

memmert

IComed with IVF module

ADDITION TO OPERATING MANUAL



CO₂ INCUBATOR ICOMED WITH IVF MODULE
ICO50MED
ICO105MED

MADE IN GERMANY.

www.memmert.com

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Please contact our customer service department before sending appliances for repair or before returning equipment, or the shipment may be refused.

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Subject to change without notice

About this manual

Purpose and target audience

These instructions are an addition to the operating manual for the ICOMed CO₂ incubator when using the IVF module. It is intended for use by trained personnel of the owner, who have the task of operating and/or maintaining the respective appliance.

If you are asked to work on the appliance, read these instructions and the operating manual for the ICOMed CO₂ incubator carefully before starting. Familiarise yourself with the safety regulations. Only perform work that is described in this manual. If there is something you do not understand, or certain information is missing, ask your manager or contact the manufacturer. Do not do anything without authorisation.

Versions

Due to individual configurations and sizes, illustrations in this manual may be slightly different to the actual appearance. Function and operation are identical.

Other documents to be observed:

- ▶ the operating manual for the ICOMed CO₂ incubator
- ▶ For operation of the appliance with MEMMERT AtmoCONTROL, observe the separate software manual
- ▶ For service and repair work, observe the separate service manual

Storage and resale

This operating manual belongs with the appliance and should always be stored where persons working on the appliance have access to it. It is the owner's responsibility to ensure that persons who are working on or are going to work on the appliance know where to find the operating manual. We recommend that it is always stored in a protected location close to the appliance. Make sure that the operating manual is not damaged by heat or humidity. If the appliance is resold or transported and then set up again at a different location, the operating manual must remain with it.

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1. Safety regulations

1.1 Terms and signs used

In this manual and on the appliance itself, certain common terms and signs are used to warn you of possible dangers or to give you hints that are important in avoiding injury or damage. Observe and follow these notes and regulations to avoid accidents and damage. These terms and signs are explained below.

1.1.1 Terms used

| | |
|------------------|--|
| ⚠ WARNING | Warns of a dangerous situation that might lead to death or serious injuries |
| ⚠ CAUTION | Warns of a dangerous situation that might lead to moderate or minor injuries |
| NOTICE | Warns of material damage |

1.1.2 Signs used

| | | | | |
|---|--|---|---|--|
|  Danger of electrocution |  Fire hazard |  Gases / vapours |  Danger of frostbite/cold burns |  Warning of gas bottles |
|  Danger of burns |  Disconnect the mains plug |  Wear gloves |  Wear safety boots |  Observe information in separate manual |
|  Information on first aid |  First aid: Rinse eyes out |  Important or useful additional information | | |

1.2 Product safety and dangers

The appliances described in this manual are technically sophisticated, manufactured using high-quality materials and subject to many hours of testing in the factory. They reflect the state of the art and comply with recognised technical safety regulations. However, there are still risks involved, even when the appliances are used as intended. These are described below.

⚠ WARNING



After removing covers, live parts may be exposed. Touching these can lead to an electrical shock. Disconnect the mains plug before removing any covers. Work on the electrical system must only be performed by qualified electricians.

⚠ WARNING



When loading the appliance with an unsuitable load, poisonous or explosive vapours or gases may be produced. This could cause the appliance to explode, and people could be severely injured or poisoned. The appliance may only be loaded with materials / test objects that do not emit any poisonous or explosive vapours when heated up.

⚠ WARNING



Leaving the door open during operation can cause the appliance to overheat or pose a fire hazard. Do not leave the door open during operation.

⚠ WARNING



Depending on operation, the surfaces in the interior of the appliance and the chamber load may still be very hot after the appliance is switched off. Touching these surfaces can cause burns. Wear heat-resistant protective gloves or wait until the appliance cools down before touching.

⚠ WARNING



Gas bottles may burst or explode at high temperatures. Keep the gas bottles away from open flames. Store gas bottles below 50 °C and ensure that the location is always well ventilated. Prevent water from penetrating as well as backflow into the gas bottles. It is essential that you read the safety notes and instructions of the gas supplier.

