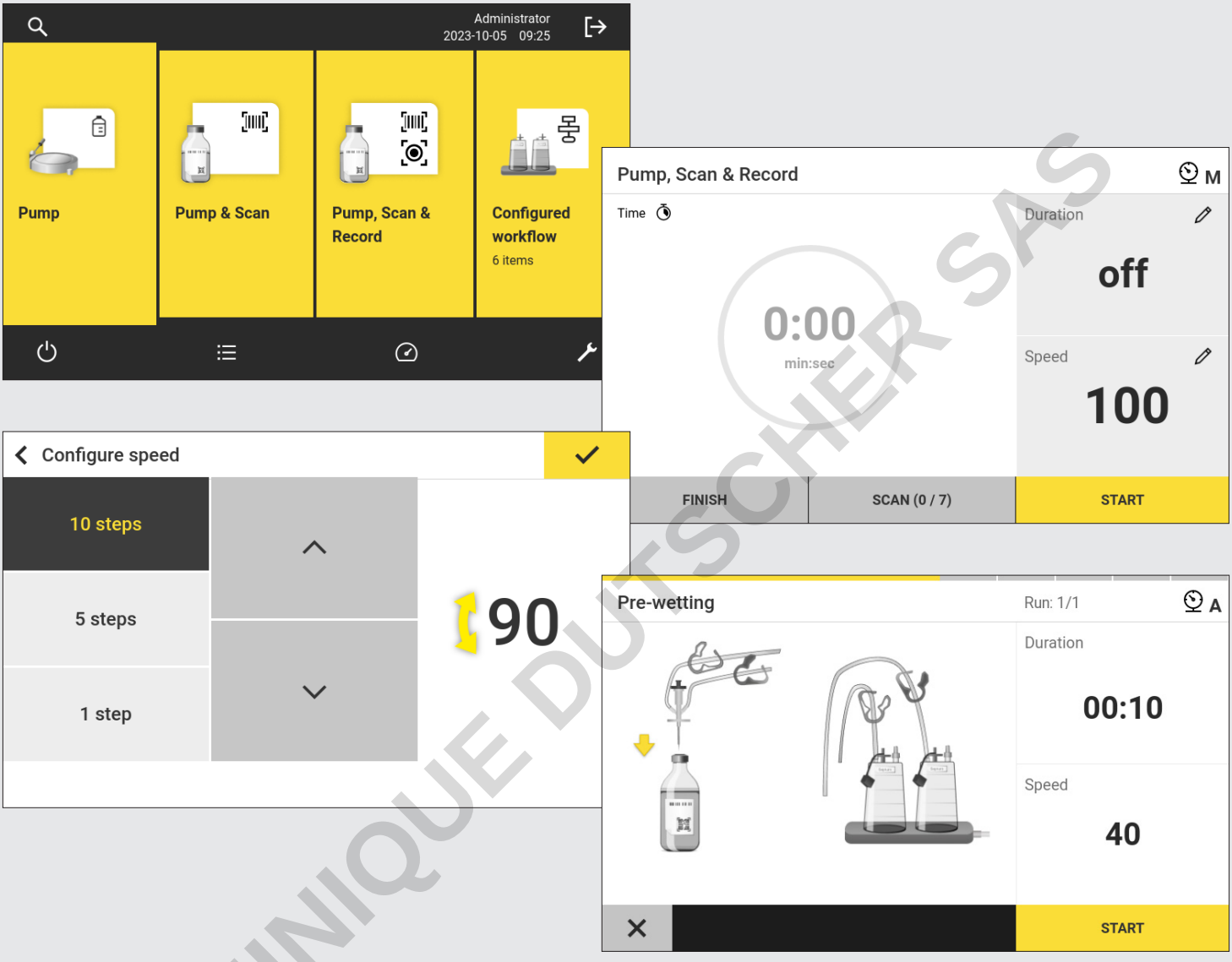
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Integrated Barcode Scanner

The integrated barcode scanner effortlessly captures material data across various formats, including QR codes, 2D matrices, and Codabar, even within the confined spaces of a sterility testing isolator. Its LED-based reader for broad format recognition and additional lighting feature for low-light conditions enable error-free documentation.



