Operating instructions

Refrigerator/freezer BL series



Philipp KIRSCH GmbH Im Lossenfeld 14 77731 Willstätt-Sand GERMANY

Telephone: +49 781 9227-0 Fax: +49 781 9227-200

Email: info@KIRSCH-medical.de Internet: www.KIRSCH-medical.de

D1004_04.22_Operating instructions BL version 3, en_GB

Supplemental directives



Preliminary note

Please note that this unit may only be used when wearing protective gloves!

About this instruction manual

This instruction manual was created for the product "Refrigerator/ freezer" (hereafter referred to as "unit").

Persons who work with the unit must have carefully read and understood this instruction manual before any work begins. To ensure safe working conditions, all specified safety warnings and instructions in this instruction manual must be observed.

In addition, special owner obligations may apply.

Keeping the manual

This instruction manual makes it possible to handle the unit safely and efficiently. This instruction manual is part of the unit; it must be kept in the immediate vicinity of the unit and be accessible to staff at all times.

Target audiences

This instruction manual is designed to provide information to the following target audiences:

- Owner of the unit
- Users of the unit

A separate service manual for this unit is available for technical customer service (hereafter referred to as "service department").

Models

This manual is valid for the following units:

Factory number from
100 03 25000 / 100 32 25000
170 04 25000 / 170 30 25000
280 09 25000 / 280 31 25000
500 06 25000 / 500 32 25000
700 03 25000 / 700 31 25000
280 73 25000 / 280 83 25000
500 72 25000 / 500 82 25000
700 72 25000 / 700 82 25000
170 05 25000
180 01 25000
320 02 25000
500 10 25000
650 01 25000



Model	Factory number from
FROSTER BL 730 PRO-ACTIVE	700 06 25000
FROSTER BL 330 ULTIMATE	320 82 25000
FROSTER BL 530 ULTIMATE	500 86 25000
FROSTER BL 730 ULTIMATE	700 86 25000

Illustrations

Illustrations in this manual are designed as an aid to basic comprehension and may deviate from the version at hand.

Manufacturer's address

Manufacturer	Philipp Kirsch GmbH
Address	Im Lossenfeld 14
	77731 Willstätt-Sand
	GERMANY
Telephone	+49 781 9227-0
Fax	+49 781 9227-200
Email	info@kirsch-medical.de
Internet	www.kirsch-medical.de

Business hours:

- Monday to Thursday: 8:00 am to 12:15 pm, 1:15 pm to 4:30 pm
- Friday: 8:00 am to 12:00 pm, 1:00 pm to 4:00 pm

Service contact

Service department	Philipp Kirsch GmbH
Address	Im Lossenfeld 14
	77731 Willstätt-Sand
	GERMANY
Telephone	+49 781 9227-777
Fax	+49 781 9227-200
Email	info@kirsch-medical.de
Internet	www.kirsch-medical.de

Orders are accepted during business hours.

More information

If you have questions or comments regarding this instruction manual or the unit, please contact your authorised regional specialist dealer or contact KIRSCH directly.





Other applicable documents

- Medical product book
- Stock directory
- Operating log



Table of contents

1	Product description	8
	1.1 Unit overview	8
	1.2 Display and control elements	12
	1.2.1 Design of the display and control unit	12
	1.2.2 Function of the key switch	12
	1.2.3 Function of buttons and displays	12
	1.3 Scope of delivery	14
	1.4 Interfaces	14
	1.5 Unit functions	15
	1.5.1 Cooling	15
	1.5.2 Defrosting	16
	1.5.3 Temperature display	17
	1.5.4 Temperature memory	17
	1.5.5 Temperature monitoring with PC-KIT-STICK	17
	1.5.6 Temperature sensor	18
	1.6 Battery	18
	1.7 Additional unit components	18
	1.7.1 Temperature documentation	19
	1.7.2 Interior lighting	20
	1.7.3 Lockable glass door	20
2	Accessories	21
	2.1 GSM module	21
3	Safety	22
	3.1 Symbols in this instruction manual	22
	3.2 Purpose	23
	3.3 Foreseeable misuse	23
	3.4 Residual risks	24
	3.5 Obligations of the owner	26
		28
	3.6.1 Electromagnetic immunity	
	3.6.2 Recommended safety distances	
	3.7 Safety markings	33
	3.8 Staff qualification	34
	3.9 Personal protective equipment	35
4	Transport and decommissioning	37
•	4.1 Unit transport	37
	4.2 Final decommissioning of the unit	39
	4.3 Putting the unit back into operation	39
E		
5	Set-up, installation and connection	40
	5.1 Setting up the unit	40
	5.2 Installing the unit	40
	5.3 Connecting the unit	40

Table of contents



6	Commissioning	42
	6.1 Activities during commissioning	42
	6.2 Programming the unit	43
	6.2.1 Target temperature	43
	6.2.1.1 Function of the target temperature	43
	6.2.1.2 Displaying and changing the target temperature	43
	6.2.2 Temperature warning limits	45
	6.2.2.1 Function of the temperature warning limits	45
	6.2.2.2 Displaying and changing the temperature warning limits	
	6.3 Instruction and unit handover	48
	6.3.1 Instructing the unit officer	48
	6.3.2 Handing over the unit	48
7	Operation	49
	7.1 Switching on the unit	49
	7.2 Switching off the unit	50
	7.3 Retrieving/erasing the temperature memory	50
	7.4 Setting up PC-KIT-NET (optional)	51
	7.5 Stocking the unit	55
8	Cleaning and disinfection	58
9	Maintenance	61
	9.1 Safety inspection	61
10	Alarms	65
	10.1 Alarm functions	65
	10.2 Handling alarms	66
11	Status displays and error messages	67
	11.1 Status displays	67
	11.2 Error messages	67
12	Decommissioning and disposal	73
	12.1 Decommissioning unit	73
	12.2 Disposing of the unit	73
13	Appendix	75
	13.1 Declaration of conformity	76
	13.2 Technical data	78
	13.3 Installation drawing	82
14	Index	1

Unit overview



Product description

1.1 Unit overview

Model BL (example)



Fig. 1: Blood bank refrigerator (housing)

- Key switch
 Display and control unit & Chapter 1.2 'Display and control elements' on page 12
 Door lock
- Glass door
- Adjustable feet
- Door handle

Unit overview



Fig. 2: Blood bank refrigerator (interior)

- Circulation cooling
- Support rails Supports Drawer
- 2
- Melt water container Cooling machine 5



FROSTER BL model (example)



Fig. 3: Blood plasma freezer (housing)

- Key switch
 Display and control unit & Chapter 1.2 'Display and control elements' on page 12
 Door lock
- Adjustable feet
- 5 Door handle

Unit overview



Fig. 4: Blood plasma freezer (interior)

- Circulation cooling
- Support rails Supports Drawer
- 2
- Melt water container Cooling machine 5



Display and control elements > Function of buttons and displays

1.2 Display and control elements

1.2.1 Design of the display and control unit

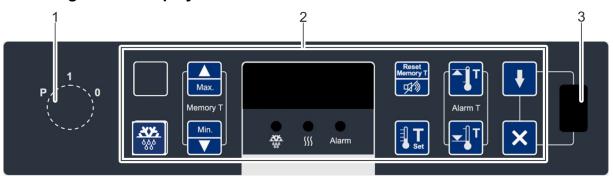


Fig. 5: Display and control unit

- 1 Key switch
- 2 Display and control unit (variable key assignment)
- 3 USB port

1.2.2 Function of the key switch

Tab. 1: Position of the key switch

Key posi- tion	Position	Function	Description		
P0	"0"	Switch off unit.	 Switch off unit (for example to perform a restart). The Display shows		
P 1 0	"1"	Switch on unit.	 Operate unit. Display and reset unit values (for example actual temperature or temperature limits). Confirm alarms. 		
P0	"P"	Program unit.	 Adjust unit (for example target values or temperature warning limits). Display parameter lists. Confirm alarms. 		



Always operate unit in key position "1" in order to prevent manipulation. During normal operation, remove key and store it safely.

1.2.3 Function of buttons and displays

For the functions of buttons and displays, see the following overview:

Display and control elements > Function of buttons and displays

Tab. 2: Buttons

Button	Description	Function
Max.	[Max.]	Display maximum value of temperature memory.
Min.	[Min.]	Display minimum value of temperature memory.
Reset Memory T	[Reset]	Reset temperature memory. Switch off buzzer.
TIT	[Temperature warning max.]	Read upper temperature warning limit.
T	[Temperature warning min.]	Read lower temperature warning limit.
T Set	[Target temperature]	Read target temperature.
\$\$\$\$	[Defrosting]	Activate additional defrosting.
当 On Off	[Additional light / additional	Combination button:
**************************************	defrosting]	Activate additional defrosting.
		Switch interior lighting on/off permanently.
Super Frost	[SuperFrost]	Activate SuperFrost function.
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	[Humidity]	Adjust humidity.
	[Light]	Switch interior lighting on/off permanently.
•	[Start]	Start data read-out via a PC-KIT-STICK.
X	[Cancel]	Cancel data read-out via a PC-KIT-STICK.
	[Unassigned button]	Unassigned button without function.

Product description







Depending on the version, certain buttons have a multiple function in combination with other buttons.

Tab. 3: Displays

Display	Description	Function
₩ ₩	'Defrosting'	Defrosting is active.
555	'Humidity'	Humidity is active (temperature consistency improved, humidity high).
Super Frost	'SuperFrost'	SuperFrost is active.
Alarm	'Alarm'	An alarm was triggered.

1.3 Scope of delivery

					-	
ı	Inte	rio	r	titt	in	as

The following interior fittings approved for operation are supplied for each unit in line with the unit specifications:

- Wire shelves
- Drawers

Lockable unit door

The unit is fitted with a lockable unit door.

Keys included in delivery

Depending on the unit components, the following keys are included in delivery:

- Unit key
- Door key (for lockable unit door)

1.4 Interfaces

The unit is equipped with the following interface for connecting additional units (hereafter referred to as "modules") for monitoring and documenting the temperature:

Unit functions > Cooling

Tab. 4: Interfaces

Interface	Module
LAN interface	PC-KIT-NET (optional)
USB port	PC-KIT-STICK
Potential-free alarm contact	Remote warning system (for example GSM-MODUL or connection to building control system (see circuit diagram on unit))

For information about connecting the modules to the unit, see the relevant product documentation.



Connect only compatible USB flash drives!

Connect only modules with the following properties to the USB port:

- Maximum memory capacity of 32 GB
- Formatted in FAT-32 format



Remove USB flash drive after use!

The USB flash drive must not remain permanently in the unit.

 Remove USB flash drive after the data transfer is completed ♦ 'Error messages and status displays of the PC-KIT-STICK' on page 72.

1.5 Unit functions

1.5.1 Cooling

Cooling machine

The unit is equipped with a cooling machine with interior evaporator for cooling chilled goods.

After initial commissioning or recommissioning, the cooling machine takes a while to cool the interior down to the set target temperature value.

Circulation cooling



With circulation cooling, the air circulates around the interior of the refrigerator. Circulation cooling is performed by means of ventilation plates and a fan.

Circulation cooling reduces physically induced temperature differences and the target temperature is kept constant throughout the interior.

Circulation cooling is set to continuous operation and is switched off automatically when the door is opened.

Product description

Unit functions > Defrosting



Condenser



Fig. 6: Condenser (example)

The condenser transfers the generated thermal energy to the ambient air.



Depending on the model, the condenser is fitted either on the back wall or in the machine room.

1.5.2 Defrosting

Automatic defrosting



The unit defrosts automatically every 12 hours.

Automatic defrosting is time and temperature-controlled.

During automatic defrosting, the system ensures that the unit maintains the target temperature value.

Melt water is conducted into the exterior melt water container and evaporates there.