⚠ WARNING



Condensation in the electrical components may cause short circuits. After transporting or storing the device under humid conditions, remove it from its packaging and let it ventilate for at least 24 hours in normal environmental conditions. Do not connect the device to the mains power during this time.

⚠ CAUTION

Danger of suffocation. CO₂ and N₂ in high concentrations can have a suffocating effect. In normal mode, the appliance emits small amounts of CO₂ and N₂ to its surroundings. You should therefore ensure that the room in which it is installed is properly ventilated. You will need to extract 250 m³ of air per hour as a minimum. Always close the stop valve or pressure reducer on the gas bottles if the appliance is not in operation.

⚠ CAUTION

High concentrations of CO₂ can cause cold burns or frostbite. Avoid contact with CO₂ gas to the eyes and skin.

CO₂ and N₂ are not dangerous substances in terms of the German Hazardous Substances Ordinance (GefStoffV). You should nevertheless familiarise yourself with the applicable safety regulations prior to handling such gas bottles.

1.3 Intended use

The CO₂ incubator IComed with IVF module is used to generate and maintain constant ambient conditions for the in-vitro fertilisation (IVF) application field, especially for the incubation of oocytes, spermatozoa and zygotes in special culture dishes for IVF application as well as for gene expression and the biosynthesis of RNA and proteins.

1.4 Requirements of the operating personnel

The incubator may only be operated and maintained by persons who are of legal age, and who have received instructions for the incubator. Personnel who are to be trained, instructed or who are undergoing general training may only be active on the incubator under the continuous supervision of an experienced person.

The incubator may only be transported by persons (fork-lift truck, manual pallet jack), who are trained for this work and who know the corresponding safety regulations.

Repairs may only be performed by qualified electricians. The regulations in the separate service manual must be observed.

1.5 Responsibility of the operator

The operator of the incubator

- ▶ is responsible for the flawless condition of the incubator and for the incubator being operated in accordance with its intended use;
- ▶ is responsible for ensuring that persons who are to operate or service the incubator are qualified to do this, have received instructions about the incubator and are familiar with this operating manual;
- ▶ must know about the applicable guidelines, requirements and operational safety regulations, and train staff accordingly;
- ▶ is responsible for ensuring that unauthorised persons have no access to the incubator;
- ▶ is responsible for ensuring that the maintenance plan is adhered to and that maintenance and repair work is properly carried out;
- ▶ ensures, for example through corresponding instructions and inspections, that the incubator and its surroundings are kept clean and tidy;
- ▶ is responsible for ensuring that personal protective clothing is worn by operating personnel, e.g. work clothes, safety shoes and protective gloves.

1.6 Changes and alterations

No independent conversions or alterations may be made to the incubator. No parts may be added or inserted which have not been approved by the manufacturer.

Unauthorised changes or alterations result in the EC declaration of conformity losing its validity, and the incubator may no longer be operated.

The manufacturer is not liable for any damage, danger or injuries that result from unauthorised changes or alterations, or from non-compliance with the provisions in this manual.

1.7 Behaviour in case of malfunctions and irregularities

The incubator may only be used when in a flawless condition. If you as the operator notice irregularities, malfunctions or damage, put the incubator out of service immediately (see Chapter 1.9) and inform your superiors.

1.8 What to do in case of accidents



1. Keep calm. Act with determination and consideration. Pay attention to your own safety.
2. Switch off the incubator and close the valves on the gas bottle.
3. Call a doctor.
4. Start first aid measures. If available: Call a trained first aid helper.

In case of contact with CO₂ to the eyes and skin:



Rinse eyes out with water for at least 15 minutes. In case of cold burns, rinse with water for at least 15 minutes. Cover over in a sterile way. Call a doctor.

After inhaling CO₂:

High concentrations can cause suffocation. Symptoms may include a loss of mobility and unconsciousness. The victim is not aware of suffocating.

Low concentrations of CO₂ can cause accelerated breathing and headaches.

