

# Alpha 3-4 LSCbasic

Part no. 102504, 102516, 102505, 102474, 102486, 102475



# **Operating Manual**

Please retain for later use!





In case of inquiries, please state the following numbers:
Order number:
Serial number:

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1	(	Gene	eral information	9
	1.1	lm	nportance of the operating manual	9
	1.2	Int	tended use	9
	1.3	W	arranty and liability1	0
	1.4	Co	opyright1	1
	1.5	Ex	xplanation of symbols1	1
	1.6	St	tandards and regulations1	1
	1.7	Sc	cope of supply1	1
2		Layo	out and mode of operation1	5
	2.1	-	ayout of the freeze-dryer1	
	2.	1.1	Functional and operating elements1	5
	2.	1.2	Name plate1	
	2.2	М	ode of operation1	8
	2.	2.1	General information on freeze-drying1	8
	2.	2.2	Freeze-drying process	0
		2.2.2	2.1 Preparation2	0
		2.2.2	2.2 Freezing2	1
		2.2.2	3 3	
		2.2.2		
		2.2.2	· · · · · · · · · · · · · · · · · · ·	
		2.2.2	5	
3			ty2	
	3.1		arking of the unit2	
	3.2	Ex	xplanation of the symbols and notes2	4
	3.3		esponsibility of the operator2	
	3.4	Re	equirements concerning the personnel2	7
	3.5		formal safety notes2	8
	3.6		afety notes concerning the transport, set-up and connection and initial start-up of the	_
	_		eeze-dryer	
		6.1 6.2	General hazards	
		6.3	Hazards caused by improper set-up2	
		6.4	Hazards caused by improper set-up	
	3.7		afety notes concerning the operation	
		7.1	Hazards caused by electricity	
	_	7.2	Hazards caused by the refrigeration system (natural, flammable refrigerants)3	
		7.3	Hazards caused by harmful products	
		7.4	Hazards caused by acids in the products	
	3.	7.5	Hazards caused by contaminated condensate (defrosting water)	
	3.	7.6	Dry-running vacuum pump: hazards caused by contaminated exhaust air3	
	3.	7.7	Hazards caused by noise3	2
	3.	7.8	Hazards caused by hot surfaces3	2
	3.	7.9	Hazards caused by cold surfaces3	3



3.7	.10 Hazards caused by breaking glass	33
3.8	Safety devices	33
3.8	.1 System check	33
3.8	.2 Earth conductor check	33
3.9	Procedures in the event of hazards and accidents	34
3.10	Maintenance and cleaning of the freeze-dryer	34
3.11	Measures to be taken to ensure safe operation of the freeze-dryer	35
3.12	Remaining hazards	36
4 5	torage and transport	37
4.1	Dimensions and weight	37
4.2	Storage conditions	37
4.3	Notes on transport	38
4.4	Packaging	39
4.5	Transport locking devices	39
5 5	et-up and connection	
5.1	Location of use	
5.2	Power supply	41
5.2	• • •	
5.2	.2 Customer-provided fuses	41
5.3	Aeration valve	42
5.4	Media drain valve	42
5.5	Vacuum sensor	43
5.6	Vacuum pump	44
5.7	Use of an interface box	
5.8	Pressure control valve	48
5.9	Installation of the accessories	49
5.9	.1 Rubber valves	52
6 (	peration	53
6.1	Initial start-up	
6.2	Preparation	53
6.3	Switching the freeze-dryer on	53
6.4	LSCbasic control system	54
6.4	.1 User interface	54
(	.4.1.1 Main window "Process"	55
6	.4.1.2 Main window "Options"	63
6	.4.1.3 Main window "?"	73
6.4	3 , 31	
6	.4.2.1 Entering set values	74
6.5	Optional extensions	78
6.6	Switching the freeze-dryer OFF	78



7 M	alfunctions and error correction	79
7.1	General malfunctions	79
7.1	1 Power failure	80
7.1	2 Insufficient vacuum	81
7	.1.2.1 Small flange connections	81
7	.1.2.2 Aeration valve, media drain valve	82
7	.1.2.3 Pressure control valve	82
7	.1.2.4 Rubber valves	82
7	.1.2.5 Vacuum sensor	83
7.1	3 Insufficient ice condenser temperature	83
7.2	Process and error messages	83
7.3	Service contact	84
8 M	aintenance and service	85
8.1	Maintenance	
8.1		
8.1	2 Ice condenser chamber	87
8.1	.3 Aeration valve, media drain valve	87
8.1		
8.1		
8.1	6 Vacuum system	89
8.1	.7 Refrigeration system	90
8.1	8 Vacuum sensor	90
8.1	9 Accessories	91
8.2	Disinfection of the drying chamber and accessories	92
8.3	Service	92
8.4	Return of defective parts	93
9 D	isposal	
9.1	Disposal of the freeze-dryer	95
9.2	Disposal of the packaging	
	echnical data	
10.1	Ambient conditions	
10.2	Technical documentation	
	ppendix	
11.1	EC declaration of conformity in accordance with the EC Machinery Directive	
11.2	Declaration of conformity – China RoHS 2	
11.3	EC declaration of conformity in accordance with the Pressure Equipment Directive	
11.4	Table of the sublimation pressure curve	105
12 G	lossary	107
13 Ir	dex	100





# 1 General information

# 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

#### Freeze-dryer and accessories

Do not use the freeze-dryer unless the following requirements are fulfilled:

- · The freeze-dryer has been properly installed.
- The freeze-dryer is in a perfect technical state.
- The freeze-dryer is not located in an area with an explosion hazard.
- No unauthorised design modifications, additions or conversions without the written approval by Martin Christ Gefriertrocknungsanlagen GmbH have been performed.
- The freeze-dryer must correspond to one of the following solvent packages:
  - Solvent package flask, part no. 102504 (with vacuum pump, type Pfeiffer Hiscroll 12 Atex)
  - 2 Solvent package flask, part no. 102516 (with vacuum pump, type Pfeiffer Hiscroll 12 Atex)
  - 3 Solvent package universal, part no. 102505 (with vacuum pump, type Pfeiffer Hiscroll 12 Atex)
  - 4 Solvent package flask, part no. 102474 (with vacuum pump, type Edwards nXDS 10iC)
  - 5 Solvent package flask, part no. 10248 (with vacuum pump, type Edwards nXDS 10iC)
  - 6 Solvent package universal, part no. 102475 (with vacuum pump, type Edwards nXDS 10iC)

The vacuum pump must be supplied separately by way of a customerprovided socket or it can be connected to the freeze-dryer via an interface box.

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 may only be used with the specified accessories made by Martin Christ Gefriertrocknungsanlagen GmbH.

The freeze-dryer is suitable for freeze-drying solid substances and liquid solutions (e.g. bacteria and virus cultures, blood plasma, serum fractions, antibodies, sera, vaccines and pharmaceutical products such as



#### 1 General information

chloramphenicol, streptomycin, vitamins, ferments and plant extracts for biochemical tests).

The intended use also includes:

- Observation of all of the notes and instructions that are included in the operating manual,
- Compliance with the inspection and maintenance instructions (see chapter 8 "Maintenance and service").

#### Requirements concerning the products used in the freeze-dryer

- The product must not contain any substances that damage the material (stainless steel 1.4404 and 1.4435, borosilicate glass, EPDM, PVDF, ceramic Al<sub>2</sub>O<sub>3</sub> and PTFE) or decrease the mechanical strength.
- The product must not contain azides.
- A reaction of the product following the supply of high amounts of energy during the freeze-drying process must be excluded.
- The solvents that are used must be of the temperature classes T1 to T4
  as per DIN EN-60079-0:2014-06. We recommend performing a
  workplace evaluation in terms of the handling of flammable solutions in
  accordance with the local labour legislation.

## **Exclusion of liability**

Any use of the freeze-dryer other than the one described here or any use going beyond this description is regarded as improper use. Martin Christ Gefriertrocknungsanlagen GmbH cannot be held liable for any damage resulting from such improper use.

# 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 11.1 - "EC declaration of conformity in accordance with the EC Machinery Directive")

# 1.7 Scope of supply

The following solvent packages are available:

#### Solvent package flask, part no. 102504:

Name	Part number
Freeze-dryer Alpha 3-4 LSCbasic	102372
Capacitive vacuum sensor CMR 364	125498
Vacuum pump Pfeiffer Hiscroll 12 Atex	610712
Interfacebox	125029
Corrugated hose, stainless steel	510085
Reducing adapter DN 25/DN 16	141717
Pressure control valve	125908
Horizontal manifold with 12 rubber valves, including a glass cover	121212



## 1 General information

# Solvent package flask, part no. 102516:

Name	Part number
Freeze-dryer Alpha 3-4 LSCbasic	102372
Capacitive vacuum sensor CMR 364	125498
Vacuum pump Pfeiffer Hiscroll 12 Atex	610712
Interfacebox	125029
Corrugated hose, stainless steel	510085
Reducing adapter DN 25/DN 16	141717
Pressure control valve	125908
Vertical manifold with 12 rubber valves	110538
Glass cover	121448

# Solvent package universal, part no. 102505:

Name	Part number
Freeze-dryer Alpha 3-4 LSCbasic	102372
Capacitive vacuum sensor	125498
Vacuum pump Pfeiffer Hiscroll 12 Atex	610712
Interfacebox	125029
Corrugated hose, stainless steel	510085
Reducing adapter DN 25/DN 16	141717
Pressure control valve	125908
Base plate, stainless steel	120921
Guide tube	122036
3 shelves	120903
Adapter ring	113412
Drying chamber made of real glass	122300
Connecting ring with 12 rubber valves	113398
Glass cover	121448





# Solvent package flask, part no. 102474:

Name	Part number
Freeze-dryer Alpha 3-4 LSCbasic	102372
Capacitive vacuum sensor CMR 364	125498
Vacuum pump Edwards nXDS 10iC	125251
Interfacebox	125029
Corrugated hose, stainless steel	510085
Reducing adapter DN 25/DN 16	141717
Pressure control valve	125908
Horizontal manifold with 12 rubber valves, including a glass cover	121212

# Solvent package flask, part no. 102486:

Name	Part number
Freeze-dryer Alpha 3-4 LSCbasic	102372
Capacitive vacuum sensor CMR 364	125498
Vacuum pump Edwards nXDS 10iC	125251
Interfacebox	125029
Corrugated hose, stainless steel	510085
Reducing adapter DN 25/DN 16	141717
Pressure control valve	125908
Vertical manifold with 12 rubber valves	110538
Glass cover	121448



#### 1 General information

## Solvent package universal, part no. 102475:

Name	Part number
Freeze-dryer Alpha 3-4 LSCbasic	102372
Capacitive vacuum sensor	125498
Vacuum pump Edwards nXDS 10iC	125251
Interfacebox	125029
Corrugated hose, stainless steel	510085
Reducing adapter DN 25/DN 16	141717
Pressure control valve	125908
Base plate, stainless steel	120921
Guide tube	122036
3 shelves	120903
Adapter ring	113412
Drying chamber made of real glass	122300
Connecting ring with 12 rubber valves	113398
Glass cover	121448



The freeze-dryer Alpha 3-4 LSCbasic may only be used with a chemical-resistant vacuum pump of the type Hiscroll 12 Atex by Pfeiffer or type nXDS 10iC by Edwards and only with the specified configurations. Otherwise, the CE mark will be rendered void.