Intuitive User Interface



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The Sterisart® Universal | Gen 4 has an intuitive and adaptable design, offering multiple modes for tailored control and efficient navigation. Each mode is designed to streamline processes and documentation

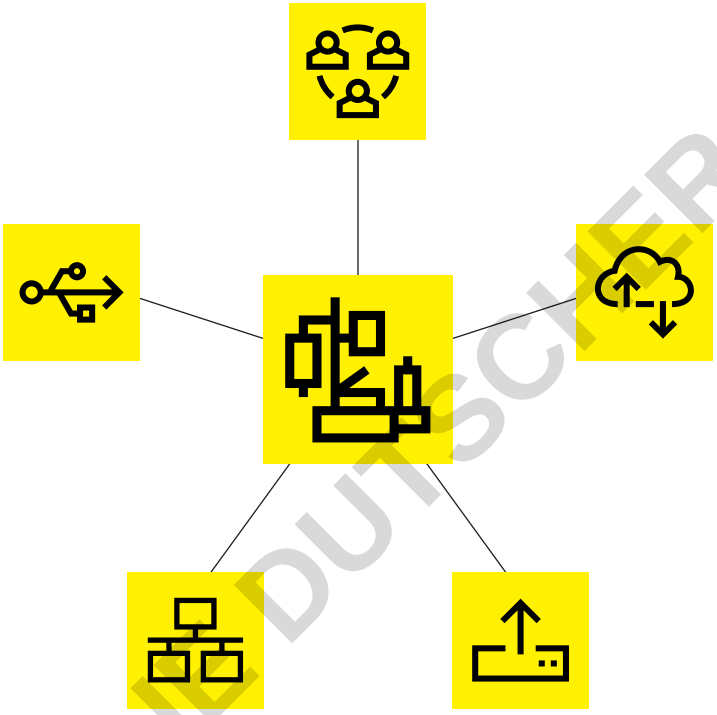
- **Pump Mode** for basic, precise pumping operations
- **Pump & Scan Mode** combines efficient pumping with barcode scanning for data capture
- **Pump, Scan & Record Mode** elevates documentation, recording every interaction and supporting SOP creation and workflow automation
- **Configured Workflow Mode** uses recorded data to build semi-automated SOPs, with graphical user guides for complex workflows

Advanced Connectivity

The Sterisart® Universal | Gen 4 pump enhances workflows with flexible connectivity options for seamless integration with existing systems.

Universal Connectivity
USB-A and USB-C ports for comprehensive data transfer

Secure Communication
REST API for secure device interaction, data access, and messaging



Network Integration
Ethernet port for seamless integration with network infrastructures

Flexible Data Handling
SMB and FTPS support for flexible data storage and transfer

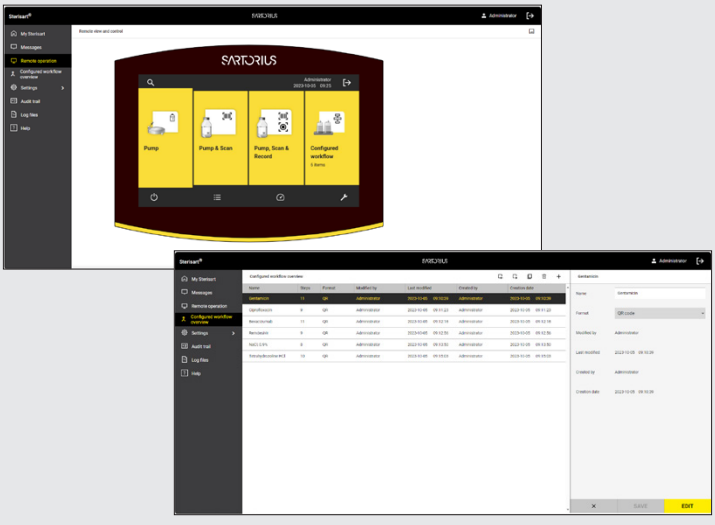
Diverse Control Options
M9-plug connectivity for versatile control tools like syringe actuators or foot switches

Workflow Management
Remote-enabled monitoring, operation, and data sharing capability

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Remote Operation and Configuration

Remote-enabled operation enhances flexibility and operator safety, especially when working with hazardous materials, such as radio pharmaceuticals. Securely operate the pump, adjust device settings, and access SOPs via a dedicated website that replicates the pump's interface.



