

Alpha 1-2 LDplus





Operating Manual

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In case of inquiries, please state the following numbers:

Order number:

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1.1 Importance of the operating manual

A fundamental requirement for the safe and trouble-free operation of the unit is to be familiar with the fundamental safety instructions and all possible hazards.

The operating manual includes important information concerning the safe operation of the freeze-dryer.

This operating manual, and in particular the notes on safety and hazards, must be observed by all persons operating the unit.

In addition, the local rules and regulations for the prevention of accidents must be complied with.

1.2 Intended use

The freeze-dryer has been exclusively designed for the freeze-drying of solid or liquid products in ampoules, vials or dishes. It is, therefore, solely intended for this application.

The freeze-dryer is suitable for freeze-drying solid substances and aqueous solutions (e.g. bacteria and virus cultures, blood plasma, serum fractions, antibodies, sera, vaccines and pharmaceutical products such as chloramphenicol, streptomycin, vitamins, ferments and plant extracts for biochemical tests).

Freeze-drying of solvent-containing products (non-aqueous media)

With regards of corrosion resistance, the use of some organic solvents in aqueous solutions with low concentrations is acceptable.

A freeze-dryer is designed to be chemically resistant to most compounds that are commonly used in freeze-drying processes. However, by necessity, the freeze-dryer is comprised of several different materials, some of which may be attacked and degraded by certain chemicals.

The methods of fabrication and/or conditions of exposure of an acrylic door, as well as the way the chemicals are applied, can influence the results. Some of these factors are listed below:

- Fabrication: Stress generated while sawing, sanding, machining, drilling, polishing, and/or forming.
- Exposure: Length of exposure, stresses induced during the life of the product due to various loads, changes in temperature etc.
- Application of chemicals: by contact, rubbing, wiping, spraying etc.



The following table can be used as a general guide for the expected degradation during normal freeze-drying processes of organic solvents with a total max. concentration of 10 vol-% in aqueous solutions.

Solvent	Acrylic glass	Stainless steel	Silicon rubber	EPDM
Acetic acid 20%	+	+	+	0
Formic acid up to 10%	+	0	0	-
Trifluoracetic acid (TFA)	-	+	0	+
Calcium chloride	+	+	+	+
Sodium phosphate	+	+	-	+
Acetone	-	+	+	+
Acetonitrile	-	+	-	0
Carbon tetrachloride	-	+	-	-
Cyclohexane	+	+	-	-
Dioxane	-	+	-	0
Methyl-t-butyl ether	+	+	0	-
Pyridine	-	+	-	0
Methanol	-	+	+	+
Ethanol	0	+	0	+
tert-Butanol	-	+	-	0
DMSO	-	+	-	+

Legend:

+ No degradation to be expected

o Moderate degradation; limited use

- Severe degradation; infrequent use recommended;

immediate thorough cleaning required

The chemical attack on devices and accessory components can be significantly reduced by immediate cleaning after the end of operation. All parts of the freeze-dryer that have come in contact with the product must be checked regularly for damages and replaced if necessary.

The following features are not permissible or must be deactivated:

omission of product temperature sensors of the PT100 or LyoRx type or of specially connected PT100 sensors (with a cable connection),



Solvents that are not listed in the table above, or the listed solvents in a concentration higher than 10% by volume, must not be used!



Freeze-drying of acid-containing products

Freeze-drying of products containing acids (with the exception of the substances already listed under "Freeze-drying of solvent-containing products" in the concentrations stated there) is only permissible if special protective measures and equipment-related precautions are taken. Otherwise, there is a risk of damage to property and personal injury. Consultation of Martin Christ Gefriertrocknungsanlagen GmbH is absolutely mandatory in order to define the measures that need to be taken!

Any other use beyond this area of application is regarded as improper use. Martin Christ Gefriertrocknungsanlagen GmbH cannot be held liable for any damage resulting from such improper use.

The intended use also includes:

- observation of all the notes and instructions included in the operating manual;
- compliance with the inspection and maintenance instruction.

The following operations are regarded as NOT PERMISSIBLE:

- operation of the freeze-dryer if it is not properly installed
- use of the freeze-dryer if it is not in a perfect technical state;
- use of the freeze-dryer within hazardous locations where there is a risk of explosions:
- use of the freeze-dryer with unauthorised additions or conversions without the written approval by Martin Christ Gefriertrocknungsanlagen GmbH;
- use of the freeze-dryer with accessories that have not been approved by Martin Christ Gefriertrocknungsanlagen GmbH, with the exception of commercially available freeze-drying vessels made of glass or plastic;
- use of the freeze-dryer with concentrated solvents;
- freeze-drying of products that may react during the freeze-drying process following the supply of high amounts of energy, e.g. solventcontaining products;
- freeze-drying of products containing azides;
- freeze-drying of products that may damage the material of the chamber walls, shelves, pipes, or seals, or that may affect the mechanical strength.

1.3 Warranty and liability

The warranty and liability are subject to our "General Terms and Conditions" that were distributed to the operator upon the conclusion of the contract.

Warranty and liability claims are excluded if they are due to one or several of the following reasons:

- improper use
- non-compliance with the safety instructions and hazard warnings in the operating manual
- improper installation, start-up, operation, and maintenance of the freeze-dryer.



1.4 Copyright

The copyright concerning the operating manual remains with Martin Christ Gefriertrocknungsanlagen GmbH.

The operating manual is solely intended for the operator and their personnel. It includes instructions and information that may not be

- duplicated,
- distributed, or
- communicated in any other way neither in full nor in parts.

Non-compliance may be prosecuted under criminal law.

1.5 Explanation of symbols

In this operating manual, specialist terms that are explained in the glossary (see chapter 12 - "Glossary") are marked by an arrow and printed in italics (e.g. \rightarrow *sublimation*).

1.6 Standards and regulations

EC declaration of conformity in accordance with the EC Machinery Directive (see chapter 11.2 - "EC declaration of conformity in accordance with the EC Machinery Directive")

1.7 Scope of supply

The scope of supply comprises:

- 1 tube of high-vacuum grease
- 1 drain hose 0.5 m (silicone 8 x 12 mm)
- 1 open spanner (size 19)
- 1 operating manual

In addition, if a vacuum pump is included:

- 1 litre of vacuum pump oil
- 1 hexagon socket key (size 6)

Accessories and commissioning

According to your order, our order confirmation, and our delivery note.



2.1 Layout of the freeze-dryer

2.1.1 Functional and operating elements

- 1 Ice condenser chamber with an internal ice condenser
- 2 Aeration and media drain valve



Fig. 1: Left side of the freeze-dryer

- 3 Pipe connection of the vacuum pump (behind the cover plate)
- 4 Ice condenser



Fig. 2: Ice condenser chamber



- 5 User interface (see chapter 6.5.1 - "User interface")
- 6 Mains power switch



Fig. 3: Front and right side of the freeze-dryer

- 7 Power supply of the pressure control valve
- 8 Name plate (see chapter 2.1.2 - "Name plate")
- 9 Power supply of the vacuum pump
- 10 Equipotential bonding screw
- 11 Mains connection
- 12 Vacuum connection
- 13 Connection of the vacuum sensor
- 14 Option: data interface for further accessories
- 15 Heat exchanger of the refrigeration unit



Fig. 4: Rear view of the freeze-dryer



2.1.2 Name plate

- 1 Serial number
- 2 Type
- 3 Refrigerant data of the 1st stage
- 4 Nominal voltage5 Year of manufacture (month/year)
- 6 Part number
- 7 Rated current / apparent power

	(€ () _	ЧI	RIST	
1	Serial 0 No.	000	0	11 / 2021	 5
3	Alpha 1-2 LDplus		101521 •	<u> </u>	
3	cool. system 1. stage		2. stage		
	refrigerant	refrigerant R1270 / R170			
	filling	36g / 6g	3		
	max. pressure	25 bar			
	max. temp.	120°C			
4	230 V / 50 H	Hz 3.	5 A	/ 0.8 kVA	— 7
	D-37520 Osterode am Harz, An der Unteren Söse 50, Germany				

Fig. 5: Example of a name plate



2.2 Mode of operation

2.2.1 General information on freeze-drying

What is freeze-drying?

Freeze-drying or lyophilisation is a procedure for the gentle drying of highquality products. The product is dried by \rightarrow *sublimation* without passing through the liquid phase.

What are typical applications for freeze-drying?

An important area of application is the drying of biotechnological and pharmaceutical products, e.g. tissues and tissue extracts, bacteria, vaccines, and sera. Products that would not keep well when they are dissolved in water can be preserved by freeze-drying. During this process, the biological properties of these sensitive substances are preserved. The compounds remain unchanged from a qualitative and quantitative point of view. After the addition of water, the products will have the same characteristics as the original products.

How does freeze-drying work?

Freeze-drying is a very gentle procedure for the extraction of water from a product in the frozen state. The drying process takes place through \rightarrow *sublimation*, i.e. the direct transition of a product from the solid phase to the gas phase. This happens under vacuum.

The following section describes the process of sublimation based on the example of water, since most products that are processed by freeze-drying are aqueous solutions. Their behaviour is based on identical fundamental principles.

The vapour pressure curve for ice and water (sublimation pressure curve) describes the phase transition as a function of the pressure and temperature. The higher the temperature is, the higher the vapour pressure.

- If the vapour pressure is higher than 6.11 mbar (A), water passes through all three phases: solid, liquid, and gas (see the illustration).
- At 6.11 mbar and 0.0098°C, the melting pressure curve, vapor pressure curve, and sublimation pressure curve meet in one point, the so-called triple point. In this point, all three phases coexist (simultaneously).
- If the vapour pressure is below 6.11 mbar (B) and energy is added, the ice will be directly converted into water vapour once the sublimation curve is reached. This transition is called "sublimation". If thermal energy is added to pure ice with a temperature of less than -30°C at a pressure of 0.37 mbar, it will be converted into water vapour once it reaches -30°C (see figure).

The vacuum prevents the melting of ice when energy is added. If thermal energy is added to a frozen product under vacuum, thawing of the product will be prevented and the water that is contained within the product will be released in the form of water vapour.





Fig. 6: Vapour pressure curve for ice and water

From a physical point of view, the freeze-drying process covers three phases (see figure below):

(1) Freezing: The product to be dried is frozen under atmospheric pressure. This can be done either directly in the freeze-dryer or in a separate deep-freeze. The freezing temperature should be approximately 10°C below the solidification point of the product.

(2) Evacuation: When the product is sufficiently frozen, the vacuum pump is activated. The pressure inside the drying chamber will be lowered to the value that corresponds to the freezing temperature in accordance with the vapour pressure curve for ice and water.

(3) Sublimation: Thermal energy is added to the product, thus starting the sublimation process. Due to the added energy, the water in the product is converted into water vapour. Since the ice condenser is much colder than the product that is to be dried, the vapour pressure in the ice condenser is considerably lower than above the product. As a result, the water vapour that is released by the product streams to the ice condenser, where it condenses on the condenser coils.

Once the free water has been extracted from the product during the main drying phase, the last traces of bound water will also be removed at a final pressure that is as low as possible and at higher temperatures. This takes place by way of \rightarrow *desorption*. This drying phase is also called final drying.





Fig. 7: Freeze-drying phases



Please find further information about basic principles, optimum procedures and applications in the brochure "Smart freeze-drying", which can be downloaded at <u>www.martinchrist.de</u> \rightarrow [Applications] \rightarrow [Lyophilisation].

2.2.2 Freeze-drying process

The main components of a freeze-dryer are:

- vacuum drying chamber or drying manifold,
- vacuum pump for generating a vacuum inside the drying chamber,
- ice condenser for binding the water vapour that is released by the product.

