MACONNECT
USER MANUAL

NOT-MCNET-EN-V06 202510
ORIGINAL INSTRUCTIONS

macopharma
We support life

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FOREWORD

1. About this manual

This user manual is part of the documentation accompanying the Maconnect and the Blade cartridge. It is intended for the users (operators and administrators) of the Maconnect and the Blade cartridge.
These instructions for use have been validated for the Maconnect software version 49340V005.
This user manual includes all the information related to the use of the Maconnect and the Blade cartridge. It details all the necessary steps to reach the intended use. It also includes information about the safety and performance of the device which the user should be aware of throughout its expected lifetime.
This user manual contains all the technical characteristics of the Maconnect and the Blade cartridge.
To facilitate its reading, this manual has been written in such a way as to reflect the life cycle of the device from its acquisition to its disposal:

- General overview
- Installation
- Use
- Settings
- Cleaning
- Maintenance
- End of life
- Error messages
- Technical characteristics

It is the responsibility of the owner of the equipment to keep this user manual for the entire expected lifetime of the device from its acquisition to its disposal.
If you have any questions regarding this manual, please contact your local Maco Pharma representative.

- **Legal notices of third-party software**

Maconnect uses a number of third-party software tools, libraries and content.
The “Software licences” section on the Maconnect attributes the authors of those works, the licences under which they are available, and indicates the terms of each license. Go to the chapter “Setting menu – Operator “ Software licenses, to have access to licenses of the software modules used.

- **Trademarks mentioned**

The applicable trademarks are available on the Maconnect device.

2. Safety

a) General safety

- **General information**

These instructions are a guide to the operator, who must be a trained professional with sufficient knowledge to handle the equipment and the welding process safely. To be trained, please contact your local Maco Pharma representative.

Maco Pharma recommends to fully read all documents provided before use.
It is the user's responsibility to follow all procedures outlined in these instructions for use.

Any use of the equipment not following the instructions for use detailed hereafter may affect the quality of the welding process and the safety of the users.

The yearly preventive maintenance can only be done by trained and certified personal to this level of operations. The curative maintenance can only be done by a qualified and certified technician.
In case of failure that requires a repair, please contact your local Maco Pharma service representative.

When the condition of the safe usage of the device is compromised, the Maconnect device must be put out of service and preserved against an accidental use.

Safe use is not guaranteed in the following conditions:

- The Maconnect is obviously damaged.
- After a storage under other storage conditions than the ones specified in chapter "INSTALLATION", paragraph "1.Transport, storage et unpacking".
- After serious damage undergone during transport.

• User training

The sterile connection device should only be used by technically trained and qualified personnel. Qualified personnel are persons who, because of their education, experience and training as well as their knowledge of relevant standards, specifications, accident-prevention regulations and operating conditions, have been authorized by persons responsible to execute the necessary activities, and can recognize and avoid possible dangers in such activities. The device is intended to be used only by professionals trained and working in the processing of blood components.
The training can be performed by your device administrator or by a Maco Pharma trained representative. Preferably, the training will be done on-site with a dedicated training module. In case of exceptional circumstances, a remote training will be organized.
To be trained, please contact your sales' representative.

The operator is the user who works daily with the machine and processes tubes. He can only make very few settings on the machine and usually has no authorization to change settings via the device menu. Please refer to the corresponding chapter for details of what the operator can adjust.

The administrator is the person in charge of the device maintenance achievable by the user at the facility. When needed this person can make adjustments to the machine. He is also responsible for the disassembly, cleaning and reassembly of the tube holder if contamination has occurred. Please refer to the corresponding chapter for details of the administrator duties and responsibilities.

• Warnings

	The manufacturer assumes no liability for defects and damage caused by improper handling and improper use of the product. Improper handling is deemed to have occurred if the operating instructions, in particular the start-up instructions and the welding instructions, are not observed.
	Warning of hot surface Inside the used blades container, the blades can be hot and cause burns and/or injury. The blades must first be cooled before being disposed of into another container.
	Connect only tubes according to specifications listed in these instructions for use.
	While a process is running (initialization, welding or reset), the tube holder is mechanically locked. Do not try to open it. If too much force is applied, the machine could be permanently damaged.
	While a process is running (initialization, weld or reset), the blade cartridge drawer is mechanically locked. Do not try to open it. If too much force is applied, the machine could be permanently damaged.
	Do not exert excessive pressure on the tube holder handle while closing or you may permanently damage it.
	If the tubes have been cleaned before welding, wait 20 seconds to avoid the release of vapours.
	Do not place sharp objects or metal on the device or in the open tube holder. This will lead to irreversible damage.
	Only official accessories from the manufacturer must be used.
	The blades are for single use only and must be disposed properly after use. The blade cartridge must be disposed properly after the use of the 50 blades inside.
	The blade cartridge and the blades must not be used more than once. Blades that have already been used no longer meet the requirements for high-quality welding.
	The blades must not be touched under any circumstances.
	The machine especially the tube holder must be cleaned and decontaminated if exposed to blood.
	To avoid the risk of electric shock, this device may only be connected to mains supply with a protective earth conductor.

	The use of accessories and cables other than those specified or supplied by Maco Pharma may result in increased electromagnetic emissions or decreased immunity of this unit and cause undesired operation.
	Use of RF portable communications devices (including devices such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the MACONNECT and its accessories (specified by Maco Pharma) should be avoided. Otherwise, the performance of these devices could be altered.
	Do not use the MACONNECT in an environment rich in oxygen, or in an explosive or inflammable atmosphere.
	Do not place more than 4kg on each tray.
	Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.
	In case a welding cycle starts without tubes in front of each other, let the welding end, remove the unconnected tube and seal it at least 5 cm from the cutting location.

• Cautions

	The user is advised to wear protective gloves when working with the machine.
	Do not throw away the packaging of the machine. This can be reused for safe transport later.
	Place the unit in a horizontal plane. The angle to the horizontal plane must be less than 5°.
	Only tubes that are dried on the surface may be welded.
	The welding of PVC leads to the release of substances. At least a suitable laboratory air refreshing must be provided and additionally a filtration device can be connected to the machine.
	Never use the device inside a place without ventilation.
	Only a shielded USB cable with a length of less than 3m may be connected to the device.

	Do not connect any self powered devices to the USB Type A connector.
	The device must be installed in such a way that it is not difficult to disconnect it from the mains supply.
	Using this device next to or stacked with other devices should be avoided because this may cause a malfunction. If such use is necessary, it is necessary to control this unit and other devices and verify normal operation.
	After every connection process, each tube connection must be visually checked by the operator.

b) Regulatory and normative conformity

Maconnect is an active medical device which, when used with its Blade cartridge, is intended to generate up to six connections between internally sterile and closed PVC tubes commonly used in blood processing applications. Thus, Maconnect and its Blade cartridge are both Class I medical device according to the European medical device regulation (Regulation 2017/745/EU), and as such they carry a CE mark as proof of conformity.

The legal manufacturer, responsible for placing Maconnect and the Blade cartridge on the market, is:

MACO PHARMA
Rue Lorthiois,
59420 Mouvaux,
FRANCE

Maconnect, as an electrical and electronic equipment, complies with the directive related to the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2011/65/EU + Directive 2015/863/EU), and directive on waste electrical and electronic equipment (WEEE 2012/19/EU). It shall not be thrown in together with household wastes. You must respect the disposal cycle following the Directive to recycle it.

Maconnect, embedding a radio module, complies with the provisions of the Radio Equipment Directive (RED 2014/53/EU).

Maconnect complies with part 15 of the FCC Rules.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This portable equipment with it's antenna complies with FCC's and with RSS102's radiation exposure limits set forth for an uncontrolled environment. To maintain compliance, follow the instructions below :
1. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. Avoid direct contact to the antenna, or keep contact to a minimum while using this equipment.

This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions:
1. This device may not cause interference, and
2. This device must accept any interference, including interference that may cause undesired operation of the device.
Maconnect is compliant with the following standards:

- IEC 60601-1:2005+AMD1 2012+AMD2 2020: Medical electrical equipment, General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014+AMD1 2020: Electromedical devices, Collateral Standards: Electromagnetic Compatibility – Requirements and Tests
- EN ISO 3826-1:2019 + AMD1 2023: Plastics collapsible containers for human blood and blood components. Annex B.5 Test for sterile connection of tubing.

Requirements of the IEC 60601-1-2:2014		
Requirements and Descriptions	**Conditions**	**Compliance**
RF Emissions CISPR11	Groupe 1and 2 / Class A	Compliant
Harmonic emissions IEC 61000-3-2	Note: The device is only used in professional healthcare facility	Not applicable
Voltage fluctuations/flicker emissions IEC 61000-3-3	Note: The device is only used in professional healthcare facility	Not applicable
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV au contact ±2 kV, ± 4kV, ±8 kV, ±15 kV in air	Compliant
Radiated RF IEC 61000-4-3	3V/m de 80 MHz à 2,7 GHz 27V/m à 385MHz 28V/m à 450MHz. 9V/m à 710, 745, 780 MHz. 28V/m à 810, 870, 930 MHz 28V/m à 1720, 1845, 1970 MHz 28V/m à 2450MHz 9V/m pour 5240, 5500, 5785MHz	Compliant
Electrical fast transient / burst IEC 61000-4-4	± 2 kV / 100kHz for the power supply lines ± 1 kV / 100kHz for the XLR cable	Compliant
Surge IEC 61000-4-5	± 0.5 kV ± 1 kV differential mode ± 0.5 kV ± 1 kV ± 2 kV common mode	Compliant
Conducted RF IEC 61000-4-6	3 Veff from 150 kHz to 80 MHz 6 Veff from 150 kHz to 80 MHz 3 Veff at 12, 25, 40 MHz 6 Veff from 6,765 MHz to 6,795 MHz 6 Veff from 13,553 MHz to 13,567 MHz 6 Veff from 26,957 MHz to 27,283 MHz 6 Veff from 40,66 MHz to 40,70 MHz	Compliant
Magnetic Field IEC 61000-4-8	Note: The device does not contain magnetically sensitive components or circuitry	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 610000-4-11	Dips of 0 % during 0,5 cycle Dips of 0 % during 1 cycle Dips of 70 % during 25 cycles Dips of 0 % during 250 cycles	Compliant

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Chatswood NSW 2067

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11 Old Jewry, 8th Floor
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Уповноважений представник в Україні:
ТОВ «ДОКСЕРВІС», код ЄДРПОУ: 39676958
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Тел.: +38(044) 337-02-37
Електронна пошта: docservicellc@gmail.com

c) Pictograms description

	General warning sign. Important indication
	Warning of hot surface
	Warning of biohazardous material
	Manufacturer's Address
	Production Date (Date format : YY-MM-DD)
	Read the Instructions For Use before using this equipment
	We advise you to read the Instructions For Use for information on the device transport
	Information regarding temperature limits
	Information regarding humidity limits
	Information regarding pressure limits
	Welder soft power switch
CE	European conformity marking
UK CA	United Kingdom Conformity assessed marking
	Ukrainian Conformity Mark
CH REP	Swiss Authorized Representative
	Do not throw in together with household wastes. This equipment must be recycled
IP2x	Protection against foreign bodies
	Do not re-use
MD	Medical device

SN	Serial number
REF	Part number or reference number
Rx Only	Federal law in the United States of America limits this device to sales on the part of or on the order of professionals authorized by the laws of the state in which the professional practices for the use of or for ordering the use of the device.
	ROHS Compliance
	Non-ionizing electromagnetic radiation
	Fragile Handle with care
	Keep dry
	Do not sit on an unsuitable surface

3. Warranty, Limitation of Liability and Proprietary Rights

a) Warranty

• Warranty conditions

Maco Pharma guarantees the proper functioning of this equipment during the whole warranty period.

