ENGLISH

USER MANUAL

MEDIFUGE CGF

MEDIFUGE CGF

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Fig. 1-1 Centrifuge

1. INFORMATION TO THE USER

1.1. Notice

Please note.
The Italian version of this manual is the master from which translations derive.
In case of any discrepancy, the binding version is the Italian text.

Read these instructions for installation, use and maintenance of the device, before beginning operation, in order to avoid improper use and any type of damage or injury.

1.2. Meaning of Pictograms

Both packaging of components and this booklet contain the symbols explained below.

Hazardous situations for the operator and/or the patient.

Biological hazard.

Electrical hazardous situation

Consult instructions for use or Consult operating instructions.

Caution, consult accompanying documents.

The device has not been sterilized; it must be sterilized before use.

Sterilized using Ethylene Oxide.

Sterilized using irradiation.

Sterile medical devices processed using aseptic techniques.

Sterilized using steam or dry heat

Batch Code

Catalogue number: this is the code of the device

Medical Device

Close to this symbol there is the serial number of the device

Unique Device Identifier: this symbol is placed close to the barcode of the device

Model

Use by date: close to this symbol there is the expiry date

Date of manufacture: this symbol is adjacent to the date that the product was manufactured

Steam sterilisable at max 135°C

Manufacturer's data: this symbol is adjacent to the name and address of the manufacturer.

Keep dry

Do not re-use

Read instruction for use

Do not resterilise

Not for general waste: this symbol is used to mark devices that are reusable and not contaminated at the end of the device life.

CE

This symbol is a mandatory marking for devices entering the European market to indicate conformity with the essential health and safety requirements set out in European Directives.
The symbol may be accompanied by a four-digit identification number of the notified body.

1.3. Warnings

This manual is designed to the centrifuge for dental practice and specialized outpatient clinic MEDIFUGE CGF with its accessories, for its intended purposes.

The Manufacturer of this medical device is:

Silfradent S.r.l.

VIA G. Di Vittorio N°35/37

47018 S. Sofia (FC), ITALY

Tel. +39 0543 970684 Fax +39 0543 970770

WEB: www.silfradent.com E-mail: info@silfradent.com

Silfradent S.r.l. congratulates and thanks you for choosing this device.

Below, we provide some preliminary information to help you in the initial use of the equipment.

It is important that you make sure that the package contains the guarantee certificate and that this is filled in and stamped by the retailer.

The accessories provided with MEDIFUGE CGF have been selected and designed to perform each operation necessary for preparing and using CGF in a sterile ambient to avoid contamination of autologous implant material.

Please note.
Before removing the equipment from packaging, check that all the components described in paragraphs 2.2 (Centrifuge) and 2.3 (accessories suitcase) are in.

After carefully extracting the components of MEDIFUGE CGF from the packaging, place them on a table and check that there are no damages deriving from transport, in this case immediately contact the retailer.

Silfradent S.r.l. has drafted this Manual with the aim to help the user and facilitate the start-up and operation of the equipment.

Silfradent S.r.l. accepts no responsibility for changes to the equipment or damages to third parties arising from misuse.

Each piece of equipment is supplied with a copy of this booklet.

Compliance with the instructions contained in this technical document is necessary for correct operation.

The use of the equipment for uses different from those indicated in these instructions and in the brochures is absolutely forbidden.

Non-compliance with the instructions herein contained results in the immediate termination of the guarantee.

Please note.
For any request, always quote:
The date of purchase, device model and serial number which can be found on the data label on the back side of the equipment**.** See par. 2.4
The removal of the data plate causes the warranty to be forfeited

1.4. Classification of the device

The equipment is classified:	
According to the type of protection against electric hazards. Equipment supplied by an external source of electric energy.	**Class I equipment**
According to the degree of protection against direct and indirect contacts.	**No applied part**
According to the degree of protection against liquid penetration.	**Console is classified as IpX0.**
According to the degree of safety of use in the presence of an anaesthetic mix inflammable with air, oxygen, or nitrous oxide.	**NO PROTECTION.**
According to the conditions of use.	**Equipment for continuous operation, the operating cycles are preset.**

1.5. Safety and safe switching off.

Always check the condition of the device before use.

If any component is not in perfect condition, stop using it immediately.

Before leaving the device unattended, close the main switch and possibly unplug the power cable.

Never use the device if it is damaged.

Check the expiration date and the integrity of the disposable accessory packaging each time before use.

Please note.
Check that the supply voltage indicated on the data plate located on the back of the centrifuge corresponds to that of the power source.

1.6. Safety Warning

1.6.1. Electric Hazards

Warning!

To avoid the risk of electric shock, this equipment must only be connected to an outlet with a protective earthing connection.
When cleaning or disinfecting be careful that no liquid enters the unit.
Never extract or handle the power cord with wet hands (risk of electric shock)
NEVER use solvents or flammable materials near this or other electrical equipment.
Damaged power cord/missing protective conductor.

- Check the mains cable before use.
- The socket outlet must have a protective contact and meet the respective national guidelines.
- Always completely insert the power cord into the socket of the device before connecting to the mains.

This equipment complies with EMC standards in force however as a guarantee of equipment safety, we recommend that the use of mobile phones in the consulting room or clinic be prohibited.
Paragraph 6 contains the information on electromagnetic compatibility.

Caution!

Never carry out any maintenance or cleaning without removing the power cord.

Please note.
Always remove the power cord from the outlet or from the connector in the back of the equipment to isolate the device from mains.

1.6.2. Mechanical Hazards

Warning!

- At the end of the cycle the machine will open by itself, do not try in any way to unlock the cover during operation, it could be dangerous for the operator and people nearby.
- In case of switching off and immediate switching on, the machine opens only when the rotor stops, do not try to force the cover.
- Never operate Centrifuge with rotor unbalanced, the machine could be dangerous for the operator and people nearby.
- Never operate Centrifuge on an unstable or tilted surface, the machine could be dangerous for the operator and people nearby.

1.6.3. Other Hazards.

Caution!

- The holders included in the rotor are used to contain the tubes of blood to be centrifuged, no other use is allowed.
- The blood must not contact the Teflon container that, in this case, they have to be carefully washed and sterilized.
- Never attempt to open the lid of the machine during the UV cycle could be harmful to the eyes.
- The reusable accessories provided in the kit, before use shall be washed, disinfected and sterilized. When packed are cleaned but not sterilized.

1.7. Precautions

Caution!

- Never use the centrifuge in a different mode than as specified in these instructions.
- Never operate the centrifuge without a rotor properly attached to the shaft.
- Never fill the tubes while they are in the rotor.
- Never put your hands in the rotor area without the rotor completely stopped.
- Never move the centrifuge while the rotor is spinning.
- Always load the rotor symmetrically. Another with the same weight should counterbalance each tube.
- Place the centrifuge near an electrical outlet easily accessible.
- Use only the test tubes recommended from Silfradent .

Warning!

No modification of this equipment is allowed.

Before each use:

- Always check the condition of the accessories
- Check the expiration date of the single use accessories indicated on the single pack.
- Avoid using parts that are not in perfect condition or expired.

