SARTORIUS

Linkit® AX

The Smart Aliquoting Solution

Product Information

The Linkit® AX solution is specifically designed to address the pain points of manual filling and aliquoting applications, without heavily investing in big and complex equipment.

This aseptic solution directs fluid from a peristaltic pump into 10 Flexsafe® bags for simultaneous, and fast filling. The plug and play concept combined with ready-to-use patented manifold design, minimizes operator effort and error. The Linkit® AX system consistently distributes fluid between the 10 bags with an accuracy of ±5.1%. It is an ideal solution for aliquoting small quantities of fluid in applications such as small-batch media preparation in cell & gene therapy operations as well as other process fluid aliquoting.

Features and Benefits

- Simplify Aliquoting Operations
- Prepare Small-Batch Media Faster
- Eliminate Contamination Risk
- Ensure Repeatable Aliquoting
- Eliminate Paper Record-Keeping
- Reduce Costs With Plug-and-Play Single-Use Setup

Linkit® AX Aliquoting Solution
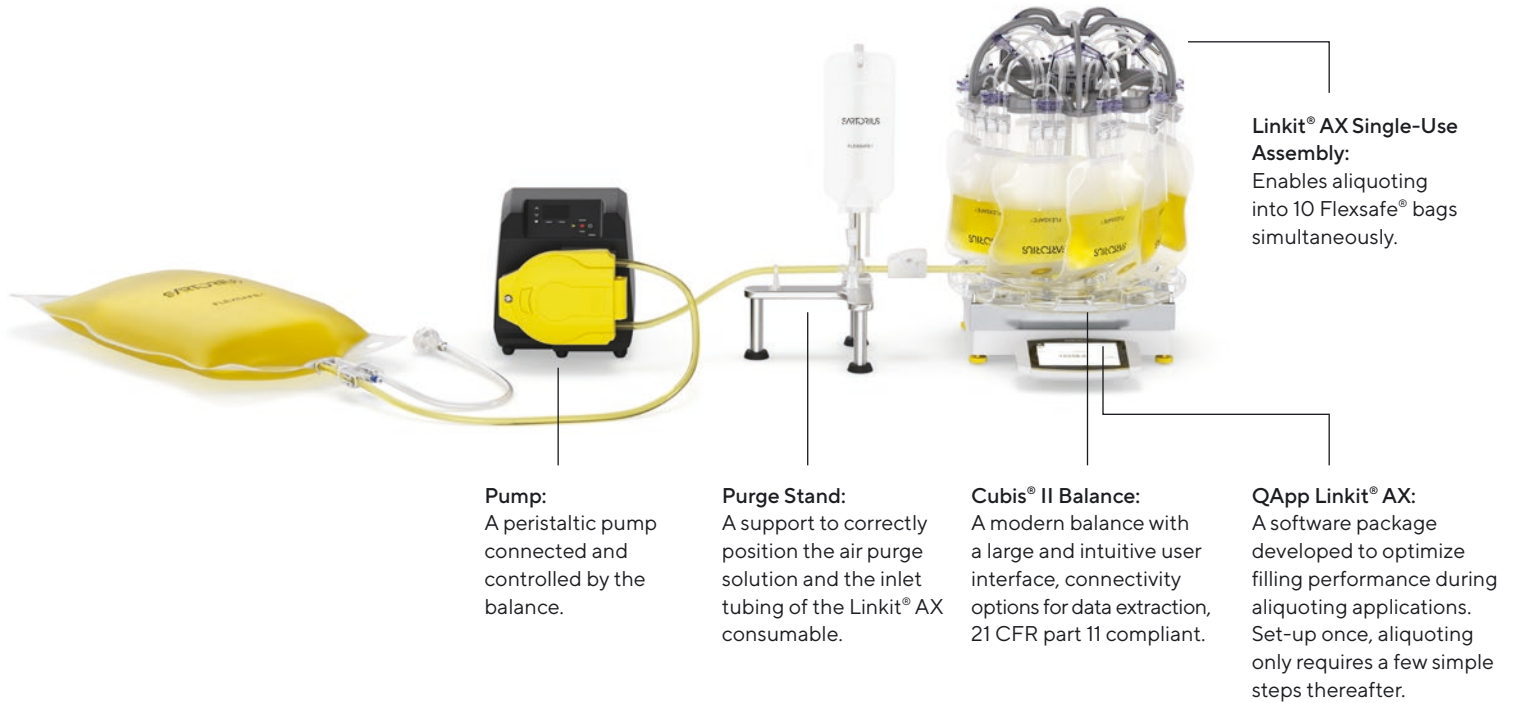
Pump:
A peristaltic pump connected and controlled by the balance.

