



D 301 *Evo*



INSTRUCTIONS MANUAL v. 1.0

Translation from original instructions

FOREWORD

This machine is part of the GIMA product range. Thanks to our modern production, assembly and testing methods and many years of experience GIMA machines satisfy the highest quality requirements.

This user manual includes:

- Safety instructions
- Instructions for installation and use
- Instructions for maintenance and repair
- Troubleshooting
- Technical data
- Declaration(s)

Using this manual will:

- Make it **easier** to get used to working with the machine
- **Prevent** malfunctions caused by non-professional use

Please observe the maintenance instructions, as they will:

- **Enhance** the machine's reliability
- **Extend** the machine's service life
- **Reduce** the costs of repair and shutdown of operations

GIMA will not accept liability for damage to this machine if:

- The machine is not operated in accordance with the instructions presented in this user manual.
- The machine is used for any purpose other than that specified in this user manual. (see safety instructions).

The guarantee expires in the event of:

- Faulty operation
- Failure in the scheduled maintenance
- Deviating dimensions

CAUTION!

The user manual should always be kept in the direct vicinity of the machine.

Only operate the machine after careful study of the user manual.

Please observe the safety instructions and instructions for preventing accidents under all circumstances.

If you need to use spare parts, use only original GIMA parts for your own safety.

This GIMA machine was built in accordance with current technical rules and regulations.

Symbols in the user manual:**CAUTION: danger****CAUTION: specific warning****CAUTION: maintenance advice**

The user

This manual is meant to be used by different users. However, all operators must observe the following restrictions.



Operation of the machine by untrained personnel could lead to serious personal injury and considerable damage.



GIMA cannot be held liable for damage caused by individuals not authorised to operate the machine.

Operating personnel

Operating personnel must be trained, through a training programme or by the operator, to perform the designated tasks and be aware of the consequences that can arise from use by untrained individuals. The machine may not be operated by persons under the influence of alcohol medicines and/or drugs.

Installation, maintenance and repairs require specialist training and may only be carried out by maintenance personnel.



If in doubt about the correct operation of the machine, consult maintenance personnel immediately.

Maintenance personnel

Based on professional training, knowledge and experience and the applicable regulations set down by the manufacturer, maintenance personnel has been trained to carry out the designated tasks and identify potentially dangerous situations independently.



When working on the machine, all maintenance personnel are obligated to work in accordance with the manual.



All specialist work is to be performed exclusively by persons authorised to perform these tasks as specified in the relevant sections of the manual.

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GIMA reserves the right to change spare parts and/or specifications without previous notice. Contents of this manual can also be changed without previous warning.

GIMA cannot be hold responsible for eventual damage caused by specifications deviating from the standard model.

Although extreme care has been exercised during writing this manual, GIMA will not accept any liability for eventual errors in this manual and/or for the consequences of (mis)interpretation of the contents.

GIMA is not responsible for damage or problems which result from the use of other than the original spare parts. If this manual has not been supplied with instructions for certain repairs, adjustments and maintenance, you should contact your dealer of GIMA .

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1 Unpacking

While unpacking the machine, use the following list to check if everything is present.

- The machine
- User manual
- Power supply cable
- Left and right foil roll holder
- Foil roll
- Foil guides (4x)
- Work table
- Bag containing:
 - Hex key
 - Phillips screwdriver
 - Fasteners
 - Covers (2x)

Check the data on the identification plate. (see fig. 1) near the power port and copy them to the following figure.

TYPE			
SERIE			
VOLT		HERTZ	
JAAR		WATT	



fig. 1 Identification plate

The packaging materials used for this machine are environmentally friendly and can be disposed of as regular household waste. We recommend keeping the packaging, so that the machine can be transported safely if required in the future.

2 Safety instructions and precautions



Please read the user manual carefully before operating the machine!

Explanation of the warning icons:

- A. Caution: hot parts on the inside of the machine



A

Safety markings on the machine:

The safety markings are complete and have been applied to the machine in such a way that they are easy to read. Please replace any damaged and illegible safety markings.

