

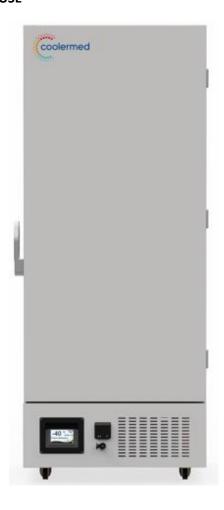


COOLERMED

M170PLZ / M260PLZ /M400PLZ / M660PLZ PLASMA FREEZER CABINET

INSTRUCTIONS FOR USE





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Dear CoolerMed user,

Thank you for choosing a CoolerMed product. Please read and keep the user manual carefully. Keep the product packaging until you are sure that the product is complete, in full and correct. If a defect occurs, contact the shipping company to report the damage. According to ICC regulations, this responsibility belongs to the customer.

When operating the device, please;

- Follow the warning labels.
- Do not remove warning signs.
- Do not operate the damaged device.
- Do not operate the device with the damaged cable.
- Do not move the device during operation.

In case of a problem, contact the CoolerMed Authorized Service.

The warranty conditions apply if the precautions described in the device's user manual are followed. CoolerMed has the right to develop and change the structure of its existing products without modifying its previously manufactured products.

The information contained in this guide belongs to CoolerMed. Information in the manual may not be reproduced or distributed without CoolerMed's permission.

Manufacturer:

ÖZTAŞ GLOBAL SOĞUTMA TEKNOLOJİLERİ VE METAL SANAYİ VE TİCARET ANONİM ŞİRKETİ M.O.S.B. IV. Kısım Ahmet Nazif Zorlu Bulvarı No:32 Yunusemre/Manisa

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1. INTRODUCTION

1.1. SPECIFIC USE AND WORKING PRINCIPLE OF THE EQUIPMENT

Plasma freezer cabinets are designed to store materials in low temperature conditions such as in hospitals, blood banks, epidemic research institutes, universities, biological drug industry, gene engineering, etc.

Coolermed Deep Freezers cool down to temperatures set between -25 °C and -42 °C and can create stable temperatures within the specified tolerances. The temperature change in the cell of the deep freezer is shown digitally. Thanks to the control system, the user has the opportunity to adjust the operating temperature between -25°C and -42 °C.

The Coolermed deep freezers are designed in the locked type in order to prevent unauthorized interference. Deep freezers have an easy-to-open door handle. Air tightness is provided with the magnetic seal which is located at the door.

Coolermed deep freezers are equipped with an advanced alarm system. If the device door remains open, power failure, temperature inside the cell goes beyond the alarm temperature limit, temperature sensor breaks and other failures that may occur in the control system, the alarm system is activated and warns the user audibly and visually. The archive of last 50 errors are kept in the memory of the control system, which can be tracked from the indicator. E-mail is sent to 10 different e-mail addresses in case of failure using the standard Ethernet connection. In case of a power failure, the cell temperature value and alarm indicators are active, as the device indicator is powered by a battery. Battery charging is done automatically. The device has a battery-powered remote alarm feature and an NC contact output for use for special alarm systems.

Coolermed deep freezers have 10 years of internal memory when installed a micro SD card with sufficient memory which holds temperature values. Also, it can also be recorded on a USB stick. Thanks to the optional weekly temperature recorder, the temperature in the cell can be recorded. The temperature recorder is of the locked type to prevent the intervention of unauthorized persons. M170PLZ/M260PLZ/M400PLZ/M660PL Deep Freezers are manufactured according to the following standards:

EN 60601-1, EN 61010-1, EN 61000-6-3, EN 62366, EN 980, EN 60601-1-4, EN 60601-1-2, EN 60601-1-6 and EN ISO 14971, EN 50419

This device complies with WEEE regulations.

COOLERMED is not responsible for any hazards that may occur due to work that does not comply with the rules set out in this guide.

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2. TECHNICAL SPECIFICATIONS 2.1. TECHNICAL SPECIFICATIONS TABLE

TECHNICAL SPECIFICATIONS	M170PLZ	M260PLZ	M400PLZ	M660PLZ
External dimensions WxDxH (mm)	730X795X1095	730x775X1750	724x778x2156,5	931x913x2168
Internal Dimensions WxDxH (mm)	490X485X640	491x489x993	489x487x1477	624x635x1607
Net Volume (L)	145	225	286	606
Gross Volume (L)	152	238	308	637
Net Weight (kg)	70	105	127	225
Gross Weight (kg)	80	115	137	240
Insulation Thickness (mm)	50	120	120	120
Operating Temperature	-25 / + -42 °C	-25 / + -42 °C	-25 / + -42 °C	-25 / + -42 °C
Set Temperature	-25	-25	-25	-25
Voltage	220 / 240V	220 / 240V	220 / 240V	220 / 240V
Frequency	50 Hz	50 Hz	50 Hz	50 Hz
Power Consumption (24h / Watt)	2,76	3,6	5,76	6,89
Ampere (A)	1,1	1,8	3,1	3,25
Data Printer (Thermal)	Option	Option	Option	Option
Replacement Battery Life	72 hours	72 hours	72 hours	72 hours
Cooler Fluid	R290A/R404a	R290a/ R404a	R290a /R404a	R290a /R404a
Racks (PCs) * Drawers (PCs)	2	3	5	5

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The capacity of the device may vary depending on the installation method and preferences.