Purge Stand:
A support to correctly position the air purge solution and the inlet tubing of the Linkit® AX consumable.

Cubis® II Balance:
A modern balance with a large and intuitive user interface, connectivity options for data extraction, 21 CFR part 11 compliant.

QApp Linkit® AX:
A software package developed to optimize filling performance during aliquoting applications. Set-up once, aliquoting only requires a few simple steps thereafter.

Linkit® AX Single-Use Assembly:
Enables aliquoting into 10 Flexsafe® bags simultaneously.

Reach Higher Throughput

The Linkit® AX concept focuses on achieving fast filling performance with a unique flow-through fluid design of the main hub. This allows for simultaneous distribution of liquid into the collection containers. Combined with an automated control functionality through the balance and pump accessories, and the ready-to-use design, the time-consuming operator handling steps can be completely removed.
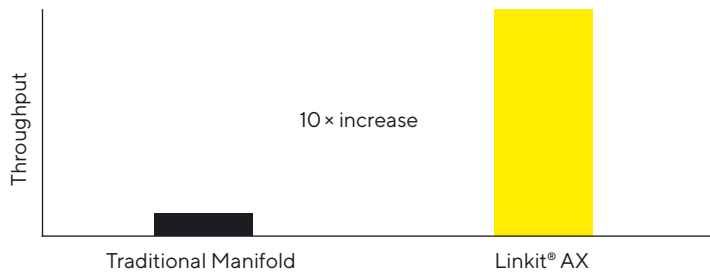
Comparison of Throughput Between Linkit® AX Solution and Traditional manifolds

Work in Full Confidence With More Automation

The QApp is a software package designed to bring automation to aliquoting applications. It starts with creating a filling program that can be repeatedly used batch-to-batch. High-precision accuracy is reached thanks to a combination of optimized QApp parameters, real-time communication between the balance and pump, and the patented fluid distribution of the main hub. The QApp also accompanies and guides the operator during a filling operation with its step-by-step approach, significantly reducing any possible handling errors.

Focus On Your Core Work, Designed for Simple and Intuitive Use

The Linkit® AX eliminates the need for handling bulky and complicated traditional manifolds. Its fully assembled, compact, small footprint solution is easily unpacked and positioned onto the balance. It is a fully closed system, ensuring sterility can be maintained and has been designed to only require one connection, either with a single-use aseptic connector or an aseptic welding operation.

Go Paperless With Cubis® II Digital and Compliant Batch Records

The Linkit® AX aliquoting single-use assembly, when used in combination with the pump and Cubis® II Balance, equipped with the MCA high-end 7" display and specific QApp, allows for full end-to-end traceability, safe and accurate data storage in compliance to FDA directive 21 CFR part 11 and EU Annex 11.