The machine can be dangerous for persons and objects if:

- The machine was not installed in accordance with the instructions;
- The machine has been placed in an unsuitable environment;
- The machine is not used properly;
- The machine has been modified or adapted in any way;
- The users do not meet the requirements;
- The safety instructions are not observed.

Remaining risks that cannot be avoided through technical adjustments:

- When feeding the foil into the machine fingers can get trapped under the seal bar. Be certain to remove your fingers from underneath before closing the seal bar with the operating lever.
- When feeding the foil into the machine your fingers may come into contact with the seal bar. Do not touch the seal bar, as this may cause serious burns.
- Be careful not to touch the cutter blade during maintenance operations, as this may cause serious injury.
- Beware of the danger of an electric shock. Your fingers may come into contact with electrically charged parts during maintenance operations. Always switch off the machine and disconnect it from the main power supply before carrying out maintenance operations.

Of course, the following apply as well:

- The relevant safety regulations to prevent accidents;
- The general safety instructions;
- Any applicable local or regional regulations.

Making alterations and adjustments to the machine:

- If any alterations or adjustments are made to the machine by unauthorised personnel, GIMA will no longer be able to guarantee the operational safety of the machine.
- GIMA does not accept liability for any parts or special components not supplied by GIMA (or any other goods not manufactured by GIMA).
- The assembly and/or installation of these articles could have a detrimental effect on the passive safety of the machine.
- GIMA is not liable for damage caused by any components other than the original components supplied by GIMA .

Using the machine for any special applications:

If the machine is used in a medically sterile environment and/or clean room, the operator is responsible for compliance with the regulations that apply specifically to that environment.



If the machine is used for the packaging of medical instruments, the operator is responsible for compliance with the regulations that apply specifically to the packaging of medical instruments.

SWITCHING ON THE MACHINE

Before switching on the machine:



The user must be thoroughly familiar with the equipment, working method and operating elements of the machine.



All operators are required to use personal protective equipment.

Please ensure the following points are in order before switching on the machine:

- The data on the identification plate corresponds with the voltage (V), frequency (Hz) and the power rating (W) of the local power supply.
- The machine does not have any notable defects.
- The operating elements all function properly.
- No foreign objects have been placed in or on the machine.



If the above points are not in order, the machine may NOT be switched on.

Working with the machine:

- Use only sealable materials that are suitable for the machine. (See capitel **Fout!** **Verwijzingsbron niet gevonden.**)
- Never open the cover of the machine while it is still connected to the power supply.
- If there is any doubt about the proper functioning of the machine, immediately disconnect the machine from the main power supply and consult maintenance personnel.
- Both the operator and the machine must be supervised throughout the operating process.
- In the event of a malfunction, do not operate the machine until the fault has been completely repaired.
- If any liquid is spilled onto the machine or an object falls into the machine, switch off the machine and immediately disconnect the machine from the main power supply. Have the machine checked by maintenance personnel before using it again.
- In the event of an unusual alarm, such as smoke emanating from the machine, switch off the machine and immediately disconnect the machine from the main power supply. Have the machine checked by maintenance personnel before using it again.



When working with the machine, the seal bars will be hot and can cause serious burns if they come into contact with the skin.



The machine is equipped with a sharp blade. This can cause serious injury.

In case of fire:

Never douse the machine with water if it catches fire. The machine is connected to the power mains, so this could cause a life-threatening situation. A fire extinguisher must be kept within reach of the machine at all times. The following types of fire extinguisher can be used to extinguish the machine:

- Powder extinguisher
- Foam extinguisher

Switching off the machine:

- Switch off the machine when it is not in use.
- If the machine will not be used for a long period of time, disconnect the machine from the main power supply.

Maintenance and repairs:

- Maintenance and repairs to the machine require specialist training and may only be carried out by authorised maintenance personnel.
- Unauthorised persons may not perform maintenance tasks.
- Switch off the machine and disconnect it from the main power supply before carrying out maintenance operations.
- Do not clean the machine with water, abrasives, chemical solvents or other fluids.



The machine contains high voltage parts, which may cause electric shock or serious personal injury.



The machine contains hazardous moving parts, which may cause serious personal injury.



When performing maintenance tasks or repairs, remember that the seal bars are still hot immediately after use. Touching these can cause serious burn injuries.