The minimum temperature of Coolermed Deep Freezers at an ambient temperature of 30° C is -



Our device is used with an EMI filter to minimize electromagnetic interference with other electrical devices.

2.2. ACCESSORIES

2.2.1. FACTORY ASSEMBLY ACCESSORIES

Thermal Printer USB **Electronic Card** 4,3" TFT display 12V battery

2.2.2 OPTIONAL ACCESSORIES

SD card Wi-fi module LAN connection socket Door lock

3. PRECAUTIONS AND RESTRICTIONS ON USE



Note the following warnings:

- Do not use the device outside the intended use.
- The device must be used by authorized and trained personnel after reading the user manual. If a problem occurs, only the authorized technical personnel should intervene in the device.
- Only spare parts and accessories provided by Coolermed should be used.
- The power line must be suitable for the power of the device and must be grounded.
- There should be no substances in the used volume that may affect the operating temperature of the device and damage the device.
- The set temperature should not damage the shape and structure of the samples against the user's request.
- Maximum load capacity for each rack should be 30 kg.
- In order not to interfere with the temperature distribution between the racks, only the cover of the rack to be used should be opened.

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- If you are working on appliances operating below 0°C, take into account that the inside of the unit and stored products are very cold. Working on equipment without gloves can cause serious injury.
- Any service or repair should be performed by a qualified customer service engineer. Performing
 work by persons with insufficient technical knowledge may adversely affect the performance of
 the unit or cause physical damage to the equipment.
- Only original spare parts may be used. Using different parts may affect the performance of the unit or cause physical injury or equipment damage.

4. OPERATIONS TO BE PERFORMED BEFORE INSTALLATION AND FIRST USE OF THE DEVICE

- Your product is tuned to 220 240 volts 50 Hz City electricity. Using a different voltage can cause your cooler to become unusable and cause a fire.
- Do not place your product in a place exposed to direct sunlight, in the influence of heat sources such as stoves, radiators, ovens, stoves, radiant, infra-red and air conditioners. Otherwise, this may cause your product to degrade performance, damage, and become unusable
- Electrical installation must comply with national regulations
- Leakage current relay and fuse must be present in your electrical installation to prevent electric shocks and fire risk.
- In case of use without grounding, our company is not responsible for any failures and damages that may occur.
- Place your product in a place without moisture and air circulation is not blocked.
- Be sure to clean the inside of your product before first use.
- After placing your product in place, leave it for two (2) hours without moving it before starting to use it.
- If your cooler is installed in very cold weather conditions, the standby time must be at least four (4) hours before starting.
- Do not unplug your product to save energy if you will not use it for a short time or leave it empty. Otherwise, more energy is used to cool down your product again.
- Your product is designed for indoor use. Do not use your product outdoors.
- Product installation, placement, maintenance and cleaning should be done as written in the manual. Do not apply anything other than the manual. In the event of any damage to your product as a result of such use, the warranty terms will be void due to user error.
- Leave the cooler on the floor and check whether it is standing properly with the help of spirit level.
- Do not reposition the cooler when the product is loaded or move it by pushing it on the wheels.

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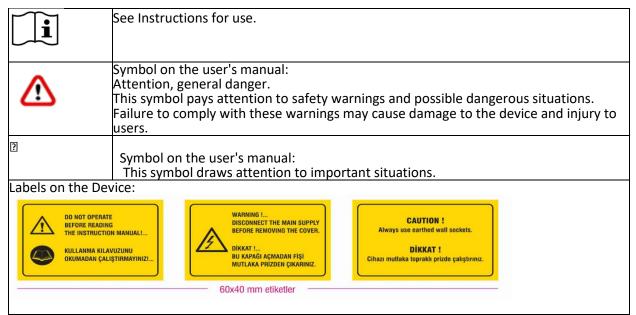






- Special attention should be paid to the glass part of products with glass doors, as the impact of a sharp, pointed object or contact with an extremely hot substance may cause the glass to break.
- Place your product on a flat floor without slope to prevent your product from sliding or tipping, be sure to lock the wheels
- Operate your product only in the use position described in the user manual.
- Do not expose your product to direct sunlight.
- To protect your product from damage, carry and store it only in normal use. Otherwise, this will result in the loss of the right to guarantee.
- Keep the cabinet key where children cannot reach with nylon bags placed inside the accessories and user guide provided with the cabinet.
- Leave your device empty.