✕ Parameters for Program	ⓘ ✓
Filter Wetting Speed	20 rpm
Air Purging Speed	50 rpm
Filling Speed	250 rpm
Slow Down at	99 %
To Speed	150 rpm
Reverse Run Speed	20 rpm

Filling Program Set-up

☰ Preview 1 of 2 PDF document on USB		Administrator 09.01.2023 13:45 ⤷
Init		
User ID	User ID	Administrator
Program Name	ProgName	Nutri-T Filling
Material Number	Material	05-11F2001-1K
Expiry Date	Expiry	
Liquid Type	Liquid	Media
Batch Number	Batch	002
Additional Information	Info	
Number of Linkit® AX	Number	1
Total Target Weight	Target	5000.0 g
Filter Wetting Speed	Filter Wetting	20 rpm
Air Purging Speed	Air Purge	50 rpm
Filling Speed	Filling	250 rpm
Slow Down at	Slow at	99 %
To Speed	To Speed	150 rpm
Reverse Run Speed	Reverse	20 rpm

Filling Report

Designed for cost-sensitive, automated aliquoting applications. The small footprint solution can easily be moved location to where it is needed most.
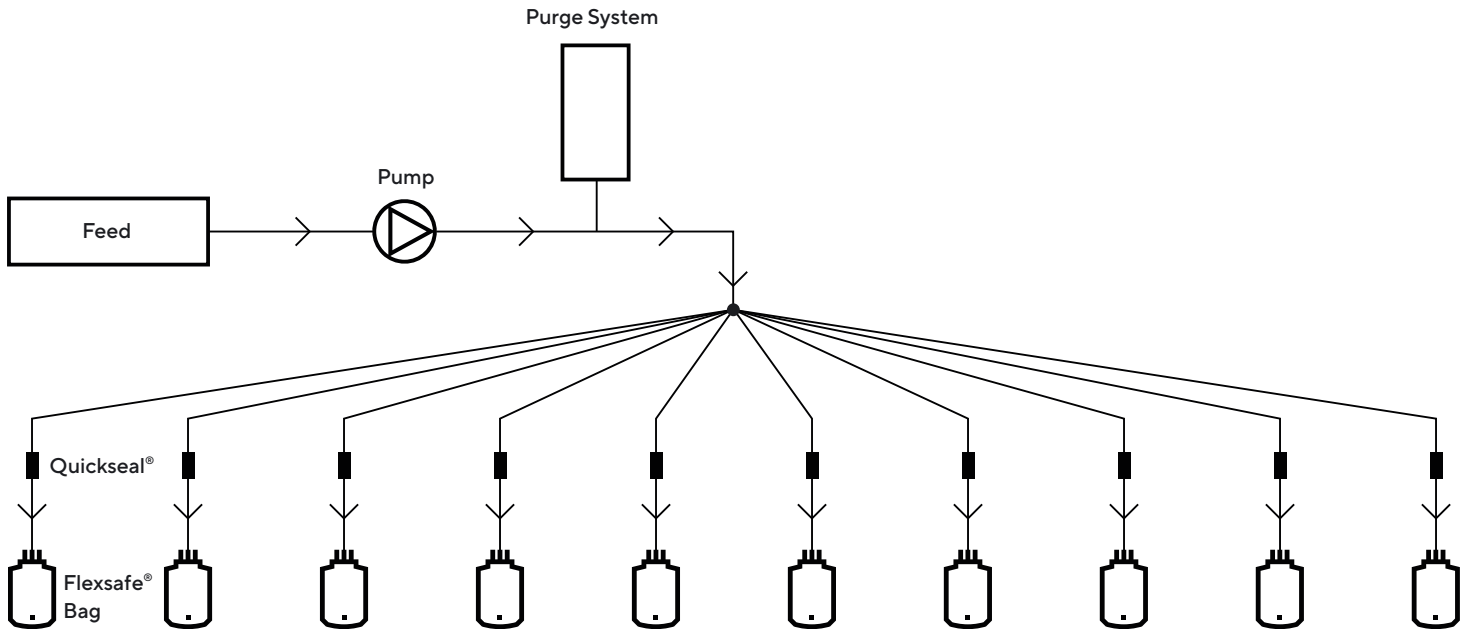
Flow schematic of a Linkit® AX solution.

