CryoVault®

Freeze & Thaw Platform

Standards Guide

End-to-End Platform Solution

MEISSNER

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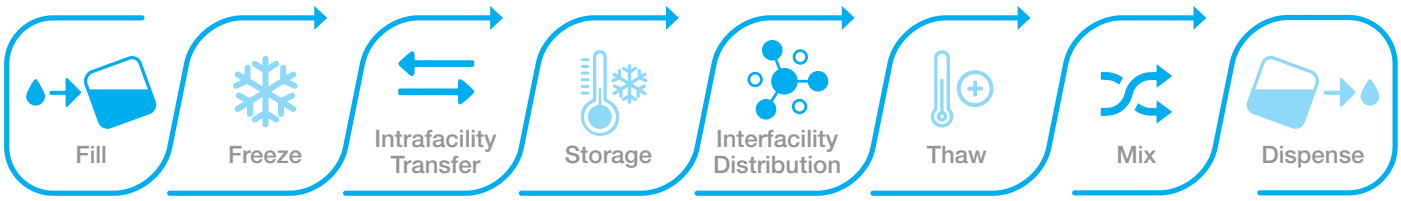
Please note: All pictures shown in this Standards Guide are for illustration purposes only and may not be an exact representation of the product. Actual product may vary due to product enhancement.

CryoVault® - The End-to-End Platform Solution for BDS Freeze/Thaw

The interfacility management of Freeze/Thaw (F/T) processes for bulk drug substances (BDS) has been a challenge fraught with issues that continue to affect biopharmaceutical manufacturing sites around the globe. Biologics manufacturers often utilize portable, jacketed, stainless steel cryovessels. These cryovessels provide commonly unitized batch sizes up to 300 L, but require extensive clean-in-place operations and cleaning validation.

Adoption of single-use technology for storage containers is highly desirable. Biocontainers (bags) may not be well suited to operate across both freeze and thaw temperatures because they are susceptible to tears during material handling processes. Moreover, bags are often frozen in a way that also makes them susceptible to damage due to the internal pressure build-up from ice bridging. Further, operational risk is heightened by the fact that a multitude of small volume containers must be utilized in order to match the typical batch volume handled by one traditional cryovessel.



CryoVault® E2E platform solution supports the full process of BDS handling from Fill to Dispense.

CryoVault® is an end-to-end (E2E) platform solution that addresses the common challenges associated with bulk drug substance F/T operations. CryoVault® includes pre-qualified F/T units and material handling equipment designed around a highly innovative rigid wall single-use storage container. The platform is carefully designed to include all process steps for the drug substance (DS) manufacturing site and the drug product (DP) filling site, as well as shipping between the sites (reference pages 6-7). The CryoVault® platform supports DS batch sizes for both clinical scale and full commercial scale.

CryoVault® features single-use rigid wall storage containers with customizable top works that, together, create a complete single-use assembly. The storage containers are modular in size and are available in sizes of 100 L (75 L nominal), 20 L (16 L nominal) and 6 L (5 L nominal) and 1.25 L (1 L nominal) to provide operational flexibility. Air blast freezers optimize F/T cycles for the storage containers and are factory qualified.

The CV300 platform accommodates the 100 L, the 20 L and the 6 L container sizes for enhanced operational flexibility. Similarly, the CV96 platform accommodates both the 20 L and the 6 L containers. Each of the CV300 and CV96 platforms feature their own F/T units and material handling equipment.

The 1.25 L container is available for testing and smaller aliquots of production value biologicals. Meissner subject matter experts are available to assist in the tailoring of a CryoVault® F/T process solution that best meets your needs in both your DS and DP sites.

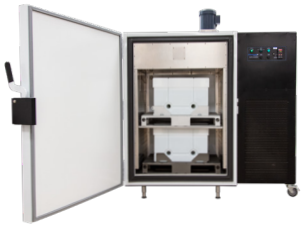
Experience **CryoVault®** Single-Use BDS Storage Containers

End users can experience Meissner's commitment to quality through our pre-qualified, single-use component library that was purposely expanded to enable F/T operations. The single-use storage containers are a notable part of this single-use systems portfolio. The rigid containers feature consistent freeze path lengths and integrated shrouds that serve a dual purpose of providing insulation and protection of the top works. These features all work in unison to provide the benefit of robust performance in this demanding application.

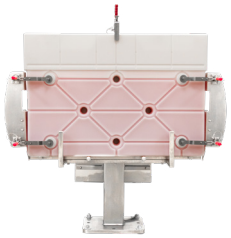
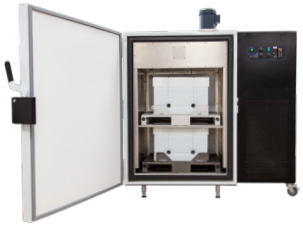
The single-use assembly's quality certification is integral to our production operations. We manufacture our single-use assemblies in a Class 7 cleanroom environment, deploying highly automated production processes, with a strong emphasis on error-proofing and electronic batch record management. Meissner Technical Services (MTS) maintains sterility validations according to ISO 11137 methodology, and conducts routine endotoxin and particulate testing.

PLATFORM	CONTAINER SIZE OPTIONS	MAXIMUM FILL VOLUME CAPACITY	BDS BATCH SIZE
CV300	100 L	300 L (4 qty. x 75 L)	20 L - 300 L
	20 L	256 L (16 qty. x 16 L)	4 L - 256 L
	6 L	160 L (32 qty. x 5 L)	1 L - 160 L
CV96	20 L	96 L (6 qty. x 16 L)	4 L - 96 L
	6 L	60 L (12 qty. x 5 L)	1 L - 60 L

Bulk Drug Substance Manufacturing Site

	Fill	Freeze	Intrafacility Transfer	Storage
CV300 PLATFORM	Fill Cart Lift Arm	Freeze/Thaw Unit	Automated Pallet Handler Transport Cart	100 L Storage Container 20 L Storage Container CV300 Pallet
CV96 PLATFORM	Universal Lab Stand with Fill/Dispense Accessory Load Cell Cart	 Freeze/Thaw Unit	Automated Lift/Mix EPBC Intrafacility Cart	20 L Storage Container CV96 Pallet 6 L Storage Container

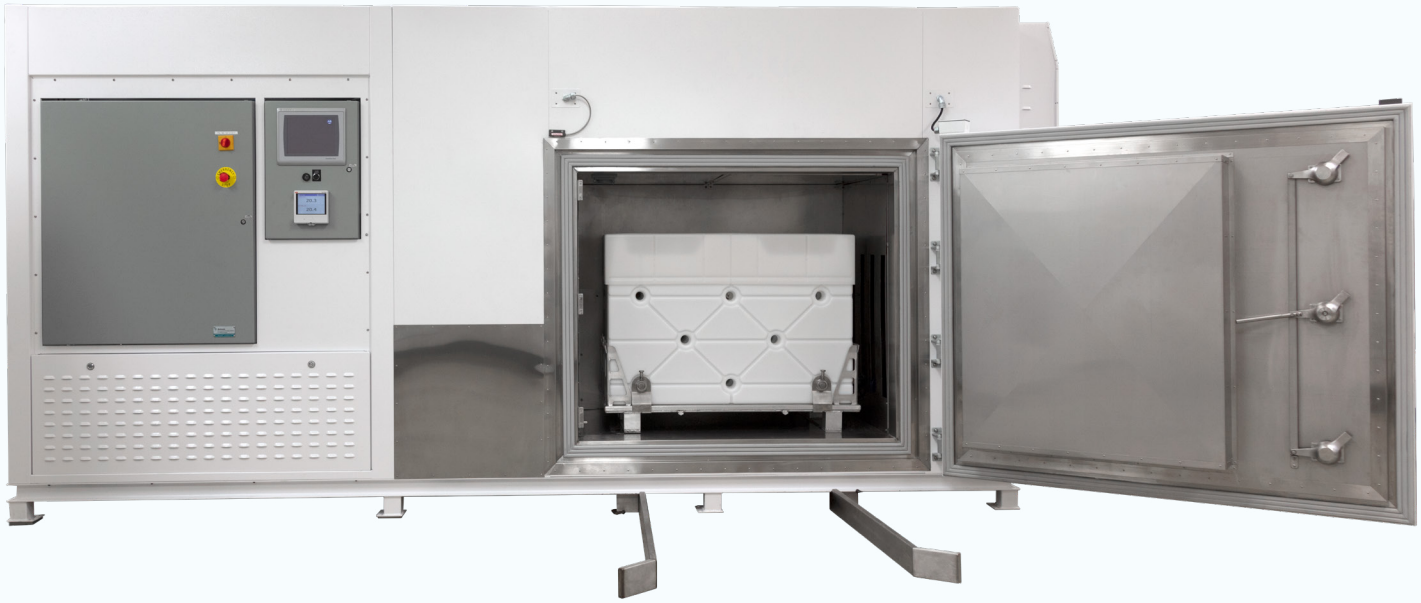
Drug Product Filling Site

Interfacility Distribution	Thaw	Mix	Dispense	
Shipping Container	Freeze/Thaw Unit	 Mixer (100 L Shown)	Dispense Cart	CV300 PLATFORM
Hold Down Rods	Rocking Platform	Mixer (20 L Shown)	Lift Arm	
Shipping Container	 Freeze/Thaw Unit	Automated Lift/Mix	Universal Lab Stand with Fill/Dispense	CV96 PLATFORM
Shipping Pallet Adapter		Mixer (20 L Shown)	Load Cell Cart	
Intrafacility Cart				

Freeze/ Thaw Unit
Overview

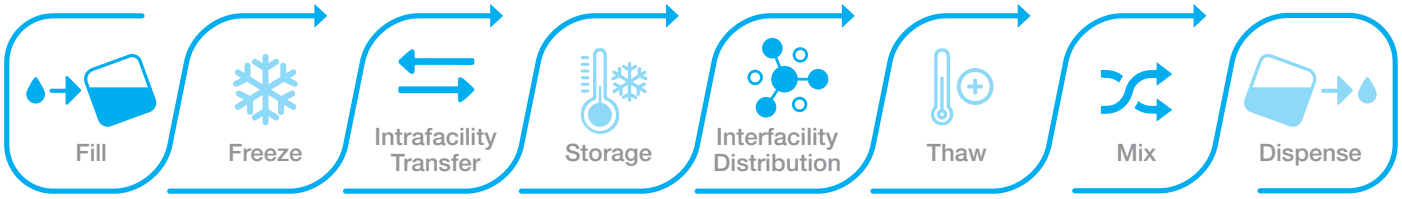
Each CryoVault® platform features pre-qualified Freeze/Thaw (F/T) units that integrate both the freeze and thaw functions into a single unit. The specific combination of air-blast freezing, pallet orientation and container interspacing, along with its headspace insulation, eliminates ice bridging in the containers. Ice bridging, when present, leads to pressure build-up which can adversely affect container integrity. This optimized operating paradigm also increases the rate of heat transfer, which is the most important consideration in avoiding cryo-concentration. All F/T units are programmable to allow end-users to establish their own freezing and thawing cycles.

CV96 PLATFORM
Freeze/Thaw Unit



CV300 PLATFORM
Freeze/Thaw Unit

CV300 Platform
Overview



The CryoVault® CV300 platform provides an E2E solution for F/T operations for high volume biopharmaceuticals. This platform is ideal for enterprises that produce large batch sizes of BDS that are otherwise handled by more traditional multi-use cryovessels. All CryoVault® equipment is available with utilities to cater to specific regional requirements.

CV300 Platform
Fill Cart

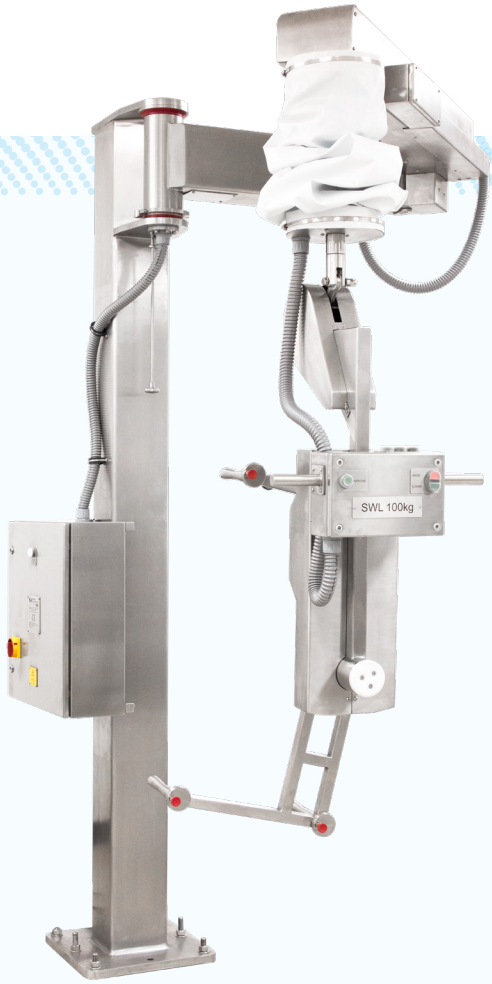
Fill

The fill cart is made out of 304 stainless steel and holds up to two (2) 100 L containers. The fill cart has a 10° angle that allows an internal dip-tube within the container to reduce the build-up of foam during filling.

Meissner Part Number	KCVM-FC082A
Maximum Storage Container Capacity	Two (2) quantity 100 L containers; 10° angle
Material	304 stainless steel
Dimensions (D x W x H)	57" x 26" x 47.5" (144.8 x 66 x 120.7 cm)
Weight	138 lb (62.6 kg) unloaded
Casters	Two (2) front-fixed; two (2) rear-swivel

Fill

CV300 Platform
Lift Arm



The electrically powered lift arm transitions the filled containers between process steps. The lift arm can hold one (1) filled 100 L container or four (4) filled 20 L containers with a pallet adapter (see page 28). The lift arm reaches a wide processing area and is ideal for loading containers onto and off of the mixer, pallets, and carts.

Meissner Part Number	KCVM-LS001A
Maximum Storage Container Capacity	One (1) quantity 100 L container
	Four (4) quantity 20 L containers
	Eight (8) quantity 6 L containers
Material	304 stainless steel
Dimensions (Radius x H)	78.7" x 108.5" (200 x 275.6 cm)
Base Dimensions (L x W)	17.8" x 17.8" (45.1 x 45.1 cm)
Weight	791.5 lb (359 kg) unloaded
Maximum Load Weight	220 lb (99.8 kg)
Utilities Required	120 V | 1 Ø | 50-60 Hz
Certification Mark (CE)	Yes

CV300 Platform
Freeze/Thaw Unit

Freeze

The Freeze/Thaw (F/T) unit holds one (1) large pallet containing up to a nominal 300 L volume distributed over four (4) 100 L containers (each with a 75 L nominal fill volume). The automated pallet handler and floor mounted guide rails facilitate the loading and unloading of the F/T unit. The unit's PLC controls F/T cycles through programmable recipes.

Meissner Part Number	U.S.: Air-cooled: KCVF-PS001A; Water-cooled: KCVF-PS101A
	Europe: Air-cooled: KCVF-PS053A; Water-cooled: KCVF-PS153A
Maximum Storage Container Capacity	Four (4) quantity 100 L containers
	Sixteen (16) quantity 20 L containers
	Thirty-two (32) quantity 6 L containers
Maximum Volume Capacity	300 L total (utilizing four [4] quantity 100 L containers)
	256 L total (utilizing sixteen [16] quantity 20 L containers)
	160 L total (utilizing thirty-two [32] quantity 6 L containers)
Temperature Range	+40 °C to -80 °C
External Dimensions (D x W x H)	72" x 188" x 88" (182.9 x 477.5 x 223.5 cm)
Internal Dimensions (D x W x H)	36" x 56" x 47" (91.4 x 142.2 x 119.4 cm)
Material	External: polyester finish, white
	Internal: 304 stainless steel
Chamber Volume	52.5 ft^3 (1.5 m^3)

Free/Thaw Unit continued on next page

(continued)

Weight	4,400 lb (1,995.8 kg) unloaded
Door Size (W x H)	56.3" x 47.2" (143 cm x 120 cm)
Refrigeration	Cascade; two (2) scroll compressors
Refrigeration Type (High; Low)	R448A; R508B
Control System	Hardware: PLC-Allen Bradley MicroLogix 1400; UL certified controls
Utilities Required	U.S.: 208-240 V | 3 Ø | 60 Hz
	Europe: 400 V | 3 Ø | 50 Hz (5 wire)
Thermal Room Load	Air-cooled: 34,000 BTU/hr
	Water-cooled: Cooling capacity approximate 3,000 BTU/hr (0.9 kW) at -80 °C. Max capacity 20,000 BTU/hr (6 kW) above -60 °C temperature.
Water Cooling Requirements	Tower Water 29.5 °C, 1.4 bar: Water flow rate at maximum load: 26.5 L/min Water flow rate average load: 15 L/min
	Chilled Water 7.2 °C, 1.4 bar: Water flow rate at maximum load: 5.7 L/min Water flow rate average load: 3.8 L/min
Certification Mark (CE)	Yes

CV300 Platform
Transport Cart

Intrafacility Transfer

The transport cart is manufactured out of 304 stainless steel and holds up to four (4) 100 L containers for intrafacility transport or storage.

Meissner Part Number	KCVM-FT084A
Material	304 stainless steel
Dimensions (D x W x H)	56" x 34" x 48.7" (142.2 x 86.4 x 121.9 cm)
Weight	162 lb (73.5 kg) unloaded
Capacity	Four (4) quantity 100 L containers
Casters	Two (2) front-fixed; two (2) rear-swivel

Intrafacility Transfer

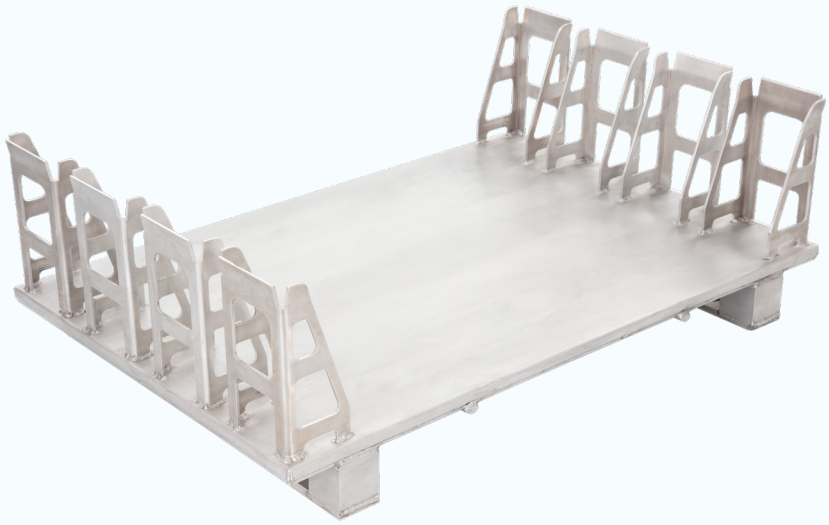
CV300 Platform
Automated Pallet Handler

The automated pallet handler interfaces with the large pallet and features pre-programmed height settings for various loading/deployment steps. Floor-mounted rails guide the automated pallet handler for safe loading of the large pallet into the Freeze/Thaw unit.