5. SYMBOLS AND LABELS



6. INSTALLATION

6.1. ENVIRONMENTAL CONDITIONS

The device works efficiently under the following ambient conditions.

Indoor use only

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Temperature values: 5°C / 40°C

Maximum humidity up to 31°C: 60%

Maximum altitude: 2,000 meters

• Temperature range to achieve maximum performance: 15°C / 25°C., humidity 55-60%

Δ

Ambient temperatures above 30°C cause the device not to function properly at the set temperature value.



The maximum cooling performance of Coolermed deep freezers at 30°C ambient temperature is - 38°C.

6.2. TRANSPORT AND SHIPPING

Due to the weight of the device, all handling and shipping must be carried out with appropriate handling equipment and experienced personnel. When transporting the device, it must be supported from the bottom, carried in an upright position and not turned upside down.

6.3. OPENING THE PACKAGE

Open the cardboard box packaging of the device. Remove the nylon with the second packaging on the device and make sure that the device is not damaged by shipping. Check that the following parts are provided with your device.

• 1 user manual and warranty certificate

6.4. POWER RATINGS

The device operates at 220-240 V, 50Hz.

Check that your power line matches the power of the device. If it's not enough, draw a new line.



Always use the device in ground-line outlets.



Against isolation errors, there must be a fuse on the power line to which the device is connected.

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6.5. DETERMINATION OF LOCATION

- Check that the location site is suitable for the purpose of use and users.
- Check that the device placed where it will be used is in four-foot contact with a flat floor.
- Check that the user can monitor the device if they do other work.
- Check that other devices around it do not occupy the site of use, make sure that other operations do not affect or damage the device.
- Leave at least 30 cm of free space to allow ventilation of the compressor on the back of the device.

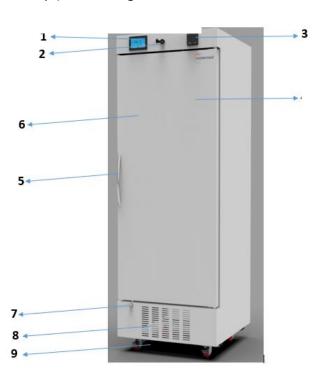
6.6. PROMOTIONAL PICTURE

1- Touch main setting screen 6 - Interior Lighting

2- USB 7-Door Lock

3- Thermal Printer 8- Compressor area

4- Wot evap (Both cooling and Rack9- Lockable wheel



4 (behind the door)

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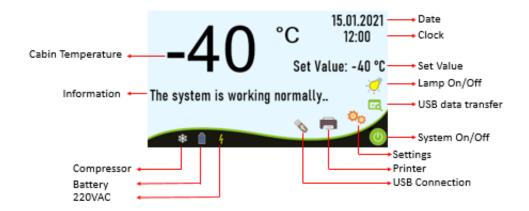
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6.7. COOLER SCREEN





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7. PRINCIPLES OF OPERATION 7.1. PROGRAMMING AND SETTINGS



After clicking Settings, the password is entered on the password screen that appears.

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After clicking the Off button for 3 sec, the system shuts down. If the battery is activated, the system continues to operate. The colour of Off button turns from green to red. If the red On/Off button is pressed for 3 sec, the system will turn on.

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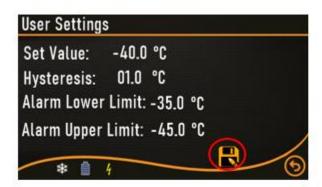
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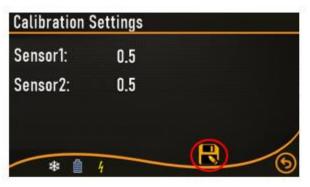






The password screen is entered with the password 1030 and the Set Settings screen appears. Here set temperature, hysteresis value, alarm sub-value and alarm parent value are set. Then click the Save button. (Note: If settings are wanted to

be saved, the Save button must be clicked.



The password screen is entered with the password 1066 and the calibration settings screen appears. Sensor calibration values are set here. Then click the Save button.

(Note: If settings are wanted to be saved, the Save button must be clicked.

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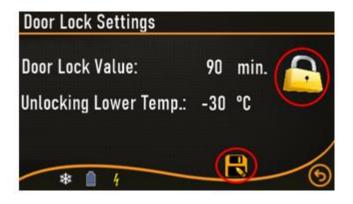
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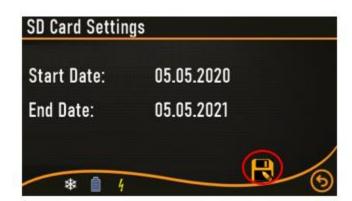




The password screen is entered with the password 1070 and the Lock Settings screen appears. Lock settings are set here. Then click the Save button. Lock is unlocked if the onscreen lock icon is clicked.

(Note: Lock in the device is optional.

(Note: If settings are wanted to be saved, the Save button must be clicked.