2.2.2.1 Preparation

The ice condenser chamber must be clean and dry. Any water residues from a preceding drying run must be removed.

The media drain valve and the aeration valve must be closed.

In the case of units that are equipped with a pressure control valve (standard on LSCplus and LSCbasic units), the vacuum pump should be warmed up ("warm-up") for at least 15 minutes prior to the start of the main drying phase. Do not subject the vacuum pump to condensable gases until the operating temperature is reached. In this way, the service life of the vacuum pump can be extended.



At the same time, the ice condenser is pre-cooled ("cool-down"). The ice condenser temperature does not have any influence on the product temperature. The sole purpose of the ice condenser is to bind the released water vapour.

2.2.2.2 Freezing

First, the product that is to be dried is frozen. Especially in the case of small filling quantities, we recommend pre-cooling the shelves as well in order to prevent the product from thawing during the evacuation.

Two very different structures of the frozen material can be distinguished:

- · crystalline structures with clearly distinguishable crystals
- amorphous structures with no crystal junctions at all (e.g. glass)

The majority of the freeze-drying products have a crystalline form.

When freezing these kinds of products, one must take into consideration that too deep and too quick freezing leads to smaller ice crystals, which has a negative effect on the duration of the drying process.

For every product to be dried, the solidification point must be determined as a first step. This is the point at which the water that is contained in the product has completely crystallised. In order to ensure an optimum freezedrying process, the product temperature should be approximately 10°C below the solidification point.

2.2.2.3 Main drying

When the product is frozen, the main drying phase commences. The vacuum pump is switched on. The pressure inside the drying chamber will be lowered to the value that corresponds to the freezing temperature in accordance with the vapour pressure curve for ice and water (sublimation pressure curve). At the same time, thermal energy will be added to the product. In the case of products in round-bottom flasks, wide-neck bottles, etc., this is realised through the environment that is considerably warmer (direct contact heat), in the case of unheated shelves by way of thermal radiation from the environment, and in the case of temperature-controlled shelves directly via the shelves. As a result, the sublimation process starts.

At the beginning of the drying process, the maximum drying rate will be reached. The more the sublimation area recedes into the product, the further the produced water vapour must pass through the layers that have already been dried.

Under certain conditions, it is possible that the vacuum inside the ice condenser chamber increases during the main drying phase (e.g. from 0.63 mbar to 0.47 mbar) although the valve towards the vacuum pump is closed. From a physical point of view, this is due to the pumping effect of the ice condenser ("cryo-pumping effect").

The required drying time depends strongly on the drying vacuum. At 1.0 mbar, one gram of ice takes up a volume of 1 m^3 of vapour, at 0.1 mbar a volume of 10 m^3 of vapour, and at 0.001 mbar a volume of 100 m^3 . The closer the vacuum is to the solidification point, the smaller is the resulting vapour volume. The drying rate increases and the drying time decreases.



2.2.2.4 Final drying

Final drying is an option whenever one requires a product with minimal residual moisture. In the physical sense, this process is a desorption process, i.e. the removal of adsorptively bound water. Final drying is performed under the lowest possible final pressure that depends on the ice condenser temperature in accordance with the vapour pressure curve for ice and water as well as on the final vacuum of the vacuum pump that is used. The process is supported by a higher shelf temperature.

2.2.2.5 End of drying and aeration

The end of the drying process is reached when both the product and shelf temperature are clearly in the positive range (+15 to +20°C) and if their difference is not greater than 5 K.

Another indication of the end of the drying process is the behaviour of the vacuum and of the ice condenser temperature. The ice condenser is no longer subject to load and reaches the final temperature of approximately - 55°C or -85°C. The pressure in the drying chamber decreases in accordance with the ice condenser temperature.

The vacuum pump will be switched off and the drying chamber will be aerated via a rubber valve or via the aeration valve. The aeration valve can also be used to flood the unit with nitrogen or another inert gas instead of ambient air.

Then, the product can be removed from the unit.

2.2.2.6 Defrosting

Defrosting of the ice condenser is carried out at room temperature or with warm water.

- At a maximum, the ice condenser chamber may be half filled with water.
- Ensure that no water gets into the pipe connection of the vacuum pump and the vacuum sensor (behind the cover plate, see figure)

1 Cover plate



Fig. 8: Eis condenser chamber



• Drain the condensate through the media drain valve at the left side of the freeze-dryer by attaching a hose on the nozzle (included in the scope of supply) and placing a vessel underneath.

In order to avoid damage, the condensate must be removed directly after the completion of the defrosting process. Then, any residual water must be removed from the ice condenser chamber by way of a cloth.

3 Safety



3 Safety

3.1 Marking of the unit

The following symbols are used for Christ freeze-dryers:

	Dangerous voltage		On (Power)	
	Hot surface	0	Off (Power)	
	Caution! Risk of bruising		Name plate (see chapter 2.1.2 - "Name plate")	
	Attention, consult the operating manual	CHRIST natürliches / natural Kältemittel / refrigerant	Filled with natural inflammable refrigerants	
	Protective earth (ground)	CE	CE mark in compliance with the directive 2006/42/EC	
Ŧ	Earth (ground)		China RoHS 2 mark (only for China)	
Ê	Unplug the mains plug			
Safety indications on the freeze-dryer must be kept readable at all times.				

NOTE NOTE

Not all of the symbols/labels are used for this type of freeze-dryer.



3.2 Explanation of the symbols and notes

This operating manual uses the following names and symbols to indicate hazards:



This symbol stands for a $\underline{\text{direct}}$ hazard to the life and health of persons.

Non-observance of these symbols <u>causes</u> serious health problems up to life-endangering injuries.



This symbol stands for a <u>direct</u> hazard to the life and health of persons due to electrical voltage.

Non-observance of these symbols <u>**causes**</u> serious health problems up to life-endangering injuries.



This symbol stands for a **<u>potential</u>** hazard to the life and health of persons.

Non-observance of these symbols <u>can</u> cause serious health problems up to life-endangering injuries.



This symbol indicates a potentially hazardous situation

Non-observance of these notes can cause minor injuries or damage to property.



This symbol indicates important information.



3 Safety

3.3 Responsibility of the operator

Operating personnel

The operator is obliged to ensure that the persons working on/with the freeze-dryer

- have been specifically ordered to do so by the operator/owner and that they have been duly informed about the specific hazards associated with the system, supply media and starting/final products as well as about the correct conduct and necessary measures to take in the event of accidents or malfunctions,
- are familiar with the fundamental health, safety and accident prevention regulations,
- have been trained in terms of the operation of this system,
- have read and understood this operating manual (in particular the safety sections and warning notes) and confirmed this with their signature.

The areas of responsibility of the personnel concerning the operation, maintenance and care of the unit must be clearly defined.

The safety-conscious work of the personnel in compliance with the operating manual and the relevant EC health and safety directives and the national laws concerning health and safety and the prevention of accidents must be checked at regular intervals (e.g. every month).

Working area

The operator must

- perform a risk assessment concerning potential accidents in connection with the freeze-dryer and take design-related countermeasures, if necessary.
- perform a risk assessment in view of the specific hazards associated with specific products that are freeze-dried in the freeze-dryer (e.g. ignition/explosion hazard, discharge of harmful product residues at the outlets of the chamber) and take the corresponding measures, if necessary.
- perform a compatibility test of all the substances that are used in the freeze-dryer (products to be dried as well as cleaning agents, etc.) and that come into contact with the chamber walls, shelves, pipes/hoses and seals. Substances that damage the material or weaken the mechanical strength must not be used.
- have the system maintained at regular intervals (see chapter 8 -"Maintenance and service").

Any parts or components that are not in perfect working order must be replaced without delay.



Additional points concerning the freeze-drying of solvent-containing products

With regards of corrosion resistance, the use of some organic solvents in aqueous solutions with low concentrations is acceptable.

Under certain circumstances, the freeze-drying of products containing solvents may lead to the formation of explosive mixtures. This is why the operator must draw up special operating instructions/SOPs including precise instructions

- concerning the deactivation of specific components, such as PT100 (see chapter 1.2 - "Intended use", section "Freeze-drying of solventcontaining products"),
- concerning the deactivation of the hot-gas defrosting of the ice condenser (if included) depending on the solvent that is used,
- concerning the chamber pressure and shelf temperature for every product that is to be processed in the freeze-dryer,
- concerning the inspection of the freeze-dryer in view of damage caused by the solvent that is used (siehe chapter 1.2 - "Intended use", Absatz "Trocknung lösungsmittelhaltiger Ausgangsprodukte").

3.4 Requirements concerning the personnel



Risk of injury if the personnel are not sufficiently qualified

If unqualified personnel perform work on the freeze-dryer or are present in the danger zone of the freeze-dryer, hazards result that can cause serious injuries and considerable damage to property.

- Ensure that all the tasks are performed by personnel with the corresponding qualifications.
- Ensure that unqualified personnel stay clear of the danger zones.



Risk of fatal injury to unauthorised persons due to hazards in the danger zone or work area

Unauthorised persons who do not fulfil the requirements described herein are not aware of the hazards in the work area. This is why there is a risk of serious or even fatal injuries for unauthorised persons.

- Ensure that unauthorised persons stay clear of the danger zone and work area.
- If in doubt, address these persons and instruct them to leave the danger zone and work area.
- Interrupt any running work if unauthorised persons are present in the danger zone or work area.

This manual uses the following personnel qualifications for various areas of activity:

Qualified electrician

Due to their special training, knowledge, experience and familiarity with the relevant standards and regulations, qualified electricians are in the position to perform work on electrical systems and to autonomously identify and prevent possible hazards.



3 Safety

Qualified electricians have been specifically trained for the environment in which they work and they are familiar with all the relevant standards and regulations.

Qualified electricians must fulfil the requirements as set out in the applicable legal provisions concerning the prevention of accidents.

Specialised personnel

Due to their special training, knowledge, experience and familiarity with the relevant regulations, specialised personnel are in the position to perform any tasks assigned to them and to autonomously identify and prevent possible hazards.

Operating personnel

It must be ensured that persons operating the unit

- have been specifically ordered to operate the unit and made aware of dangers originating from the freeze-dryer, supply media, starting and end products by the operator,
- are familiar with the fundamental regulations concerning workplace safety and accident prevention
- have been trained in terms of the operation of this unit, and
- have read and understood this operating manual (and in particular the safety sections and warning notes) and confirmed this with their signature.

3.5 Informal safety notes

This operating manual is part of the product.

- This operating manual must be kept at the location of use of the freezedryer. Ensure that it is accessible at all times.
- The operating manual must be handed over to every subsequent owner or user of the freeze-dryer.
- Any changes, additions or updates received must be added to the operating manual.
- In addition to the operating manual, the general and operational rules and regulations for the prevention of accidents and the protection of the environment must be provided.
- All of the safety and hazards notes on the freeze-dryer must be kept readable at all times. If necessary, they must be replaced.



3.6 Safety notes concerning the transport, set-up and connection and initial start-up of the freeze-dryer

The following notes and instructions must be observed in order to protect all persons and property.

3.6.1 General hazards



General risk of injury

Among the general hazards during the transport, set-up and connection and start-up of the freeze-dryer are impact hazards, crushing hazards, grazing hazards, cutting hazards, etc.

- This may lead to severe injuries.
- Comply with the fundamental health and safety rules and regulations as well as with the rules and regulations for the prevention of accidents!
- Wear personal protective equipment (safety shoes, work gloves, and hardhat)!

3.6.2 Hazards caused by improper transport



Risk of injury caused by the uncontrolled movement of loads

Units that are not properly fastened or secured may shift, or fall over.

 Prior to transporting or setting-up the freeze-dryer, read the chapter 4 -"Storage and transport" thoroughly!