An optional functionality within the QApp enables the possibility to perform a reverse run after performing a filling operation. This enables all the remaining fluid within the filling tubes to be pushed back into the feed container, saving costly fluids.

Integrating Linkit® AX Into Your Process

The Linkit® AX single-use assembly is available with different configurations dependent on process needs.

The main processing unit has a fixed design, however certain options are available to choose from and inlets | outlets can be configured to meet and easily integrate any specific process requirements.

■ Select Options

- Flexsafe® bag: 500 or 1,000 mL
- Purge system: Sartopore® Air Midisart® 0.2 μm or 500 mL Flexsafe® bag

■ Inlet | Outlet Process Configurations

- Inlet Linkit® AX to feed container
- Outlet 1 (and 2 on 1,000 mL Flexsafe® bag)

All Linkit® AX single-use assemblies are assembled in ISO 7 certified cleanrooms in accordance with applicable cGMP guidelines. Each system undergoes a variety of in-process quality inspections including 100% visual inspection and 100% leak testing (pressure decay) of the main distribution assembly hub and Flexsafe® bag chambers.

Source all your needs for process optimization, customized validation and regulatory support with Confidence® Services for Linkit® AX. Confidence® provides the closest interpretation of current regulatory requirements and industry standards by working with you to define relevant test conditions for all your process components. Services include, but are not limited to:
- Extractables assessment | Leachable studies
- Toxicological assessment | Safety evaluation
- Physio-Chemical studies

To support you in your regulatory needs, specific documentation is available upon request:

- Validation guide
- Extractables guide
- Technical drawing
- Inspection guide
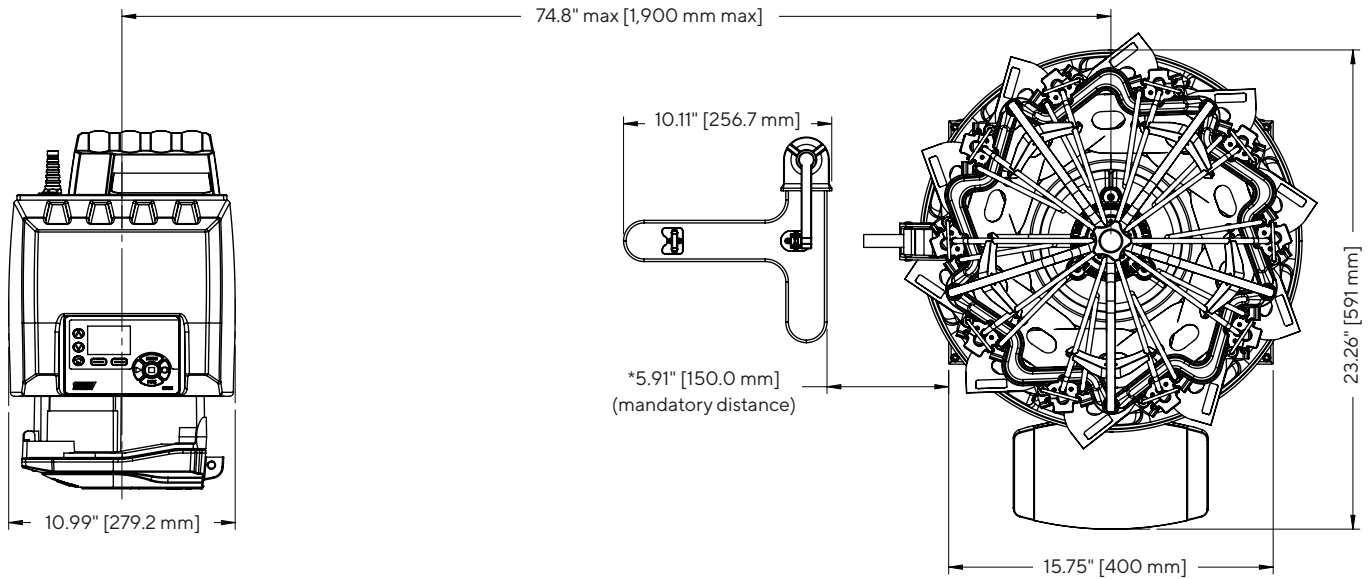- Product compliance statement
- Instructions for use