When the defrosting process is active, the *'Defrosting'* LED display lights up on the Display.

Additional defrosting

In addition to automatic defrosting, it is possible to start the defrosting process manually.



Press button [Additional defrosting] for four seconds.

⇒ The defrosting process begins.

Unit functions > Temperature monitoring with PC-KIT-STICK

1.5.3 Temperature display



Fig. 7: Display

The temperature is shown on the Display of the unit's display and control unit & Chapter 1.2 'Display and control elements' on page 12.

The Display indicates the temperature of the chilled goods.



The temperature display does not indicate the current air temperature of the interior.

The alarm function and the temperature warning limits are based on the temperature of the chilled goods as shown on the Display.

1.5.4 Temperature memory



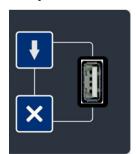
The temperature memory records the maximum and minimum temperature values reached during operation.

The temperature memory begins recording when the target temperature is reached or, at the latest, after two hours of operation.

The temperature memory is reset automatically when the unit is restarted or reset.

The temperature memory can be retrieved and erased manually Chapter 7.3 'Retrieving/erasing the temperature memory' on page 50.

1.5.5 Temperature monitoring with PC-KIT-STICK



The temperature memory of the unit documents the maximum and minimum temperature values.

PC-KIT-STICK is the easiest method of automatic temperature documentation.

The data transfer is performed via a USB flash drive. Even while the data are read out, the temperatures is constantly documented. An unlimited number of units can be incorporated % 'Interfaces' on page 15.

For constant temperature monitoring, the unit can be equipped with temperature documentation via the network \Leftrightarrow Chapter 1.7.1 'Temperature documentation' on page 19.

Additional unit components



1.5.6 Temperature sensor

The unit is equipped with multiple temperature sensors.

For the functions of the respective temperature sensors, see the following table:

Colour	Description	Function
	Evaporator sensor (red)	Controls the defrosting phase
	Control sensor (brown)	Controls the monitoring unit
	Control sensor (violet)	Controls the monitoring unit

1.6 Battery

Battery function

The battery powers the temperature monitoring for up to 30 hours in the event of a power failure.

Temperature monitoring ensures that the temperature progression is stored and the temperature alarm is triggered if necessary.

The battery charges during normal operation and is monitored by an automatic charging system.

Technical data for the battery:

■ 6 V, 4 Ah



The battery does not supply the unit!

The battery only provides power to the temperature monitoring. The battery does not provide a back-up to the unit and therefore ensure that the interior temperature is maintained.

1.7 Additional unit components

The unit is equipped with standard equipment.

The standard equipment can be supplemented with additional unit components.

The following additional components are available for the unit:

- Temperature documentation via the network
- Interior lighting

18

Additional unit components > Temperature documentation

1.7.1 Temperature documentation

The unit can optionally be equipped with additional temperature documentation.

The following table contains an overview of additional unit components.

For more information on installation and use, see the documentation for the relevant product.

For information about the software for temperature documentation, see the *@"Assembly and connection manual – PC-KIT-NET"*.

Tab. 5: Temperature documentation options

Description	Function	Figure
PC-KIT-NET	Automatic temperature documentation and monitoring via the network (LAN). Unlimited connection of units possible. Simultaneous data access for up to 20 clients per server. Two server accesses possible.	TCP/IP 707750.003
Disc-type pen-recording ther- mometer	Depending on the model, it is either installed in the machine room cover of the refrigerator or freezer or integrated in an additional housing extension.	Parents Control of the Control of th
Pen-recording thermometer for placing in the unit	The easiest way to retrofit temperature documentation. Temperature measuring range from +25 °C to -40 °C. Not suitable for FROSTER BL 180 PRO-ACTIVE and FROSTER BL 650 PRO-ACTIVE	
External temperature documentation	The sensor makes it possible to measure the temperature and transfer the data to existing interfaces on site. The user/owner may have to check for compatibility.	

Product description



Additional unit components > Lockable glass door

1.7.2 Interior lighting

Interior lighting (optional)

The unit is optionally equipped with interior lighting.

The interior lighting automatically switches on when the door is opened and switches off when the door is closed.



In units with a glass door, the interior lighting can be permanently switched on or off with the *[Light]* button.

1.7.3 Lockable glass door

Door lock

Your unit can be equipped with a lockable glass door.

For more information on installing the glass door, contact KIRSCH.

GSM module

2 Accessories

The unit can be equipped with the following accessories:

GSM module

2.1 GSM module



Fig. 8: GSM module

The GSM module is used to forward alarm messages to a mobile or fixed-line telephone network via text message.



To operate the GSM module you need a SIM card (not supplied).

A GSM module can manage up to three units. You can use the supplied software to adjust the alarm limits (upper and lower warning limit). You need a temperature sensor to do so (not supplied).

The GSM module has three inputs:

- Two inputs for the potential-free contact
- One input for the optional temperature sensor

Alarm messages are forwarded to the GSM module via the potential-free contact (connection for remote warning system). When the alarm limits are reached, an optical and acoustic signal is triggered on the GSM module and an alarm text message is sent.

The acoustic alarm is acknowledged by sending a confirmation text message to the GSM module or by pressing a button on the GSM module. The optical alarm remains until the fault has been rectified and also acknowledged.

Units without a potential-free contact can be retrofitted with a temperature sensor.

Symbols in this instruction manual



3 Safety

This section provides an overview of all important safety aspects for optimal protection of patients and staff, and for safe and trouble-free operation of the unit.

Non-compliance with the instructions and safety warnings in this instruction manual can cause considerable risks.

3.1 Symbols in this instruction manual

Safety instructions

Safety instructions are marked with symbols in this instruction manual. Safety instructions are initiated by signal words that express the degree of risk.

In order to avoid accidents, injury and damage and ensure maximum patient safety, always comply with safety instructions and act with care.



DANGER!

This combination of symbol and signal word indicates an immediately hazardous situation that will lead to death or serious injury unless avoided.



WARNING!

This combination of symbol and signal word indicates a potentially hazardous situation that can lead to death or serious injury unless avoided.



CAUTION!

This combination of symbol and signal word indicates a potentially hazardous situation that can lead to minor or slight injury unless avoided.



NOTICE!

This combination of symbol and signal word indicates a potentially hazardous situation that can lead to property damage or environmental damage unless avoided.

Hints and recommendations



This symbol highlights useful hints and recommendations as well as information for efficient and trouble-free use of the unit.

Foreseeable misuse

Other markings

Mark	Explanation
_	Step-by-step instructions
⇔	Results of actions
\$	References to sections in this instruction manual
	Lists without a specified order
	References to the instruction manuals for accessories and optional parts

3.2 Purpose

The blood bank refrigerator is used for commercial storage of blood reserves. The blood plasma freezer is used for commercial storage of blood plasma. The blood bank refrigerator and the blood plasma freezer are medical products of risk class IIa as per (EU) Regulation 2017/745 (Medical Device Regulation).

3.3 Foreseeable misuse

The unit is not designed for domestic use. The unit is used for commercial storage of chilled goods in line with its intended purpose.

Do not use the unit to cool warm goods. Do not store chilled goods in the unit if their cooling chain was interrupted during delivery or stock transfer.

Do not store food or drink in the unit.

Do not store chilled goods that exceed the carrying capacity of the wire shelves and drawers.

Residual risks



3.4 Residual risks

Infection of the user



WARNING!

Danger of infection due to inadequate hygiene, disinfection and sterilisation!

Contact with parts that have not been cleaned, sterilised or disinfected poses the danger of infection.

- Comply with the applicable requirements for personal hygiene, disinfection and sterilisation.
- Clean, disinfect and sterilise the unit before filling it for the first time.
- Clean, disinfect and sterilise the unit in line with this instruction manual during operation.

Escaping refrigerant



WARNING!

Danger due to escaping refrigerant!

The refrigerant used in the unit is explosive and pressurised, and can cause serious injury if it comes into contact with the eyes or skin.

- During transport and set-up, do not bend or pierce the tubing and the evaporator.
- Do not damage the surface coat (scratching it off, for example).
- Wear safety glasses and protective gloves when handling the refrigerant circuit.

Hot surface



WARNING!

Danger due to hot surface!

The marked areas of the unit can cause severe skin injuries if touched.

- Do not touch areas of the unit marked in this way.
- These areas are very hot and can still cause burns several hours after the unit has been switched off.



Eco cooling machines



WARNING!

Danger due to unauthorised intervention in the cooling circuit!

The cooling machine contains the natural refrigerant propane R290 / isobutane R600a. The refrigerant used in the unit is flammable and can cause serious injury if it comes into contact with the eyes or skin. Unauthorised intervention in the cooling circuit poses a danger of injury!

On site, only the entire cooling machine can be replaced.

The cooling machine is a permanently technically sealed system in line with EN 1127-1.

Contamination of chilled goods



CAUTION!

Danger to chilled goods due to contamination!

A dirty unit can contaminate the stored chilled goods. A contamination can damage or destroy the chilled goods.

- Do not store contaminated chilled goods in the unit
- After any contamination, clean, disinfect and sterilise the unit and the chilled goods.
- Clean, disinfect and sterilise the unit in line with this instruction manual during operation.
- Comply with the applicable requirements for personal hygiene, disinfection and sterilisation.

Blocked interior ventilation



CAUTION!

Danger of damage and injury due to blocked interior ventilation!

Without adequate ventilation of the cooling machine the air circulation inside the unit is no longer ensured. This can lead to a temperature drop inside the unit, which can damage the chilled goods.

- Make sure that the ventilation in the upper area is clear.
- Do not cover ventilation grille with chilled goods.

Obligations of the owner



Missing power supply



CAUTION!

Danger of damage and injury due to missing power supply!

In the event of a power failure, the battery supplies power only to the warning system. The cooling unit is switched off, which can damage or destroy the chilled goods.

- Make sure that the unit is protected from power failures (for example by an uninterruptible power supply).
- After a power failure, make sure that the cooling unit is supplied with power again.
- If necessary move the chilled goods to another location and inform the service department.

Blocked outside ventilation



NOTICE!

Danger of damage due to blocked outside ventilation!

Without adequate ventilation of the cooling machine the unit can overheat and be damaged.

- Do not set up units in close proximity to each other.
- Make sure that the ventilation (back and front) on the unit is clear.
- Do not cover the cooling machine.
- Allow only qualified staff to install the unit.

3.5 Obligations of the owner

Owner

According to the Medical Devices Act, the owner is the natural or legal person entered in the medical product book.

The owner is obliged to maintain the following documents and keep them to hand:

- Medical product book
- Stock directory
- Operating log
- Instruction manual

The owner is obliged to make the instruction manual and the medical product book available to the users. They can delegate this task to an unit officer.

Obligations of the owner



Inform your specialist dealer of any location changes!

If the unit is set up at a different location by the owner or the unit officer, inform the responsible medical product advisor about the change of location.

Operating log

An operating log must be maintained for this unit in line with the Medical Devices Operator Ordinance.

The operating log contains the following information about the unit:

- Set-up location
- Maintenance
- Modifications
- Repairs

Medical product book

The medical product book contains the following information about the unit:

- Description and other information for identifying the medical product
- Proof of function testing and of staff instruction
- Proof of instruction
- Name of unit officer, date of instruction, and name of instructed person
- Information on safety checks and maintenance
- Information on malfunctions and operating errors
- Reporting of incidents to the authorities and to KIRSCH

Stock directory

The stock directory contains at least the following information:

- Description, sort and type
- Lot code or serial number
- Year of procurement of the medical product
- Name or company and address of the owner
- Identification number of the CE marking added by the notified body (where required according to the regulations of the Medical Devices Act)
- In-company identification number (if available)
- Location and company allocation
- The deadline for safety inspection specified by the owner



3.6 EMC and requirements of the electrical standards

Requirements for electromagnetic compatibility (EMC)



WARNING!