When the password "1085" is entered on the password screen, SD card settings screen appears. SD card recording start and end dates are set here. Then click the Save button.

(Note: If settings are wanted to be saved, the Save button must be clicked.

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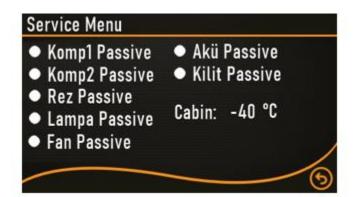






The password screen is entered with the password 1080 and the factory settings screen appears. Lock can be made active or passive here. Temperature unit can be set. Language options of the device can be set. Then click the Save button.

(Note: If settings are wanted to be saved, the Save button must be clicked.



The password screen is entered with the password 1090 and the service menu screen appears. Component that you want to make active is clicked. Thus, operation of the components is tested.



The password screen is entered with the password 1095 and the version check screen appears. Software versions are checked here.

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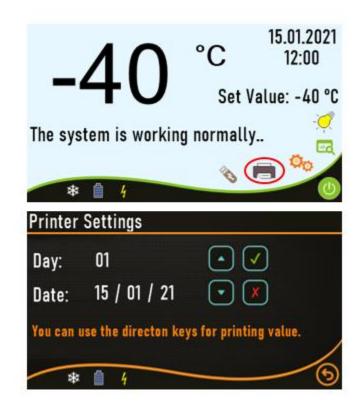
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If you click the printer icon on the Main Screen, you enter to the printer settings screen.

On the Printer settings screen, the day to be printed out is selected with the Arrow keys. Then the Confirmation button is clicked and the printer starts to give outputs.



If the USB data transfer key is pressed on the Main Screen, 30-day recordings will start to be over-written on USB.

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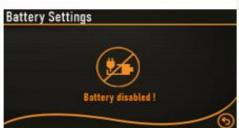




If the Battery key is pressed on the Main Screen, the battery settings screen appears.



If the battery icon is clicked on this screen, the battery is disabled and the screen shown below appears.



If the battery icon is clicked on this screen, the battery is enabled again.



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When the text is clicked, it returns to the main screen but continues to give an audible warning. If you want to mute it, click the Mute button on the main screen.

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The cabin comes to the set value

Set Value: -40 °C Cabin Value: -32 °C



TEMP. HIGH

The cabin comes to the set value

Set Value: -40 °C Cabin Value: -32 °C ≉ 🖺 4

NO POWER

Please insert the cabinet plug.

Set Value: -40 °C Cabin Value: -40 °C



DOOR OPENED

Please close the door...

Set Value: -40 °C Cabin Value: -40 °C



SENSOR ERROR

The cabin comes to the set value

Set Value: -40 °C Cabin Value: -32 °C

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8. DEVICE INSTALLATION AND FIRST INSTALLATION

Remove and disassemble all packaging materials and bottom wooden pallet of the product before placement. (Removing the cooler may be necessary to remove the base pallet).

Use only original Coolermed spare parts. Non-genuine spare parts can be a hazard to you and damage your product.

Place your product in the desired area. During placement, pay attention to the placement rules written in the manual.

Get your product to expand and balance through a deep spirit level. After product placement, the wheel brake (Figure 1) must be locked, or if there is no wheel brake, the device must be guaranteed to not move.

- Do not put your product outdoors in a way that it will be exposed to open air. (on the street, the avenue, etc.)
- In order for your product to cool properly, do not put materials such as cardboard or boxes in front of the lower shutters.
- Do not expose to direct sunlight. As a result of sunlight coming to the glass of your cooler, the working time will increase. This means that energy consumption will increase.
- Place the cooler cabinet by pushing it to the back.
- Make sure that there is a 150 mm (15 cm) gap between the wall and the back of your cooler when approaching your product to the wall. Air circulation is essential in the back area to get a good efficiency from the cooler cabinets.
- Place and operate your product so that it is on its feet or wheels without exposing it to any slope.
- Care should be taken not to close the fan suction mouth during product placement in the cooler.

Your device is designed for indoor use only.

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8.1. NOT MAKING ELECTRICAL CONNECTION



WARNING!

Do not plug your product into a multiple outlet, do not use an extension cord.

Do not contact the cables of your product connected to the network on hot surfaces.

The outlet you will use must be grounded. In addition, the outlet to be used must be at least 10-16 A strong and protected by an appropriate fuse. Be sure to seek help from our technical service or a qualified electrician regarding the insurance that must be present in the network to which your outlet is connected.

The mains voltage and frequency must be the same as the value written in the label information on the inside of your product. If your mains voltage is far below or above the specified value, be sure to provide the desired voltage using a voltage regulator. You can get help from an expert electrician on this issue. Do not place the cable of your product on the passageways. This can cause injury to you and damage to your cooler.