Maintenance work on the electrical wiring:

Switch off the machine and disconnect it from the main power supply before carrying out maintenance operations to the electrical wiring. Be absolutely certain that there is no power supply to the machine. Place a warning sign on the machine to ensure that no one switches it on.

3 General description

The D 301 *Evo* is a heat sealer for the packaging of medical instruments in laminated foil. After the instruments have been placed in a bag, the bag is sealed. The bag is placed under the seal bar, which is closed by manually pulling down the operating lever. This causes the seal bar to shut, sealing the bag in just a few seconds. Once the bag has been sealed, the instruments in the sealed bags can be sterilised in a steam autoclave.

The D 301 *Evo* is easy to operate. After the machine has been switched on, the seal bar will start heating to the standard sealing temperature. This takes only a few minutes. The machine will start sealing immediately after the seal bar has been lowered by means of the operating lever. After 4 seconds the on/off switch will start to blink and the sealer will emit a sound signal. The machine switches off automatically if it is not used for 30 minutes.

The D 301 *Evo* uses prefabricated plastic bags as well as rolls of laminated foil. Plastic bags can be made to measure from this foil, which can be cut to the dimensions of your choice with the machine's integrated cutter. The machine seals bags in all foil widths, up to the maximum width of the seal bar.

The machine can seal laminated foil and/or plastic bags that are suitable for steam sterilisation.

Sealing cycle

The complete sealing cycle of the machine comprises the following steps:

- Insert the laminated foil bag into the machine under the seal.
- Pull the operating lever to close the seal bar.
- Cut off the excess foil above the seal by sliding the cutter back and forth.
- After 4 seconds the on/off switch will start to blink and the machine will emit a sound signal. The seal is ready.
- Open the seal bar and take the bag out of the machine. Your packaged instruments can now be sterilised in a steam autoclave.



The D 301 EVO *Evo* can only seal laminated foil and/or plastic bags that can withstand steam sterilisation.