Danger due to failure to comply with requirements for electromagnetic compatibility!

Electrical medical equipment is subject to specific requirements for electromagnetic compatibility (EMC). Failure to comply with the safety requirements leads to a risk of property damage and injury. In addition, failure of the medical equipment may result in damage to or destruction of the chilled goods.

Make sure that electrical medical equipment is installed and commissioned in accordance with the following information:

- It is prohibited to use any accessories other than those described and sold by the manufacturer. Spare parts that are not genuine Kirsch spare parts may increase electromagnetic emitted interference or reduce the electromagnetic immunity of the unit.
- Portable and mobile HF equipment (e.g. mobile phones) can have an impact on electrical medical equipment. The recommended safety distances must be maintained.
- The unit must not be set up next to, above or below another unit. If this is unavoidable, check the unit before use under operating conditions to verify that it functions correctly.



NOTICE!

This unit is not a life-saving or life-sustaining unit.



Instructions and manufacturer's declaration – electromagnetic emitted interference

This unit is designed for use in the electromagnetic environment described below. The customer or user of this unit must make sure that the unit is used in the appropriate environment.

Radiation test	Conformity	Electromagnetic environment – guidelines
HF emissions Test: CISPR 11	Group 1	This unit uses HF energy exclusively for its internal functioning. Its HF emissions are therefore very low and it is unlikely that it will cause interference in nearby electronic equipment.
HF emissions Test: CISPR 11	Class B	The unit can be used in all facilities and homes, as well as in facilities that are connected directly to the public low-voltage grid that supplies private households.
Harmonics IEC 61000-3-2	Class A	
Voltage fluctuations Flicker IEC 61000-3-3	Fulfils the requirements	

3.6.1 Electromagnetic immunity

Instructions and manufacturer's declaration – electromagnetic emitted interference

This unit is designed for use in the electromagnetic environment described below. The customer or user of this unit must make sure that the unit is used in the appropriate environment.

Immunity test	IEC 60601 test level	Con- formity	Electromagnetic environment – guidelines
Discharge of static electricity (DSE) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	Yes	The underlying surface should be made of wood, concrete or ceramic tiles. If underlying surface is made of synthetic materials, the relative humidity should be at least 30%.
Rapid transient electric disturbances/bursts IEC 61000-4-4	±2 kV/ 100 kHz power cables ±1 kV for input and output lines	Yes	The quality of the power supply must be equivalent to that of a typical commercial or hospital environment.
Voltage impulses/surges IEC 61000-4-5	1 kV, conductor-conductor ±2 kV, conductor-earth	Yes	The quality of the power supply must be equivalent to that of a typical commercial or hospital environment.



EMC and requirements of the electrical standards > Recommended safety distances

Immunity test	IEC 60601 test level	Con- formity	Electromagnetic environment – guidelines
Voltage drops, short interruptions and voltage fluctuations in the power supply lines IEC 61000-4-11 For the charger only	0% UT: ½ period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT: 1 period 70% UT: 25/30 periods single-phase: at 0 degrees 0% UT: 250 periods single-phase	Yes	The quality of the power supply should be equivalent to that of a typical commercial or hospital environment. If the unit has to remain continuously in operation even in the event of interruptions to the power supply, it should be connected to an uninterruptible power supply.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	Yes	Magnetic fields at mains frequency should indicate levels that are typical for an application in a commercial or hospital environment.

Note: UT is the mains alternating voltage prior to application of the test level.

3.6.2 Recommended safety distances

Recommended safety distances must be complied with between portable and mobile HF telecommunication devices (e.g. mobile phones) and the product, which is not life-sustaining.

The product is designed for operation in an electromagnetic environment in which HF disturbances are controlled. The customer or user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF telecommunication devices (transmitters) and the product — depending on the output power of the communication device, as specified below.

Rated power of trans- mitter (W)	Safety distance, dependent on the transmission frequency (m)				
	150 kHz to 80 MHz 80 MHz to 800 MHz 800 MHz to 2.7 GHz				
	D=1.2 √P	D=1.2 √P	D=1.2 √P		
0.01	0.12	0.12	0.23		
0.1	0.38	0.38	0.73		
1	1.2	1.2	2.3		
10	3.8	3.8	7.3		
100	12	12	23		

EMC and requirements of the electrical standards > Recommended safety distances

For transmitters whose maximum rated power is not listed in the table above, the recommended safety distance d in metres (m) can be determined using the equation in the corresponding column, where P is the maximum rated power of the transmitter in watts (W) according to the information from the manufacturer of the transmitter.

Notes: At 80 MHz and 800 MHz the higher frequency range applies. These guidelines may not apply to all cases. The propagation of electromagnetic variables is affected by absorption and reflection from buildings, objects and people.



WARNING!

These guidelines might not apply in every situation. The propagation of electromagnetic variables is affected by absorption and reflection from buildings, objects and people.

The product is designed for operation in the environment described below. The user must make sure that the unit is used in the appropriate environment.

Immunity test	IEC 60601 test level	Conformity	Electromagnetic environment – guide- lines		
Conducted HF dis-	3 Vrms	Yes	Portable and mobile radio devices must not		
turbances acc. to IEC 61000-4-6	150 kHz to 80 MHz		be used at distances to the product (including the lines) shorter than the recom-		
	6 Vrms	Yes	mended safety distance as calculated using the transmission frequency-specific equa-		
	150 kHz to 80 MHz in ISM and amateur radio fre-		tion.		
	quency allocations		Recommended safety distance:		
			$d = 1.2 \sqrt{P}$		
			d = 1.2 \sqrt{P} , 80 MHz to 800 MHz d = 2.3 \sqrt{P} , 800 MHz to 2.7 GHz		
Radiated HF disturbances acc. to IEC 61000-4-3	Professional Healthcare 3 V/m 80 MHz to 2.7 GHz	Yes	Where P is the maximum rated output power of the transmitter in watts (W) according to the information from the manufacturer and d is the recommended distance in matres (m). The field strengths of ste		
	Home Healthcare	Yes	in metres (m). The field strengths of stationary HF transmitters, according to the		
	10 V/m		electromagnetic site investigation a, should be less than the conformity value in the indi-		
	80 MHz to 2.7 GHz		vidual frequency ranges b.		
			Disturbances can occur in the vicinity of units that are marked with the following symbol: (*p*).		

NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies.



EMC and requirements of the electrical standards > Recommended safety distances

NOTE 2: These guidelines might not apply in every situation. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects and people.

a: Field strengths of stationary transmitters, e.g. base stations for wireless telephones (mobile/cordless) and land mobile radio installations and transmitters for amateur radio, MW and VHF transmission, cannot be forecast precisely on a theoretical basis. To assess the electromagnetic environment due to stationary HF transmitters, an electromagnetic site investigation should be considered. If the measured field strength at the site where the product is to be used exceeds the corresponding HF conformity value specified above, the unit should be observed to check for normal operation. If any abnormal performance is noted, further measures may be necessary, such as realigning or moving the product.

b: In the frequency range of 150 kHz to 80 MHz, the field strengths should be under 3 V/m.

Test specification for IMMUNITY OF ENCLOSING INTERFACE vis-à-vis wireless HF communication devices

TETRA 400				level (V/m)
121101 400	Pulse modula- tion ^{b)}	1.8	0.3	27
	18 Hz			
GMRS 460	Fm ^{c)}	2	0.3	28
FRS 460	\pm 5 kHz			
	Deviation			
	1 kHz sine			
LTE band 13, 17	Pulse modula- tion ^{b)}	0.2	0.3	9
	18 Hz			
GSM 800/900 TETRA 800 iDEN 820 CDMA 850	Pulse modula- tion ^{b)} 217 Hz	2	0.3	28
G F L1	GMRS 460 FRS 460 TE band 13, 7 GSM 800/900 FETRA 800 DEN 820	tionb) 18 Hz SMRS 460 Fmc) ERS 460 ± 5 kHz Deviation 1 kHz sine TE band 13, 7 Pulse modulationb) 18 Hz SSM 800/900 Pulse modulationb) ETRA 800 DEN 820 CDMA 850	tion ^{b)} 18 Hz GMRS 460 Fm ^{c)} 2 FRS 460 ± 5 kHz Deviation 1 kHz sine TE band 13, 7 Pulse modulation ^{b)} 18 Hz GSM 800/900 Pulse modulation ^{b)} 217 Hz CDMA 850	tion ^{b)} 18 Hz GMRS 460 Fm ^{c)} 2 0.3 FRS 460 ± 5 kHz Deviation 1 kHz sine TE band 13, 7 Pulse modulation ^{b)} 18 Hz GSM 800/900 Pulse modulation ^{b)} 217 Hz CDMA 850

Safety markings

Band ^{a)} (MHz)	Service ^{b)}	Modulation ^{b)}	Max. output (W)	Distance (m)	Immunity test level (V/m)
1700 – 1990	GSM 1800 GSM 1900 CDMA 1900, DECT LTE band 1, 3, 4, 25, UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
2400 – 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5100 – 5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9

Note: To reach the INTERFERENCE TEST LEVEL, the distance between the transmitter antenna and the ME UNIT or ME SYSTEM can be reduced to 1 m, if necessary. A testing distance of 1 m is permitted according to IEC 61000-4-3.

3.7 Safety markings

Type plate

The type plate is mounted in the interior of the unit.

^{a)} For some services, only the uplink frequencies are included.

^{b)} The carrier should be modulated with a square wave signal with a duty cycle of 50%.

c) Alternatively to frequency modulation, a 50% pulse modulation at 18 Hz can be used. As this does not correspond to the current modulation, this would be the worst case.

Staff qualification







Fig. 9: Example type plate (BL 176 PRO-ACTIVE)

3.8 Staff qualification

The type plate contains the following information:

- Model
- Factory no.
- Refrigerant type and quantity
- Alternating current
- Climate class
- Refrigerator capacity (volume of entire interior)
- Net capacity (volume of usable interior)
- Cooling unit
- Power consumption
- Additional heaters with output > 100 W

Inadequate staff qualification

WARNING!

Danger of damage and injury due to commissioning by unqualified staff!

If commissioning is performed incorrectly by unqualified staff, serious damage to the chilled goods can result, which in turn can seriously harm patients.

- Have all tasks performed only by staff qualified for those tasks.
- Keep unauthorised persons away from the working area.

Staff qualifications

Medical products may in principle be set up, operated, used and maintained only by persons who have the necessary training or skills and experience.

This manual specifies the staff qualifications for various fields of activity as listed below:

Inspector

The inspector is responsible for the safety inspection according to the Medical Devices Operator Ordinance.

They must only perform these tasks if they have the necessary qualifications and independence:

- They must have the training, skills and practical experience to ensure that the safety inspections are performed correctly.
- They must not be subject to any direction as regards the inspection activity.
- They must have suitable measuring and testing equipment.

Trained medical technicians are suitable, for example.

The inspector must provide proof of their qualification upon request by the responsible authority.



System/network administrator (recommended)

The system/network administrator has the training, IT skills and experience required to set up the system requirements and working environment, including all technical equipment, to enable the software to be used.

The system/network administrator performs the following duties:

- Installing KIRSCH-DATANET
- Integrating the unit in the network

The system/network administrator has been authorised by the owner to manage the users of the software and to make settings to the software.

Unit officer

The unit officer is the person who is nominated for this task by the owner of the unit and has received instruction on their duties.

Enter the name of the unit officer and the date of instruction in the medical product book and confirm with your signature.

The unit officer meets the following requirements:

- The unit officer knows the intended purpose, the foreseeable misuse and the residual risks of the unit.
- The unit officer is familiar with the instruction manual and all other safety-related documents.
- The unit officer has been instructed in the technically correct and safe handling of the unit.

The unit officer performs the following tasks:

■ The unit officer instructs users in how to handle the unit.