If the supply cord is damaged, this cord must be replaced by its manufacturer or its service agent or equally qualified personnel to prevent a dangerous situation.

8.2. FIRST OPERATION OF THE PLASMA STORAGE CABINET

- Clean the interior and all accessories before starting your product for the first time.
- If your product is too shaken during transportation and placement, leave your cooler for two (2) hours without running. In this way, if the compressor oil is infected with the system, it will return. If it is operated without paying attention to this condition, you can damage the compressor.
- Connect the plug of your product to an outlet installed in accordance with regulations with alternating current of 220 240V / 50 Hz only.
- When your product is running, you will hear a slight amount of compressor noise.
- The fan inside your product will stop when you open the door of your cabinet.

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9. PERIODIC MAINTENANCE AND CLEANING

9.1. PERIODIC MAINTENANCE

- Clean the condenser surface using a vacuum cleaner every three months. Cleaning can be done by the user staff or technical service.
- As long as the device is cleaned regularly, it also does not need periodic maintenance.
- In the event of an error in the device, authorized service should be called. Nobody should interfere with the device, except the authorized service.

9.2. CLEANING

- Unplug your cabinet before cleaning.
- Wait for the inner parts of your product to reach ambient temperature before internal cleaning.
- Always wear protective gloves during cleaning and maintenance. This will protect you from injuries.
- Rémove accessory parts from inside clean with soft cotton cloth and warm soapy water.
- Dry with dry cotton cloth. Products that are not dried can darken over time.
- After cleaning, make sure that there is no wet or damp area inside.
- You can restore your products again two (2) hours after starting your product according to the operating method specified in this guide.
- Exterior cleaning should be done with cotton cloth and warm water.
- Prevent cleaning water from entering the preflight panel and lighting sections during cleaning.
- Clean the door seal using only clean soapy water.

9.3. SHIPPING

- Carry your product according to the instructions specified on the packaging box. Do not move sideways, vertically, reclining, or in an open position.
- Protect your product from impact during transport.
- Do not carry your product when it is plugged in or full.
- Secure your product to the carrier vehicle during transportation in order not to cause any accident or to prevent your product from falling or sliding.

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10. TROUBLESHOOTING

If your device is not working at all, check these:

- The On-Off button is at the on position,
- The fuse of the device is intact,
- The plug is fully connected to the socket,
- Outlet is not defective,
- The mains voltage exists.

10.1. ERROR CODES

ERROR 1: If the freezer cabinet temperature falls below the set lower limit, we will first be warned audibly and then in writing.

ERROR 2: If the cabin temperature of the freezer rises above the specified upper limit, it warns us first audibly and then in writing.

ERROR 3: If the door of the freezer cabinet is left open or if it remains open above the given time, the door open error will appear on the screen.

ERROR 4: If no energy gets into the freezer cabinet, an audiovisual alarm is indicated.

ERROR 5: If a sensor is not connected to input 1 on the card, a cooler sensor error will appear on the screen.



WARNING!

In case of failure, please contact your nearest Coolermed Authorized Service.

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10.2. WHAT TO DO BEFORE CALLING AUTHORIZED SERVICE IN CASE OF FAILURE

PROBLEM	REASON	SOLUTION
Your device does not work, there is no sound on the device, or there is only fan sound.	The thermostat might have done it. It is unplugged The fuse could have blown or broken. Condenser lamellae may be clogged and contaminated.	It will work again when it reaches the appropriate temperature. Insert the plug in correctly. Apply to a qualified electrician clean the condenser lamellae.
Your device's internal temperature is high	The outdoor temperature is too high or the thermostat setting is incorrect. Close to the rear wall, the ventilation shutter is blocked or the front closed condenser lamellae are very dirty.	Move your device to a place where the external environment is lower. Adjust the distance between the device and the wall to the position it should be. Clean the condenser lamellae.
The internal temperature of the device is very low	Thermostat setting is wrong	Adjust the thermostat again.
The lights of your device are not lit, or one is lit.	Lamp button is off, lamp is defective or adapter is defective	Contact the Authorized Service.



WARNING!

In the event of a malfunction, the products stored in the refrigerator will be destroyed according to hospital regulations if the medical staff decides that the vaccines in the refrigerator are defective.

If the error has not disappeared, despite the actions recommended above by the user, it must be notified to the Authorized Service, and the stored products in the Cabinet should be taken to another Cabinet and prevented from deteriorating.

• During service, the cabinet must be disconnected from the network and the plug must be

- unplugged.
- If a gas charge is to be made in the Cabinet, it is necessary to check with the appropriate scales and equipment and make sure that the correct gas

is pressed. Sayfa 25 / 28

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- If it is necessary to weld during service, environmental safety must be taken at the working Point Fire Tube, fire blanket must be kept.
- At the end of the service service, all functions of the Cabinet should be checked, run for a while and put in place after it is seen to meet the set values.

