

Sterisart® Universal | Gen 4

Where Convenience Meets
Compliance



Your Key Benefits

- Universal sterility testing pump designed for benchtop use or for integration in isolators
- Low profile and compact footprint
- Flexible, modular and open design
- 316L mirror finish stainless steel
- Sleek design for impeccable hygiene: easy disassembly and smooth contours
- Real-Time pressure detection in the Sterility testing canisters
- 7" high performance touch screen display with integrated barcode scanner
- Built for 21 CFR Part 11 & EU GMP Annex 11: Advanced software for sterility testing featuring user access control, audit trail, secure data handling, electronic signatures, and reports

Overview



Sterisart® Universal Gen 4	Basic	Essential	Advanced
Ordering code	16421-B	16421-E	16421-A
Hardware			
Sterility Testing Pump	●	●	●
Display & Integrated Barcode scanner	○	●	●
Software			
21 CFR Part 11 Conformity	○	○	●

Device Specifications

Type:	Peristaltic Pump
Speed:	0 - 100
Pressure during pumping at 20 °C, in operation, maximum:	3.5 bar

Protection Class

Device protection class intergrated into an aseptic processing unit with isolator integration kit, according to EN/IEC 60529-1 IP 65

Operational Conditions

	Unit	Value
Temperature		
In operation	°C	+ 10 - + 40
Relative humidity, in operation		
Non-condensing	%	90
Air pressure	kPa	70 - 105

Electrical Specifications

	Unit	Value
AC voltage	V _{AC}	100–240 (± 10%)
Frequency	Hz	50–60
Current consumption, maximum	A	1
Power consumption, typical	VA	100
Power supply only permitted via the power supply cable supplied by Sartorius		
Protection class according to IEC 61010-1		
Device		I
Control unit		I
Overvoltage category according to IEC 61010-1		
Device		II
Control unit, installed		I