The technical data, information and product features described in the instructions for assembly and use correspond to current specifications at the time of publication of this manual.

Modifications may be made to the product on the basis of technical innovations, although this does not entitle the user to the corresponding modifications on appliances which have already been installed

1.8. MEDIFUGE CGF Features

Internal code	Power supply	External fuses
MF 200	230 Vac +/-10%50/60 Hz 120VA	2x T 1,25 AL 250 V
MF 200 100	100-115 Vac 50/60 Hz 120VA	2x T 2 AL 250 V

Operator interface	Three digits LED display two buttons
Motor	DC 24 V 6500 rpm
Max speed	3500 rpm
Internal fuses replaceable only by service personnel	1 x T 6,3 AL 250 V 1 x T 0,63 AL 250 V
Dimensions D x W x H	280 x 320 x 240
Weight	9,4 kg (only the centrifuge)
Environmental operating conditions	Internal use, height up to 2000 m above sea level, Humidity up to 80% Ambient Temperature 2°C TO 40°C

1.9. Waste Disposal

Hazardous health waste

Sanitary waste means any material contaminated by:
- human or animal blood;
- micro-organisms even if genetically modified and cell cultures that could cause infections, allergies, poisonings and other damages to the human organism;
- human or animal tissues;
- human or animal organic liquids;
- carcasses of animals used for experimentation or other scientific purposes.

Disposable accessories must be disposed of as hazardous medical waste.

Reusable accessories (metal containers or tools) must be disposed of only after placed in safe condition.

The equipment must not be considered a solid urban waste, it is an electrical and electronic equipment (WEEE).

For further information consult the office of Silfradent S.r.l. closer to you.

- No hazardous waste must be discharged into the sewers or municipal waste.
- Every person who uses, handles, or eliminates hazardous biological waste materials must be informed about the appropriate disposal methods.
- It is the responsibility of each user to follow the established procedures and to comply with applicable national laws and regulations.

1.10. Guarantee

Silfradent S.r.l. guarantees to the purchaser that it will repair or - to its sole discretion - replace any part which is defective with regard to construction or materials, in normal conditions of use, for the period of one year from the date shown on the serial number plate on the back of the equipment.

Silfradent S.r.l. is not liable for any damage depending on:

- External causes (poor quality of liquids or incorrect installation)
- Use of the equipment not in compliance with the regulations in force
- Unsuitable repair
- Changes made by unauthorized third parties
- Inadequate preservation of accessories.

Repairs and maintenance of the device are the responsibility of Silfradent S.r.l. technicians or staff authorized by Silfradent S.r.l.

Only original spare parts must be used for repairs and maintenance of the **MEDIFUGE CGF.**

Please note.

For use and repairs of MEDIFUGE CGF Centrifuge only original spare parts must be used.

Replacement of accessories must be with parts supplied or recommended by Silfradent S.r.l.

The guarantee is provided ex-factory SILFRADENT S.r.l.
The guarantee does not cover defects or damage arising from:
- Use not in compliance with the instructions of this manual.
- Incorrect or unsuitable maintenance by the user.
- Unauthorized opening of the external casing.
- Unauthorized tampering or changes.
- Operation not in compliance with the environment specifications indicated for the product.
- Use of non original accessories.
- Cleaning with unsuitable products

1.11. Transport and Storage

In the case of return shipment, wrap the product correctly by using the original package, if possible.

It is advisable to insure the package.

The customer has full responsibility for damages arising from unsuitable packaging.

Transport and storage of the equipment **MUST BE CARRIED OUT** into original packaging at a temperature range of -40 to +70 °C ", with relative humidity 10 to 90% and pressure range between 500 and 1060 HPA.

2. DESCRIPTION

2.1. Field of Application and Use

2.1.1. Description of CGF

It is every surgeon's wish to have material that heals wounds and prevents all the secondary effects of surgical procedures (oedema, dehiscence, infection, haematoma, etc.). Growth Factors are molecules that can certainly activate these processes. They can be natural or synthetic. The distinctive feature of GFs (Growth Factors) is the excellent reactivity even at very low concentrations. In fact, we are in the order of µg.

It is certainly better to extract GFs directly from the patient's tissue. Blood is the donor tissue that is the easiest to handle.

The best-known GF extraction techniques are:

- Fibrin Sealant (Tissucol Baxter)
- cPRP platelet concentrate (Marx 1998)
- Platelet rich plasma (PRP)
- Plasma rich in growth factors (PRGF E. Anitua)
- Fibrin rich plasma (2001 J. Choukroun)
- CGF (Concentrated Growth Factors 2006, IAIO)

The C.G.F. (Concentrate Growth Factors) is a reparative biomaterial comparable to the platelet and fibrin concentrate, which enhances the characteristics of this technique. The autologous matrix consists of a Fibrin block and a platelet concentrate, with a large amount of:

- Plasma cytokines
- Platelets: thrombocytes
- Activated fibrin
- Leukocytes
- GF
- Antibodies

Special biological properties of C.G.F.:

- Blood coagulation with the formation of a flexible and elastic fibrin network.
- Neo-angiogenesis (promoting vascularization and graft survival)
- Plasma cytokine activation
- Local immune system activation
- Release of GFs from Platelet disaggregation and fibrin concentrate.

CGF-induced processes:

- Angiogenesis
- Immunisation
- Proliferation of fibroblasts and osteoblasts.
- Repair stimulation and modulation

Structural and mechanical properties of CGF:

- slow and natural polymerization leads to a concentration of physiological thrombin
- Trimolecular and multiple fibrin monomer junctions
- thin, soft, elastic, and permeable network allows for the colonization of reparative cells, red blood cells, white blood cells, platelets, and anti-bodies.

C.G.F. is prepared by drawing the patient's blood into 10 ml glass tubes PV 200R, which are centrifuged immediately with **MEDIFUGE CGF** by Silfradent S.r.l.

Up to 8 tubes can drawing and centrifuged simultaneously.

A single centrifugation without adding any other substance gives 3 fractions in each tube. A lower part where all the red blood cells are located, an upper part with the platelet poor plasma (PPP), and a fibrin clot between these two fractions, which will be removed from the tube and separated from the red fraction using scissors. The clot can be used in form of a membrane by pressing it or crushed into smaller fragments.

2.1.2. Intended Use

The centrifuges **MEDIFUGE CGF** by Silfradent S.r.l. with the accessories of the kit were designed to process blood obtaining C.G.F. in a sterile environment so as not to contaminate the material to be implanted.

Any use other than that specified is not allowed.

MEDIFUGE CGF is a centrifuge for dentistry, cosmetic surgery and general surgery.

This centrifuge must be used combined to the selected or specially designed accessories of this kit to obtain fibrin clots and blood components to be used in:

- periodontology
- implantology
- Maxillo-facial surgery
- cosmetic surgery
- general surgery
- healing of ulcers
- healing of wounds.

The environment of use of the centrifuge must be at a maximum temperature between 20 and 25 °C since the separation of the blood to obtain the CGF must be done inside this temperature range.