3.6.3 Hazards caused by improper set-up



Risk of injury caused by poor accessibility of the freeze-dryer In cramped spaces or locations with poor accessibility, sharp edges and

In cramped spaces or locations with poor accessibility, sharp edges and corners may protrude into the work area.

This may lead to injuries caused by impact hazards or grazing hazards.

- Ensure that the freeze-dryer is set up freely accessible!
- Comply with the fundamental health and safety rules and regulations as well as with the rules and regulations for the prevention of accidents!





3.6.4 Hazards caused by improper connection



Risk of injury caused by consequences of improper connection Improper connection may lead to a hazardous electrical incident at a later time during the operation of the freeze-dryer.

This may lead to severe damage to health or even life-threatening injuries.

- Ensure that the local mains voltage matches the nominal voltage that is stated on the name plate.
- Do not place any dangerous material, e.g. glass vessels containing liquid substances, within the safety area of 30 cm around the freezedryer. Spilled liquids may get into the freeze-dryer and damage the electrical or mechanical components.
- Work on the power supply system must only be performed by certified electricians.
- Have the electrical equipment of the unit inspected regularly.
- Defects such as loose or burnt cables must be eliminated immediately.

3.7 Safety notes concerning the operation

The following notes and instructions concerning the operation of the freezedryer must be observed in order to protect all persons and property.

3.7.1 Hazards caused by electricity



Danger of life caused by electric shock

There is a risk of electric shock when touching current-carrying components.

This may lead to ventricular fibrillation, cardiac arrest, or respiratory paralysis.

- Only qualified electritians are authorised to perform work on the electrical system of the freeze-dryer!
- The electrical equipment of the freeze-dryer must be checked at regular intervals by a qualified electrician!
- Defects such as loose connections or burnt cables must be eliminated immediately.



3.7.2 Hazards caused by the refrigeration system (natural, flammable refrigerants)



Risk of explosion due to refrigerants

The refrigerants used are highly flammable and can form an explosive mixture if their concentration in the ambient air is sufficiently high. There is an explosion hazard.

Work on the refrigeration system of the freeze-dryer must only be carried out by qualified specialist personnel who have been trained to handle flammable refrigerants!

• Ensure good ventilation and make sure that no ignition sources (e.g. soldering iron, welding equipment) are present!

3.7.3 Hazards caused by harmful products



Risk of poisoning/infection caused by the products When loading and unloading the drying chamber, the personnel are exposed to the product.

Skin contact or the inhalation of particles may cause severe damage to health depending on the product in question.

Wear suitable protective clothes, gloves, and respiratory protection!

Risk of poisoning/infection caused by the products

When performing maintenance work on parts coming into contact with the product (e.g. all parts inside the chamber), the personnel may be exposed to product residues.

Skin contact or the inhalation of particles may cause severe damage to health depending on the product in question.

- Take suitable decontamination measures prior to commencing the maintenance!
- Wear suitable protective clothes, gloves, and respiratory protection!

3.7.4 Hazards caused by solvents in the products



Explosion hazard caused by solvents in the products

When freeze-drying products containing solvents, gas mixtures may form. These gas mixtures may be ignited on certain components of the freezedryer.

There is an explosion hazard.

- Solvents that are not included in the table in chapter 1.2 "Intended use", or the listed solvents in a concentration higher than 10% by volume, must not be used!
- Refer to the safety data sheets of the products that are used!

3 Safety



3.7.5 Hazards caused by acids in the products



Risk of injury caused by acids in the products

Products containing acids may damage the material of the components of the freeze-dryer and affect the mechanical strength.

This may lead to severe injuries.

- Freeze-drying of products containing acids is only permissible if special protective measures and equipment-related precautions are taken! Consultation of Martin Christ Gefriertrocknungsanlagen GmbH is absolutely mandatory in order to define the measures that need to be taken!
- Refer to the safety data sheets of the products that are used!

3.7.6 Hazards caused by contaminated condensate (defrosting water)



Risk of poisoning/infection caused by contaminated condensate (defrosting water)

The condensate may contain harmful substances originating from the product.

Contact with the condensate may cause severe damage to health.

- Ensure the environmentally sound disposal of the condensate in compliance with the local rules and regulations!
- Wear suitable protective clothes, gloves, and respiratory protection when performing any work on the drain system (especially when cleaning the valves and replacing the seals)!

3.7.7 Hazards caused by hot surfaces



Risk of burns on hot surfaces

After a drying process, the surfaces inside the chamber may still be hot. There is a risk of burns when touching the surfaces.

- · Wear suitable protective clothes and gloves!
- Do not touch the surfaces on purpose!

3.7.8 Hazards caused by cold surfaces



Risk of freezing to cold surfaces

The ice condenser coils can already be cold during the loading phase. There is a risk of freezing to the ice condenser coils when touching the surfaces.

- Wear suitable protective clothes and gloves!
- Do not touch the surfaces on purpose!



3.8 Safety devices

3.8.1 System check

An internal system check system monitors the data transfer and sensor signals with regard to plausibility. Errors are detected by continuous self-monitoring of the system. Error messages are displayed in the main window under "Process & equipment messages" (see chapter 6.5.3.3 - "Process and equipment information").

3.8.2 Earth conductor check

For the earth conductor check, there is an equipotential bonding screw on the rear panel of the freeze-dryer. An earth conductor check can be carried out with the aid of a suitable measuring instrument.

3.9 Procedures in the event of hazards and accidents

Hazardous electrical incident:

• Set the control switch to the "0" position in order to interrupt the power supply completely.

Fire:

- A fire in the electrical control system must be extinguished with a CO₂ fire extinguisher!
- Burning oil must be extinguished with a CO₂ fire extinguisher or powder fire extinguisher!

Electric shock:

 While ensuring your own safety, interrupt the circuit as quickly as possible (control switch). Keep the affected persons warm and calm.
Get medical attention immediately! Check consciousness and breathing continuously. In the case of unconsciousness of lack of normal breathing, perform cardiopulmonary resuscitation (CPR).

Burns:

- Cool small-area burns (e.g. finger) immediately with cold water for approximately 2 minutes.
- Do not cool if larger areas of the body surface are burnt since there is a risk of hypothermia.
- Cover the burns loosely and in a sterile manner (e.g. with sterile dressing).
- Keep the affected persons warm and calm.

IF IN DOUBT, CALL THE EMERGENCY PHYSICIAN (AMBULANCE)!

3 Safety



3.10 Maintenance and cleaning of the freeze-dryer

The substances and materials that are used must be properly handled and disposed of (Please refer to the safety data sheets!). This applies particularly to

- the handling of solvents, lyes, and acids,
- the changing and topping-up of operating supplies.

Compliance with the national rules and regulations must be ensured.

3.11 Measures to be taken to ensure safe operation of the freeze-dryer

In order to ensure the safe operation of the freeze-dryer, please comply with the following points prior to every freeze-drying process:

Set-up, connection and operation

- Ensure that the freeze-dryer was set up and connected properly (see chapter 5 "Set-up and connection").
- Check the freeze-dryer and the accessories before every start-up for any visible signs of damage.
- Do not hit or move the freeze-dryer during its operation.
- Do not lean against or rest on the freeze-dryer during its operation.
- Stop the freeze-dryer immediately in the event of a malfunction. Eliminate the malfunction (see chapter 7 - "Malfunctions and error correction") or contact the after-sales service of Firma Martin Christ Gefriertrocknungsanlagen GmbH (see chapter 7.3 - "Service contact").
- Ensure that all repairs are performed only by authorised and specialised personnel.

Fire prevention

• Fuses protect certain electrical circuits within the freeze-dryer against over-current conditions. Always use fuses of the same type and rating.

Safety area

- Maintain a safety distance of at least 30 cm (12 inches) around the freeze-dryer.
- Do not store any dangerous goods in the safety area of the freezedryer.
- Do not place any dangerous material, e.g. glass vessels containing liquid substances, within the safety area of 30 cm around the freezedryer. Spilled liquids may get into the freeze-dryer and damage the electrical or mechanical components.
- Do not stay in the safety area longer than what is absolutely necessary for the operation of the freeze-dryer.



Accessories

- Do not use the freeze-dryer with accessories that shows signs of damage.
- Only use accessories that have been approved by the manufacturer (except for commercial vessels made of glass or synthetic materials).
 We explicitly warn against the use of equipment of poor quality!
 Breaking glass or bursting vessels can cause dangerous situations.

Handling hazardous materials

- The generally applicable regulations for handling flammable substances in laboratories / workplaces must be observed.
- During sample preparation, loading and unloading of samples and defrosting, appropriate safety precautions must be observed.
- Depending on the used solvent, hot gas defrosting should be avoided.
- Caution when handling hazardous materials such as strong acids or bases, radioactive substances and volatile organics: If such substances are spilled, they must be cleaned up immediately.
- If a sample with hazardous materials such as strong acids or bases, radioactive substances or volatile organics is spilled inside a chamber, they must be cleaned up immediately.
- Caution when handling solvents: Keep sources of ignition away from solvents.
- When using flammable or hazardous solvents, the vacuum pump must be vented to or operate inside a fume hood.

3.12 Remaining hazards

All Christ freeze-dryers were built state-of-the-art and according to the accepted safety rules. Danger to life and limb of the operator, or of third parties, or impairments of the units or other material assets, however, cannot be completely excluded when the units are being used.

Use the freeze-dryer

- only for the purpose that it was originally intended for (see chapter 1.2 -"Intended use") and
- only if it is in a perfect running state.
- Immediately eliminate any problems that can affect safety.

4 Storage and transport



4 Storage and transport

4.1 Dimensions and weight

Values for the freeze-dryer without a vacuum pump:

	Alpha 1-2 LDplus
Height:	345 mm
Width:	315 mm
Depth (including vacuum connection):	460 mm
Weight:	approx. 28 kg

4.2 Storage conditions

In order to ensure the protection against mechanical and climatic influences, the guidelines of the German Federal Association for Wooden Packages, Pallets, and Export Packaging (Bundesverband Holzpackmittel, Paletten, Exportverpackung e.V.), the so-called HPE packaging guidelines, must be applied when packing and storing the freeze-dryer.

The storage must be:

- dust-free
- dry

•

- free from excessive temperature fluctuations
- free from a mechanical load.



4.3 Notes on transport

- Use suitable packaging for the transport, and if at all possible, the original packaging.
- Install all transport safety devices (see chapter 4.5 "Transport safety device").
- Over short distances, the freeze-dryer can be transported by a suitable number of persons who reach under it from the sides.
- When lifting the freeze dryer, always reach under the freeze-dryer from the side. Do not grab the unit at the plastic control panel (see figures below).



Fig. 9: Lifting the freeze-dryer



The freeze-dryer Alpha 1-2 LDplus weighs approx. 28 kg!

• When setting the unit down, ensure that the feet are upright (see figures below).





Fig. 10: Unit feet



4 Storage and transport

4.4 Packaging

The freeze-dryer is packaged in a cardboard box or in a wooden crate, depending on the scope of supply.

- After opening the packaging, take out the box containing the accessories.
- Remove the packaging material.
- Lift the freeze-dryer upwards and out of the crate/cardboard box. When lifting the unit, always reach under the freeze-dryer from the side.



The freeze-dryer Alpha 1-2 LDplus weighs approx. 28 kg!

• Retain the packaging for any possible future transport of the freezedryer.

4.5 Transport safety device

Prior to start-up, the vacuum sensor must be installed (see chapter 5.4 - "Vacuum sensor").



Prior to any transport, the vacuum sensor must be deinstalled.




5.1 Location of use

Use the freeze-dryer solely in closed and dry spaces.



Refrigeration problems of the freeze-dryer are often caused by insufficient conditions at the location of use. This is why compliance with the following conditions is absolutely mandatory!

