SARTORIUS

Product Datasheet



Sterisart® Universal | Gen 4

Where Convenience Meets Compliance

DOMINIQUE DUTSCHE

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

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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 I USB-C

	Unit	Value
Ethernet connection		
Transmission rate	Mbps	100

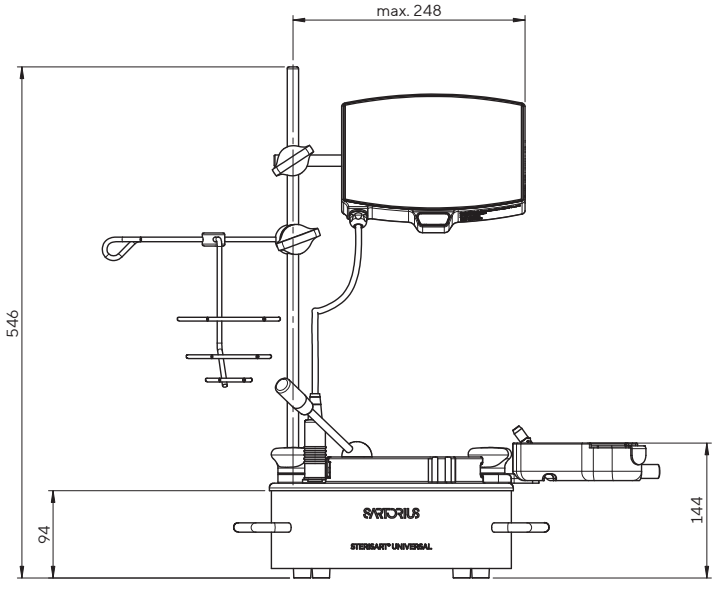
Scanner

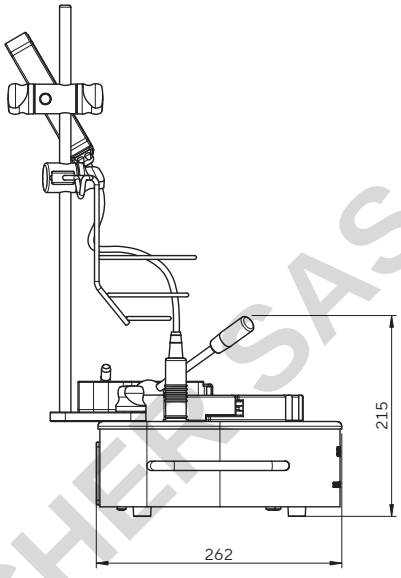
Type:	Integrated 1D / 2D barcode scanner
Codes that can be scanned:	UPS-A, UPS-E, UPC-E1, EAN-13, EAN-8, Code 39, Interleaved, Industrial, Matrix, Codabar, Code 128, UCC/EAN 128, ISBT 129, Code 93, Code 11, MSI/Plessey, UK/Plessey, China Post, GS1 DataBar, GS1 Databar Limited, GS1 Databar Expanded, GS1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

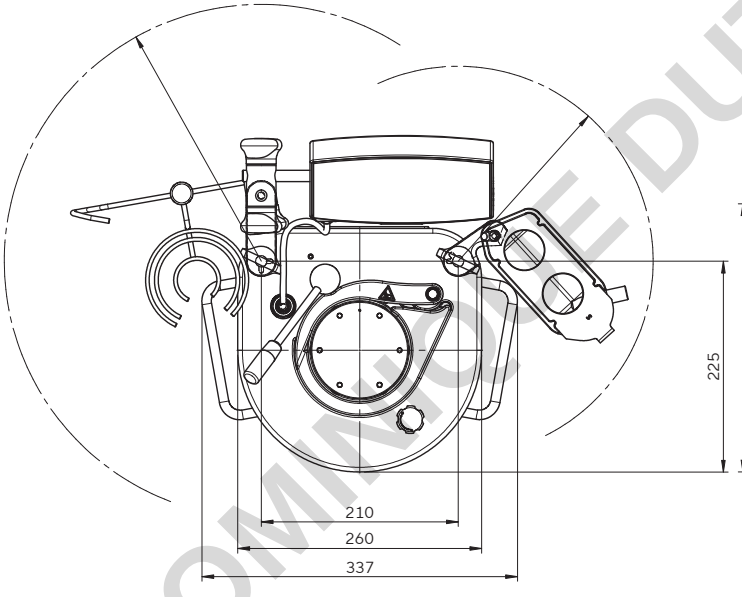


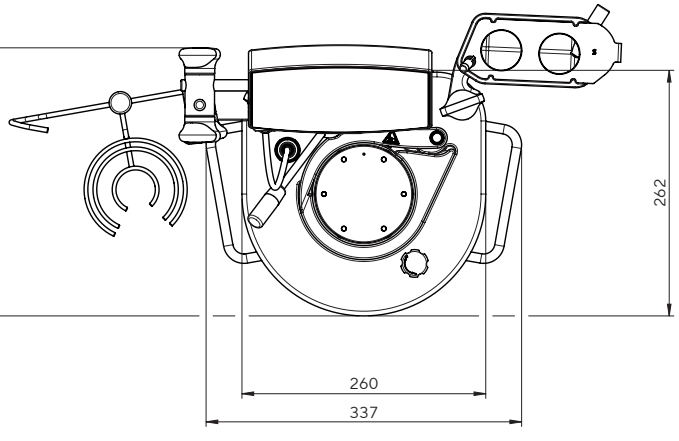
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Dimensions









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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

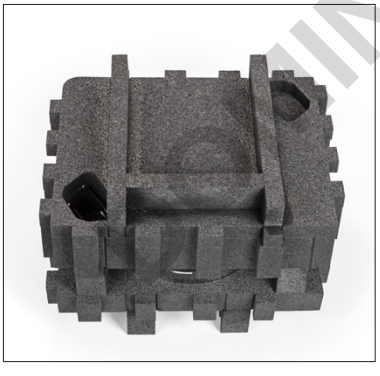
Housing, plug insert, control unit housing, stand, bottle holder, protective cap, base plate, lever, clamp, rotor:	Polished stainless steel AISI 316L (1.4404 or 1.4435)
Sealing insert for screw connection (control unit):	Thermoplastic polyurethane (TPU)
Operating display:	Natural quartz glass
Connection 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).