Performance Specifications

Linkit® AX Aliquoting Solution

| Distribution Accuracy Between Bags	Single unit	±5.1%
Filling Accuracy	Single lot	±5.9%
	Multiple lots	±9.7% @4σ
Volume Range		From 200 mL to 1,000 mL
Operating Temperature Range		Room Temperature
Operating Pump Speed (Optimal)		250 rpm

Technical Specifications

74.8" max [1,900 mm max]

10.11" [256.7 mm]

*5.91" [150.0 mm]
(mandatory distance)

23.26" [591 mm]

15.75" [400 mm]

10.99" [279.2 mm]

Linkit® AX Single-Use Assembly

|	
Collection Container	▪ 500 mL Flexsafe® bag ▪ 1,000 mL Flexsafe® bag
Aseptic Disconnect	Quickseal® ⅛" × ¼"
Purge System	▪ Sartopore® Air Midisart® 0.2 μm Filter ▪ Flexsafe® 500 mL bag
Feed Tube Length	1,110 mm (43.7")
Feed Tube Diameter (ID × OD)	⅜" × ⅝"
Weight	3.2 – 4.3 kg | 7 lb 1 oz – 9 lb 8 oz (dependent on design)
Ordering quantities	By units of 2
Delivery (L × W)	2 or 4 units on a pallet: 800 × 1,200 mm (31.5 × 47.2")
Product Box Dimension (L × W × H)	520.7 × 520.7 × 597 mm (20.5 × 20.5 × 23.5")
Manufacturing Environment	ISO 7

Sterilization Method	Gamma Irradiation (25 kGy – 45 kGy)
Shelf Life	2 years
Biocompatibility	USP<88> Class VI
Bacterial Endotoxin	USP <85>
Particulate Matter	USP <788>
Biological Reactivity Test In Vitro	USP<87> and ISO10993-5

Ø20.34"
[516.6 mm]

Ø18.55"
[471.1 mm]

21.60" [548.7 mm]
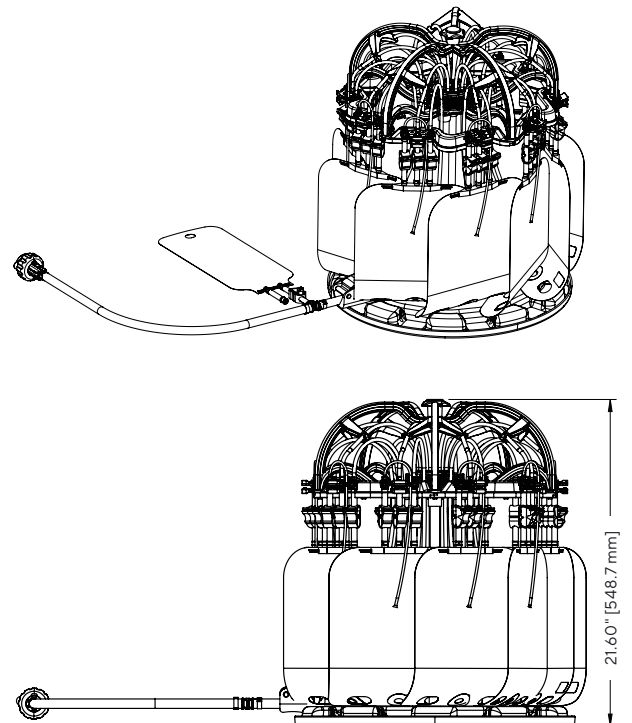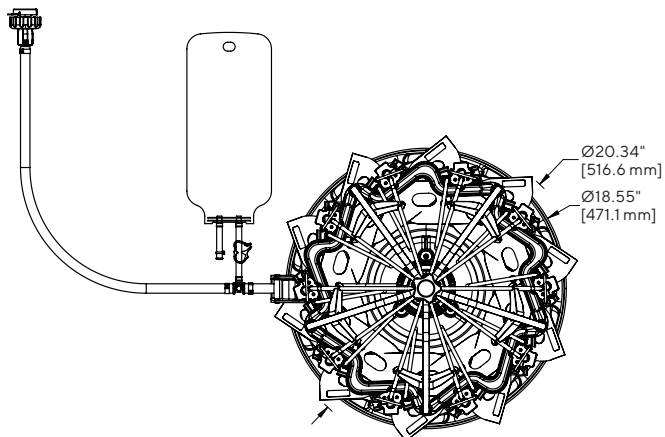
Cubis® II Balance (MCA36201) & Pump Communication Cable