2.1.3. General Description

MEDIFUGE CGF is a powerful and versatile centrifuge that offers direct operation, for maximum ease to use.

MEDIFUGE CGF is the result of a close collaboration with experienced dentists and surgeons and of a careful study of current technological innovations in the electromechanical and electronic field.

The rotor shape and the inclination of the tubes were designed to obtain great results during the use.

The machine is designed to operate only with original rotor and test tubes holder.

MEDIFUGE CGF has two operating cycles for blood centrifugation in order to obtain fibrin concentration and fibrin clots.

To protect the motor the control card is equipped with a current and voltage control to avoid electrical overloads. When occurring a failure of the machine or of the of the control card the lid remains closed until the stop of the rotor.

2.2. Equipment of Centrifuge

1	**Centrifuge**	
1	**MF2COPR Rotor**	
8	**Tube holders made with Teflon®, to contain 10ml test tubes**	
1	**Power cord**	
1	**Certificate of Guarantee**	
1	**Declaration of Conformity**	
1	**User's Manual and Maintenance**	

The centrifuge is supplied with the rotor already fixed to motor shaft and the tube-holder inserted in their sites.

Please note!
The rotor and the tube holders supplied with the device are the only ones usable with the machine. They were designed for the specific intended use.

2.3. Accessories Provided with the MEDIFUGE CGF

Please note!

The images of accessories may vary

2.3.1. Disposable Parts

Please note!

- The materials listed below have an expiry date indicated on the packaging. Always check this date before use.
- These materials have been sterilised by the manufacturer; therefore, on the packaging is marked the symbol of the sterilisation method.
- Always check integrity of packaging to make sure of their sterile condition

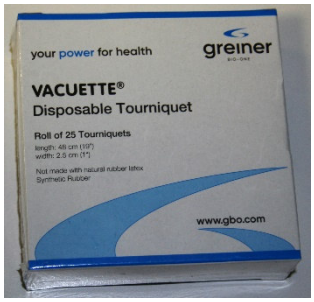
Do not dispose as solid urban waste, refer to a special waste collection centre

Disposable devices subject to expiry.

The expiry date is beside or under this symbol.

Sterilization Methods

STERILE EO	Device sterilized using Ethylene Oxide.
STERILE R	Device sterilized using irradiation.
STERILE A	Sterile medical devices processed using aseptic techniques.
STERILE	Sterilized with steam or dry heat.

No	Quantity	Code	Description	Image
1	50	**CGF K1 TMP01**	Swab soaked of disinfectant liquid to be used on the patient's blood sampling point.	
2	25	**CGF K1 LCE**	Latex free disposable tourniquets	
3	24	**CGF K1 AGO**	**SAFETY Blood Collection Set:** Needle diameter G21 for Vacuette system.	
4	30	**CGF K1 CER01**	**Haemostatic plasters** for after-sampling dressing.	
5	100	**PV 200R**	Silfradent glass vacuum tube without additives	

2.3.2. Sterilizable Containers

The containers in the following list have been chosen for their shape and size, in order to ensure maximum ergonomics during the process.

Instruments of the next table are supplied non-sterile; therefore, they must be cleaned and sterilised before use.

Can be steam sterilised up to 135°C

No	Quantity	Code	Description	Image
7	1	**CGF K1 SPF**	**Fibrin separator:** Stainless steel vessel used to separate the liquid part from the fibrin clot, in combination with the grid **CGF K1 GSP**	
9	1	**CGF K1 DFD**	**Dappen for fibrin:** Stainless steel container that facilitates the formation of the fibrin clot combined with the saline.	
10	1	**CGF K1 DPC**	**Dappen for platelet:** Cylindrical stainless steel container intended to contain red blood clots to prevent the oxidation.	
11	1	**CGF K1 DPT**	**Dappen for particulate:** stainless steel container intended to keep the fibrin clot cut into particles.	

2.3.3. Commercial Tools

Some components of this KITs are commercial devices already used in the medical field and they were chosen for their features and shape. They are listed in the following.

Tools provided in non-sterile condition, before use must be cleaned and sterilized.

Can be steam sterilised up to 135°C

No	Quantity	Code	Description	Image
12	1	**CGF K1 FPS**	**Blunt scissors**	
13	1	**CGF K1 PAD**	**Straight anatomic pliers**	
14	1	**CGF K1 SPD**	**Straight spatula**	
16	1	CGF K1 COM	**Compactor**	

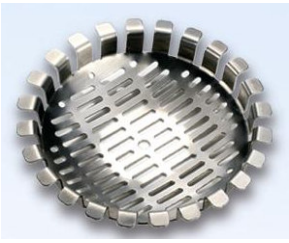
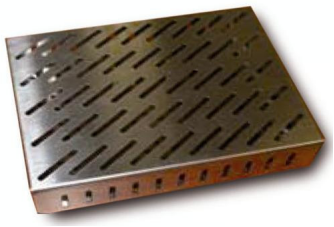
2.3.4. Instruments Specially Designed for the CGF

The components of the kits listed in this table, were specially designed to facilitate the operations necessary to prepare and use the CGF.

Tools provided in non-sterile condition, before use must be cleaned and sterilized.

Can be steam sterilised up to 135°C

No	Quantity	Code	Description	Image
15	1	**CGF K1 FMP**	**Membrane shaping pliers:** stainless steel tool designed to form membranes by pressing fibrin clot	

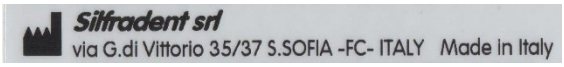
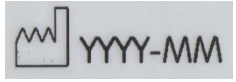
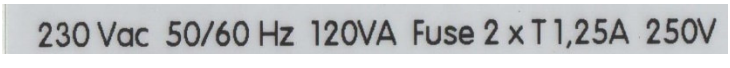
No	Quantity	Code	Description	Image
17	1	**CGF K1 PMS**	**Spatula applicator for membrane:** Stainless steel tool designed to ease handling fibrin clots or membranes	
6	1	**CGF K1 PPR**	**Stainless steel tube holder:** this base contains the tubes while preparing CGF	
8	1	**CGF K1 GSP**	**Grid for fibrin separator:** Stainless steel grid, designed to separate the liquid part from the fibrin clot in combination with the Dappen for fibrin separation **CGF K1 SPF**.	
18	1	**CGF K1 TRA**	**Tray for tools:** This is the container for tools to be sterilised.	

Caution!

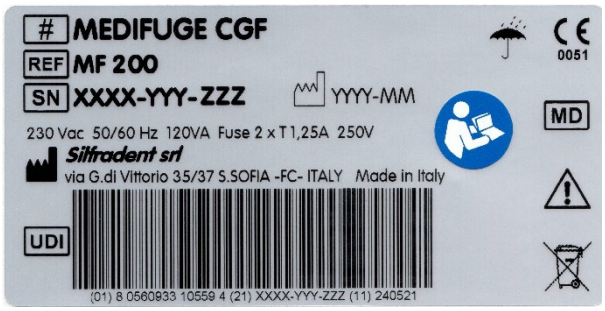
All the operations to obtain the fibrin clots must be carried out in an environment with a controlled temperature ranging between 20 and 25 °C.
The machines and materials used must be kept at room temperature.