11. LIMITATION OF LIABILITY

All technical information contained in this guide, instructions for use operation and maintenance of the device, includes the latest information about your device. The manufacturer must not follow the instructions in this user guide, repair operations that are not authorized to use the device outside of the intended use, changes that are not allowed on the device, and use spare parts that are not approved by the manufacturer.

12. WASTE MANAGEMENT

The user is responsible for evaluating each part as waste in an appropriate way. Parts that are thought to be infected should be disinfected with methods that are valid and appropriate (steam sterilization, chemical methods) before disposal.

Electronic parts used, except for power and current sources, must be disposed of in accordance with the rules specified for the waste of electronic devices.

Sayfa 26 / 28

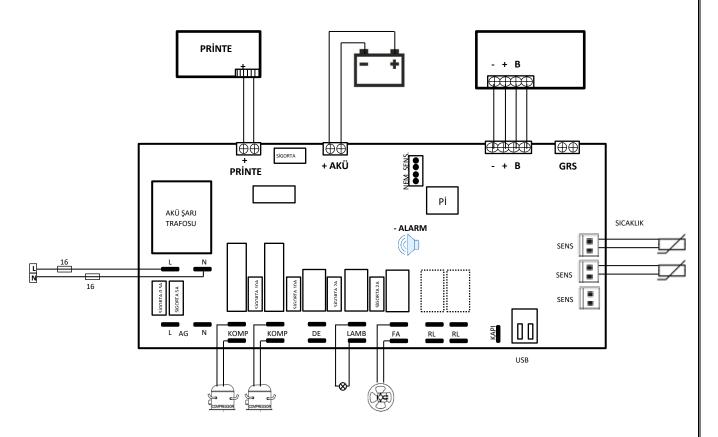
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13. ELECTRICAL CIRCUIT DIAGRAM



Sayfa 27 / 28

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M.O.S.B. 4. KISIM AHMET NAZİF ZORLU BULVARI NO:32 45030 YUNUSEMRE MANİSA TÜRKİYE

CM.TD.02.KL.02_EN Rev. No: 04 Rev. Date 21/01/2022





14. TYPE LABEL

Since the technical data for the product differs in each product, it is indicated on the Type label on the cabinet.

The type label is located on the inside of your cabinet.

Below is the Type label image.

	TİP ETİKETİ	
MODEL REF	M400PLZ	e de la companya della companya della companya de la companya dell
TYPE	PLASMA STORAGE REFRIGERATOR	coolermed
CLIMATE CLASS		
POWER/CURRENT W/A		C€
VOLTAGE/ FREQENCY V/Hz		2195
LAMP POWER W		
REFRIGERANT GAS / QUANTITY		RoHS
EXTERNAL DIMENSIONSI (W*D*H)		
PRODUCT WEIGHT (KG)		
ŞİRKETİ	GUTMA TEKNOLOJİLERİ VE METAL SANAYI ET NAZİF ZORLU BULVARI NO:32MANİSA/TÜ	
w SN	CM.TD.02.FR.001_	rev02_05.01.2022
UBB NO	U .B .B. N. O	L

Sayfa 28 / 28

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MEDICAL ULTRA-LOW TEMPERATURE FREEZERS

Technology Meets Experience

Just as LWF670 deep freezer, which can be set at -86°C allows the storing of stem cells and in vitro fertilization products; the M400PLZ plasma freezer, which can be set to -40°C, allows storing the most sensitive products, such as plasma and plasma products, in the most accurate and reliable conditions.

With 120 mm insulation thickness, audible, and visual alarm systems, Coolermed ultra-low temperature freezers offer many additional technical advantages as an option which hospitals, clinics, and laboratories prefer.



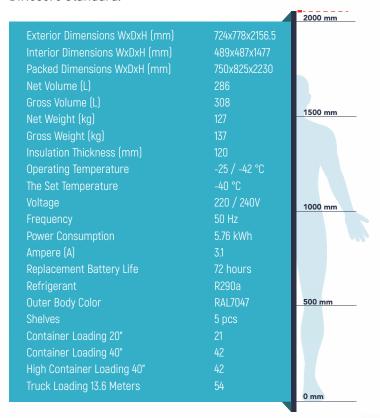
GENERAL FEATURES OF ULTRA-LOW TEMPERATURE FREEZERS

- · Stainless steel inner body
- · Anti corrosive powder painted steel outer body
- · High density polyurethane for insulation
- · Block door.(Double-glazed glass aluminum door with magnetic gasket)
- Temperature measurement accuracy with the precision of 0,1°C
- 4.3" TFT LCD touch screen
- · USB port (data transfer)
- · Lockable doors
- · Off-the-shelf cooling system
- · Data printer (Thermal)
- · Defrosting feature
- · Visual and audible alarm system for high and low temperature, power outage, door open (prob) fault
- \cdot Ability to view and record information from the screen for 72 hours with the battery when the power is turned off
- · Self-charging battery
- \cdot Reporting daily operating temperature
- \cdot Thanks to the built-in SD card (data storage and fault recording for 10 years)
- \cdot Easy to move by swivel castor with breaks
- Password protection

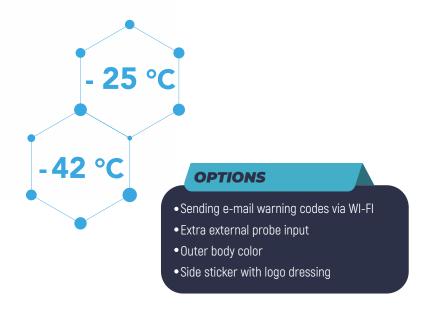


M400PLZ

Manufactured following the DIN58375 standard.