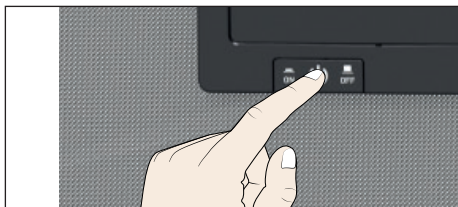
Anyone affected should breathe fresh air, using a breathing device independent of recirculating air. Keep the person warm and calm. Call a doctor. In case of respiratory arrest, use artificial respiration.

If gas is escaping:

Leave the room immediately, warn others and ventilate the room. If you re-enter the room, use a breathing device independent of recirculating air if it has not been established that the atmosphere is harmless.

1.9 Switching off the appliance in an emergency

Press the main switch on the ControlCOCKPIT (Fig. 1) and disconnect the power plug. This disconnects the appliance from the power supply at all poles.



*Fig. 1
Switch off the appliance by pressing the
main switch*

2. Design and description

2.1 Design



Fig. 2 Design

- 1 ControlCOCKPIT with capacitive function keys and LCD displays (for description and operation see ICOMed operating instructions)
- 2 Main switch
- 3 Outlet
- 4 IVF module
- 5 Markable drawers
- 6 Unlocking handle
- 7 Inner glass door

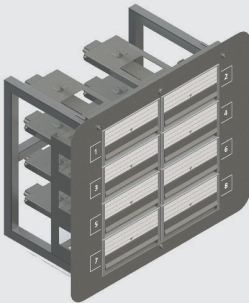
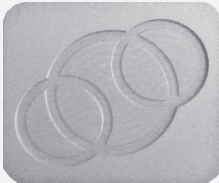
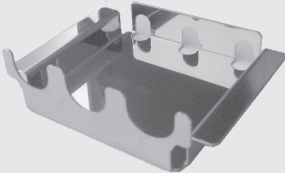

2.2 Description

The ICOMed CO₂ incubator with IVF module is used to generate and maintain constant ambient conditions for the in-vitro fertilisation (IVF) application field. For this purpose, it is equipped with a slide-in unit - the IVF module - which in turn contains eight (ICOMed 105) and six (ICOMed 50) drawers, into which Petri dishes and 4-well plates as well as tube holders can be inserted on the included inserts.

The drawers in the IVF module can be pulled out individually after opening the door to insert or remove inserts and preparations.

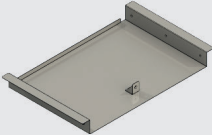
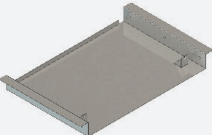
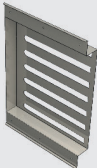
1 When the door is opened, the temperature, humidity and CO₂ control is interrupted until it closes again.

2.3 Standard package

| Standard package | |
|---|---|
| IVF module |  |
| Drawer insert for Petri dishes ICOMed 50: 12 units ICOMed 105: 16 units |  |
| 2 holders for IVF tubes |  |
| Magnetic foil |  |
| Custom calibration certificate | |

3. IVF-Module installation

3.1 Additional package for self-installation of the IVF module

| Additional package for self-assembly | |
|--|---|
| Bottom mounting frame |  |
| Top mounting frame |  |
| Side mounting frame (2 pieces included) |  |
| Allen key screws M6x70 | 3 units |
| Round-head screws M4x8 | 12 units |

3.2 Assembly

Installation is only necessary if the IVF module is not already installed in the ICOMed incubator at the factory.

3.2.1 Cleaning

The components for the installation frame are cleaned at the factory by Memmert. However, shipping and packaging may cause contamination.

If necessary, clean the interior of the cabinet and the individual parts of the installation frame in advance.

The sterilisation process prior to start-up is not basic cleaning for dirt particles.

3.2.2 Checking the temperature sensor

Strong vibrations during transport could result in the temperature sensors being moved in their holders in the ceiling of the working chamber. Check whether the Temperature sensor is located correctly and if necessary, adjust in position in the holders (Fig. 3).

3.2.3 Fitting the installation frame

⚠ CAUTION



Risk of injury.
Wear gloves and work shoes.