2.4. Data label for MEDIFUGE CGF

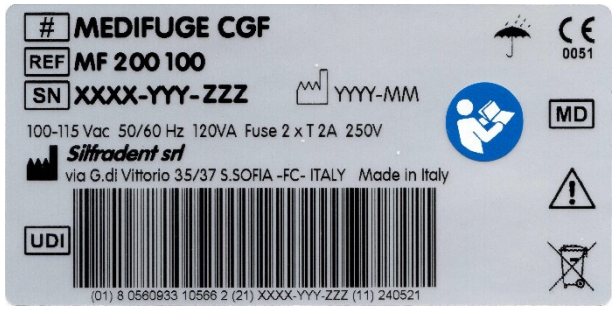
The data plate is in the back side of the centrifuge. It contains the data listed below

	Manufacturer's address on machine data label		
	Manufacturer's address on packaging		
	Model		Catalog number of 230 Vac powered device
	Catalog number of the centrifuge assembly and accessories		Catalog number of 100-115 Vac powered device
	Serial number		Date of manufacture
	Supply voltage, nominal power, and type of fuses for MF 200		

100-115 Vac 50/60 Hz 120VA Fuse 2 x T 2A 250V	Supply voltage, nominal power, and type of fuses for MF 200 100
CE 0051 — The equipment complies to CE requirements verified by competent body Nr 0051 IMQ S.p.a.	Refer to safety regulations and to Instruction Manual
Non smaltire come rifiuti solidi urbani ma servirsi dei centri di raccolta	MD — Medical Device
Keep dry	Follow instruction for use
UDI (01) 8 0560933 10559 4 (21) XXXX-YYY-ZZZ (11) 240521	UDI code of the device

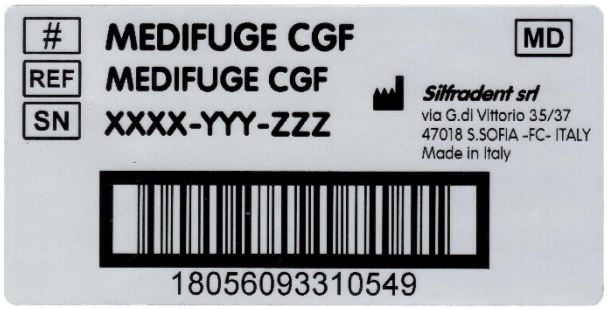


Data label for 230 Vac type

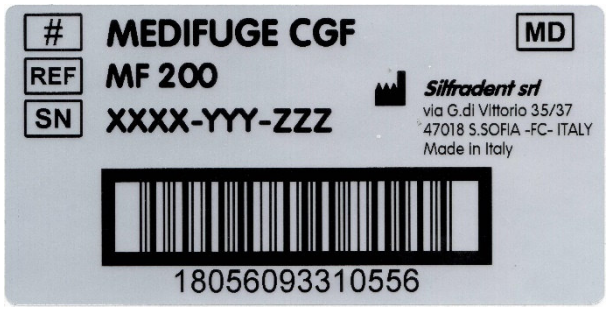


Data label for 100-115 Vac type

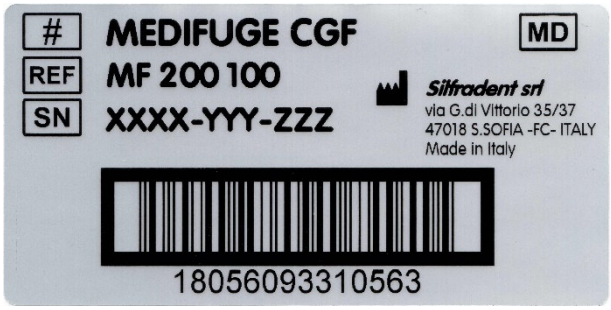
2.4.1. Data label of primary packaging



Packaging label of MEDIFUGE CGF



Packaging label of MF 200



Packaging label of MF 200 100

2.4.2. Rotor Label

Rotor label

REF MF2COPR	Code of rotor
LOT XXXX-YYY	Lot number
Silfradent S.SOFIA - FORLI' - ITALY	Manufacturer

2.5. Fuses

The devices is equipped with two internal protection fuses located on the power card which can only be replaced by authorized personnel and with two external fuses which can be accessed from the back by removing the power cord from connector on the equipment and opening the appropriate cover.

External fuses Glass fuses Dim. Ø 5 x 20mm accessible from the back of the console	**2 x T 1,25 AL 250V** for code **MF 200** **2 x T 2 A L 250V** for code **MF 200 100**
Internal fuses Glass fuses Dim. Ø 5 x 20mm Replaceable only by service personnel.	**1x T 6,3 A L 250V** **1x T 0,63 A L 250V**

3. INSTALLATION AND MAINTENANCE OF THE CENTRIFUGE

3.1. Installation and Use

3.1.1. Removing the Equipment from Packaging

Even though during the transport preparation and packing stages all precautions were taken in order to prevent any forwarding-related damage, it is important to check the integrity of the equipment, once taken out from its packing.

- Make sure the outside of the package has not been subjected to shock or deformation.
- Make sure that packaging of the accessories is not damaged.
- Open the packaging and place on a plane surface all the components and make sure they are intact.
- Check for the integrity of disposable devices packaging.

In case any damage is found, an appropriate letter of complaint should be immediately sent to the supplier.

The equipment packing material should be kept intact in case it is necessary to send the machine back for control or overhauling.

In case of return to the supplier always dispatch all components in order to allow the supplier to verify.

3.1.2. Preparing the Centrifuge

Make sure that in the vicinity of the point where the device is placed there are no objects (cables, hoses etc.) which could interfere with its stability.

Keep at least 15 cm free around the machine, this allows a good aeration of the machine and a safe operation.

Make sure that mains socket is easily accessible.

Make sure that machine is not close to excessive hot sources or exposed to direct sunrays, the chamber of rotor could warm up and damage the blood components inside.

An accurate positioning facilitates the good operation of the centrifuge.

Check that the power supply voltage indicated on the data label located on the back of the machine corresponds to that of the mains power.

Make sure that the mains switch in the back of the machine is turned off (position 0) before connecting the power cable to the mains socket.

Turn on the centrifuge, it will automatically open the lid.

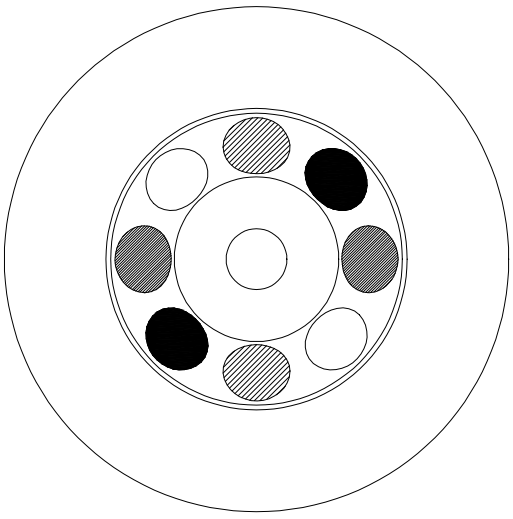


Fig. 3-1 rotor loading

Completely clean the centrifuge and sterilize the tube-holders before use.