Should the equipment present a defect during the warranty period, it will be repaired free of charge by our technical department.

The equipment should be returned to your Maco Pharma local service representative. Equipment returns must be made only in the original packaging or in accordance with safe packaging. No liability is assumed for transport damage by Maco Pharma.

• Warranty execution

Under this warranty, Maco Pharma will provide the free replacement of all faulty parts. This warranty also covers Maco Pharma incurred labour costs and any shipping charges to return the equipment back to the customer.

• Warranty period

This warranty is valid for one year from the date of the installation of the equipment on site. Repairing or replacing parts of the equipment during the warranty period does not extend the duration of the warranty.

• Exclusions

The warranty does not apply if the damages or defects have been caused by the following:

- Any inappropriate or abnormal use or inappropriate storage, drop or excessive shocks;
- Any repair attempt, device opening, or modification not executed by our local Maco Pharma service representative or any trained and certified personal;
- Any connection to non-approved devices;
- Any inappropriate packaging used when shipping the equipment;
- Any accident or natural disaster including, but not limited to, lightning, water, fire, public disorders;
- Any damage caused by malfunctions of foreign origin and notably a voltage different from the one provided for by our technical features.

• Miscellaneous

This warranty applies to all accessories sold together with the equipment.

b) Limitation of Liability

• Maco Pharma's liability

Maco Pharma is not liable if the user does not follow the recommendations set forth in this user manual or in any other documentation related to the Maconnect and its Blade cartridge.

In no event shall Maco Pharma be liable for any loss of product, business interruption, loss of information, loss of time, financial or property loss, or any other indirect or consequential damages arising out of any case of use not in accordance with this user manual or in any other documentation related to the Maconnect and its Blade cartridge, or in any case of electric, electronic and/or mechanical failures applicable to such active devices.

Maco Pharma shall only be liable in case of gross negligence, deliberate concealment of defects, and in the cases specified by law.

• Customer's Liability

The customer shall be liable for all damages caused by Maconnect and its Blade cartridge to persons or property from the time of its acquisition, its installation or upon transfer of risks.

Similarly, the customer shall be liable for all risks of damage, loss, theft, modification, alteration, misuse, partial or total destruction of the Maconnect, its Blade cartridge and its packaging, however caused, even if arising from a fortuitous event or force majeure, from the time of its acquisition, its installation or upon transfer of risks.

The customer shall be liable for damages or defects caused directly by its action, inaction, or omission in the event of:

- Improper, abnormal use, use not in accordance with the user manual of the equipment;
- improper installation, operation, maintenance, repair ;
- willful misconduct;
- gross negligence;
- negligent use, storage, handling, or other negligence.

• Force Majeure

Except the obligation of the payment of a sum of money, the liability of Maco Pharma or of the Customer may be disregarded if the suspension or non-performance by Maco Pharma or the customer of the obligations for which it is responsible is the result of an event constituting force majeure in accordance with Article 1218 of the French Civil Code.

Force majeure may include, but is not limited to, man-made or natural disasters, earthquakes, fires, riots, floods, shortages of materials, strikes, delays in transportation or the inability to obtain labor or materials through normal channels.

c) Proprietary rights

No part of this document may be reproduced or transmitted in any form or by any means – electronic format, paper format or photocopying - unless expressly authorized by Maco Pharma.

Maconnect is a registered trademark owned by Maco Pharma.

The software embedded in the memory of the Maconnect and the related documentation are entrusted to the user for use with the equipment only by license.

The software is protected by copyrights, all rights reserved. The embedded software can only run on one device at a time and may only be used on the hardware into which it is embedded. This software may not be separated from the hardware provided by Maco Pharma, or distributed, reproduced, translated, disassembled, decompiled, analyzed, adapted, modified, incorporated, or combined with any other software, except as permitted by law.

GENERAL OVERVIEW

1. Description of the Maconnect

MACONNECT DEVICE

The Maconnect and its Blade cartridge, used together, are intended to generate up to six connections between internally sterile and closed PVC tubes commonly used in blood processing applications.

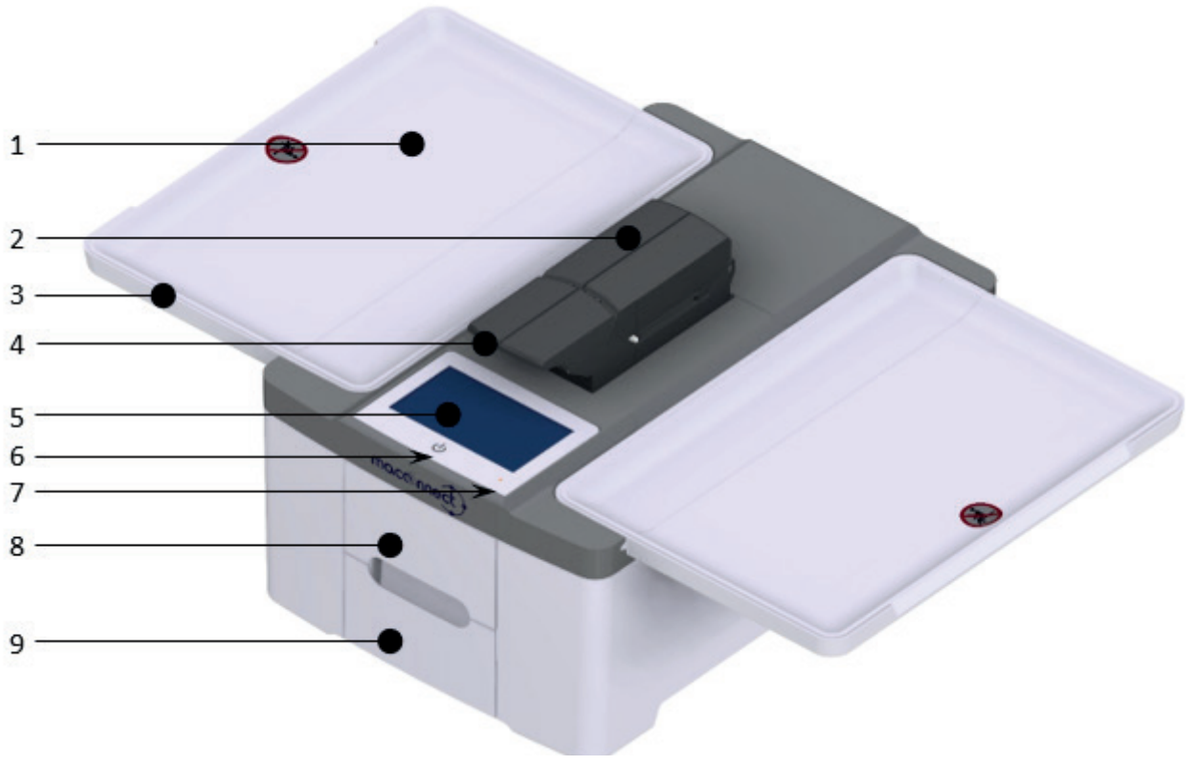

Figure 1. Front view Maconnect

Item	Designation
1	Blood bag tray
2	Tube holder
3	Tray support
4	Tube holder handle
5	Touchscreen colour display
6	Soft power switch
7	Indication LED
8	Blade cartridge drawer
9	Used blades container

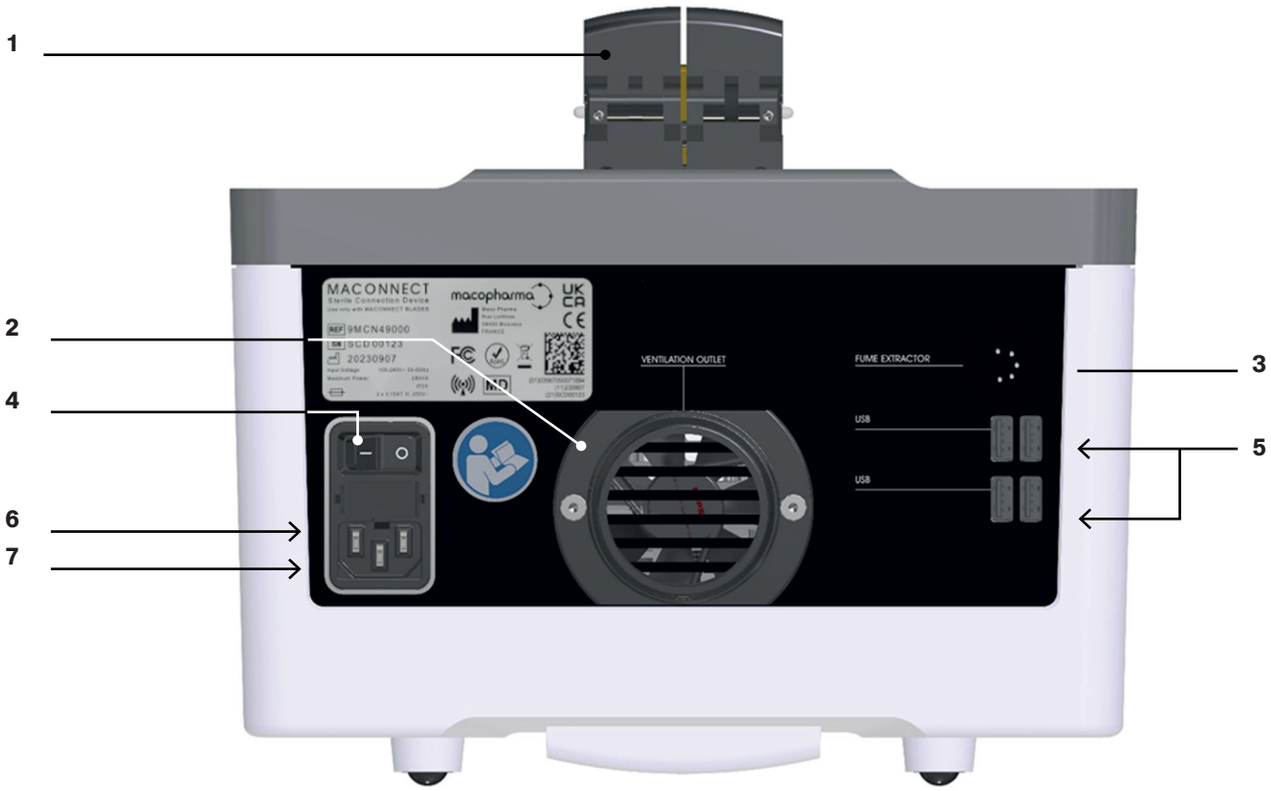

Figure 2. Rear view Maconnect

Item	Designation
1	Tube holder
2	External air filter system outlet
3	XLR 5-pole connector for an external air filter system
4	Mains power supply switch
5	4 x USB Type A accessories connector
6	2 x 3.15AT Fuse
7	Connector plug for mains power cord

⚠	Do not apply any voltage to the XLR connector for the external air filter system which exceeds 24VDC / 2A.
⚠	Do not connect any self-powered devices to the USB Type A connector.

