Sterisart®
Easy Configuration

Drag & Drop Software Designed to Increase Process Reliability During Sterility Testing

Benefits

- Step-by-step guidance through each sterility test programmed, such as for USP <71> or Ph. Eur. 2.6.1
- FDA 21 CFR Part 11 compliant electronic records
- User account management, audit trail and password protection
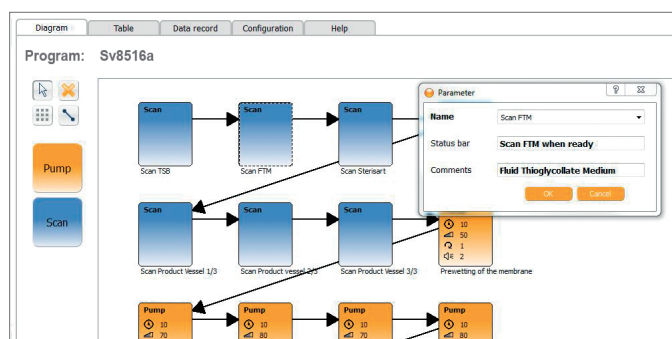- Scanning, saving and printing of process-relevant data and records on materials

Product Information

Sterisart® Easy Configuration software for the Sterisart® Universal pump 16420 enables fast and uncomplicated creation of programs for individual products and process workflows in order perform sterility testing of parenterals in compliance with international pharmacopeias, guidelines and regulations, such as (c)GMPs.

A computer is all that is need for programming. Afterwards, the programs can be transferred to the internal memory of the Sterisart® pump 16420 and later retrieved and run as needed. At the end of a process, data collected can be transmitted back to your computer using an SD card or the RS-232 interface port on the Sterisart® Universal pump.

User account management, audit trail and password protection ensure the security of your data for transparent tracking of any changes made or programs aborted.

Use

Sterisart® Easy Configuration software permits customized programming of workflows for performing sterility testing according to international pharmacopoeias and regulatory requirements. The drag & drop elements allow convenient, intuitive selection of the settings.

The bar code scanner built into the Sterisart® Universal pump 16420 reliably prevents documentation errors and is capable of reading all standard bar codes (Code 39; CODABAR; CODE128) on materials. For sterility testing according to the USP <71> or Ph. Eur. 2.6.1, for instance, such materials usually include the following:
- Culture media: Tryptic Soy Broth (TSB); Fluid Thioglycollate
- Medium (FTM)
- Sterisart® sterility test units
- Rinsing fluids (Fluid A, D, K)
- Isopropyl myristate (IPM)
- Product to be examined in a container
- Further materials as required

The process-specific workflows are exceptionally easy to program just by using the drag & drop buttons for the functions "Pump" and "Scan", where scanning is optional and can be performed both at the beginning and end of a process. The programming steps are clearly shown as buttons and as tables. At the end of a sterility test, these data can be saved or printed using a computer. A record showing all scanned data can also be printed and either manually or electronically signed for documentation purposes.

Data can be exchanged between your computer and the Sterisart® Universal pump 16420 either using an SD card or the RS-232 COM port on the pump.

All components required for easy data exchange are provided by the Sartorius Communication Kit:
- 1 GB SD card
- USB male to female converter
- RS-232 to RS-232 converter
- RS-232 cable (approx. 2 m or 6.6 ft.)
- Driver CD, USB to serial port
- Card reader, RS-232 to SD

The integrity, security and reproducibility of data transfer using the Sterisart® Easy Configuration software have been validated as part of the Sartorius IQ/OQ documents available.

Ordering Information

Order Number	Description
16420	Sterisart® Universal Pump
1Z----0004	Sterisart® Easy Configuration Software
1ZE---0040	Communication Kit