Always check the rotor is secured to the motor shaft before starting the **MEDIFUGE CGF**.

Always insert the tubes in pairs and inside opposite holders to balance the rotor as shown in Fig. 3 1 this avoid vibrations that could damage the blood components and results in hazards.

Select the centrifugation cycle to be used as explained in the paragraph 4 and press the START button.

Wait for the end of cycle, which will be marked by a beep every minute, at the cycle end after rotor stopping will automatically open the lid.

Please note!

- The equipment should be used by qualified medical personnel only, trained in the techniques for preparation of fibrin.
- At the end of each cycle the automatically open lid, never try to unlock it during operation, could be hazardous for user or people nearby.
- When machine switches off and immediately switches on, the lid opens only when rotor is stopped, **never try to unlock it.**

Warning!

Never unlock lid during UV cycle, could be hazardous for sight.

CAUTION!

Since it is a device powered with a voltage of 230V or 100-115V you must apply all the necessary precautions**.**
Make sure that environment where machine is used comply to electric regulations in force.
Make sure that the mains socket is connected to the protective earth.

3.2. Maintenance and Cleaning

The drugs and chemicals products used in dental practice or clinic could cause damages to the surfaces of the machine.

As the extent of the damage is directly related to the reaction time, you should immediately clean the damaged part by using a soft cloth.

Residues of disinfectants on surfaces can be removed with detergent or neutral detergent.

Please note!
Never use abrasive detergents

CAUTION!

Pay attention that the liquid does not leak in the equipment, during cleaning or disinfection.
Never use flammable products to clean the device or its accessories.
Never carry out any maintenance or cleaning without removing the power cord.

3.2.1. Cleaning of the Centrifuge

The cleaning of the external surface of the centrifuge can be performed with a soft cloth moistened with water and / or mild detergent.

The enclosure is not waterproof, liquid may penetrate during cleaning.

Never use abrasive products on the outer surface of the machine or on the inner surface of the rotor chamber, could be scratched.

The Centrifuge is produced with plastic materials and stainless steel, it can be cleaned following the procedures used in the doctor's office or in the clinic where it is used.

3.2.2. Disinfecting the Centrifuge

The disinfection of the rotor chamber can be performed with alcohol solutions respecting the instructions of the manufacturer of the disinfectant. The process is explained in the instructions of each product.

On the market there are disinfectants with different concentrations, below we listed the maximum concentrations of the elements of the preparations tested and deemed acceptable.

Be careful not to exceed the levels indicated:

– Ethanol 96%	– =max 40g/100g desinf.
– Propanol	– =max 35g/100g desinf.
– Glutaraldehyde 25%	– =max 75mg/100g desinf.
– Ethyl hexanol	– =max 10mg/100g desinf.
– Formaldehyde solution	– =max 10mg/100g desinf.

Please note.

Silfradent S.r.l. accepts no responsibility for preparations that are different or in a greater concentration than the above indications.

3.2.3. Sterilization of the Centrifuge

The tubes-holders can be removed from the rotor and sterilized in autoclave; they are manufactured in Teflon®.

3.2.4. Cleaning of Accessories

All reusable components of the KITs have their own maintenance procedures; however, it is important to put emphasis on the importance of sterility of the materials used in the process of preparing and using the CGF. Immediately after use on the patient, reusable instruments must be disinfected by placing them in solutions with recognized effectiveness even on HIV, to reduce the risk of infection on personnel.

It is therefore important to avoid "dry out" the residues of the intervention on instruments to avoid compromising the effectiveness of disinfection and sterilization and to prevent corrosion on the instruments.

Many of the products used have corrosive effects on the patient, it would be appropriate to remove them as soon as possible by the tools.

Residues of disinfectants on surfaces can be removed with neutral cleaners.

The instruments that can be disassembled, or otherwise articulated, must be opened so that the disinfectant can go in contact with all their parts.

The products for pre-disinfection must be a combination of disinfectant and cleanser, in no case, the liquid must be for example saline solution because the contact with the tools could leads to corrosion or formation of rust.

After decontamination, instruments must be rinsed with running water and resistant residues can be removed using brushes with bristles of nylon or nylon-based sponges.

Avoid the abrasive cleaners and excessive manual pressure.

Pay close attention not to bump or drop tools.

Use non-corrosive detergents, preferably enzymatic nature.

Cleaning with ultrasounds is particularly effective in removing stubborn dirt, however, requires special attention because the tools placed close to one another and containers too loaded can cause scratches on the instruments.

After being dried the instruments must be immersed in a disinfectant solution different from that used immediately after patient use.

After that time necessary for disinfection is passed, should be rinsed with demineralized water, decontaminated, and dried immediately to avoid stain.

3.2.5. Sterilization of Accessories

The next phase is the packaging that has the purpose to maintain the sterility of the instruments until their use.

The packaging material most widely used are bags or rolls made with film of paper and plastic materials for autoclave,

Do not put too many tools in the bags, so as to leave enough space between them, and effect a smooth passage of the steam.

The sterilization system recommended is with the saturated steam autoclave. The recommended sterilization cycles with saturated steam autoclaves with fractionated vacuum are:

- 134°C, exposure time of 7 minutes and pressure 2.1 bars or
- 121°C, exposure time of 15 minutes and pressure 1.1 bars.

Exposure times refer to the machine in the regime of temperature and pressure with values already achieved.

It is to emphasize the importance of the drying cycle for wrapped instruments, because if it is not done properly could compromise the integrity of the instrument triggering corrosion, and altering the maintenance of sterility same because any remaining water, could give rise to the formation of bacteria, which would put the doctor in condition of transmit any infections to the patient without his knowledge.

Warning!
For the protection of personnel, all procedures for decontamination and cleaning of instruments must be performed using appropriate personal protective equipment.
Reusable instruments used for cleaning must be cleaned, disinfected and sterilized after use.

Please note:
Never use metal brushes or sponges as these will damage the instruments.

3.2.6. Maintenance of the Centrifuge

The lid of the rotor must be intact and remain locked with the latch when closed.

Before use, always check that rotor assembly is properly fixed to the motor shaft and does not cause vibration.

A slight vibration during the acceleration phase is normal.

Every two years, call technical service to check the electrical implant.

Caution!

Before use always check that the enclosure of the **MEDIFUGE CGF** is intact and they are no accessible electric parts
When enclosure is damaged contact customer service.
The power cord must not have incisions or damage that may result in a risk of electric shock

3.2.7. Technical Support

MEDIFUGE CGF technical support is provided by Silfradent S.r.l. In case of technical problems, the equipment must be either repaired by Silfradent 's technicians or sent back to the manufacturer.