Meissner Part Number	KCVM-AJ001A
Maximum Storage Container Capacity	Four (4) quantity 100 L containers
	Sixteen (16) quantity 20 L containers
	Thirty-two (32) quantity 6 L containers
Material	304 stainless steel
Dimensions (D x W x H)	83" x 32" x 48.7" (210.8 x 81.3 x 123.8 cm)
Weight	661 lb (299.8 kg) unloaded
Maximum Load Weight	992 lb (450 kg)
Utilities Required	120 V | 1 Ø | 50-60 Hz
Battery	Type: HZY-EV 12-110 Haze Battery 12 V 119 AH Gel; 24 V; 12 hours charge time
Certification Mark (CE)	Yes

CV300 Platform
CV300 Pallet

Storage



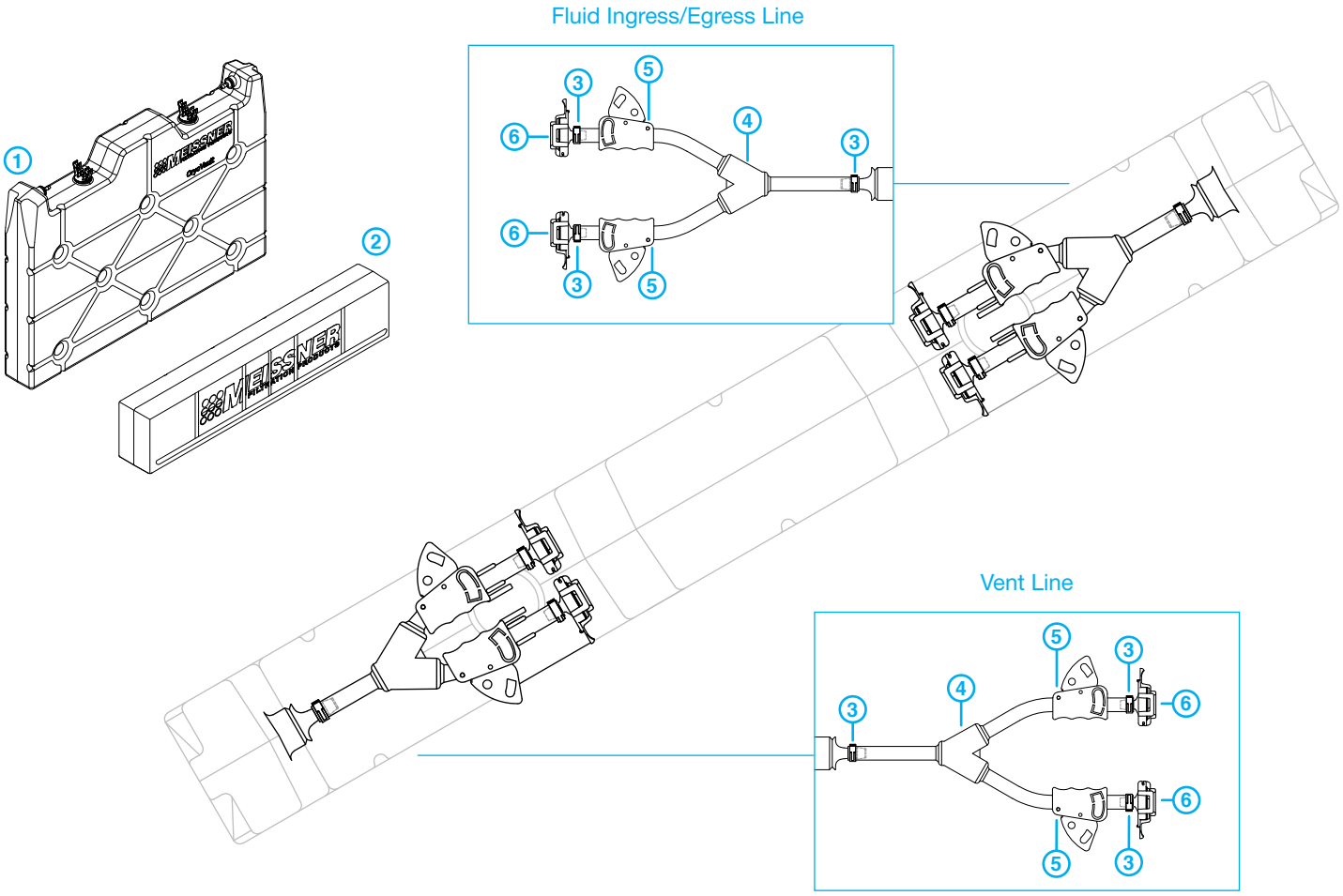
A fully palletized load of four (4) 100 L containers matches the volume of one (1) 300 L jacketed stainless steel or Hastelloy cryovessel. The CV300 pallet interfaces with Freeze/Thaw units for the CV300 platform as well as the shipper. The CV300 pallet requires hold down rods to secure containers during transport. The CV300 pallet can also hold four (4) 20 L or eight (8) 6 L containers in the same pallet space occupied by one (1) 100 L container with the use of the pallet adapter. (See page 28.)

Meissner Part Number	KCVM-PA084A
Maximum Storage Container Capacity	Four (4) quantity 100 L containers
	Sixteen (16) quantity 20 L containers
	Thirty-two (32) quantity 6 L containers
Material	Anodized aluminum
CV300 Dimensions (D x W x H)	47.3" x 31.5" x 16" (120.1 x 80 x 40.6 cm)
Weight	78 lb (35.4 kg) unloaded
Certification Mark (CE)	Yes

Storage

CV300 Platform

100 L BDS Container with Platinum-Cured Silicone Tubing



Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	100 L Container - 2 x ⅜" HB	91R71C87	1	HDPE
2	100 L Shroud	91R40S80	1	LDPE
3	Band Clamp, 17.0 mm	92L96T53	6	Stainless Steel
4	⅜" x ⅝" Overmolded Y-Junction	91T11N57	2	Platinum Silicone
5	Pure-Fit® Clamp, Large	91L00P80	4	Polypropylene
6	Aseptic Connector, ⅜" HB, AseptiQuik® G	91S33N50	4	Polycarbonate
7	Tamper Evident Re-closable Poly-bag (not pictured)	7620-04	4	Polyethylene
8	Cable Tie, Small (not pictured)	92M93C12	4	Nylon
9	Outer Packaging, Poly-Bag (not pictured)	7600-60	2	Polyethylene

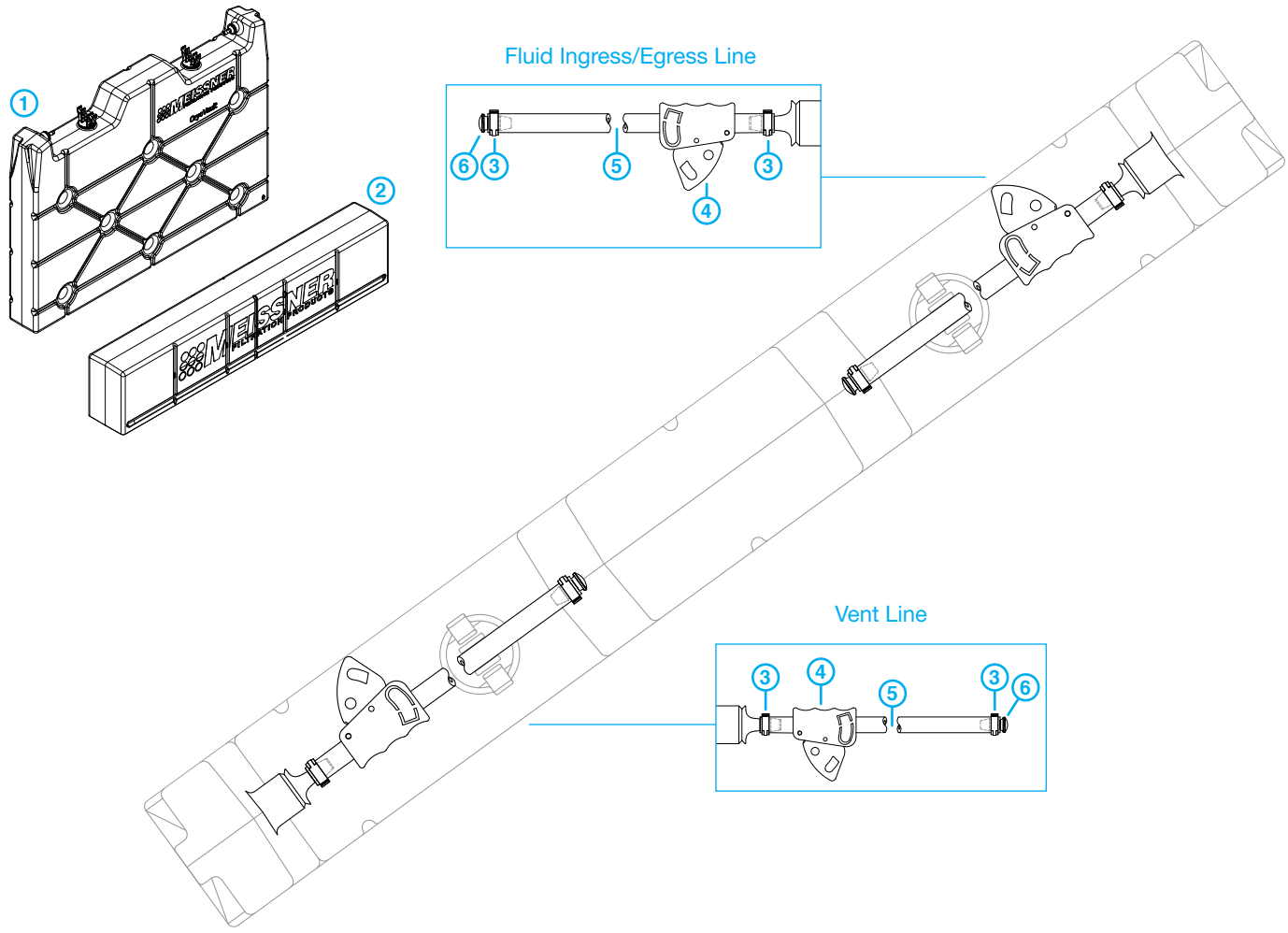
Standards Part No.

Part Number	Material	Container Volume	Maximum Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC2708H-N00-B9060-01	HDPE	100 L	75 L	46.4" x 6.2" x 31.4"	40.1 lb
				117.9 x 15.7 x 79.8 cm	18.2 kg

CV300 Platform

100 L BDS Container with M-Flex™ TPE Tubing

Storage



Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	100 L Container - 2 x ⅜" HB	91R71C87	1	HDPE
2	100 L Shroud	91R40S80	1	LDPE
3	Band Clamp, 18.5 mm	92L96T24	4	Stainless Steel
4	Pure-Fit® Clamp, Large	91L00P80	2	Polypropylene
5	⅜" x ⅝" M-Flex™ Tubing, 24" Length	91T47G57-24	2	M-Flex™ TPE
6	⅜" HB Plug	91H02P50	2	Polypropylene
7	Outer Packaging, Poly-Bag (not pictured)	7600-60	2	Polyethylene

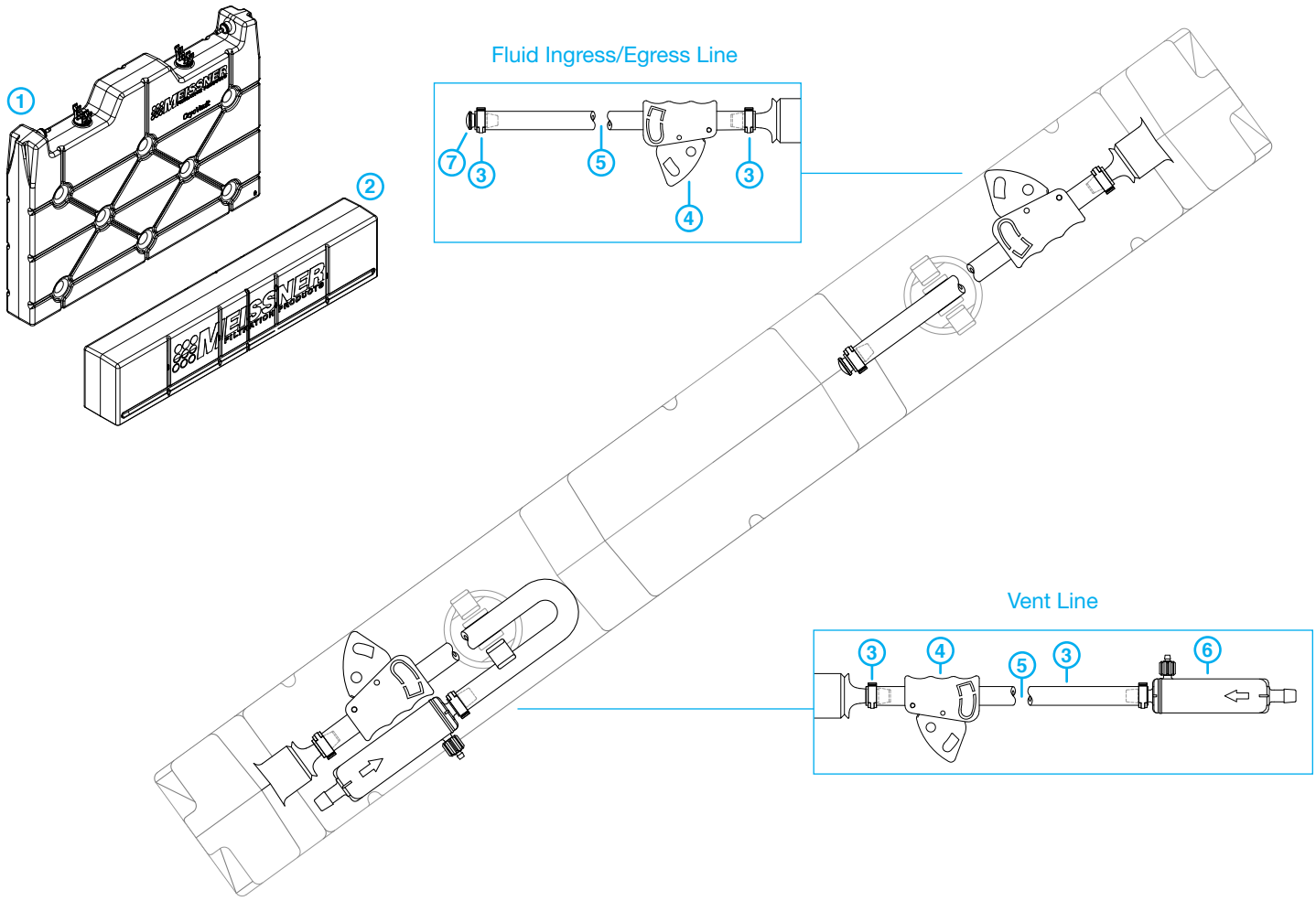
Standards Part No.

Part Number	Material	Container Volume	Maximum Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC2708H-N00-C0600-01	HDPE	100 L	75 L	46.4" x 6.2" x 31.4"	40.1 lb
				117.9 x 15.7 x 79.8 cm	18.2 kg

Storage

CV300 Platform

100 L BDS Container with M-Flex™ TPE Tubing plus capsule vent filter



Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	100 L Container - 2 x ⅜" HB	91R71C87	1	HDPE
2	100 L Shroud	91R40S80	1	LDPE
3	Band Clamp, 18.5 mm	92L96T24	4	Stainless Steel
4	Pure-Fit® Clamp, Large	91L00P80	2	Polypropylene
5	⅜" x ⅝" M-Flex™ Tubing, 24" Length	91T47G57-24	2	M-Flex™ TPE
6	Meissner Capsule Filter	CM2VTV0.2-226	1	PP/Steridyne®
7	⅜" HB Plug	91H02P50	1	Polypropylene
8	Outer Packaging, Poly-Bag (not pictured)	7600-60	2	Polyethylene

Standards Part No.

Part Number	Material	Container Volume	Maximum Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC2708H-VV2-C0600-01	HDPE	100 L	75 L	46.4" x 6.2" x 31.4"	40.1 lb
				117.9 x 15.7 x 79.8 cm	18.2 kg

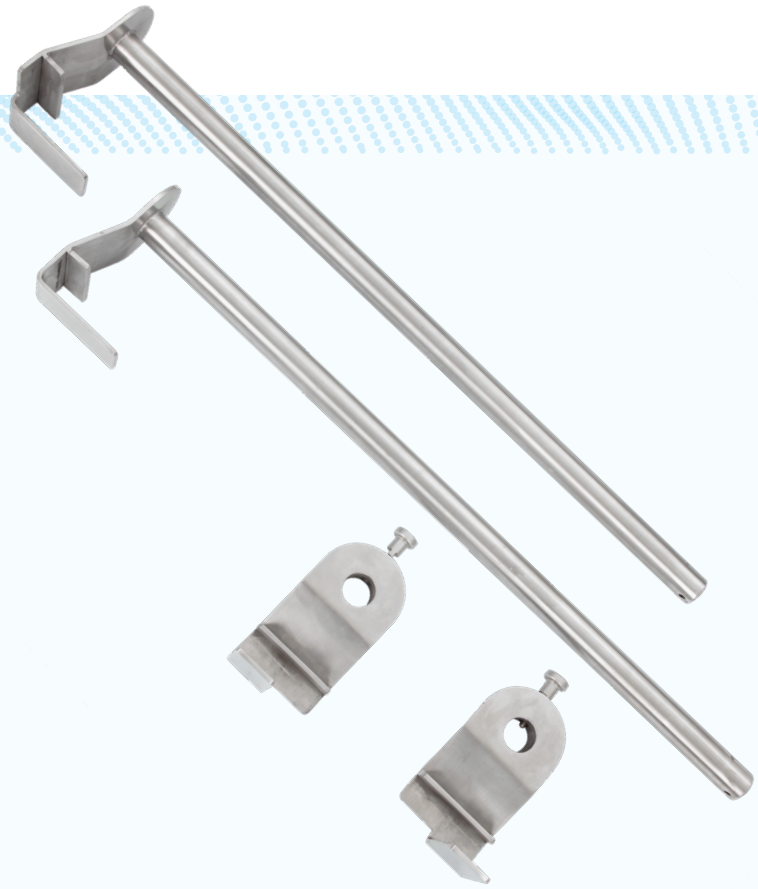
CV300 Platform
Shipping Container

Interfacility Distribution

The shipper can hold 200 kg of dry ice to maintain the internal temperature at or below -40 °C for an estimated 100 hours. The shipper accommodates one (1) large pallet which can hold up to four (4) 100 L containers, up to sixteen (16) 20 L containers or thirty-two (32) 6 L containers with the use of the pallet adapter. The shipper is qualified in accordance with ASTM D4169 and ISTA 3E standards.

Meissner Part Number	KCVS-AS300P
Maximum Storage Container Capacity	One (1) quantity loaded large pallet
Material	MDPE insulated with CFC
External Dimensions (D x W x H)	60.7" x 47.8" x 61.5" (154.3 x 121.3 x 156.2 cm)
Internal Dimensions (D x W x H)	54" x 40.7" x 40.1" (137.2 x 103.5 x 101.9 cm)
Weight	619.9 lb (281.2 kg) unloaded
Shipper Compliance	ASTM D4169, ISTA 3E
Clearance (door)	53.9" (137 cm)
Temperature Control	Passive cooling with dry ice (up to 200 kg)
Storage Duration	100 hours

CV300 Platform
Hold Down Rods



Hold down rods secure containers to the CV300 pallet when loaded into the shipper for interfacility transport. The hold down rods are also compatible with the use of the pallet adapter.

Meissner Part Number	KCVM-PA300A
Material	304 stainless steel
Dimensions (D x W x H)	32" x 3.5" x 8" (81.3 x 8.9 x 20.3 cm)

CV300 Platform
Freeze/Thaw Unit

Thaw

The Freeze/Thaw unit holds one large pallet containing up to a nominal 300 L volume of DS, distributed over four (4) 100 L containers. The automated pallet handler and floor mounted guide rails facilitate the loading and unloading of the Freeze/Thaw unit.