Scale Interval (readability)	100 mg
Maximal Capacity	36.2 kg
Minimum Capacity	820 g
Repeatability	At 5% load 20 mg, at max load 50 mg*
Weight	15.8 kg (34 lb 13 oz)
Data Ports	COM-RS232, USB-A, USB-B, USB-C, Cat7 Ethernet
Communication Protocols	SICS, miniSICS, SBI, Webservices
Report Export	USB-A, USB-B, Cat7 Ethernet
Report Format	PDF, CSV, xlsx
Display Type, Size	MCA high-end 7" Touchscreen
Linkit® AX Pan Dimensions (L×W)	300×400 mm (11.8×15.7")
Linkit® AX Pan Weight	3.5 kg (7 lb 11 oz)
Pump Communication Cable Type, Length	9-pin male RS232 plug and 5-pin female M12 cable, 2 m (6.5 ft)
Cable Length	2 m (min) (6.5 ft)
Power Source Voltage	100–240 (±0%) V
Power Frequency	50–60 (±5%) Hz
Maximum Power Used	30 W
IP Protection According to IEC 60529-1	IP 54

*Already considered in filling accuracy performance.
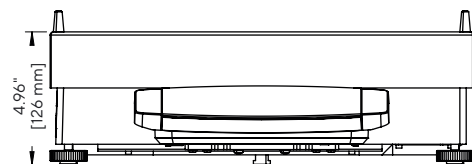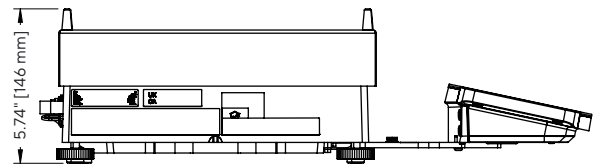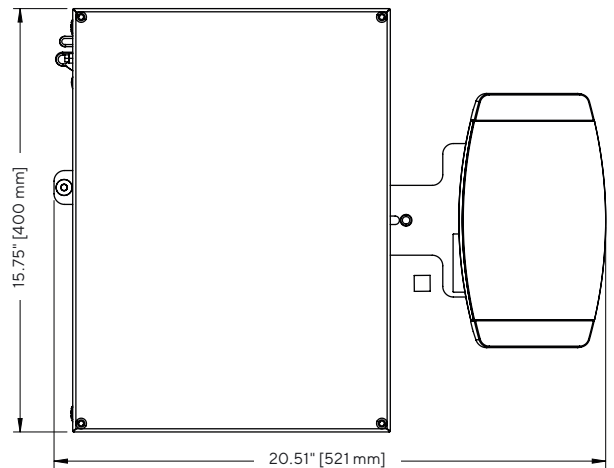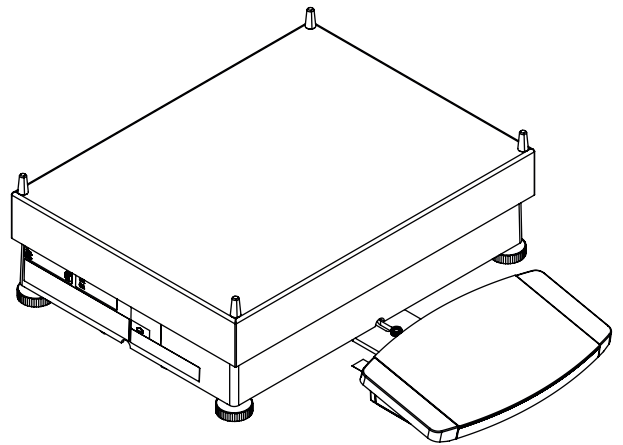
Peristaltic Pump