The Maconnect sterile connection device is used for the sterile connection of PVC tubing. For this purpose, up to six tubings on the left side and up to six tubings on the right side are inserted, the tube holder is closed with the handle and a run is initiated with the start slider. During the cycle, the tubes are cut, melted, vertically aligned and joined together. After a short cooling phase, which improves the quality of the welded joint(s), the tube holder can be opened and the interconnected tubes and the waste tubes are removed. After removing all tubes, the device is reset and the used blade is ejected into the used blades container.

UNINTERRUPTED POWER SUPPLY

In order to guarantee functional safety, an energy storage device (consisting of capacitors) has been integrated into the device to safely complete the welding. In case of a power outage during a connection, the process will be safely completed because there is an uninterrupted power supply (UPS) in the device.

BLADE CARTRIDGE

The Blade cartridge contains a total of 50 single-use blades. With the help of the level indicator located on the blade cartridge itself, the quantity of the remaining blades can be estimated. The blade cartridge is delivered in a cardboard package with a closed blister package inside, which must only be opened just before use.

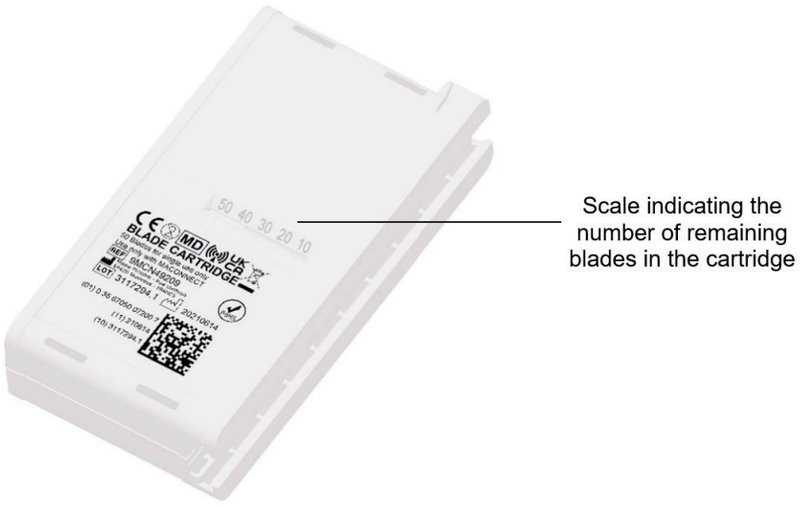

Figure 3. Unpacked blade cartridge with 50 blades inside

⚠	The packaging of the Blade cartridge must only be opened just before use.
⚠	For safety reasons, use gloves when inserting the Blade cartridge into the Maconnect device.
⚠	The blades must not be touched under any circumstances.
⚠	Blades are for single use only.

EXTERNAL AIR EXTRACTOR SYSTEM CONNECTOR

The Maconnect device includes an external air extractor system connector. The smoke that is generated during welding can be extracted with the help of this connection. Make sure that the air flow does not exceed 5 litres per minute. If the air flow is too high, the welding quality may be negatively affected.

	Make sure that the air flow of your external air filter system connected to the device does not exceed 20m3/ hr or 5 L/min.
	The room airflow renewal, where the device is used, must be well dimensioned to extract chemicals generated by tubes connections during the usage time and for a maximum production rate

The XLR connector is implemented to be used with an air extractor system.

- Do not apply any voltage to the XLR connector for the external air filter system which exceeds 24VDC / 2A.
- The cable connected to the XLR connector shall be protected with a 2A fuse type T2AL.

TUBING SPECIFICATIONS

The machine has been validated for tubes with the following dimensions:

Tube's specifications:	PVC
	Inner diameter within: 2.9mm < ID < 3.4mm Outer diameter within: 3.9mm < OD < 4.5mm
Tube's sterilization:	Steam sterilized, Ethylene Oxide sterilized (EO) or irradiation sterilized (BETA)

	The device can connect tubes with a minimal length of 4.5cm (1.8") allowing to have 1.5 cm (0.6") waste tubes after the welding.
	If the dimension of your tubes differs from the specified dimension above and in chapter Technical caracteristics, clarify the use with the manufacturer.
	The machine shall be used for PVC blood transfusion tube systems only.
	The inserted tubes must be dry on the outside.

2. DELIVERED EQUIPMENT AND ACCESSORIES

PACKAGING LIST

❑ Maconnect, Sterile Connection Device ..... ref. : 9MCN49000

Complete package including:

✓ 1 x Maconnect, Sterile Connection Device
✓ 2 x Large tray supports ..... ref. : 9MCNE49232
✓ 2 x Small tray supports ..... ref. : 9MCNE49229
✓ 2 x Blood bag trays ..... ref. : 9MCNE49230
✓ 1 x Torque Screwdriver torx 4,2Nm ..... ref. : 9MCNHOF21175042
✓ 1 x 4mm Hexagon Screwdriver bit .....ref. : 9MCN253201
✓ 1 x Cardboard packaging ..... ref. : 9MCN49289
✓ 1 x IFU, Instruction for use including CE Declaration of Conformity..... ref. : 9MCNIFUEN

Power supply cord list:

- ❑ Power supply cord (South Africa) ..... ref. : 9H05-288
- ❑ Power supply cord (Argentina) ..... ref. : 9H05-289
- ❑ Power supply cord (Australia) ..... ref. : 9H05-290
- ❑ Power supply cord (Brazil) ..... ref. : 9H05-291
- ❑ Power supply cord (China) ..... ref. : 9H05-292
- ❑ Power supply cord (Denmark) ..... ref. : 9H05-293
- ❑ Power supply cord (Europe) ..... ref. : 9H05-113
- ❑ Power supply cord (Israel) ..... ref. : 9H05-294
- ❑ Power supply cord (United Kingdom) ..... ref. : 9CABLEUK
- ❑ Power supply cord (Switzerland) ..... ref. : 9H05-295
- ❑ Power supply cord (USA, Canada) ..... ref. : 9H05-296
- ❑ Power supply cord (Italia) ..... ref. : 9H05-044
- ❑ Power supply cord (India) ..... ref. : 9H05-298
- ❑ Power supply cord (Thailand) ..... ref. : 9H05-299

If, despite all our best efforts, a component is missing in your package, please contact your local sales representative. We shall meet your requirements in the shortest time possible.

ACCESSORIES

- ❑ Blade Cartridge, 50 blades for single use only ..... ref. : 9MCN49209

3. Intended use

The Maconnect and its Blade cartridge, used together, are intended to generate up to six connections between internally sterile and closed PVC tubes commonly used in blood processing applications.

4. Indications

There is no specific medical indication related to the Maconnect and its Blade cartridge.
There is no specific patient target group related to the Maconnect and its Blade cartridge.
The Maconnect and its Blade cartridge must be used by authorized personnel who have received specific training for its use.

5. Contraindications

There are no known contraindications associated with the use of the Maconnect and its Blade cartridge.

6. Undesirable side effects

There are no known undesirable side effects associated with the use of the Maconnect and its Blade cartridge.

7. Performance and expected clinical benefits

The performance features of the Maconnect are related to the intended functional characteristics. The device generates up to six connections between internally sterile and closed PVC tubes commonly used in blood processing applications.

There is no direct clinical benefit claimed from the use of the Maconnect and its Blade cartridge.

8. Place of use

The Maconnect and its Blade cartridge are intended to be used in blood centers and hospitals.

INSTALLATION

1. Transport, storage and unpacking

1.1. Transport

The Maconnect is shipped in a carboard box (dimensions: L x W x H = 59cm x 39cm x 36.5cm (23” x 15” x 14”)).

The Maconnect must be transported under the following conditions:

- In its cardboard box
- Relative humidity: ..... 20 to 80 % (without condensation)
- Temperature: .....-10°C (14°F) to +60°C (140°F)
- Pressure: .....500 to 1060 hPa

1.2. Storage

Before use and in case of storage, the Maconnect must be stored in its transport cardboard box.
The storage temperature shall remain between - 10°C and + 60°C and the relative humidity shall remain between 20 % and 80 %.
The transport packaging must be protected from any environmental risks (water, gas, dust, shock, etc.).

1.3. Unpacking

	On receipt of the Maconnect, first check the external integrity of the box and then ensure all elements listed in the delivery note delivered with the Maconnect are present. If any part is missing or is damaged, please contact your local Maco Pharma service representative. We advise you to keep the packaging in case the device is shipped to a technical center for repair.

1.4. Moving Maconnect

	The Maconnect’s weight is 13.5kg (28.7lb) without tray support and 14.4kg (30.9lb) with tray supports. The sterile connection device has a grip recess on the lower left and lower right sides to carry the device. The Maconnect must be handled with two hands as shown on the picture and on both sides.
	The sterile connection device has a grip recess on the lower left and lower right sides to carry the device. The Maconnect must be handled with two hands as shown on the picture and on both sides.

Note: Maco Pharma recommends to strictly follow all applicable rules related to handling heavy load for workers

Figure 4. How the device can be carried

2. On-site preparation

2.1. Place of use

⚠	The room airflow renewal, where the device is used, must be well dimensioned to extract chemicals generated by tubes connections during the usage time and for a maximum production rate of 50 cycles per hour.

2.2. Working area

⚠	Ensure that the unit is placed in a safe horizontal plane. The angle to the horizontal plane must be less than 5°.

2.3. Power supply

⚠	To avoid the risk of electric shock, this device may only be connected to a mains supply with an earth grounding.
⚠	The device must be installed in such a way that it is not difficult to disconnect it from the mains supply.

Item	Description
Maconnect 110-240 V AC, 50/60 Hz. AC power supply:	1 wall socket (110-240 V, + earth ground)

2.4. Cyber security

Maconnect has been designed with cybersecurity in mind. Contact your local Sales representative for the SBOM (Software Bill of Materials) or other questions regarding cybersecurity on the Maconnect device.