Meissner Part Number	U.S.: Air-cooled: KCVF-PS001A; Water-cooled: KCVF-PS101A
	Europe: Air-cooled: KCVF-PS053A; Water-cooled: KCVF-PS153A
Maximum Storage Container Capacity	Four (4) quantity 100 L containers
	Sixteen (16) quantity 20 L containers
	Thirty-two (32) quantity 6 L containers
Maximum Volume Capacity	300 L total (utilizing four [4] quantity 100 L containers)
	256 L total (utilizing sixteen [16] quantity 20 L containers)
	160 L total (utilizing thirty-two [32] quantity 6 L containers)
Temperature Range	+40 °C to -80 °C
External Dimensions (D x W x H)	72" x 188" x 88" (182.9 x 477.5 x 223.5 cm)
Internal Dimensions (D x W x H)	36" x 56" x 47" (91.4 x 142.2 x 119.4 cm)
Material	External: polyester finish, white
	Internal: 304 stainless steel
Chamber Volume	52.5 ft^3 (1.5 m^3)

Freeze/Thaw Unit continued on next page

(continued)

Weight	4,400 lb (1,995.8 kg)
Door Size (W x H)	56.3" x 47.2" (143 cm x 120 cm)
Refrigeration	Cascade; two (2) scroll compressors
Refrigeration Type (High; Low)	R448A; R508B
Control System	Hardware: PLC-Allen Bradley MicroLogix 1400; UL certified controls
Utilities Required	U.S.: 208-240 V | 3 Ø | 60 Hz
	Europe: 400 V | 3 Ø | 50 Hz (5 wire)
Thermal Room Load	Air-cooled: 34,000 BTU/hr
	Water-cooled: Cooling capacity approximate 3,000 BTU/hr (0.9 kW) at -80 °C. Maximum capacity 20,000 BTU/hr (6 kW) above -60 °C temperature.
Water Cooling Requirements	Tower Water 29.5 °C, 1.4 bar: Water flow rate at maximum load: 26.5 L/min Water flow rate average load: 15 L/min
	Chilled Water 7.2 °C, 1.4 bar: Water flow rate at maximum load: 5.7 L/min Water flow rate average load: 3.8 L/min
Certification Mark (CE)	Yes

CV300 Platform
Rocking Platform

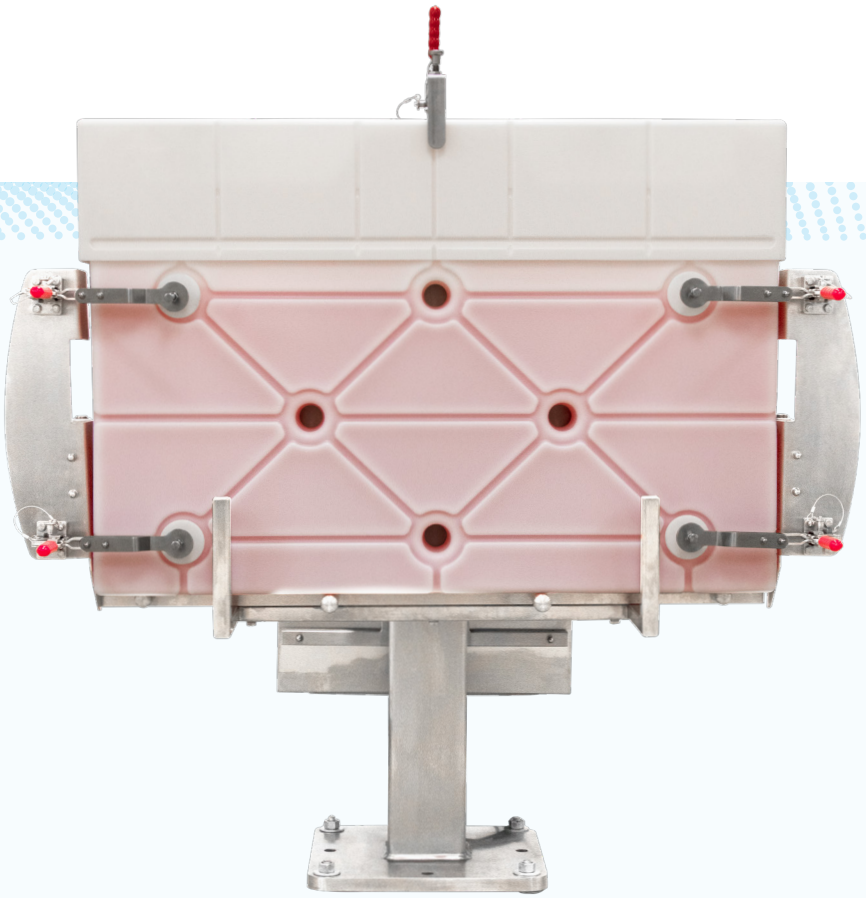
Thaw

The rocking platform is designed to fit into the CV300 Freeze/Thaw unit to gently agitate the CV300 pallet of BDS containers to accelerate the thaw cycle.

Meissner Part Number	KCVM-RS001A
Material	304 stainless steel
Dimensions (D x W x H)	42.7" x 48.8" x 13" (108.5 x 124 x 33 cm)
Weight (without cart)	195.1 lb (88.5 kg)
Utilities Required	120 V | 1 Ø | 50-60 Hz
Certification Mark (CE)	Yes

Mix

CV300 Platform
Mixer



The mixer homogenizes the thawed DS and holds one (1) 100 L container, four (4) 20 L containers or eight (8) 6 L containers with the pallet adapter. The mixer is fully PLC controlled to set mixing time, rock angle, and cycle rate for repeatable operations.

Meissner Part Number	KCVM-MS001A
Maximum Storage Container Capacity	One (1) quantity 100 L container
	Four (4) quantity 20 L containers
	Eight (8) quantity 6 L containers
Material	304 stainless steel
Dimensions (D x W x H)	48.5" x 63.1" x 63" (123.2 x 160.3 x 160 cm)
Base Dimensions (L x W)	18" x 18" (45.7 x 45.7 cm)
Weight	2,833 lb (1,285 kg) unloaded
Maximum Load Weight	220 lb (100 kg)
Utilities Required	120 V | 1 Ø | 50-60 Hz
Certification Mark (CE)	Yes

CV300 Platform
Dispense Cart

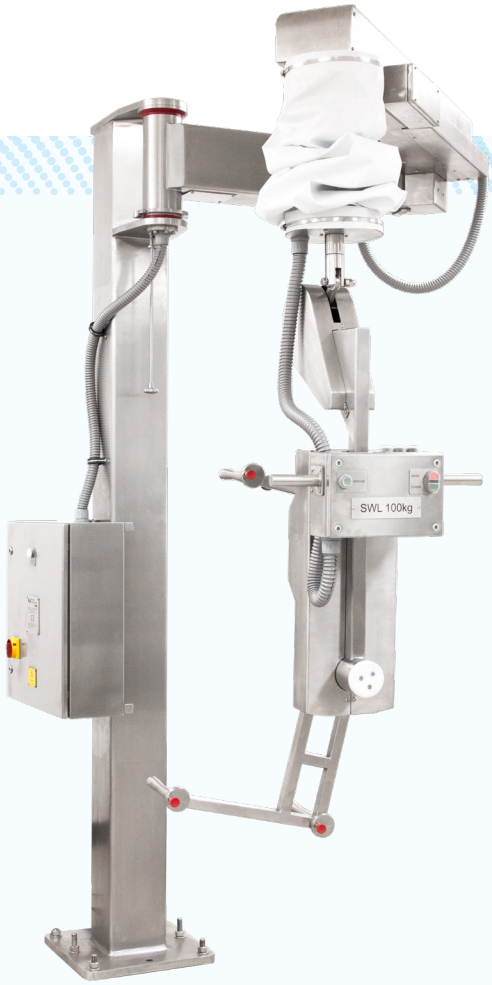
Dispense

The dispense cart is made out of 304 stainless steel and holds one (1) 100 L container positioned at an angle of 100° to facilitate the dispensing of DS after thawing, while minimizing hold-up volume.

Meissner Part Number	KCVM-DC081A
Maximum Storage Container Capacity	One (1) quantity 100 L container; 100° angle
Material	304 stainless steel
Dimensions (D x W x H)	58" x 26" x 47.5" (147.3 x 66 x 120.7 cm)
Weight	147.9 lb (67.1 kg)
Casters	Two (2) front-fixed; two (2) rear-swivel

Dispense

CV300 Platform
Lift Arm



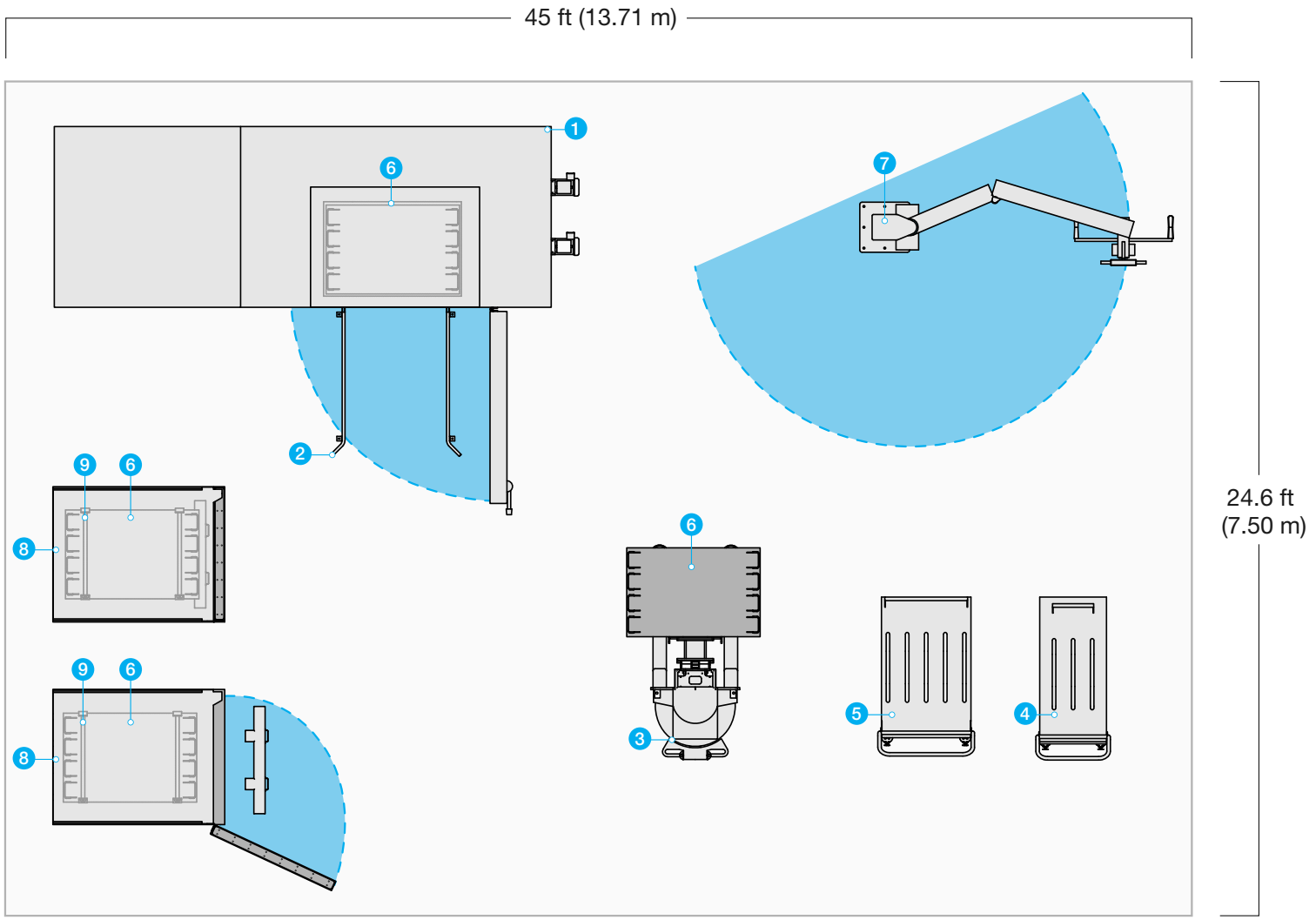
The electrically powered lift arm transitions the filled containers. The lift arm can hold one (1) filled 100 L container, four (4) filled 20 L containers or eight (8) filled 6 L containers with a pallet adapter. The lift arm reaches a wide processing area and is ideal for loading BDS containers onto and off of the mixer, pallets, and carts.

Meissner Part Number	KCVM-LS001A
Maximum Storage Container Capacity	One (1) quantity 100 L container
	Four (4) quantity 20 L containers
	Eight (8) quantity 6 L containers
Material	304 stainless steel
Dimensions (Radius x H)	78.7" x 108.5" (200 x 275.6 cm)
Base Dimensions (L x W)	17.8" x 17.8" (45.1 x 45.1 cm)
Weight	791.5 lb (359 kg) unloaded
Maximum Load Weight	220 lb (99.8 kg)
Utilities Required	120 V | 1 Ø | 50-60 Hz
Certification Mark (CE)	Yes

CryoVault® CV300

KCVP-PS051S

Standard Bundle - DS Manufacturing Site

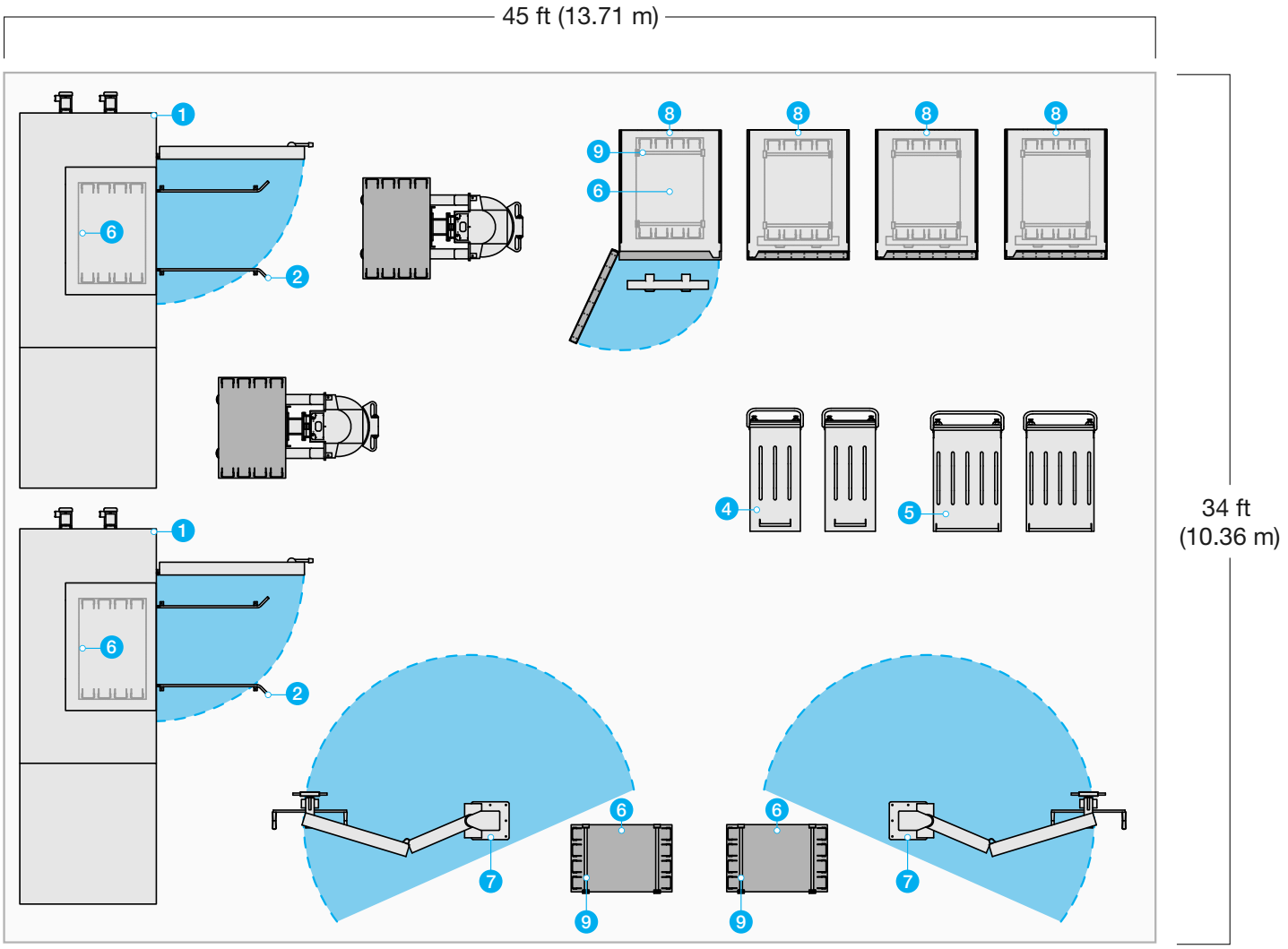


ITEM	DESCRIPTION	PART NO.	QTY
1	Freeze Thaw Unit; Water Cooled	KCVF-PS151A	1
2	Guide Rails	KCVM-GR001A	1
3	Automated Pallet Handler	KCVM-AJ001	1
4	Filling Cart	KCVM-FC082A	1
5	Transport Cart	KCVM-FT084A	1
6	Large Pallet	KCVM-PA084A	4
7	Lift Arm	KCVM-LS001A	1
8	Shipper	KCVM-AS300P	2
9	Hold Down Rods	KCVM-PA300A	4

CryoVault® CV300

KCVP-PS051P

Premium Bundle - DS Manufacturing Site



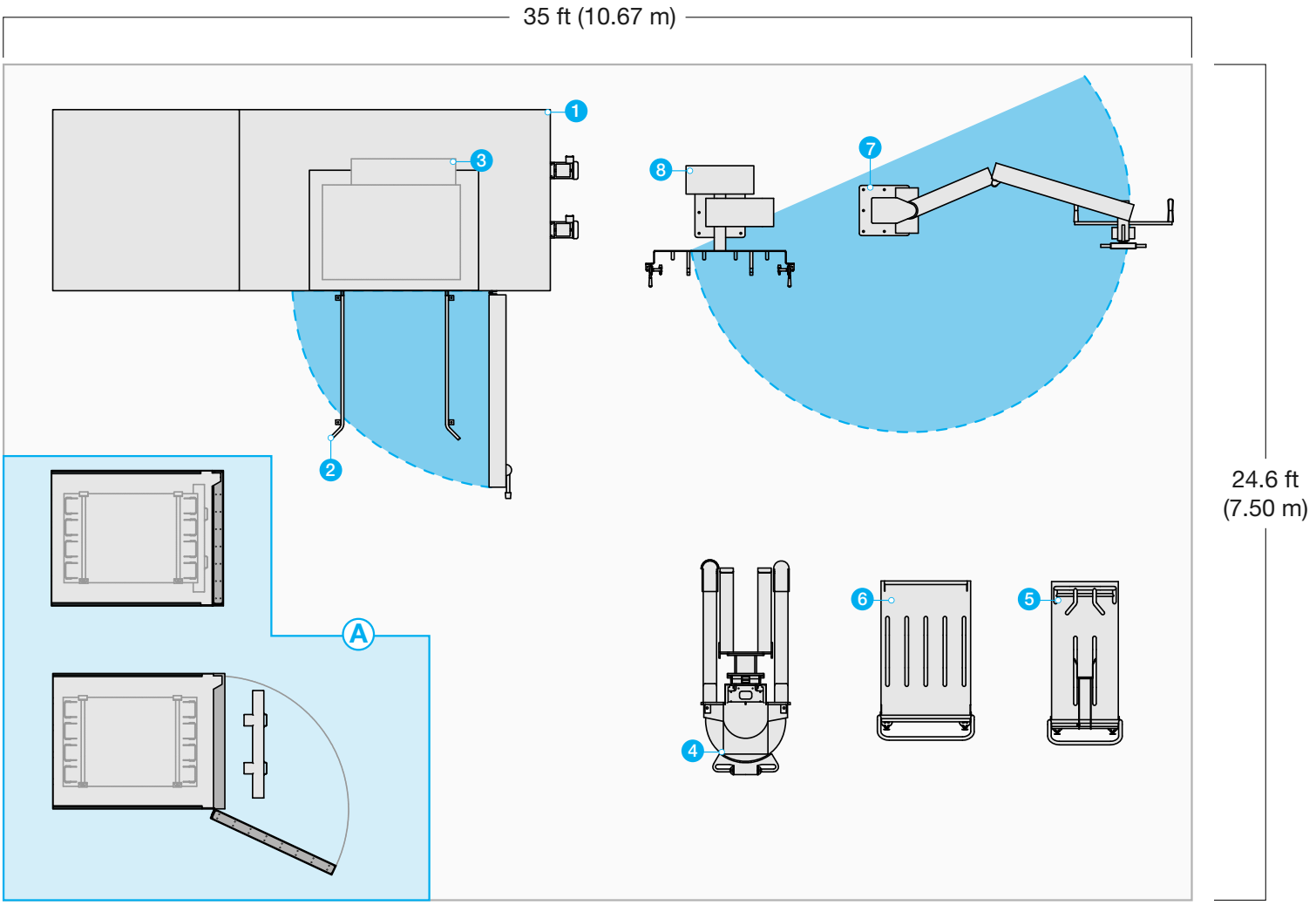
Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY
1	Freeze Thaw Unit; Water Cooled	KCVF-PS151A	2
2	Guide Rails	KCVM-GR001A	2
3	Automated Pallet Handler	KCVM-AJ001	2
4	Filling Cart	KCVM-FC082A	2
5	Transport Cart	KCVM-FT084A	2
6	Large Pallet	KCVM-PA084A	16
7	Lift Arm	KCVM-LS001A	2
8	Shipper	KCVM-AS300P	4
9	Hold Down Rods	KCVM-PA300A	16