User

The user is the person who uses and operates the unit according to its intended purpose. The unit may only be used and operated by trained specialist staff.

The user has been instructed in the technically correct and safe use of the unit in accordance with the relevant laws and ordinances.

General staff qualification requirements

Staff members must be persons who can be expected to perform their work reliably. Persons whose reactions are impaired, e.g. by drugs, alcohol or medication, are not permitted.

When choosing employees, observe the age and vocation regulations that apply at the deployment site.

3.9 Personal protective equipment

Personal protective equipment protects staff members from dangers that could affect their safety or health at work.

Always wear the personal protective equipment specified in the various chapters of this manual before starting the relevant task.



Observe instructions on personal protective equipment that are installed in the working area.

When performing various tasks on and with the unit, staff must wear personal protective equipment. This is indicated specifically in the individual chapters in this manual. This personal protective equipment is explained below:



NOTICE!

Wear suitable protective gloves when using the unit. These gloves must comply with either PPE Ordinance 2016/424 or the MDD Directive 93/42/EEC (which will be superseded on 27 May 2021 by MDR Regulation 2017/745).



Chemical-resistant protective gloves

Chemical-resistant protective gloves protect the hands from aggressive chemicals.



Protective gloves

Protective gloves protect the hands from friction, abrasions, piercing or deeper injuries as well as from contact with hot surfaces.



Safety shoes

Safety shoes protect the feet from crushing, from falling parts, and from slipping on slippery ground.



Unit transport

4 Transport and decommissioning

4.1 Unit transport

On delivery, the unit is transported after consultation with the specialist dealer.

When transporting the unit during a change of location while the unit is still operating, observe the following safety instructions.

Safety during transport



WARNING!

Danger of crushing injuries from falling unit!

If the unit is tilted, it will fall over in an uncontrolled fashion. When the unit falls over, there is a danger of crushing to the hands and feet.

- Wear safety shoes and safety gloves when transporting the unit.
- Transport the unit in an upright position.



WARNING!

Danger due to escaping refrigerant!

The refrigerant used in the unit is explosive and pressurised, and can cause serious injury if it comes into contact with the eyes or skin.

- During transport and set-up, do not bend or pierce the tubing and the evaporator.
- Do not damage the surface coat (scratching it off, for example).
- Wear safety glasses and protective gloves when handling the refrigerant circuit.

Transport and decommissioning







NOTICE!

Danger of damage to the melt water container!

The units in the table below are equipped with a melt water container on their underside, which can be damaged by incorrect transport:

- Place unit on pallet and transport it.
- Do not lift unit with forklift or pallet truck unless it is on a pallet.

BL 520 PRO-ACTIVE	BL 520 ULTIMATE
BL 720 PRO-ACTIVE	BL 720 ULTIMATE
FROSTER BL 530 PRO-ACTIVE	FROSTER BL 530 ULTIMATE
FROSTER BL 730 PRO-ACTIVE	FROSTER BL 730 ULTIMATE

Transporting the unit to a new location

Protective equipment: ■ Safety shoes

Protective gloves

Decommission the unit as shown in section % 'Final decommissioning of the unit' on page 39.

1. Transport the unit to the new location.



Waiting time before recommissioning:

Once the unit has been transported, set up the unit and wait one hour before recommissioning, so that the refrigerant can distribute itself evenly throughout the refrigerant circuit again.

2. Recommission the unit as shown in section & 'Putting the unit back into operation' on page 39.



Inform your specialist dealer of any location changes!

If the unit is set up at a different location by the owner or the unit officer, inform the responsible medical product advisor about the change of location.

Putting the unit back into operation

4.2 Final decommissioning of the unit



NOTICE!

Wear suitable protective gloves when using the unit. These gloves must comply with either PPE Ordinance 2016/424 or the MDD Directive 93/42/EEC (which will be superseded on 27 May 2021 by MDR Regulation 2017/745).

Final decommissioning of the unit

Insert unit key in key switch.



- 1. Turn unit key to position "0".
- 2. Unplug power plug.
- 3. Remove unit key.
- **4.** Leave unit door open to prevent the formation of odours and mould.

4.3 Putting the unit back into operation



NOTICE!

Wear suitable protective gloves when using the unit. These gloves must comply with either PPE Ordinance 2016/424 or the MDD Directive 93/42/EEC (which will be superseded on 27 May 2021 by MDR Regulation 2017/745).

Putting the unit back into operation

Before recommissioning, clean and disinfect the unit % Chapter 8 'Cleaning and disinfection' on page 58.

- 1. Plug in power plug.
- 2. Insert unit key in key switch.



- 3. Turn unit key to position "1".
 - ⇒ The Display shows the interior temperature.
- 4. Check target temperature and adjust if necessary ♥ Chapter 6.2.1.2 'Displaying and changing the target temperature' on page 43.



Lead time of the temperature alarm!

The temperature alarm is active at the earliest when the target temperature is reached, and at the latest after two hours of unit operation.

5. When the unit has reached its target temperature, place the chilled goods in the unit.

Connecting the unit



5 Set-up, installation and connection

5.1 Setting up the unit

Set-up

When setting up the unit, observe the following set-up conditions:

- Select a dry and well ventilated set-up location.
- Do not set up the unit next to heat sources.
- Avoid direct sunlight.
- Set up the unit on a firm, level surface.
- Compensate for uneven ground with adjustable feet.
- Do not cover, block or line the ventilation grille.
- Do not cover, block or line the cooling machine.
- Maintain a minimum distance of 2 cm between wall and unit (for example by means of a spacer).
- Maintain a minimum distance of 2 cm between units.
- Comply with the minimum available space at the set-up location in order to avoid a potentially explosive as defined in DIN EN378-1 for the use of refrigerators and freezers with combustible refrigerants (R600a, R290a).



The basis for calculating the minimum available space at the set-up location is the largest fill quantity of refrigerant in the existing or planned refrigerators. For the respective fill quantity of refrigerant, see table \$\infty\$ Chapter 13.2 'Technical data' on page 78.

R600a: volume = refrigerant fill quantity / 8.6 g/m³ R290a: volume = refrigerant fill quantity / 7.6 g/m³

5.2 Installing the unit

Overview of units suitable for installation

BL 100 PRO-ACTIVE

Installing

Have the unit installed only by staff qualified for the task. If in doubt, contact KIRSCH ♥ 'Manufacturer's address' on page 4.

Install the unit as shown in the installation drawing provided.

5.3 Connecting the unit

Connecting



The unit is designed according to protection class I and protection type IP 20 and is ready to be plugged in.



Set-up, installation and connection

Connecting the unit

Ensure the connection conditions specified in the technical data and on the type plate.

- **1.** Check the connecting cable of the power plug for damage.
- 2. Plug in power plug.

Activities during commissioning



6 Commissioning

Personnel: Unit officer



NOTICE!

Wear suitable protective gloves when using the unit. These gloves must comply with either PPE Ordinance 2016/424 or the MDD Directive 93/42/EEC (which will be superseded on 27 May 2021 by MDR Regulation 2017/745).

6.1 Activities during commissioning

Commissioning sequence



WARNING!

Danger of damage and injury due to commissioning by unqualified staff!

If commissioning is performed incorrectly by unqualified staff, serious damage to the chilled goods can result, which in turn can seriously harm patients.

- Have all tasks performed only by staff qualified for those tasks.
- Keep unauthorised persons away from the working area.

Commissioning consists of the following activities:

- 1 Clean and disinfect the interior of the unit & Chapter 8 'Cleaning and disinfection' on page 58.
- 2 Switch on the unit & Chapter 7.1 'Switching on the unit' on page 49.
- 3 Program the unit ♥ Chapter 6.2 'Programming the unit' on page 43.
- 4 Wait until the target temperature is reached.
- 5 Stock the unit & Chapter 7.5 'Stocking the unit' on page 55.
- 6 Instruct the unit officer Chapter 6.3 'Instruction and unit handover' on page 48.

Programming the unit > Target temperature

6.2 Programming the unit

Ensure only authorised personnel have access to the key



NOTICE!

Danger due to faulty programming!

By putting the key in key position "P" it is possible to access the programming functions of the unit. Programming that is unsuitable for the chilled goods can cause damage to the chilled goods.

- Have programming performed by qualified employees.
- Once programming is complete, turn the key switch to position "1" and remove the key.
- Secure the key against unauthorised access.
- Do not operate the unit in key position "P".

6.2.1 Target temperature

6.2.1.1 Function of the target temperature

The target temperature specifies the temperature at which the unit is operated to store the chilled goods in optimal conditions.

The target temperature of the unit is preset by KIRSCH.

The preset value of the target temperature is in accordance with the unit-specific standards. Do not modify the target value.



Changes to the target value do not change the temperature warning limits. These are adjusted manually $\$ Chapter 6.2.1.2 'Displaying and changing the target temperature' on page 43.

6.2.1.2 Displaying and changing the target temperature

Changes must be performed by qualified employees



WARNING!

Danger due to manipulation of the target temperature!

The factory-set values for the target temperature comply with the valid DIN standards. Incorrect changes to the target temperature and the temperature warning limits can cause irreparable damage to the chilled goods.

If in doubt, contact our service department ∜ 'Service contact' on page 4. Programming the unit > Target temperature



Displaying the target temperature



Press button [Target temperature].

⇒ The current target temperature is displayed.

Changing the target temperature

1. Insert unit key in key switch.



NOTICE!

Danger due to faulty programming!

By putting the key in key position "P" it is possible to access the programming functions of the unit. Programming that is unsuitable for the chilled goods can cause damage to the chilled goods.

- Have programming performed by qualified employees.
- Once programming is complete, turn the key switch to position "1" and remove the key.
- Secure the key against unauthorised access.
- Do not operate the unit in key position "P".



2. Turn unit key to position "P".



3. Press and hold button [Target temperature].





4. Use button [Min.] or [Max.] to set the required target value.



- 5. Turn unit key to position "1".
 - The unit regulates the temperature to the specified target value.



Monitor the temperature progression!

The unit will not reach the new target value immediately after the change is made.

Monitor the temperature progression on the Display or using optional temperature documentation (e.g. KIRSCH-PC-KIT).

6. Read the current temperature and monitor the subsequent temperature progression until the target temperature is reached.

Programming the unit > Temperature warning limits



Consequences of modified target temperature

As soon as the target temperature is reached, the temperature warning limits must be adjusted so that the target temperature is above or below the temperature warning limits. Otherwise the temperature alarm will be triggered \$\infty\$ Chapter 6.2.2.2 'Displaying and changing the temperature warning limits' on page 46.

The set target temperature is saved automatically. The target temperature is retained after a power failure and after the unit has been switched off.

7. When the unit has reached its target temperature, stock the unit.

6.2.2 Temperature warning limits

6.2.2.1 Function of the temperature warning limits

The temperature warning limits define how much deviation the unit will tolerate between the actual temperature and the target temperature. The temperature warning limits are unit-specific. They can be adapted to the requirements of the chilled goods.

The values for the temperature warning limits are set at the factory and comply with the valid DIN standards for the unit.



Recommended temperature warning limits

The temperature warning limits must not be the same as the target temperature.

For blood reserves, set the temperature limits as follows:

- Upper temperature warning limit: at least 2 °C higher than the target temperature
- Lower temperature warning limit: at least 2 °C lower than the target temperature



Recommended temperature warning limits for FROSTER

To ensure that the unit functions properly, the temperature warning limits must be set for FROSTER models as shown in table ♥ 'Temperature warning limits' on page 46.