- The table must be stable and have a solid, even tabletop
- Ensure sufficient ventilation. Do not place any paper, cloth or similar material behind or under the unit, since otherwise the air circulation will be impaired.
- Keep a safety distance of at least 30 cm around the freeze-dryer so that the vents in the unit remain fully effective.
- The ambient temperature must be in the range of +5°C to +25°C. A potential night-time setback of the air conditioning system must be taken into consideration.
- Prevent the room temperature from rising, for example due to closed doors at night.
- Do not subject the freeze-dryer to thermal stress, e.g. by positioning it near heat generators.
- Prevent thermal overload, e.g. caused by other equipment in the direct vicinity of the freeze-dryer.
- Do not set up the vacuum pump in the area of the heat exchanger ventilation grid (see chapter 2.1.1 "Functional and operating elements").
- In the case of water-cooled systems, ensure that the water circuit provides a sufficient amount of cooling water.
- Avoid direct sunlight (UV radiation).



5.2 Power supply

5.2.1 Type of connection

	Danger of life caused by electric shock
/4	There is a risk of electric shock when touching current-carrying components.
DANGER	This may lead to ventricular fibrillation, cardiac arrest, or respiratory paralysis.
	 Only qualified electritians are authorised to perform work on the electrical system of the freeze-dryer!
	 The electrical equipment of the freeze-dryer must be checked at regular intervals by a qualified electrician!
	 Defects such as loose connections or burnt cables must be eliminated immediately.
DANGER	The operating voltage on the name plate must correspond to the local supply voltage!
	Christ freeze-dryers are units of protection class I. Freeze-dryers of this

Christ freeze-dryers are units of protection class I. Freeze-dryers of this type have a three-wire power cord with an IEC C13 connector (see chapter 10 - "Technical data").



The removable power cord must not be replaced with a power cord of inadequate rating!

An equipotential bonding screw is located on the back below the mains power input (see chapter 2.1.1 - "Functional and operating elements"). This equipotential bonding screw can be used to perform an earth conductor check.

5.2.2 Customer-provided fuses

Sufficiently rated fuse protection of the freeze-dryer in the electrical system of the building is required.



5.3 Aeration and media drain valve

The aeration and media drain valve is located on the left side of the unit (see chapter 2.1.1 - "Functional and operating elements").

After the end of a freeze-drying process, the unit will be aerated via the aeration valve.

Additionally, it is used to drain off the condensate and the defrosting water.

- Connect the drain hose (included in the scope of supply) to the hose connector.
- Place a collecting vessel under the unit.

The hose must be laid with a continuous slope and the end of the hose must always be above the liquid level in the collecting vessel. This prevents water and dirt residues from being sucked into the ice condenser chamber if there is negative pressure when the media drain valve is opened.

5.4 Vacuum sensor



Please refer to the separate operating manual of the vacuum sensor!

In order to protect the vacuum sensor against transport damage, it comes supplied in its original packaging. Prior to commissioning the freeze-dryer, the sensor must be installed.

- 1 Vacuum sensor
- 2 Clamping rings
- 3 Connection socket



Fig. 11: Position of the vacuum sensor and the connection socket

- Switch the unit off by actuating the mains power switch.
- Take the vacuum sensor out of its original packaging and fasten it to the connector with a bow-shaped connecting piece, two clamping rings (DIN16KF) and two centring rings (included in the scope of supply).



•

screws on the connector.

Î NOTE

It is absolutely essential to comply with the manufacturer's instructions in the separate operating manual of the vacuum sensor!

Plug the connector to the connection socket and hand-tighten the



Fig. 12: Vacuum sensors of different manufacturers



The vacuum sensor comes supplied in a calibrated state.

After the freeze-dryer has been switched on, the vacuum sensor needs several minutes until it is ready for operation.



5.5 Vacuum pump



It is absolutely essential to refer to the separate instruction manual of the vacuum pump and exhaust filter (if applicable)!

The vacuum pump must be connected to the vacuum connection of the unit and to the electrical socket at the back of the unit, which is marked accordingly (see chapter 2.1.1 - "Functional and operating elements").



The vacuum pump is supplied with power by the unit, but the maximum current for the vacuum pump is limited. It is absolutely essential to refer to the label of the electrical outlet for the vacuum pump (see the following picture)!

If the current requirement of the vacuum pump is higher than the value that is stated on the label, the pump must be supplied separately via an on-site power socket.

 • VI-XD120 Drecksteuervertil Presure Control Valv

 • Presure Control Valv

 • max. 3A

 • max. 3A

 • Max. TABLE

 <td

Fig. 13: Indication of the maximum current for the vacuum pump (example)

The oil mist that escapes from the pump during operation must be retained or discharged via an exhaust filter (oil mist separator).

- We strongly recommend using an oil mist separator. The filter prevents air pollution by the oil mist that is emitted more or less strongly by the pump depending on the working pressure.
- The exhaust gases must be discharged in a proper manner.
- The hose line must be laid in such a manner that any condensation water cannot flow back into the pump. In the case of a rising hose line, we recommend using a condensate trap (Woulff bottle or wash bottle).

1 Label indicating the maximum current



5.6 Pressure control valve

The pressure control valve is integrated in the suction pipe between the vacuum pump and ice condenser chamber. During certain, specified process phases, it interrupts the volume flow to the vacuum pump (see chapter 2.2.1 - "General information on freeze-drying").



Pressure control

valve

1

Observe the installation direction of the pressure control valve!

Fig. 14: Installation of the pressure control valve



5.7 Rubber valves

The rubber valves (part no. 121860) enable the connection of round-bottom flasks, wide-neck filter bottles, or distributors for ampoules to a manifold or drying chamber. Depending on the connector of the components, the blue plug can be removed.

- 1 Locking handle
- 2 Aeration connection
- 3 Vessel connection
- 4 Rubber plug
- 5 Connection to freezedryer (e.g. via a manifold)



Fig. 15: Rubber valve



The rubber valves come supplied in an ungreased state. This is why a thin layer of vacuum grease must be applied to the connector of the freezedryer as well as to the vessel connector prior to start-up in order to ensure trouble-free operation.

In position A (see figure below), the aeration connector is open and the vessel connector is closed. The accessory will be aerated while the vacuum inside the drying chamber is maintained. As a result, vessels can be exchanged without any interruption of the drying process.

In position B, the aeration connector is closed and the vessel connector is open. The connected accessory is connected to the freeze-dryer.

In position C, the aeration connector and the vessel connector are closed.



Fig. 16: Possible positions of the locking handle

6 Operation



6 Operation

6.1 Initial start-up



Before the initial start-up, please ensure that your freeze-dryer is properly set up and installed (see chapter 5 - "Set-up and connection")

6.2 Installation of accessories

The accessories must be completed in accordance with the drying method that is applied as well as in accordance with the scope of supply.

6.3 Preparation

The ice condenser chamber must be clean and dry.

- Remove any water residues from the preceding run.
- Close the aeration valve and the media drain valve.
- Ensure that all of the valves of the accessories are closed.
- Switch the vacuum pump on.

6.4 Switching the freeze-dryer on

• Actuate the mains switch.

The control unit performs a self-test and an initialisation. This may take several seconds.

 Follow the safety instructions and hazard warnings (see chapter 3 -"Safety")!



6.5 LDplus control system

The control system LDplus ("Lyo Display plus") was specifically developed for the control of freeze-drying processes. The clear user interface enables the intuitive operation of the unit.



Fig. 17: Start screen of the LDplus control system (example)

6.5.1 User interface

- 1 Left function key
- 2 Right function key
- 3 "Up" key
- 4 "Down" key
- 5 Display



Fig. 18: User interface of the LDplus control system

Function keys (1+2)

Function keys are keys whose function depends on the menu and operating state of the unit. The current function is displayed directly next to the key in the field with a black background.

Ice condenser	Section time
°C	h:m
-40	0:0000
mode Standby	menu

Fig. 19: Indication of the current functions of the function keys; here, on the left, the "mode" function and on the right the "menu" function.

"Up" and "down" keys (3+4)

These keys are used to select the functions and values that are available in the menu or to change the selected parameters.

In addition, these keys also control the indication of the measurement value channels in the value windows. The "up" key is assigned to the left value window, whereas the "down" key controls the right value window.

• For a selection, press the "up" or "down" key repeatedly until the desired measurement value channel is indicated in the respective value window.

6 Operation



Display (5)

The main window of the display is divided into the value windows, an area indicating the current function of the function keys, and a status line. The main window displays all of the relevant process data, such as set and actual values, menus, and process information (see the illustration).

- 6 Value window
- 7 Current function of the function keys
- 8 Status line



Fig. 20: Layout of the LDplus control system display

Value windows (6)

The value windows are displayed after the initialisation of the control system. There are two value windows with an identical layout. The indication of the measurement value channels is controlled by way of the "up" and "down" keys (see above).

- 9 Measurement value channel
- 10 Set value (only in the run mode)
- 11 Unit of the measurement value
- 12 Actual value



Fig. 21: Value windows

The available measurement values can be displayed in the left as well as in the right value window so that a combination of the following values can be selected:

- Total time (indicates the total runtime of the process)
- Section time (indicates the runtime of an individual phase, e.g. freezing, warm-up of the vacuum pump, or main drying)
- Ice condenser temperature
- Vacuum in mbar (indicates the vacuum in the drying chamber; only possible if a vacuum sensor is installed)
- Vacuum converted into °C (indicates the vacuum inside the drying chamber, converted based on the vapour pressure curve for ice and water, see chapter 2.2.1 - "General information on freeze-drying"; only possible if a vacuum sensor is installed)

<u>Current function of the function keys (7)</u> See function keys (1+2)



Status line (8)

The status line at the bottom of the screen indicates the current operating state, active phase, and any pending information. The status line is visible at all times.

- 13 Symbol of the operating state
- 14 Active phase15 Symbol of pending information



Fig. 22: Status line

Operating state (13)

- Standby The freeze-dryer is in the standby mode. All of the various units are switched off.
- ▶ co The freeze-dryer is in the run mode. The unit performs a continuous run.
- (-) The freeze-dryer is in the run mode. The timer is activated.

Active phases (14)

- Freezing The ice condenser is cooled.
- Warm-up The ice condenser is cooled and the vacuum pump is activated while the pressure control valve is closed. If no pressure control valve is integrated, the drying chamber must be separated from the vacuum pump by way of a manual valve or similar.
- Main drying The drying chamber is evacuated while the ice condenser is cooled. If a vacuum control system is included, the vacuum is controlled based on the corresponding set value for the main drying phase.
- Final drying The final drying phase is only available if a vacuum control system is included. It is possible to define different control parameters (set vacuum, timer) for the main drying and final drying phases.

Pending information (15)

i

The symbol flashes every second if there is pending information concerning the process or the freeze-dryer (error messages, process messages, or general information).

The information can be viewed under "Process & equipment info" (see chapter 6.5.3.3 - "Process and equipment information")

6 Operation

6.5.2 Mode

The mode can be called up with the left function key if a value window is active. The individual phases can be selected as follows:

HRIS

- Press the left function key "mode". The menu "Start with phase..." will be displayed (see the illustration).
- Select the desired menu item by way of the up/down keys.
- Confirm with the right function key "enter".

Start v	vith phase
F	reezing
Warm-u	p vacuum pump
Ma	ain Drying 🔰 🗍
back Standby	enter

Fig. 23: Selecting a mode

Starting the freeze-drying process

The freeze-drying process comprises four phases:

- Freezing
- Warm-up vacuum pump
- Main drying
- Final drying

If "main drying" or "final drying" is selected, the system enquires as to whether the vacuum pump shall warm up beforehand.