CryoVault® CV300

KCVP-PP051S

Standard Bundle - DP Filling Site



Bill of Materials

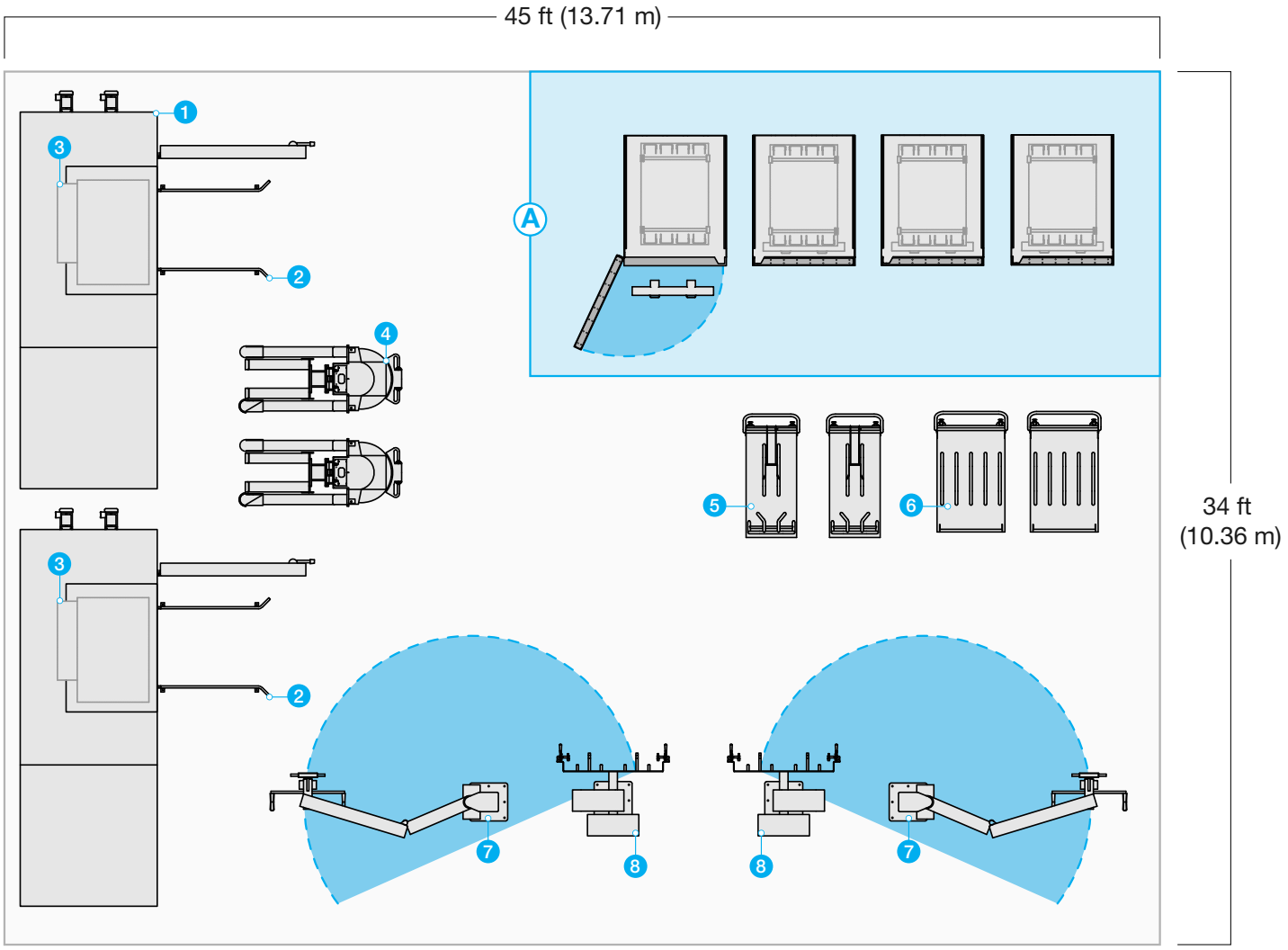
ITEM	DESCRIPTION	PART NO.	QTY
1	Freeze Thaw Unit; Water Cooled	KCVF-PS151A	1
2	Guide Rails	KCVM-GR001A	1
3	Rocking Platform	KCVM-RS001A	1
4	Automated Pallet Handler	KCVM-AJ001	1
5	Dispense Cart	KCVM-DC081A	1
6	Transport Cart	KCVM-FT084A	1
7	Lift Arm	KCVM-LS001A	1
8	Mixer	KCVM-MS001A	1

NOTES	
A	Space shown as a placeholder; needed upon receipt from DS site

CryoVault® CV300

KCVP-PP051S

Premium Bundle - DP Filling Site

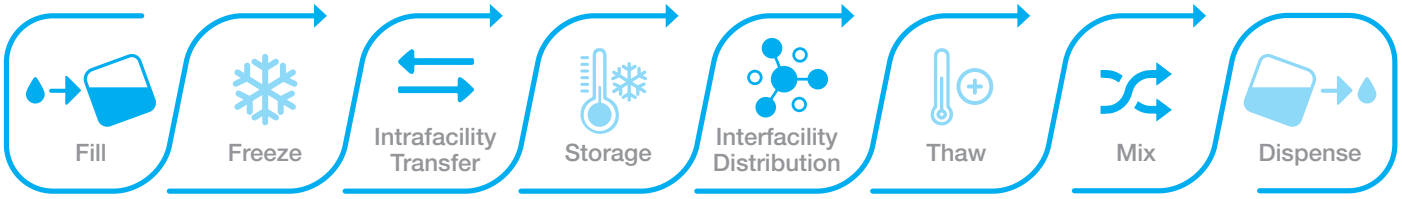


Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY
1	Freeze Thaw Unit; Water Cooled	KCVF-PS15A	2
2	Guide Rails	KCVM-GR500A	2
3	Rocking Platform	KCVM-RS001A	2
4	Automated Pallet Handler	KCVM-AJ001	2
5	Dispense Cart	KCVM-DC081A	2
6	Transport Cart	KCVM-FT084A	2
7	Lift Arm	KCVM-LS001A	2
8	Mixer	KCVM-MS001A	2

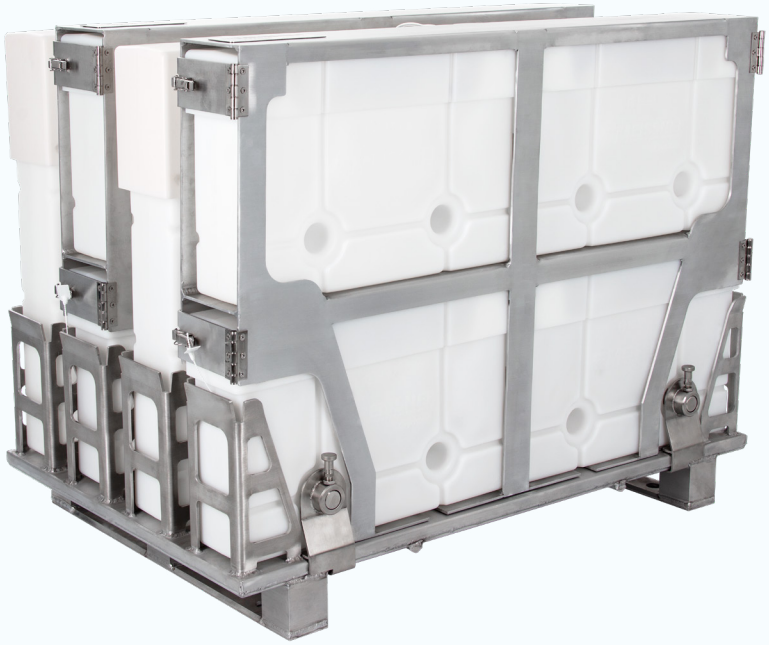
NOTES	
A	Space shown as a placeholder; needed upon receipt from DS site

Scalability
Overview



CryoVault® scales with your BDS needs. The 20 L and 6 L containers are compatible across both the CV300 and CV96 platforms through the use of a pallet adapter. The reduced width of the 6 L container allows for two (2) 6 L containers to fit into the space normally occupied by a single 20 L container.

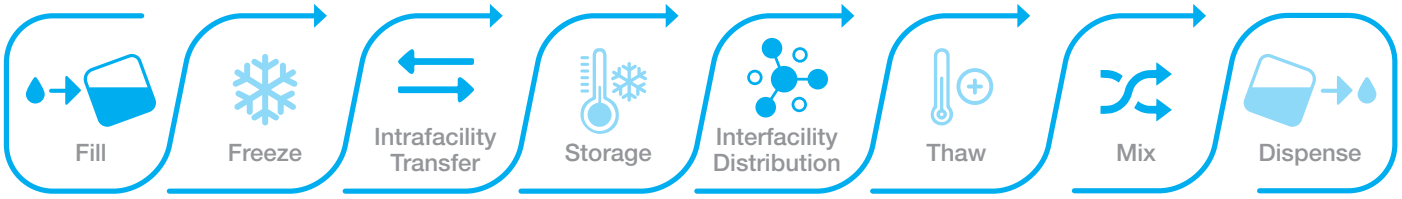
Scalability
Pallet Adapter



The pallet adapter enables the use of a 20 L container with the CV300 Freeze/Thaw unit, mixer and shipper. The pallet adapter can hold four (4) 20 L containers in the same pallet space occupied by one (1) 100 L container. The pallet adapter also allows up to eight (8) 6 L containers to be used in the same pallet space occupied by one (1) 100 L container. The CV300 pallet can accommodate a total of sixteen (16) quantity 20 L containers, or thirty-two (32) quantity 6 L containers with use of four (4) quantity pallet adapters. Container sizes can be varied within the same pallet load.

Meissner Part Number	KCVM-PA064A
Maximum Storage Container Capacity	Four (4) quantity 20 L containers/pallet adapter
	Eight (8) quantity 6 L containers/pallet adapter
Material	Anodized aluminum
Dimensions (D x W x H)	48" x 7" x 32" (121.9 x 17.8 x 81.3 cm)
Weight	31 lb (14.1 kg) unloaded

CV96 Platform
Overview



The CryoVault® CV96 platform provides an E2E solution for F/T operations supporting a volume of approximately 96 L, which is often sufficient for clinical trial batches. This platform is also ideal for enterprises that produce high-tier, low-volume commercial batch sizes. All equipment is available with utilities to cater to specific regional requirements.

Fill

CV96 Platform

Fill/Dispense Accessory

The fill/dispense accessory is a fixture that orients a CryoVault® container to its optimized fill and dispense angles. The 20 L container has a 100° dispense angle, and the 6 L container has a 160° dispense angle. The fill/dispense accessory is compatible with both the dual end-ported biocontainer cart and universal lab stand for individual container fill and dispense operations.

Meissner Part Number	KCVM-DA001B (20 L container)
	KCVM-DA041B (6 L container)
Maximum Storage Container Capacity	One (1) quantity 20 L container; 100° angle
	One (1) quantity 6 L container; 160° angle
Material	304 stainless steel
Dimensions (D x W x H)	14" x 12" x 10.8" (35.6 x 30.5 x 27.4 cm)
Weight	11 lb (5 kg) unloaded

CV96 Platform
Universal Lab Stand

Fill

The universal lab stand is a tabletop fixture that holds a single 20 L container or one (1) 6 L container. The universal lab stand is used in conjunction with the fill/dispense accessory that adjusts manually to reach preset optimum angles for DS fill and dispense.

Meissner Part Number	FAUS-001A
Maximum Storage Container Capacity	One (1) quantity 20 L container
	One (1) quantity 6 L container
Material	304 stainless steel
Dimensions (D x W x H)	19" x 18" x 39" (48.3 x 45.7 x 99.1 cm)
Weight	15.5 lb (7 kg) unloaded

Fill

CV96 Platform

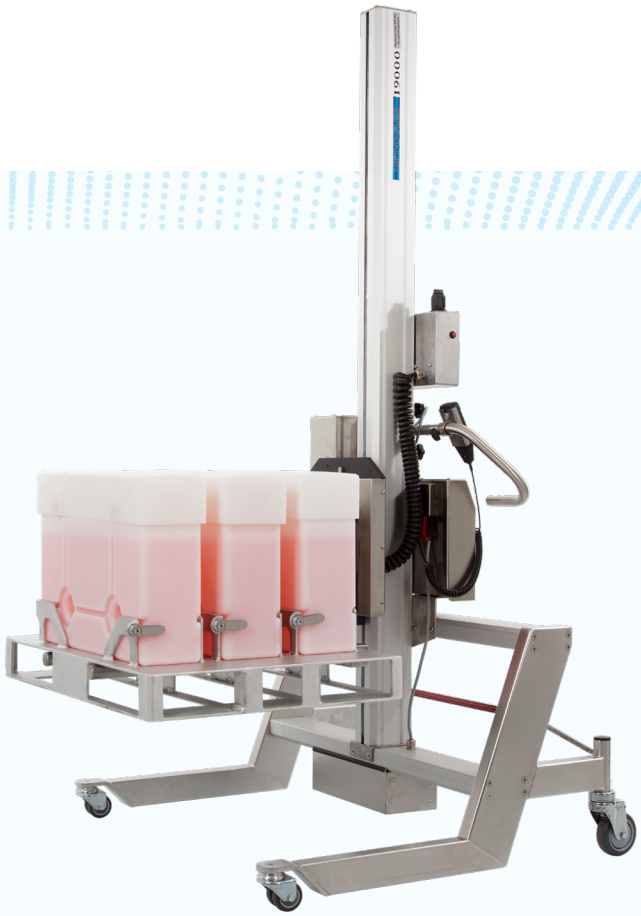
Dual End-Ported Biocontainer Cart

The dual end-ported biocontainer cart (EPBC) provides end-users with the option to fill and dispense 20 L containers and 6 L containers when a tabletop is not available. The cart is used in conjunction with the fill/dispense accessory that adjusts manually to reach the optimum angles for DS fill and dispense. The cart provides mobility for intrafacility transport of a BDS container, if needed.

Meissner Part Number	FABC-020H
Maximum Storage Container Capacity	One (1) quantity 20 L container
	One (1) quantity 6 L container
Material	304 stainless steel
Dimensions (D x W x H)	22" x 28.5" x 48-72" (55.9 x 72.4 x 121.9-182.9 cm)
Weight	45 lb (20.4 kg) unloaded
Casters	Four (4) swivel

CV96 Platform
Automated Lift/Mixer

Intrafacility Transfer



The automated lift/mix provides versatility in handling 20 L containers, 6 L containers, and the CV96 pallets. Fixed arms (part no. KCVM-AJPA01) are designed to interface with the containers counter bores for secure fill/dispense angle rotation, while the fixed flat forks (part no. KCVM-AJPA03) integrate well with the CV96 pallets, for loading/unloading. The optimal dispense angle for the 20 L container is 100° while the optimal dispense angle for the 6 L container is 160°.

Meissner Part Number: Lift/Mix	U.S.: 20 L container: KCVM-AJ500B; 6 L container: KCVM-AJ400B
	Europe: 20 L container: KCVM-AJ550B; 6 L container: KCVM-AJ450B
Meissner Part Number: Fork Options (See description in inset above.)	Fixed Fork Arms: KCVM-AJPA01
	Fixed Flat Fork Arms: KCVM-AJPA03
Maximum Storage Container Capacity	Three (3) quantity 20 L containers; 100° angle
	Six (6) quantity 6 L containers; 160° angle
Material	304 stainless steel
Dimensions (D x W x H)	40.4" x 45.6" x 76.7" (102.6 x 115.8 x 194.8 cm)
Weight	170 lb (77 kg) unloaded
Maximum Load Weight	200 lb (91 kg)
Casters	Four (4) swivel
Battery Voltage	24 V (Type: lead gel cell)
Recharge Time	6-8 hours
Utilities Required	120 V | 1 Ø | 50-60 Hz
Certification Mark (CE)	Yes

Fill

CV96 Platform
Load Cell Cart

The load cell cart holds one CV96 pallet and displays a dynamic weight reading during filling of the 20 L containers or the 6 L containers.

Meissner Part Number	FSCS02B-LC
Maximum Storage Container Capacity	One (1) CV96 pallet
	Three (3) quantity 20 L containers
	Six (6) quantity 6 L containers
Material	304 stainless steel
Dimensions (D x W x H)	24" x 32" x 33.7" (61 x 81.3 x 85.7 cm)
Weight	132.9 lb (60.3 kg) unloaded
Maximum Load Weight	496 lb (225 kg)
Casters	Four (4) swivel
Utilities Required	120 V |1 Ø | 50-60 Hz

CV96 Platform
Intrafacility Cart

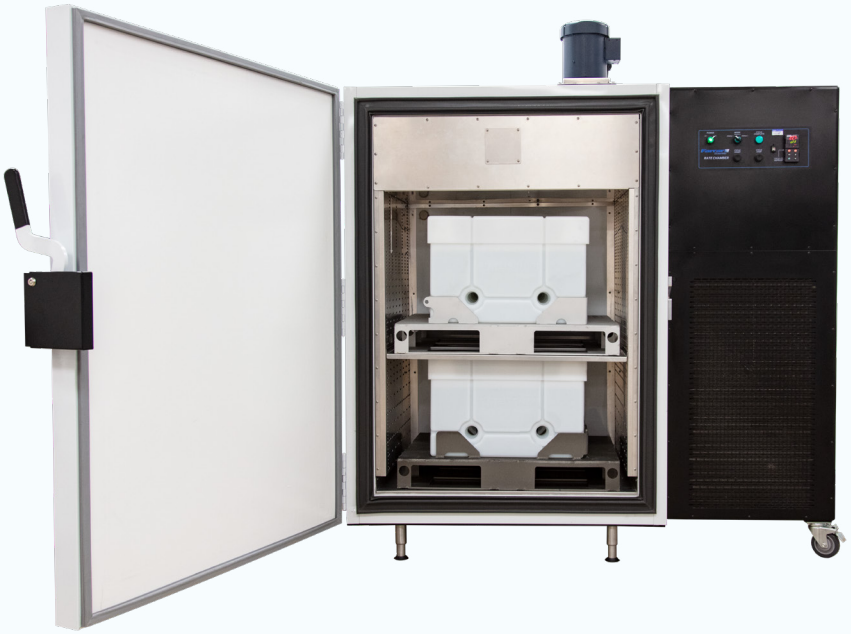
Intrafacility Transfer

The intrafacility cart is compatible with CV96 pallets and is used to transition containers in areas where large material handling equipment may not be appropriate.

Meissner Part Number	FSCS02B
Maximum Storage Container Capacity	Three (3) quantity 20 L containers
	Six (6) quantity 6 L containers
Material	304 stainless steel
Dimensions (D x W x H)	24" x 32" x 9.5" (61 x 81.3 x 24.1 cm)
Weight	54 lb (24.5 kg) unloaded
Casters	Four (4) swivel

Freeze

CV96 Platform
Freeze/Thaw Unit



The Freeze/Thaw unit holds two (2) CV96 pallets that, when combined, contain up to a nominal 96 L that is distributed over six (6) 20 L containers, each with a nominal fill of 16 L. Up to twelve (12) 6 L containers can be frozen, alternatively, as well. The Freeze/Thaw unit's microprocessor controls the F/T cycles through temperature and time set-points.

The automated lift facilitates the loading and unloading of the Freeze/Thaw unit (see page 34).

