

# VirTis AdVantage Pro™

## Laboratory Benchtop Freeze Dryer



### Key Features

- Experience the advantages of a tray dryer in a benchtop unit.
- Operate the unit using Intellitronics' vivid, full-color touchscreen.
- Receive alarm alerts via email.
- Stopper vials automatically with the pneumatic stoppering option.
- Condense up to 4 liters of ice over 24 hours.
- Order with up to three (3) usable shelves.

### Electrical Requirements

	XL	EL
Voltage	208-230 VAC	208-230 VAC
Hertz	50 / 60 Hz	50 / 60 Hz
Breaker Amperage (Type D)	15 A	15 A
Phase	Single	Single
Receptacle <sup>s</sup>	6-15R (Domestic Only)	6-15R (Domestic Only)

### Performance Specifications

	XL	EL
Shelf Temperature Control Range*	-40 to 60 °C	-55 to 60 °C
Lowest Shelf Temperature <sup>†</sup> (50 Hz / 60 Hz)	-57 °C / -60 °C	-62 °C / -65 °C
Shelf Pull-Down from 20 °C to -40 °C <sup>‡</sup>	≤ 40 minutes	≤ 30 minutes
Temperature Uniformity <sup>¶</sup>	± 1.0 °C	± 1.0 °C
Lowest Condenser Temperature <sup>†</sup> (50 Hz / 60 Hz)	-67 °C / -70 °C	-82 °C / -85 °C
Maximum Condenser Capacity	6 L	6 L
Maximum Ice Condensing Capacity in 24 hours <sup>  </sup>	4 L	4 L
Maximum Deposition Rate <sup>  </sup>	0.17 L/hour	0.17 L/hour
Vacuum Rate of Rise	≤ 60 mT/hour (≤ 0.08 mbar/hour)	≤ 60 mT/hour (≤ 0.08 mbar/hour)
Number of Compressors	1	2
Compressor Horsepower	3/4	1/3, 3/4

**Note:** Performance specifications are based on SP Scientific test data from units operating at an ambient room temperature of approximately 20 °C. SP Scientific recommends an operating range of 15-25 °C (59-77 °F).

### Utility Requirements

	XL	EL
Compressed Air (Stoppering Option Only)	60 - 90 psig (4.1 - 6.2 bar)	60 - 90 psig (4.1 - 6.2 bar)
Approx. Peak Heat Generated (With Vacuum Pump)	5,000 BTU/h (1.5 kW)	7,000 BTU/h (2 kW)
Approx. Peak Heat Generated (Without Vacuum Pump)	4,000 BTU/h (1.2 kW)	6,000 BTU/h (1.8 kW)

### Agency Approvals

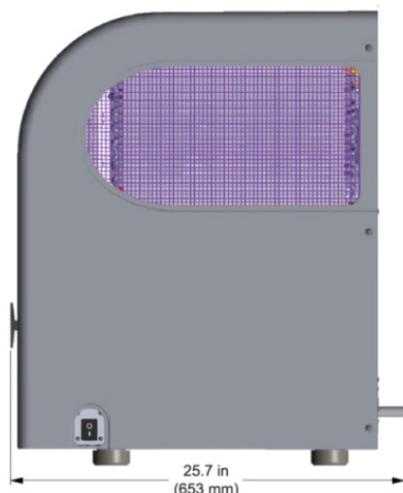
CCE (2006/42/EC)	(2004/108/EC)	(2006/95/EC)
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	F gas	Charge (kg)	GWP		
Gas #1	R245fa	0.255	1030	CO2e	
Gas #2	R5000	0.285	13390		4,080
Gas #3	N/A	N/A	N/A		

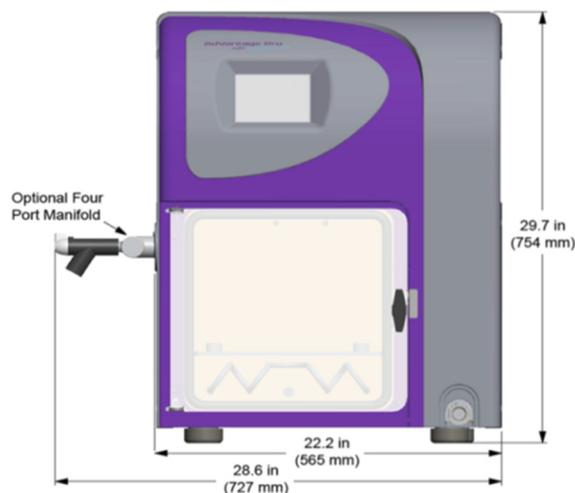
	F gas	Charge (kg)	GWP		
Gas #1	R407C	0.360	1774	CO2e	
Gas #2	R508B	0.22	13306		3,600
Gas #3	N/A	N/A	N/A		