Changing the phase

The freeze-dryer is in the run mode. In order to switch over to the next phase or to stop the process by way of "standby":

 Press the left function key "mode". The menu "Select mode" will be displayed (see the illustration).

Select mode	
Continue with phase	<u> </u>
Standby	
	U
back ► ∞ Freezing	enter

Fig. 24: Selecting a mode

- Select the menu item "Continue with phase..." by way of the up/down keys and confirm the selection with the right function key "enter".
- Select the desired phase by way of the up/down keys and confirm the selection with the right function key "enter".

Continue with phase	
Freezing	0
Warm-up vacuum pump	
Main Drying	U
back 🕨 🕨 🗠 Freezing	enter

Fig. 25: Continuing the freeze-drying process



Warm-up vacuum pump

Prior to a freeze-drying process, the vacuum pump usually needs to warm up in order to reach its operating temperature.

For this purpose, the warm-up phase can be started. The desired duration can be preselected (see chapter 6.5.3.4 - "Options").

The following processes take place during the warm-up phase.

- The ice condenser is cooled.
- The vacuum pump is activated while the pressure control valve is closed. If no pressure control valve is integrated, the drying chamber must be separated from the vacuum pump by way of a manual valve or similar.

After the preset warm-up time, the following information will be displayed:



Fig. 26: Message at the end of the warm-up phase

• Confirm the message and continue the process with the desired phase.

Aborting the warm-up phase

During the warm-up phase, the functions "Continue with phase" or "Standby" can be selected by way of the left function key "mode". Selecting one of these functions will abort the warm-up phase.



6 Operation

6.5.3 Main menu

•

The main menu can be selected from the main window by way of the right function key "menu". It includes the following submenus:

- Change set values (see chapter 6.5.3.1 "Changing set values")
- Special functions (see chapter 6.5.3.2 "Special functions")
- Process & equipment info (see chapter 6.5.3.3 "Process and equipment information")
- Options (see chapter 6.5.3.4 "Options")
- Tutorial (see chapter 6.5.3.5 "Tutorial")
- 1 Menu bar
- 2 Menu title
- 3 Selection frame
- 4 Scroll bar
- 5 Function key "exit menu"
- 6 Function key "open menu item"



Fig. 27: Layout of the main menu

6.5.3.1 Changing set values

• Select the "Change set values" function in the main menu.

Change set values	
Freezing	
Main Drying	[
Final Drying	Ų
back Standby	enter

Fig. 28: Menu "Change set values"

• Select the set value by way of the up/down keys. The selected value will be displayed in a selection frame.

Set values main drying		
Timer		∞h:m 🔋
Vacuum	-20 °C	1.0 mbar
back ■ Standby		edit

Fig. 29: Manual mode - set value selection

 Confirm with the right function key "edit". The selected value will be displayed in inverted form.

Set values main drying		
Timer		∞h:m [
Vacuum	-20 °C	1.0 mbar
cancel Standby		ok

Fig. 30: Inverted indication of the selected set value



- Change the set value by way of the up/down keys.
- Confirm with the right function key "ok".

The modification of the set value is now complete.

Set values for the "freezing" phase

<u>Timer</u>

The timer is used to define the duration of the phase. Settings between one minute and 200 hours are possible. If, when starting at 00:00 h:m, the "down" key is pressed, the symbol ∞ will appear. It indicates that the timer is deactivated and that the freeze-dryer is in the continuous mode. After the preselected time has elapsed, the system enquires as to whether the next phase is to be started.



It is possible to specify an automatic phase change from "Freezing" to "Warm-up vacuum pump" (see chapter 6.5.3.4 - "Options" / Settings / Automatic phase change).

Set values for the phases "Main drying" and "Final drying"



The set values for the "Final Drying" phase are only available if the optional pressure control system is installed.

<u>Timer</u>

The timer is used to define the duration of the phase. Settings between one minute and 200 hours are possible. If, when starting at 00:00 h:m, the "down" key is pressed, the symbol ∞ will appear. It indicates that the timer is deactivated and that the freeze-dryer is in the continuous mode.



It is possible to specify an automatic phase change from "Main drying" to "Final drying" (see chapter 6.5.3.4 - "Options" / Settings / Automatic phase change).

Vacuum



For this set value, the optional vacuum control system must be installed.

The range of possible values goes from 6.1 mbar to 0.0010 mbar, converted into steps of 1°C in accordance with the vapour pressure curve for ice and water (see chapter 2.2.1 - "General information on freeze-drying").

6 Operation



6.5.3.2 Special functions

The freeze-dryer is equipped with one or several optional accessories. The components can be controlled by way of this function.

- Select the "Special functions" function in the main menu.
- Select the option by way of the up/down keys. The selected value will be displayed in a selection frame.

Special functions	
Defrosting ice condenser	
Lifting hoist	[
	Ų
back Standby	enter

Fig. 31: "Special functions" menu

- Confirm with the right function key "enter". The possible functions will be displayed.
- If an option is selected that is not installed, a corresponding message will be displayed:



Fig. 32: Message if an option is not available

Defrosting the ice condenser

As standard, the freeze-dryer is equipped with a defrosting system. The ice condenser chamber is supplied with heat that melts the ice off the ice condenser.

The freeze-dryer must be in the standby mode and completely aerated.



During the defrosting process, the chamber should not be covered in order to prevent the deactivation of the system due to overheating.

- The defrosting time and temperature can be set in the main menu under "Options" (see chapter 6.5.3.4 "Options").
- Select the function "Defrosting ice condenser" under "Special functions" in the main menu (see above).
- Start the defrosting process by way of the right function key "start".

The progress of the defrosting process will be displayed in a dialogue box.

Defrosting ice condenser		
Temperature D	efrosting	21°C
0:00 h:m	26 %	0:01 h:m
►©□	efrosting	stop

Fig. 33: Progress bar of the defrosting process

When the specified defrosting time has elapsed, the defrosting process will be stopped. The dialogue box disappears automatically.



Option: Electrical lifting hoist

The freeze-dryer can be retrofitted with an electrical lifting hoist that facilitates the attachment and removal of drying chambers.

The freeze-dryer must be in the standby mode and completely aerated.



The drying chamber cannot be moved in the "Main drying" and "Final drying" phases.

- Select the function "Lifting hoist" under "Special functions" in the main menu (see above).
- Move the drying chamber by way of the up/down keys.



Fig. 34: Operation of the electrical lifting hoist

• After the completion of the process, exit the menu via the left function key "back".

6.5.3.3 Process and equipment information

The menu "Process & equipment info" provides the user with information concerning error, process, and system messages.

In the event of a message, a sound signal will be issued, the symbol "i" will appear on the status line, and the process and equipment information window will be displayed. If the user is currently in a menu, the window will not be displayed until the user exits the main menu.

- 1 Message
- 2 Status of the information
- 3 Number of active messages
- 4 Function key "exit menu"
- 5 Function key "acknowledge message"



Fig. 35: Structure of the "Process & equipment info" menu



6 Operation

Regardless of the presence of a message, the menu can be activated at all times in order to view any messages that are present.

• Select the "Process & equipment info" function in the main menu.



The error messages are listed in detail under chapter 7 - "Malfunctions and error correction".

Status of the information

All of the information that is displayed receives a certain status:

- Information present, not acknowledged
- 💿 🛹 Information present, acknowledged
- Cause of the message no longer present, information not acknowledged

The sound signal is issued until all of the information has been acknowledged.

If the cause of the message is no longer present and if the information has been acknowledged it will be removed from the process and equipment information window.

The menu cannot be exited by way of the left function key "back" until all of the information has been acknowledged.

6.5.3.4 Options

The following values can be adjusted in the "Options" menu:

- · Display contrast
- Language
- Settings
- Service menu

Options	
Change display contrast	
Select language	[
Settings	U
back Standby	enter

Fig. 36: "Options" menu

Changing the display contrast

- · Select the menu "Change display contrast".
- Adjust the contrast by way of the up/down keys.
- Confirm the entry with the right function key "ok".



Fig. 37: Menu for changing the display contrast



Selecting a language

The LDplus control system can be used in various language versions.

- Select the menu "Select language".
- Select the desired language by way of the up/down keys.
- Confirm the entry with the right function key "enter".

Select language	
Deutsch	
English	
Francais	Ų
back Standby	enter



Settings

This menu can be used to adapt the operation and process control of the freeze-dryer's control system to your specific requirements.

- Select the desired menu.
- Change the value by way of the up/down keys.
- Confirm the entry with the right function key "ok".

Settings	
Warm-up vacuum pump	5 min. 🏼 🕯
Change phase automatically	no
Click at button push	no U
back Standby	edit

Fig. 39: "Settings" menu

Warm-up vacuum pump

This item is used to adjust the duration of the warm-up phase. Values between 5 and 60 minutes are possible.

Automatic phase change

If the "Change phase automatically" option is selected, the system will automatically switch over to the next phase after a preset time (see chapter 6.5.3.1 - "Changing set values" / Timer).

Click at button push

If this setting is active, a confirmatory sound signal will be issued whenever a key/button is pressed.

High temperature resolution

If this setting is active, temperatures will be displayed in the value window with a resolution of $1/10^{\circ}$ C (instead of 1°C).

Time defrosting

Here, the time that is needed for defrosting the ice condenser can be preselected. Settings between one minute and 200 hours are possible.

Temperature defrosting

This value defines the maximum temperature of the ice condenser chamber or ice condenser during the defrosting process. Values between 10 and 60°C are possible.



6 Operation

Service menu

	Service menu	
	LDplus configuration	î
	Load default settings	[
	Extendend service menu	Ų
back	■ Standby	enter

Fig. 40: Service menu

LDplus configuration

Here, the following accessory components (options) can be configured:

- Vacuum sensor
- Vacuum control system
- Installed options must be activated with "yes".
 - Options that are not installed must be deactivated with "no".

Load default settings

This menu item is used to reset all of the set values and parameters to the delivery state of the freeze-dryer. The system will issue a corresponding enquiry prior to performing this step.

Extended service menu

The extended service menu is reserved for service technicians. This area is protected by a password and is not accessible to the user.

6.5.3.5 Tutorial

The tutorial provides information concerning the most important functions of the LDplus control system.

The tutorial is available in German, English, and French.

Please us text of the	e the keys Up and Down to scroll the e tutorial	Î
LDplus C	control System	Ų
exit	■ Standby na	ext

Fig. 41: Tutorial

- Select the "Tutorial" function in the main menu.
- Browse the tutorial by way of the up/down keys.
- Click the left function key repeatedly in order to exit the tutorial.





6.6 Switching the freeze-dryer OFF

The freeze-dryer must be in the standby status.

• Switch the freeze-dryer off by pressing the mains switch.

7 Malfunctions and error correction



7 Malfunctions and error correction

Malfunctions are displayed in the dialogue box "Process & equipment messages" (see chapter 6.5.3.3 - "Process and equipment information"). An acoustic signal sounds when an error message is generated.

- Eliminate the source of the problem (see the following chapter).
- Acknowledge the error message.

7.1 General malfunctions

7.1.1 Power failure

The control system continues with the process after a power failure. The preselected conditions remain saved even during a process run.

In the event of a power failure in the drying phase, the batch may become unusable. Whether the batch can be saved or not depends on the drying phase in which the product was when the power failure occurred.

- In the final drying phase, the product has reached a residual moisture content of approx. 5%. Below this value, the product is generally not damaged even if the power failure lasts for a longer period of time.
- If the product is in the main drying phase, we recommend aerating the unit, removing the product, and storing it in a deep-freeze. The defrosted condensate must be drained off prior to the next start.

7.1.2 Insufficient vacuum



The vacuum checks must be carried out when the ice condenser is frozen.

7.1.2.1 Small flange connections

Leakages are often due to improper small flange connections between the various components and hose connections or to leakages in the valves.