Transporatation and Storage conditions

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

Packaging





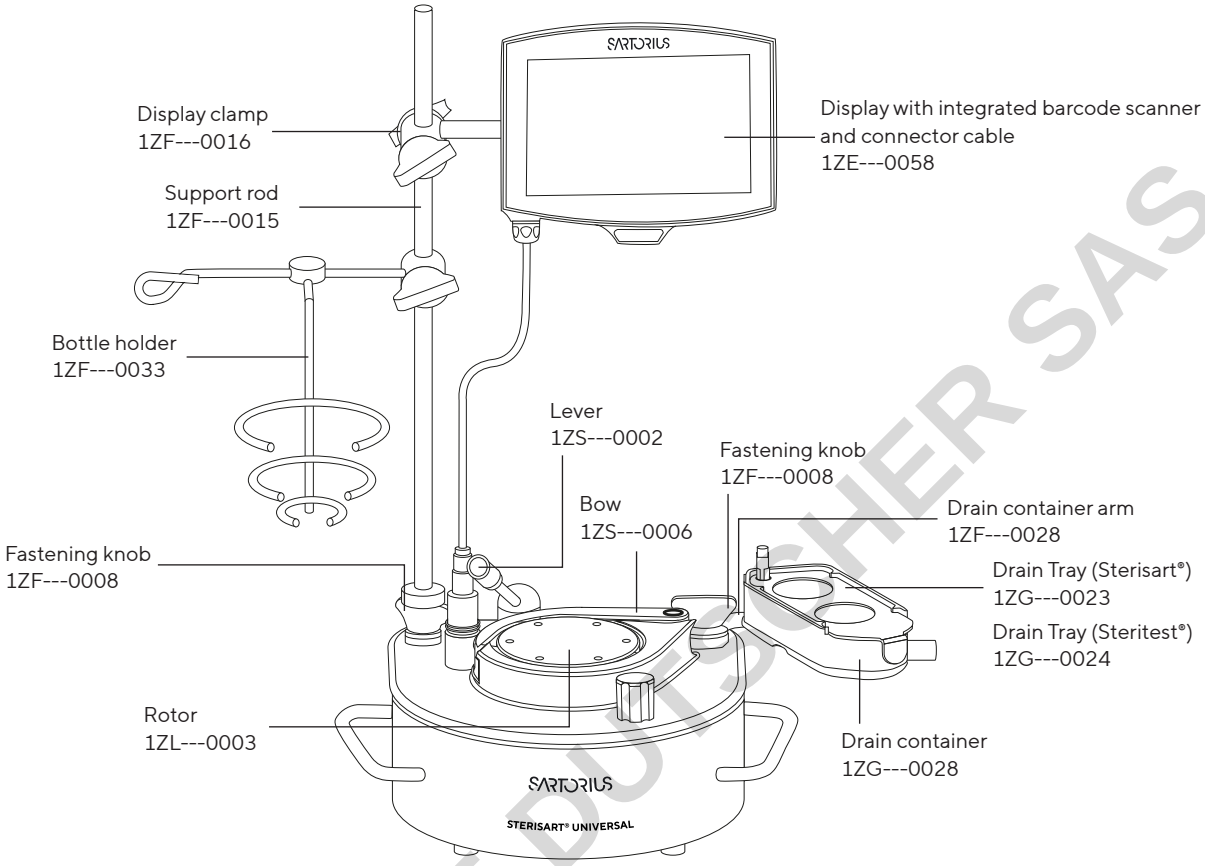


Transit | External Packaging: Cardboard carton
Primary Packaging: ARPLANK 30 *

* 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.

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Accessories and Replacements



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



Foot Switch
1ZE---0033

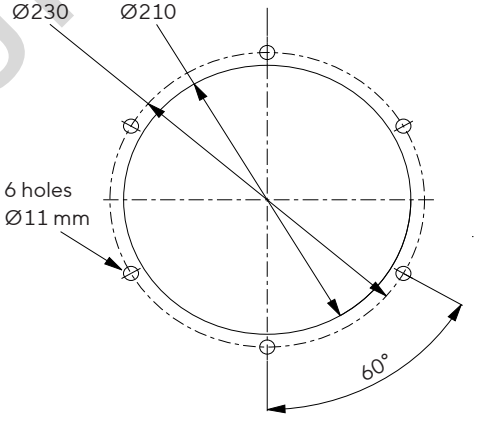


Display extension cable (2.9 m)
1EE---0015

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 (⌀ 6,4 × ⌀ 18 × 1,6)
- 1x sensorboard protection cover
- 1x cylinder head screws M3 × 12



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Service Support

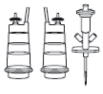
Benefit from our global service support ensuring assistance wherever you operate, backed by our exceptional and responsive team. Our comprehensive package includes proficient IQ/OQ services and annual maintenance to guarantee optimal performance and longevity for your Sterisart® Universal Pump.

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	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								
	16466-----CA-GSD		16467-----CA-GSD					

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