Interfaces

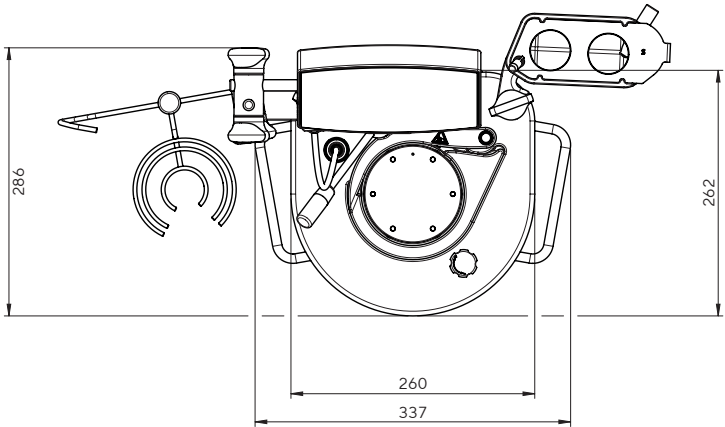
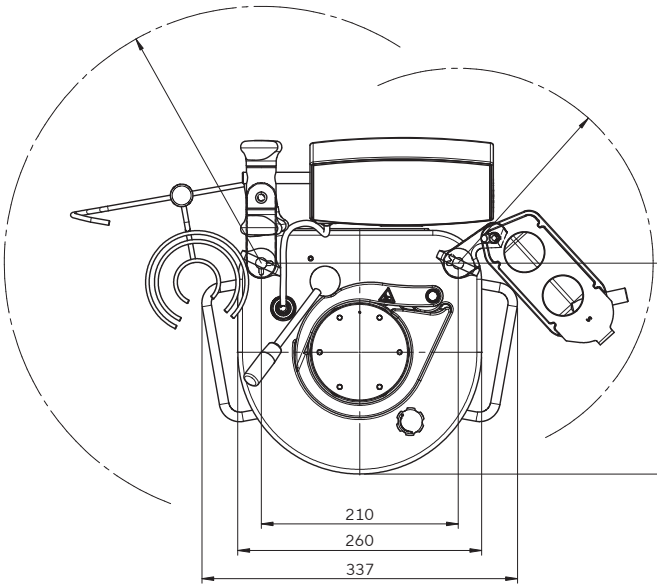
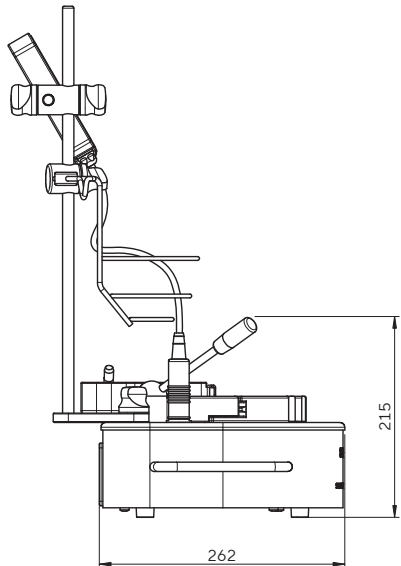
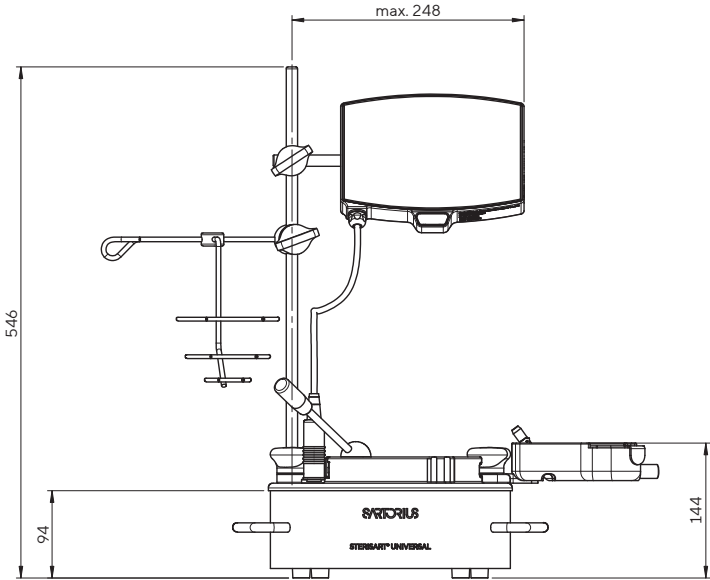
M9 plug, 4-pin	Communication: With accessories, e.g., foot switch and syringe actuator	
USB connection	USB-A USB-C	
	Unit	Value
Ethernet connection		
Transmission rate	Mbps	100

Scanner

Type:	Integrated 1D / 2D barcode scanner
Codes that can be scanned:	UPS-A, UPS-E, UPC-E1, EAN-13, EAN-8, Code 39, Interleaved, Industrial, Matrix, Codabar, Code 128, UCC/EAN 128, ISBT 129, Code 93, Code 11, MSI/Plessey, UK/Plessey, China Post, GS1 DataBar, GS1 Databar Limited, GS1 Databar Expanded, GS1 Composite, PDF417, MicroPDF417 and QR Code
Other scanners that can be connected:	External USB barcode scanners from third-party providers



Dimensions



Weights

Weight of device without components:	11.5 kg
Weight of device with stand, bottle holder and collection vessel:	13.2 kg
Weight of control unit:	2.1 kg

Materials of Construction

Housing, plug insert, control unit housing, stand, bottle holder, protective cap, base plate, lever, clamp, rotor:	Polished stainless steel AISI 316L (1.4404 or 1.4435)
Sealing insert for screw connection (control unit):	Thermoplastic polyurethane (TPU)
Operating display:	Natural quartz glass
Connection cable:	PVC, resistant to vaporized hydrogen peroxide (VHP)
Control unit connection plug:	Nickel-plated brass with matted chrome coating
Connector grommet:	TPE
Collection vessel:	Polypropylene, high temperature resistance (PP-HT)
Lever casing:	PEEK
Clamp friction bearing:	PEEK, Iglidur X
Lever friction bearing:	Iglidur X
Static seals:	FPM, NBR
Rotating seals:	Fluorinated rubber
Operating display seal (adhesive):	Silicone
Waste tubing:	Silicone