4 Dimensional sketch

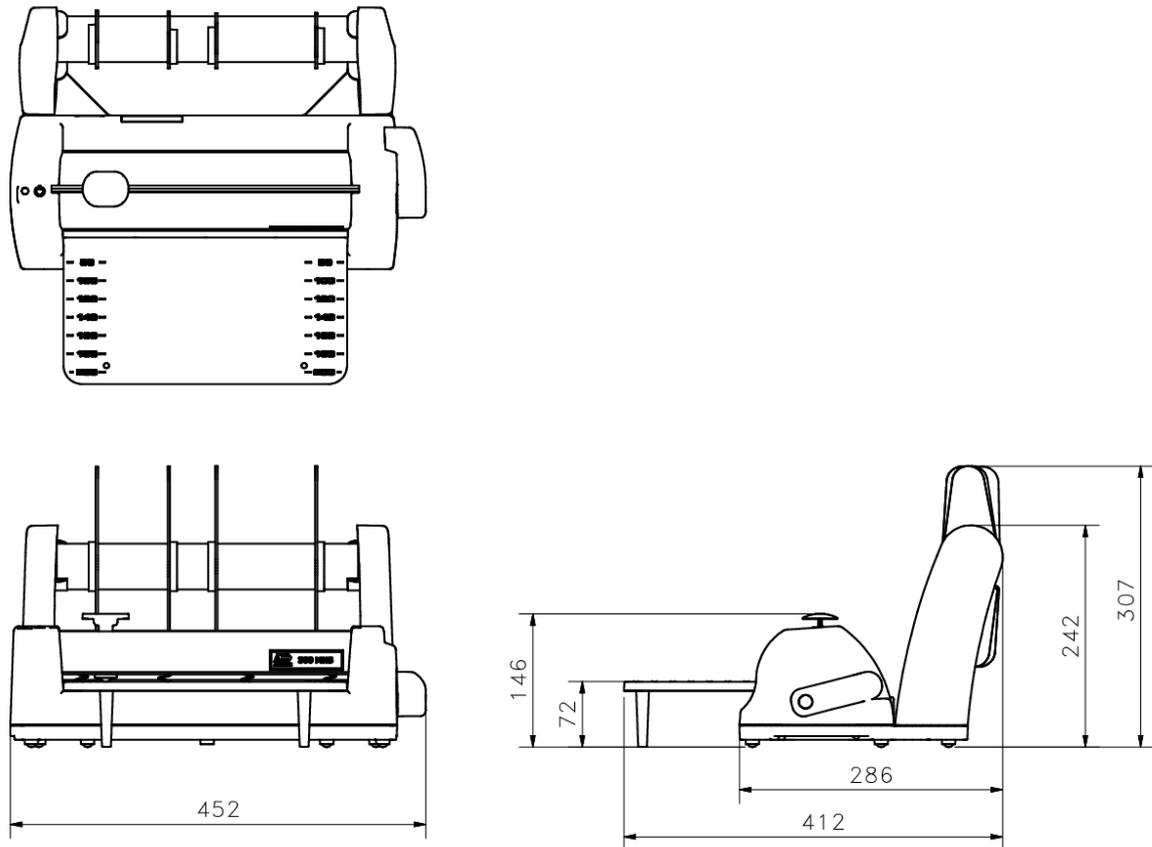


fig. 2 Dimensional sketch

5 Specifications

5.1 Operating specifications

- | | |
|----------------------------|---|
| - Operating speed: | Max. 12 runs per minute |
| - Ambient temperature: | +5° . . . +40° Celsius |
| - Relative humidity: | 30% . . . 95% rel. (without condensation) |
| - Attachment, base : | Rubber legs |
| - Extraction, ventilation: | Use in a ventilated room |

5.2 Non-permitted applications

- Use in an explosive environment
- Use in a freezer/walk-in refrigerator
- Packaging of toxic, corrosive or irritating substances
- Packaging of explosive materials
- Packaging of toxic, suffocating or irritating gases
- Packaging of hazardous dustlike products

6 Installation



The machine may only be installed by authorised maintenance personnel. (see foreword).



Installing the machine under unauthorised circumstances may cause lasting damage to some of its components.



All operators are required to use personal protective equipment.



Make sure that there is enough space around the machine to ensure its safe operation, maintenance and repairs.

6.1 Installation

Place the machine in a ventilated, well-lit room. Make sure that the machine is not exposed to direct sunlight, extreme temperatures, moisture, dust or sand. The machine must not be exposed to mechanical shocks or vibrations.

Place the machine on a sturdy, flat surface to ensure optimum stability.

6.1.1 Installation with a spindle

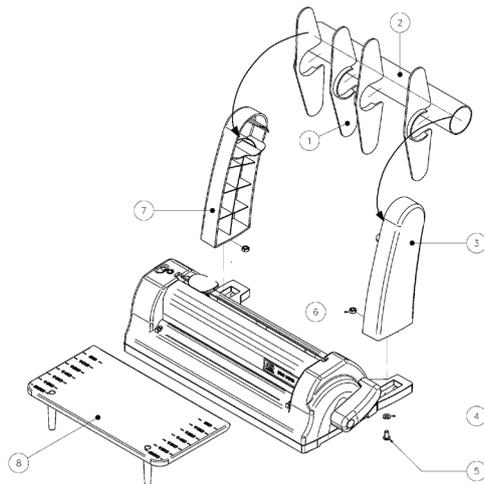


fig. 3 Mounting the spindle to the work table

Insert the nut (6) into the groove at the bottom of the spindle holders (3 and 7). Next, slot the spindle holders (3 and 7) into the grooves in the machine. Screw both spindle holders onto the machine with the washer (4) and the bolt (5). Insert the spindle (with a roll of foil) (2) into the spindle holders (3 and 7). Mount the four foil roll guides (1) onto the spindle (2).