In your request, please indicate the name and code of the device and its serial number, found on the data label on the back of the console (**fig. 3-2**).

When the **MEDIFUGE CGF** is returned to the Manufacturer always send all parts to allow full verification of the functionality.

On request of technical personnel Silfradent will provide all the technical information and spare parts required for repair the device

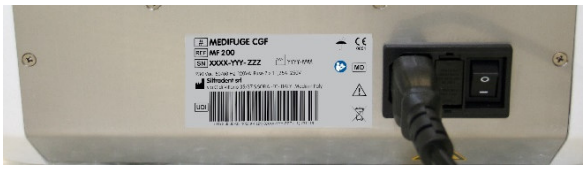


fig. 3-2 data label location

3.2.8. Removing the Rotor

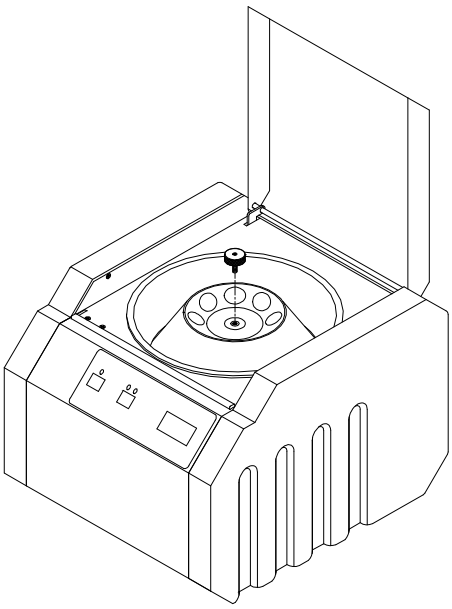


fig. 3-3 unscrew knob

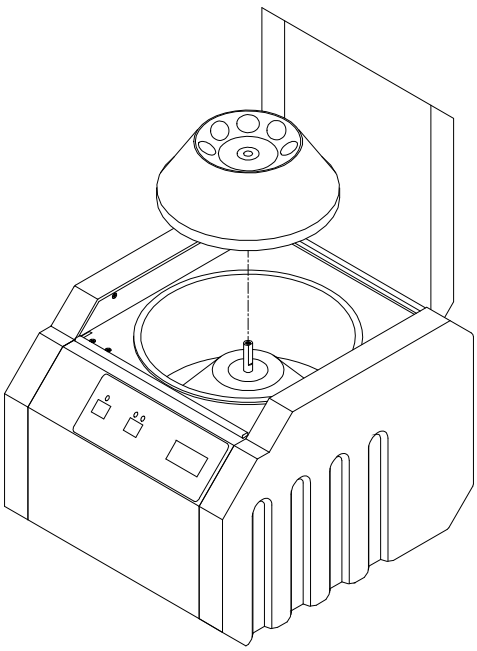


fig. 3-4 extract the rotor

To remove the rotor:

- Keep locked the rotor with a hand
- Unscrew the knob over the rotor (fig. 3-3).
- Remove the rotor by pulling it upwards (fig. 3-4).

To replace the rotor:

- Insert the rotor until it leans at the bottom.
- Lock the rotor.
- securely tighten the knob

3.2.9. Replacement of the UV Lamp

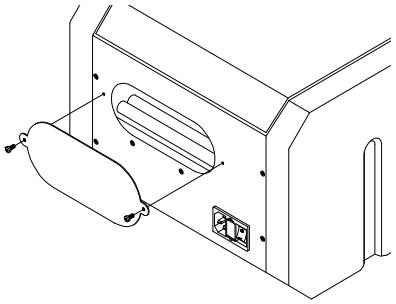


fig. 3-5 removal of cover of the lamp

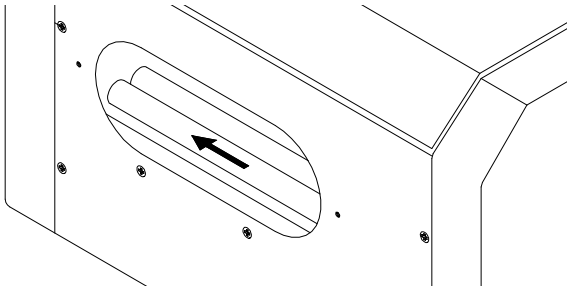


fig. 3-6 removal of the lamp

To replace the UV lamp

- Loosen the screws and remove the metal plate in the back of **MEDIFUGE CGF** as shown in fig. 3 5
- Pull the UV lamp in the direction indicated by the arrow in fig. 3 6
- Insert the new UV lamp and press so as to fully insert the base
- be careful not to dirty the glass of the lamp.
- Replace the cover and fasten the two screws.

3.2.10. Manual opening of the lid

Warning!
Always, before manually open the lid:

- switch off the machine
- detach power cord
- and wait for rotor stopped.

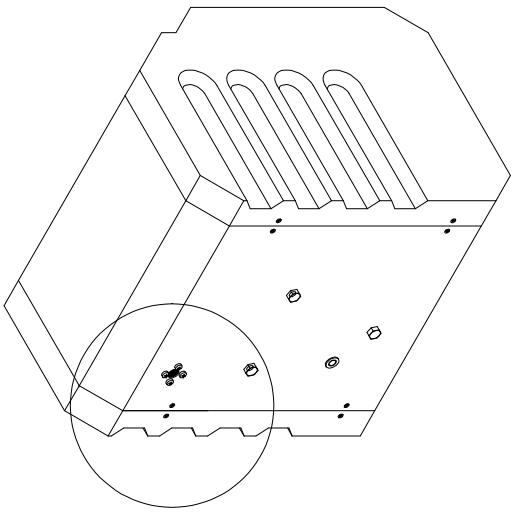


Fig. 3-7 bottom view

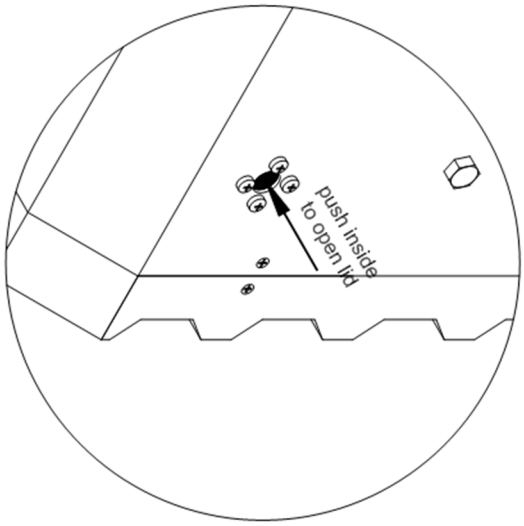


Fig. 3-8 opening hole

To open the lid, press with a pen inside the hole located under the machine in the front left side as shown in Fig. 3-8