Programming the unit > Temperature warning limits

Temperature warning limits

Tab. 6: Temperature warning limits for BL and FROSTER BL

Model	Lower temperature warning limit	Target temperature	Upper temperature warning limit
BL 100 PRO-ACTIVE	+2 °C	+4 °C	+6 °C
BL 176 PRO-ACTIVE			
BL 300 PRO-ACTIVE			
BL 520 PRO-ACTIVE			
BL 720 PRO-ACTIVE			
BL 300 ULTIMATE			
BL 520 ULTIMATE			
BL 720 ULTIMATE			
FROSTER BL 178 PRO-ACTIVE	-55 °C	-32 °C	-27 °C
FROSTER BL 330 PRO-ACTIVE			
FROSTER BL 530 PRO-ACTIVE			
FROSTER BL 730 PRO-ACTIVE			
FROSTER BL 330 ULTIMATE			
FROSTER BL 530 ULTIMATE			
FROSTER BL 730 ULTIMATE			
FROSTER BL 180 PRO-ACTIVE	-55 °C	-41 °C	-37 °C
FROSTER BL 650 PRO-ACTIVE			

6.2.2.2 Displaying and changing the temperature warning limits

Displaying the temperature warning limits

Upper temperature warning limit



- 1. Press button [Temperature warning max.].
 - ⇒ The upper temperature warning limit is shown on the Display.

Lower temperature warning limit



- 2. Press button [Temperature warning min.].
 - ⇒ The lower temperature warning limit is shown on the Display.

Programming the unit > Temperature warning limits

Changing the temperature warning limits

Ĭ

Recommended temperature warning limits

The temperature warning limits must not be the same as the target temperature.

For blood reserves, set the temperature limits as follows:

- Upper temperature warning limit: at least 2 °C higher than the target temperature
- Lower temperature warning limit: at least 2 °C lower than the target temperature



Recommended temperature warning limits for FROSTER

To ensure that the unit functions properly, the temperature warning limits must be set for FROSTER models as shown in table ♥ 'Temperature warning limits' on page 46.

1. Insert unit key in key switch.



2. Turn unit key to position "P".



3. Press and hold button [Temperature warning max.].



Press button [Max.] repeatedly until the value for the new upper temperature warning limit is reached.



5. Press button *[Min.]* repeatedly until the value for the new lower temperature warning limit is reached.



- **6.** Turn unit key to position "1".
 - ⇒ The Display shows the current interior temperature.



The set temperature warning limits are saved automatically. The temperature warning limits are retained after a power failure and after the unit has been switched off.

Instruction and unit handover > Handing over the unit

6.3 Instruction and unit handover

6.3.1 Instructing the unit officer

Instruction

The nomination and instruction of an unit officer are among the owner duties as specified in the Medical Devices Operator Ordinance. The instruction covers at least the following contents:

- 1 Nominate the unit officer after consultation with the owner.
- 2 Instruct the unit officer about the intended purpose, the foreseeable misuse and the residual risks of the unit.
- Instruct the unit officer in the technically correct and safe handling of the unit.
- 4 Inform the unit officer about permitted connections with other medical products and accessories.

Once instruction is complete, record the following information in the medical product book:

- Name of the unit officer
- Date of instruction
- Signature of the medical product officer

6.3.2 Handing over the unit

Handing the unit over to the owner

The unit has been commissioned \mathsepsilon Chapter 6 'Commissioning' on page 42.

- 1. Instruct the unit officer.
- 2. Create the medical product book.
- 3. Create a stock directory.
- **4.** Hand the medical product book, stock directory and instruction manual over to the owner.

Switching on the unit

7 Operation

Personnel: User

Protective equipment: Protective gloves



NOTICE!

Wear suitable protective gloves when using the unit. These gloves must comply with either PPE Ordinance 2016/424 or the MDD Directive 93/42/EEC (which will be superseded on 27 May 2021 by MDR Regulation 2017/745).

7.1 Switching on the unit

1. Insert the key into the key switch.



- 2. Turn unit key to position "1".
 - ⇒ The Display shows the interior temperature.
- **3.** Remove the key and store it so it is protected against unauthorised access.
- 4. Check target temperature and adjust if necessary ♥ Chapter 6.2.1.2 'Displaying and changing the target temperature' on page 43.



Lead time of the temperature alarm!

The temperature alarm is active at the earliest when the target temperature is reached, and at the latest after two hours of unit operation.

5. Stock the unit when the target temperature is reached.



The door is stiff when it is first opened

Cooling creates a vacuum in the interior, so you may require additional force when opening the door for the first time.

Retrieving/erasing the temperature memory



7.2 Switching off the unit

1. Insert unit key in key switch.



- 2. Turn unit key to position "0".
 - ⇒ The unit switches to standby mode and the Display shows ☐ ☐ F.



Only switch the stocked unit off for short periods!

To protect the chilled goods, only switch the stocked unit off for short periods.

To shut down the unit for a longer period, proceed as described in ∜ Chapter 4.2 'Final decommissioning of the unit' on page 39.

7.3 Retrieving/erasing the temperature memory

Retrieving the temperature memory



The temperature memory records the temperature from the moment the target temperature is reached.

Restarting the unit resets the temperature memory.



- 1. Press button [Max.].
 - ⇒ The maximum value of the temperature memory is displayed.



- 2. Press button [Min.].
 - ⇒ The minimum value of the temperature memory is displayed.

Erasing the temperature memory

50



1. Press and hold button [Max.].



- 2. Press button [Reset].
 - ⇒ The Display shows - -.

The maximum value of the temperature memory is erased.



3. Press and hold button [Min.].

Setting up PC-KIT-NET (optional)



4. Press button [Reset].

⇒ The Display shows - - -.

The minimum value of the temperature memory is erased.

7.4 Setting up PC-KIT-NET (optional)

Tab. 7: Factory settings TCP/IP

IP address of unit	192.168.0.101
Subnet mask	255.255.255.0
IP address of standard gateway	192.168.0.200



If you want to commission more than one unit, the following applies:

Always connect one unit after the other to the network and complete the network connection on the PC.



The IP address of the unit and the IP address of the standard gateway must be configured in the same address field:

IP address of unit (example)	<u>180.160.15.</u> 1
IP address of standard gateway (example)	<u>180.160.15.</u> 2



For temperature monitoring via the network, the KIRSCH-DATANET software (version 5.0 or higher) must be installed (complete assembly and connection manual is supplied with PC-KIT-NET).

Setting up the IP address on the unit



Every unit needs its own IP address that is not yet in use in your local network.

At the factory, the IP address is set to: 192.168.0.101



- 1. Insert unit key in key switch.
- 2. Set unit key to "P".

Setting up PC-KIT-NET (optional)





Press and hold [Max.] and [Min.] simultaneously for four seconds.

⇒ The display shows 🖁 ₫ г.



Press [Max.] or [Min.] to go to level 45r and confirm with Set.



5. Press [Min.] to select the parameter 1.50.



6. Press and hold [Target temperature].

⇒ The first three digits of the IP address are displayed.



7. Use [Max.] and [Min.] to set the selected digits of the required IP address.

⇒ The number changes on the display in steps of one.



8. Release [Target temperature].

⇒ The first three digits of the IP address have been entered.



9. Press [Min.] to select the next parameter 151.

10. Press and hold [Target temperature].

⇒ The next digits of the IP address are displayed.

11. At levels L52 and L53 repeat steps 6 to 10 until the IP address of the unit has been entered completely.



12. Set key switch to "1" to complete your input.

⇒ The IP address of the unit has been set up.

Setting up the subnet mask on the unit



At the factory, the subnet mask is: 255.255.255.0



- 1. Insert unit key in key switch.
- 2. Set unit key to "P".



- **3.** Press and hold [Max.] and [Min.] simultaneously for four seconds.
 - ⇒ The display shows 🖫 🖟 г.







Press [Max.] and [Min.] to go to level 45r and confirm with Set.





5. Press [Min.] to select the parameter 155.



- **6.** Press and hold [Target temperature].
 - ⇒ The first three digits of the subnet mask are displayed.



- **7.** Use [Max.] and [Min.] to set the selected digits of the required subnet mask.
 - ⇒ The number changes on the display in steps of one.



- **8.** Release [Target temperature].
 - The first three digits of the subnet mask have been entered.



- 9. Press [Min.] to select the next parameter 155.
- 10. Press and hold [Target temperature].
 - ⇒ The next digits of the subnet mask are displayed.
- 11. At levels L57 and L58 repeat steps 6 to 10 until the subnet mask has been entered completely.



- **12.** Set key switch to "1" to complete your input.
 - ⇒ The subnet mask has been set up.

Setting up the IP address of the standard gateway on the unit



The standard gateway of each unit needs its own IP address that is not yet in use in your local network.

At the factory, the IP address of the standard gateway is set to: 192.168.0.200



- 1. Insert unit key in key switch.
- 2. Set unit key to "P".



- Press and hold [Max.] and [Min.] simultaneously for four seconds.
 - ⇒ The display shows 🖺 🖟 г.



Press [Max.] and [Min.] to go to level 45r and confirm with Set.



5. Press [Min.] to select the parameter L & D.

Setting up PC-KIT-NET (optional)

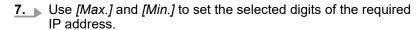




6. Press and hold [Target temperature].

⇒ The first three digits of the IP address are displayed.





⇒ The number changes on the display in steps of one.



8. Release [Target temperature].

The first three digits of the IP address have been entered.



9. Press [Min.] to select the next parameter 4.5.1.

10. Press and hold [Target temperature].

⇒ The next digits of the IP address are displayed.

11. At levels L62 and L63 repeat steps 6 to 10 until the IP address of the standard gateway has been entered completely.



12. Set key switch to "1" to complete your input.

⇒ The IP address of the standard gateway has been set up.

Connecting the unit to the local network

Personnel:

System/network administrator (recom-

mended)

Materials:

Network cable (EIA/TIA-568 standard), (included in the scope of delivery of PC-KIT-NET)

Requirements:

- tional unit components' on page 18 and @ "Assembly and connection manual - PC-KIT-STICK/PC-KIT-NET").
- The KIRSCH-DATANET software (version 5.0 or higher) has been installed on the local PC or local network.
- **1.** ▶ Switch off the unit ♦ Chapter 7.2 'Switching off the unit' on page 50.
- 2. Unplug the power plug.
- 3. Remove the dust cover from TCP/IP output.
- 4. Insert the network cable in the TCP/IP output.
- **5.** Connect the network cable to the network socket.
 - ⇒ The unit has been connected to the network.
- **6.** Insert the power plug in the socket.
- 7. ▶ Switch on the unit ♦ Chapter 7.1 'Switching on the unit' on page 49.

Stocking the unit

Reading out the MAC IP address on the unit



- 1. Insert unit key in key switch.
- 2. Set unit key to "P".

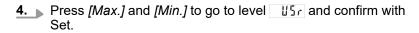


- Press and hold [Max.] and [Min.] simultaneously for four seconds.
 - ⇒ The display shows 🖫 🛣 🛣 г.











- **5.** Press [Min.] to select the parameter 1.10.
 - ⇒ The first digits of the MAC address are displayed.



The first two displayed digits "00" are not part of the MAC address.



- **6.** Press [Min.] to select the next parameter 1.11.
 - ⇒ The next digits of the MAC address are displayed.
- 7. At levels L72 to L75, repeat step 5 until the MAC address has been completely read out.



- 8. Set key switch to "1" to complete your input.
 - ⇒ The MAC address has been read out.

7.5 Stocking the unit



CAUTION!

Danger of damage due to interrupted cooling chain during stock transfer!

If the cooling chain of the chilled goods is interrupted by a stock transfer, the prescribed storage conditions are no longer met. This can damage the chilled goods.

- Do not subject chilled goods to light during the stock transfer.
- Do not place chilled goods near radiators during the stock transfer.
- Make sure that chilled goods are stored in the replacement unit according to the specifications of the relevant manufacturer.

Stocking the unit





CAUTION!

Danger to chilled goods due to contamination!

A dirty unit can contaminate the stored chilled goods. A contamination can damage or destroy the chilled goods.