6.1.2 Installation without a spindle

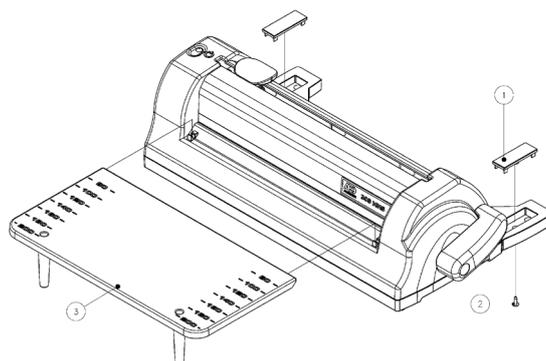


fig. 4 Installation without a spindle

Insert the guards (1) into the grooves on the machine and attach them to the machine with the screws (2).

6.1.3 Installing the work table

Slit the work table (8) in the grooves of the machine (see fig. 3).

6.1.4 Installing the cutter

Insert the cutter (with the blade) into the cutter guide groove at the top of the machine. (see fig. 3).



Caution: do not cut yourself! The blade is extremely sharp.

6.2 Connecting the machine to the main power supply

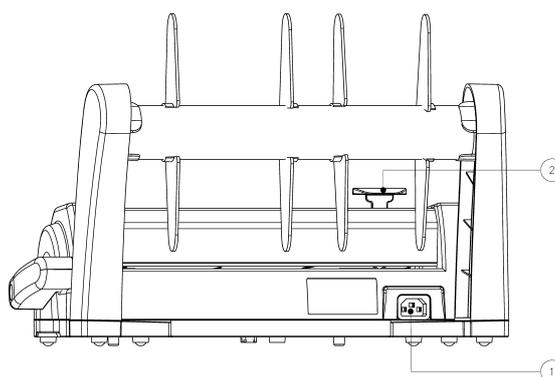


fig. 5 Connection point

1	Power port
---	------------

Insert the female plug of the power cord into the power port (1) of the machine (see fig. 5). Next, plug the power cord into the wall socket.



Connect the machine only to a power supply with earth connection and overvoltage protection that has been secured with max. 16A.

7 Operating parts

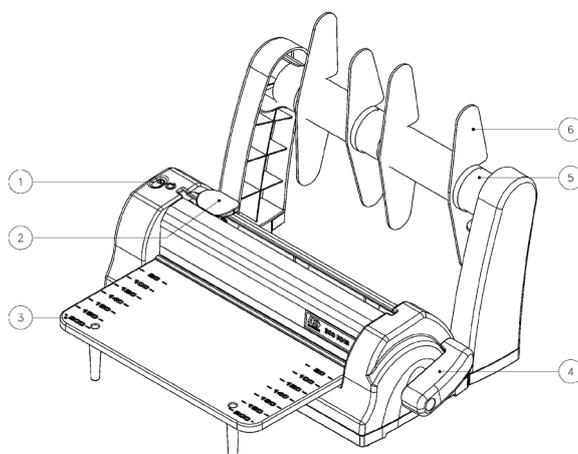


fig. 6 Operating parts

No.	Name	Function
1	On/off switch	To switch the machine on and off
2	Cutter	To cut the excess foil from above the seal To cut foil to the desired size
3	Work table	To measure the foil on the roll
4	Operating lever	To close the seal bar and start the sealing process
5	Spindle	Spindle on which to place 1 or 2 rolls of foil
6	Foil guides	Keep the roll(s) of foil in place

7.1 Safety applications

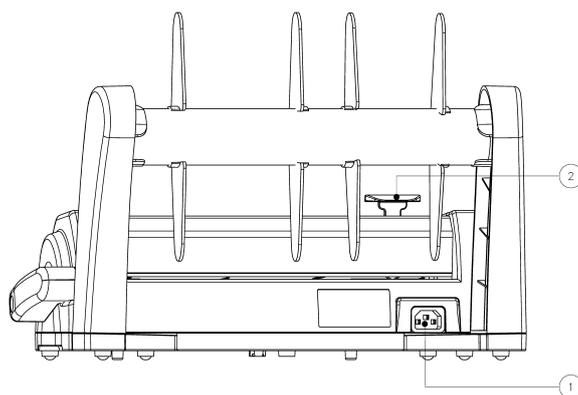


fig. 7 Safety applications

No.	Name	Function
1	Safety fuses	In the event of a short circuit, the machine will be switched off by the two safety fuses (2 AT) on the print
2	Cutter	The cutter has been designed to ensure safe operation of the blade
3	Heating elements	Will not heat to temperatures above 190°C



8 Operation



The machine may only be used by authorised personnel. (see foreword).