MADD Medical Devices according to Medical Device Directive [93/42/EEC].





M400PLZ

The ultra-low temperature freezers store plasma and plasma products in reliable conditions in the operating temperature range (-25°C) - (-42°C). The M400PLZ and M660PLZ ultra-low temperature freezers, which are preferred because of their cooling performance and technical equipment, have net volume options of 286 lt and 606 lt. Its lockable door system prevents unauthorized persons from accessing the products inside the cabinet.

With data transfer technology, it is ensured that it can be connected to the local network with a LAN, and when the power is turned off, information can be accessed from the screen with a battery for 72 hours, and the traceability of products with recording capabilities is ensured.

EC CERTIFICATE

AT SERTİFİKA

According to Annex V of the Directive 93/42/EEC on Medical Devices

93/42/AT Tıbbi Cihaz Yönetmeliği Ek V'e göre

Production Quality Assurance System

Üretim Kalite Güvencesi

Certificate Number: 2195-MED-1928401

Sertifika Numarası

Manufacturer:

Üretici

ÖZTAŞ SAÇ DEMİR İNŞAAT METAL MAMÜLLERİ MAKİNA SANAYİ VE

TICARET ANONIM SIRKETI

Keciliköy OSB Mahallesi Ahmet Nazif Zorlu Bulvarı No:32 Yunusemre MANİSA

TÜRKİYE

Product(s):

Product details are stated on the following page(s).

Ürün(ler)

Ürün detayları ilerleyen sayfa(lar)da belirtilmiştir.

Model(ler)

Model(ler)

Product models are stated on the following page(s).

model(ioi)

Ürün modelleri ilerleyen sayfa(lar)da belirtilmiştir.

Referans Rapor No

Reference Report No: MM0757-P001-R01, MM0757-P001-R02, MM0757-P002-R01, MM0757-P004-R01,

MM0757-P003-R03

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK V bölüm 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK V, bölüm 4'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir.

Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır. Steril kondisyondaki sınıf I ürünler için kalite yönetim sistemi değerlendirmesi üretimin steril kondisyonun sağlanması ve korunmasıyla limitlidir. Ölçüm fonksiyonlu sınıf I ürünler için Kalite yönetim sistemi değerlendirmesi üretimin cihazların metrolojik şartlara uyumunu sağlamasıyla limitlidir.

This EC certificate is valid till 2024-05-26.

Bu AT Sertifikası 2024-05-26 tarihine kadar geçerlidir.

Issue Date/Yayın Tarihi: Revision No./ Revizvon No.: 2019-10-11 03 Rev./Rev.

Revision Date/ Revizyon Tarihi: 2021-04-30

Rukiye BALKAN Deputy General Manager Genel Müdür Yardımcısı

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Certificate Number: 2195-MED-1928401

Sertifika Numarası

Product specifications:

Ürün detayları:

Product(s)	Model(s)
1. Blood Refrigerator 1. Kan Saklama Dolabi	M260KN, M390KN, M660KN, M900KN
2. Plasma Storage Refrigerator 2. Plazma Saklama Dolabı	M170PLZ, M260PLZ, M400PLZ, M660PLZ
3. Ultra Low Temperature Medical Type Freezer 3. Ultra Düşük Sıcaklıklı Medikal Tip Dondurucu	LWF170, LWF270, LWF370, LWF470, LWF670
4. Outdoor / Cold Chain Vaccine and Blood Bank Refrigerator 4. Dış Ortam / Soğuk Zincir Aşı ve Kan Saklama Dolabı	AC 25, AC 50, AC 100, AC 150, AC 200



CERTIFICATE INFO AMENDMENT

SERTIFIKA BİLGİ DEĞİŞİKLİĞİ

According to Article 120(3) of the Regulation (EU) 2017/745 on Medical Devices

(AB) 2017/745 Tıbbi Cihazlar Yönetmeliği Madde 120(3)'ye göre

Effected Certificate Number(s): 2195-MED-1928401

Etkilenen Sertifika Numarası(ları):

ÖZTAŞ GLOBAL SOĞUTMA TEKNOLOJİLERİ VE METAL SANAYİ VE

Üretici TICARET A.S.