- Do not store contaminated chilled goods in the unit.
- After any contamination, clean, disinfect and sterilise the unit and the chilled goods.
- Clean, disinfect and sterilise the unit in line with this instruction manual during operation.
- Comply with the applicable requirements for personal hygiene, disinfection and sterilisation.

During operation, the unit can be stocked with chilled goods at any time.

If the unit door is opened for more than 60 seconds during stocking, the door-open alarm is triggered *Chapter 10 'Alarms'* on page 65.

Observe the following when stocking the unit:

- Make sure that the chilled goods match the intended purpose of the unit.
- Make sure that no infected or contaminated chilled goods are stored.
- Make sure that the chilled goods are stored in closed containers.
- Observe the maximum carrying capacity of the wire shelves and drawers.
- Before and during stocking, comply with the applicable regulations on personal hygiene.
- Before and during stocking, comply with the safety requirements relevant for the type of chilled goods.

Stocking the unit



CAUTION!

Danger of injury from broken drawers or shelves and falling chilled goods after overloading!

The carrying capacity of the shelves and drawers is limited. If the shelves and drawers are overloaded, they can break. There is a danger of cutting injuries caused by broken edges. Falling chilled goods can cause bruising.

- Load the drawers and shelves with a maximum of 100 kg/m² (as per DIN 58345/58371/58375).
- Store chilled goods in break-proof containers.
- Make sure that the chilled goods are stable and cannot fall over.

Stocking the unit

Requirements:

- The unit has been commissioned and the target temperature has been reached.
- The cooling chain for the chilled goods as specified by the relevant manufacturer has been maintained.
- 1. Stock the unit with chilled goods.
- **2.** If the door is open for more than 60 seconds, deactivate the door-open alarm if necessary.



8 Cleaning and disinfection

Suitable disinfectants

The disinfectants listed in the following table have been tested by KIRSCH at the factory.

Adhere to the instruction manuals of the relevant manufacturers.

Tab. 8: Disinfectants

Disinfectants	Manufacturer
Incidin liquid	Ecolab Deutschland GmbH
Mikrozid AF liquid	Schülke & Mayr GmbH
Bacillol 30 Foam	Bode Chemie GmbH



Using other disinfectants

If disinfectants other than those mentioned above are used, test them at an inconspicuous location before their first use.

Use only acid-free disinfectants.

If in doubt, contact KIRSCH.

Cleaning and disinfecting the unit

Protective equipment:

Chemical-resistant protective gloves



CAUTION!

Danger to chilled goods due to contamination!

A dirty unit can contaminate the stored chilled goods. A contamination can damage or destroy the chilled goods.

- Do not store contaminated chilled goods in the unit.
- After any contamination, clean, disinfect and sterilise the unit and the chilled goods.
- Clean, disinfect and sterilise the unit in line with this instruction manual during operation.
- Comply with the applicable requirements for personal hygiene, disinfection and sterilisation.





CAUTION!

Danger of damage due to interrupted cooling chain during stock transfer!

If the cooling chain of the chilled goods is interrupted by a stock transfer, the prescribed storage conditions are no longer met. This can damage the chilled goods.

- Do not subject chilled goods to light during the stock transfer.
- Do not place chilled goods near radiators during the stock transfer.
- Make sure that chilled goods are stored in the replacement unit according to the specifications of the relevant manufacturer.

Requirements:

- The chilled goods have been transferred.
- The unit has been switched off *⇔* Chapter 7.2 'Switching off the unit' on page 50.
- 1. Remove drawers and shelves.



NOTICE!

Danger of damage to the electrical system due to unsuitable cleaning agents!

The unit contains sensitive electronic parts. If the electronic parts come into contact with unsuitable cleaning agents, this can lead to a loss of function in the unit.

- Use cleaning agents free from sand and acid.
- Do not use chemical solvents.
- Do not bring cleaning agents into contact with electrical parts.
- 2. Clean interior with warm water, dry it, and then disinfect it with a suitable disinfectant (& 'Disinfectants' on page 58).
- **3.** Clean the drawers and shelves with washing-up liquid, dry them and disinfect them with a suitable disinfectant (% 'Disinfectants' on page 58).
- **4.** Put drawers and shelves back in the unit.
- **5.** Wipe the door seal only with clear water and rub until thoroughly dry.
- **6.** Switch on the unit & Chapter 7.1 'Switching on the unit' on page 49.

Cleaning the housing Painted housing

Treat the housing with cleaning and care products for painted surfaces.

Cleaning and disinfection



\sim · ·	1			
Stainl	000	CTAAL	hai	ICIDA
Jiann	C33	31661	1100	IJIIIU

____ Treat the housing with cleaning and care products for stainless steel.

9 Maintenance

Interval	Maintenance work
At least every 6 months	Check the condenser $%$ Chapter 9.1 'Safety inspection' on page 61.

9.1 Safety inspection

Personnel: Inspector

Protective equipment: Protective gloves



NOTICE!

Wear suitable protective gloves when using the unit. These gloves must comply with either PPE Ordinance 2016/424 or the MDD Directive 93/42/EEC (which will be superseded on 27 May 2021 by MDR Regulation 2017/745).



Safety inspection as per DIN EN 62353

Safety inspections are used to assess the safety of medical electrical units and medical electrical systems or parts thereof.

Perform the safety inspection before commissioning, during servicing, inspection and maintenance, after repairs, or when repeat inspections take place.



Perform safety inspection every two years!

The unit should be inspected by the owner in line with DGUV regulation 3 (formerly BGV A3).

Subject the unit to a safety inspection at regular intervals, but at least every two years.



Contents of the safety inspection

The safety inspection performed by the owner contains the following individual inspections and their documentation:

- 1 Visual inspection
- 2 Function check
- 3 Temperature check
- 4 Temperature alarm test
- 5 Inspection of the condenser
- 6 Documentation of the test results



NOTICE!

If there is any doubt that the unit is in the correct condition, immediately stop using the unit. To prevent unintended use, label the unit accordingly. Contact the service department $\mbox{\ensuremath{$\phi$}}$ 'Service contact' on page 4.

Visual inspection

- **1.** Check the entire unit for completeness, correct set-up and damage.
- 2. Check the following parts of the unit individually for damage:
 - Door handle
 - Interior
 - Door seal
- **3.** If there is damage and functionality is not ensured, decommission the unit and contact the service department % 'Service contact' on page 4.

Function check

- Check that the following parts of the unit are functional:
 - Door handle

Checking the temperature

Tool: Calibrated temperature measuring device

- 1. Create a simulation of chilled goods for the sensor.
- 2. Attach measuring sensor in the interior at medium height.
- 3. Read temperature after 120 minutes.
- 4. After the check, clean and disinfect the unit % Chapter 8 'Cleaning and disinfection' on page 58.

Testing the temperature alarm



1. Turn unit key to position "P".



- **2.** Press buttons [Temperature warning max.] and [Temperature warning min.] simultaneously and hold for approx. four seconds.
 - ⇒ The Display shows a flashing decimal point (_____).
 The test function starts, the electronic delay is switched off for 10 minutes.
- 3. ▶ Heat the monitoring sensor (♦ Chapter 1.5.6 'Temperature sensor' on page 18) (for example with your fingers).
- **4.** Wait until the warning limit is exceeded and the buzzer sounds.
 - ⇒ The Display alternates between the current temperature and the error message.
- **5.** Cool down the monitoring sensor (for example with a cooling spray).
- **6.** Wait until the warning limit is exceeded and the buzzer sounds.
 - ⇒ The Display alternates between the current temperature and the two error messages (upper and lower temperature alarm).



- 7. Turn unit key to position "1".
 - ⇒ The test function is completed, the electronic delay is switched on again.

The Display displays the current temperature of the chilled goods.



The test function is ended automatically after 10 minutes.

8. After the check, clean and disinfect the unit % Chapter 8 'Cleaning and disinfection' on page 58.

Checking the condenser

Remove the dust from the condenser (Fig. 6) at least every six months in order to avoid affecting the performance of the cooling machine.



Requirement:

- The back of the unit is accessible.
- **1.** Dust off the condenser (for example with a brush or vacuum cleaner).
- 2. Check the condenser for visible damage and wear.

Documenting test results



- Date of performance
- Results of the individual tests
- Other test results



The owner is obliged to keep the documentation of the safety inspection at least until the next inspection.



10 Alarms

10.1 Alarm functions

Alarm functions

If a function of the unit is faulty or defective, an alarm is triggered.

Every alarm is displayed visually as well as acoustically.

The display alternates between the visual alarm and the temperature. The message is displayed until the alarm is acknowledged. Acknowledging the alarm does not rectify the error.

The acoustic alarm is output as an alarm sound (hereafter referred to as "buzzer").

The unit is equipped with the following alarm functions:

- Temperature alarm
- Door-open alarm
- Power failure warning
- Alarm in case of defective display and control unit

Depending on the cause that triggered the alarm, the following measures are required:

- 1 Deactivate buzzer & 'Deactivating the buzzer' on page 66
- 2 Acknowledge alarm & 'Acknowledging the alarm' on page 66
- 3 Inform the service department & 'Service contact' on page 4

Tab. 9: Alarm functions (overview)

Alarm function	Display	Buzzer	Cause	Measure
Temperature alarm	ŁHI	J	 The temperature is over the temperature warning limit. The remote warning contact has been triggered. 	Deactivate buzzer.Determine cause and rectify.
	FTO	J	 The temperature is below the temperature warning limit. The remote warning contact has been triggered. 	
Door-open alarm	door	•	 The door is open for more than 60 seconds. The door-open alarm is not forwarded via the remote warning contact. 	Deactivate buzzer.Close door.

Handling alarms



Alarm function	Display	Buzzer	Cause	Measure
Power failure warning	PF	J	 The power supply of the unit has failed. The remote warning contact has been triggered. 	 Deactivate buzzer. Determine cause of power failure and rectify. The monitoring unit remains in operation for approx. 72 hours. Acknowledge alarm.
Alarm in case of defective battery	BALL	1	 The power supply for the temperature documentation has failed. The alarm function has failed. 	 ■ Inform the service department. ■ Replace the battery ♦ 'Service contact' on page 4.
Alarm in case of defective display and control unit	ASS. \$\$\$ Alarm	J	The display and control unit is defective.	 Unplug power plug. Inform the service department & 'Service contact' on page 4.

10.2 Handling alarms

Deactivating the buzzer

The buzzer sounds.



- 1. Press button [Reset].
 - ⇒ The buzzer is deactivated.
- 2. Determine cause of the alarm and rectify.

Otherwise the buzzer will sound again every 30 minutes.

Acknowledging the alarm

The buzzer is deactivated, the alarm cause has been rectified, but the alarm continues to appear on the display.



____ Press button [Reset].

 \Rightarrow The alarm has been acknowledged. The display shows the temperature of the chilled goods.

Error messages

11 Status displays and error messages

11.1 Status displays

Status displays provide information to the user (for example regarding an ongoing defrosting process).

A status display is not accompanied by an acoustic signal (hereafter referred to as "buzzer")

A status display does not require any immediate action by the user.

Tab. 10: Status displays

Display	Buzzer	Description	Measure	Unit key
**	-	LED display [Defrosting] lights up: ■ The defrosting process is active.	-	-
Alarm	+	■ One or more alarms have been triggered (collective alarm).	-	-
OFF	-	Standby display: The unit is connected to the power grid and the key switch is set to position "0".	■ Turn key switch to position "1" to switch on the unit.	✓

11.2 Error messages

Do not make repairs yourself



WARNING!

Danger due to incorrect repairs or changes!

Incorrect repairs or changes can cause serious injury (e.g. electric shocks) and damage (e.g. fire, damage to chilled goods).

- Have repairs performed by the service department
- Use KIRSCH replacement parts.
- Do not make independent additions or changes to the unit.
- If in doubt, contact KIRSCH.