## In addition, every package includes:

- 1 tube of high vacuum grease
- 1 litre of vacuum pump oil
- 1 set of small parts
- 1 drain hose 0.4 m (EPDM DN 10, electrically conductive)
- 1 operating manual



# 2.1 Layout of the freeze-dryer

# 2.1.1 Functional and operating elements

- Ice condenser chamber
- 2 LSCbasic control system (see chapter 6.4.1 - "User interface")
- 3 Mains power switch



Fig. 1: Total view of the freeze-dryer

- 4 Pipe connection of the vacuum sensor
- 5 Pipe connection of the vacuum pump (behind the cover plate)
- 6 Ice condenser

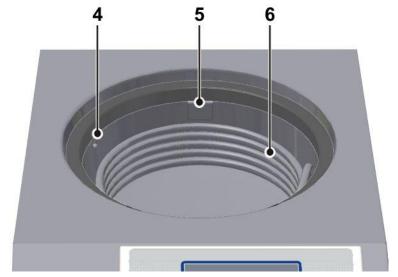


Fig. 2: Ice condenser chamber



- 7 Aeration valve
- 8 Media drain valve

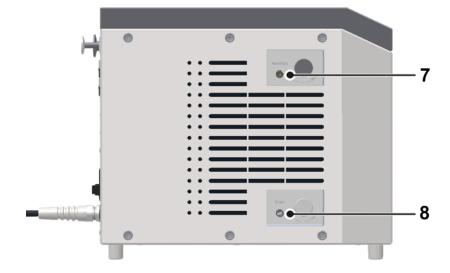


Fig. 3: Left side of the freeze-dryer

## 9 Touchpanel



Fig. 4: User interface with touchpanel

- 10 Heat exchanger of the refrigeration unit
- 11 Name plate (see chapter 2.1.2 - "Name plate")
- 12 Vacuum connection
- 13 Serial interface
- 14 Electrical connection of the vacuum sensor
- 15 Connection of the vacuum sensor
- 16 Power supply of the pressure control valve
- 17 Power supply of the vacuum pump (4.0 A max.)
- 18 Mains fuse
- 19 Mains cable
- 20 Equipotential bonding screw

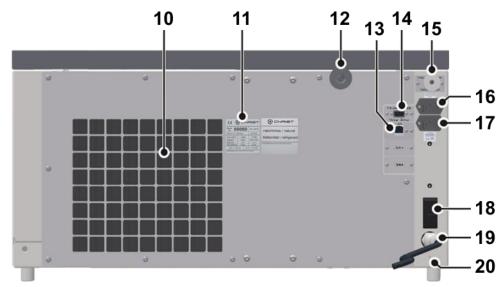


Fig. 5: Rear view of the freeze-dryer

## 2.1.2 Name plate

- 1 Serial number
- 2 Type
- 3 Refrigerant data of the 1st stage
- 4 Nominal voltage
- 5 Year of manufacture (month/year)
- 6 Part number
- 7 Refrigerant data of the 2<sup>nd</sup> stage
- 8 Rated current / apparent power



Fig. 6: 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 high-quality 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.

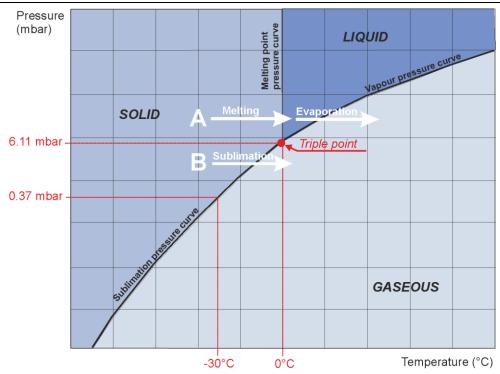


Fig. 7: Vapour pressure curve for ice and water

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 deepfreeze. 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.



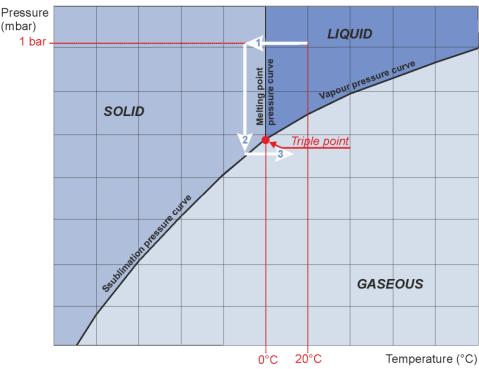


Fig. 8: Freeze-drying phases



Please find further information about basic principles, optimum procedures and applications in the brochure "Smart freeze-drying", which can be downloaded at  $\underline{\text{www.martinchrist.de}} \rightarrow [\text{Applications}] \rightarrow [\text{Lyophilisation}].$ 

# 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.



In the case of a solvent-containing product or of a product with a high salt concentration, the product may thaw during the freeze-drying process. This is indicated by easily visible foaming. To prevent this, the product must be frozen down to a very deep temperature, e.g. in liquid nitrogen, prior to placing it in the freeze-dryer.

#### 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 m³ of vapour, at 0.1 mbar a volume of 10 m³ of vapour, and at 0.001 mbar a volume of 100 m³. 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

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 -105°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 with hot gas**

As standard, the freeze-dryer is equipped with a hot-gas defrosting system. In order to defrost the ice condenser, heated refrigerant is fed through the heating coil.

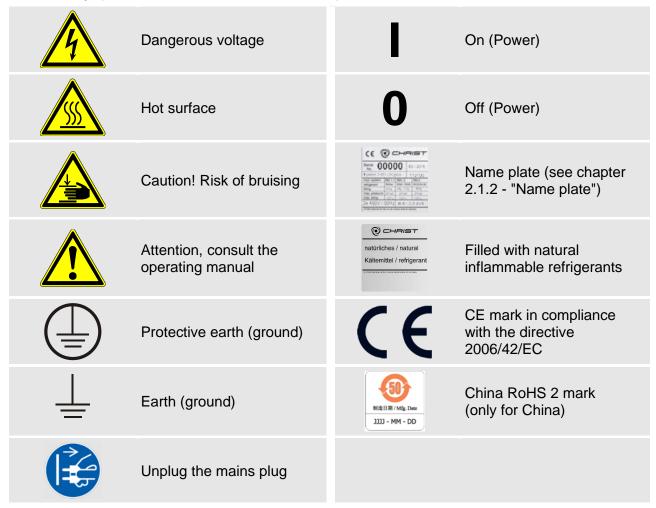
In order to avoid damage, the condensate must be drained off through the media drain valve directly after the completion of the defrosting process. Then, any residual water must be removed from the ice condenser chamber by way of a cloth.

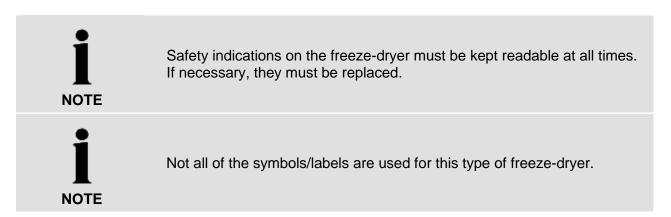


# 3 Safety

# 3.1 Marking of the unit

The following symbols are used for Christ freeze-dryers:







# 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 **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 **potential** 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.



# 3.3 Responsibility of the operator

The operator is the person who uses the freeze-dryer for commercial or economic purposes or lets a third party use it and who bears the legal product responsibility for the protection of the users, personnel or third parties during operation.

#### **Operating personnel**

The operator is obliged to ensure that

- the persons working on/with the freeze dryer
  - have been specifically ordered to operate the system by the operator,
  - have been trained in terms of the operation of this system.
  - 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 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 are 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 are checked at regular intervals (e.g. every month).

#### Work area

The operator must

- observe the system limits defined by the manufacturer in which a risk assessment for explosive atmospheres has been performed. The defined system limits include
  - the drying chamber up to the aeration valve, drain valve and pressure control valve,
  - the glass cover with/without a manifold,
  - the chamber made of real glass.
- ensure that the freeze-dryer must correspond to one of the following solvent packages:
  - Solvent package flask, part no. 102504 (with vacuum pump, type Pfeiffer Hiscroll 12 Atex)
  - 2 Solvent package flask, part no. 102516 (with vacuum pump, type Pfeiffer Hiscroll 12 Atex)
  - 3 Solvent package universal, part no. 102505 (with vacuum pump, type Pfeiffer Hiscroll 12 Atex)
  - 4 Solvent package flask, part no. 102474 (with vacuum pump, type Edwards nXDS 10iC)
  - Solvent package flask, part no. 10248 (with vacuum pump, type Edwards nXDS 10iC)
  - 6 Solvent package universal, part no. 102475 (with vacuum pump, type Edwards nXDS 10iC)



The vacuum pump must be supplied separately by way of a customerprovided socket or it can be connected to the freeze-dryer via an interface box.

- provide standard operating procedures (SOPs) for the freeze-drying of the various products, including specifications concerning the chamber pressure, because freeze-drying products with a high solvent concentration may lead to the formation of potentially explosive gas mixtures. The solvents that are used must be of the temperature classes T1 to T4 as per DIN EN-60079-0:2014-06.
- comply with the specifications of DIN EN 378-1:2018-04 and DIN EN 378-2:2018-04 for refrigeration systems and heat pumps.
- comply with the specifications of DIN EN 378-3:2017-03 and DIN EN 378-4:2017-03 for refrigeration systems and heat pumps.
- perform a risk assessment concerning potential accidents in connection with the freeze-dryer and take appropriate countermeasures, if necessary, for example the use of a safety cabinet.
- 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. The use of substances that damage the material (stainless steel 1.4404 and 1.4435, borosilicate glass, EPDM, PVDF, ceramic Al2O3 and PTFE) or decrease the mechanical strength is prohibited.
- have the system maintained at regular intervals (see chapter 8 -"Maintenance and service").
- replace without delay any parts or components that are not in perfect working order.



# 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:

### **Operating personnel (users)**

The operating personnel operates and monitors the freeze-dryer during normal operation and within the framework of its intended use. In the event of malfunctions or other problems, the operating personnel informs the respective specialised personnel.

It must be ensured that the persons operating the system

- have been specifically ordered to operate the system by the operator,
- have been trained in terms of the operation of this system,
- are familiar with the fundamental health, safety and accident prevention regulations,
- have read and understood this operating manual (in particular the safety sections and warning notes) and confirmed this with their signature.

#### 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.

#### **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.



# 3.5 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 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 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!

#### 3.7.5 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)!



## 3.7.6 Dry-running vacuum pump: hazards caused by contaminated exhaust air



#### Danger of poisoning/infection due to contaminated exhaust air

The exhaust air may contain harmful substances originating from the product.

Contact with particles in the exhaust air (especially by inhalation) may result in severe damage to health.

- Use a silencer with integrated filter elements or depending on the product – guide the exhaust gases from the outlet of the vacuum pump to a suitable treatment system in order to prevent the discharge of harmful substances into the surrounding atmosphere! Compliance with the national rules and regulations for the protection of the environment must be ensured!
- Work on the vacuum pump must only be carried out by qualified specialist personnel!

## 3.7.7 Hazards caused by noise



#### Risk of noise-induced hearing loss

Depending on the local conditions, a harmful sound pressure level may occur.

High sound pressure levels can cause noise-induced hearing loss.

Wear suitable personal hearing protection if necessary!

#### 3.7.8 Hazards caused by hot surfaces



#### Risk of burns on hot surfaces

During the operation of the freeze-dryer and half an hour afterwards, the outer surface of the freeze-dryer, especially the vacuum pump, may 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!
- Prior to performing any maintenance work on the vacuum pump or the oil mist separator, let the components cool!