- Loosen the connection and place the centring ring (with sealing ring inside) in a centred manner between the flange connections.
- Seal the connection with the clamping ring by tightening the wing nut.
- Ensure that the centring ring neither slips out of place nor gets jammed.



7 Malfunctions and error correction



Fig. 42: Small flange and centring ring



Fig. 44: Attaching the clamping ring



Fig. 43: Small flange with centring ring and small flange



Fig. 45: Tightened clamping ring

7.1.2.2 Aeration and media drain valve

A malfunction of the aeration and media drain valve may have several causes. One potential source are contaminants such as product residues within the valve.

- · Switch the freeze-dryer off and disconnect the mains plug.
- Clean the valve (see chapter 8.1.3 "Aeration valve, media drain valve").
- Put the freeze-dryer into operation again.

If there is still a leakage, the freeze-dryer must be checked by qualified specialist personnel (see chapter 7.3 - "Service contact").

7.1.2.3 Pressure control valve

A malfunction of the pressure control valve may have several causes.



The inspection of the valve must be carried out by qualified specialist personnel (see chapter 7.3 - "Service contact").





7.1.2.4 Rubber valves

In order to identify a leaking rubber valve, the valves must be checked individually:

- Remove the rubber valve and seal the connection at the drying chamber with a rubber stopper.
- Check the tightness under vacuum until the leaking valve has been localised.
- Clean the valve or replace it if necessary.

7.1.2.5 Vacuum sensor

Vacuum sensors have a limited service life and can be ordered as spare parts.

Capacitive vacuum sensors

Capacitive vacuum sensors may experience a measurement drift due to long-term use, soiling or sudden aeration. In this case, the vacuum sensor must be adjusted (see chapter 8.1.9 - " Vacuum sensor ").

7.1.3 Insufficient ice condenser temperature



Ensure sufficient ventilation. Do not place any paper, cloth, or similar material behind or under the unit, since otherwise the air circulation will be impaired.

The refrigeration unit is equipped with a protective device against overpressure in the refrigeration system and with a thermal motor protection switch.

The protective devices trip

- when the ambient temperature is too high
- when the air circulation of the heat exchanger of the refrigeration system is insufficient
- when the refrigeration system is overloaded.

In these cases, the refrigeration unit will be switched off automatically. If the permissible operating conditions are re-established after a cool-down phase of several minutes, the refrigeration unit will be switched on again automatically.

The malfunctions are displayed in the process and equipment information window.

The minimum ice condenser temperature of approx. -55° C or approx. -85° C (depending on the type of freeze-dryer) is reached when the ice condenser is not loaded and the ice condenser chamber is evacuated.



7 Malfunctions and error correction

7.2 Process and equipment messages

Error message	Possible cause	Remedy
Vacuum 6.11 mbar not reached The value of 6.11 mbar is not reached within 15 minutes with an open pressure control valve. The pressure control valve will be closed and the vacuum pump will be switched off.	The aeration and media drain valves are soiled.	 Clean the valve (see chapter 8.1.3 - "Aeration valve, media drain valve") and replace it if necessary.
	 The small flange connections are not properly connected. A seal is soiled or damaged. The cover or drying chamber is not properly attached. The ground-in stopper is not inserted correctly or it is missing. The vacuum pump is switched off or defective. 	 Loosen the connection. Place the centring ring with the inner sealing ring in a centred manner between the flange connections and connect it with the clamping ring. Ensure that the centring ring neither slips out of place nor gets jammed. Clean the seal and replace it if necessary. Check the cover and drying chamber. Grease the ground-in stopper evenly and over the entire sealing surface with vacuum grease and install it. Switch the vacuum pump on.
		Refer to the separate instruction manual of the vacuum pump.
Defective vacuum sensor The control system registers an invalid measurement value.	 The vacuum sensor is not connected correctly. The calibration is faulty. The vacuum sensor is soiled (e.g. due to water residues). The vacuum sensor is defective. 	 Check the vacuum sensor connectors. Calibrate the vacuum sensor (see the separate operating instructions of the vacuum sensor). Clean the vacuum sensor. Check the vacuum display with the aid of a reference device (if available). See chapter 7.1.2.5 - "Vacuum sensor"
Overpressure of refrigeration unit 1	The overpressure switch of the refrigeration unit has tripped.	 Let the freeze-dryer cool down. Ensure sufficient air circulation (see chapter 7.1.3 - "Insufficient ice condenser temperature").
Overpressure of refrigeration unit 2	The overpressure switch of the refrigeration unit has tripped.	 Let the freeze-dryer cool down. Ensure sufficient air circulation (see chapter 7.1.3 - "Insufficient ice condenser temperature").
Ice condenser overtemperature Ice condenser temperature > +65°C. All of the units will be switched off and the freeze-dryer will be automatically set to standby.	 The defrosting process has been performed with the cover closed. 	Remove the cover and let the freeze-dryer cool down.





Error message	Possible cause	Remedy
Ice condenser temperature > 20°C The ice condenser temperature rises to a non-permissible value during the freeze-drying process. The pressure control valve will close automatically in order to prevent the vacuum pump from being damaged.	Insufficient cooling.	• Observe the behaviour of the refrigeration system. If necessary, inform the service department (see chapter 7.3 - "Service contact").
Defective ice condenser temperature sensor	• The temperature sensor is not connected or it is defective.	 Inform the service department (see chapter 7.3 - "Service contact").
Defective temperature sensor of the defrosting heater	• The temperature sensor is not connected or it is defective.	 Inform the service department (see chapter 7.3 - "Service contact").
Mains power failure (see chapter 7.1.1 - "Power failure")	 The power supply has been interrupted. The mains power connector is not connected. The fuses have tripped. The mains power switch has been switched off. 	 Check the mains fuse. Connect the mains power connector firmly. Check the customer-provided fuses. Switch the mains power switch on.
Default settings loaded All of the settings have been reset to the delivery state of the freeze-dryer.	 Error in the parameter memory. Manual execution in the service menu. 	No measure required.
IO communication error (0x20)	Error in the LDplus IO module.	 Inform the service department (see chapter 7.3 - "Service contact").

7.3 Service contact

In the event of queries, malfunctions, or spare part enquiries:

From Germany:

Contact Martin Christ Gefriertrocknungsanlagen GmbH An der Unteren Söse 50 37520 Osterode (Germany) Tel. +49 (0) 55 22 / 50 07-44 44 E-mail: <u>support.lab@martinchrist.de</u>

Outside Germany:

Contact our agency in your country. All agencies are listed at <u>www.martinchrist.de</u> \rightarrow [Sales Partners]



If you would like to utilise our after-sales-service, please state the type of your freeze-dryer and its serial number.



The freeze-dryer and the accessories are subject to high mechanical and chemical stress. Thorough maintenance performed by the user extends the service life and prevents premature failure.



If corrosion or other damage occurs due to improper care, the manufacturer cannot be held liable or subject to any warranty claims.

- Thoroughly clean the freeze-dryer immediately after use to prevent or at least significantly reduce the damage to the materials of construction (see also chapter 1.2 "Intended use", section "Freeze-drying of solvent-containing products").
- Use soap water or other water-soluble, mild cleaning agents for cleaning the freeze-dryer and the accessories.
- Do not use corrosive and aggressive substances.
- Do not use solvents.
- Do not use agents with abrasive particles.
- Do not expose the freeze-dryer or its accessories to intensive UV radiation (e.g. sunlight) or thermal stress (e.g. by heat generators).
- Do not turn the unit upside down in order to clean it.

8.1 Maintenance

8.1.1 General

The general state of the freeze-dryer must be checked at regular intervals. Any defects must be eliminated immediately! The following points are of particular importance:

- dirt
- leaks
- corrosion
- bent system components
- loose screw and flange connections
- higher noise levels
- loose cables
- open cable ducts
- missing or illegible safety notes and hazard warnings
- missing or illegible inscriptions on components, pipes (direction of flow) and cables
- etc.





Cleaning of the freeze-dryer

Risk of burns on hot surfaces

After a drying process, some or all of the surfaces inside the chamber may still be hot.

There is a risk of burns when touching the surfaces.

- Wear suitable protective clothes and gloves!
- Do not touch the surfaces on purpose!
- Let the chamber cool down prior to commencing the maintenance!





When performing maintenance work on parts coming into contact with the product (e.g. all parts inside the chamber, vacuum pump), the personnel may be exposed to product residues.

Skin contact or the inhalation of particles may cause severe damage to health depending on the product in question.

- Take suitable decontamination measures prior to commencing the maintenance!
- Wear suitable protective clothes and gloves!
- Switch the freeze-dryer off by actuating the mains power switch and disconnect the power cord from the wall outlet before cleaning.
- If the freeze-dryer has been contaminated with toxic, radioactive, or pathogenic substances, clean the inside immediately with a suitable decontamination agent (depending on the type of contamination, see chapter 8.2 - "Disinfection of the drying chamber and accessories").
- Remove product residues thoroughly with a cloth.
- Open the lid/drying chamber when the freeze-dryer is not in use so moisture can evaporate.

8.1.2 Ice condenser chamber

Before each start-up, ensure that the ice condenser chamber is free from water residues.

- Open the media drain valve to drain off any liquid. Then, close the valve.
- If necessary, wipe the ice condenser chamber dry with a cloth.



8.1.3 Aeration valve, media drain valve

Contaminants such as product residues may lead to an insufficient vacuum. In this case, the aeration valve and the media drain valve must be cleaned.

- Switch the freeze-dryer off and disconnect the mains plug. ٠
- Remove the valve core. •
- Clean the valve core and the opening with a moist cloth.
- Clean the O-rings and inspect them for any damage. Damaged O-rings • must be replaced.
- Valve opening 1
- 2 Valve core 3 O-rings



Fig. 46: Valve opening and valve core with O-rings (example, varies depending of the type of freeze-dryer)

- Reinsert the valve core.
- Put the freeze-dryer into operation again. •

If the vacuum is still insufficient, the freeze-dryer must be checked by qualified specialist personnel (see chapter 7.3 - "Service contact").



8.1.4 Heat exchanger (only for air-cooled freeze-dryers)

A lamellar heat exchanger is used for cooling the refrigerant that is compressed by the refrigeration unit. This air-cooled heat exchanger is located at the back of the unit (see chapter 2.1.1 - "Functional and operating elements").

Dust and dirt impair the cooling effect of the air flow. Dust on the lamellas prevents the exchange of heat and, thereby, impairs the performance and power of the refrigeration unit. Strong soiling may cause the unit to fail.

This is why the selected set-up location should be as clean as possible.

- Check the heat exchanger at least once per month for soiling and clean it if necessary.
- Please contact the Christ service department if you have any queries (see chapter 7.3 "Service contact").

8.1.5 Electrical system



Danger of life caused by electric shock

There is a risk of electric shock when touching current-carrying components.

This may lead to ventricular fibrillation, cardiac arrest, or respiratory paralysis.

• Only qualified electricians are authorised to perform work on the electrical system of the freeze-dryer!

The electrical equipment of the freeze-dryer must be checked at regular intervals by a qualified electrician. Defects such as loose connections or burnt cables must be eliminated immediately.

8.1.6 Vacuum pump



Please refer to the separate operating manual of the vacuum pump!

The stress of the vacuum pump in conjunction with a freeze-dryer is usually not very high. This is why the recommendations in this operating manual may differ from the information that is provided by the pump manufacturers. Under normal operating conditions, the following maintenance tasks concerning the vacuum pump must be performed at regular intervals:

- Check the oil level of the vacuum pump once per week. If necessary, top it up with oil.
- Check the state of the oil at regular intervals (depending on the frequency of use of the freeze-dryer and the product that is used). It must be changed when it becomes cloudy, contains particles or changes colour.