Before switching on the machine, make sure that all the safety features are present and functioning properly.



All operators are required to use personal protective equipment.



Operators must stand in front of the machine, within easy reach of the on/off switch and the operating lever.



After an unexpected power failure, the machine will need to be restarted manually by setting the on/off switch to 'on'.

8.1 Switching the machine on

To switch the machine on:

- Press on the on/off switch until the machine emits a sound signal. The LED in the on/off switch will now light up red, showing that the machine is warming up. See also section 10.1 for troubleshooting steps for the on/off switch.

8.2 Switching the machine off

To switch the machine off:

- Press on the on/off switch until the machine emits a sound signal. The LED in the on/off switch will now extinguish, showing that the machine has been switched off.



The machine switches off automatically if it is not used for 30 minutes.

8.3 Sealing



Failure to carefully follow the seal cycle instructions below can result in serious personal injury and/or material damage.



For the best possible result and ease of operation, the bag must be filled by three quarters lengthwise and there must be at least 30 mm of free space between the product and the inside of the seal.



Never place bags containing labels or adhesive tape between the seal bars.

8.3.1 *Sealing prefabricated bags*

1. Slide the cutter to the left.
2. Place the bag on the work table and insert the foil entirely under the seal bar. Make sure that the transparent part is facing upwards during the sealing process.
3. Lower the seal bar by pushing the operating lever forwards. The bag will now be sealed. After 4 seconds the machine will emit a sound signal indicating that the sealing process has been completed.
4. Raise the seal bar by pulling back the operating lever.
5. Remove the bag from the work table. The machine is now ready to seal the next bag.

8.3.2 *Making bags from a roll of foil*

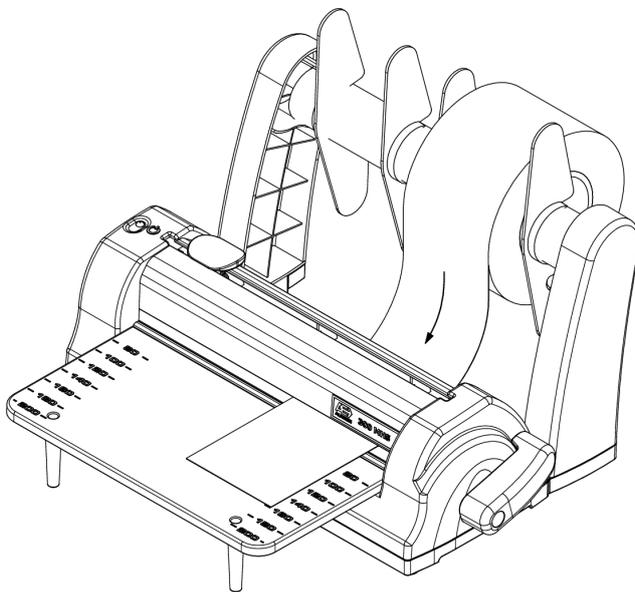


fig. 8 Guiding the foil

1. Place a roll of foil on the spindle and clamp this between two foil guides so that the roll will stay in place. Make sure that the transparent side will be facing up during the sealing process.
2. Slide the cutter to the left.
3. Guide the foil from the rear of the machine underneath the seal bar.
4. Pull on the foil until it has reached the desired length. The length can be measured on the work table.
5. Lower the seal bar by pushing the operating lever forwards. The foil will now be sealed. After 4 seconds the machine will emit a sound signal showing that the sealing process has been completed.
6. Cut the foil by sliding the cutter to the other side of the machine.
7. Raise the seal bar by pulling back the operating lever.
8. Remove the bag from the work table. The bag can now be filled and subsequently sealed.
9. If no bags are made, remove the film between the seal bar.



9 Maintenance

9.1 General maintenance instructions



Only authorised maintenance personnel are allowed to perform repair work on the machine. (see foreword).



Always follow safety instructions carefully during maintenance operations.



All operators are required to use personal protective equipment.