Meissner Part Number	U.S. Air-cooled: KCVF-CS003A; Water-cooled: KCVF-CS103A
	Europe Air-cooled: KCVF-CS053A; Water-cooled: KCVF-CS153A
Serial No. (Farrar)	5,000 Series (Please note: 4,000 series is shown in photos.)
Maximum Storage Container Capacity	Six (6) quantity 20 L containers
	Twelve (12) quantity 6 L containers
Maximum Volume Capacity	96 L total (utilizing [6] quantity 20 L containers)
	60 L Total (utilizing twelve [12] quantity 6 L containers)
Temperature Range	+40 °C to -80 °C
External Dimensions (D x W x H)	33.3" x 68.7" x 77" (84.6 x 174.5 x 195.6 cm)
Internal Dimensions (D x W x H)	24.8" x 33.8" 42.7" (63 x 85.9 x 108.5 cm)

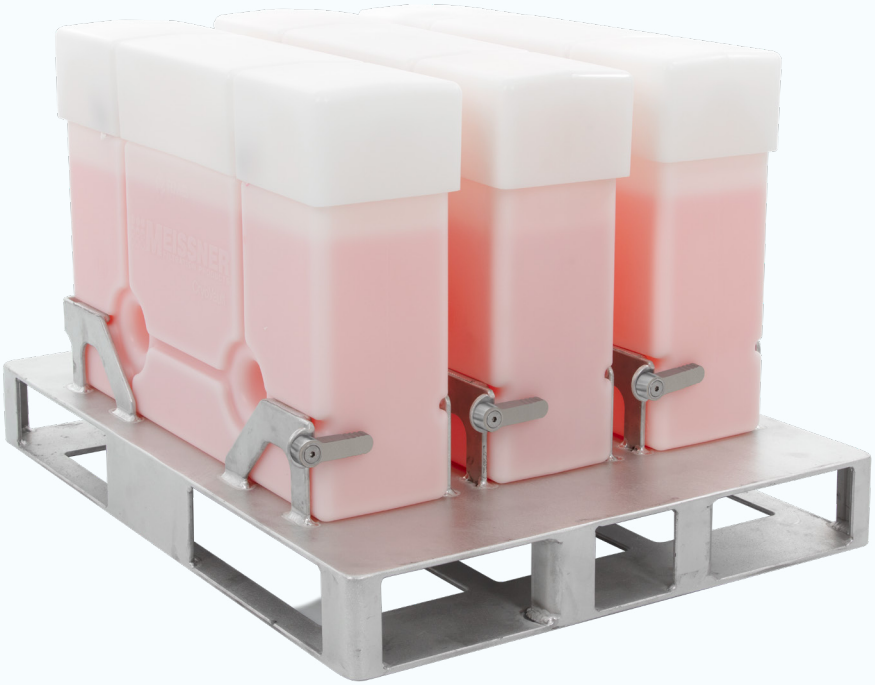
Freeze/Thaw Unit continued on next page

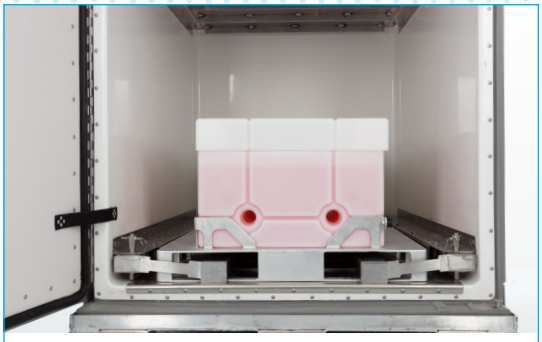
(continued)

Material	External: Powder coated, galvanized steel, painted beige
	Internal: All stainless steel
Chamber Volume	20.4 ft^3 (577.7 L)
Weight	995 lb (451.3 kg)
Door Size (W x H)	44.1" x 61" (112 x 155 cm)
Refrigeration	Cascade; two (2) scroll compressors
Refrigeration Type (High; Low)	R404A; R508B
Utilities Required	U.S.: 208-240 V | 3 Ø | 60 Hz, 26 FLA
	Europe: 400 V | 3 Ø | 50 Hz, 24 FLA
Control System	Hardware: Watlow PM-8 Microprocessor; UL Certified Controls
Thermal Room Load	Air-cooled: 38,000 BTU/hr; Water-cooled: 1,000 BTU/hr
Water Cooling Requirements	Tower Water 29.5 °C, 1.4 bar: Water flow rate at maximum load: 26.5 L/min Water flow rate average load: 15 L/min
	Chilled Water 7.2 °C, 1.4 bar: Water flow rate at maximum load: 5.7 L/min Water flow rate average load: 3.8 L/min
Certification Mark (CE)	Yes

CV96 Platform

CV96 Pallet





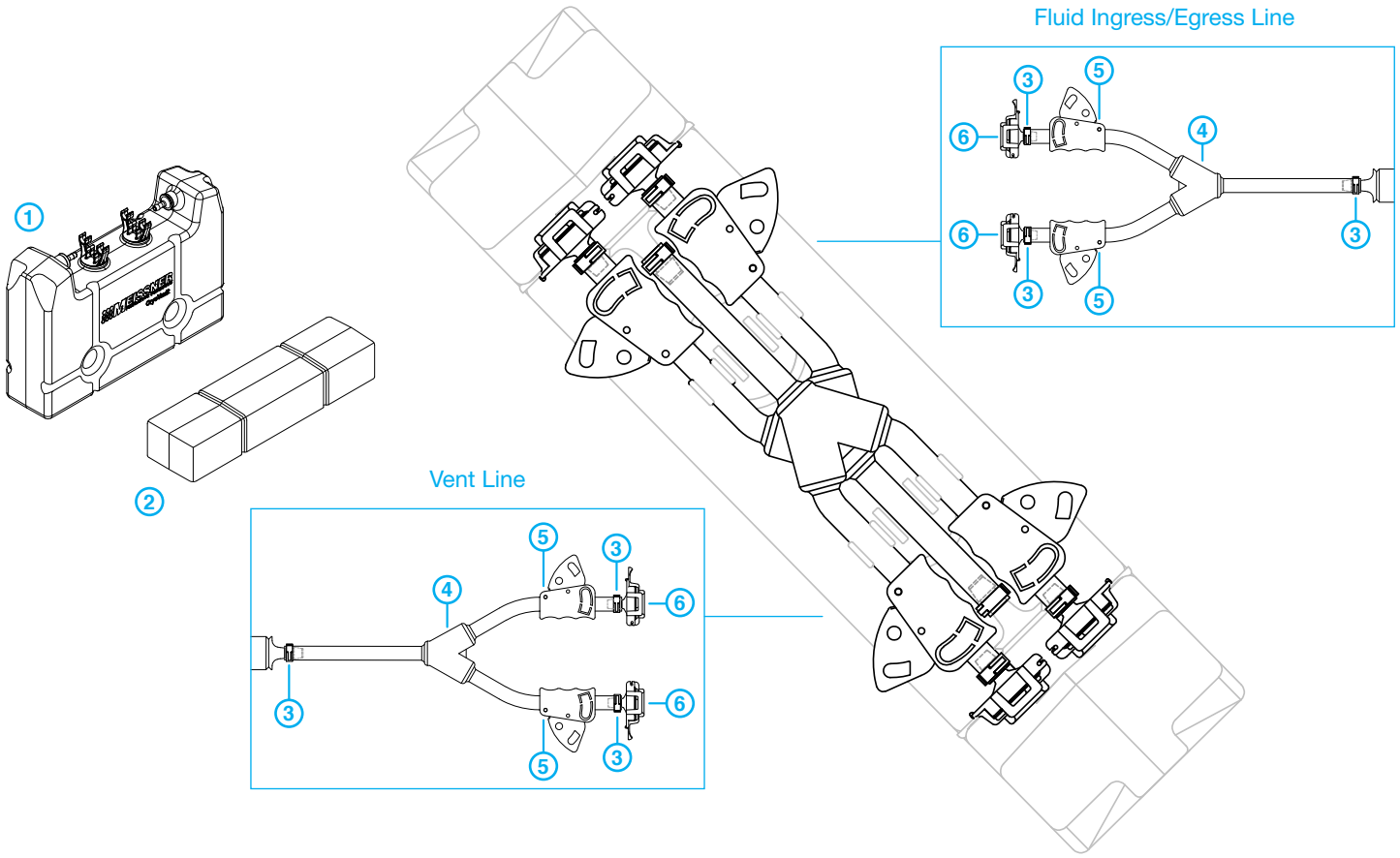
The CV96 pallet holds up to three (3) 20 L containers or up to six (6) 6 L containers. The CV96 pallets are made of lightweight anodized aluminum. Two (2) CV96 pallets fit in to the Freeze/Thaw unit for the CV96 platform. The CV96 pallet has a latch to secure each of the 20 L storage containers in place during transportation.

Meissner Part Number	KCVM-PS063B
Maximum Storage Container Capacity	Three (3) quantity 20 L containers
	Six (6) quantity 6 L containers
Material	Anodized aluminum
CV96 Dimensions (D x W x H)	24" x 32" x 7.4" (61 x 81.3 x 18.8 cm)
Weight	37 lb (16.8 kg) unloaded

CV96 Platform

20 L BDS Container with Platinum-Cured Silicone Tubing

Storage



Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	20 L Container - 2 x ⅜" HB	91R71C67	1	HDPE
2	20 L Shroud	91R71S60	1	HDPE
3	Band Clamp, 17.0 mm	92L96T53	6	Stainless Steel
4	⅜" x ⅝" Overmolded Y-Junction	91T11N57	2	Platinum Silicone
5	Pure-Fit® Clamp, Large	91L00P80	4	Polypropylene
6	Aseptic Connector, ⅜" HB, AseptiQuik® G	91S33N50	4	Polycarbonate
7	Tamper Evident Re-closable Poly-bag (not pictured)	7620-04	4	Polyethylene
8	Cable Tie, Small (not pictured)	92M93C12	4	Nylon
9	Outer Packaging, Poly-Bag (not pictured)	7600-24	2	Polyethylene

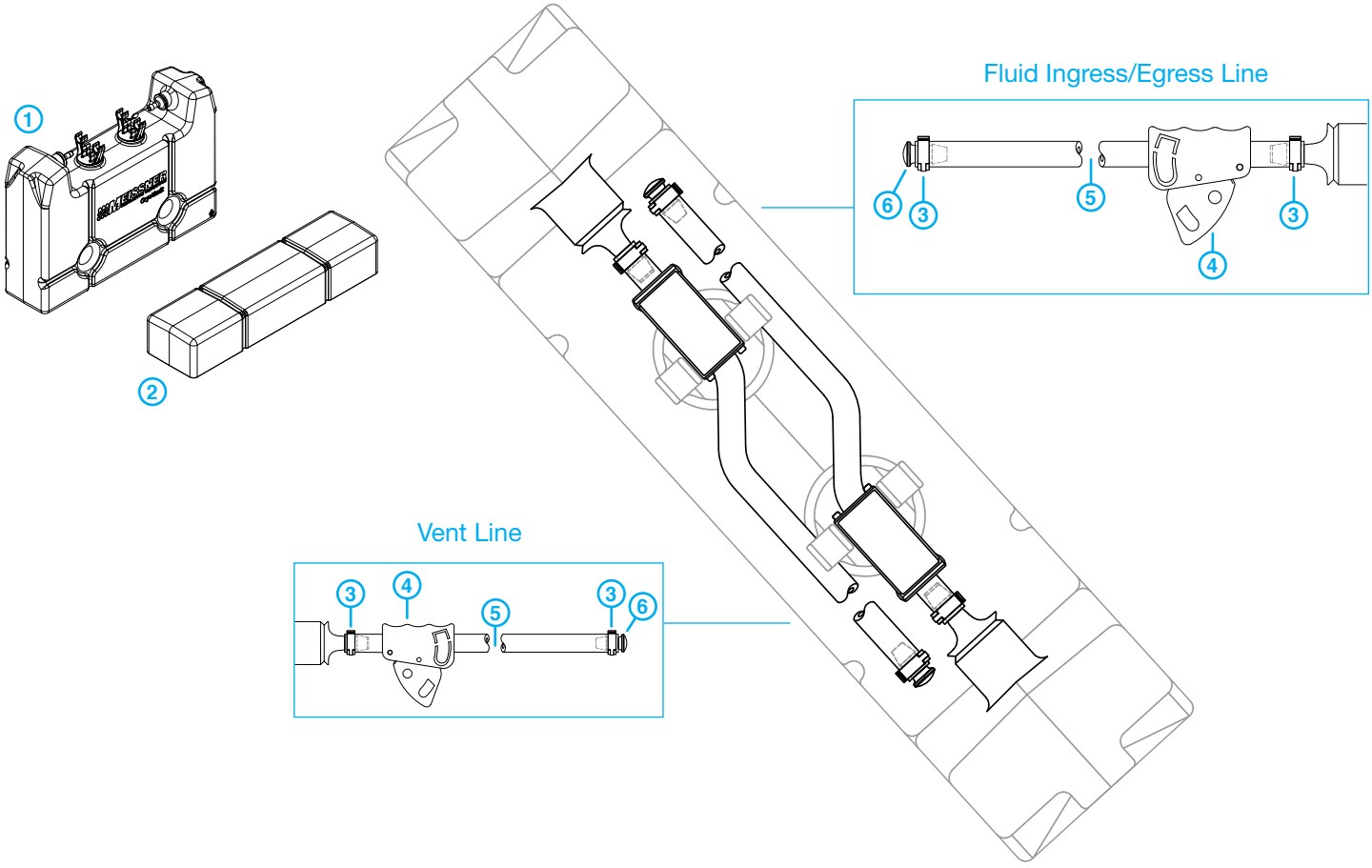
Standards Part No.

Part Number	Material	Container Volume	Maximum Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC2706H-N00-B9060-01	HDPE	20 L	16 L	22.9" x 5.9" x 15.2"	9.9 lb
				58.2 x 15.0 x 38.6 cm	4.5 kg

Storage

CV96 Platform

20 L BDS Container with M-Flex® TPE Tubing



Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	20 L Container - 2 x ⅜" HB	91R71C67	1	HDPE
2	20 L Shroud	91R71S60	1	HDPE
3	Band Clamp, 18.5 mm	92L96T24	4	Stainless Steel
4	Pure-Fit® Clamp, Large	91L00P80	2	Polypropylene
5	⅜" x ⅝" M-Flex® Tubing, 24" Length	91T47G57-24	2	M-Flex™ TPE
6	⅜" HB Plug	91H02P50	2	Polypropylene
7	Outer Packaging, Poly-Bag (not pictured)	7600-24	2	Polyethylene

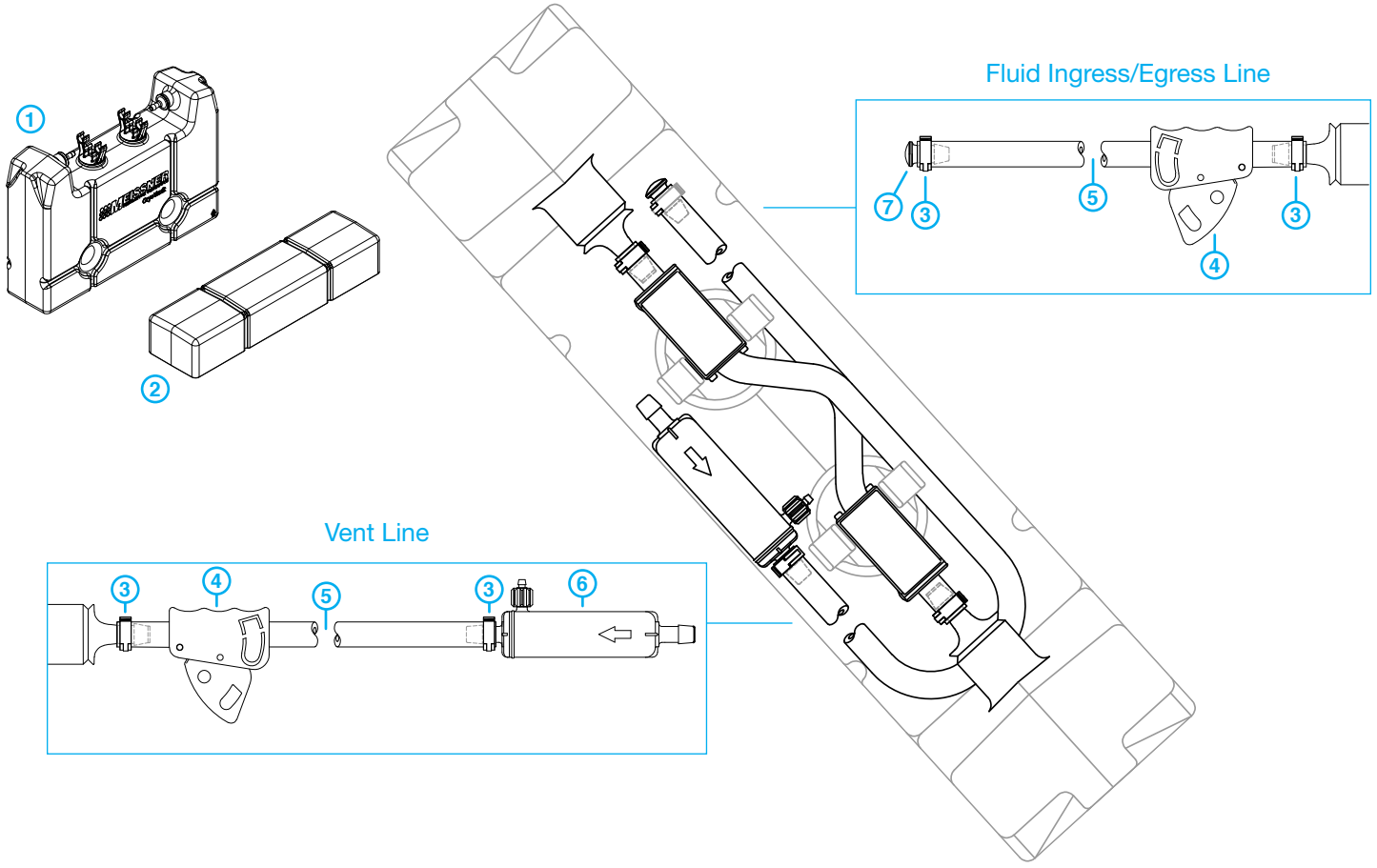
Standards Part No.

Part Number	Material	Container Volume	Maximum Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC2706H-N00-C0600-01	HDPE	20 L	16 L	22.9" x 5.9" x 15.2"	9.9 lb
				58.2 x 15.0 x 38.6 cm	4.5 kg

CV96 Platform

20 L BDS Container with M-Flex®
TPE Tubing with capsule vent filter

Storage



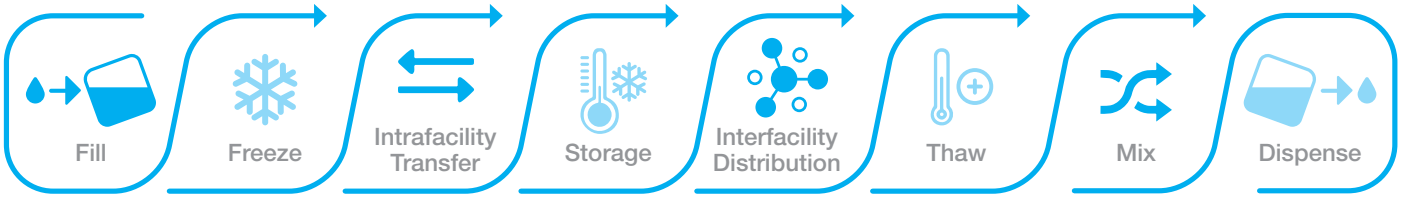
Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	20 L Container - 2 x ⅜" HB	91R71C67	1	HDPE
2	20 L Shroud	91R71S60	1	HDPE
3	Band Clamp, 18.5 mm	92L96T24	4	Stainless Steel
4	Pure-Fit® Clamp, Large	91L00P80	2	Polypropylene
5	⅜" x ⅝" M-Flex™ Tubing, 24" Length	91T47G57-24	2	M-Flex™ TPE
6	Meissner Capsule Filter	CM2VTV0.2-226	1	PP/Steridyne®
7	⅜" HB Plug	91H02P50	1	Polypropylene
8	Outer Packaging, Poly-Bag (not pictured)	7600-24	2	Polyethylene

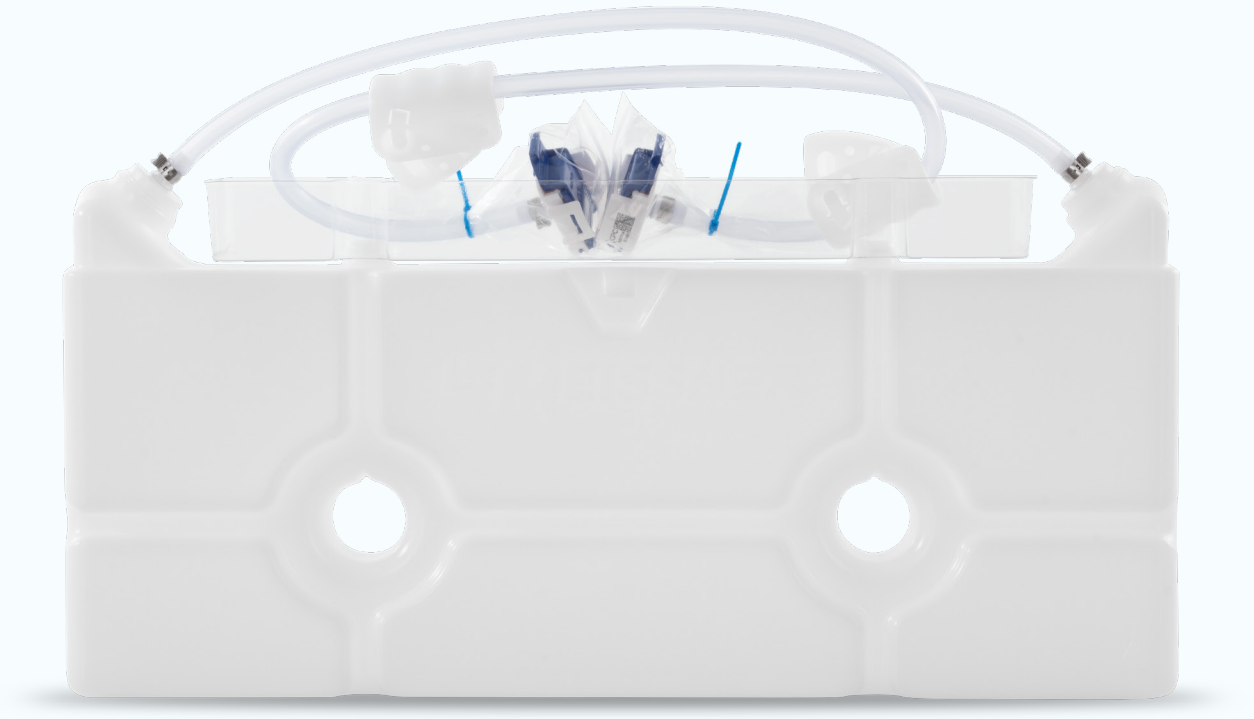
Standards Part No.