- Check the running pump for any unusual noise.
- Ensure that the pump has reached its operating temperature prior to changing the oil.
- Perform the first oil change after approximately 100 operating hours.
- The other oil changes depend on the operating conditions. In general, an interval of 500 to 1,000 operating hours is sufficient.
- Please contact the Christ service department if you have any queries (see chapter 7.3 "Service contact").

8.1.7 Exhaust filter (oil mist separator)



Please refer to the separate operating manual of the vacuum pump and the exhaust filter!

The oil mist that is emitted by the vacuum pump in quantities that depend on the working pressure must be led to the outside or to an exhaust hood or similar. If this is not possible, the pump must be equipped with an exhaust filter (oil mist separator).

- Observe the liquid level in the collecting vessel of the filter.
- Remove the condensate in time (please refer to the information provided by the manufacturer in the separate operating manual).

8.1.8 Refrigeration system



Risk of explosion due to refrigerants

The natural refrigerants used are highly flammable and can form an explosive mixture if their concentration in the ambient air is sufficiently high.

There is an explosion hazard.

- Work on the refrigeration system of the freeze-dryer must only be carried out by qualified specialist personnel who have been trained to handle flammable refrigerants!
- Ensure good ventilation and make sure that no ignition sources (e.g. soldering iron, welding equipment) are present!

The refrigerant circuit is a closed system. Only certified and qualified persons are authorised to perform work on the refrigeration system!



8.1.9 Vacuum sensor



Please refer to the separate operating manual of the vacuum sensor!

The vacuum sensor has only a limited service life.

- The vacuum sensor is maintenance-free.
- Remove any soiling on the outside with a cloth.

Capacitive vacuum sensors

Measurement drift due to long-term use, soiling or sudden aeration may occur.

• Capacitive vacuum sensors must be adjusted at least once per year. Depending on the actual conditions of use, shorter adjustment intervals may be necessary.

8.1.10 Accessories



For the care of the accessories, special safety measures must be considered as these are measures that will ensure operational safety at the same time.

Chemical reactions as well as stress-corrosion (combination of oscillating pressure and chemical reaction) can affect or destroy the metal and plastic parts. Barely detectable cracks on the surface can expand and weaken the material without any visible signs.

- Check the material regularly (at least once a month) for
 - cracks
 - visible damage of the surface
 - pressure marks
 - signs of corrosion
 - other changes.
- Replace any damaged components immediately for your own safety.
- Immediately rinse off the accessories if any liquids that may cause corrosion come into contact with them.
- Clean the accessories outside the freeze-dryer once a week or preferably after each use.



8.2 Disinfection of the drying chamber and accessories



If dangerous materials (e.g. infectious and pathogenic substances) are used, the freeze-dryer and accessories must be disinfected.

- Use commercially-available disinfectants such as, for example, Incidur[®], Meliseptol[®], Sagrotan[®], Buraton[®], or Terralin[®] (available at specialised trade).
- The freeze-dryers and the accessories consist of various materials. A possible incompatibility must be considered.
- Before using cleaning or decontamination agents that were not recommended by us, contact the manufacturer to ensure that such a procedure will not damage the freeze-dryer.
- Please contact us if you have any queries (see chapter 7.3 "Service contact").

8.3 Service



In the event of service work that requires the removal of the panels, there is a risk of electric shock or mechanical injury. Only qualified specialist personnel is authorised to perform this service work.

The freeze-dryer is subject to high mechanical stress. In order to be able to withstand this high level of stress, high-quality components were used during the production of the freeze-dryer. Nevertheless, wear cannot be excluded and it may not be visible from the outside.

This is why we recommend having the freeze-dryer checked by the manufacturer during an inspection once per year.

Information and appointments:

From Germany:

Contact

Martin Christ Gefriertrocknungsanlagen GmbH An der Unteren Söse 50 37520 Osterode (Germany) Tel. +49 (0) 55 22 / 50 07-44 44 E-mail: <u>support.lab@martinchrist.de</u>



Outside Germany:

Contact our agency in your country. All agencies are listed at <u>www.martinchrist.de</u> \rightarrow [Sales Partners]



If you would like to utilise our after-sales-service, please state the type of your freeze-dryer and its serial number.



8.4 Return of defective parts

Although we exercise great care during the production of our products, it may be necessary to return a unit or accessory to the manufacturer.

In order to ensure the quick and economical processing of returns of freeze-dryers, rotational vacuum concentrators, spare parts, or accessories, we require complete and extensive information concerning the process. Please fill in the following forms completely, sign them, enclose them with the return package, and send them together with the product to:

Martin Christ Gefriertrocknungsanlagen GmbH An der Unteren Söse 50 37520 Osterode (Germany)

1. Declaration of decontamination

As a certified company and due to the legal regulations for the protection of our employees and of the environment, we are obliged to certify the harmlessness of all incoming goods. For this purpose, we require a declaration of decontamination.

- The form must be filled in completely and signed by authorised specialist personnel only.
- Affix the original form in a clearly visible manner to the outside of the packaging.



We will return the part/unit if no declaration of decontamination is provided!

2. Form for the return of defective parts

This form is for the product-related data. They facilitate the assignment, and they enable the quick processing of the return. If several parts are returned together in one packaging, please enclose a separate problem description for every defective part.

- A detailed problem description is necessary in order to perform the repair quickly and economically.
- Upon request, we will prepare and submit to you a cost estimate prior to performing the repair. Please confirm such cost estimate within 14 days. If the cost estimate has still not been confirmed after 4 weeks, we will return the defective part/unit. Please note that you must bear the incurred costs.



The part/unit must be packaged in a transport-safe manner. Please use the original packaging for the unit, if at all possible.

If the product is dispatched to us in unsuitable packaging, you will be charged the cost for returning it to you in new packaging.

The forms can be downloaded online from <u>www.martinchrist.de</u> \rightarrow [Service] \rightarrow [Overhaul, repair and leak testing].

9 Disposal



9 Disposal

9.1 Disposal of the freeze-dryer

Martin Christ Gefriertrocknungsanlagen GmbH is a registered manufacturer of electric and electronic devices that are solely intended for commercial use.

• Comply with all local rules and regulations.

9.2 Disposal of the packaging

- Dispose of the packaging, after having separated the individual materials.
- Comply with all local rules and regulations.


10 Technical data

Manufacturer:	Martin Christ Gefriertrocknungsanlagen GmbH An der Unteren Söse 50 37520 Osterode (Germany)
Туре:	Alpha 1-2 LDplus
Part number:	101521 (230 V / 50 Hz, air-cooled) 101522 (230 V / 60 Hz, air-cooled) 101527 (115 V / 60 Hz, air-cooled)
Performance data	
<u>Ice condenser</u> - capacity: - performance: - temperature: - chamber volume:	2.5 kg max. 2 kg / 24 h max. approx. –55°C approx. 3.5 l
Shelf or product temperature during freezing in the ice condenser chamber	approx. –20°C
<u>Max. shelf surface (\rightarrow double chamber method)</u> : drying outside the ice condenser chamber	3 shelves, Ø 200 mm, A _{total} =0.092m ² distance up to 80 mm, with accessory, part no. 120893
drying in injection vials with sealing under vacuum or nitrogen atmosphere outside the ice condenser chamber	2 shelves, \varnothing 200 mm, $A_{total}{=}0.054~m^2$ distance 25-70 mm, with accessory, part no. 121015
drying in round bottom flasks	8 pieces, with accessory, part no. 121450
Connection requirements	
(without vacuum pump and accessories)	
Electrical connection:	1 x 230 V / 50 Hz 1 x 230 V / 60 Hz 1 x 115 V / 60 Hz
Protection class:	1
IP protection category according to DIN 60529:	11
Apparent power:	0.8 kVA (at 230 V / 50 Hz) 0.85 kVA (at 230 V / 60 Hz) 0.75 kVA (at 115 V / 60 Hz)
Nominal current:	3.5 A (at 230 V / 50 Hz) 3.8 A (at 230 V / 60 Hz) 6.3 A (at 115 V / 60 Hz)
Power supply of the pressure control valve:	230 V, 50/60 Hz, 20 VA / 0.5 A max.
Power supply of the vacuum pump:	230 V, 50/60 Hz, 3.0 A max.
Refrigerant data	
Refrigerant: - Global warming potential (GWP): - Filling quantity: - Max. permissible pressure: - CO ₂ equivalent:	R1270 3 36 g 25 bar < 0.01 t

10 Technical data



Refrigerant data	
Refrigerant: - Global warming potential (GWP): - Filling quantity: - Max. permissible pressure: - CO ₂ equivalent:	R170 3 6 g 25 bar < 0.01 t
Physical data (without vacuum pump and accessories)	
Dimensions - height: - width:	345 mm 315 mm
- depth (Incl. vacuum connection):	460 mm
Weight:	approx. 28 kg
Noise level according to DIN 45635:	49 dB(A)
EMC according to EN 55011:	Class B
Heat emission:	0.51 kW min. 0.91 kW max.
Equipment connections	
	Small flange connection DN25KE
vacuum connection.	(ISO 28403, DIN 2861)
Aeration and media drain valve:	Hose nozzle DN10 (outside diameter 12 mm)
Mains input:	IEC C13 connector
Vacuum sensor:	SUB D-9 VCP 63
Option: Data interface (LAN):	RJ 45

10.1 Ambient conditions

- Use in closed spaces
- Altitudes up to 2,000 m
- Ambient temperature between +5°C and +25°C
- Maximum relative humidity of 80%
- Mains voltage fluctuations of up to ± 10% of the rated voltage

10.2 Technical documentation

The technical documentation of this freeze-dryer (e.g. circuit diagram, cooling system) and the safety data sheets of the manufacturers (e.g. for refrigerant) is not attached to this operating manual.

You can order these documents from our service department.



11.1 Brief operating instructions Functional and operating elements

- 1 Ice condenser chamber with an internal ice condenser
- 2 Aeration and media drain valve



Fig. 47: Left side of the freeze-dryer

- 3 Pipe connection of the vacuum pump (behind the cover plate)
- 4 Ice condenser



Fig. 48: Ice condenser chamber

- 5 User interface
- 6 Mains power switch



IRIST

Fig. 49: Front and right side of the freeze-dryer

- 7 Power supply of the pressure control valve
- 8 Name plate
- 9 Power supply of the vacuum pump
- 10 Equipotential bonding screw
- 11 Mains connection
- 12 Vacuum connection
- 13 Connection of the vacuum sensor
- 14 Option: data interface for further accessories
- 15 Heat exchanger of the refrigeration unit



Fig. 50: Rear view of the freeze-dryer





Fig. 51: User interface of the LDplus control system

Step-by-step instructions – shelf drying

1 Freeze the sample separately, e.g. in a deep-freeze.





7 The operating panel displays the vacuum, the ice condenser temperature, and the current operating mode.



8 The end of the process is reached when the ice condenser is no longer loaded and when it again reaches a final temperature of approximately - 50°C to -54°C. The pressure decreases as a function of the ice condenser temperature.



The drying time depends on the layer thickness of the sample, the solids content of the sample, and the amount of heat that is supplied during the drying process. In the case of a layer thickness of 1 cm, the freeze-drying process usually takes 24 hours.

- 9 Switch the vacuum pump off and aerate the drying chamber via the media drain valve or via a rubber valve.
- 10 Switch the unit off by actuating the mains power switch and take the product out of the freeze-dryer.
- 11 Switch the unit on again and start the defrosting process.



Ensure that no water gets into the pipe connection of the vacuum pump or vacuum sensor.