4. OPERATION

4.1. Description of Control Panel

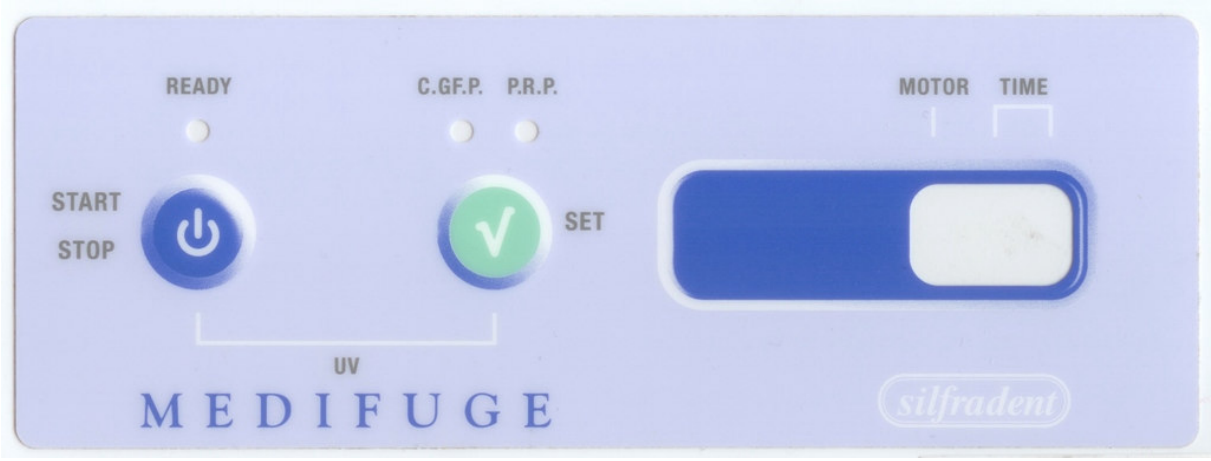


fig. 4-1 MEDIFUGE CGF keyboard

	**START /STOP**	When the LED "READY" is on starts the selected cycle. Pressed for about three seconds at the same time as "SET " button, it starts the UV cycle.
	**SET**	Selection of operating cycle Pressed for about three seconds at the same time as "START/STOP " button, it starts the UV cycle.

4.2. Setting and Viewing Operating Data

4.2.1. Description of Operation

When the centrifuge is on, automatically opens the lid and the CGFP cycle (fig. 4-2) is selected.
By pressing the SET button you can select the CGFP cycle (fig. 4-2) or the PRP cycle (fig. 4-3), The selected cycle is indicated by a LED, and when the machine is stopped, on the display.
The PRP cycle is divided in two centrifugation phases.
Two LEDs indicating the cycles are located over the SET button(see the figures below).

fig. 4-2 ciclo CGFP

fig. 4-3 ciclo PRP

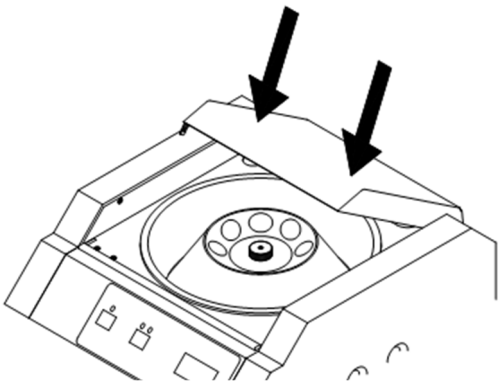


Fig. 4-4

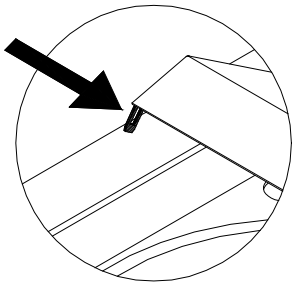


Fig. 4-5

The tab shown in Fig. 4-5 must always be vertical and not deformed. Any deformation could prevent the reopening of the lid.

Close the lid of the centrifuge accompanying it with both hands until the insertion of the latch which will be signalled by the click of a spring and by LED READY located over the START / STOP button (Fig. 4-6).

Never try to force the latch of the lid or block its functioning when the Centrifuge is rotating, could be hazardous for the operator or people nearby.

The machine is ready to start by pressing "START/STOP" (Fig. 4-6).

The display shows a figure rotating under the words "MOTOR" and the blinking indication "on".

When three minutes at the end of the cycle, at the end of each minute until the end of the cycle you will hear a beep and the display starts to show the remaining minutes.

At the end of the working cycle a long beep is emitted, and the lid opens automatically

Fig. 4-6

Fig. 4-7 tempo ciclo

Inside the centrifuge there is a UVC lamp used for a cycle of decontamination. This cycle starts by pressing at the same time the two buttons on the panel for 3 seconds after the lid has been closed. The display shows the figure of Fig. 4-8 where the first figure indicates the motor rotation state, the second is a U and indicates the UV cycle, the third number indicates the remaining minutes. At the end of every minute the machine emits a beep. The machine rotates at low speed with UVC lamp switched on. At the end of the cycle UV the lid opens automatically.

When, during a working or UV cycle the machine is turned off and then turned on, the lid will not open until the rotor is rotating, and the display shows, on the middle digit, a rotating character . In order to interrupt the cycle you have to press the STOP button and the lid will open only when rotor is stopped and the display shows, on the middle digit, a rotating character

Fig. 4-8

4.3. General Description of CGF Preparing Process

- Make sure that all the instruments and containers of the KIT are clean and sterile.
- Apply the tourniquet CGF K1 LCE; the stasis should not cause pain to the patient.

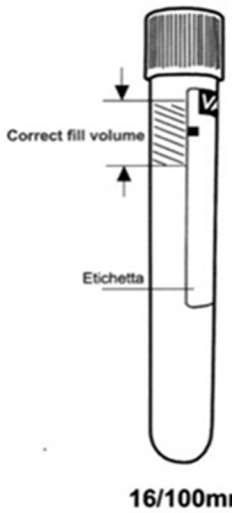


Fig. 4-9 filling level of tubes

- Carefully disinfect the puncture site with a disinfectant swab CGF K1 TMP01.
- Leave to dry after cleaning.
- Take the PV 200R tube and draw blood using the safety blood collection set CGF K1 AGO and wait for the blood to stop entering due to the negative pressure. The Fig. 4-9 shows the correct filling level of the tube.
- Insert the tubes in the **MEDIFUGE CGF** rotor (always in pairs opposite each other as shown **in** Fig. 3-1 within two minutes from the blood collection
- Start the machine.
- When **MEDIFUGE CGF** has completed its cycle and opens the lid, remove the tubes and place them in the tube holder CGF K1 PPR.
- Open a tube and gently pour the serum into the particulate Dappen dish CGF K1 DPC
- Place the Fibrin separator grid CGF K1 GSP onto the Fibrin separator CGF K1 SPF and pour the remaining content of the tube.
- Take the fibrin clot using the straight anatomic pliers CGF K1 PAD

- Cut out 2 mm in the red part using the scissors CGF K1 FPS leaving them on the grid CGF K1 GSP.
- Place the fibrin clot in the fibrin Dappen dish CGF K1 DFD
- add a vial of saline solution.

In this condition the fibrin may be used within one hour, although it is preferable to use it before.