Part Number	Material	Container Volume	Maximum Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC2706H-VV2-C0600-01	HDPE	20 L	16 L	22.9" x 5.9" x 15.2"	9.9 lb
				58.2 x 15.0 x 38.6 cm	4.5 kg

CV96 Platform
6 L BDS Container Overview



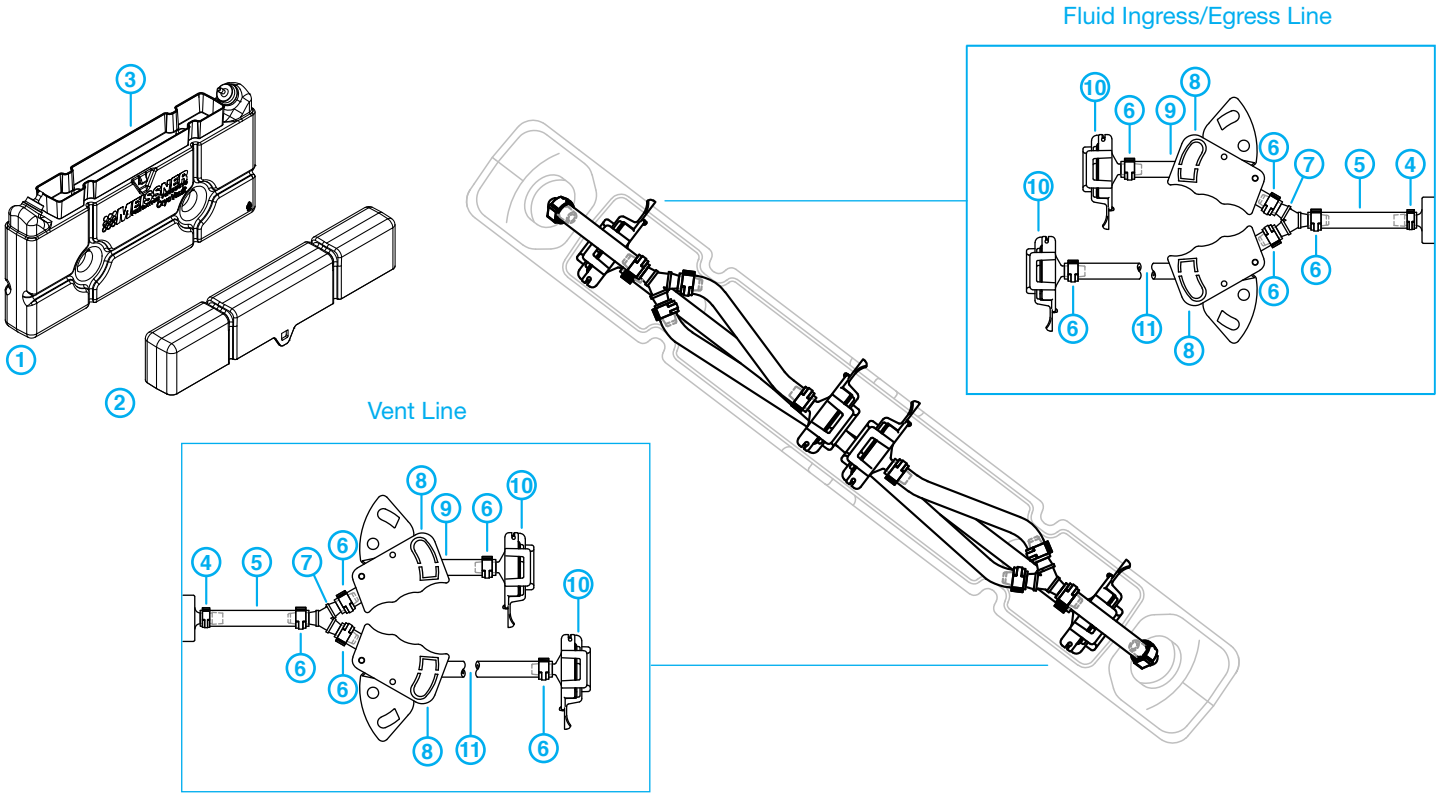
The 6 L container was designed to handle smaller process volumes, while preserving the same operational benefits of the larger containers in the portfolio. Two (2) 6 L BDS containers fit the pallet space occupied by one (1) 20 L container. The fill/dispense accessory is also compatible with the 6 L container. Similar to the larger container sizes, the top works are customizable.



CV96 Platform

6 L BDS Container with Platinum-Cured Silicone Tubing

Storage



Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	6 L Container - 2 x ¼" HB	91R71C45	1	HDPE
2	6 L Shroud	91R71S40	1	HDPE
3	6 L Support Tray	92R97L00	1	PETG
4	Band Clamp, 10.9 mm	92L96T04	2	Stainless Steel
5	¼" x 7/16" Tubing, 3" Length	91T11G34-3	2	Platinum Silicone
6	Band Clamp, 12.3 mm	92L96T13	10	Stainless Steel
7	¼" HB Y-Fitting	91H02Y44	2	Polypropylene
8	Pure-Fit® Clamp, Large	91L00P80	4	Polypropylene
9	¼" x 7/16" Tubing, 13" Length	91T11G34-5	2	Platinum Silicone
10	Aseptic Connector, ¼" HB, AseptiQuik® G	91S33N40	4	Polycarbonate
11	¼" x 7/16" Tubing, 13" Length	91T11G34-13	2	Platinum Silicone
12	Tamper Evident Re-closable Poly-Bag (not pictured)	7620-04	4	Polyethylene
13	Cable Tie, Small (not pictured)	92M93C12	4	Nylon
14	Outer Packaging, Poly-Bag (not pictured)	7600-24	2	Polyethylene

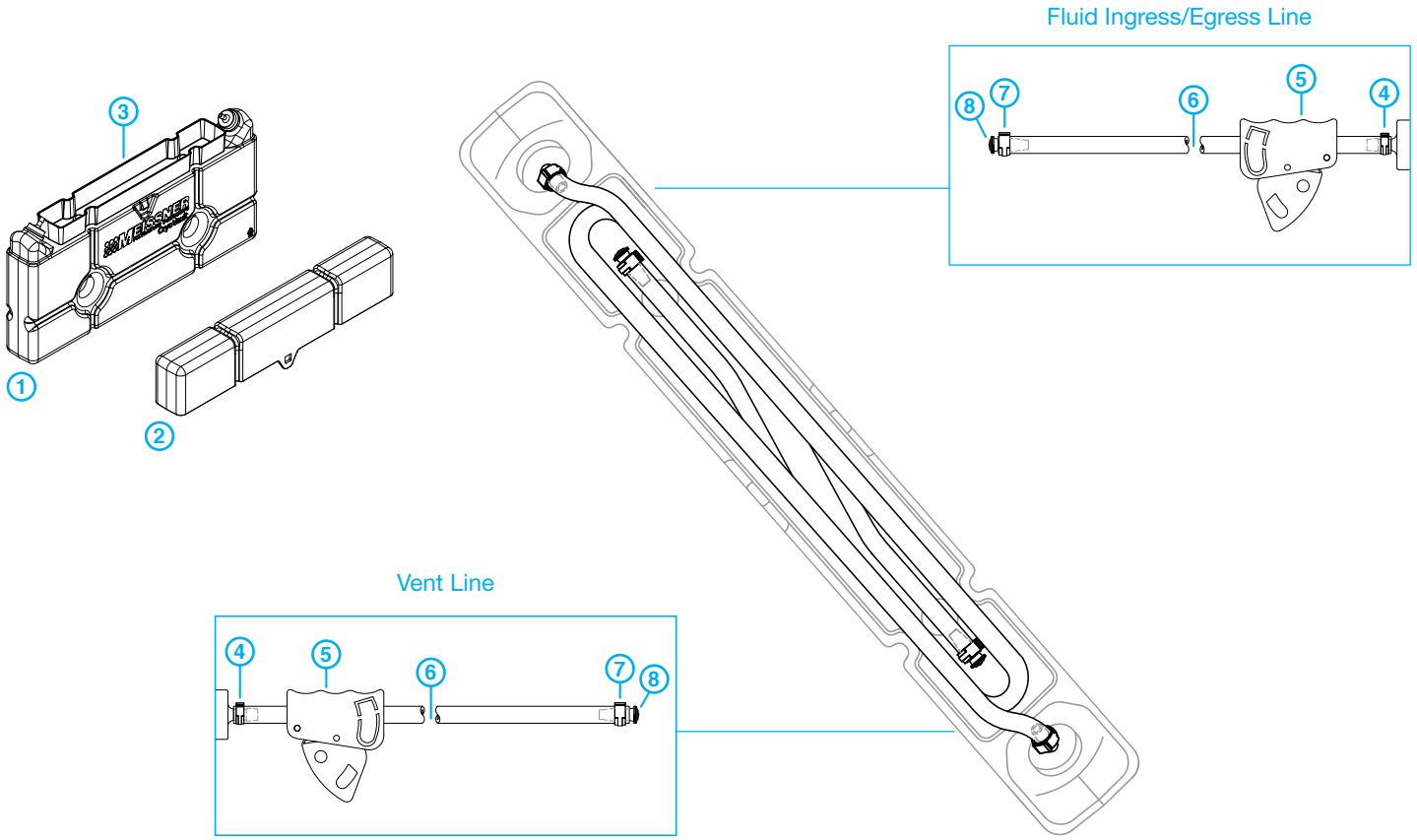
Standards Part No.

Part Number	Material	Container Volume	Maximum Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC2704H-N00-B9060-01	HDPE	6 L	5 L	22.4" x 2.9" x 12.6"	4.5 lb
				56.9 x 7.4 x 32.0 cm	2 kg

Storage

CV96 Platform

6 L BDS Container with M-Flex® TPE Tubing



Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	6 L Container - 2 x ¼" HB	91R71C45	1	HDPE
2	6 L Shroud	91R71S40	1	HDPE
3	6 L Support Tray	92R97L00	1	PETG
4	Band Clamp, 13.3 mm	92L96T15	2	Stainless Steel
5	Pure-Fit® Clamp, Large	91L00P80	2	Polypropylene
6	¼" x $^{7}/_{16}$" M-Flex® Tubing, 24" Length	91T47G34-24	2	M-Flex® TPE
7	Band Clamp, 12.3 mm	92L96T13	2	Stainless Steel
8	¼" HB Plug	91H02P40	2	Polypropylene
9	Outer Packaging, Poly-Bag (not pictured)	7600-16	2	Polyethylene

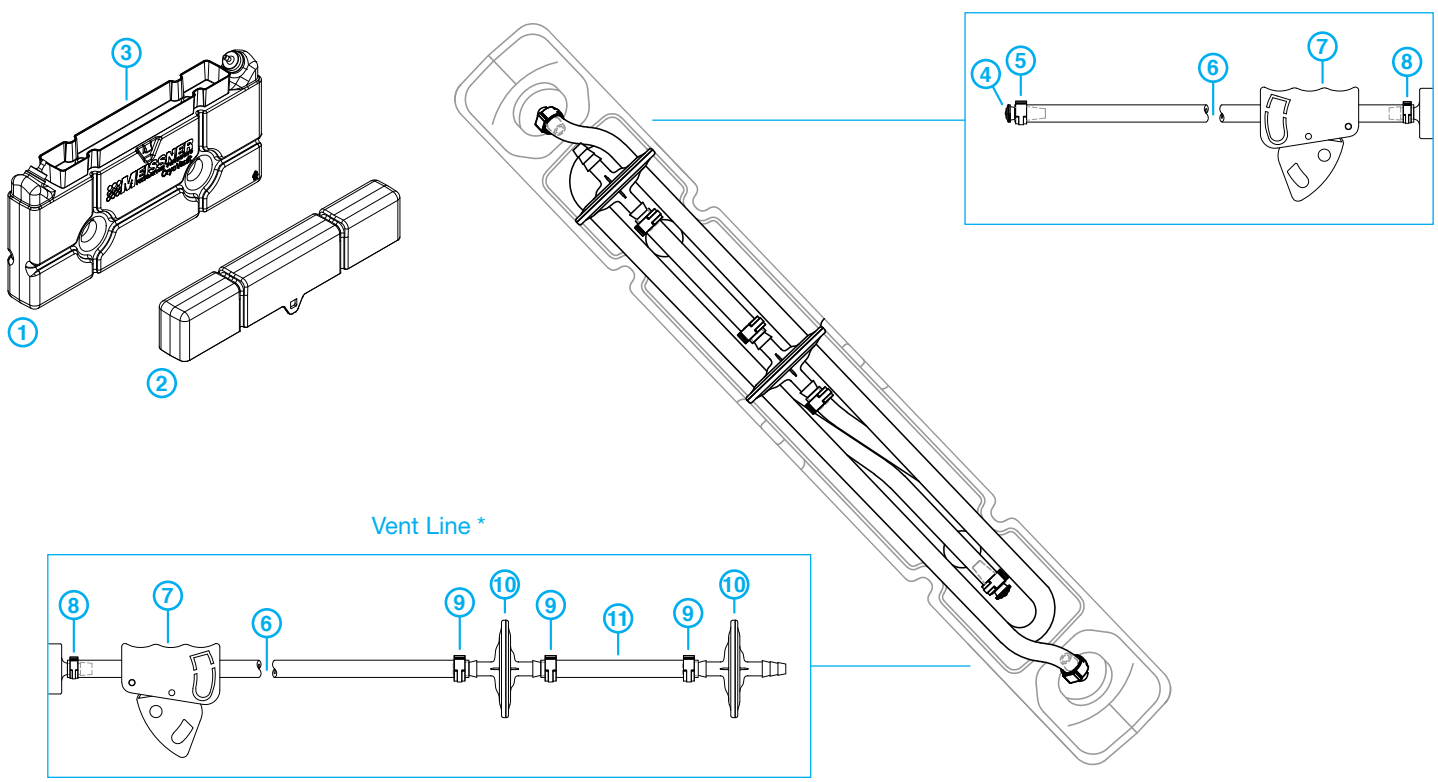
Standards Part No.

Part Number	Material	Container Volume	Maximum Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC2704H-N00-C0600-01	HDPE	6 L	5 L	22.4" x 2.9" x 12.6"	4.5 lb
				56.9 x 7.4 x 32.0 cm	2 kg

CV96 Platform

6 L BDS Container with M-Flex® TPE Tubing with vent filters

Storage



Bill of Materials

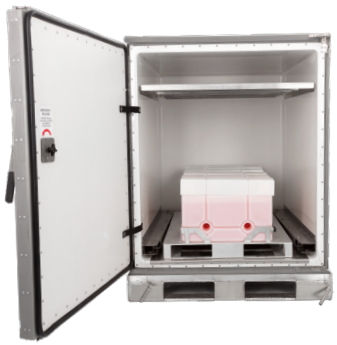
ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	6 L Container - 2 x ¼" HB	91R71C45	1	HDPE
2	6 L Shroud	91R71S40	1	HDPE
3	6 L Support Tray	92R97L00	1	PETG
4	¼" HB Plug	91H02P40	1	Polypropylene
5	Band Clamp, 12.3 mm	92L96T13	1	Stainless Steel
6	¼" x 7/16" M-Flex® Tubing, 24" Length	91T47G34-24	2	M-Flex® TPE
7	Pure-Fit® Clamp, Large	91L00P80	2	Polypropylene
8	Band Clamp, 13.3 mm	92L96T15	2	Stainless Steel
9	Band Clamp, 14.5 mm	92L96T21	3	Stainless Steel
10	Meissner 50 mm Vent Filters *50 mm vent filters must be removed during freeze/thaw operations.	CB2VTV0.2-330	2	PP/Steridyne®
11	¼" x 7/16" Pharma-50 Tubing, 4" Length	91T11G34-4	1	Platinum Silicone
12	Outer Packaging, Poly-Bag (not pictured)	7600-16	2	Polyethylene

Standards Part No.

Part Number	Material	Container Volume	Maximum Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC2704H-VV2-C0600-01	HDPE	6 L	5 L	22.4" x 2.9" x 12.6"	4.5 lb
				56.9 x 7.4 x 32.0 cm	2 kg

CV96 Platform
Shipping Container

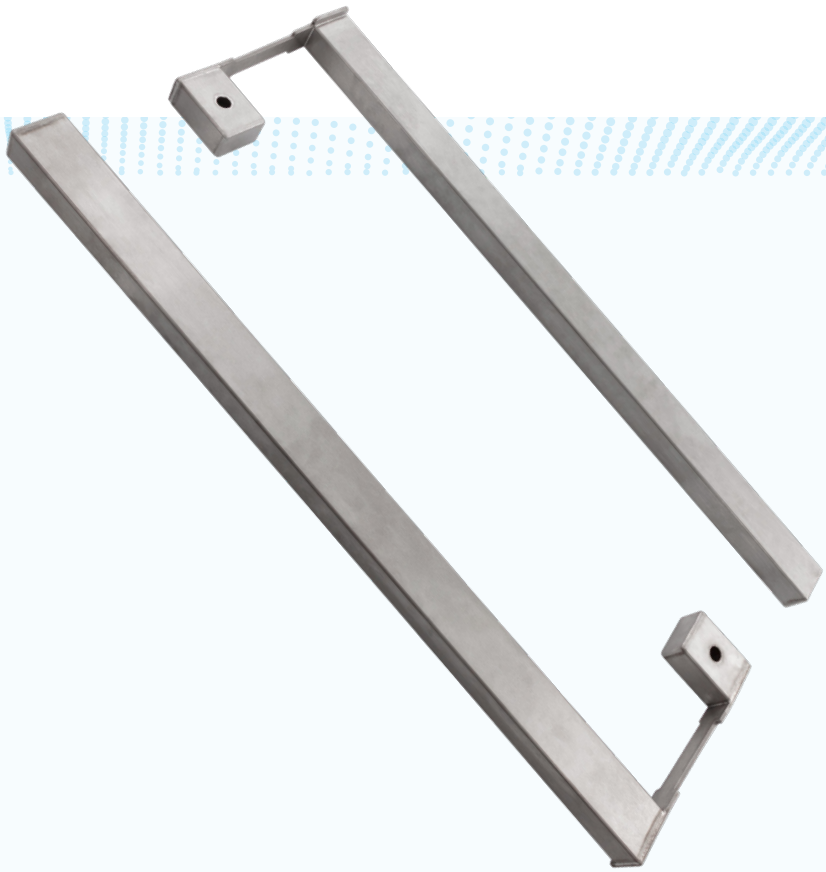
Interfacility Distribution



The shipper can hold 200 kg of dry ice to maintain the internal temperature at or below -40 °C for an estimated 100 hours. The shipper accommodates up to sixteen (16) 20 L containers or thirty two (32) 6 L containers with the use of the shipping pallet adapter (see page 28). The shipper is qualified in accordance with ASTM D4169 and ISTA 3E standards.

Meissner Part Number	KCVS-AS300P
Material	MDPE insulated with CFC
External Dimensions (D x W x H)	60.7" x 47.8" x 61.5" (154.3 x 121.3 x 156.2 cm)
Internal Dimensions (D x W x H)	54" x 40.7" x 40.1" (137.2 x 103.5 x 101.9 cm)
Weight	619.9 lb (281.2 kg) unloaded
Capacity	One (1) quantity loaded CV300 pallet
Shipper Compliance	ASTM D4169, ISTA 3E
Clearance (door)	53.9" (137 cm)
Temperature Control	Passive cooling with dry ice (up to 200 kg)
Storage Duration	100 hours

CV96 Platform
Shipping Pallet Adapter

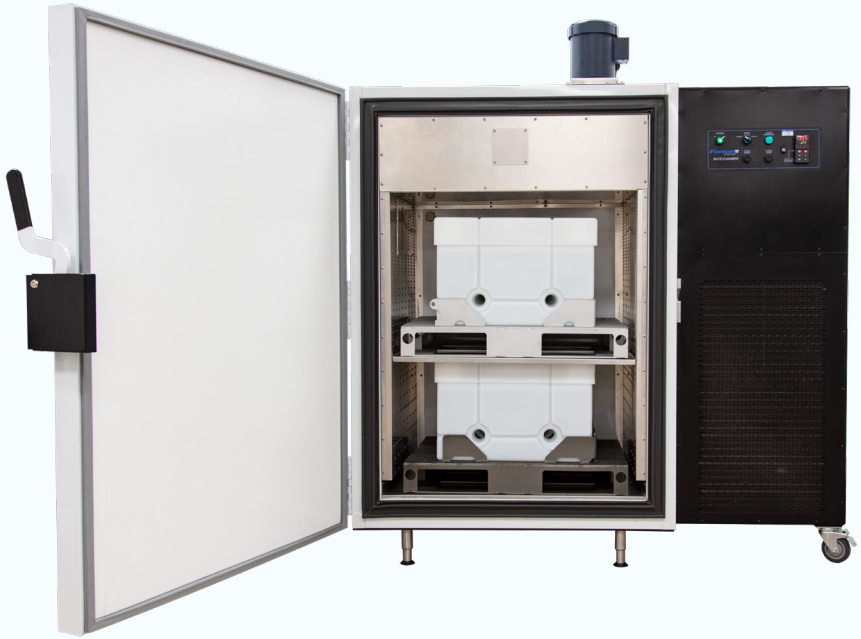


A shipping pallet adapter will allow two (2) CV96 pallets collectively holding six (6) 20 L containers, or twelve (12) 6 L containers to fit into the same shipper used for the interfacility transfer of 100 L containers.

