
Operating Manual **pfm Mobile Cooling** **System MCS 400**

Please read this operating manual carefully before using the instrument for the first time and make certain that you are familiar with the method of operation to ensure that it is used in the correct way.

www.pfmmedical.com



Note

Dear Customer,

Please read this operating manual carefully before using the instrument for the first time and make certain that you are familiar with the method of operation to ensure that it is used in the correct way.

All the information in this operating manual applies to the pfm Mobile Cooling System MCS 400.

Serial number: _____

Please enter the serial number of your instrument here. It can be found on the nameplate.

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Part 1 – Safety instructions

Please read this operating manual carefully before working with the pfm Mobile Cooling System MCS 400. Make sure that you are familiar with the instrument's method of operation. Always observe the following precautions during operation of the instrument. Failure to do so is contrary to the recognised technical regulations and the intended use of the instrument.

In case of infringement, pfm medical gmbh does not accept any form of liability.

1.1 Key to symbols



Caution! This symbol indicates a possible danger to life and health. Failing to observe these instructions can result in severe health impacts, including life-threatening injuries.

NOTE

Indicates useful information

WARNING

Indicates a dangerous situation



Manufacturer



Date of manufacture



Consult operating manual

PLEASE NOTE The up-to-date electronic operating manual can be found on our website:
<http://www.pfmmedical.com/downloads>



In vitro diagnostic (IVD) medical device



Catalogue number



Serial number



CE marking



Biohazard warning



Cold surface warning



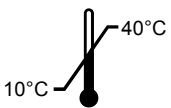
Wear protective gloves



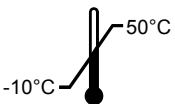
Keep dry



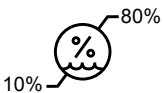
Fragile, handle with care



Permissible temperature range at the place of use
+10°C - +40°C



Permissible temperature range for storage and transportation
-10°C - +50°C



Permissible humidity range for storage and transportation, and at the place of use
10% - 80% (non-condensing)

! 1.2 Intended purpose

The pfm Mobile Cooling System MCS 400 allows cooling of human and animal tissue specimens to below room temperature for a set period during sectioning at the microtome and can be used in the histological laboratory in the field of medicine, research and industry. It can be applied as a diagnostic aid related to an in-vitro examination within the histopathological process and may only be

operated by appropriately trained personnel. The product facilitates the preparation of tissue samples which, after further processing, are diagnosed by a pathologist and provide information on the physiological or pathological condition.

! 1.3 User group/user profile

- ▶ The pfm Mobile Cooling System MCS 400 must only be operated by appropriately trained staff who are familiar with the instrument's method of operation.
- ▶ Before using the instrument for the first time, the operating manual must be read so that the user is familiar with the method of operation. This is essential to ensure proper handling.

NOTE

The operating manual should be accessible to everyone.

! 1.4 Material-related hazards

The manufacturers' safety data sheets comprise the physical data, documenting heat resistance, chemical resistance, reactivity and also chronic and acute toxicity. Customers are advised to request this documentation. Any employee who is either involved in the procedure or who may be exposed to hazards posed by the material in question should be supplied with all hazard-related information and granted unrestricted access to this information.

WARNING

Caution! Do not open the base plate, otherwise the tightness is no longer given.

Caution! If cooling gel leaks out, the instrument should immediately be taken out of operation. If this occurs, contact a service technician.

! 1.5 Operating the instrument

- ▶ Do not start up the instrument if it is damaged or leaking.
- ▶ During operation, the surface of the instrument may be very cold.
- ▶ Wear cold gloves when taking the instrument out of the refrigerator.
- ▶ The surface of the pfm Mobile Cooling System MCS 400 must not be damaged or scratched with sharp or pointed objects.
- ▶ Observe all warnings.
- ▶ Warnings on the instrument must not be removed or obscured.
- ▶ Do not open the instrument housing.
- ▶ The instrument must only be opened and repaired by service technicians trained and authorised by pfmmedical.
- ▶ No corrosive, acidic or alkaline solutions should be used in the vicinity of the instrument. This could cause corrosion and damage the instrument and accessories.