If you need to perform maintenance operations that are not specified in this manual, please contact your dealer or GIMA .



Before carrying out maintenance operations ensure that the machine has been completely switched off. (see section 12.1).



When performing maintenance tasks or repairs, remember that the seal bars are still hot immediately after use. Touching these can cause serious burn injuries.



Do not clean the machine with water, abrasives, chemical solvents or other fluids.

Note: please also follow the safety instructions for the cleaning agents.



Make sure there is a repair kit near the machine with the recommended spare parts. (see section 11) so that defective parts can be replaced quickly and the production process will not be interrupted longer than necessary.

9.2 Maintenance schedule

The following maintenance schedule is based on regular use of the machine. If the machine is used intensively or in extreme conditions, maintenance should be performed at shorter intervals.

Weekly maintenance:

Weekly maintenance may be performed by operating personnel. (see foreword). Always switch off the machine and disconnect it from the main power supply before carrying out maintenance operations.

Component	Description
Machine	Clean the exterior of the machine with a damp cloth and soft soap
Machine	Disinfect the machine with Isopropyl alcohol

Monthly maintenance:

Monthly maintenance may only be performed by authorised maintenance personnel. (see foreword). Always switch off the machine and disconnect it from the main power supply before carrying out maintenance operations.

Component	Description
Cutter	Check to see if the cutter is working properly. If necessary, replace the blade. (See section 9.3)

9.3 Replacing the blade

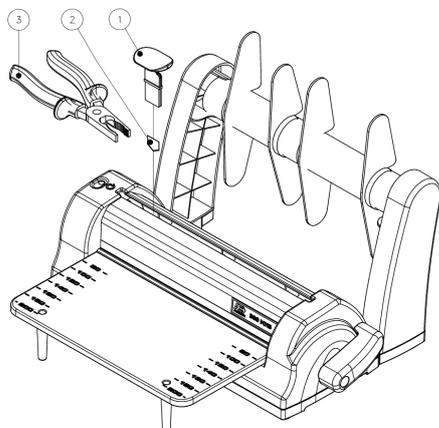


fig. 9 Replacing the blade



Caution: do not cut yourself! The blade is extremely sharp.

A blunt blade can easily be replaced as follows:

- Remove the cutter (1) from the machine.
- Remove the blade (2) from the cutter with a pair of pliers (3).
- Insert a fresh blade into the cutter using the pliers.
- Slot the cutter back into the guides.

10 Troubleshooting

Below you will find a table specifying the most common malfunctions. If a problem is not listed in this table, contact your dealer or GIMA (see the reverse of this manual for contact details).



Problems to the machine may only be resolved by authorised maintenance personnel. (see foreword).



In the event of a malfunction, always switch off the machine first. Then consult the manual.

Problem	Cause	Solution
The machine will not start.	The machine is not plugged in properly.	Insert the plug into the wall socket properly.
	The plug has not been connected properly to the machine.	Insert the plug into the machine properly.
	Internal malfunction.	Contact your dealer or GIMA .

10.1 Codes and fault codes for the on/off switch

LED Colour	Buzzer	Meaning
Off	Off	The machine has been switched off.
Green, continuous	Off	The machine has been switched on; the seal bar has reached the desired temperature.
Green, flashing (slowly)	Off	The machine is busy sealing.
Green, flashing (fast)	Continuous	The sealing process is complete. Use the operating lever to open the seal bar.
Red, continuous	Off	The machine has been switched on, but the temperature of the seal bar is too high or too low. Wait until the machine has reached the desired temperature.
Red, flashing (slowly)	On/off	The seal bar is closed and the temperature is too low. Raise the seal bar by pulling back the operating lever. Wait until the machine has reached the desired temperature.
Red, flashing (slowly)	On/off	The seal bar has remained closed for too long and the temperature is too high or too low. Use the operating lever to open the seal bar.

10.2 Deactivating the buzzer:

The buzzer can easily be switched off as follows:

1. Switch off the machine.
2. Press the on/off switch for about 10 seconds until you hear two short bleeps. The buzzer has now been deactivated. This will remain so until it has been reactivated.
3. To reactivate the buzzer, simply repeat the above steps.