Keçiliköy OSB Mahallesi Ahmet Nazif Zorlu Bulvar No: 32 / Yunusemre /

MANISA / TÜRKİYE

Product(s):

Manufacturer:

No Change

Ürün(ler)

Değişiklik mevcut değildir.

Model(s):

No Change

Model(ler)

Değişiklik mevcut değildir.

Reference Report No:

MM0762-P006-R01

Referans Rapor No

Definition of the Change:

The change of company title

Değişikliğin Tanımı

Firma unvan değişikliği

SZUTEST, Notified Body 2195, declares and the above mentioned manufacturer has initiated an insignificant change according to Article 120(3) of (EU) 2017/745 and MDCG 2020-3 guidance and therefore the information on the effected 93/42/EEC certificate(s) has been changed as described above.

This document is a confirmation for authorities and cannot be used as other purposes.

2195 kimlik numaralı Onaylanmış Kuruluş SZUTEST, yukarıda belirtilen üreticinin (AB) 2017/745 Regülasyonu Madde 120(3)'e ve MDCG 2020-3 rehber dokümanına göre önemli olmayan bir değişiklik yürüttüğünü ve bu sebeple etkilenen 93/42/AT sertifika(lar)ındaki bilgilerin yukarıdaki gibi değiştiğini beyan eder.

Bu doküman yetkili otoriteler için bir onay niteliğinde olup farklı bir amaçla kullanılamaz.

Issue Date/Yayın Tarihi:

2022-03-14

Deputy General Manager Genel Müdür Yardımcısı

SZUTEST UYGUNLUK DEĞERLENDİRME A.S.

Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE





CERTIFICATE

This certificate is granted to the organization,

ÖZTAŞ GLOBAL SOĞUTMA TEKNOLOJİLERİ VE METAL SANAYİ TİCARET ANONİM ŞİRKETİ

Keçiliköyosb Mahallesi Ahmet Nazif Zorlu Bulvarı No:32 Yunusemre / Manisa / Türkiye

Branch: Muradiye Mahallesi Sanayi Caddesi Öztaş Ltd. Şti. Apartmanı

No:26 Yunusemre / Manisa / Türkiye

CUTTING, SHAPING, WELDING, SALES AND MARKETING OF STEEL AND OTHER METAL MATERIALS- DESIGN, MANUFACTURING SALES AND MARKETING OF COMMERCIAL TYPE REFRIGERATOR, MEDICAL TYPE REFRIGERATOR AND INDUSTRIAL TYPE REFRIGERATOR CABINETS

EA 17, 18

according to the scope,

ISO 9001:2015

to certify that Quality Management System in accordance with standard's clauses is established and being implemented.

First Date of Issue : 01.03.2019

Date of Issue : 28.02.2022

Certificate Period : 3 Years

Reissue Due Date : 28.02.2023

Certificate No : 01.19.7859.113419.D

First Quality Critification
System Certificate Approved
Maltepe / İstanbul / Türkiye







FQC, India & Head Office FQC First Quality Certification Pvt. Ltd. SC0 37, Sector-12, Panchkula - 134109, Haryana, India T: +91 172 6535975 // F: +91 172 4416931 www.fccert.com info@fccert.com FQC, Turkey & Critical Location
FQC Uluslar Arası Belgelendirme ve Eğit. Hiz. A.Ş.
Cevizli Mah. Tansel Cad. No:12/18 Kat:4 D: 28-29 Maltepe / İstanbul / Türkiye
T: +90 216 444 21 41 / +90 216 457 69 08 F: +90 216 457 98 69
www.fqcglobal.org info@fqcglobal.org

Bu belge, müşterinin FQC'nin kurallarına ve sözleşme şartlarına uyduğu sürece geçerlidir. Sertifika geçerlilik durumu FQC' nin internet sitesinden takip edilir. This document shall remain valid as long as the customer obeys FQC rules and terms of the contract. Certificate validity may be checked on FQC website.

CERTIFICATE



Medical Devices Quality Management System
CERTIFICATE NO: 31928401

ÖZTAŞ GLOBAL SOĞUTMA TEKNOLOJİLERİ VE METAL SANAYİ VE TİCARET A.Ş.

Keçiliköy OSB Mahallesi Ahmet Nazif Zorlu Bulvar No: 32 YUNUSEMRE MANİSA/TÜRKİYE

EN ISO 13485:2016

Design, Manufacturing, Sales-Marketing, Technical Service Activities of Medical Type Refrigerator (Blood Storage, Plasma Storage, Vaccine-Serum Kit Storage, Ultra Low Temperature Medical Type Freezer)

Approves that the Medical Devices Quality Management System implemented for above scope.

Issue Date

11.10.2019

Expiry Date

10.10.2022

Revision Date/No

14.03.2022 / 2





Pepoty General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on http://public.szutest.com.tr or by using BDS No on https://tdbs.turkak.org.tr.