# VirTis AdVantage Pro™

## Laboratory Benchtop Freeze Dryer



**Dimensional Data**



**Shelf Configuration**

	XL	EL		Shelf Clearance	Shelf Area
Width	22.2 in (565 mm)	22.2 in (565 mm)	1 Shelf	6.2 in (158 mm)	143 in <sup>2</sup> (922 cm <sup>2</sup> )
Depth	25.7 in (653 mm)	25.7 in (653 mm)	2 Shelves	2.9 in (73 mm)	286 in <sup>2</sup> (1,844 cm <sup>2</sup> )
Height	29.7 in (754 mm)	29.7 in (754 mm)	3 Shelves	1.75 in (44.5 mm)	429 in <sup>2</sup> (2,766 cm <sup>2</sup> )
Weight	310 lb (140 kg)	310 lb (140 kg)	Nominal Shelf Size (W x D x TH): 10.2 X 14 X 0.4 in (260 X 355 X 9.5 mm)		

**Material of Construction**

Chamber Construction	AISI Type 316L SS
Shelf Construction	AISI Type 316L SS
Chamber Door	Full-View Acrylic
Condenser Coil	AISI Type 316L SS
Four Port Manifold (Optional)	AISI Type 316L SS
Quickseal Body (Optional)	Neoprene
Quickseal Knob (Optional)	Polypropylene

**Additional Information**

Vacuum Pump (Required, not included)	Two-Stage Rotary Vane or Suitable Dry Pump
Defrost Type	Hot Gas
Refrigerant	CFC Free
Condenser Type	Internal
Stoppering (Optional)	Top-Down Pneumatic
Compressed Air Inlet (Stoppering Option) <sup>††</sup>	1/4-inch BSPT fitting
Inert Gas Port	3/8-inch Hose Barb fitting

**Note:** Dimensional data specifications are for standard AdVantage Pro lyophilizers. Specifications may vary based on optional components (i.e., optional four port manifold).

\* Shelf temperature is controlled to within ± 1.0 °C of the setpoint within the Shelf Temperature Control Range.

† The Lowest Shelf Temperature and Lowest Condenser Temperature values may be lower than or equal to the Performance Specifications.

‡ Shelf pull-down times are based on tests performed with no load at “pre-seal” pressure (approximately 400-500 mbar). The increased mass of stainless steel and additional heat transfer fluid for units with more than one shelf will increase the pull-down time. Use the following multipliers when determining the pull-down time specification for the following shelf configurations: 2-shelf units, standard pull-down time x 1.5 and 3-shelf units, standard pull-down time x 2.

¶ Shelf temperature deviations shall not exceed the specification relative to the mean of the highest and lowest temperature readings.

§ SP Scientific can configure any unit to conform to the electrical requirements of a wide range of international voltage and phase configurations. The AdVantage Pro includes an IEC60320 C20 receptacle on the back of the unit. This receptacle allows for country-specific power leads to be supplied. Contact SP Scientific for more information.

∖ The specified Maximum Ice Condensing Capacity in 24 Hours and the Maximum Deposition Rate are based on the process of freeze-drying water as aggressively as possible. The freeze dryer’s ability to collect ice at an hourly rate or over a specified period will always be application-dependent

\* The optional shelf latching kit allows for two to one shelf latching on two-shelf units, which increases shelf clearance to 5.6 in (142.2 mm) and 3 to 2 shelf latching on 3-shelf units, which increases shelf clearance to 2.6 in (66 mm). 3 to 1 shelf latching is unavailable.

† The Advantage Pro is configured with a 1/4-inch BSPT bulkhead fitting. A BSPT to 1/4-inch NPT adapter shall be provided with the unit, which will allow users to choose between a 1/4-inch BSPT fitting and a 1/4-inch NPT fitting.