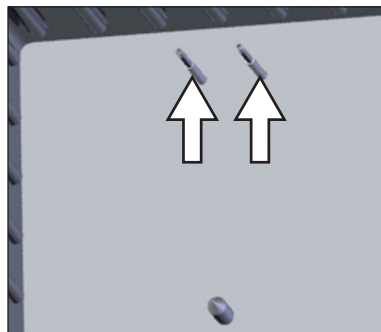


Fig. 3 Temperature sensor

Required tools

Allen key sizes 2.5 and 5

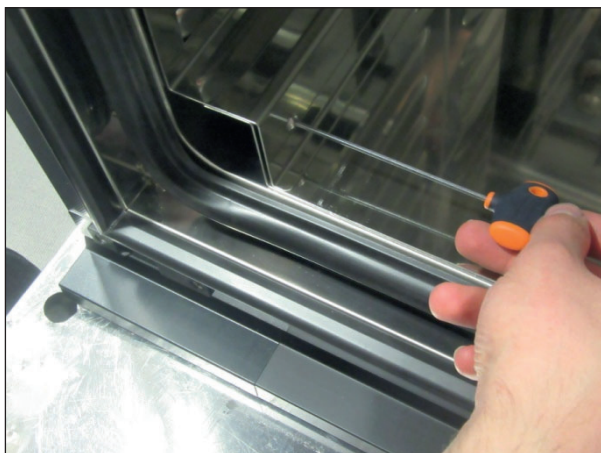
1. Position the lower mounting frame centrally on the bottom of the unit so that the shelf on the front side protrudes approx. 10 mm into the interior of the unit. The fixing screw (A) must face forward.



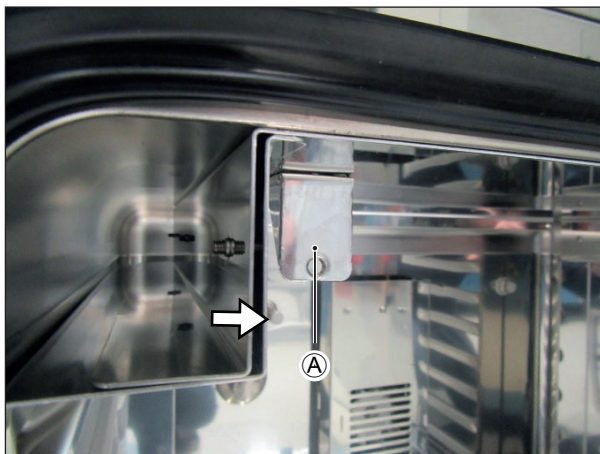
2. Slide the side mounting frame on the left and right side over the heating beading. The side installation frames rest on the lower installation frame.



3. Slightly tighten the side mounting frames on both sides with six M4 x 8 pan-head screws. Ensure an even gap between the side and lower installation frames.



4. Place the upper mounting frame on the side mounting frame and slide it in carefully. The fixing screws ① must face forward. The upper frame rests on the side frame.
5. Tighten the upper mounting frame evenly on both sides with six M4 x 8 pan-head screws.
6. Then tighten all 12 screws in sequence so that the gap between the side and top/bottom mounting frames is approximately equal.
7. Test whether the mounting frame is firmly seated.



3.2.4 Insert IVF module

⚠ WARNING



Risk of injury due to the weight of the IVF module. The IVF module 50 weighs approx. 25 kg, the IVF module 105 approx. 35 kg. Always hold the IVF module with both hands.

1. Grip the IVF module by the frame with both hands and insert it into the tube (Fig. 4).
2. Fasten the IVF module with 3 screws M6 x 70 (Fig. 5).