Recommended Model	Sartorius customized Watson Marlow 630DUN/R with connection port M12
Tubing Max Wall Thickness (WT) And Internal Diameter (ID)	3.2 mm (⅒") and 15.9 mm (⅝")
Flow Rate With Max WT And OD Tubing	4–11,000 mL/min @ 0.1–265 rpm
Operating Temperature	5 °C–40 °C (41 °F–104 °F)
Storage Temperature	–25 °C–65° C (13 °F–149 °F)
Speed	0.1–265 rpm
Weight	20.5 kg (45 lb 3 oz)
IP	IP66 to BS EN 60529, equivalent to NEMA 4X
Power Source Voltage	100–120 V	200–240 V
Power Frequency	50	60 Hz
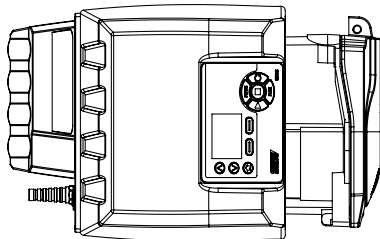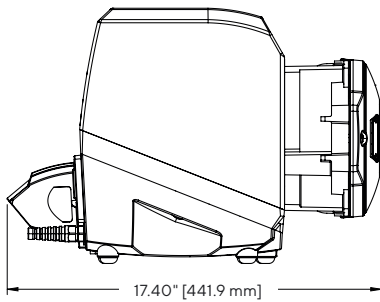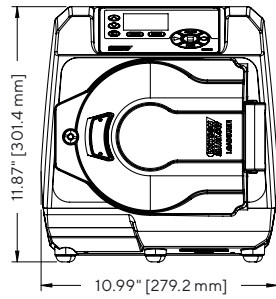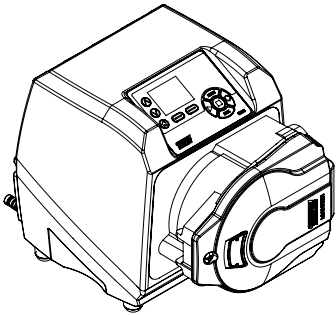
Purge Stand

Filter Purge Stand	
Weight	4.0 kg (8 lb 13 oz)
Material	316L Stainless Steel, MPU100, PU
Bag Purge Stand	
Weight	4.5 kg (9 lb 15 oz)
Material	316L Stainless Steel, MPU100, PU