# Guide To Choosing A Benchtop Freeze Dryer *including maintenance*



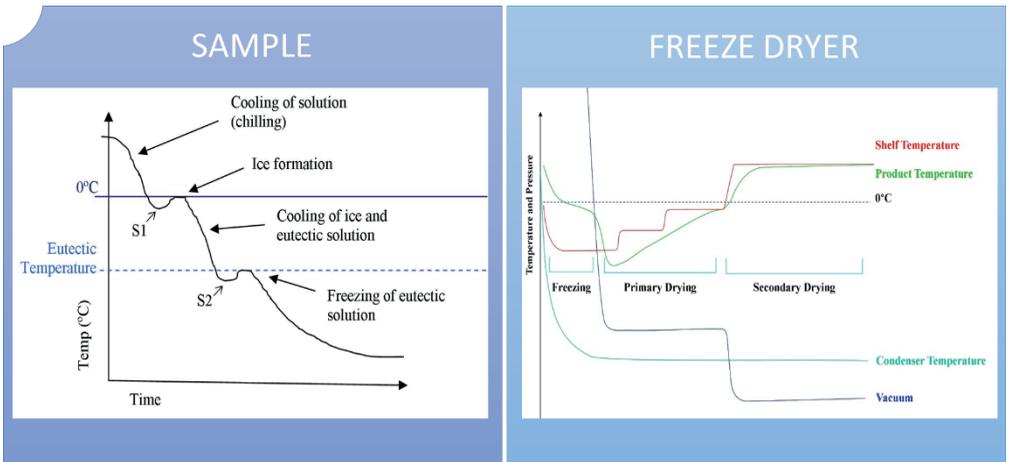
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# Introduction

## Freeze Drying

Freeze drying, also known as lyophilisation, is a process used in many different industries including food, pharmaceuticals, materials, biotechnology and research. It is used for many reasons including enhancing shelf-life, reducing sample weight, creating a particular structure, and increasing solubility. For further information please refer to **Introduction to Freeze Drying** booklet.



## Choosing a freeze dryer

Freeze dryers can be complicated pieces of specialised equipment, with controlled heating, cooling and vacuum interacting with each other to provide the best drying conditions. They are used for many different types of product and there are therefore a variety of different types of system with hundreds of options to enable them to suit the requirements of different industries and applications.

Selecting the correct freeze dryer and options to suit the technical and commercial constraints of a project requires planning. Cost effective entry models manifold freeze dryers offer 'plug and play' solution to lyophilization technology with various manifolds and condenser options to suit your product and containers. To make sure you get the right system there are a number of questions that should be considered at an early stage.

## 1. What's the product?

Products may be freeze dried with different goals in mind– for example, to maintain **flavour** or appearance, to extend **shelf life**, to create a particular **structure**, to slow down **biological activity**, to prevent **decay**. Different products also have vastly different regulatory requirements and cost tolerances: freeze-dried strawberries for a breakfast cereal will not have the same burden of regulation as an injectable vaccine, but it will likely be much more cost-sensitive. It's important to understand exactly what the goal is and how success is measured to make sure that the equipment is up to the job without being overcomplicated.



Some of the relevant equipment variables may include: how stringently temperature is controlled; whether the temperature of the product is directly monitored, and how; the process temperatures and condenser capacities; and what level of cycle programming, monitoring, reporting and data security are required. Some of those requirements might not be available on a benchtop machines, therefore a floor standing R&D system would need to be selected to meet those needs – also available through Biopharma Group.

## 2. What solvents are involved?

A significant proportion of products for freeze drying have only one solvent: water. Water is straightforward to deal with as its behaviour is well understood – with a relatively high freezing temperature, making it simple to freeze dry. However many products contain other solvents in greater or lesser concentrations and sometimes in combination. The different thermal characteristics of **non-aqueous solvents** may require lower process temperatures in the condenser (and shelves on fully controllable freeze dryers, like the Advantage range) and this has to be specified at the outset – it cannot be retrofitted.

Some non-aqueous solvents are **corrosive** to freeze dryer components especially plastics. To avoid constantly replacing parts, machines can be built to resist corrosion with stainless steel and glass, replacing acrylic parts, for example: the chamber door. Equally, the vacuum pump can be upgraded from a standard two-stage oil-sealed rotary vane pump, to a **dry chemically resistant vacuum pump**, where aggressive/corrosive solvents are to be processed. However not all solvents are

suitable for freeze drying so this is likely to be one of the first questions we will ask you.