When integrated into an isolator, all components above the workbench are compatible with Vaporized Hydrogen Peroxide (VHP). This compatibility was validated through a four-year simulation involving continuous exposure to VHP (200 SKANFOG cycles; Maximal concentrations measured were in excess of 500 PPM).

Transportation and Storage conditions

	Unit	Value
Temperature		
Dry storage and transport	°C	-20 - +50
Storage duration under both extreme values, maximum	h	12

Packaging



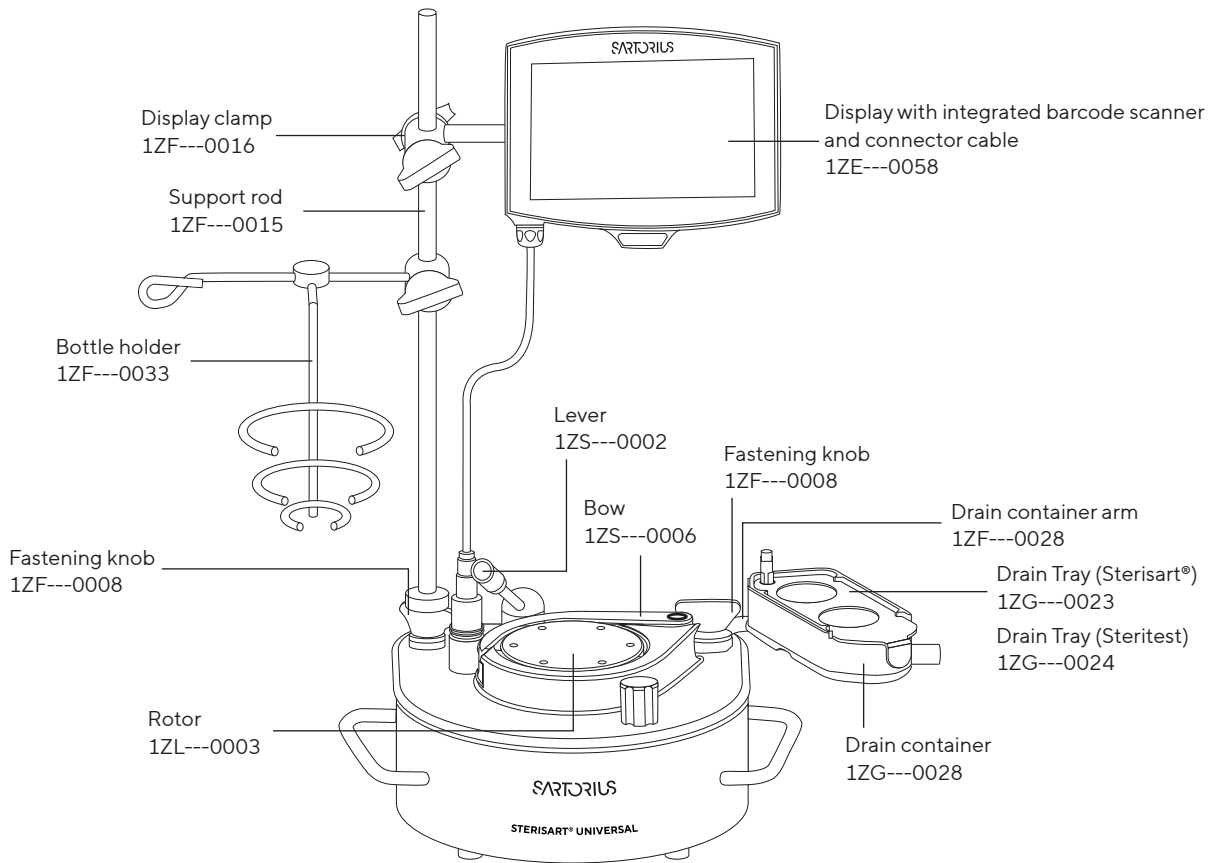
Transit | External Packaging: Cardboard carton