⚠	Don’t insert a USB key from an unknow user into the device.

2.5. TRAYS SUPPORT INSTALLATION

The device is delivered with 2 small trays already installed on the right and the left side of the device. To replace the 2 small trays, you need to slide off the trays from the device and replace them by the 2 large blood bag trays.

⚠	Do not place anything weighing more than 4kg on each tray.

Figure 5. Small trays support removal

Figure 6. Large trays support insertion

3. PUTTING INTO SERVICE

⚠	Please ensure that your device is installed and verified by a Maco Pharma trained and certified personal before using it.


maconnect

1. START-UP OF THE STERILE CONNECTION DEVICE

Turn on the mains power supply switch. The indicator LED turns orange and indicates that the device is under voltage.

Press the soft power switch ⏻ to start the device. Wait until the initialization screen appears. The LED remains orange as long as the equipment is under voltage.

⚠	To avoid the risk of electric shock, this device may only be connected to a mains supply with an earth grounding.
⚠	The device must be installed in such a way that it is not difficult to disconnect it from the mains supply.

2. INITIALIZATION PROCESS

Before the initialization process, the device invites you to perform 2 steps. First, remove and empty the used blade container (Figure 7). Secondly remove the blade cartridge (Figure 8). The initialization screen appears (Figure 9).

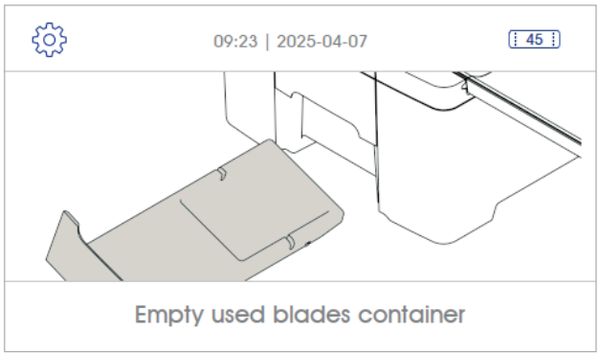

Figure 7. Remove and empty the used blade container

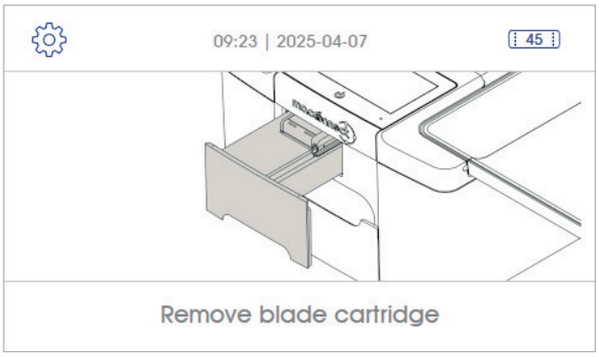

Figure 8. Remove the blade cartridge

Slide to the right or press the button to perform the initialization. Wait until the device asks to insert the tubes. Notice: The initialization must be performed before starting the welding process.

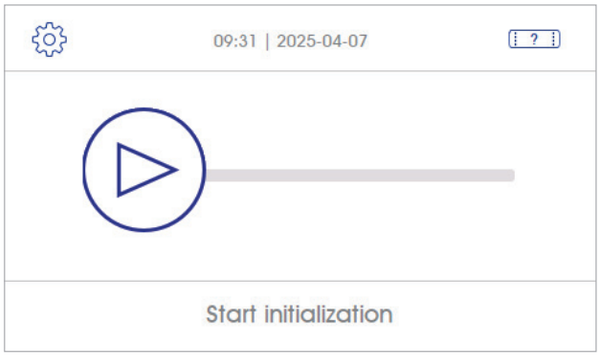

Figure 9. Slider initialization screen

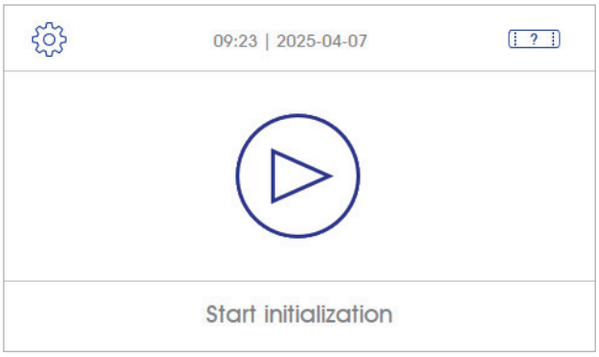

Figure 10. Button initialization screen

3. BLADE CARTRIDGE CONTROL

Blade cartridge transportation can cause misalignment of the blades inside the cartridge. Before inserting the blade cartridge inside the blade cartridge drawer, check the good alignment of the blades inside the cartridge as showed in figures 11 to 14.

In case of a misalignment of the blade cartridge like in figures 11 and 13, carefully tap the blade cartridge with the front view on a clean surface. This will allow the blade to move into the correct position.

Wrong alignment of the blades inside the cartridge

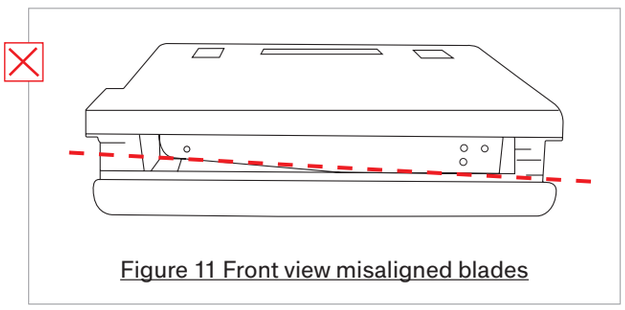

Figure 11 Front view misaligned blades

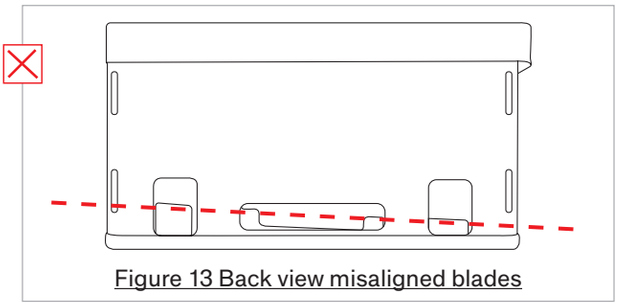

Figure 13 Back view misaligned blades

Correct alignment of the blades inside the cartridge

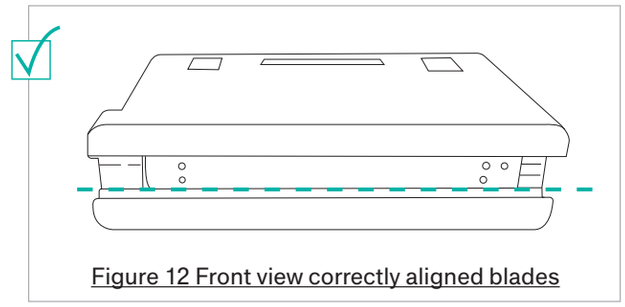

Figure 12 Front view correctly aligned blades

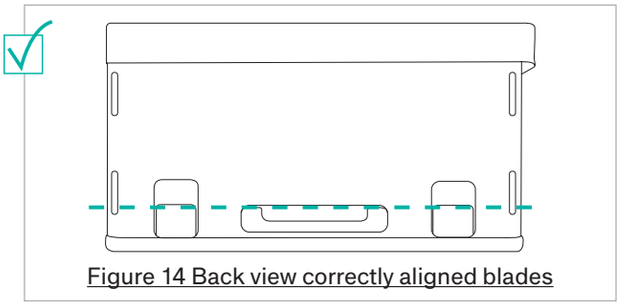

Figure 14 Back view correctly aligned blades

4. BLADE CARTRIDGE INSTALLATION

To install the blade cartridge, open the blade cartridge drawer located at the front of the device and position the blade cartridge inside the container as shown in the figure below.

Figure 15. Blade cartridge installation

5. Weld preparation

After the initialization process, you will be instructed step by step to insert the tubes. Before doing so, a valid blade cartridge must be inserted into the blade cartridge container as described in the paragraph “Blade cartridge installation”.
In the upper right corner you can see the symbol 50 with the quantity of remaining blades in your blade cartridge. Now you are ready to insert the tubes.

⚠	Do not deviate from the order of these instructions
⚠	The user is advised to wear protective gloves when working with the machine
⚠	Always dry your hands, gloves and tubes thoroughly before using the sterile connection device
⚠	If the tubes have been cleaned before welding, wait long enough to avoid the release of vapours, especially flammable vapours

In a first step you have to open the tube holder and then lift the middle layer until both remain open.

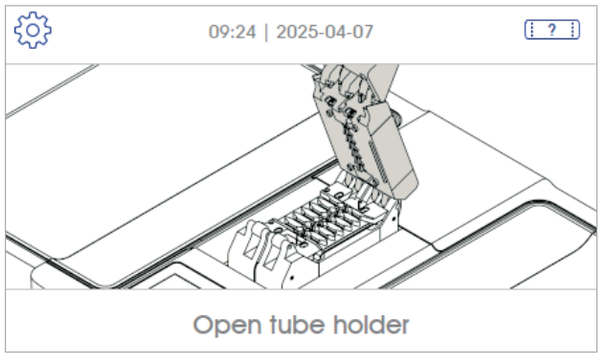

Figure 16. Open tube holder

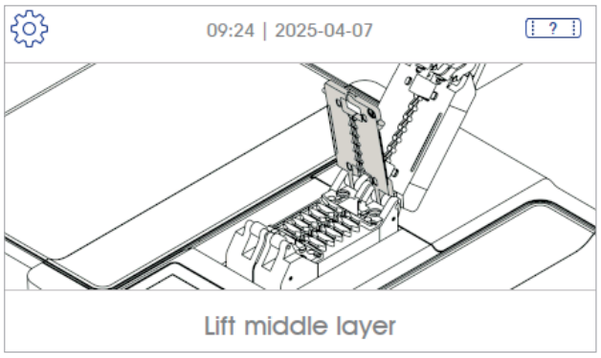

Figure 17. Lift middle layer

Insert first the tubes in the lower part of the tube holder. Make sure that the bags or tubes to be connected are correctly placed on the left side tray. Now close the middle layer so that the upper tubes can be inserted.

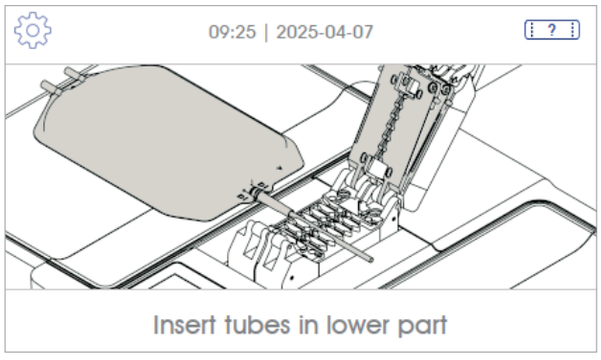

Figure 18. Insert tubes in lower part

Insert the tubes in the upper part of the tube holder. Make sure that the bags or tubes to be connected are correctly placed on the right side tray, then close the tube holder.