21 CFR Part 11 Compliance

Designed for strict adherence to 21 CFR Part 11, the Sterisart® Universal | Gen 4 pump has comprehensive tools that streamline compliance.

User Access Control

User Access Control limits system access exclusively to authorized personnel. It can be customized to fit specific password policies or integrated with LDAP for single sign-on.

Audit Trail

The Audit Trail function logs every system interaction in detail, providing clear, time-stamped records of all activities. It offers accessible data viewing and exporting.

Data Backup

Automated, scheduled data backup is critical for maintaining data integrity across various platforms and safeguarding it against unexpected events.

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Secure Documentation & Electronic Signatures

Protect data integrity with customizable, GMP-compliant electronic reports that provide consistent formatting across all documents.

- Tamper-proof reports
- MD5 checksums for security and compliance
- Password-secured electronic signatures



State-Of-The-Art Rotor Head

The Sterisart® Universal | Gen 4 rotor head is designed for superior accuracy and reliability, delivering precise liquid displacement for consistent distribution into Sterisart® canisters. Its specialized design reduces tubing wear, increases durability, and ensures a continuous flow without air pockets to prevent foaming. Additionally, the rotor head easily disassembles for routine cleaning and maintenance.



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Fail-Safe Tube Locking

Intuitive tubing guide and clamp simplify setup and accurate positioning, eliminating the risk of tube displacement or movement.

The manual locking mechanism offers a straightforward way to secure the tubing in place, without the complications commonly associated with automated locking systems.



Real-Time Pressure Sensing

The Real-time sensor monitors pressure and alerts the operator to excess levels. It has two modes: visual prompts for manual intervention and automatic pump speed adjustment for pressure stabilization. The sensor can also be disengaged for customized operation.



Versatile Drain Container

The drain container securely holds testing canisters, preventing vibration during use. Its versatile slide-out tray design accommodates a wide variety of canisters on the market, making it ideal for laboratories that require adaptability and consistency in their processes.



Comfortable Operation

This pump is designed for ease of use, with adjustable components and a versatile drain container for easy access. Adjust the swivel, tilt, and height of the display and bottle holder for optimal comfort.



Multi-Functional Bottle Holder

The stainless-steel bottle holder provides stable support for a wide range of containers, including vials and plastic or glass bottles of varying sizes. Its extended hook accommodates infusion bags and medical devices, providing a versatile solution for different sterility testing requirements.



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Enhanced Cleanability

Constructed from mirror-finish **316L grade stainless steel**. Its highly polished surface adheres to stringent decontamination standards, including protocols for vaporized hydrogen peroxide (VHP) cleaning.

To further support cleanings, the design features **easy disassembly** to eliminate hard-to-reach areas, facilitating thorough cleaning and inspection of all components

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Complete Sterility Testing Solution

The Sterisart® pump is a key component of the **Sterisart® system**, a complete and closed filtration solution for sterile pharmaceutical lot-release testing. It adheres to USP <71>, Ph. Eur. 2.6.1, JP 4.06, and other global sterility testing standards.

The portfolio offers devices tailored to a range of testing needs, including **Sterisart® canisters** with a patented dual needle design for safe, efficient testing. These canisters also come with a septum port for sterile sampling across diverse testing requirements.

Ordering Information:

- Sterisart® Universal | Gen 4 - Basic (**16421-B**)
- Sterisart® Universal | Gen 4 - Essential (**16421-E**)
- Sterisart® Universal | Gen 4 - Advanced (**16421-A**)

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