A pre-processing step such as **evaporation** can sometimes be used to draw off unfavourable solvents using a Genevac evaporator, for example, allowing the remaining product to be more easily freeze dried. Biopharma can advise on this and supply centrifugal evaporators where needed.

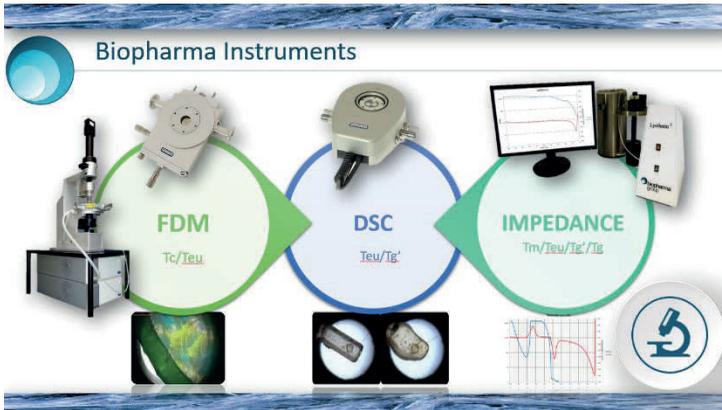
For solvent compability with parts and recommended condenser temperature, please refer to the table below with few examples:

### Tolerance of acrylic to some common solvents

Chemical/Solvent	Acrylic Compatibility	Melting PT (C°)	Recommended Condenser	LN2 Trap
Acetic Acid (Glacial)	N	16.5	-53	Y
Acetone	N	-94.9	-105	Y
Acetonitrile	N	-45	-53	N
Cyclohexane	N	6.5	-53	N
Diethylene Glycol	N	-10.45	-53	N
Hydrchloric Acid	Y	-27.3	-53	N
Hydrogen Peroxide (28%)	N	-0.43	-53	N
Methyl alcohol (100%)	N	-97	-105	Y
Nitric Acid (Concentrated)	N	-43	-53	N
Propylene Glycol	Y	-59	-85	N

### 3. Is the product ready for freeze drying?

Not all types of product or formulation can be easily freeze dried. Alternative stabilisation methods may be more suitable for a specific product, while other products may require pre-processing. Our laboratory has dealt with hundreds of different types of product and is also able to advise on formulation and cycle optimisation. So if you need some support, do not hesitate to contact us.



#### 4. What is the end use?

When the product leaves the freeze dryer, what happens to it? Will it be eaten, injected, incorporated into another product, or sent for further analysis? The answers will tell you a great deal about construction, data security, cleaning and any ancillary equipment requirements.

**Foods and medical treatments** – from chemotherapy drugs to artificial skin– will likely require production within a **clean room environment**. Not all freeze dryers are suitable for use in clean rooms, as exhaust gases and particles must not contaminate a controlled environment.

Equipment cleaning and sterilisation procedures are also likely to be stringent. For larger systems it may be possible to automate cleaning (**CIP**) and sterilisation (**SIP**). In smaller systems it's important to make sure the dimensions of the chambers and position of the system will accommodate manual cleaning procedures. Other related procedures can also be partially or completely automated to minimise contamination, for example loading and unloading product on to the freeze dryer shelf.

Systems used for **research and development** will often need more sophisticated monitoring and feedback tools to provide the process data needed for analysis and evaluation.

The product use will also affect the level to which the system must be tested before use. Systems being used for **commercial production** will often need to be validated on installation and the chain of paperwork leading up to construction is often more complex, involving User Requirement Specifications (URS), Functional Description/Design Specification (FDS), Factory Acceptance Testing, Site Acceptance Testing (SAT) and finally Installation and Operational Qualification (IQ/OQ). Systems used for research and development will often need more sophisticated monitoring

and feedback tools to provide the process data needed for analysis and evaluation.