#### 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!
- Prior to performing any maintenance work, let the chamber cool!



## 3.7.9 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!

## 3.7.10 Hazards caused by breaking glass



#### Risk of injury due to an imploding real-glass drying chamber

External mechanical stress (e.g. shocks or impacts) can destroy the realglass drying chamber.

The resulting glass fragments may lead to life-threatening injuries.

- Ensure that the area around the freeze dryer is free from objects which may damage the real-glass drying chamber by way of shocks or impacts.
- The safety film of the real-glass drying chamber binds the glass fragments in case of breakage. This is why removing the safety film is strictly prohibited.
- The real-glass drying chamber must be free from scratches, cracks, chipped areas and corroded glass. These types of defects may severely weaken the glass structure.

# 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" (chapter 6.4.1.1 - "Main window "Process"", chapter 7.2 - "Process and error messages").

#### 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 CO<sub>2</sub> fire extinguisher!
- Burning oil must be extinguished with a CO<sub>2</sub> 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)!

# 3.10 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 Martin Christ Gefriertrocknungsanlagen GmbH. This does not apply to commercially available freeze-drying vessels made of glass. We explicitly warn against the use of equipment of poor quality! Breaking glass or bursting vessels can cause dangerous situations during the freeze-drying process.



# 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

### 4.1 Dimensions and weight

Values for the freeze-dryer without a vacuum pump:

	Alpha 3-4 LSCbasic	
Height:	415 mm	
Width:	780 mm	
Depth:	635 mm	
Weight:	approx. 86 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 locking devices").
- 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).

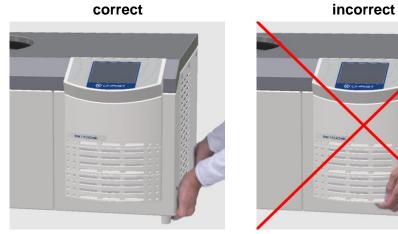
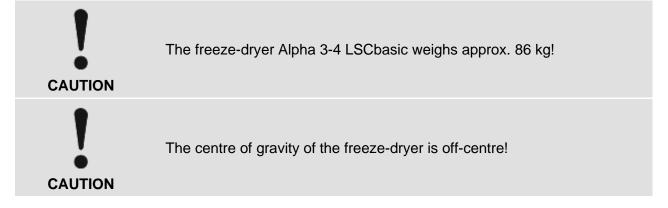


Fig. 9: Lifting the freeze-dryer



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



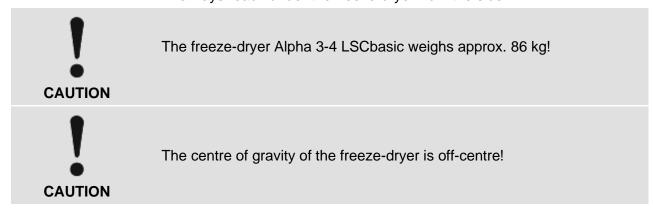
Fig. 10: Unit feet



### 4.4 Packaging

The freeze-dryer is packaged in a wooden crate.

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



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

### 4.5 Transport locking devices

Prior to commissioning, the following transport locking devices must be removed:

• Install the vacuum sensor that had been removed for transport(see chapter 5.5 - "Vacuum sensor").



Reinstall the transport locking devices prior to any transport.



### 5 Set-up and connection

#### 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").
- Avoid direct sunlight (UV radiation).



### 5.2 Power supply

#### 5.2.1 Type of connection



#### 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.



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 type have a three-wire power cord with an IEC C13 connector (see chapter 10 - "Technical data").

An equipotential bonding screw is located on the back (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 valve

The aeration valve is located on top of 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.



The aeration hose must be made of electrically conductive material to prevent the accumulation of electrostatic charges.



The ice condenser chamber can be flooded with nitrogen via the hose nozzle of the aeration valve.

#### 5.4 Media drain valve



# 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!

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



The aeration hose is made of electrically conductive material to prevent the accumulation of electrostatic charges.



#### 5.5 Vacuum sensor

#### Installation



Compliance with the installation instructions in the operating manual provided by the manufacturer of the vacuum sensor is mandatory!

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.

#### Pfeiffer CMR 364 (capacitive)

- 1 Vacuum sensor
- 2 Connection socket

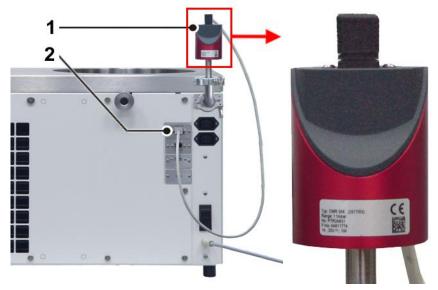


Fig. 11: Position of the vacuum sensor and the connection socket

- 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 (DIN25KF) and two centring rings (included in the scope of supply).
- Plug the connector to the connection socket at the rear side of the freeze-dryer and hand-tighten the screws on the connector.



The vacuum sensor comes supplied in a calibrated state.



#### 5 Set-up and connection

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



For an explanation concerning the  $\square$  working range of the vacuum sensor and the procedure for adjusting the set values, see chapter 6.4.2.1 - "Entering set values".

### 5.6 Vacuum pump

The freeze-dryer Alpha 3-4 LSCbasic may only be used with a chemical-resistant vacuum pump of the type Hiscroll 12 Atex by Pfeiffer or type nXDS 10iC by Edwards and only with the specified configurations. Otherwise, the CE mark will be rendered void.



#### Danger of poisoning/infection due to exhaust air

The exhaust air may contain harmful substances originating from the product.

Contact with particles in the exhaust air (especially by inhalation) may result in severe damage to health.

- Use a silencer with integrated filter elements or depending on the product – guide the exhaust gases from the outlet of the vacuum pump to a suitable treatment system in order to prevent the discharge of harmful substances into the surrounding atmosphere! Compliance with the national rules and regulations for the protection of the environment must be ensured!
- When working on the vacuum system (and especially on the vacuum pump), it may be necessary to wear suitable protective clothing, gloves and a breathing mask depending on the product!



Refer to the separate instruction manual of the vacuum pump and silencer!



The current required by the vacuum pump type Pfeiffer Hiscroll 12 Atex or type Edwards nXDS 10iC is greater than the maximum permissible current for the freeze-dryer (see the following picture). This is why the pump must be supplied separately by way of a customer-provided socket. Alternatively, it can be connected to the freeze-dryer via an interface box (see chapter 5.7 - "Use of an interface box").



 Label indicating the maximum current

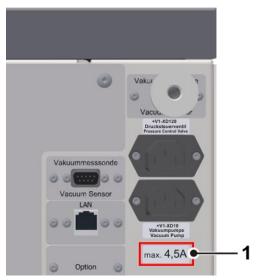


Fig. 12: Indication of the maximum current for the vacuum pump (example)

The vacuum exhaust gases of the dry-running vacuum pump are completely free from oil particles. However, small quantities of debris from worn seals may be emitted. That is why, even when working with non-harmful substances, the exhaust gases must either be led to the outside through the roof via a pipe that is properly connected to the outlet of the vacuum pump, or they must be filtered by way of a silencer with integrated filter elements that is connected to the outlet of the vacuum pump.

Freeze-dryers with a dry-running vacuum pump require a silencer with filter elements. The silencer is removed for transport and must be installed prior to commissioning the freeze-dryer:

- Switch the freeze-dryer off.
- Clean the vacuum connector of the freeze-dryer with a cloth.
- Fasten the silencer to the vacuum connector by way of the supplied centring ring and clamping ring.

#### 5.7 Use of an interface box

The current consumption of certain vacuum pumps is higher than what is permissible for use with the freeze-dryer (see the label stating the maximum current values for the vacuum pump at the IEC C13 connector, illustration above). These pumps must be provided with power via a customer-provided power outlet and they must be operated separately. Alternatively, they can be connected to the freeze-dryer via the interface box. The advantage of the interface box is that, in this case, the vacuum pump can be controlled/actuated via the freeze-dryer.

Its connection requires separate dedicated circuits and power sockets for the freeze-dryer and for the interface box.

#### 5 Set-up and connection

#### Connection of the interface box

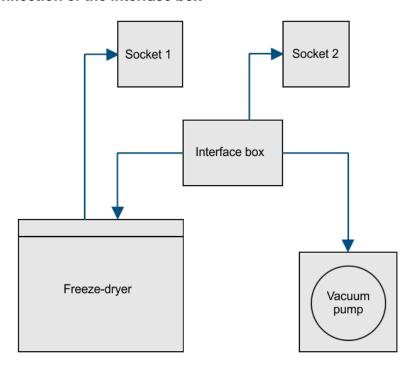
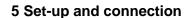


Fig. 13: Connection of the interface box (schematic diagram)

- Connect the connecting cable of the vacuum pump with the designated IEC C13 connector of the interface box (see the following picture, item 1).
- 1 IEC C13 connector for the vacuum pump



Abb. 14: Connector for the vacuum pump at the interface box





- Connect the built-in connecting cable of the interface box (see the following picture, item 2) to the IEC C13 connector for the vacuum pump at the back of the freeze dryer (item 4).
- Connect the mains power cable of the interface box to the designated IEC C14 connector (see the following picture, item 3) and establish the power supply.
- Establish the power supply of the freeze-dryer.
- 2 Connection with the freeze-dryer
- 3 Mains power connector of the interface box

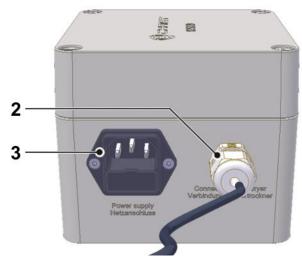


Fig. 15: Connectors for mains power and freeze-dryer at the interface box

4 IEC C13 connector for the vacuum pump at the back of the freeze-dryer



Fig. 16: Back of the freeze-dryer (example)



### 5.8 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")



Observe the installation direction of the pressure control valve.