1.6 General precautions

Please take special note of the following warnings:

Risk of infection

When working with infectious materials, appropriate safety measures must be implemented. The specimens used may potentially be infectious. The general laboratory rules regarding protection against infections must therefore be observed.

Risk of radioactivity

When working with radioactive materials, the radiation protection regulations must be followed. Protective clothing must be worn in accordance with the rules and regulations that apply in your laboratory for handling radioactively contaminated materials. For the disposal of radioactive waste, the applicable regulations will apply in each instance.

WARNING

Caution! Cold surface warning.
During operation, the surface of the instrument may be very cold.



Caution! Wear cold gloves when taking the instrument out of the refrigerator.



Part 2 – Introduction

2.1 View of the pfm Mobile Cooling System MCS 400



1 Working surface

2.2 Technical data for the Mobile Cooling System MCS 400

- | | |
|---|--|
| ▶ Dimensions (W/D/H): 220 x 220 x 25 mm | ▶ Temperature: up to -20°C |
| ▶ Storage surface: 195 x 195 mm | ▶ Cooling duration: approx. 1 hour at room temperature |
| ▶ Capacity: 20 - 25 paraffin blocks | ▶ Weight: 1.4 kg |

2.3 Scope of delivery

pfm Mobile Cooling System MCS 400
REF: 400400S

Scope of delivery
1 pfm Mobile Cooling System MCS 400

NOTE

The up-to-date electronic operating manual can be found on our website: <http://www.pfmmedical.com/downloads>

Part 3 – Operating instructions

3.1 Transportation, unpacking and setting up the instrument

- ▶ Before unpacking the instrument, please check that it is complete and undamaged.
- ▶ Disassemble the packaging and remove the instrument.
- ▶ Please read the operating manual carefully before using the instrument for the first time.
- ▶ The instrument should be placed on a stable, vibration-free table.
- ▶ The instrument must be placed on a non-combustible, flat surface.
- ▶ Room temperature at the installation location of the instrument between +10°C and +40°C.
- ▶ Relative humidity at the installation location of the instrument max. 80% (non-condensing).
- ▶ Ambient temperature during the transportation and storage of the instrument: between -10°C and +50°C.
- ▶ Relative humidity during the transportation and storage of the instrument: max. 80% (non-condensing).

The operator is responsible for checking that the instrument is working properly and safely. The operator shall assume responsibility for any use of special equipment and/or materials for operating the instrument.

NOTE

If possible, retain the original packaging for the entire lifetime of the instrument so that you can repack the instrument correctly if it needs to be sent for servicing.

3.2 Initial operation

- ▶ The pfm Mobile Cooling System MCS 400 requires pre-cooling for approx. three to five hours in a refrigerator/freezer.
- ▶ The retained cold is evenly transferred through the surface of the cooling plate to the paraffin blocks laid on it.
- ▶ The surface of the pfm Mobile Cooling System MCS 400 can be cooled down to -20°C.
- ▶ The system cools the specimens sufficiently for approx. one hour (depending on local conditions) to ensure the right temperature for sectioning.

WARNING

Caution! In the event of a reduction or loss of cooling capacity, the instrument should immediately be taken out of operation. If this occurs, contact a service technician.

3.3 Temperature setting

Depending on the refrigeration capacity of the refrigerator/freezer, the pfm Mobile Cooling System MCS 400 can be cooled down to -20°C.

3.4 Change history

State of revision	Change
Rev.2022-12-12	Corporate identity guidelines
Rev.2024-01-01	Corporate identity guidelines

Part 4 – Cleaning, care and disposal

4.1 Cleaning and care

For the instrument to function reliably, it must be kept clean by the user. The cooling surface is made of anodised aluminium and is easy to clean. Mild household detergents are suitable for this purpose. Do not use any aggressive cleaning agents or solvents. Do not allow liquids to penetrate the inside of the instrument. Wipe off condensation on the surface of the pfm Mobile Cooling System MCS 400 with a soft lint-free cloth.