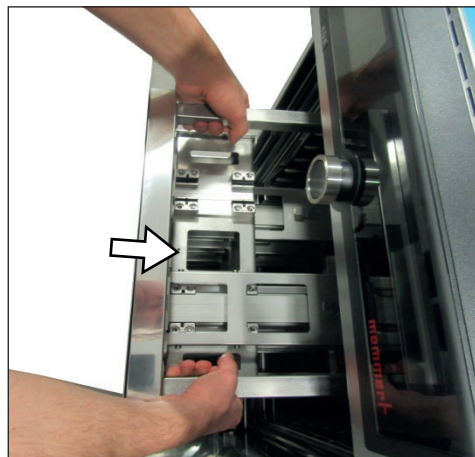


Fig. 4 Insert the IVF module into the tube with both hands

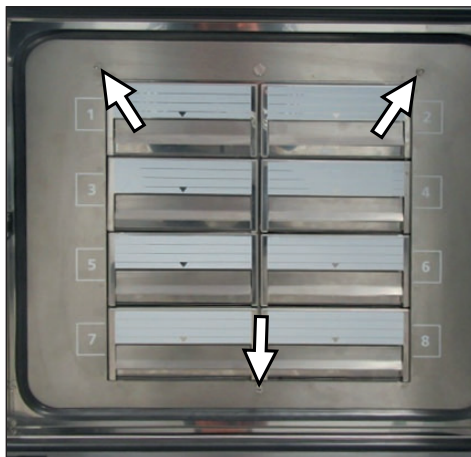


Fig. 5 Fasten IVF module

3.2.5 Removing the drawers

The drawers can be removed for cleaning purposes and to remove the IVF module.

1. The drawers are secured by a locking mechanism. To pull out a drawer, lift the tab at the point marked with an arrow and pull out the drawer (Fig. 6).
2. The drawer is secured against being pulled out by the mounting bracket mounted in the rear area of the drawer. To release the safety device, push the lever upwards to release it (Fig. 7).



Fig. 6 To pull out a drawer, lift the tab

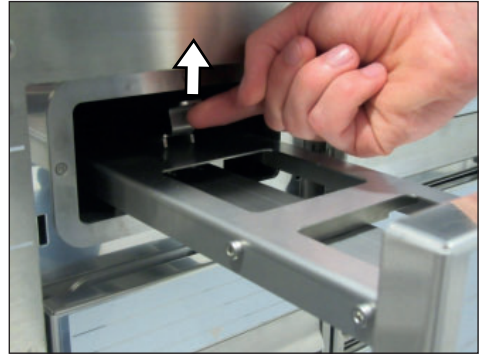


Fig. 7 Press the safety lever upwards to remove the drawer

3.2.6 Remove IVF module

WARNING



Risk of injury due to the weight of the IVF module. The IVF module 50 weighs approx. 25 kg, the IVF module 105 approx. 35 kg. Always hold the IVF module with both hands.

1. Loosen the 3 screws for fastening in the interior with an Allen key (size 5, see Fig. 5).
2. Remove the upper left or right drawer (see section 3.2.5).
3. Reach into the drawer opening and pull out the slide-in unit until the frame is within reach (Fig. 8).
4. Grip the IVF module by the frame with both hands and pull it out of the tube (Fig. 9).



Fig. 8 Pull the slide in unit out of the drawer opening

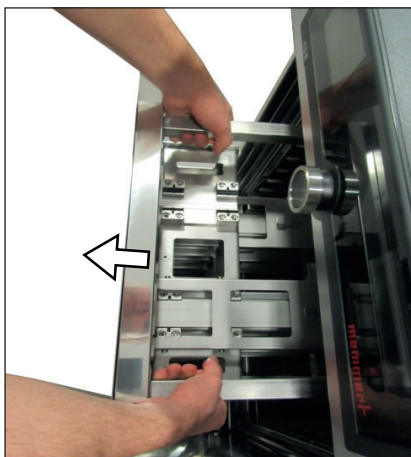


Fig. 9 Pull the IVF module out of the tube with both hands

4. Putting into operation

4.1 Connecting the appliance

Connect the appliance to the power, water and CO₂ supply as described in the ICOMed operating manual.

4.2 Switching on the appliance

Switch on the appliance as described in the ICOMed operating manual at the main switch.

4.3 Sterilising the appliance

Before the appliance can be used, it has to be sterilised. Sterilisation programs are stored in the device. How they are carried out is described in the ICOMed incubator's operating instructions. Preparation is as described below.