Meissner Part Number	KCVM-PA100A
Material	304 stainless steel
Dimensions (D x W x H)	46.8" x 13" x 3.2" (118.9 x 33 x 8.1 cm)
Weight	33 lb (15 kg) unloaded

CV96 Platform
Freeze/Thaw Unit

Thaw



The Freeze/Thaw unit holds two (2) EUR 6 pallets that, when combined, contain up to a nominal 96 L of DS that is distributed over six (6) 20 L containers. Up to twelve (12) 6 L containers can also be thawed as well.

Meissner Part Number	U.S. Air-cooled: KCVF-CS003A; Water-cooled: KCVF-CS103A
	Europe Air-cooled: KCVF-CS053A; Water-cooled: KCVF-CS153A
Serial No. (Farrar)	5,000,000 Series (Please note: 4,000,000 series is shown in photos.)
Maximum Storage Container Capacity	Six (6) quantity 20 L containers
	Twelve (12) quantity 6 L containers
Maximum Volume Capacity	96 L total (utilizing six [6] quantity 20 L containers)
	60 L total (utilizing twelve [12] quantity 6 L containers)
Temperature Range	+40 °C to -80 °C
External Dimensions (D x W x H)	33.3" x 68.7" x 77" (84.6 x 174.5 x 195.6 cm)
Internal Dimensions (D x W x H)	24.8" x 33.8" 42.7" (63 x 85.9 x 108.5 cm)
Material	External: Powder coated, galvanized steel, painted beige
	Internal: All stainless steel

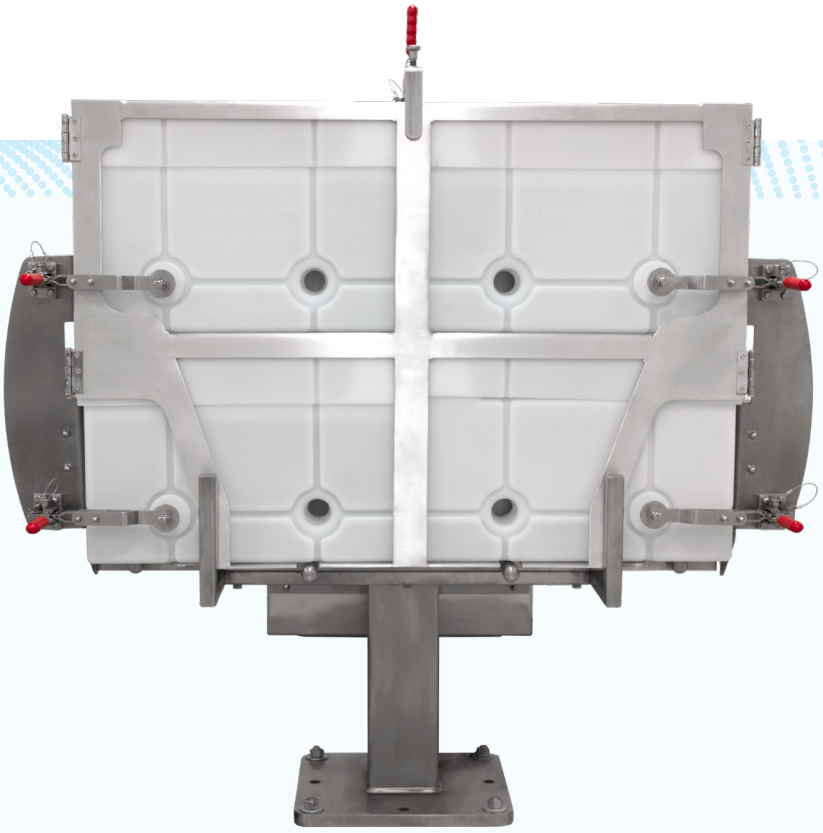
Freeze/Thaw Unit continued on next page

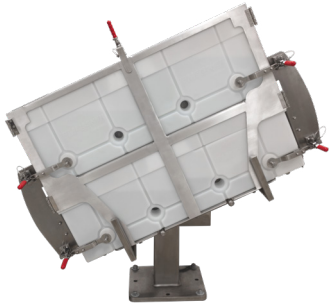
(continued)

Chamber Volume	20.4 ft³ (577.7 L)
Weight	995 lb (451.3 kg)
Door Size (W x H)	44.1" x 61" (112 x 155 cm)
Refrigeration	Cascade; two (2) scroll compressors
Refrigeration Type (High; Low)	R404A; R508B
Control System	Hardware: Watlow PM-8 Microprocessor; UL Certified Controls
Utilities Required	U.S.: 208-240 V | 3 Ø | 60 Hz, 26 FLA
	Europe: 400 V | 3 Ø | 50 Hz, 24 FLA
Thermal Room Load	Air-cooled: 38,000 BTU/hr; Water-cooled: 1,000 BTU/hr
Water Cooling Requirements	Tower Water 29.5 °C, 1.4 bar: Water flow rate at maximum load: 26.5 L/min Water flow rate average load: 15 L/min
	Chilled Water 7.2 °C, 1.4 bar: Water flow rate at maximum load: 5.7 L/min Water flow rate average load: 3.8 L/min
Certification Mark (CE)	Yes

Mix

CV96 Platform
Mixer





The mixer homogenizes the thawed DS and holds four (4) 20 L containers or eight (8) 6 L containers with the pallet adapter (see page 28). The mixer is fully PLC controlled to set mixing time, rock angle, and cycle rate for repeatable operations.

Meissner Part Number	KCVM-MS001A
Maximum Storage Container Capacity	Four (4) quantity 20 L containers
	Eight (8) quantity 6 L containers
Material	304 stainless steel
Dimensions (D x W x H)	48.5" x 63.1" x 63" (123.2 x 160.3 x 160 cm)
Base Dimensions (L x W)	18" x 18" (45.7 x 45.7 cm)
Weight	2,833 lb (1,285 kg) unloaded
Maximum Load Weight	220 lb (100 kg)
Utilities Required	120 V | 1 Ø | 50-60 Hz
Certification Mark (CE)	Yes

CV96 Platform
Automated Lift/Mixer

Dispense

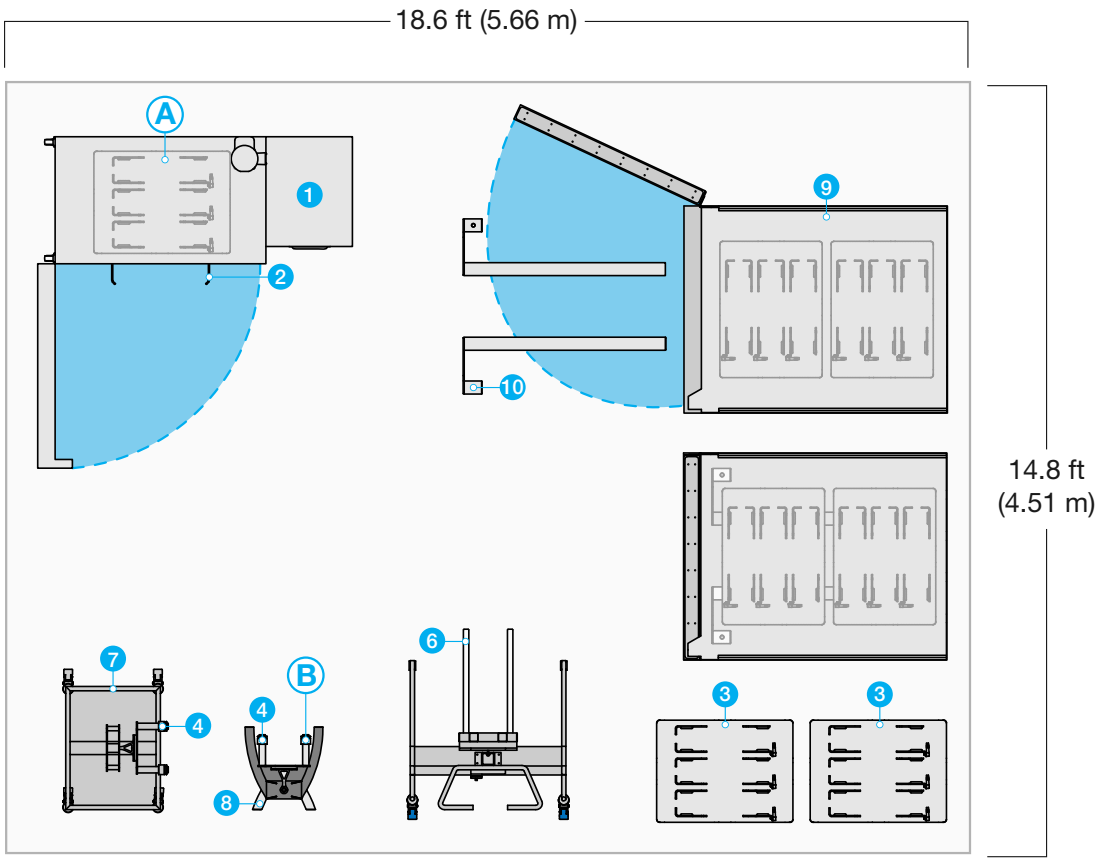
The automated lift/mix provides versatility in handling 20 L containers, 6 L containers, and the CV96 pallets. The optimal dispense angle for the 20 L container is 100° while the optimal dispense angle for the 6 L container is 160°.

Meissner Part Number	U.S.: 20 L container: KCVM-AJ500B; 6 L container: KCVM-AJ400B
	Europe: 20 L container: KCVM-AJ550B; 6 L container: KCVM-AJ450B
Maximum Storage Container Capacity	Three (3) quantity 20 L containers; 100° angle
	Six (6) quantity 6 L containers; 160° angle
Material	304 stainless steel
Dimensions (D x W x H)	40.4" x 45.6" x 76.7" (102.6 x 115.8 x 194.8 cm)
Weight	240.1 lb (108.9 kg) unloaded
Maximum Load Weight	200 lb (91 kg)
Casters	Four (4) swivel
Battery Voltage	24 V (Type: lead gel cell)
Recharge Time	6-8 hours
Utilities Required	120 V | 1 Ø | 50-60 Hz
Certification Mark (CE)	Yes

CryoVault® CV96

KCVP-CS001S

Standard Bundle - DS Manufacturing Site



Bill of Materials

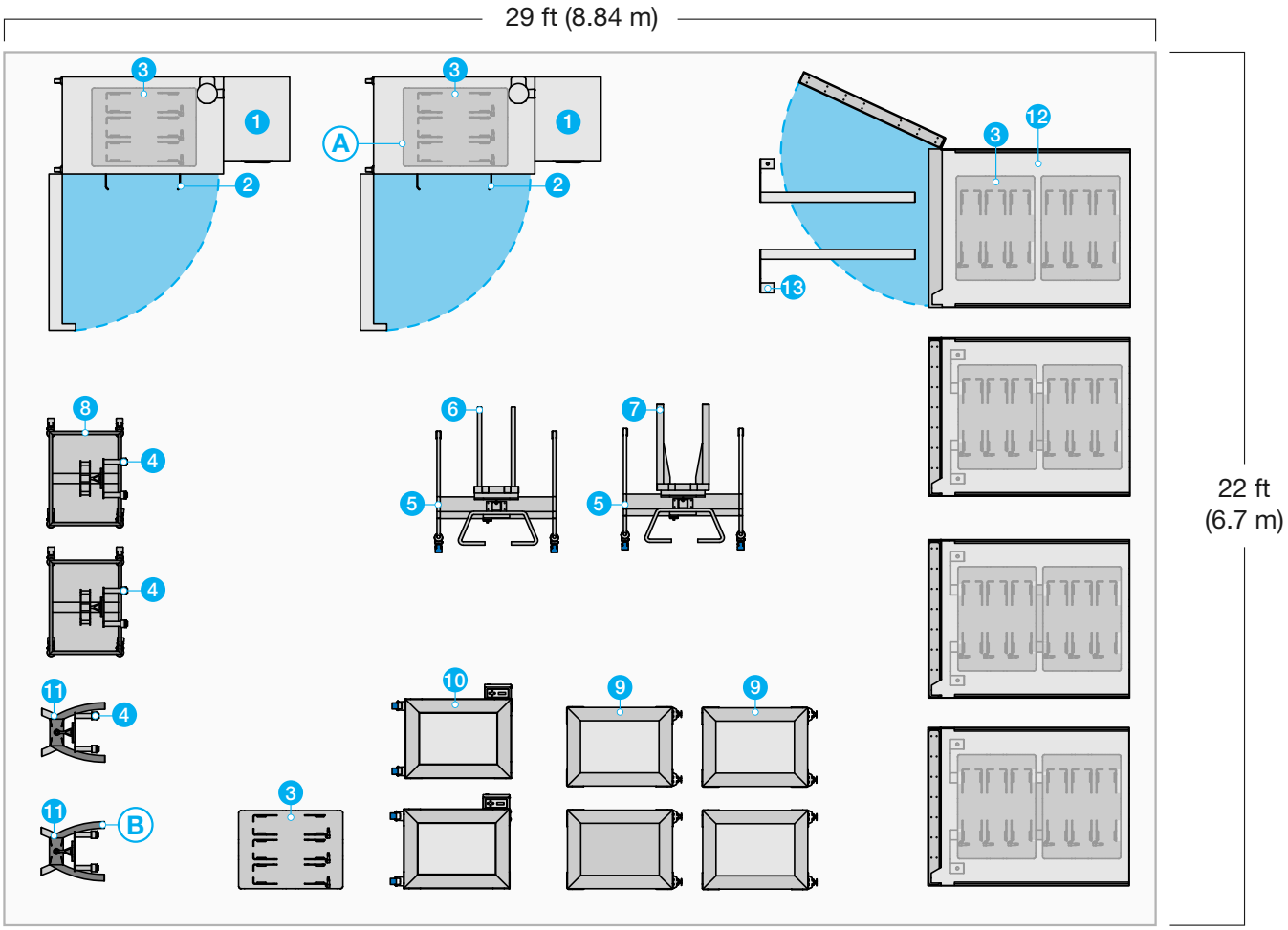
ITEM	DESCRIPTION	PART NO.	QTY
1	Freeze Thaw Unit; Water Cooled	KCVF-CS103A	1
2	Guide Rails	KCVM-GR500A	1
3	Small Pallet	KCVM-PS063A	8
4	Fill/Dispense Accessory	KCVM-DA001B	2
5	Automated Lift/Mix - Base Unit	KCVM-AJ500B	1
6	Fixed Arms	KCVM-AJPA01	1
7	Dual End-Ported Biocontainer Cart	FABC-020H	1
8	Universal Lab Stand	FAUS-001A	1
9	Shipper	KCVS-AS300P	2
10	Shipping Palllet Adapter	KCVM-PA100A	2

NOTES	
A	Space as a placeholder; needed upon receipt from DS site
B	Fill/Dispense Accessory can be used with multiple pieces of equipment

CryoVault® CV96

KCVP-CS001P

Premium Bundle - DS Manufacturing Site



Bill of Materials

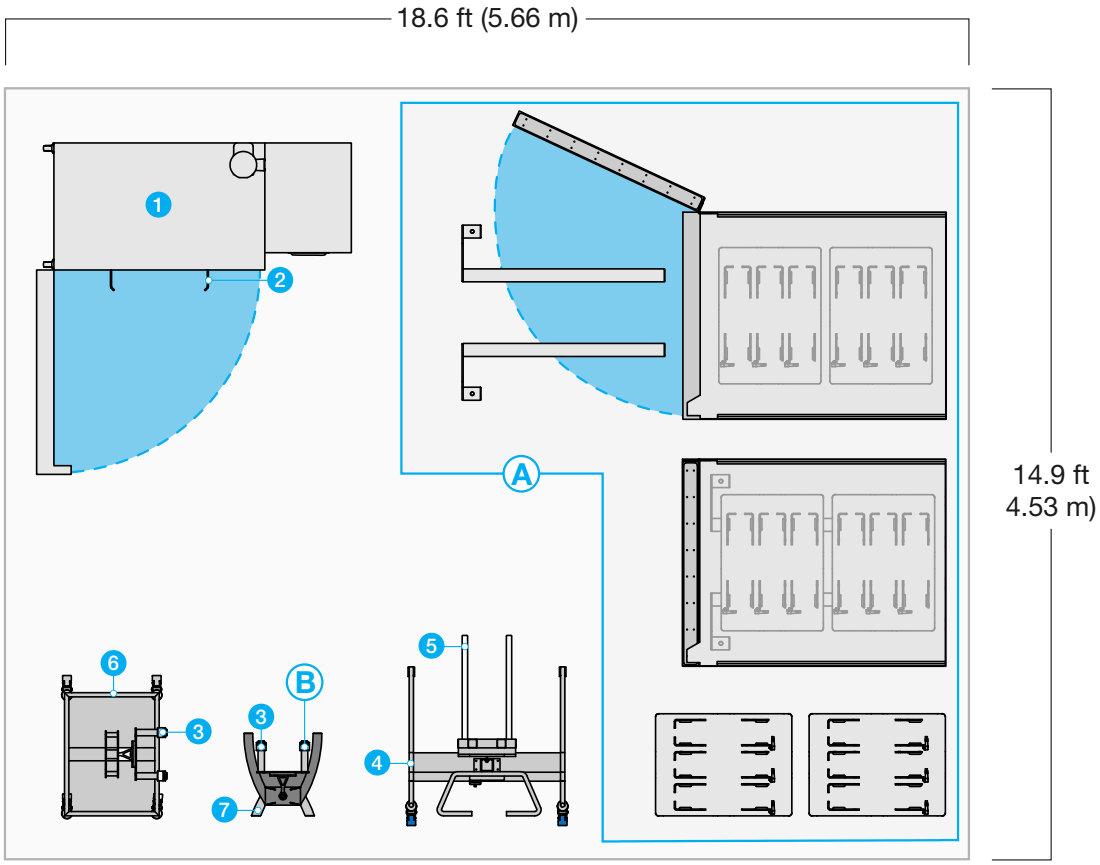
ITEM	DESCRIPTION	PART NO.	QTY
1	Freeze Thaw Unit; Water Cooled	KCVF-CS103A	2
2	Guide Rails	KCVM-GR500A	2
3	Small Pallet	KCVM-PS063A	16
4	Fill/Dispense Accessory	KCVM-DA001B	4
5	Automated Lift/Mix - Base Unit	KCVM-AJS00B	2
6	Fixed Arms	KCVM-AJPA01	1
7	Fixed Flat Forks	KCVM-AJPA03	1
8	Dual End-Ported Biocontainer Cart	FABC-020H	2
9	Intrafacility Cart	FSCS02B	4
10	Load Cell Cart	FSCS02B-LC	2
11	Universal Lab Stand	FAUS-001A	2
12	Shipper	KCVS-AS300P	4
13	Shipping Pallet Adapter	KCVM-PA100A	4

NOTES	
A	Freeze/Thaw unit shown with (2) Small Pallets
B	Fill/Dispense Accessory can be used with multiple pieces of equipment