⚠	Do not apply excessive pressure on the tube holder handle or you may damage it. If it does not close, please check that there is no object in between and if the tubes are inserted correctly before pursuing.

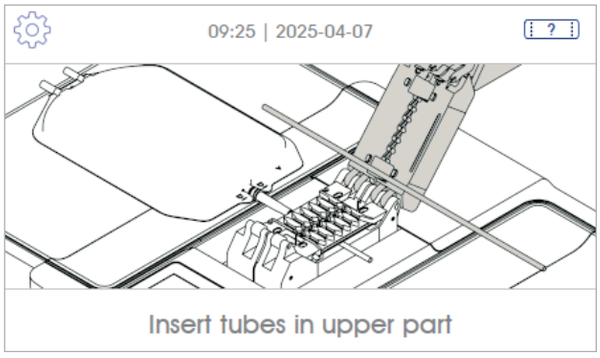

Figure 19. Insert tubes in upper part

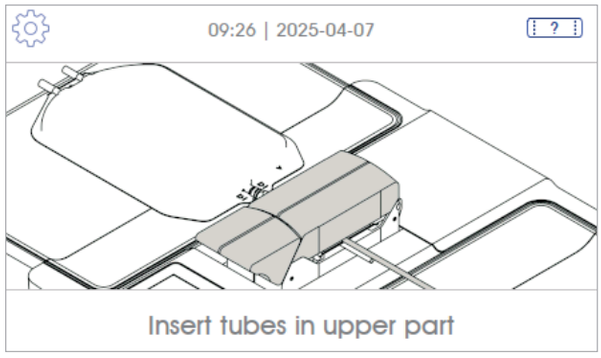

Figure 20. Close tube holder

6. Weld process

The Maconnect is now ready for a welding run and the screen to start the welding appears. Note: A welding run can only be started if the middle layer and the tube holder are closed properly and the blade cartridge container, with a valid blade cartridge, is closed. Check also if the blade cartridge contains at least one blade. Slide to the right or press the button to start the welding run.

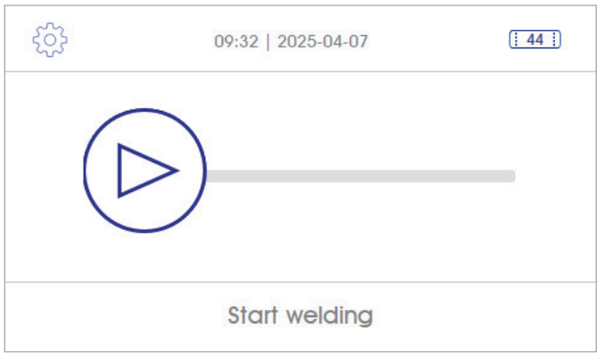

Figure 21. Screen to start a welding with the slider

Figure 22. Screen to start a welding with the button

⚠	While the welding process is running, the tube holder and the blade cartridge container are mechanically locked. Do not try to open them. If too much force is applied, the machine could be permanently damaged.

After a successful welding run, you will be instructed step by step to remove the tubes. Open the tube holder and remove the upper waste tubes.

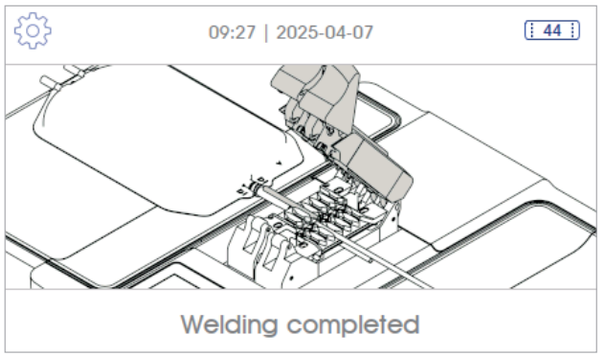

Figure 23. Remove upper waste tubes

Lift the left middle layer so the welded tubes can be removed.

⚠	After every welding process, each tube connection must be visually checked by the operator.

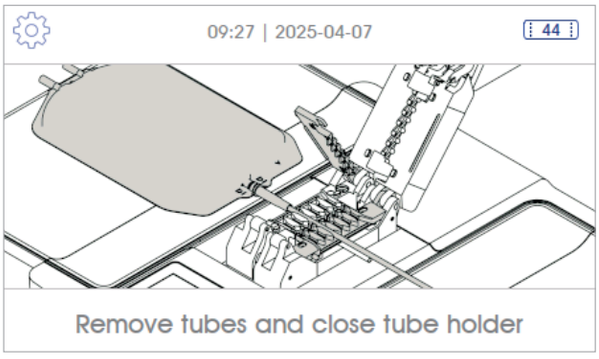

Figure 24. Lift left middle layer

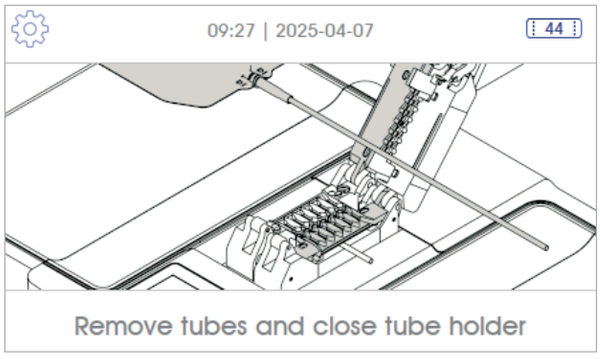

Figure 25. Remove welded tubes

After the welded tubes are removed, lift the right middle layer and remove the lower waste tubes. Close the tube holder so that the Maconnect is ready for the reset process.

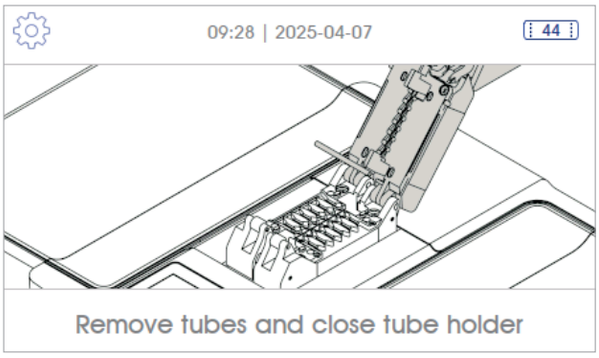

Figure 26. Remove lower waste tubes

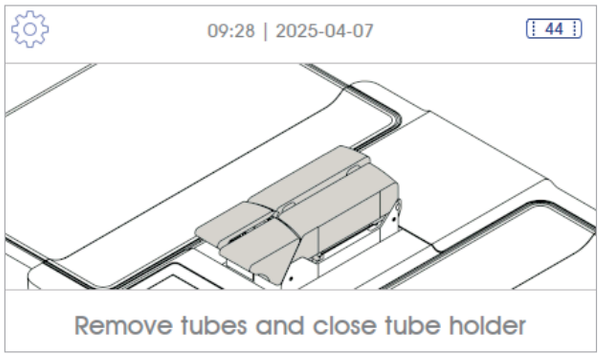

Figure 27. Close tube holder

7. RESET PROCESS

⚠	Please make sure that all the tubes are removed before the reset process starts. If not, the welded tubes inside can be damaged.

During this process the vertical displacement of the tube holder is reset and the inserted blade is ejected into the used blades container. Slide to the right or press the button to start the reset process.
After a successful reset, the Maconnect is ready for the welding of the next set of tubes.

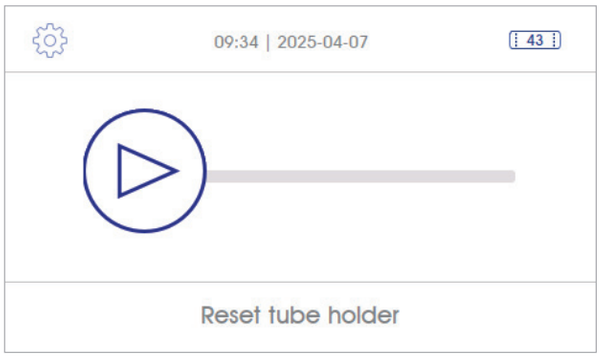

Figure 28. Screen to reset with the slider

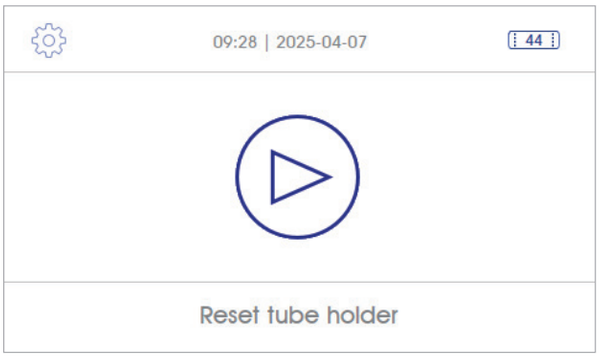

Figure 29. Screen to reset with the button

⚠	If the used blades container is full, the device asks to empty it. It is strongly recommended to empty the used blades container periodically before the device asks to do it.
⚠	While the reset process is running, the tube holder and the blade cartridge container are mechanically locked. Do not try to open them. If too much force is applied, the machine could be permanently damaged.

8. SHUTDOWN OF THE WELDER

Press and hold the soft power switch ⏻ and wait until the shutdown message appears on the screen. Press “OK” if you want to shut down the machine and wait until the screen gets black. Turn off the main power switch on the back of the Maconnect. The LED indicator turns off.