WARNING



Danger of burns! The incubator becomes very hot inside during the sterilisation process. Do not open door. If you open the door, the on-going sterilisation process will be terminated and destroyed.

NOTICE

The sterilisation programme is not intended to sterilise the chamber load but only to sterilise the interior of the appliance. The ICOMed IVF incubator is not a steriliser with respect to the Law on Medical Products.

4.3.1 Preparation

1. Open the door, pull out the drawer and leave it open for five minutes so that the humidity can evaporate.
2. Check and make sure that there is no more chamber load in the drawers.
3. Wipe labels if they are present.
4. Place inserts for Petri dishes and/or 4-well plates and tube holders (Fig. 10 and Fig. 11).

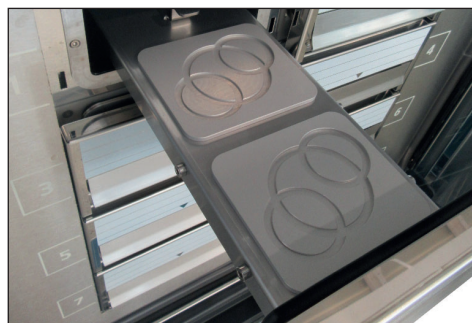


Fig. 10 Inserts for Petri dishes and / or 4-well plates inserted

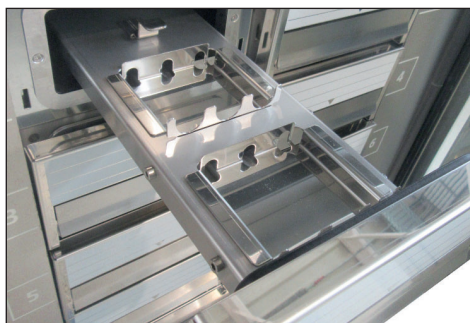


Fig. 11 Tube holder inserted

5. Close all drawers and the door.
6. Attach magnetic foil to the door (Fig. 12).
7. Carry out the sterilisation program as described in the ICOMed incubator's operating instructions.

NOTICE

Do not leave the appliance unattended during the sterilisation process.

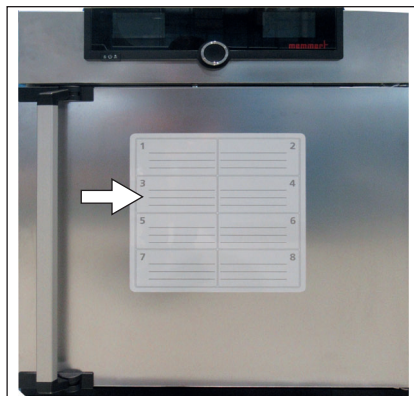


Fig. 12 Magnetic foil

5. Operation

5.1 Preparation

Warm the device for 4 hours at 37 °C before incubating (without incubation material, but with inserted Petri dish holders and media holders as well as media). Do not activate the humidity control before the chamber has been heated for at least 4 hours. Depending on the use, set the rest of the parameters (CO₂ and O₂) (see ICOMed operating instructions).

5.2 Start the incubation process

1. Wipe off any descriptions on the magnetic foil and the drawers.
2. Insert the Petri dishes with the incubation charge.
3. Close the door.
4. Label the outer magnetic film and drawers with whiteboard pens to assign the samples (do not use permanent markers).

NOTICE

Only open the outer door for checking purposes and otherwise keep the door closed. When the door is opened, the temperature, humidity and CO₂ control is interrupted until it closes again.

5.3 After the incubation process

Open the appliance, pull out one of the drawers and let the appliance ventilate for 30 minutes.

6. Cleaning

WARNING



Danger due to electric shock. Disconnect the mains plug before any cleaning or maintenance work.

CAUTION



Danger of cuts due to sharp edges. Always wear gloves when working inside the chamber.

Metal surfaces can be cleaned with normal stainless steel cleaning agents. To clean the chamber interior, the interior fittings have to be removed (instructions from page 15).

Wipe the IVF module with fuzz-free cloths and cleaning/disinfection agent.

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