- Pressure control valve
- 2 Connection to the vacuum pump



Fig. 17: Installation of the pressure control valve



#### 5.9 Installation of the accessories

The accessories of the respective packages (see chapter 1.7 - "Scope of supply") must be installed as shown in the illustrations below:

Solvent packages flask with vacuum pump Pfeiffer Hiscroll 12 Atex or Edwards nXDS 10iC, part no. 102504 and 102474

- 1 Freeze-dryer
- 2 Vacuum pump
- 3 Reducing adapter DN 25/ DN 16
- 4 Corrugated hose (stainless steel)
- 5 Glass cover
- 6 Vacuum sensor
- 7 Manifold
- 8 Rubber valve



Fig. 18: Freeze-dryer Alpha 3-4 LSCbasic with solvent package flask and vacuum pump Pfeiffer Hiscroll 12 Atex or Edwards nXDS 10iC, part no. 102504 or 102474



#### 5 Set-up and connection

Solvent packages flask with vacuum pump Pfeiffer Hiscroll 12 Atex or Edwards nXDS 10iC, part no. 102516 and 102486

- 1 Freeze-dryer
- 2 Vacuum pump
- 3 Reducing adapter DN 25/ DN 16
- 4 Corrugated hose (stainless steel)
- 5 Glass cover
- 6 Vacuum sensor
- 7 Manifold
- 8 Rubber valve

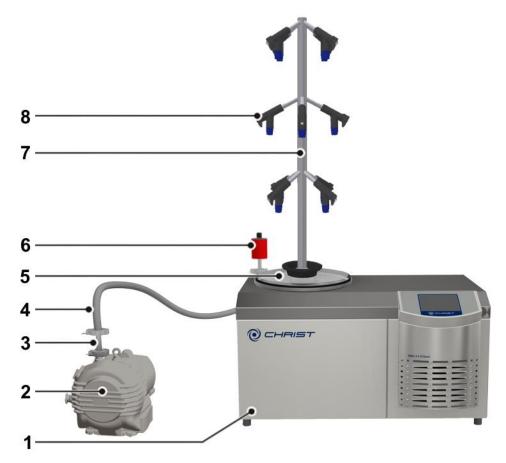


Fig. 19: Freeze-dryer Alpha 3-4 LSCbasic with solvent package flask and vacuum pump Pfeiffer Hiscroll 12 Atex or Edwards nXDS 10iC, part no. 102516 or 102486





Solvent package universal with vacuum pump Pfeiffer Hiscroll 12 Atex or Edwards nXDS 10iC, part no. 102505 and 102475

- 1 Freeze-dryer
- 2 Vacuum pump
- 3 Reducing adapter DN 25/ DN 16
- 4 Corrugated hose (stainless steel)
- 5 Adapter ring
- 6 Vacuum sensor
- 7 Base plate (stainless steel)
- 8 Guide tube
- 9 Drying chamber made of real glass, with three shelves inside
- 10 Connecting ring with rubber valves
- 11 Glass cover

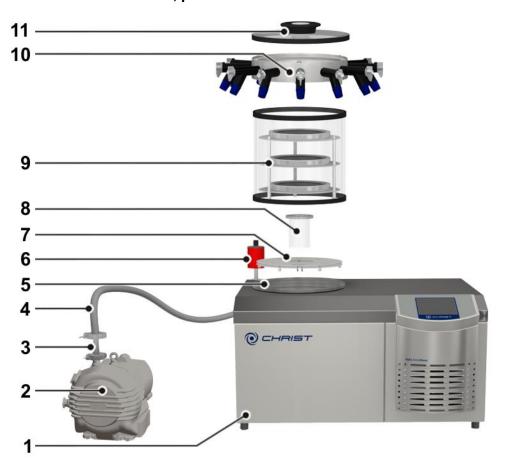


Fig. 20: Freeze-dryer Alpha 3-4 LSCbasic with solvent package universal and vacuum pump Pfeiffer Hiscroll 12 Atex or Edwards nXDS 10iC, part no. 102505 or 102475

#### 5 Set-up and connection

#### 5.9.1 Rubber valves

The rubber valves 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)

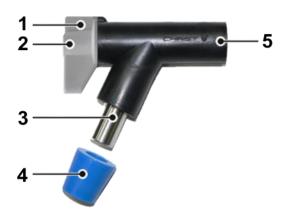


Fig. 21: Rubber valve



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.

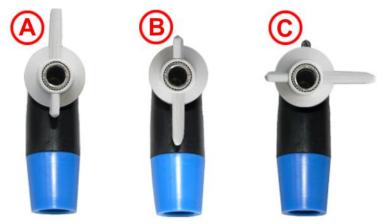


Fig. 22: Possible positions of the locking handle



### 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 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.

### 6.3 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")!



### 6.4 LSCbasic control system

The control system LSCbasic (Lyo Screen Control basic) was specifically developed for the control of freeze-drying processes. The clear user interface enables the intuitive operation of the unit.



### Alpha 3-4 LSCbasic

Serial number 12345

www.martinchrist.de

Fig. 23: Start screen of the LSCbasic control unit (example)

#### 6.4.1 User interface

The system is operated via a touch panel, i.e. by touching the buttons on the display. Every button is marked by a frame. Pressing the button activates the associated function. Depending on the function, a dialogue box opens, a value can be changed, or a transaction can be confirmed.

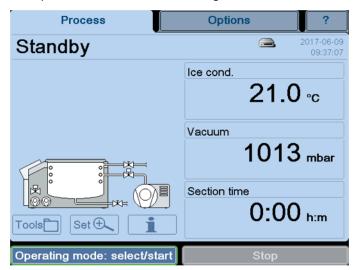


Fig. 24: User interface LSCbasic



The user interface is divided into three main windows that can be called up by touching the corresponding buttons:

#### **Process**

This window is also the standard user interface. It is used to control the freeze-drying process manually.

#### **Options**

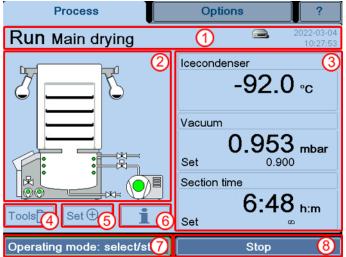
This window is used for personalised settings that enable the users to adapt the system as far as possible to their respective area of activity.

#### ?

In this window, the users can find all of the relevant information concerning the control system at a glance. In the event of enquiries at the factory, these data facilitate the assignment and expediting of the processing of the enquiries.

#### 6.4.1.1 Main window "Process"

This main window shows all of the relevant process data. Here, the individual phases of a freeze-drying process can be controlled manually.



- 1 Status line
- 2 Schematic system diagram
- 3 Value windows
- 4 Button "Tools"
- 5 Button "Set" (set values)
- 6 Button "Process and equipment messages"
- 7 Button "Operating mode: select/start"
  - Button "Stopp"

8

Fig. 25: Overview of the main window "Process"

#### Status line (1)

This line shows the operating status of the freeze-dryer as well as the active phase.

The status line also shows the current date and time. The clock is battery-buffered and must be reset after a failure (siehe chapter 6.4.1.2 - "Main window "Options"", section "Administration").

In addition, the drive symbol provides information concerning the status of the external data storage device or of the network drive. The following symbols are possible:



No symbol	No USB storage device or LAN network connected
	USB storage device connected
	Active process recording on a USB storage device
	Network available, but no network drive connected
	Network drive connected (e.g. LyoLogplus)
	Network drive connected and active process recording

### **Button "Schematic system diagram" (2)**

The left side of the user interface shows a schematic view of the system including all of its components. Active components are displayed in green. Touching a component calls up its name and  $\rightarrow$  reference designation.



The schematic system diagram always includes a drying chamber, even if a manifold is installed in its place.

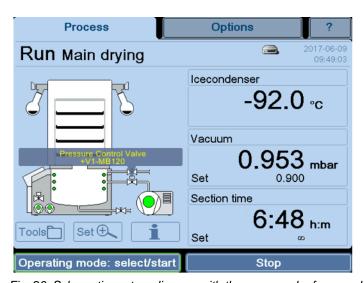


Fig. 26: Schematic system diagram with the name and reference designation of the component



#### Value windows (3)

This area shows the current process data. The three value windows can be configured as desired.

- Select the button of the value window that is to be adapted. A dialogue box with the possible parameters opens:
  - Total time (duration of the entire freeze-drying process up to this moment)
  - Section time (duration of the current section up to this moment)
  - Ice condenser (temperature of the ice condenser)
  - Vacuum (value of the vacuum inside the ice condenser chamber)
  - Temperature 

    vacuum (conversion of a vacuum value into a temperature value based on the vapour pressure curve for ice and water)

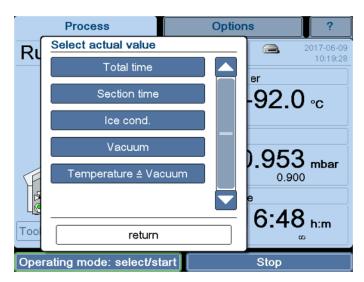


Fig. 27: Dialogue box "Select actual value

• Select the desired configuration or exit the dialogue box by pressing the "return" button.

In this way, it is possible to configure a personalised overview of the actual values.

#### Dialogue box "Tools" (4)

This dialogue box is used to call up various aids and resources.

#### Vapour pressure curve for ice and water

A diagram shows the relationship between the pressure and sample temperature for aequous systems. The pressure and temperature values can be changed by way of the buttons or by moving the arrows (see item 1 in the screenshot). The other value will be adapted automatically.



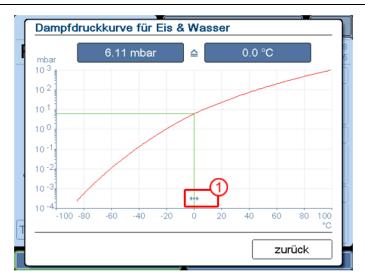


Fig. 28: Dialogue box "Vapour pressure curve for ice and water

#### Option: USB process recording

(see chapter 6.5 - "Optional extensions")

- Select the "USB process recording" function in the dialogue box "Tools".
- Select the input fields ("Batch data"). A keyboard for the data input will be displayed.
- If necessary, select the "Options" tab, choose between manual or automatic recording, and define a recording interval.
- Press the "return" button in order to close the dialogue box.

The process recording will now run in the background.



Fig. 29: Dialogue box "USB process recording"

#### Button "Set" (5)

This button is used to enter the set values for the individual phases of the freeze-drying process prior to the start of the process. Value ranges have been saved for the various phases. These value ranges can be displayed in the input window with the aid of the buttons "min" or "max" (see chapter 6.4.2.1 - "Entering set values").



#### Dialogue box "Process and equipment messages" (6)

This dialogue box is used to view and save all of the error messages and other messages. In the event of an error or message, the window "Process and equipment messages" will open automatically. In addition, a sound signal is emitted until the error is acknowledged.

There are three categories of faults:

Red: error messagesOrange: process messagesYellow: general messages

The representation of the message provides information about its current status. A double frame around a message means that the error has not been eliminated yet. The colour of the button "quit" changes from blue to grey once the message has been acknowledged.



Abb. 30: Representation of an error message

The advantage of this system is that faults that occurred during the night can be discovered the next day even if the cause of the fault has already been eliminated.

The dialogue box cannot be quit until all of the messages have been acknowledged.

If a message has been acknowledged even though the fault has not been eliminated, the button "Process and equipment messages" will be displayed in the respective colour of the fault in the main window.



Fig. 31: Dialogue box "Process and equipment messages"

- The fault has been eliminated, but the message has not been acknowledged
- 2 The fault has not be eliminated and the message has not been acknowledged yet
- 3 The fault has not been eliminated yet, but the message has been acknowledged



#### **Details**

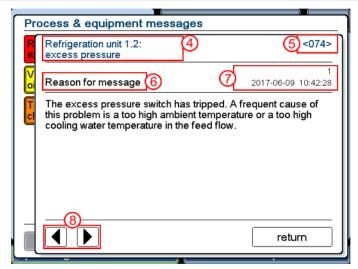
Tapping the message displays details concerning the error message:

- Cause of the message
- Effects of the message
- Measures to eliminate the error
- → Reference designation
- Error counter (indicates how often this error has occurred) and the time stamp of the last error message.

Use the arrow buttons to open the individual windows.



The error message text is always followed by an error code. Always indicate the error code in the event of enquiries or service requests!



- 4 Error message
- 5 Error code
- 6 Detailed information
- 7 Error counter and time stamp of the last error
- 8 Arrow buttons

Fig. 32: Detailed information on an error message



The texts of the process and error messages are not included in this operating manual.

The associated documents can be requested from our service department.



#### Dialogue box "Operating mode: select/start" (7)

After the set values have been entered for the process, the process can be started with this function (see chapter 6.4.2 - "Starting a freeze-drying process").