**Project life cycle documentation** is becoming a greater pre-requisite for R&D machines, in addition to pilot/commercial scale freeze dryers. Biopharma are able to supply a full life cycle document package, if required, inclusive of:

- Equipment Specifications
- Engineering drawings
- Bill of materials
- Factory test data
- Factory Calibration Records
- Operator's Manuals
- Certificates for potential product contact areas
  - Material certificates
  - Passivation certificates
  - Ra certificates

## 5. What quantities do you want to freeze dry?

Batch size is usually given in terms of volume of product or number of a specific type of container (e.g. vials, bulk trays, 96 well plates). It may be useful to consider the required throughput per week or per month, then calculate the batch variables.

You can freeze your sample directly in the shelf in a fully controlled manner, in the condenser using a less controlled approach, or externally – but ultimately, the sample needs to be fully frozen prior introducing it to the manifold and then switching on the vacuum to initiate lyophilization.



Batch parameters will enable the **condenser size** to be estimated, normally given in terms of weight or volume capacity over a specific time period. The overall condenser capacity needs to be greater than the total batch volume to allow for the irregularity of vapour flow rates and decreasing efficiency due to ice build-up as the cycle progresses. This is especially relevant with bulk or high moisture content products. However other parameters such as container type

and fill volume may make available **shelf area** a more significant consideration than condenser size.

Where batch size is being calculated from a throughput requirement, it's important to factor in not just the duration of the cycle but time for loading/unloading, defrosting, cleaning and maintenance. Sometimes it may be more effective to have entire system or component back up to provide redundancy and allow for flexibility of requirements.

## 6. What is the unit or container type?

Is the product precisely dosed into vials, liquid or slurry in to trays, individual fruit pieces, racks of eppendorf tubes for PCR based processing? The dimensions of the vials or tubes is important for calculating how many can be fitted onto a shelf, or inside a wide opening glasware on the manifold freeze dryer. Also, to provide a suitable amount of **shelf spacing**, both of which will determine how much product can be processed in the chamber at any one time.

For the manifold type freeze dryers, as per the image on page 1 of the document, a variety of styles are available, and designed to be interchangeable. There are a number of considerations when selecting a manifold. In a multi-user lab it is often best to utilize a robust stainless steel manifold. In applications where inorganic solvents are being utilized or you are rack drying and want to ensure visibility an acrylic manifold would be preferred. In applications with organic solvents the stainless steel manifolds will provide long lasting use.

Vials generally need to be sealed in the chamber by means of a built-in **stopping** mechanism. Pneumatic stopping is available only on systems with fully controllable shelves, like the Advantage Pro, range and above this functionality cannot be retrofitted.



It is possible to get more product on a shelf in trays as a slurry or small pieces than in vials, consequently the vapour load will be greater and the condenser will have to be sized accordingly.

Changing the container type can increase or decrease the amount of product that can fit on a shelf and depth of product in the container, but whenever any batch parameters are changed the effect on the freeze drying cycle must also be assessed. The container dimensions can also affect the rate at which vapour leaves the product, which in turn affects the drying rate and temperature of the product and the vapour load on the freeze dryer condenser. All these factors can result in a previously optimal cycle suddenly producing defects.

Biopharma can provide data on shelf area and container capacity once the container dimensions are known.

## 7. Where will the freeze dryer be positioned?

Freeze dryers can be operated in a multitude of locations. Sometimes a freeze dryer has to fit on the bench of a small academic lab and sometimes the entire plant room will be constructed around it. There has to be sufficient space for the freeze dryer itself and there must be sufficient height, width and weight clearance for the route to site. Many systems can be built in different configurations to make them fit in a different space or to make them cleanroom-friendly, but of course these requirements must be stated before construction.



Like many refrigeration based systems freeze dryers will work more efficiently in a

cool environment. Many laboratories and cleanrooms are air conditioned and temperature controlled in the range 20°C – 22°C which is ideal.

## 8. Manifold freeze dryer maintenance and servicing

All freeze dryers benefit from regular servicing to maintain optimum performance and site positioning should ensure there is sufficient room for engineers to access the key components. All Biopharma's systems are supported by a service department that can provide technical services such as scheduled maintenance, training, spares and repairs. We currently maintain approximately 700 systems across the UK and Ireland, ranging from simple benchtop systems to automated production machines.

Entry model systems like the BTP are designed to be a '**plug and play**' type of instrument, with **minimal maintenance** required, often undertaken by the end user. Parts like gaskets and vacuum pump oil can be supplied via Biopharma.