Primary Packaging: ARPLANK 30 *



* ARPLANK 30 consists of 30% recycled content originating from post-consumer recycled polyethylene. It provides reduced electrical surface resistivity and is ideal for the protection and transportation of electro-sensitive goods. It is 100% recyclable.

Accessories and Replacements



Drain Tubing (1 m)
1ZA---0002



Foot Switch
1ZE---0033



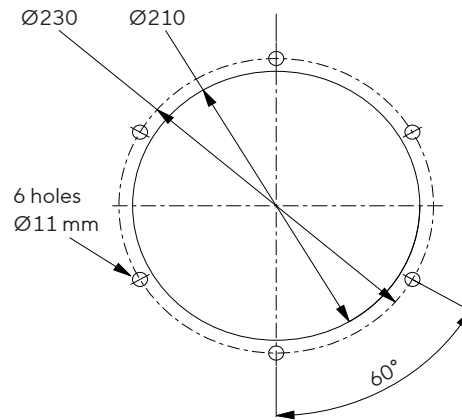
Display extension cable (2.9 m)
1EE---0015

Isolator Installation



Isolator Cutout:

The Sterisart®Universal | Gen 4 can be integrated in an isolator equipped with a standard round cutout and is compatible with the cutout for the previous generation (16420, 16419)



Isolator installation Kit :

Order Code: 1ZE-0057

Contains:

- 1x stainless steel adapter
- 2x brass bolts to secure the housing
- 2x countersink screws M5 × 12
- 2x silicone o-rings (270 mm × 3 mm)
- 3x cylinder head screws M6 × 12
- 3x cylinder head screws M6 × 8
- 3x body washers (Ø 6,4 × Ø 18 × 1,6)
- 1x sensorboard protection cover
- 1x cylinder head screws M3 × 12



Service Support









Benefit from our global service support ensuring assistance wherever you operate, backed by our exceptional and responsive team. Our comprehensive package includes proficient IQ/OQ services and annual maintenance to guarantee optimal performance and longevity for your Sterisart® Universal Pump.

Order Codes:

Sterisart® Universal Pump IQ/OQ:	84QAM04
Sterisart® Annual maintenance/ Preventive Maintenance:	84MAM04
Sterisart® upgrade including requalification (IQ/OQ):	84UBM04

Sterisart® Sterility Testing Canisters

Our Sterility Testing Pump is more than just a device; it is a comprehensive solution. At the heart of this lies our Sterisart® Sterility Testing Canisters:

Sample Type								
Product Container	Closed	Closed	Open	Closed	Closed with bow-fill seals	Syringes	Male luer locks or female slip	Male luer locks
Regenerated Cellulose	Standard		Standard		Standard		Standard	
Standard	16466-----GBD	16476-----GBD	16467-----GBD	16475-----GBD	16477-----GBD	16469-----GBD	16468-----GBD	16478-----GBD
Septum	16466-----GSD	16476-----GSD	16467-----GSD	16475-----GSD		16469-----GSD		
Cellulose Acetate	Standard		Standard		Standard		Standard	
Standard	16466-----CA-GSD		16467-----CA-GSD					

Germany

Sartorius Lab Instruments GmbH & Co. KG
 Otto-Brenner-Strasse 20
 37079 Goettingen
 Phone +49 551 308 0

USA

Sartorius Corporation
 565 Johnson Avenue
 Bohemia, NY 11716
 Phone +1 631 254 4249
 Toll-free +1 800 635 2906

 For further information, visit
www.sartorius.com