Fig. 33: Dialogue box "Operating mode: select/start" (The version of the dialogue box that is displayed depends on the equipment of the freeze-dryer.)

#### Button "Standard unit test"

Apart from the process phases of the freeze-drying process ("Freezing", "Warm-up", "Main drying" and "Final drying") and the operating mode "Defrosting", the button "Standard unit test" is also available. This button opens a selection of tests with fixed parameters. After consultation with the manufacturer, these tests can be performed in order to check the functionality and processes of the freeze-dryer.

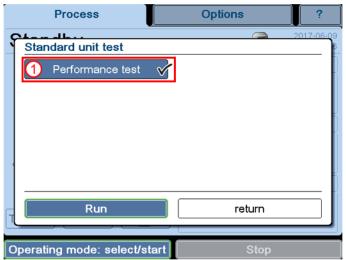


Fig. 34: Dialogue box "Standard unit test"



#### Performance test (1)

This test is used to determine the following performance parameters of a freeze-dryer:

- · vacuum decrease rate
- final vacuum
- minimum ice condenser temperature



Prior to performing a test, ensure that the chamber is dry and unloaded and that the ice condenser is defrosted!

#### Procedure:

- In the main window "Process", select the button "Standard unit test" under "Operating mode: select/start".
- Select "Performance test" and start the test via the "Run" button.

The test will be performed. The parameters will be measured at defined points of time, evaluated, and displayed in a dialog box (see the following illustration).

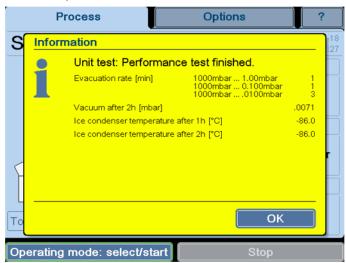


Fig. 35: Results of the performance tests

#### Evaluation:

Please contact Martin Christ Gefriertrocknungsanlagen GmbH for an assessment of the results.

#### Button "Stop" (8)

Pressing this button stops the current process. The freeze-dryer switches to standby.



#### 6.4.1.2 Main window "Options"

The main window "Options" is where the basic configuration of the control system is defined. It enables the optimum adaptation of the freeze-dryer to its specific area of application.

#### General

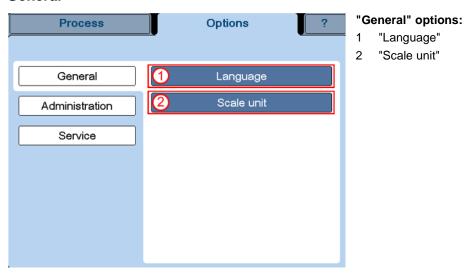


Fig. 36: Overview of the main window "Options/General"

#### Language (1)

The control system can be used in several languages which can be selected via the dialogue box.



Fig. 37: Dialogue box "Change language"

#### Scale unit (2)

This dialogue box is used to change the unit of measurement for the temperature and vacuum values.

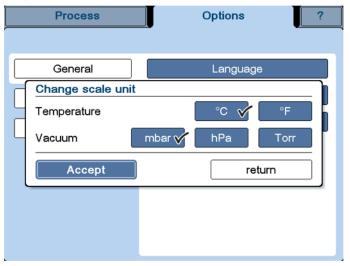


Fig. 38: Dialogue box "Change scale unit"

#### Administration

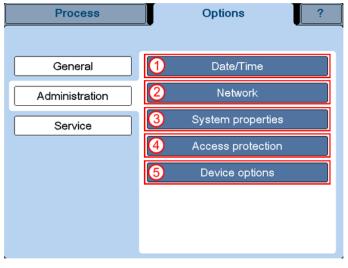


Fig. 39: Dialogue box "Options" / "Administration"

# "Administration" options:

- 1 "Date/Time"
- 2 "Network"
- 3 "System properties"
- 4 "Access protection"
- 5 "Device options"



#### Date/Time (1)

The control system is equipped with an integrated, battery-buffered clock. After a failure of the buffer battery, the date and time must be reset.



Fig. 40: Dialogfenster "Datum/Zeit ändern"

#### Network (2)

This dialogue box is used to change the network settings.



The changes will not become effective until after a restart of the freezedryer.

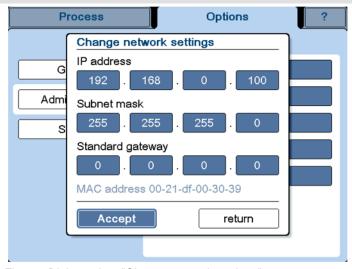


Fig. 41: Dialogue box "Change network settings"

#### System properties (3)

This dialogue box is used to change the system settings.

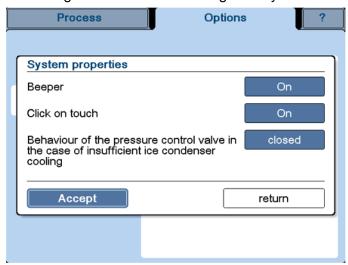


Fig. 42: Dialogue box "System properties"

Beeper: The beeper sounds in the event of a malfunction, for example.

- If the setting is "On", the beeper sounds at intervals of a few seconds until the message is acknowledged.
- If the setting is "Silent", the beeper sounds once when the malfunction occurs.
- If the setting is "Off", the beeper will not sound at all.

*Click on touch:* If this function is active, a clicking sound can be heard whenever the system registers that a button has been touched.

Behaviour of the pressure control valve in the case of insufficient ice condenser cooling: If this function is active (button "closed"), the pressure control valve will close at an ice condenser temperature of ≥ 20°C during the drying process in order to avoid damage to the vacuum pump caused by the withdrawal of condensable gases. Selecting the button again deactivates the function (button "controlled").



#### Access protection (4)

In this dialogue box, the access rights can be managed on several levels and they can be protected with a password.

In the factory setting with activated access protection, data can be viewed but not edited.



Fig. 43: Dialogue box "Access protection"



Nur bei aktiviertem Zugriffsschutz können die weiteren Schaltfelder aktiviert werden.

Password timer runtime: In order to prevent unauthorised access, the system will automatically switch back to the default setting after a predefined period of time.

In this case, there is a small lock symbol in the status line and below this symbol the remaining time until the lock will be active is counted down. At the same time, a button with a big lock symbol will be displayed under the status line.



Fig. 44: Countdown of the password timer and the button with the lock symbol

 The button with the lock symbol blocks any access immediately and the system switches to the default setting.



Fig. 45: Access blocked, data editing not possible

Operator/maintenance/administrator password: For each of these access levels, certain editing rights have been defined. They can be enabled with the corresponding password.

The rights of the various access levels are detailed in the following table.

Action	Operator	Service	Administrator
Editing of the data of the current process run (e.g. selection of the operating mode, changing of set values)	<b>√</b>	✓	<b>√</b>
Editing of maintenance functions (e.g. oil change of the vacuum pump)		✓	✓
Editing of the default settings (e.g. editing of the access protection configuration, creating and editing of programs, editing of system settings)			<b>√</b>

#### Device options (5)

This dialogue box lists all of the device options that are available for the freeze-dryer in question. A list of all the possible options can be found at chapter 6.5 - "Optional extensions"zu finden. Options that require a seriesnumber-specific release code are marked with the symbol "6".

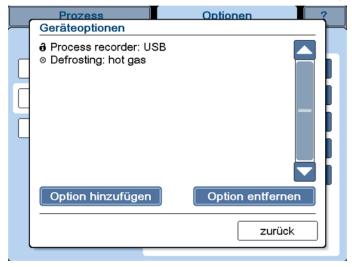


Fig. 46: Dialogue box "Device options" (example)

If the freeze-dryer is to be extended by an option, this option must be enabled via this dialogue box.

- Select the button "Add option". An input window opens.
- Enter the six-digit CHRIST activation code that was supplied for this option. Note that the code is case-sensitive.

Options can be removed in the same way.



The changes will not become effective until after a restart of the freezedryer..



#### **Service**

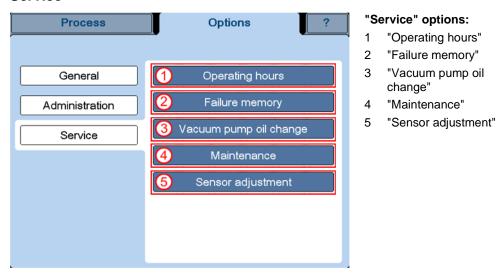


Fig. 47: Dialogue box "Service" (varies depending on the type of freeze-dryer)

#### Operating hours (1)

This dialogue box is used to view the number of operating hours of the various components of the freeze-dryer, e.g. the refrigeration unit, vacuum pump or pressure control valve. In addition to the name, the respective  $\rightarrow$  reference designation is also displayed.

These data are provided for informational purposes only. They cannot be edited.

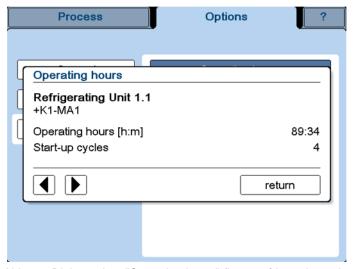


Abb. 48: Dialogue box "Operating hours" (here: refrigeration unit 1.1)



#### Failure memory (2)

The failure memory stores the most recent messages of the process and equipment information system. The messages can be viewed in this dialogue box. The failure memory includes the last 32 messages. If this number is exceeded, the oldest message will be overwritten.

Use the arrow keys to select the individual messages.

The error message text is always followed by an error code.



Always indicate the error code in the event of enquiries or service requests!

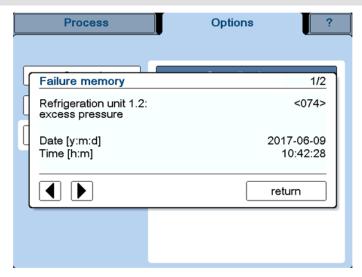


Fig. 49: Dialogue box "Failure memory"



#### Vacuum pump oil change (3)



This option only applies to oil-sealed vacuum pumps!

The system monitors the oil change interval of the vacuum pump. The interval can be adapted to the vacuum pump model and utilisation. When the end of an oil change interval is reached, a corresponding message will be displayed.

- · Acknowledge the message.
- Change the oil of the vacuum pump.
- Reset the operating hour counter in the dialogue box "Vacuum pump oil change" by way of the "reset" button.

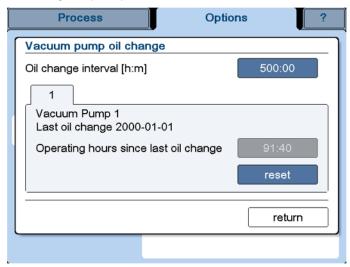


Fig. 50: Dialogue box "Vacuum pump oil change" "

#### Maintenance (4)

The maintenance interval of the freeze-dryer is set at 3,000 operating hours or at least one maintenance per year.

When the end of a maintenance interval is reached, a corresponding message will be displayed.

- Acknowledge the message.
- Make an appointment for the maintenance of your freeze-dryer.
- After the maintenance, our service engineer will reset the operating hour counter in the dialogue box "Maintenance"..



Fig. 51: Dialogue box "Maintenance "

#### Sensor adjustment (5)

In this dialogue box, the sensors are adjusted based on a predefined reference value.



Sensors that are not properly adjusted will lead to incorrect measurements which, in turn, will have a negative effect on the process control.



Only specialised personnel are authorised to perform the sensor adjustment.