Error messages

Transferring chilled goods



NOTICE!

Danger to chilled goods due to defective or faulty unit!

A defect or fault in the unit means that its cooling performance is no longer ensured. Reduced cooling performance can cause considerable damage to chilled goods.

- Select an alternative storage location for the chilled goods.
- Ensure operating and storage conditions.
- Transfer chilled goods to new location.



Error messages

Occurrence of error messages

Error messages indicate a malfunction of the unit.

Error messages and the temperature display alternate on the display.

If there is more than one error, the errors are shown one after the other on the display.

In addition to the information on the display, the buzzer sounds to report the error.

The unit indicates the following errors visually and acoustically:

- Unit errors
- Software errors

When error messages occur, proceed as described below:

Procedure in case of error messages

- 1. Deactivate buzzer.
- 2. Assess error display according to the table (Chapter 11 'Status displays and error messages' on page 67).
- 3. Perform the recommended measures.
- **4.** Acknowledge the alarm messages.



For repairs, contact the service department:

The following company has been commissioned and authorised by KIRSCH to provide service for the unit: \$ 'Service contact' on page 4



CAUTION!

Danger of damage due to interrupted cooling chain during stock transfer!

If the cooling chain of the chilled goods is interrupted by a stock transfer, the prescribed storage conditions are no longer met. This can damage the chilled goods.

- Do not subject chilled goods to light during the stock transfer.
- Do not place chilled goods near radiators during the stock transfer.
- Make sure that chilled goods are stored in the replacement unit according to the specifications of the relevant manufacturer.



Meaning of "X" for error and status messages

X is not shown on the display.

Instead, the display shows a number that describes the relevant part.



Error messages

Tab. 11: Error messages of the unit

Display	Buzzer	Description	Measure	Unit key required
FXL	1	 Sensor X: Error or short circuit in the relevant sensor. The cryostat is running in the emergency program. 	Contact the service department.	-
FXH	J	 Sensor X: Error or break in the relevant sensor. Cryostat is running in the emergency program. 	Contact the service department.	-
LXL	1	Fan X: ■ Speed of the relevant fan too low. ■ The temperature of the chilled goods can fluctuate.	 Transfer chilled goods to new location. Contact the service department. 	-
LXH	J	 Fan X: Speed of the relevant fan too high. ■ The temperature of the chilled goods can fluctuate. 	Transfer chilled goods to new location.Contact the service department.	-
FRI	J	 Fan does not reach required minimum speed after an unit restart. The temperature of the chilled goods can fluctuate. 	 Transfer chilled goods to new location. Contact the service department. 	-
dFR	✓	 Fan: Difference between the speeds of the fans is too great. The temperature of the chilled goods can fluctuate. 	 Transfer chilled goods to new location. Contact the service department. 	-
r 🛚 🗶 L	✓	Relay X: Defect in the relevant relay. The temperature of the chilled goods can fluctuate.	Transfer chilled goods to new location.Contact the service department.	-
- DXX	√	Relay X: Defect in the relevant relay. The temperature of the chilled goods can fluctuate.	Transfer chilled goods to new location.Contact the service department.	-

Error messages

Display	Buzzer	Description	Measure	Unit key required
PRr	1	 Synchronisation error: Synchronisation error between control unit and monitoring circuit. No secured function of the cooling controller. 	■ Set key switch to "0". ■ Unplug power plug and switch on again <i>⇔ Chapter 7.1 'Switching on the unit' on page 49</i> .	√
[pn	1	 Connection problem: Synchronisation error between control unit and monitoring circuit. No secured function of the cooling controller. 	 Transfer chilled goods to new location. Contact the service department. 	-
EE	1	 Control error: Error during self-test in the cooling controller. The monitoring circuit takes over temperature control. 	Contact the service department.	-
door	1	Door-open alarm: ■ Door is open for more than 60 seconds.	Close door.	-
PWFF	1	 Battery defective: Battery must be replaced. The temperature documentation and alarm in the event of power failure fail. 	 Switch off alarm. Inform the service department. Replace the battery 'Service contact' on page 4. 	-
PF	1	 Power failure: Unit is not cooling. Alarm is active. The remote warning contact is triggered. 	■ Check power supply.	-
Ł XI	•	Temperature alarm (high): The upper temperature warning limit is reached or exceeded (for example due to very warm chilled goods or because the door was open too long).	 ■ View and check the temperature warning limit ∜ Chapter 6.2.2.2 'Displaying and changing the temperature warning limits' on page 46. ■ If necessary, correct values of the temperature warning limits. ■ Monitor the temperature progression. ■ If it does not normalise, contact the service department. ■ Transfer chilled goods to new location. 	√



Error messages

Display	Buzzer	Description	Measure	Unit key required
FLO	J	 Temperature alarm (low) The lower temperature warning limit is reached or exceeded (for example after the door has been opened for a longer period while the cooling machine cools down the unit). Safety equipment triggers, monitoring circuit has switched off the cooling machine. 	 View and check the temperature warning limit ♥ Chapter 6.2.2.2 'Displaying and changing the temperature warning limits' on page 46. If necessary, correct values of the temperature warning limits. Monitor the temperature progression. If it does not normalise, contact the service department. Transfer chilled goods to new location. 	

Tab. 12: Error messages and status displays of the PC-KIT-STICK

Display	Buzzer	Description	Measure	Unit key
MEXX	-	 Status display: Copying process is running. XX represents the progress of the copying process in percent. 	Do not remove USB flash drive.	-
rdy	-	Status display: Copying process is complete.	Remove USB flash drive.	-
NE03	-	Status display: Memory of the USB flash drive is full.	Use USB flash drive with sufficient memory capacity.	-
UETI	-	Error message: ■ The USB flash drive cannot be read.	Use a USB flash drive for- matted in FAT-32 format.	-
UE 72	-	Error message:USB flash drive was removed while copying process was ongoing.	Remove USB flash drive and try again after 1 minute.	-

Disposing of the unit

12 Decommissioning and disposal

12.1 Decommissioning unit

Decommissioning

- 1. Switch off unit.
- 2. Transfer chilled goods to new location.
- 3. Unplug power plug.
- **4.** Cut through connecting cable.
- **5.** Remove or destroy locks.
- **6.** Remove door.

12.2 Disposing of the unit

Disposing of the battery



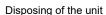
ENVIRONMENT!

Danger to the environment due to incorrect disposal of the battery!

If the battery is disposed of separately, proceed as follows:

- Do not damage, burn or short-circuit the batterv.
- Dispose of the battery in accordance with regional regulations.
- If in doubt, consult the local communal authority or special disposal specialists regarding environmentally friendly disposal.

Decommissioning and disposal





Disposing of the unit



ENVIRONMENT!

Danger to the environment due to incorrect disposal of the unit!

If substances hazardous to the environment are handled incorrectly, and especially if they are disposed of incorrectly, this can cause serious damage to the environment.

- Do not independently remove and dispose of the cooling machine.
- If substances hazardous to the environment (refrigerant, for example) accidentally enter the environment, take suitable measures immediately. If in doubt, contact the responsible communal authority to report the damage and enquire about the measures to be taken.
- Dispose of the unit in accordance with the regional regulations for electrical and electronic units.
- If in doubt, consult the local communal authority or special disposal specialists regarding environmentally friendly disposal.



13 Appendix

Depending on the model, the appendix contains the following applicable documents:

- Declaration of conformity
- Technical data
- Installation drawing



13.1 Declaration of conformity

EC Declaration of Conformity

We.

Philipp Kirsch GmbH Im Lossenfeld 14 77731 Willstätt-Sand Germany

hereby declare on our sole authority that the devices of type BL described below, to which the declaration refers, comply with the applicable requirements of Regulation (EU) 2017/745 for medical devices (Medical Device Regulation).

The devices belong to Class IIa according to Appendix VIII of the Regulation above. The named authority, mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart, s included in the conformity procedure according to Appendix IX of Directive (EU) 2017/745.

Registration-Nr.: D1423300013

Single Registration Number (SRN): DE-MF-000005605

We furthermore declare that the devices described below comply with the applicable requirements of the RoHS Directive 2011/65/EC and the protection requirements of the standards below at the time that the device was placed on the market.

Manufacturer	Device category	Туре	Serial numbers from serial number onwards	Basis-UDI-DI
KIRSCH	Refrigerator	BL 100 PRO-ACTIVE	100 32 25000	426068858BLPROACTIVEF4
KIRSCH	Refrigerator	BL 100 PRO-ACTIVE	100 03 25000	426068858BLPROACTIVEF4
KIRSCH	Refrigerator	BL 176 PRO-ACTIVE	170 30 25000	426068858BLPROACTIVEF4
KIRSCH	Refrigerator	BL 176 PRO-ACTIVE	170 04 25000	426068858BLPROACTIVEF4
KIRSCH	Refrigerator	BL 300 PRO-ACTIVE	280 31 25000	426068858BLPROACTIVEF4
KIRSCH	Refrigerator	BL 300 PRO-ACTIVE	280 09 25000	426068858BLPROACTIVEF4
KIRSCH	Refrigerator	BL 520 PRO-ACTIVE	500 32 25000	426068858BLPROACTIVEF4
KIRSCH	Refrigerator	BL 520 PRO-ACTIVE	500 06 25000	426068858BLPROACTIVEF4
KIRSCH	Refrigerator	BL 720 PRO-ACTIVE	700 31 25000	426068858BLPROACTIVEF4
KIRSCH	Refrigerator	BL 720 PRO-ACTIVE	700 03 25000	426068858BLPROACTIVEF4
KIRSCH	Refrigerator	BL 300 ULTIMATE	280 73 25000	426068858BLULTIMATENN
KIRSCH	Refrigerator	BL 300 ULTIMATE	280 83 25000	426068858BLULTIMATENN
KIRSCH	Refrigerator	BL 520 ULTIMATE	500 72 25000	426068858BLULTIMATENN
KIRSCH	Refrigerator	BL 520 ULTIMATE	500 82 25000	426068858BLULTIMATENN
KIRSCH	Refrigerator	BL 720 ULTIMATE	700 72 25000	426068858BLULTIMATENN
KIRSCH	Refrigerator	BL 720 ULTIMATE	700 82 25000	426068858BLULTIMATENN

Applied guidelines, standards or other normative documents:

- EU- Regulation 2014/53/EU (ULTIMATE Type)
- DIN EN ISO 9001:2015
- DIN EN ISO 13485:2016
- DIN EN ISO 14971:2020
- DIN 58371:2010-09
- EN 61010-1:2010+A1:2019
- EN 61010-2-11:2017
- EN 60601-1-2:2015 +A1:2021
- IEC 60601-1-2:2014+A1:2020
- EN/IEC 61000-3-2:2014
- EN/IEC 61000-3-3:2013 (:2019)





We also declare that the devices of type FROSTER-BL described below, to which the declaration refers, comply with the conformity assessment procedure according of of Regulation (EU) 2017/745 for medical devices (Medical Device Regulation).

The devices belong to Class IIa according to Appendix VIII of the Regulation above. The named authority, mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart, s included in the conformity procedure according to Appendix IX of Regulation (EU) 2017/745.

Registration-Nr.: D1423300013

Single Registration Number (SRN): DE-MF-000005605

We furthermore declare that the devices described below comply with the applicable requirements of the RoHS Directive 2011/65/EC and the protection requirements of the standards below at the time that the device was placed on the market.