For users operating oil-sealed pumps (as opposed to oil-free 'dry' vacuum pumps), it is imperative **vacuum pump oil** is regularly checked and clean, for the best vacuum and overall efficiency of the system. Checking and changing the oil on a consistent basis will greatly extend the life of the vacuum pump. Where oil needs to be changed, users should do so immediately after shutting down the freeze dryer while the oil is still hot – please refer to the equipment manual for step by step guide. To assist with regular changes, the BTP system had built in **alarm** to prompt the user to check the oil level, colour and general appearance of the pump.



The **gas ballast** valve supports the removal of some contaminants from the pump oil. During freeze drying or cold trap use, vapours may bypass the condenser and end up in the vacuum pump. If this occurs, the vapours will potentially degrade the oil, causing excessive wear and poor vacuum pressure. When the ballast is open, it allows a controlled amount of air into the second stage pump cylinder. This reduces the partial pressure, increases the pump's operating temperature and releases the vapors. Ensure that the port is closed during the freeze drying, as this will affect the ultimate vacuum level.

## Types of freeze dryer

### Benchtop Manifold-Type—VirTis BTPro

This type of freeze dryer is compact and incredibly flexible with a range of condenser temperatures available to as low as  $-103^{\circ}\text{C}$  for processing the widest range of products. A number of different accessories enable you to freeze dry product in trays, vials, ampoules, freeze-drying flasks, plates and more.

- Available in varying refrigeration types, from the 'ES'  $-52^{\circ}\text{C}$ , 'EL'  $-82^{\circ}\text{C}$  lowest condenser, to the 'ZL'  $-102^{\circ}\text{C}$  lowest condenser temperature (recommended if processing non-aqueous solvents)
- Total condenser capacity 3 to 9 litres (subject to model opted)
- Heavy gauge stainless steel condenser – again, desired when processing aggressive materials, such as organic solvents/acids



- Acrylic drum manifold, Tree type, or Vertical manifolds options. Do note that dependent on the frequency, concentration, volume, and of course nature of the potential organic solvents that may be used, our stainless steel manifold might be suggested, to minimise the risk of accessory corrosion by aggressive solvents, such as acetonitrile, methanol, DMSO, and chloroform, for example.
- One touch start up and shut down to ensure your product and freeze dryer be protected from inappropriate procedures
- Manual vacuum level control available – enables user to set a pre-defined vacuum set-point i.e. 500mT, if preferred
- Please note the **sample must be completely frozen externally**, prior to connecting to the sample ports, and remain frozen throughout the whole procedure – if material is added to the dryer and exposed to a vacuum when it isn't fully frozen then a risk of product 'boiling off' will be more likely, and vapour could by-pass the condenser and reach the pump, in many cases. Again, an occurrence we seek to avoid
- Data trending - real time graphical screen data logging allows the user to review the critical parameters, such as vacuum/condenser temperature, on a real-time basis, if required during the run



Operation is typically simple, with features such as **one-button start-up** and automatic condenser defrost and the ability to control the freeze drying process through **vacuum control**. Some control systems can also allow data capture and remote viewing.

However for more sophisticated product and process development, full shelf temperature control (freezing and drying) and cycle programming is recommended- available on Adbantage range of freeze dryers.

Each system can be configured to accommodate your processing requirements- condenser size, refrigeration type and type of manifold. If the system will only be used to freeze one product, it's possible to be very specific about capacities and requirements. If the system will be used for lots of products, more flexibility will be required. You should familiarise yourself on any regulatory requirements in advance, and Biopharma will be able to advise on the available options to ensure compliance.

To avoid doubt in such cases, consider writing a User Requirement Specification (URS) which should identify key operating requirements. The questions in the next section will assist you to define your needs and chart below outlines the BTP configurations to assure that your selection will be suitable for your application.