#### 6.4.1.3 Main window "?"

This main window includes the most important information concerning your freeze-dryer:



1 Freeze-dryer type

- 2 Control system type
- 3 Serial number
- 4 Manufacturer contact data
- Details concerning the software version

Fig. 52: Freeze-dryer system information, here for Alpha 2-4 LSCplus



In the event of enquiries at the manufacturer, please state the number that is stated here.

## 6.4.2 Starting a freeze-drying process

Freeze-drying processes are started in the main window "Process". The set values for the individual process phases ("Freezing", "Warm-up", "Main drying" and "Final drying") are defined prior to the start of the process (see chapter 6.4.2.1 - "Entering set values"). Then, the freeze-drying process can be started via the dialogue box "Operating mode: select/start".



If the freeze-drying process is to be started directly with the "Main drying" phase, the vacuum pump must be warmed up approximately 15 minutes prior to the process start. Failure to do so will result in a corresponding warning message when the process starts.



If the value "∞" (infinite) is selected for a process phase, the next phase must be started manually via the button "Operating mode: select/start".

The set values of the active phase can be changed during the process run. In this case, the control system adapts the freeze-dryer to the new set values as quickly as possible.

#### 6 Operation

After the completion of a phase, the freeze-dryer switches to the next phase without switching to standby. The transition from "Freezing" to "Warm-up" takes place automatically. After the completion of the "Warm-up" phase, a dialogue box opens:

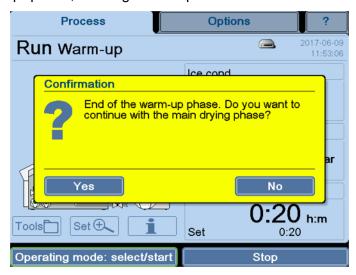


Fig. 53: Dialogue box after the completion of the warm-up phase

The freeze-dryer will remain in the "Warm-up" phase until a confirmation is issued.

Normally, the transition from "Main drying" to "Final drying" takes place automatically.

After the completion of the "Final drying" phase, there will be another enquiry with which the freeze-drying process will be completed. The freeze-dryer remains in the "Run" mode until the enquiry is confirmed.

The process can be stopped any time by way of the "Stop" button. In this case, the freeze-dryer will be switched to standby.

## 6.4.2.1 Entering set values

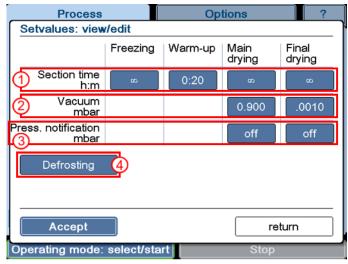
The system has stored set values for every phase, and for every value there are pre-defined value ranges that can be determined in the various dialogue boxes by pressing the buttons "min" and "max" (see hereinbelow, Fig. "Numerical keypad for entering numerical values").

Fields that are displayed in the form of buttons can be edited.



### Viewing or editing the set values

Press the button "Set" (see chapter 6.4.1.1 - "Main window "Process"").
 The following dialogue box will be displayed:



- 1 Set value "Section time"
- 2 Set value "Vacuum"
  - Set value "Pressure notification"

Fig. 54: Dialogue box "Set values: view/edit"

## Section time (1)

The section time defines the duration of the individual phases and is stated in hours and minutes (h:m).

## Vacuum (2)



During the freeze-drying process, the vacuum sensor has a  $\rightarrow$  working range between 0.005 mbar and 1 mbar. The default vacuum value stored in the system is 0.9 mbar. It is not possible to get a useful reading above 1 mbar.



The capacitive vacuum sensors, which are necessary for the freezedrying of solvent-containing products, can only provide information about part of the vacuum control range due to their design.

#### 6 Operation

If a value beyond the working range is entered, an error message will be issued (see the following illustration) and the system will automatically correct the value.

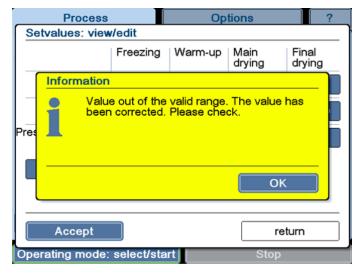


Fig. 55: Warning issued when the vacuum limit is exceeded

- If the value is above the upper limit of the working range, the actual value will be displayed as ">1 mbar" in the value window.
- If the value is the lower limit of the working range or below this limit, the
  actual value will be displayed as "<0.005 mbar" in the value window
  while the set value is displayed as "MinV".</li>
   As a result of this setting, the pressure control valve remains
  permanently open so that operation at the final vacuum of the freezedryer is possible.

#### Pressure notification (3)

As an additional safety feature for controlling the vacuum during the freezedrying of solvents, an  $\rightarrow$  *alarm pressure level* can be entered for every freeze-drying section. This value must be within the working range of the vacuum sensor.



This is only a passive safety feature. The user is responsible for taking the appropriate measures.



#### Defrosting (4)

This button is used to pre-define the defrosting time and temperature.

Numerical values can be edited with the aid of a numerical keypad:

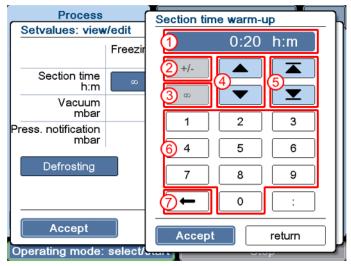


Fig. 56: Numerical keypad for entering numerical values

- 1 Set value display
- 2 Button for changing the sign (e.g. when entering temperature values)
- 3 "∞" (infinite)
- 4 Button for editing the value in pre-defined steps
- 5 Selection of a possible maximum or minimum value
- 6 Input of a value via the numerical keypad
- 7 Button for deleting the displayed value
- Confirm the new value and quit the numerical keypad by pressing the button "Accept".
- · Confirm the input and quit the dialogue box via the button "Accept".



If the dialogue box is closed by the button "return", the changes will be discarded.



# 6.5 Optional extensions

The basic unit is extendable with the following optional functions:

#### **USB** process recorder

see also chapter 6.4.1.1 - "Main window "Process"", dialogue box "Tools" This feature enables the recording of a running process on a USB storage medium. After the end of the process recording, the process data can be viewed on the PC with LyoLogplus and be printed. It is also possible to import the data directly into an Excel file.

# LyoLogplus data logging software

LyoLogplus is a data logging software program by Martin Christ Gefriertrocknungsanlagen GmbH that is specifically adapted to the requirements of freeze-drying processes. Apart from the graphical representation of the measurement data of currently running processes, it also enables the data export for additional evaluation.

# 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

Malfunctions are displayed in the dialogue box "Process & equipment messages" (see chapter 7.2 - "Process and error messages"). 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

Type of error	Possible reason	Correction		
No indication on the display	<ul> <li>No power in the mains supply (see chapter 7.1.1 - "Power failure").</li> <li>Power cord is not plugged in.</li> <li>Fuses have tripped.</li> <li>The mains power switch is set to off.</li> </ul>	<ul> <li>Check the mains power supply fuse.</li> <li>Plug in the power cord correctly.</li> <li>Check the on-site fuses</li> <li>Switch mains power switch ON.</li> </ul>		
The touchpanel does not react at all or it does not react correctly	The sensitivity of the touchpanel is misadjusted.	Contact the service department (see chapter 7.3 - "Service contact")		
The password input fails	The password is not correct.	<ul> <li>Inform the administrator.</li> <li>If you have lost the administrator password: contact the service department (see chapter 7.3 - "Service contact")</li> </ul>		
Insufficient vacuum	Incorrect connection of the small flange connection(s).	<ul> <li>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.</li> </ul>		
	Dirty or damaged lid or door seal.	<ul> <li>Clean the lid or door seal and replace it if necessary.</li> </ul>		
	<ul> <li>The ground-in stopper of the attached drying chamber is not installed correctly.</li> </ul>	<ul> <li>Grease the ground-in stopper evenly and over the entire sealing surface with vacuum grease.</li> </ul>		
Leakage in the media drain valve	<ul> <li>The media drain valve is soiled with drying residues or wool particles from cleaning cloths.</li> <li>The O-rings are worn</li> </ul>	<ul> <li>Clean the media drain valve (see chapter 8.1.3 - "Aeration valve, media drain valve")and replace it if necessary.</li> <li>Replace the O-rings.</li> </ul>		
Leakage in a rubber valve	The valve is soiled.	Check the valves individually (see chapter 7.1.2.4 - "Rubber valves")		



#### 7 Malfunctions and error correction

Type of error	Possible reason	Correction
The displayed vacuum value is not correct	<ul> <li>Incorrect calibration</li> <li>The vacuum sensor is soiled (e.g. due to water residues)</li> <li>The vacuum sensor is defective.</li> </ul>	<ul> <li>Calibrate the vacuum sensor (see the separate operating instructions of the vacuum sensor).</li> <li>Clean the vacuum sensor.</li> <li>Check the vacuum display with the aid of a reference device (if available).</li> <li>see chapter 7.1.2.5 - "Vacuum sensor"</li> </ul>
The vacuum pump is not activated	<ul> <li>See the separate operating instructions of the vacuum pump.</li> </ul>	<ul> <li>See the separate operating instructions of the vacuum pump.</li> </ul>
Insufficient ice condenser or shelf temperature	<ul> <li>The overpressure switch of the refrigeration unit has tripped.</li> <li>The thermal circuit breaker has tripped.</li> </ul>	<ul> <li>Let the unit cool down.</li> <li>Ensure sufficient air circulation (see chapter 7.1.3 - "Insufficient ice condenser temperature")</li> </ul>
During the start, the error message "Refrigeration unit 1.2 overpressure" is displayed	<ul> <li>Excessive ambient temperature</li> <li>Longer period of non-utilisation of the freeze-dryer</li> </ul>	<ul> <li>Decrease the ambient temperature.</li> <li>Acknowledge the message. If the message is displayed repeatedly, inform the service department (see chapter 7.3 - "Service contact")</li> </ul>
The error message "Refrigeration unit x.x overpressure" is displayed during a freeze-drying process	Leakage on the low pressure side (suction side) of the refrigeration system leads to a pressure increase	Acknowledge the message. If the message is displayed repeatedly, inform the service department (see chapter 7.3 - "Service contact")



If it is impossible to eliminate the errors, contact the Christ service department!

#### 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.



Fig. 57: Small flange and centring ring



Fig. 59: Attaching the clamping ring



Fig. 58: Small flange with centring ring and small flange



Fig. 60: Tightened clamping ring



#### 7 Malfunctions and error correction

## 7.1.2.2 Aeration valve, media drain valve



# 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.

 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)!

A malfunction of the aeration valve or the 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 8.1.8 - "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. -105°C is reached when the ice condenser is not loaded and the ice condenser chamber is evacuated.

# 7.2 Process and error messages

The control system displays the complete process and error messages (see chapter 6.4.1.1 - "Main window "Process"", dialogue box "Process and equipment messages"), which is why they are not included in this operating manual.

You can order these documents from our service department.



#### 7 Malfunctions and error correction

# 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: <a href="mailto:support.lab@martinchrist.de">support.lab@martinchrist.de</a>

## **Outside Germany:**

Contact our agency in your country. All agencies are listed at <a href="https://www.martinchrist.de">www.martinchrist.de</a> → [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 Maintenance and service

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 the damage to the materials of construction chapter 1.2 "Intended use".
- 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).

## 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.



#### 8 Maintenance and service

## 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!



# 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, 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.

#### Cleaning the drying chamber and the cover

The outside of the drying chamber, which is made of real glass, is covered with a safety film to provide protection against shattering.