CryoVault® CV96

KCVP-CP001S

Standard Bundle - DP Filling Site



Bill of Materials

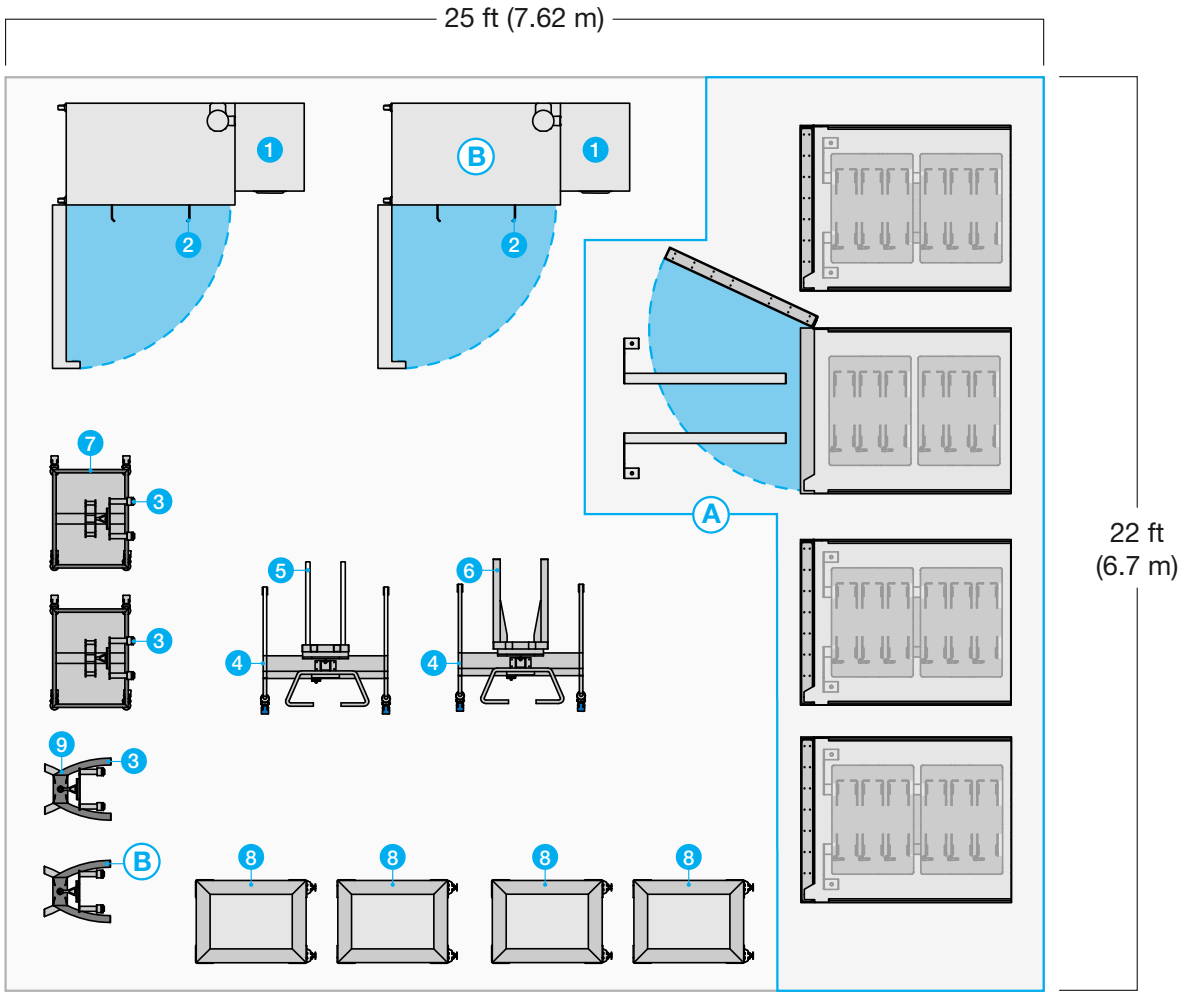
ITEM	DESCRIPTION	PART NO.	QTY
1	Freeze Thaw Unit; Water Cooled	KCVF-CS103A	1
2	Guide Rails	KCVM-GR500A	1
3	Fill/Dispense Accessory	KCVM-DA001B	2
4	Automated Lift/Mix - Base Unit	KCVM-AJ500B	1
5	Fixed Arms	KCVM-AJPA01	1
6	Dual End-Ported Biocontainer Cart	FABC-020H	1
7	Universal Lab Stand	FAUS-001A	1

NOTES	
A	Space as a placeholder; needed upon receipt from DS site
B	Fill/Dispense Accessory can be used with multiple pieces of equipment

CryoVault® CV96

KCVP-CP001P

Premium Bundle - DP Filling Site



Bill of Materials

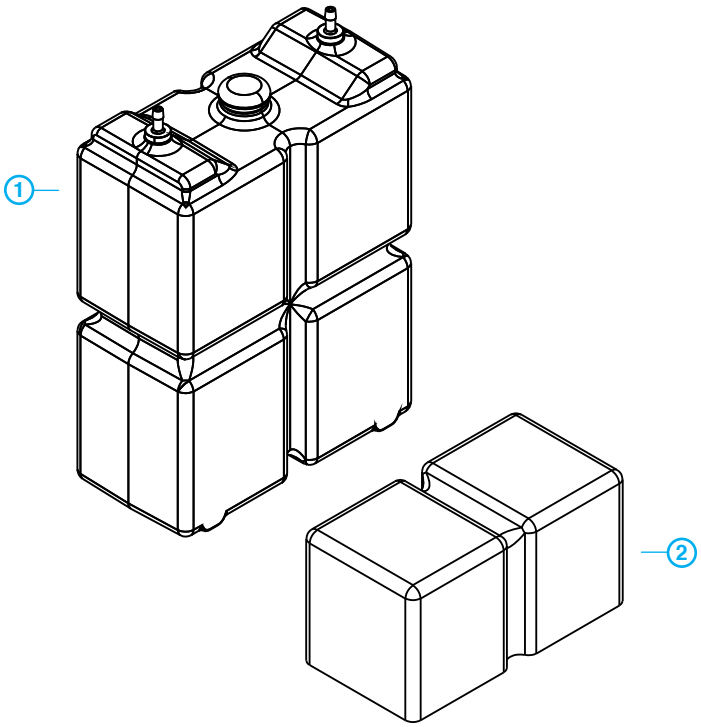
ITEM	DESCRIPTION	PART NO.	QTY
1	Freeze Thaw Unit; Water Cooled	KCVF-CS103A	2
2	Guide Rails	KCVM-GR500A	2
3	Fill/Dispense Accessory	KCVM-DA001B	4
4	Automated Lift/Mix - Base Unit	KCVM-AJ500B	2
5	Fixed Arms	KCVM-AJPA01	1
6	Fixed Flat Forks	KCVM-AJPA03	1
7	Dual End-Ported Biocontainer Cart	FABC-020H	2
8	Intrafacility Cart	FSCS02B	4
9	Universal Lab Stand	FAUS-001A	2

NOTES	
A	Space as a placeholder; needed upon receipt from DS site
B	Fill/Dispense Accessory can be used with multiple pieces of equipment

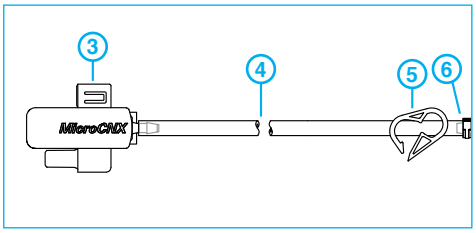
Storage

1.25 L CryoVault® Container*

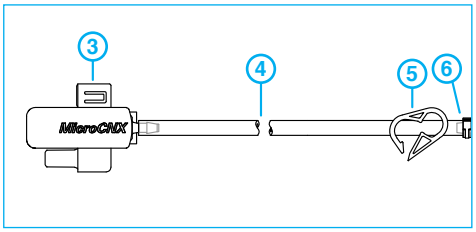
*We have expanded operational scalability with the 1.25 L (fill volume) container, while accommodating shipping restrictions for biohazardous materials. For more information, including platform scalability contact Meissner directly.



Fluid Ingress/Egress Line



Vent Line



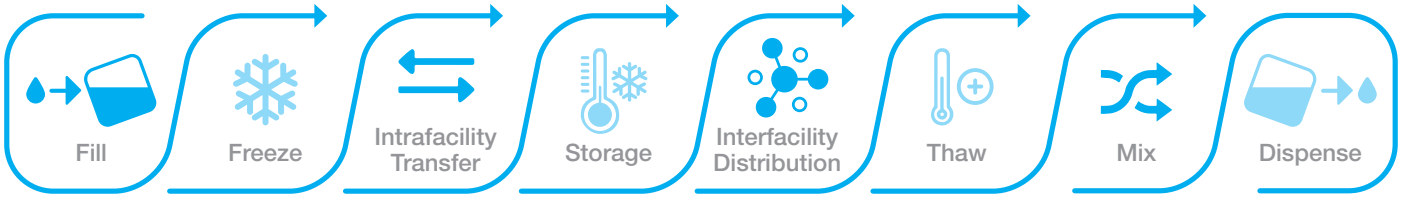
Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	1.25 L Container - 2 x 1/8" HB	91R71C13	1	HDPE
2	1.25 L Shroud	91R71S10	1	HDPE
3	Aseptic Connector, 1/8" HB, MicroCNX®	91S33A75	2	Polycarbonate
4	1/8" x 1/4" M-Flex® Tubing, 12" Length	91T47G11-12	2	M-Flex® TPE
5	Ratchet Pinch Clamp, Small	91L01R42	2	Polypropylene
6	Band Clamp, 8.0mm	92L96T06	2	Stainless Steel
7	Tamper Evident Re-closable Poly-bag (not pictured)	7620-04	2	Polyethylene
8	Cable Tie, Small (not pictured)	92M93C12	4	Nylon
9	Outer Packaging, Poly-Bag (not pictured)	7600-16	2	Polyethylene

Standards Part No.

Part Number	Material	Container Volume	Maximum Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC2701H-N00-C2220-01	HDPE	1.25 L	1 L	5.49" x 2.66" x 9.79"	0.73 lbs
				13.94 x 6.76 x 24.84 cm	333 grams

Getting Started
Stability Containers

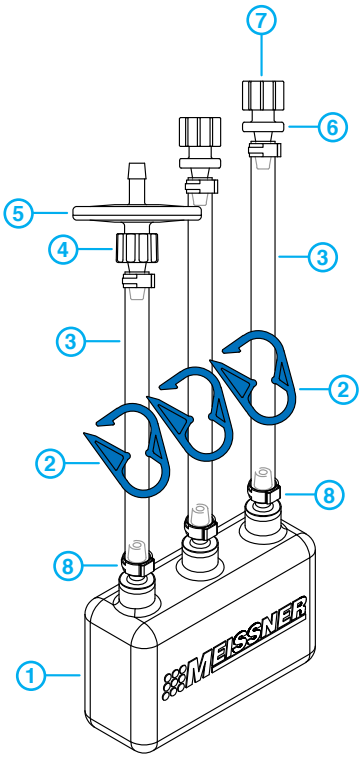


CryoVault® includes two small container sizes for process development or stability containers when use of the larger 6 L and 20 L containers may not be desirable. The 120 mL and 40 mL stability containers are ideal for compatibility studies, stability or shelf life studies, process development, and they can hold a tailgate sample for larger containers. The 40 mL stability container holds a nominal volume of 30 mL and the 120 mL stability container holds a nominal volume of 100 mL.

Stability Containers

40 mL BDS Container with M-Flex® TPE Tubing

Storage



Bill of Materials

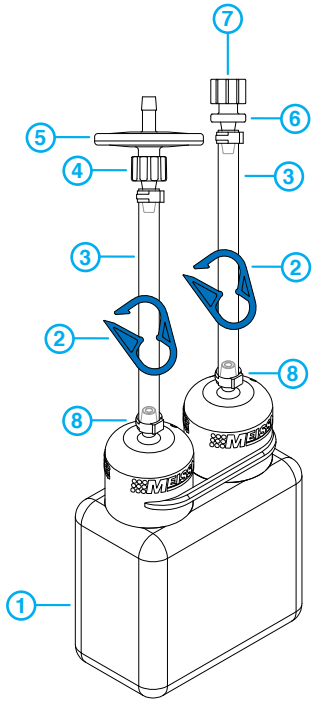
ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	40 mL Stability Container - 3" x ⅛" HB	91R71B84	1	HDPE
2	Ratchet Pinch Clamp, Small	91L01R42	3	Polypropylene
3	⅛" x ¼" M-Flex® Tubing, 3" Length	91T47G11-3	3	M-Flex® TPE
4	⅛" HB x Male Luer Adapter	91A02L21	1	Polypropylene
5	Meissner 25 mm Filter	CA2VTV0.2-EG0	1	PP/Steridyne®
6	⅛" HB x Female Luer Adapter	91A02L22	2	Polypropylene
7	Male Luer Plug	91S02A03	2	Polypropylene
8	Band Clamp, 8.0 mm	92L96T03	6	Stainless Steel
9	Outer Packaging, Poly-Bag (not pictured)	7600-09	2	Polyethylene

Standards Part No.

Part Number	Material	Container Volume	Maximum Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC3790H-VV2-C0600-01	HDPE	40 mL	30 mL	2.7" x 1.0" x 2.2"	1.3 oz
				6.9 x 2.5 x 5.6 cm	36.9 g

Stability Containers

120 mL BDS Container with M-Flex® TPE Tubing



Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	120 mL Stability Container - 3" x ⅛" HB	91R71B93	1	HDPE
2	Ratchet Pinch Clamp, Small	91L01R42	2	Polypropylene
3	⅛" x ¼" Tubing, 3" Length	91T47G11-3	2	M-Flex® TPE
4	⅛" HB x Male Luer Adapter	91A02L21	1	Polypropylene
5	Meissner Syringe Filter	CA2VTV0.2-EG0	1	PP/Steridyne®
6	⅛" HB x Female Luer Adapter	91A02L22	1	Polypropylene
7	Male Luer Plug	91S02A03	1	Polypropylene
8	Band Clamp, 7.0 mm	92L96T03	4	Stainless Steel
9	Outer Packaging, Poly-Bag (not pictured)	7600-09	2	Polyethylene

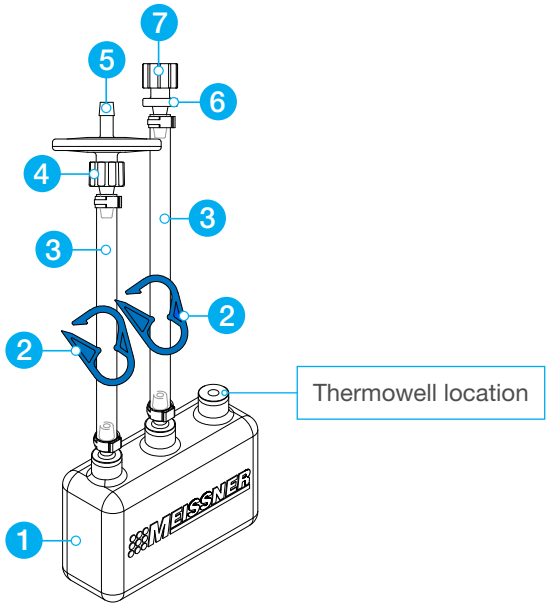
Standards Part No.

Part Number	Material	Container Volume	Maximum Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC2791H-VV2-C0600-01	HDPE	120 mL	100 mL	2.7" x 1.5" x 3.8"	3.0 oz
				6.9 x 3.8 x 9.7 cm	85 g

Stability Containers

40 mL BDS Container
Benchtop Standard

Storage



Bill of Materials

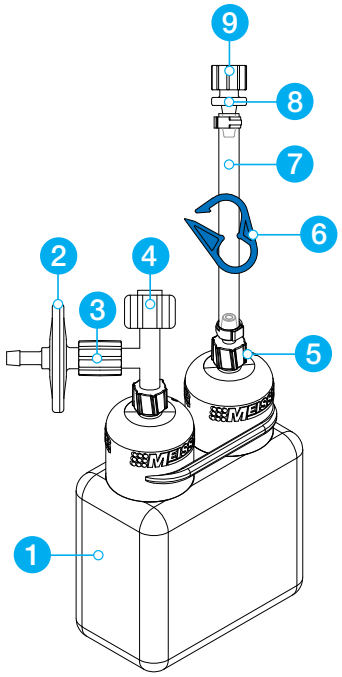
ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	40 mL Stability Container - 2 x 1/8" HB, 1 x Thermowell for 30 mL Fill	91R71T83	1	HDPE
2	Ratchet Pinch Clamp, Small	91L01R42	2	Polypropylene
3	1/8" x 1/4" Tubing, 3" Length	91T11G11-3	2	Pit. Silicone
4	1 /8" HB x Male Luer Adapter	91A02L21	1	Polypropylene
5	Meissner Syringe Filter	CA2VTV0.2-EGO	1	PP/Steridyne®
6	1/8" HB x Female Luer Adapter	91A02L22	1	Polypropylene
7	Male Luer Plug	91S02A03	1	Polypropylene
8	Band Clamp, 7.0 mm	92L96T03	4	Stainless Steel
9	Outer Packaging, Poly-bag (not pictured)	7600-09	2	Polyethylene

Standards Part No.

Part Number	Material	Container Volume	Container Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC3790H-VV2-C0030-01	HDPE	40 mL	30 mL	2.7" x 1.0" 2.2"	1.3 oz
				6.9 x 2.5 x 5.6 cm	36.9 g

Stability Containers

120 mL BDS Container
Benchtop Standard



Bill of Materials

ITEM	DESCRIPTION	PART NO.	QTY	MATERIAL
1	120 mL Stability Container - 2x Female Luer	91R71B91	1	HDPE
2	Meissner Syringe Filter	CA2VTV0.2-EGO	1	PP/Steridyne®
3	Male Luer x Male Luer Coupling	92S30A08	1	Polycarbonate
4	Tuohy Borst Luer Tree	91S30A10	1	Polycarbonate
5	1/8" HB x Male Luer Adapter	91A02L21	1	Polypropylene
6	Ratchet Pinch Clamp, Small	91L01R42	1	Polypropylene
7	1/8" x 1/4" Pharma-50 Tubing, 3" Length	91T11G11-3	1	Plt. Silicone
8	1/8" HB x Female Luer Adapter	91A02L22	1	Polypropylene
9	Male Luer Plug	91S02A03	1	Polypropylene
10	Band Clamp, 7.0 mm	92L96T03	2	Stainless Steel
11	Outer Packaging, Poly-bag (not pictured)	7600-09	2	Polyethylene

Standards Part No.

Part Number	Material	Container Volume	Container Fill Volume	Dimensions (L x W x H)	Gross Weight
DVC2791H-VV2-B9070-01	HDPE	120 mL	100 mL	2.7" x 1.5" x 3.8"	3.0 oz
				6.9 x 3.8 x 9.7 cm	85 g

BenchTop Freezer

Small Scale
Freeze/Thaw Unit

Freeze

The Bench Top Freezer system expands the CryoVault® platform by providing a small-scale representative freeze and thaw solution to complement our production-scale CV96 and CV300 portfolios. This system supports process and product development for the entire CryoVault® platform, but only requires a fraction of the footprint and process fluids to do so.

Heat Exchanger

Meissner Part Number	CryoVault® Bench Top Freezer - Heat Exchanger: KCVF-BF001A
Maximum Storage Container Capacity	Ten (10) quantity 40 mL or 120 mL containers
Maximum Volume Capacity	1 L total (utilizing ten [10] quantity 120 mL containers) 0.3 L total (utilizing ten [10] quantity 40 mL containers)
Container Temperature Range	-60 °C to 40 °C
Dimensions (D x W x H)	18.8" x 15" x 12.9" (476 x 381 x 327 mm)
Weight	62 lbs (28kg)
Power Requirements	5 VDC (supplied via USB port)

Benchtop Freezer continued on next page

(continued)

Temperature Control Unit

Meissner Part Number	Unistat® 705 temperature control unit (208V 60Hz): KCVF-CU705A Unistat® 705 temperature control unit (230V 50Hz): KCVF-CU755A
Temperature Range	-75 °C to 250 °C
Dimensions (D x W x H)	15.76" x 16.73" x 28.35" (400 x 425 x 720 mm)
Weight	209.48 lbs (95kg)
Refrigerant	R452A; R170
Power Requirements	Temperature Control Unit: available as 230V 1~50Hz, 12.5 A max or 208 2~ 60Hz, 20A

Glossary

Container: Refers to the single-use CryoVault® container for Bulk Drug Substance (BDS) storage and transport.

M-Flex™: Thermoplastic elastomer (TPE) tubing used in Meissner's single-use assemblies.

Bulk drug substance (BDS): Refers to the bulk volume of drug substance processed during freeze and thaw operations.

Drug substance (DS): Primarily refers to the site that manufactures drug substances and the storage container.

Drug product (DP): Primarily refers to the site that receives drug substances for formulation into drug product and subsequent filling.

End-to-End (E2E): Term used to describe the scope of the CryoVault® platform's dual site support for all process steps within F/T operations.

CV300 Pallet Dimensions: 47.3" x 31.5" x 16" (120.1 x 80 x 40.6 cm).

CV96 Pallet Dimensions: 24" x 32" x 7.4" (61 x 81.3 x 18.8 cm).

Freeze/Thaw (F/T): A term that combines Freeze and Thaw.

High-density polyethylene (HDPE): Material that comprises the rigid container body for all containers and stability containers.

Shroud: A rectangular cover that fits over the top of the CryoVault® container and provides the dual benefit of insulation and top works protection.

Single-use assembly: Refers to the single-use components assembled by Meissner.

Top works: Collectively refers to the container's tubing, vent filters, and connectors.

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MEISSNER

1001 Flynn Road • Camarillo, CA 93012 • USA
+1.805.388.9911 • +1.805.388.5948 Fax
www.meissner.com