1. Main screen

Current date / time

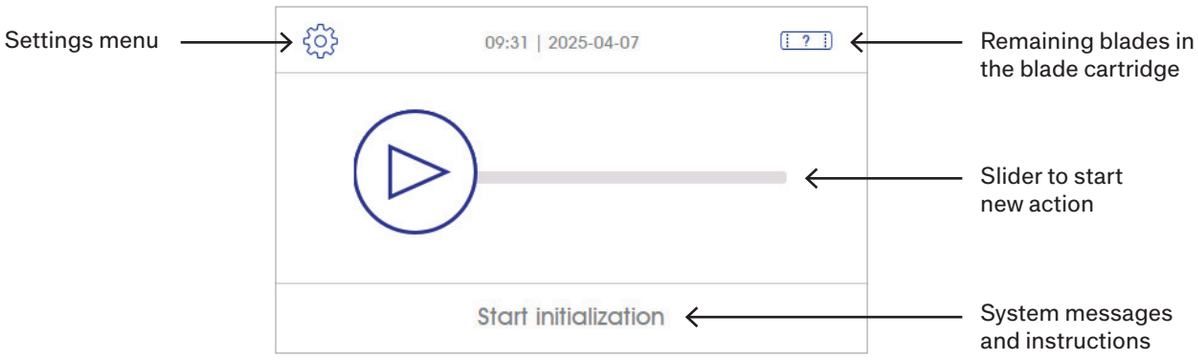

Figure 30. Main screen with the slider after start-up

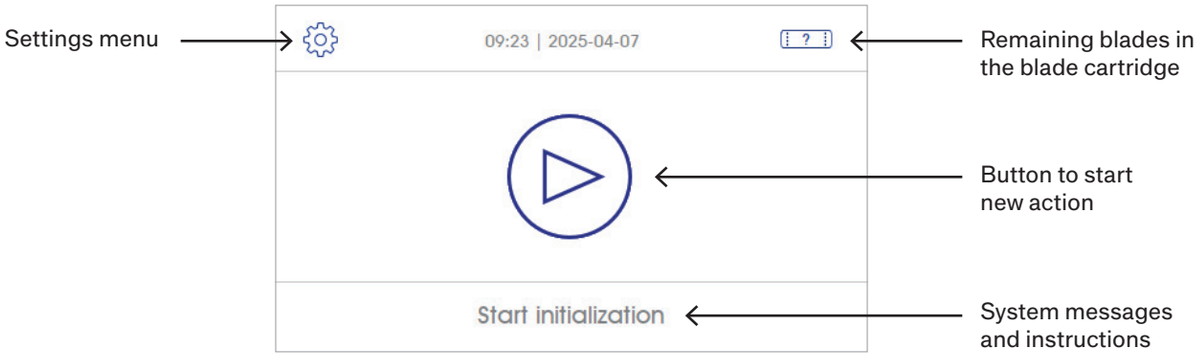

Figure 31. Main screen with the button after start-up

2. Settings menu, operator

Press the gear wheel symbol on the top right of the display to open the screen menu.

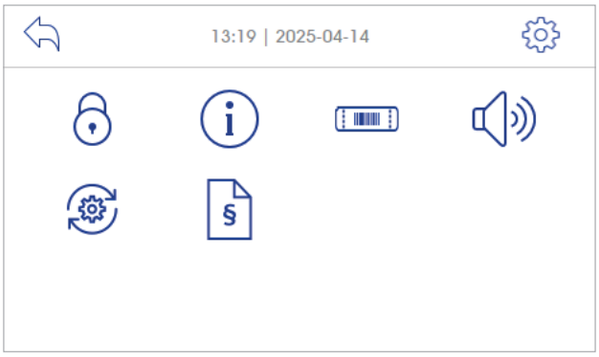

Figure 32. Menu as operator

Login screen

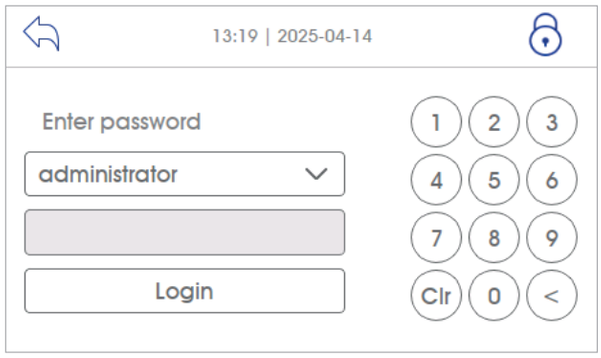

Figure 33. Login Screen

In this menu the user has the possibility to log in as administrator or technician, if he is authorized.

Back to Operator mode.

Device information

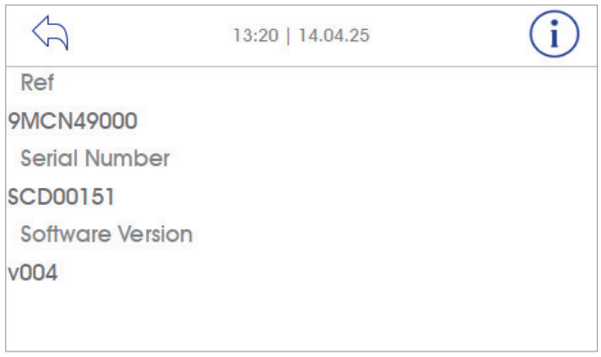

Figure 34. Device information screen

In this view, the part and serial number of the device as well as the version of the software can be viewed

Blade information

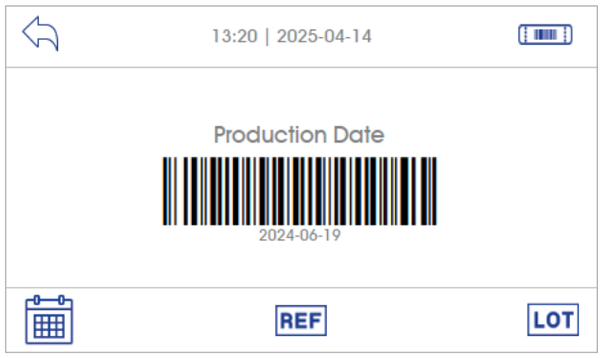

Figure 35. Blade information screen

View of the production date, part or lot number of the inserted blade cartridge.

Buzzer off/on

Maintenance condition

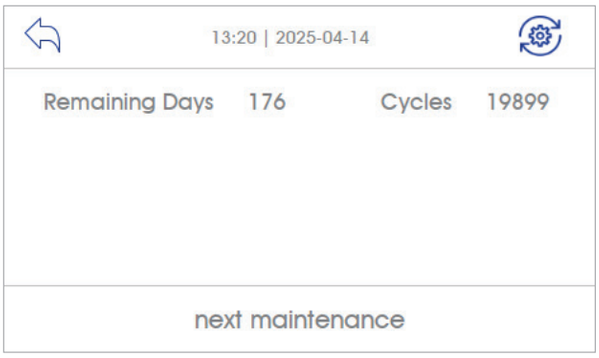

Figure 36. Maintenance condition screen

Maintenance of the machine must be carried out if the corresponding time or number of welding cycles require it.

Software licences

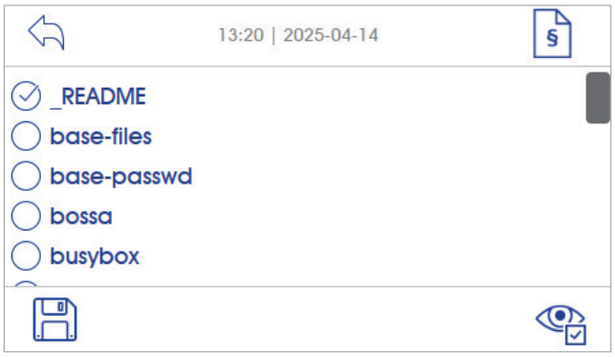

Figure 37. Software licences screen

Licence information of the software.
To export licence information, connect a formatted memory stick to the USB type-A connector and press

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3. SETTINGS MENU, ADMINISTRATOR

Press the gear wheel symbol on the top right of the display, log in as administrator, then you will see the following screen menu.

Figure 38. Menu as administrator

Date/Time

Figure 39. Date / time menu

Change actual date, time and format by pressing

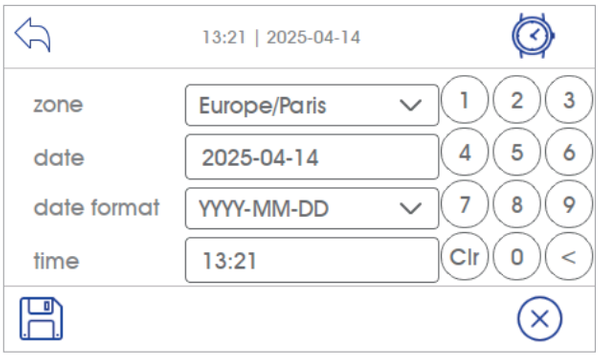


Figure 40. change date / time menu

Language selection

Choose your preferred language for the operator. The language will be changed automatically after activating the corresponding checkbox.

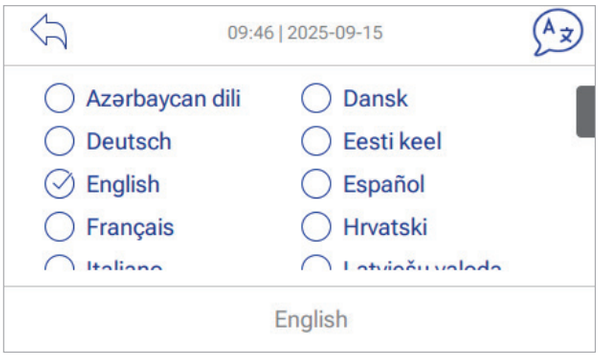


Figure 41. Change languages

Confirmation action selection

Choose your preferred confirmation button between the slider or the button. The initialization, the welding, the reset and the alignment will be automatically changed after the selection.

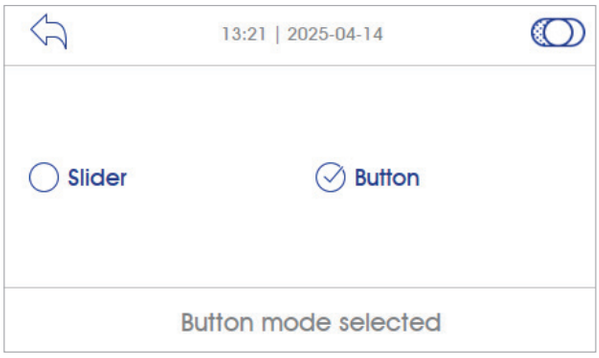


Figure 42. Confirmation action selection

Align tube holder for cleaning

If needed, the administrator can clean the tube holder. To do so, please carefully read chapter CLEANING, section 4.

CLEANING

	Never put sharp or metal items on the device or between the open tube holder layers. This will lead to irreversible damages.
	Do not apply excessive pressure on the tube holder handle or you may damage it.
	Never immerse your welder in a liquid solution.
	Never sterilize the welder or the tube holder in any sterilization system.

1. When to clean the device

We recommend you to keep your device as clean as possible and to clean it immediately in case of fluid leakages or spills. Otherwise we recommend a cleaning once every week. Regular cleaning will provide better performances over time. Only use the products listed in the paragraph below.

In case of blood splashes, particularly in the tube holder, the administrator must be notified immediately. The tube holder must be decontaminated and clean before further use.

2. How to clean the device

	Do not directly spray the cleaning solution on the device. We recommend to use a soft cloth saturated with the cleaning solution and then to wipe and dry the equipment with a dry soft cloth.