- Take a portion of the red clot from the grid CGF K1 GSP and place it on the platelet Dappen dish CGF K1 DPC closing the cap to prevent oxidation.

Caution!
Do not shake the tube before inserting it in the centrifuge.

Please note:
We recommend preparing at least 4 tubes.

4.3.1. Prepare a Membrane with the CGF K1 FMP

With the fibrin clot obtained with the procedure described above it is possible prepare a membrane:

- take a fibrin clot and place it on the plate with the raised edge of the "Membranes shaping pliers" CGF K1 FMP
- close the CGF K1 FMP and press to obtain a membrane of the desired thickness.

The membrane prepared can be sutured and can remain exposed.

Use the membrane positioning spatula CGF K1 PMS to place the membrane on the implant site without any contamination risk.

To accelerate the healing, you can wet the wound with serum contained in the fibrin separator CGF K1 SPF using a brush.

4.4. Using CGF with the Homogenizer ROUND UP

To achieve good results in the repair/regeneration of bone tissue you can use the ROUND UP, the homogenizer that allows to obtain a homogeneous compound without dimensional or structural changes:

- with scissors CGF K1 FPS break the fibrin clot into particulates
- place the particulates into the Dappen for particulate CGF K1 DPC
- dry them with the Garza topper CGF K1 GAR.
- Add fragments of autologous or synthetic bone in the same amount as the fibrin
- add a small part of material left aside in the fibrin Dappen dish CGF K1 DFD.
- put everything in the stainless-steel inner container of the ROUND UP and close the cover securely.
- Insert the stainless-steel container in the Teflon outer one and close it securely.
- place the container in ROUND UP following the instructions of the machine.
- Set 7 seconds and start the machine.

The result is a homogeneous gel without structural or dimensional changes usable for filling.

5. TROUBLESHOOTING

Warning!
Only technicians authorized by Silfradent S.r.l. can access to the internal parts of the equipment.
For repairs or further information contact Silfradent S.r.l.

Warning!
Do not try to open the **MEDIFUGE CGF**, dangerous voltage is present inside the equipment
Before carrying out any maintenance or repair, always remove the power cord.

Please note.
The wiring diagrams and technical support information are available to the personnel responsible.
For repairs and additional information is required to contact Silfradent S.r.l.

5.1. Troubleshooting and solutions

PROBLEM	POSSIBLE CAUSE	SOLUTION
The display shows the inscription **OL** with a fix **O** and a blinking **L** until the motor runs then the lid opens.	Rotor blocked or overload.	Check that the rotor is mounted correctly. **If the problem persists, contact the service centre.**

PROBLEM	POSSIBLE CAUSE	SOLUTION
The display shows **E0**, and then when the rotor stops, the cover is opened.	The sensor of the lid has been damaged while the motor was running. Fast voltage dips at any speed	Wait that lid opens and/or the motor stops, then switch off/on the machine
The display shows **E1**, then when the rotor stops, the cover is opened.	Slow voltage dips (higher then 500 milliseconds) while the motor is running at a speed higher then 800 rpm. The power card could be damaged.	Wait that lid opens and/or the motor stops, then switch off/on the machine. **If the problem persists, contact the service centre.**
The display shows **E2**, then when the rotor stops, the cover is opened.	Possible problems on power card	Wait that lid opens and/or the motor stops, then switch off/on the machine. **If the problem persists, contact the service centre.**
The display shows **E3**, then when the rotor stops, the cover is opened.	Connection cable between cards interrupted or unplugged. Defective logic card.	Wait that lid opens and/or the motor stops, then switch off/on the machine. **If the problem persists, contact the service centre.**
The display shows **E4**	Connection cable between cards interrupted or unplugged. Defective power card.	Wait that lid opens and/or the motor stops, then switch off/on the machine. **If the problem persists, contact the service centre.**
The display shows **E5**	Rotor not correctly fitted on the motor shaft. Defective power card	Wait that lid opens and/or the motor stops. Check if the knob to fix rotor is correctly locked. Now switch off/on the machine. **If the problem persists, contact the service centre.**
The display shows **E6**, then when the rotor stops, the cover is not opened	Output Voltage below the expected value. Possible problem on power Pc Board	For to open the machine, wait about 20 seconds to stop the rotor, then switch off / on the machine from the main switch.
The display shows **E6** and the machine does not open	Probable problem on the power board.	To open the machine, wait for the rotor to stop (approx. 20 seconds) then turn the machine off and on again.
The display shows **E7**	The cover is open or was not opened before closing. You tried to start the machine with cover open.	Close the lid, wait for the light (**READY**) switches on, then press the **START** button. If the problem persists, switch off / on the machine from the main switch, open the lid for 1 second and then close it. Now press **START** button. **If the problem persists, contact the service centre.**
You hear a long Beep pressing the Start button.	You tried to restart the centrifuge while the rotor is moving.	Wait that the motor stops and the cover is open. Now close the lid, wait that the light READY is switched on and then press START button.

PROBLEM	POSSIBLE CAUSE	SOLUTION
Nothing is on.	Mains plug not inserted correctly into the socket.	Check the insertion in the socket.
	Fuses interrupted in the plug filter	Replace fuses with the same components, the correct values are given in paragraph 2.5 of this manual and on data label behind the machine next to the filter plug. If, once replaced the fuses, they are again interrupted, contact the service centre.
	Power cord damaged	Replace the cable
	Internal fuses broken	Contact the seller or manufacturer.
	Rear switch off.	Turn on the switch
	Defective Switch. Failure to electronic control Board.	Contact the service centre.
The engine does not run.	Faulty components on the card	Contact the service centre.
The lamp UVC doesn't switch on	Exhausted Lamp	Replace the UV lamp
	Failure of the lamp circuit	Contact the service centre.
	Lamp unplugged	Follow instruction of section 3.2.9

5.2. Safety Warning

- **Never use the MEDIFUGE CGF in a manner other than as specified in these instructions.**
- **Never operate the MEDIFUGE CGF without the rotor correctly mounted.**
- **Never fill the tubes while they are in the rotor.**
- **Never put hands in the rotor area unless the rotor is completely stopped.**
- **Never move the centrifuge while the rotor is spinning.**
- **Never use solvents or flammables near this or other electrical equipment.**
- **Always load the rotor symmetrically. Each tube should be counterbalanced by another tube of the same type and weight.**
- **Locate the centrifuge within easy access to an electrical outlet.**
- **Use only tubes recommended by Silfradent.**

Attention!

In the event of a serious accident, always notify Silfradent S.r.l. and the competent authority.

6. ELECTROMAGNETIC ENVIRONMENT

MEDIFUGE CGF comply with the requirements of electromagnetic immunity and emission of the standard EN 60601-1-2:2015 for a device falling in the Group 1 class B for use in a professional healthcare environment.

Silfradent S.r.l.
Via G. Di Vittorio n°35/37 47018 S. Sofia (FC), italy
Tel +39 0543 970684 Fax +39 0543 970770
WEB: www.silfradent.com
E-mail: info@silfradent.com