		ń		
Manufacturer	Device category	Туре	Serial numbers from serial number onwards	Basis-UDI-DI
KIRSCH	Freezer	FROSTER BL 178 PRO-ACTIVE	170 05 25000	426068858BLFROSTERPAJD
KIRSCH	Freezer	FROSTER BL 180 PRO-ACTIVE	180 01 25000	426068858BLFROSTERPAJD
KIRSCH	Freezer	FROSTER BL 330 PRO-ACTIVE	320 02 25000	426068858BLFROSTERPAJD
KIRSCH	Freezer	FROSTER BL 530 PRO-ACTIVE	500 10 25000	426068858BLFROSTERPAJD
KIRSCH	Freezer	FROSTER BL 650 PRO-ACTIVE	650 01 25000	426068858BLFROSTERPAJD
KIRSCH	Freezer	FROSTER BL 730 PRO-ACTIVE	700 06 25000	426068858BLFROSTERPAJD
KIRSCH	Freezer	FROSTER BL 330 ULTIMATE	320 82 25000	426068858BLFROSTERULTP2
KIRSCH	Freezer	FROSTER BL 530 ULTIMATE	500 86 25000	426068858BLFROSTERULTP2
KIRSCH	Freezer	FROSTER BL 730 ULTIMATE	700 86 25000	426068858BLFROSTERULTP2

Applied guidelines, standards or other normative documents:

- EU- Regulation 2014/53/EU (ULTIMATE Type)
- DIN EN ISO 9001:2015
- DIN EN ISO 13485:2016
- DIN EN ISO 14971:2020
- DIN 58371:2010-09
- EN 61010-1:2010+A1:2019
- EN 61010-2-11:2017
- EN 60601-1-2:2015 +A1:2021
- IEC 60601-1-2:2014+A1:2020
- EN/IEC 61000-3-2:2014
- EN/IEC 61000-3-3:2013 (:2019)

(E 0483

Willstätt, 28.03.2022 Dr. Jochen Kopitzke Managing Director

Joh Kopitch



13.2 Technical data

	BL 100 PRO-ACTIVE	BL 176 PRO-ACTIVE	BL 300 PRO-ACTIVE/ ULTIMATE*	BL 520 PRO-ACTIVE/ ULTIMATE*
Capacity in litres	95	170	280	500
Temperature setting approx. in °C	+4	+4	+4	+4
Voltage	220–240	220–240	220–240	220–240
Frequency in Hz	Frigen = 50/60 Eco = 50	Frigen = 50/60 Eco = 50	Frigen = 50/60 Eco = 50	Frigen = 50/60 Eco = 50
Refrigerant quantity in grams	Frigen = 100 Eco = 42	Frigen = 80 Eco = 30	Frigen = 80 Eco = 30	Frigen = 350 Eco = 90
Power consumption in watts	Frigen = 142 Eco = 92	Frigen = 160 Eco = 120	Frigen = 164 Eco = 95	Frigen = 327 Eco = 250
Normal consumption in kWh/24	Frigen = 0.64 Eco = 0.51	Frigen = 1.50 Eco = 1.22	Frigen = 1.66 Eco = 0.63	Frigen = XXX Eco = 1.5
Perm. ambient temperature in °C	+10 to +38	+10 to +38	+10 to +38	+10 to +38
Exterior dimensions including wall distance (WxDxH) in cm	54 x 54 x 82	70 x 77 x 122	67 x 75 x 124/ 67 x 75 x 131*	77 x 76 x 195.5
Interior dimensions (WxDxH) in cm	44 x 43 x 47 (usable width 2 cm, usable depth 7 cm, usable height 8 cm less)	55 x 52 x 60 (usable width 3 cm, usable depth 9 cm, usable height 13 cm less)	55 x 51 x 100 (usable width 2 cm, usable depth 5 cm, usable height 10 cm less)	62 x 56 x 140 (Usable width 2 cm, usable depth 11 cm, usable height 13 cm less)
Exterior dimensions with door open 90° (WxD) in cm	54 x 106	70 x 136	67 x 133	77 x 144
Shelf size (WxD) in cm	-	-	-	-
Clear drawer dimension (WxDxH) in cm	37 x 32 x 8.5	50 x 34 x 10	49 x 39 x 10 upper drawers 51 x 31 x 10 bottom drawer	56 x 39 x 10
Max. load capacity drawer/shelf in kg	25 / -	50 / -	50 / -	50 / -

Technical data

	BL 100 PRO-ACTIVE	BL 176 PRO-ACTIVE	BL 300 PRO-ACTIVE/ ULTIMATE*	BL 520 PRO-ACTIVE/ ULTIMATE*
Net/gross weight in kg	50 / 54	46 / 52	47 / 57	69 / 80
Noise emission (for Ecool R600a) in dB(A)	40.5	38.6	40.3	41.2

	BL 720	FR BL 178	FR BL 180	FR BL 330
	PRO-ACTIVE/	PRO-ACTIVE	PRO-ACTIVE	PRO-ACTIVE/
	ULTIMATE*			ULTIMATE*
Capacity in litres	700	170	170	300
Temperature setting approx. in °C	+4	approx32	approx41	approx32
Voltage	220–240	220–240	220–240	220–240
Frequency in Hz	Frigen = 50/60 Eco = 50	50	50	50
Refrigerant quantity in grams	Frigen = 350 Eco = 90	Frigen = 400	Frigen = 480	Frigen = 350 Eco = 90
Power consumption in watts	Frigen = 342 Eco = 250	500	453	440
Normal consumption in kWh/24	Frigen = XXX Eco = 1.56	4.88	6.54	6.59
Perm. ambient temperature in °C	+10 to +38	+10 to +32	+10 to +32	+10 to +32
Exterior dimensions including wall distance (WxDxH) in cm	77 x 98 x 195.5	70 x 77 x 122	70 x 77 x 122	74 x 78 x 159 74 x 78 x 166*
Interior dimensions (WxDxH) in cm	62 x 77 x 140 (usable width 2 cm, usable depth 11 cm, usable height 13 cm less)	55 x 52 x 60 (usable width 3 cm, usable depth 11 cm, usable height 13 cm less)	60 x 57 x 128 (usable width 3 cm, usable depth 11 cm, usable height 13 cm less)	60 x 57 x 140 (usable width 2 cm, usable depth 10 cm, usable height 13 cm less)
Exterior dimensions with door open 90° (WxD) in cm	77 x 166	70 x 136	70 x 136	74 x 142
Shelf size (WxD) in cm	-	-	-	

Technical data

	BL 720 PRO-ACTIVE/ ULTIMATE*	FR BL 178 PRO-ACTIVE	FR BL 180 PRO-ACTIVE	FR BL 330 PRO-ACTIVE/ ULTIMATE*
Clear drawer dimension (WxDxH) in cm	56 x 60 x 10	50 x 34 x 10	52 x 32 x 10	54 x 37 x 10
Max. load capacity drawer/shelf in kg	50 / -	50 / -	50 / -	50 / -
Net/gross weight in kg	75 / 88	92 / 105	100 / 110	120 / 135
Noise emission (for Ecool R600a) in dB(A)	41.8	50.3	51.2	50.4

	FR BL 530 PRO-ACTIVE/ ULTIMATE*	FR BL 650 PRO-ACTIVE	FR BL 730 PRO-ACTIVE/ ULTIMATE*
Capacity in litres	500	650	700
Temperature setting approx. in °C	approx32	approx41	approx32
Voltage	220–240	220–240	220–240
Frequency in Hz	50	50	50
Refrigerant quantity in grams	Frigen = 620	Frigen = 820	Frigen = 620
Power consumption in watts	740	990	790
Normal consumption in kWh/24	10.81	14.32	11.1
Perm. ambient temperature in °C	+10 to +32	+10 to +32	+10 to +32
Exterior dimensions including wall distance (WxDxH) in cm	77 x 76 x 195.5	83 x 102 x 197	77 x 98 x 195.5
Interior dimensions (WxDxH) in cm	60 x 57 x 140	62 x 76 x 131 (usable width 3 cm, usable depth 11 cm, usable height 14 cm less)	62 x 77 x 140
Exterior dimensions with door open 90° (WxD) in cm	77 x 144	86 x 177	77 x 166
Shelf size (WxD) in cm	-	-	-

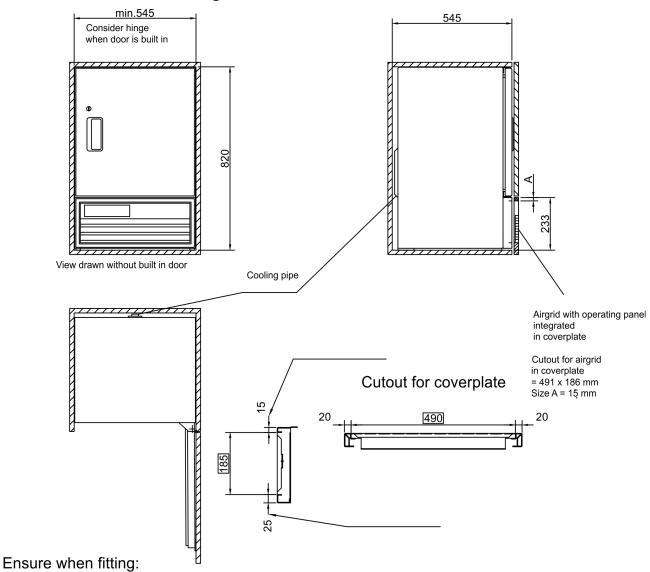


Technical data

	FR BL 530 PRO-ACTIVE/ ULTIMATE*	FR BL 650 PRO-ACTIVE	FR BL 730 PRO-ACTIVE/ ULTIMATE*
Clear drawer dimension (WxDxH) in cm	56 x 39 x 10	59 x 56 x 22 top drawer 59 x 62 x 22 bottom four drawers	56 x 60 x 10
Max. load capacity drawer/shelf in kg	50 / -	50 / -	50 / -
Net/gross weight in kg	161 / 183	220 / 260	202 / 237
Noise emission (for Ecool R600a) in dB(A)	51.5	62.3	49.7



13.3 Installation drawing



Supply and exhaust air air takes place via frontsided airgrid. For that do not block with subjects or even blind it, so that the ventilation of the cooling machine keeps warranted.

Drawing.Nr.: 225-033-1

82

Fig. 10: Installation drawing for BL 100 PRO-ACTIVE



14 Index

A	Disposal
About this instruction manual	Documenting test results 64
Additional defrosting	Door key
Alarm functions	Drawers
Alarms (overview) 65	E
Appendix	Error messages (overview) 69
В	F
Button functions (overview)	Final decommissioning
C	Foreseeable misuse 23
Change of location	Function check 62
Character	н
Checking the condenser 63	Handover
Circulation cooling	Tiandovei
Cleaning	I
Housing	Images on the display (overview) 12
Interior	Installation
Commissioning	Installation drawing 82
Handover	Instruction
Instruction 48	Interfaces
Process	Interior fittings
Programming 43	K
Staff qualification 42	Key switch
Condenser	Rey Switch
Connection	L
Contact	LAN interface
Cooling	M
Cooling machine	
Customer service 4	Manufacturer's address
D	Medical product book
Declaration of conformity	0
Decommissioning	Operating log 27
Defrosting (automatic)	Operation
Defrosting (manual)	Retrieving/erasing the temperature memory 50
Disinfectants	Setting up PC-KIT-NET 51
Disinfection	Switching off
Display	Switching on

Index



Other applicable documents	Symbols
Owner obligations	т
P	Target temperature
PC-KIT-NET	TCP/IP module
Potential-free contact	Technical data
Protective equipment	Temperature alarm test 63
Protective gloves	Temperature check 62
Purpose	Temperature display
R	Temperature memory
	Temperature sensor (overview)
Recommissioning	Temperature warning limits
Residual risks	(overview)
S	changing 47
Safety	displaying
Safety inspection 61, 62	Transport
Service department	Type plate
Set-up	U
Set-up conditions	Unit door
Shelves	Glass door (optional)
Staff	Unit key
Status displays (overview) 67	•
Stock directory	USB port
Storage	V
Switching off	Visual inspection 62
Switching on	