Bag purge stand illustrated. For filter purge stand consider height 185.3 mm (7.30") – no bag rod holder.
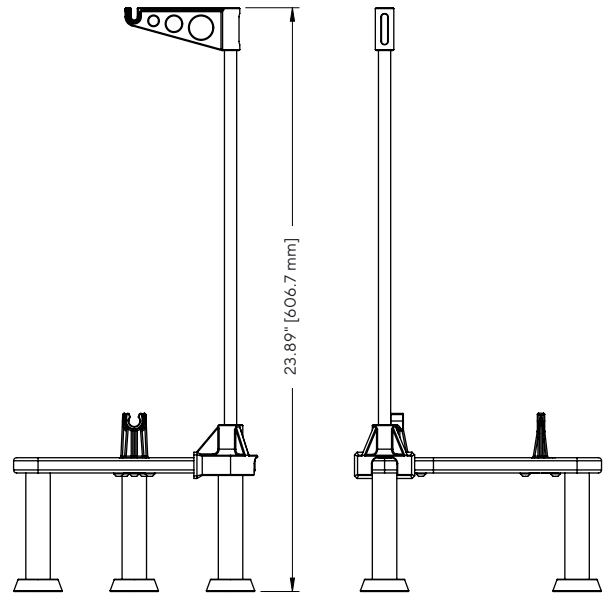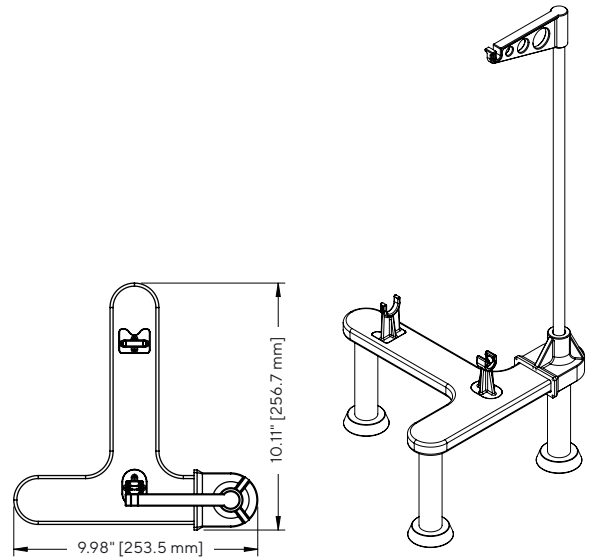
Ordering Information for Initial Set-up

1. Select the Set-up Kit According to Regional Requirements

Item	Description	Order Number
Linkit® AX kits for initial set-up	Cubis® II balance, Linkit® AX QApp, Linkit® AX accessory set for Cubis® II balance, Peristaltic pump and communication cable	Please contact your local sales representative

2. Select Purge System Type

Item	Order Number
Purge stand for filter purge system	SMTRSTPD10
Purge stand for bag purge system	SMTRSTPD20

3. Are Additional Accessories Required?

Item	Order Number
Small diameter Quickseal® cutter for tubes up to 0.25" OD	QSCUTTERSD
Silicone protection caps for ¼" (6.4 mm) OD Quickseal® collars (pack of 50)	QS04CAPSILNT
Label printers	YDP30
Standard paper and ink ribbon for label printer YDP30 (90 m)	69Y03285
Self-adhesive paper and ink ribbon for label printer YDP30 (90 m)	69Y03286

4. Linkit® AX Single-Use Assembly

Part Number	FYM312731	FYM312732	FYM312733	FYM312734	FYM312735	FYM312736
Linkit® AX inlet line connector type	Opta (female)	Aseptiquick G	Opta (female)	Aseptiquick G	Opta (female)	Aseptiquick G
Flexsafe® bag volume	1,000 mL		500 mL			
Purge system	500 mL Flexsafe® bag					
Flexsafe® bag outlet 1 tubing material, ID × OD and end type	³⁄₃₂" × ⁵⁄₃₂" PVC - Heat seal				⅛" × ¼" TPE - Tube plug	
Flexsafe® Bag outlet 2 tubing material, ID × OD and end type	⅛" × ¼" TPE– Tube plug		-			

Technical drawings can be provided upon request.

Additional configurations can be made through the Sartorius Configurator. Please contact your Sales Representative for more information.

For more information about tubing sets and assemblies, visit
www.sartorius.com/en/products/fluid-management/single-use-tubing/tubing-sets-assemblies

For more information about Quickseal® Disconnectors, visit
www.sartorius.com/en/products/fluid-management/aseptic-disconnectors/quickseal

For more information about Tuflux® Silicone and TPE Tubing, visit
www.sartorius.com/en/products/fluid-management/single-use-tubing/tuflux-silicone-tpe-tubing

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