For technical reasons, inclusions are possible. However, they do not prevent the film from performing its function.

To prevent the safety film from being damaged, compliance with the following points is mandatory for cleaning:

 If the freeze-dryer has been contaminated with toxic, radioactive, or pathogenic substances, clean immediately with a suitable decontamination agent (see chapter 8.2 - "Disinfection of the drying chamber and accessories").





• Clean with plenty of water immediately after use in order to ensure that all the contaminants are flushed off and not wiped off.



Do not clean the film while dry.

- Use soft cloths, soft sponges made of synthetic fibres or rubber squeegees and common household cleaning agents (glass cleaner) for cleaning. The cleaning agents must be free from abrasive agents.
- Do not use hard sponges, cloths or brushes for cleaning.
- · Avoid strong mechanical stress during cleaning.

#### 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



# 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.

 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)!

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.
- 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.



#### 8 Maintenance and service

- 1 Valve opening
- 2 Valve core
- 3 O-rings



Fig. 61: Valve opening and valve core with O-rings, here: drain valve (example illustration)

- If necessary, apply a thin layer of high vacuum grease (part no. 126210) to the valve insert and reinsert it.
- 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 system

The dry-running vacuum pump requires only minimal maintenance.



Comply with the maintenance instructions of the manufacturer in the separate operating instructions of the vacuum pump and silencer!

In addition, the following must be taken into consideration:



#### Risk of burns on hot surfaces

During the operation of the freeze-dryer and half an hour afterwards, the outer surface of the vacuum pump may be hot.

There is a risk of burns when touching the surfaces.

- Prior to performing any maintenance work on the vacuum pump, let the components cool!
- Wear suitable protective clothes and gloves!



## Danger of poisoning/infection due to contaminated exhaust air

The exhaust air may contain harmful substances originating from the product.

Contact with particles in the exhaust air (especially by inhalation) may result in severe damage to health.

- Use a silencer with integrated filter elements or depending on the product – guide the exhaust gases from the outlet of the vacuum pump to a suitable treatment system in order to prevent the discharge of harmful substances into the surrounding atmosphere! Compliance with the national rules and regulations for the protection of the environment must be ensured!
- Work on the vacuum pump must only be carried out by qualified specialist personnel!

The number of operating hours of the vacuum pump can be monitored by way of the LSCbasic control system (see chapter 6.4.1.2 - "Main window "Options""/"Service"/"Operating hours" and "Vacuum pump oil change").





#### 8 Maintenance and service

# 8.1.7 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!

#### 8.1.8 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.

## Option: 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.



## 8.1.9 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.
- Use only the accessories that have been specified by Martin Christ Gefriertrocknungsanlagen GmbH.



# 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: <a href="mailto:support.lab@martinchrist.de">support.lab@martinchrist.de</a>



### **Outside Germany:**

Contact our agency in your country. All agencies are listed at  $\underline{www.martinchrist.de} \rightarrow [Sales Partners]$ 



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!



#### 8 Maintenance and service

## 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  $\underline{\text{www.martinchrist.de}} \rightarrow [\text{Service}] \rightarrow [\text{Overhaul, repair and leak testing}].$ 



# 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 3-4 LSCbasic
Part number	102504, 102516, 102505, 102474, 102486, 102475

Performance data	
Ice condenser - capacity - performance - temperature - chamber volume - Ice condenser defrosting temperature:	4 kg max 2.5 kg / 24 h max approx. –105°C approx. 11 I +60°C max.
$\underline{\text{Max. shelf surface area}} \ (\rightarrow \textit{double chamber method}): \\ \text{drying outside the ice condenser chamber}$	3 shelves, Ø 200 mm each A <sub>total</sub> =0.094m <sup>2</sup>
drying in round bottom flasks	12 pieces

Connection requirements – freeze-dryer (without vacuum pump and accessories)	
Electrical connection	1 x 230 V / 50 Hz
Protection class	I
IP protection category according to DIN 60529	11
Apparent power	1.7 kVA
Nominal current	7.3 A
Pressure control valve connection	230 V, 50/60 Hz, 20 VA max.
Vacuum pump connection	230 V, 50/60 Hz, 4.0 A max.

Connection requirements – vacuum pumps	
Vacuum pump Pfeiffer Hiscroll 12 Atex - Electrical connection - Nominal current	200-240 V, 50/60 Hz 4 A (connection to separate socket necessary!)
Vacuum pump Edwards nXDS 10iC - Electrical connection - Nominal current	220-240 V, 50/60 Hz 6 A (connection to separate socket necessary!)



#### 10 Technical data

Refrigerant data	
Refrigerant - Global warming potential (GWP) - Filling quantity - Max. permissible pressure - CO <sub>2</sub> equivalent	R1270 3 120 g 25 bar < 0.01 t
Refrigerant - Global warming potential (GWP) - Filling quantity - Max. permissible pressure - CO <sub>2</sub> equivalent	R1150 3 64 g 25 bar < 0.01 t

Physical data (without vacuum pump and accessories)	
<u>Dimensions</u> - height - width - depth	415 mm 780 mm 635 mm
Weight	approx. 86 kg
Noise level according to DIN 45635	54 dB(A)
EMC according to EN 55011	Class B
Heat emission	1.3 kW min 1.7 kW max

Equipment connections	
Aeration	Hose nozzle DN6 (outside diameter 10 mm max.)
Drain	Hose nozzle DN10 (outside diameter 12 mm)
Vacuum connection	Small flange connection DN25KF (ISO 28403, DIN 2861)
Vacuum sensor	SUB D-9
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 Appendix

# 11.1 EC declaration of conformity in accordance with the EC Machinery Directive



# EC - DECLARATION OF CONFORMITY

in accordance with the EC Machinery Directive 2006/42/EC, annex II, part 1, section A

The product named hereinafter was developed, designed, and manufactured in compliance with the relevant, fundamental safety and health requirements of the listed EC directives and standards. In the event of modifications that were not authorised by us or if the product is used in a manner that is not in line with the intended purpose, this declaration will be rendered void.

Product name:	Freeze-dryer	
Product type:	Alpha 3-4 LSCbasic	
Order number:	102504, 102516, 102505, 102474, 102486, 102475	
Directives:	2006/42/EG Machinery Directive 2014/35/EU Low Voltage Directive 2014/30/EU EMC Directive 2011/65/EU RoHS Directive	
Underlying standards:	DIN EN 378-1:2021-06 DIN EN 378-2:2018-04 DIN EN 378-3:2020-12 DIN EN 378-4:2019-12 DIN EN 61000-6-2:2006-03 DIN EN 61000-6-4:2011-09	

#### Martin Christ Gefriertrocknungsanlagen GmbH

An der Unteren Söse 50 37520 Osterode Germany Authorised representative for CE matters:
S. Krippendorff

Osterode, 19/09/2022

F. Harms, Management

CE\_MaschRL\_Alpha3-4\_LSCbasic\_2022-09-19\_en.docx

Page 1 / 1





# 11.2 Declaration of conformity – China RoHS 2



## DECLARATION OF CONFORMITY

China RoHS 2 (Administrative Measures for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products)

Freeze-dryer models: Alpha 1-2 LDplus, Alpha 1-4 LSCbasic, Alpha 2-4 LSCbasic, Alpha 3-4 LSCbasic, Alpha 1-4 LSCplus, Alpha 2-4 LSCplus, Beta 1-8 LSCbasic, Beta 2-8 LSCbasic, Beta 1-8 LSCplus, Beta 2-8 LSCplus, Gamma 1-16 LSCplus, Gamma 2-16LSCplus, Delta 1-24 LSCplus, Delta 2-24 LSCplus

Rotational Vacuum Concentrator models: RVC 2-18 CDplus, RVC 2-18 CDplus HCI-resistant, RVC 2-25 CDplus, RVC 2-33 CDplus, RVC 2-33 CDplus with infrared heating

Cooling trap models: CT 02-50 SR, CT 04-50 SR

Cooling bath model: CB 18-40

Christ Gefriertrocknungsanlagen GmbH has made reasonable effort to avoid the use of hazardous substances in the products (freeze-dryers and RVC).

A Product Conformity Assessment (PCA) was performed in order to determine whether the concentration of harmful substances in all homogeneous materials of the component parts is above or below the MCV limit (Maximum Concentration Value limit) as defined in GB/T 26572:

Mercury and its compounds: 0.1 % Cadmium (Cd) and its compounds: 0.01 %

Lead (Pb) and its compounds: 0.1 % Hexavalent chromium (Cr (VI)) and its compounds: 0.1 %

Polybrominated biphenyls (PBB): 0.1 % Polybrominated diphenyl ethers (PBDE): 0.1 %

表1 产品中有害物质的名称及含量 Table 1: Name and content of hazardous substances in the product						
部件名称 Component		有害物质 Hazardous substance				
part (PCA)	RA Lead (Pb) Recury (Hg) (Cd) (Cd) SPP SPP SPP SPP SPP SPP SPP SPP SPP SP					
Electronic PCB, cables	X <sup>1)</sup>	0	0	О	0	0
Display	0	0	0	0	0	0
Housing	X <sup>2)</sup>	0	0	0	0	0
Base, metal, accessories	X <sup>2)</sup>	0	0	0	0	0
本表格依据SJ/T 11364的规定编制。 This table is made according to SJ/T 11364.						

Declaration\_China\_RoHS2\_2021-11-25\_en-chr

Page 1 / 2



## 11 Appendix



- 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.
- <sup>2)</sup> 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

F. Harms, Management

Declaration\_China\_RoHS2\_2021-11-25\_en-chn

Page 2 / 2



# 11.3 EC declaration of conformity in accordance with the Pressure Equipment Directive



# EC - DECLARATION OF CONFORMITY

in accordance with the EC Pressure Equipment Directive 2014/68/EU

The refrigeration units in freeze-dryers which are listed hereinafter were developed, designed, and manufactured in accordance with the relevant, fundamental safety and health requirements of the listed EC directives and standards.

In the event of modifications that were not authorised by us or if the product is used in a manner that is not in line with the intended purpose, 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		

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Osterode, March 8, 2022

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Page 1 / 1

# 11 Appendix





# 11.4 Table of the sublimation pressure curve

°C	= mbar						
0	6,110	-20	1,030	-40	0,120	-60	0,011
-1	5,620	-21	0,940	-41	0,110	-61	0,009
-2	5,1770	-22	0,850	-42	0,100	-62	0,008
-3	4,760	-23	0,770	-43	0,090	-63	0,007
-4	4,370	-24	0,700	-44	0,080	-64	0,006
-5	4,020	-25	0,630	-45	0,070	-65	0,0054
-6	3,690	-26	0,570	-46	0,060	-66	0,0047
-7	3,390	-27	0,520	-47	0,055	-67	0,0041
-8	3,010	-28	0,470	-48	0,050	-68	0,0035
-9	2,840	-29	0,4202	-49	0,045	-69	0,0030
-10	2,560	-30	0,370	,50	0,040	-70	0,0026
-11	2,380	-31	0,340	-51	0,035	-71	0,0023
-12	2,170	-32	0,310	-52	0,030	-72	0,0019
-13	1,980	-33	0,280	-53	0,025	-73	0,0017
-14	1,810	-34	0,250	-54	0,024	-74	0,0014
-15	1,650	-35	0,220	-55	0,021	-75	0,0012
-16	1,510	-36	0,200	-56	0,018	-76	0,0010
-17	1,370	-37	0,180	-57	0,016	-77	
-18	1,250	-38	0,160	-58	0,014	-78	
-19	1,140	-39	0,140	-59	0,012	-79	





# 12 Glossary

## Working range of the vacuum sensor

Deviating from the information provided by the manufacturer, the capacitive vacuum sensor used for the freeze-drying process can be used within the following specified working ranges:

Type:	Sensor type	Working range	Measurement error
Pfeiffer CMR363	10 mbar, capacitive	0.05 – 10 mbar	0.02 mbar
Pfeiffer CMR364	1 mbar, capacitive	0.005 – 1 mbar	0.002 mbar

#### Reference designation

Within the life cycle of industrial systems, a uniform equipment identification system is required for planning, design, implementation, operation, maintenance and dismantling so that all of the objects within the system can be clearly identified at any time. The reference designations (also known as device tags) are affixed to the equipment or components and entered into the technical documents (e.g. circuit diagram).