- 12 Drain the defrosting water via the defrosting water valve on the left-hand side of the unit. To do so, connect a hose to the hose connector and collect the defrosting water in a suitable vessel.
- 13 Keep the freeze-dryer open (i.e. without the lid or drying chamber) when it is not in use so that moisture can evaporate. This increases the service life of the vacuum sensor.





11.2 EC declaration of conformity in accordance with the EC Machinery Directive

		7
EC – DE in accordance with the	ECLARATION OF CONFORMITY EC Machinery Directive 2006/42/EC, annex II, part 1, section	on A
The product named hereina the relevant, fundame	Ifter was developed, designed, and manufactured in compliance Intal safety and health requirements of the listed EC directives	ce with
In the event of modifications that is not in line with	s that were not authorised by us or if the product is used in a m n the intended purpose, this declaration will be rendered void.	nanner
Product name:	Freeze-dryer	
Product type:	Alpha 1-2 LDplus	
Order number:	101521, 101522, 101527	
Directives:	2006/42/EGMachinery Directive2014/35/EULow Voltage Directive2014/30/EUEMC Directive	
Martin Christ Gefrier An der Unteren Söse 37520 Osterode Germany Osterode, 08/11/2021 F. Harms, Manageme	rtrocknungsanlagen GmbH 50 Authorised representative for CE matters: S. Krippendorff 1 ent	
CE_MaschRL_Alpha1-2_LDplus_2021-11-08_en.do	xx	Page 1 / 1





11.3 Declaration of conformity – China RoHS 2

	DEC	LARATI		ONFOR	MITY	
China RoHS 2 (Administrative Measures for the Restriction of the Use of Hazardous						
	Subs	tances in El	ectrical and E	ectronic Prod	lucts)	
Freeze-dryer ı Alpha 3-4 LSC Beta 2-8 LSCI Gamma 2-16L	models: Alpha Cbasic, Alpha basic, Beta 1- SCplus, Delt	a 1-2 LDplus, 1-4 LSCplus 8 LSCplus, E a 1-24 LSCpl	Alpha 1-4 LSC , Alpha 2-4 LS Beta 2-8 LSCpli lus, Delta 2-24	Cbasic, Alpha 2 Cplus, Beta 1-8 us, Gamma 1-1 LSCplus	-4 LSCbasic, 3 LSCbasic, 16 LSCplus,	
Rotational Vac RVC 2-25 CD	cuum Concer plus, RVC 2-3	ntrator models 33 CDplus, R	s: RVC 2-18 CI VC 2-33 CDplu	Dplus, RVC 2-1 is with infrared	8 CDplus HCl heating	-resistant,
Cooling trap n	nodels: CT 02	2-50 SR, CT (04-50 SR			
Cooling bath r	model: CB 18	-40				
Christ Gefriert hazardous sul	rocknungsan bstances in th	lagen GmbH ne products (f	has made reas reeze-dryers a	sonable effort to	o avoid the use	e of
A Product Cor concentration above or below Mercury and it Lead (Pb) and	nformity Asse of harmful su w the MCV lir ts compounds l its compound	ssment (PCA bstances in a nit (Maximum s: 0.1 % ds: 0.1 %	a) was performe all homogeneou n Concentration Cadmium (Cd Hexavalent ch	ed in order to d us materials of a Value limit) as) and its compo promium (Cr (V	etermine whet the componen s defined in GE punds: 0.01 % I)) and its com	her the t parts is 3/T 26572: pounds: 0.1 %
A Product Cor concentration above or below Mercury and it Lead (Pb) and Polybrominate	nformity Asse of harmful su w the MCV lir ts compounds I its compoun ed biphenyls (Table 1:	ssment (PCA bstances in a nit (Maximum s: 0.1 % ds: 0.1 % (PBB): 0.1 % 表1 Name and con	a) was performed all homogeneous Concentration Cadmium (Cd Hexavalent ch Polybrominate 产品中有害物质的 tent of hazardous	ed in order to d us materials of value limit) as and its compo- romium (Cr (V ed diphenyl eth- b各称及含量 s substances in t	etermine whet the componen s defined in GE bunds: 0.01 % I)) and its com ers (PBDE): 0.	her the t parts is 3/T 26572: pounds: 0.1 % 1 %
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A Product Cor concentration above or below Mercury and if Lead (Pb) and Polybrominate Polybrominate Component part (PCA) Electronic PCB, cables Display Housing Base, metal, accessories	nformity Asse of harmful su w the MCV lin ts compounds l its compounds d biphenyls (Table 1: 留 Lead (Pb) X ⁽¹⁾ O X ⁽²⁾	ssment (PCA bstances in a nit (Maximum s: 0.1 % ds: 0.1 % PBB): 0.1 % \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$ \$\$\$\$ \$\$\$\$ \$\$\$\$ \$\$\$\$ \$\$\$\$\$\$\$\$	A) was performant all homogeneous Concentration Cadmium (Cd Hexavalent ch Polybrominate mathematication mathe	ed in order to d us materials of a Value limit) as and its compo- promium (Cr (V ed diphenyl eth d diphenyl eth s substances in t 害物质 us substance 六价格 Hexavalent Chromium (Cr (VI)) 0 0 0 0	etermine whet the componen s defined in GE ounds: 0.01 % I)) and its com ers (PBDE): 0. he product 多溴联苯 Poly- brominated biphenyls (PBB) 0 0 0 0 0	her the t parts is B/T 26572: pounds: 0.1 % 1 %





- O: 表示该有害物质在该部件所有均质材料中的含量均在GB/T 26572规定的限量要求以下。 Indicates that the content of the harmful substance in all homogeneous materials of the component part is below the limit as defined in GB/T 26572.)
- X: 表示该有害物质至少在该部件的某一均质材料中的含量超出GB/T 26572规定的限量要求。(企业可在此处,根据实际情况对上表打"X"的技术原因进行进一步说明。)
 - Indicates that the content of the harmful substance in at least one homogeneous material of the component part exceeds the limit as defined in GB/T 26752. (Contact the manufacturer for further technical information according to the actual situation.)
- ¹⁾ Contains parts in compliance with exemptions 6c, 7c.I, 7c.II and 37 of 2011/65/EU RoHS.
- ²⁾ Contains parts in compliance with exemptions 6a, 6b and 6c of 2011/65/EU RoHS.

Apart from the exemptions given in this table, none of the substances listed above have been intentionally added to the product or metallic coatings.

Martin Christ Gefriertrocknungsanlagen GmbH

An der Unteren Söse 50 37520 Osterode Germany

Osterode, 25/11/2021

9 F. Harms, Management

Declaration China RoHS2 2021-11-25 en-chn

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11.4 EC declaration of conformity in accordance with the Pressure Equipment Directive

	© CHRIST	
EC – DECLARAT in accordance with the EC Pre	Sure Equipment Directive 2014/68/EU	
The refrigeration units in freeze-dryers which manufactured in accordance with the relevar listed EC dire	are listed hereinafter were developed, designed, and nt, fundamental safety and health requirements of the actives and standards.	
In the event of modifications that were not a that is not in line with the intended p	uthorised by us or if the product is used in a manner urpose, this declaration will be rendered void.	
Product name:	Refrigeration unit in a freeze-dryer	
Relevant unit types:	All laboratory systems of the following types: Alpha, Beta, Gamma, Delta Pilot systems of the following types: Epsilon 1-4,Epsilon 2-4 Epsilon 2-6D, Epsilon 2-10D	
Max. permissible pressure: Max. permissible temperature:	25 bar 120°C	
Directives:	2014/68/EU Pressure Equipment Directive	
Underlying standards:	AD 2000 EN 378	
Applied conformity assessment procedures:	Module A Category I	
Martin Christ Gefriertrocknungsanla An der Unteren Söse 50 37520 Osterode Germany Osterode, June 3, 2021 F. Harms, Management	Authorised representative for CE matters: S. Krippendorff	
CE_DruckGRL_Labor+Pilot_2021-06-03_en.doc	Page 1 / 1	





11.5 Table of the sublimation pressure curve

°C	= mbar	°C	= mbar	°C	= mbar	°C	= mbar
28	37.79	1	6.57	-26	0.57	-53	0.025
27	35.64	0	6.11	-27	0.52	-54	0.024
26	33.60	-1	5.62	-28	0.47	-55	0.021
25	31.66	-2	5.17	-29	0.42	-56	0.018
24	29.83	-3	4.76	-30	0.37	-57	0.016
23	28.08	-4	4.37	-31	0.34	-58	0.014
22	26.43	-5	4.02	-32	0.31	-59	0.012
21	24.86	-6	3.69	-33	0.28	-60	0.011
20	23.37	-7	3.39	-34	0.25	-61	0.009
19	21.96	-8	3.01	-35	0.22	-62	0.008
18	20.,63	-9	2.84	-36	0.20	-63	0.007
17	19.37	-10	2.56	-37	0.18	-64	0.006
16	18.17	-11	2.38	-38	0.16	-65	0.0054
15	17.05	-12	2.17	-39	0.14	-66	0.0047
14	15.98	-13	1.98	-40	0.12	-67	0.0041
13	14.97	-14	1.81	-41	0.11	-68	0.0035
12	14.02	-15	1.65	-42	0.10	-69	0.0030
11	13.12	-16	1.51	-43	0.09	-70	0.0026
10	12.27	-17	1.37	-44	0.08	-71	0.0023
9	11.47	-18	1.25	-45	0.07	-72	0.0019
8	10.72	-19	1.14	-46	0.06	-73	0.0017
7	10.01	-20	1.03	-47	0.055	-74	0.0014
6	9.35	-21	0.94	-48	0.050	-75	0.0012
5	8.72	-22	0.85	-49	0.045	-76	0.0010
4	8.13	-23	0.77	-50	0.040	-77	
3	7.58	-24	0.70	-51	0.035	-78	
2	7.06	-25	0.63	-52	0.030	-79	





12 Glossary

Desorption

Desorption (from Latin de-sorbere, sorbere = sup up, suck in) describes a phenomenon whereby molecules are released from the surface of a solid. In order to be able to desorb, the particle must have, or be provided with, a sufficient amount of energy in order to overcome the binding energy.

Eutectic point

The eutectic point is the point at which a homogenous mixture (e.g. a eutectic alloy) passes directly from the liquid to the solid phase without the formation of a crystal mixture that consists of different phases.

Single-chamber method

At the single-chamber method, the freezing as well as the subsequent drying of the product are both performed in the ice condenser chamber. The sample is frozen as a result of the low temperature of the ice condenser

 $(-55^{\circ}C \text{ in the case of one-stage systems or }-85^{\circ}C \text{ in the case of two-stage systems})$. The inside of the chamber can be cooled to approximately $-20^{\circ}C$ or $-40^{\circ}C$. The moderate supply of the frozen sample with energy, which is necessary during the main drying phase, is ensured by heatable shelves on which the product is placed.

Double-chamber method

Drying on shelves outside the ice condenser chamber is referred to as a double-chamber system. The advantage compared to the \rightarrow single-chamber method is the considerably higher product capacity. In addition, the product chamber can be isolated from the ice condenser chamber by an intermediate valve in order to perform a so-called \rightarrow pressure increase test for determining the end of the drying process. In freeze-dryers without an active shelf cooling, the samples need to be pre-frozen externally, e.g. in a deep-freeze or freezer cabinet. After the transfer of the product into the freeze-dryer, the actual \rightarrow sublimation is started.

Reference designator

During the service life of industrial systems, a standardised reference designation system is required for the planning, design, realisation, maintenance, and disassembly stages in order to be able at all times to identify every single component within the system in an unambiguous manner. The reference designators) are affixed to the components and entered into the technical documentation (e.g. circuit diagrams).

Sublimation

Sublimation (from Latin "sublimis" = high up in the air, raised), is a thermodynamic process of the direct transition of a substance from the solid phase to the gas phase.

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