#### BTP Selection Guide

Solvents	Load and Refrigeration Capacity		Manifold Material Choice	Vacuum Pump Considerations
Water	<b>3ES</b> 3 litre / -52°C	<b>9ES</b> 9 litre / -52°C	Acrylic or stainless steel. Multiple user labs may have better experience with stainless steel.	Standard oil sealed, rotary vane direct drive pump. When working in low pressure conditions consider a dry scroll pump if oil backstreaming is a concern.
Water and inorganic solvents	<b>8ZL</b> 8 litre / -102°C	<b>9EL</b> 9 litre / -82°C	Maximize use of acrylic and minimize use of stainless steel.	Standard pump with corrosion resistant oil or combination standard pump with diaphragm pump.
Water & organic solvents	<b>8ZL</b> 8 litre / -102°C	<b>9EL</b> 9 litre / -82°C	Maximize use of stainless steel and minimize use of acrylic if possible.	Standard pump with corrosion resistant oil or combination standard pump with diaphragm pump.
Water & both organic and inorganic solvents	<b>8ZL</b> 8 litre / -102°C	<b>9EL</b> 9 litre / -82°C	Maximize use of acrylic if higher in organic solvents. Maximize use of stainless steel if higher in organic solvents.	Combination standard pump with diaphragm pump.

## Benchtop shelf-type—fully controllable VirTis AdVantage

Where a processing control is required, the VirTis AdVantage series of instrument is popular in R&D environment due to its unique design and controls. Those freeze dryers offer users multi-step, multi-recipe programmability capable of simulating conditions on much larger production systems. The negative temperature on the shelves can be controlled for efficient primary drying protocols, as well as, assisting with annealing step, where required. Cycles may therefore be determined at the R&D level, prior to progressing to the larger pilot and production volumes.



The the Advantage Pro has a silicon fluid circulating in the shelving (up to 3 shelf are available)- allowing control of +/- 1°C. The sample can be frozen in-situ of freeze dryer. All processes can be controlled with the desired temperatures, monitored and scaled up to much larger production batches. Condenser capacity is smaller than floor-standing models—typically up to around 6 litres—but for labs that are cramped for space these systems fit a lot of functionality into a small space. The vacuum pump is not contained within the main unit so can be placed underneath if bench space is limited.

- Available in two refrigeration models, from the 'XL' -67°C lowest condenser, to the 'EL' -82°C lowest condenser temperature --recommended if processing non-aqueous, lower melting point solvents--
- Shelf temperatures can range between -62°C and +60°C --subject to refrigeration design chosen--
- Option to select either 1, 2, or 3 x processing shelves. Shelf dimensions are -- 270mm by 355mm--
- Total condenser capacity 6 litres, 4 litres/24 hours
- Availability to use up to 4 x product probes
- Precise shelf temperature control
- Option to use pneumatic stoppering: to close vials under vacuum or an inert gas
- On board control system with multiple recipes each with multi-step controlled freezing drying steps to manipulate ice crystal structure --ability to carry out product annealing is possible--, as well as precise drying set-points, all accurately reproducible
- Compatibility to link the system to a PC/laptop using specific software allowing the user to store data for later manipulation and report writing, if required



## Floor-standing shelf freeze dryers

This type of freeze dryer is the most common as options and accessories make them extremely versatile. Condenser temperatures are typically available as low as  $-82^{\circ}\text{C}$  and capacity ranges from around 20 to 50 litres – making them large enough for some **scale-up** and **small production** applications. Control systems and computer workstation packages ensure compliance to various laboratory and production regulatory regulations such as cGMP or 21CFR11, are also available.

Alternatively they provide a range of process monitoring technologies for **product & process R&D**.



Although many standard designs exist, large-scale production systems are often custom assembled from modules because of the range of requirements that may be available and the other machinery the freeze dryer may have to interact with.

<https://biopharma.co.uk/bps/freeze-drying/freeze-dryers/pharma-production-freeze-dryers-2/>

Nonetheless, the new Line of Sight range includes a standard design production machine capable of adhering to cGMP and software compliance, such as:

- 21 CFR Part 11 and GAMP5
- CIP/SIP and VHP compatible
- ControLyo – controlled nucleation available
- Isolator ready – with auto locking doors
- Easily integrated into an aseptic filling line and loading systems



**Wolflabs**

# Wolf Laboratories Limited

[www.wolflabs.co.uk](http://www.wolflabs.co.uk)

Tel: 01759 301142

Fax: 01759 301143

[sales@wolflabs.co.uk](mailto:sales@wolflabs.co.uk)



**Use the above details to contact us if this literature doesn't answer all your questions.**

**Pricing on any accessories shown can be found by keying the part number into the search box on our website.**

The specifications listed in this brochure are subject to change by the manufacturer and therefore cannot be guaranteed to be correct. If there are aspects of the specification that must be guaranteed, please provide these to our sales team so that details can be confirmed.