#### **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.

#### Pressure notification

When a certain vacuum value is exceeded (depending on the solvent mixture to be freeze-dried), the oxygen level of the system increases. As a result, the risk of an explosive atmosphere inside the system also increases. The alarm pressure level is a tool with which the user can increase the safety level when freeze-drying solvent-containing products. The alarm pressure level is an optional limit value which can be set by the user and which must be within the working range of the vacuum sensor (1 mbar to 0.005 mbar). When the specified alarm pressure level is reached, a warning and an optional sound signal are issued and the event is documented in the error list. The user is responsible for taking the appropriate measures.

#### **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.

#### **Double-chamber method**

Drying on shelves outside the ice condenser chamber is referred to as a double-chamber system. In freeze-dryers without active shelf cooling, the samples need to be prefrozen 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.





# 13 Index

A	directives25
Access protection67	Condensate, contaminated (hazards)
Accessories 35, 85, 91	
Accessories (installation)49	Connection (hazards)29
Accident prevention25, 28	Connection of the vacuum sensor17
Accident prevention regulations25	Connection requirements96
Acids34	Contaminated condensate (hazards)
Acids (hazards)31	
Administration64	Contaminated defrosting water (hazards)
Aeration 40, 74	
Aeration (connection97	Control system type73
Aeration valve 16, 42	Cooling system97
Aeration valve (cleaning and care)87	Copyright11
Aeration valve, malfunction 82	Corrosion 85, 91
Ambient conditions97	Cost estimate94
Ambient temperature 40, 97	Cracks91
Apparent power 17, 96	Customer-provided fuses41
Areas of responsibility25	D
В	Damage to the materials of construction 85
Beeper 66	Danger of infection due to exhaust air44
Behaviour of the pressure control valve in the	Danger of poisoning due to exhaust air 44
case of insufficient ice condenser cooling	Dangerous materials92
66	Data interface (LAN)97
Breaking glass (hazards)33	Date/Time65
Button "Standard unit test" 61	Declaration of conformity - China RoHS 2101
Button "Stop"	Declaration of conformity (Machinery
С	Directive)11, 99
CE mark in compliance with the directive	Declaration of conformity (Pressure
2006/42/EC23	Equipment Directive)103
Changing of operating supplies34	Declaration of decontamination93
Chemical reactions91	Decontamination agents92
China RoHS 2 – Declaration of conformity101	Defrosting
Circuit diagram97	Defrosting water, contaminated (hazards)
Cleaning34	
Cleaning agents85, 92	Defrosting with hot gas
Cleaning of the freeze-dryer86	Describe 107
Cleaning the accessories85	Details concerning the software version 72
Cleaning the freeze-dryer85	Details concerning the software version73
Click on touch66	Device options
CO2 equivalent97	Device tag107
Compatibility test	



# Index

Dialogue box "Operating mode: select/start"	Freeze-dryer, cleaning and care	
Dialogue box "Process and equipment	Freeze-drying phases	
messages59	Freeze-drying process	
Dialogue box "Schematic system diagram" 56	Freeze-drying process, start	
Dialogue box "Tools"57	Functional and operatin elements	15
Dimensions	G	
Direct hazard to the life and health24	General conditions	10
Disinfectants	General information on freeze-drying	18
Disinfection of the drying chamber and	General malfunctions	
accessories92	General work (maintenance)	
Displayed vacuum value is not correct 80	Global warming potential	
Disposal of the freeze-dryer	H	
Disposal of the packaging95		4.0
Double-chamber method107	Hazard warnings9	
Drain (connection)	Hazards (acids)	
	Hazards (breaking glass)	
E	Hazards (connection)	
Earth conductor check33	Hazards (contaminated condensate)	
EC declaration of conformity (Machinery Directive)		
EC declaration of conformity (Pressure		, 87
Equipment Directive)103	Hazards (electricity) 30, 41	, 89
Electrical connection96	Hazards (exhaust air)32	, 89
Electrical connection of the vacuum sensor 17	Hazards (general, transport to	
Electrical system (maintenance)89	commissioning)	
Electricity (hazards) 30, 41, 89	Hazards (noise)	
EMC according to EN 5501197	Hazards (products, harmful)31	
Entering set values74	Hazards (refrigeration system)	30
Environmental protection	Hazards (set-up)	
Equipment connections97	Hazards (surfaces, cold)	33
Equipotential bonding screw 33, 41	Hazards (surfaces, hot)32, 86	, 89
Error correction79	Hazards (transport)	28
Error messages	Health and safety	25
Exhaust air (hazards)32, 89	Health and safety rules and regulations an	nd
Exhaust gases (hazards)	regulations for the prevention of acciden	
Exhaust gases of the vacuum pump 44	25	
Explanation of symbols11	Heat emission	
Explanation of the symbols and notes 24	Heat exchanger17	, 88
•	Hot-gas defrosting	22
External data storage device55	Humidity	97
F	1	
Failure memory70	Ice condenser	06
Filling quantity (regfrigerant)97	Ice condenser chamber	
Final drying22		
Form for the return of defective parts 94	Ice condenser chamber, cleaning and care	
Freeze-dryer type73	Ice condenser defrosting temperature	
7 - 71	Importance of the operating manual	9



#### Index Marking of the unit ......23 Important information ...... 24 Materials of construction, damage ......85 Infectious substances ......92 Informal safety notes......28 Max. humidity.......97 Initial start-up ...... 53 Maximum current for the vacuum pump ..... 45 Inspection by the manufacturer......92 Media drain......74 Installation der Vakuummesssonde .......... 43 Media drain valve (cleaning and care)...... 87 Instruction .......25 Media drain valve, malfunction......82 Mode of operation......18 Insufficient ice condenser or shelf temperature......80 Ν Insufficient ice condenser temperature...... 83 Name plate ......17 Insufficient vacuum ......79, 81 Network ...... 65 Network drive......55 Interface box ...... 45 No indication on the display ......79 IP protection category according to DIN Noise (hazards) ......32 60529 ...... 96 Noise level ......97 Noise measurement......25 Language......63 Nominal current ......96 Layout of the freeze-dryer ...... 15 Nominal voltage ...... 17, 29 Leakage in a rubber valve......79 Notes on safety and hazards ......9 Leakage in the media drain valve......79 Notes on transport .......38 Location of use ......40 Operating hours ......69 LSCbasic control system.....54 Operating mode: select/start ......61 Lyes......34 Operating personnel ......25 LyoLogplus data logging software......78 Operating state ......55 М Operating voltage......41 Main drying ...... 21 Operational safety......91 Main window "?"......73 Operator (responsibility)......25 Main window "Options" ...... 63 Operator/maintenance/administrator Main window "Process"......55 Mains cable......17 Option: USB process recording......58 Mains fuse ...... 17 Optional extensions ......78 Mains voltage......97 Ρ Maintenance ...... 34, 72 Packaging......39, 95 Maintenance (electrical system)......89 Part number ...... 17, 96 Maintenance (general work)......85 Password input fails ......79 Maintenance (vacuum sensor) ...... 90 Password timer runtime ......67 Maintenance (vacuum system) ......89 Pathogenic substances...... 86, 92 Maintenance and service ......85 Performance data ......96 Maintenance performed by the user........... 85 Performance test......62 Malfunction of the pressure control valve ... 82 Physical data ......97 Malfunctions......79 Potential hazard to the life and health ...... 24 Manufacturer...... 85, 92, 95, 96 Potentially hazardous situation......24 Manufacturer contact data ......73



# Index

Power failure80	Safety notes concerning the transport	28
Power supply41	Safety-conscious work	25
Power supply of the pressure control valve 17	Scale unit (unit of measurement)	64
Power supply of the vacuum pump17	Schematic system diagram	56
Preparation20, 53	Scope of supply	11
Pressure control valve48	Sensor adjustment	72
Pressure control valve, malfunction 82	Serial interface	17
Pressure marks91	Serial number 17, 73, 84, 9	93
Pressure notification107	Service	92
Prevention of accidents9	Service contact	84
Procedures in the event of hazards and	Service life	85
accidents34	Service work	92
Process and equipment messages59	Set process values	58
Process and error messages83	Set-up (hazards)	29
Process data55	Set-up and connection	40
Products, harmful (hazards)31, 86	Signs of corrosion	91
Protection class41, 96	Small flange connections	81
Q	Solvents	34
Qualified electrician27	Solvents	85
R	Specialised personnel27, 8	88
	Specialist personnel 82, 92, 9	
Radioactive substances86	Standard unit test	61
Rated current	Standards and regulations	11
Reference designation 60, 69, 107	Starting a freeze-drying process	73
Refrigerant97	Status line	55
Refrigerant data17, 97	Storage	37
Refrigeration problems	Storage and transport	
Conditions at the location of use40	Storage conditions	
Refrigeration system (hazards)30	· ·	91
Remaining hazards36	Sublimation10	07
Requirements concerning the personnel27	Supply voltage	41
Responsibility of the operator25	Surfaces, cold (hazards)	
Return of defective parts93	Surfaces, hot (hazards)	
Risk assessment25	Switching the freeze-dryer OFF	
Rubber valves52, 82	Switching the freeze-dryer on	
S	System check	
Safety and hazard notes28	System properties	
Safety data sheets97	T	
Safety devices33	•	^-
Safety distance 29, 40	Table of the sublimation pressure curve 10	
Safety instructions	Technical data	
Safety notes concerning set-up and	Technical documentation	
connection28	Thermal stress	
Safety notes concerning the initial start-up. 28	Tools	
Safety notes concerning the operation 30	Topping-up of operating supplies	
	Touchpanel	16

Index



#### Touchpanel does not react......79 Vacuum pump exhaust gases......44 Toxic substances ......86 Vacuum pump is not activated ......80 Vacuum pump oil change......71 Vacuum sensor (maintenance) ......90 Transport locking devices ......39 Vacuum sensor (working range) ...... 107 Transport to commissioning (hazards, Vacuum system (maintenance)......89 general)......28 Vakuummesssonde (Installation) ...... 43 Type...... 17, 96 Value windows......57 Type of connection......41 Vapour pressure curve for ice and water...... U Ventilation......83 Units of protection class I ......41 Vents ......40 USB process recorder......78 Viewing or editing the set values......75 USB process recording ...... 58 W Use of an interface box ......45 User interface ......54 Warranty and liability......10 UV radiation.......40, 85 Weight ...... 37, 97 Working range (vacuum sensor) ...... 107 V Vacuum connection ...... 17. 97 Vacuum pump connection......96 Year of manufacture ......17