WARNING

Caution! When handling disinfectants and cleaning agents, always follow the manufacturer's instructions regarding safety, dilution and exposure time.

4.2 Returning the Mobile Cooling System MCS 400 for repair or maintenance

Repairs and maintenance work are usually carried out on site. If this is not possible for any particular reason, the instrument can be sent to pfm medical gmbh. Before you send an instrument to pfmmmedical for a service, it must be suitably cleaned and decontaminated. This also applies to instruments undergoing a service on site. Contaminated instruments pose a potential health hazard for anyone coming into contact with them due to infectious agents, pathogens or medicinal products. The legal requirements for the handling of contaminated instruments are specified in various regulations, including the Occupational Safety and Health Act (ArbSchG), the Biological Agents Ordinance (BioStoffV), the Occupational Safety Act (ASiG) and the Accident Prevention Regulations (UVV). To confirm that the instrument has been decontaminated, please complete the decontamination certificate carefully. You can find the current certificate on our website:
<http://www.pfmmmedical.com/downloads>.

Servicing can only be carried out if a certificate is fully completed in advance and enclosed with the instrument. If it is found that the instrument poses a potential hazard, we reserve the right to return the instrument to the sender immediately at the sender's expense.

WARNING

Caution! Always send the instrument in the original packaging. Please contact pfmmmedical if you no longer have the original packaging.

4.3 Decontamination

For the regular disinfection of the work surfaces and other surfaces of the pfm MCS 400, we recommend using single-use disinfectant wipes, for example those recommended by

the RKI (Robert Koch Institute) or the VAH (Association for Applied Hygiene) list: "Mikrozid AF" and "Bacillol AF".

4.4 Warranty

The instrument has been carefully checked and tested by us. However, in the event of any defect, apart from minor defects, occurring in an instrument or spare part distributed by us up to one year from delivery, we undertake to remedy the defect to the extent specified below, without prejudice to any statutory or other contractual claims, even where the defect was not present on delivery to the customer, provided that there has been no unauthorised interference with the instrument by third parties. This warranty does not cover normal wear and tear, nor does it constitute a guarantee of quality or durability of the instrument.

The remedying of defects under this warranty shall be carried out, at our discretion, by the replacement or repair of defective parts. Furthermore, spare parts can be supplied for up to 5 years after delivery of the instrument. Any warranty claims on the part of the customer beyond the above are hereby excluded, without prejudice to any statutory or other contractual claims. This applies in particular to any compensation claims for damage, consequential damage or costs relating to the defect. Transportation of the instrument to us and return transportation during this period shall be at the customer's risk.

To assert a claim under this warranty, the instrument concerned must be sent to us, at the customer's expense and risk, with a detailed description of the defect, and specifying the purchase order number, delivery note number and invoice number. Our address is: Wankelstraße 60, 50996 Köln, Germany.

Claims under this warranty expire 6 months from assertion of the claim, but not before the end of the warranty period. This warranty and any claims, rights and obligations arising therefrom are subject solely to the material law of the Federal Republic of Germany, to the exclusion of Private International Law and the UN Convention on Contracts for the International Sale of Goods. Our standard terms and conditions of supply and payment apply in addition.

All serious incidents that occur in connection with the device must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient are located.

4.5 Declaration of Conformity

The current Declaration of Conformity form can be found on our website: <http://www.pfmmedical.com/downloads>

4.6 Disposal when put out of use

When the instrument is put out of use, dispose of it in accordance with the applicable laboratory guidelines and legal provisions. Prior to disposal, the instrument should be decontaminated.

Contact

Do you have any questions?

Our Customer Solutions Team will be happy to advise you.

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