11 Recommended spare parts

GIMA recommends always having the following spare parts on hand so that defective parts can be replaced quickly and the production process will not be interrupted longer than necessary.

Article number	Name	Number per machine
82010	Blade (set 5 pcs)	1
82011	Self adhesive seal rubber	1
82017	Sealing bar	1

12 Taking out of operation, transportation and storage

12.1 Taking out of operation



The machine may only be put out of operation by authorised maintenance personnel. (see foreword).



While the machine is being put out of operation all safety regulations must be observed.



All operators are required to use personal protective equipment.



The machine must be switched off properly before it can be taken out of operation. (see section 8.2).



No special tools or equipment are required to put the machine out of operation.

12.1.1 Switching off the main power supply

Switch the machine off.

Disconnect the power cord from the power supply.

Disconnect the female plug of the power cord from the machine power port.

12.2 Transportation and storage



Always observe the applicable safety precautions when transporting or storing the machine.



GIMA cannot be held liable for damage incurred during transportation and/or storage.



Never transport or store the machine upside down.



To prevent irreparable damage to the machine, also observe specifications applicable to the storage and transportation environment. (see Chapter 5).

12.2.1 Transport

Before transporting the machine it must be put out of operation in the correct manner. We recommend transporting the machine in its original packaging.

The machine's centre of gravity is at the bottom. As such, it will remain stable during transport in normal circumstances. For safe transport of the machine, please take the weight of the machine into consideration before starting all transport operations. (see section 13).

The relative light weight of the machine allows it to be transported manually. The machine must be lifted from the underside.

12.2.2 Storage

Before putting the machine in storage it must be put out of operation in the correct manner. We recommend storing the machine in its original packaging.

13 Technical details

General

Dimensions H x W x D:	307 mm(H) x 452 mm (W) x 412 mm (D)
Weight:	± 3 kg
Seal length:	300 mm
Seal width:	12 mm
Seal temperature:	180 °C

Electrical wiring

Max. capacity:	300 W
Stand-by capacity:	< 0,5 W
Voltage:	230 V
Main power supply deviation:	<10%
Frequency:	50 Hz
Fuses:	2 AT
Connector cable length:	± 1.8 m

Emission

Sound:	< 80 dB(A)
Hand/arm vibration:	< 2.5 m/s ²

14 To discard

In accordance with the directive 2012/19/EU, the logo below indicates that the equipment concerned is not to be disposed of as ordinary waste at the end of its useable life. The equipment is to be delivered to a suitable depot that will dispose of the equipment in a proper way in accordance with the legislation on this subject, or to the supplier of new equipment in case of replacement.

The owner of the equipment is responsible for proper disposal of the equipment. For further information we advise you to contact your local waste facility.



Appropriate disposal of Waste of Electric and Electronic Equipment prevents unnecessary pollution of the environment and negative influence on general health.



15 Conditions of guarantee

15.1 Liability

- We exclude any liability as far as it has not been arranged by law.
- Our liability will never exceed the amount of order.
- Subject to the general valid regulations of the law, we are not obliged to any compensation of damage of which kind ever, directly or indirectly, under which company damage, to movable' and immovable or to persons, both to the opposite party as to third persons.
- In no way we are liable for damage arisen from or caused by the supplied or by the unsuitability of this for the purpose for which the opposite party has purchased the Sealer.

15.2 Guarantee

- With due observance of the restrictions stated hereafter, we allow 12 months of guarantee to the products supplied by us. This guarantee is restricted to the occurring manufacture errors and does not imply interruptions caused by any form of wear spare parts subject to use.
- To spare parts or enclosures obtained from third persons we do not give longer guarantee than this third supplier does.
- Guarantee expires if the opposite party and/or third parties associated make improper use of the supplied.
- Guarantee also expires if the opposite party and/or third parties associated execute activities and/or modifications to the supplied.
- In case we replace spare parts to fulfill our guarantee engagement, the spare parts replaced become property of GIMA packaging machines.
- In case the opposite party does not come up completely, partially or does not come up in time to the obligations arisen from the engagement closed between the parties, we are not obliged to guarantee as long as the situation continues.

16 Electrical diagram