For adequate cleaning, please execute the following operations:
- Switch off the welder with the main power switch located at the back of the device,
- Disconnect the power supply cord so that the device is not under any voltage,
- Take a soft cloth saturated with cleaning solution,
- Gently clean the surface of the device,
- Gently clean the inside and outside of the tube holder,
- Wipe the surface with a dry soft cloth to eliminate cleaning solution left over.
- Reconnect the power supply cord and turn on the machine

3. Cleaning products

For an optimal cleaning, use a soft detergent followed by an antiseptic solution for thorough asepsis.
All the surface of the device can be cleaned with the following solutions:
- Medical Alcohol or solutions based on propan-2-ol
- Chlorine bleach solution or Diluted chlorine bleach
- Neutral detergent

⚠	Do not use any cleaning solution with solvent.
⚠	Do not use any cleaning solution based on hydrogen peroxide ingredient.

4. CLEANING OF THE TUBE HOLDER BY THE ADMINISTRATOR

⚠	Only the administrator is authorized to disassemble and assemble the tube holder with a specific tool and only if he has been trained and certified by a Macopharma representative.
⚠	To remove the tube holder, the administrator needs special rights. In order to get these permissions, a corresponding administrator password is required. This is given to the administrator during the Product training.
⚠	Never remove the tube holder before the machine has been put into the intended state (see chapter INSTALLATION).
⚠	Always switch off the mains power and disconnect the power supply cord from the device before removing the tube holder.
⚠	Never connect and/or turn on the device if the tube holder is disassembled.
⚠	Machine and tube holder match to each other. When reinstalling the tube holder, make sure that the serial number of the tube holder matches the serial number on the alignment blocks of the machine.

In case of blood splashes, particularly in the tube holder, the administrator must be notified by the operator immediately. To facilitate cleaning of the tube holder, the administrator will remove the tube holder from the device. The tube holder will be cleaned and reinstalled. The administrator must follow the following instructions.

Uninstall the tube holder:

1. Setting up, start-up and initialize the device as described in chapters INSTALLATION and USE.
2. ⚙ Go to the settings menu as described in chapter SETTINGS.
3. 🔒 Login as administrator with the provided password. Afterwards you will see the following menu:

Figure 43. Menu as Administrator

4. Go to the menu to set the machine to the intended condition to be able to remove the tube holder. Afterwards you will see the following menu:

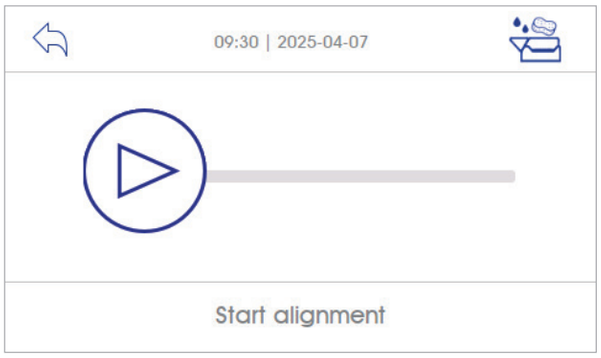


Figure 44. Screen to align with the slider

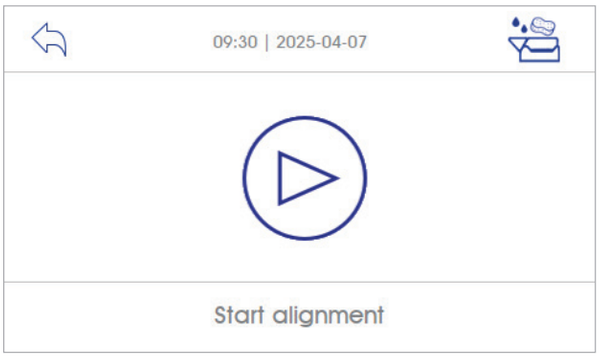


Figure 45. Screen to align with the button

5. Start the alignment of the tube holder so that it is ready to be removed. Afterwards you will see the following screen:

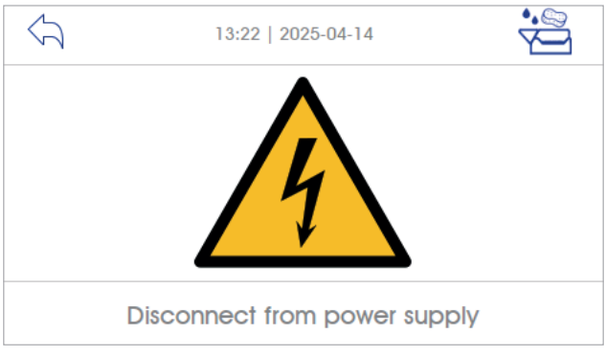


Figure 46. Disconnect Power supply

Turn off the mains power supply switch and disconnect the power supply cord now.

6. Disassemble the tube holder with the hexagon screwdriver provided with the device.

Figure 47. Dismantling of the tube holder

7. Make sure that the power cord is disconnected from the unit and that the unit is switched off while the tube holder is removed! Then, you can clean the tube holder afterwards.

⚠	Manipulate the tube holder with care.
⚠	Do not touch any part located inside the device and which can be accessible when the tube holder is removed.
⚠	Do not insert any object inside the device when the tube holder is removed.
⚠	Do not use any cleaning solution on parts located inside the device. In case of blood splashes located on parts inside the device, please contact immediately your local technician/ sales representative.

Reinstallation of the tube holder after cleaning:

⚠	Machine and tube holder are **matched** to each other. When reinstalling the tube holder, make sure that the **serial number** of the tube holder (indicated below by *) matches the serial number on the alignment blocks of the machine.

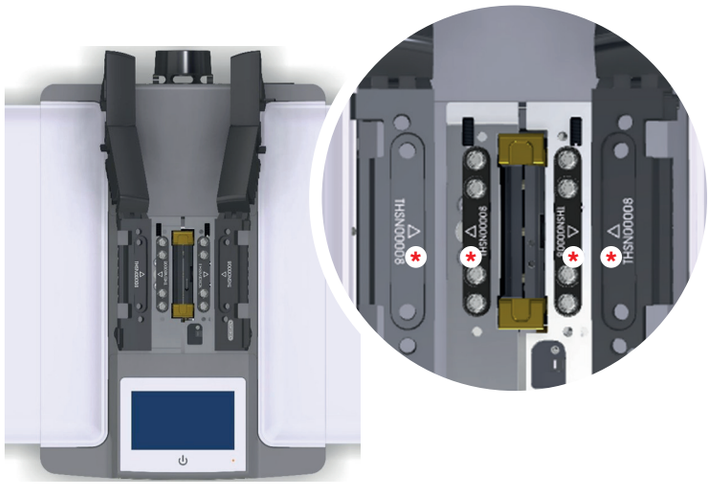
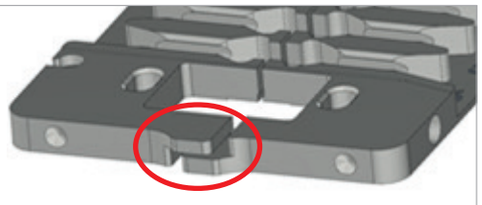
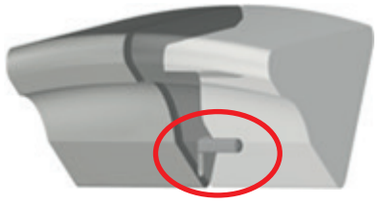


Figure 48. Serial Number control before tube holder reinstallation.

1. Reinstall the tube holder with the tool intended for this purpose. When assembling the tube holder, make sure that the bolts of the handle interlock and the left and right middle layers are assembled in the correct order. Make sure that the screw including the o-ring is mounted.



Left middle layer Right middle layer



Interlock between left and right handle

Figure 49. Right positioning of the middle layer and the pin

2. First, softly tighten all four screws with low torque. Then tighten all four screws with the hexagon screwdriver delivered with the device.

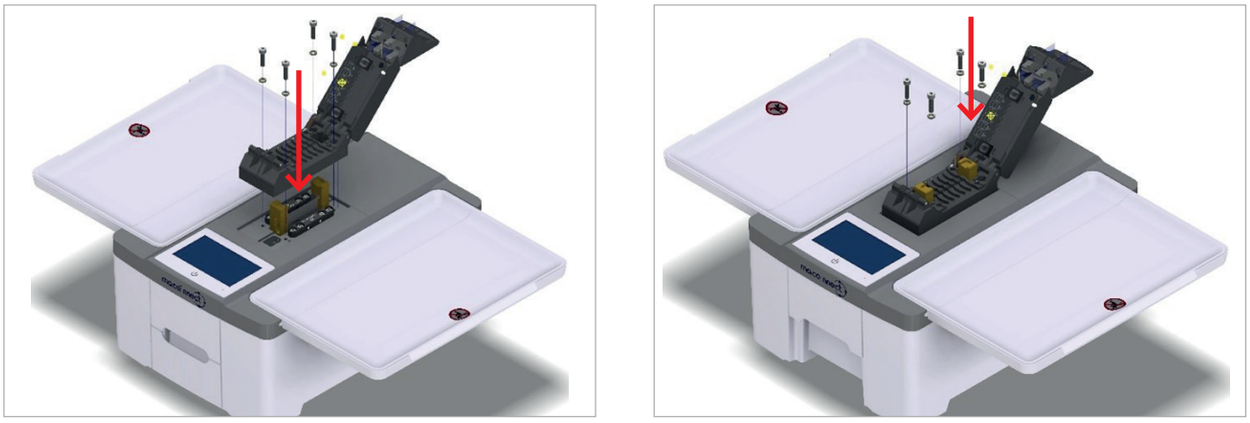


Figure 50. Tube holder screwing

3. Reconnect the mains power supply cord, switch on the device and start-up the welder as described in chapter USE, section “1. Start-up of the sterile connection device”.

4. Initialize the welder as described in chapter USE, section “2. Initialization process”. Perform a test weld and validate the result. If the test is successful, the machine can be released for production again.

MAINTENANCE

1. User maintenance

a) User maintenance responsibilities

In terms of maintenance on the Maconnect, the user's responsibilities are:
- To regularly clean the Maconnect. The recommendations are detailed in the previous chapter.
- To plan the preventive maintenance with a Maco Pharma certified service representative.

b) Fuses replacement

1. Disconnect the power cord.
2. Use a flat screwdriver to extract the fuses drawer from the back plate of the device.
3. Replace the fuse only with a fuse of the same type and rate.
4. Put back in place the fuses drawer inside its housing and push it until you hear a click that confirms the correct positioning.
5. Connect the power cord to the device power connector.

Fuse type and rate: 250V 3.15A Time-lag

	To avoid the risk of electric shock, this device may only be connected to mains supply with a protective earth conductor.
	In case of a wrong replacement of the fuses, the device may be damaged.

2. Maintenance by authorized personnel

The Maconnect sterile connection device has been designed to ensure optimum welding quality throughout its lifespan, assuming that all necessary maintenances have been carried out correctly over time.
A preventive maintenance has to be done once a year or every 20 000 welding cycles.

- 45 days before the yearly maintenance or at 17 000 cycles, the pictogram  will be displayed close to the setting icon to remind you to contact your local Macopharma service representative to perform the preventive maintenance.

- At 0 day or 0 cycle remaining, the device will display the following pictograms   and ask you to press ok before starting every cycle. Then, during the cycle, the pictogram will be displayed close to the setting icon to remind you that the maintenance must be performed as soon as possible by your local Macopharma service representative.

	In case of an improper preventive maintenance schedule, the connection quality could not be compliant with the standard.

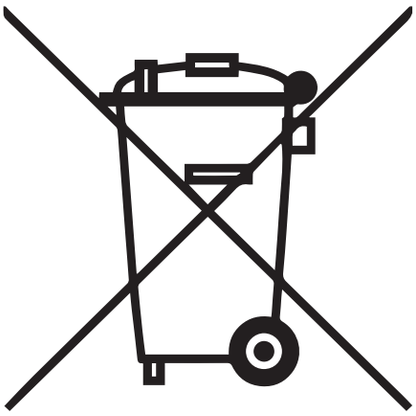
Note: The yearly preventive maintenance can only be done by trained and certified personal to this level of operations.

The curative maintenance can only be done by a qualified and certified technician.
In case of failure that requires a repair, please contact your local Maco Pharma service representative.

All the technical documents corresponding to the service manual, the circuit diagrams, the component part lists or the installation and operational qualification, are available only to the qualified technician.

END OF LIFE

The equipment, including accessories and empty non-rechargeable and rechargeable batteries as well as the blade cartridge, does not belong in your regular household waste; such equipment is manufactured from high-grade materials and must be recycled and reused. The European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) requires that electrical and electronic equipment be collected and disposed of separately from other unsorted municipal waste, with the aim of recycling it. The crossed-out waste bin symbol indicates that separate collection is required.



To dispose of your equipment, please contact your sales' representative.

Used blades are considered as biohazard, dispose of them properly according your local disposal procedures.

The packaging is made of environmentally friendly materials that can be used as secondary raw materials. If you no longer need this packaging, bring it to your local recycling and waste disposal facility according to the regulations applicable in your country.

Note: We advise you to keep the packaging in case the device is shipped to a technical center for repair.

ERROR MESSAGES AND CURRATIVE MAINTENANCE PROCEDURE

The following information is indicated to help you to solve issues and errors that may occur during the device use.
An error message does not necessarily mean that the device is defective. Therefore, refer to the following chapters to identify the root cause and to see the appropriate solutions.

1. How to understand and treat errors messages

The Maconnect is designed with 3 different processes: Initialization, welding and reset.
Each process consists of one or several runs that are executed sequentially. Each run is composed of one or several steps.

Process	Run number	Description
Initialization	1	Device Initialization
	12	Check if the waste container is full of blades
Welding	5	Prepare for the blade insertion
	6	Insert the blade into the cutting mechanism
	2	Lock the tube holder
	7	Heating the blade
	8	Welding the tubes
	9	Cooling the tubes and unlock the tube holder
Reset	10	Eject the blade and reset Tube Holder
	12	Check if Waste Container is full

2. Main error screens

a) Error rxxsyy

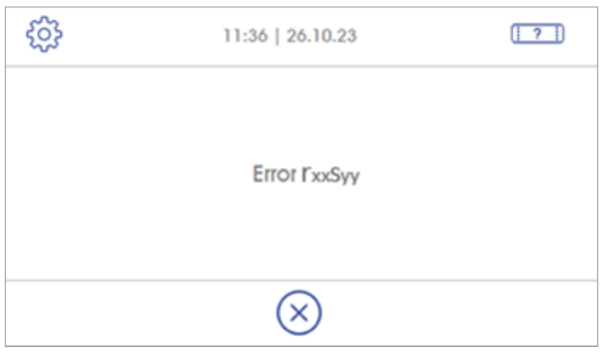


Figure 51. Error screen

xx corresponds to any decimal number following the run defined by numbers from 00 to 12.
yy corresponds to any decimal number following the step defined by the numbers from 00 to 200

Please refer to the list detailed in the section “List of errors” below to identify the root cause and see the appropriate solutions to solve it.
When an error occurs repeatedly, take a note of it to inform your Maco Pharma service representative and press the ⊗ button and then initialize the device following chapter USE, section “2. Initialization process”.

b) Machine failure

Figure 52. Machine failure screen

Root Cause

The message with the pictogram ⚠ is displayed after 3 consecutive unsuccessful initializations. To prevent any damage, the device is locked.
Further investigation is needed, please, contact your Maco Pharma service representative.

Solution

Visually check whether a blade is locked in the cutting axis. When is not, remove the used blade container and check below the device if there is a blade stuck inside the groove used to eject the blade.
If one or more blades are stuck inside the device and you are unable to remove it yourself, please contact your Maco Pharma service representative.

Unlocking the device

You are authorized to unlock the device only if jammed blades are removed from the groove used to eject the blade.
To unlock the device, login as an “Administrator” in the Settings Menu following the instructions in chapter SETTINGS, section “3. Settings menu, administrator”. The following setting menu is displayed:

Figure 53. Administrator with warning pictogram

Press the warning pictogram ⚠ on the menu to access to the unlocking screen.

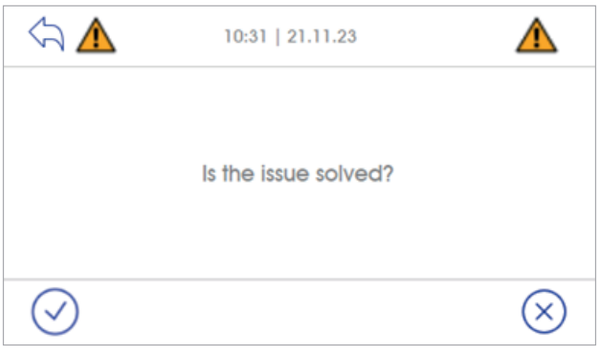


Figure 54 Device Unlocking screen

If the issue is solved, press the ✓ button to unlock the device, otherwise press the ✕ button. After the unlocking, please initialize the device following chapter USE, section “2. Initialization process”.

If the issue is not solved, please use your local instructions to prevent any further usage by other operators and contact your Maco Pharma service representative.

c) Preventive maintenance due date reached

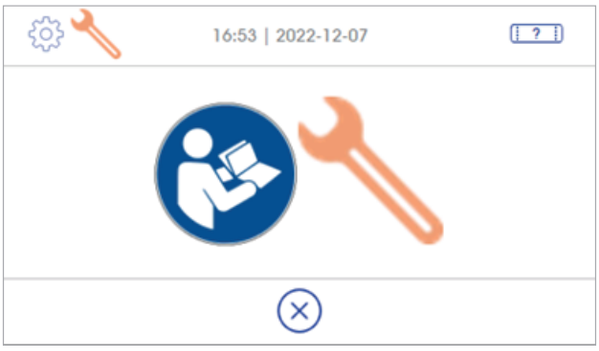


Figure 55 Preventive maintenance due date reached

Root Cause

The message with the pictograms is displayed when there is 0 days or 0 cycles remaining to perform the preventive maintenance of the device.

Solution

The preventive maintenance must be performed as soon as possible. Contact your local Maco Pharma service representative to do so.

3. Operating problems

Operating problem	Potential root cause	Solution
The device does not turn on	Mains power cord not connected or defective. Circuit breaker open.	Check power cord connection. Check the circuit breaker on the power network
	Fuse defect	Check fuse on the back side.
The tube holder cannot be opened or closed	Unlock process failed.	Reboot and initialize the device.
The used blades container cannot be opened	A blade is jammed.	Try to open and close the container carefully a few times.
The blade cartridge container cannot be opened	Welding run has not finished.	Wait for the cycle to be completed. Remove tubes and reset the tube holder. If this is not possible, reboot the machine.
The device displays every time the same error message after the welding cycle, the reset or the initialization.		Refer to the chapter ERROR MESSAGES, section “4. List of errors” below to identify the root cause and see the appropriate solutions. Contact your Maco Pharma service representative.

	If the error persists, please contact your local MacoPharma service representative.

4. List of errors

Error report	Potential root cause	Solution
r1sx	Problem during the initialization of the device	Contact your Maco Pharma service representative. *Note: After 3 r1sx errors, the device will be locked.*
r6b	Connection between the blade cartridge and the device loss	Remove the tubes from the tube holder and follow the chapter USE, section “2. Initialization process”. In case of too many r6b errors, contact your Maco Pharma service representative
r7s5	Problem to heat the blade.	Contact your Maco Pharma service representative.
r10s6	The blade didn’t fall properly inside the blade container during the reset step and is potentially jammed.	Remove the used blade container and check below the device, around the groove used to eject the blade if a blade is jammed. Contact your Maco Pharma service representative.

	The device should be reinitialized after each error. You will be prompted to do so by the device. If the error cannot be corrected by the measures described above, please contact your local Maco Pharma service representative.
	If an error message not listed is displayed, and remains after an initialization, please contact your Maco Pharma service representative.

TECHNICAL CHARACTERISTICS

Commercial reference:	Maconnect, ref. 9MCN49000
Tube's specifications:	PVC
	Inner diameter within 2.9mm < ID < 3.4mm
	Outer diameter within 3.9mm < OD < 4.5mm
	Ask your sales representative for other dimensions
Tube's sterilization:	Steam sterilized, Ethylene Oxyde sterilized (EO) or irradiation sterilized (BETA)
Welding cycle time:	≈30 seconds (Welding ≈ 20s, Cooling ≈ 10s)
Degree of Protection:	IP2x
Weight:	Without tray support: 13.5kg (28.7lb)
	With tray support: 14.4kg (30.9lb)
Dimension:	Without tray support: L x W x H = 27 x 41 x 23cm
	With tray support: L x W x H = 59 cm x 41cm x 23cm (23" x 16" x 9")
Mains power supply:	100-240Vac, 50-60Hz, 2.8A (maximum at 100Vac)
Mains power supply fuse:	2 x 250V 3.15A Time-Lag
Operating Temperature:	Device: +10°C (50°F) to +40°C (104°F)
	Tubes: +4°C (39°F) to 28°C (82°F)
Relative humidity:	20 to 80% (without condensation)
Altitude:	Up to 2000m (6'500 ft)
Conditions of storage / transport	
• Relative humidity:	20 to 80 % (without condensation)
• Temperature:	-10°C (14°F) to +60°C (140°F)
• Pressure:	500 to 1060 hPa
In and out connections:	USB cable type A with shielding (USB 2.0)
	XLR Connector 24V, 2A max.
Fume extraction connector:	53mm (2") diameter, External air filter system with maximum 20m3/ h or 5 L / min
Packaging:	Cardboard box, L x W x H = 59cm x 39cm x 36.5cm (23" x 15" x 14")
Wireless RFID:	
• Standard used:	ISO/IEC 14443
• Frequency:	13.56MHz
• Maximum power:	0.6W
• Field strength:	155dBµA/m

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