

## **OPERATING MANUAL**

#### REVISIONS

The following table lists the subsequent editions/revisions of the manual. The "Description" field briefly describes the topic of the last revision.

	Code	Rev.	Date	Description	
	97050573	0	07-2012	First issue (translation from the original in Italian)	
	97050573	1	09-2012	Text and image adaptation	
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ENGLISH

#### INTRODUCTION 1.

#### Dear Customer,

thank you for choosing this product. We hope it will perform to your full satisfaction. This manual describes all the procedures for proper installation and use of the machine. Should you have any questions, please do not hesitate to contact us. We would also welcome any suggestions you may have to improve our product or service.

#### Note, warning and hazard symbols used in this manual.





	HAZARD
λ	THIS SYMBOL INDICATES A POTENTIAL HAZARD TO PEOPLE. OPERATE ACCORDING
7	TO THE PROCEDURES INDICATED IN THE MANUAL IN ORDER TO PREVENT POSSIBLE
	INJURY TO THE USER AND/OR THIRD PARTIES.



HAZARD THIS SYMBOL INDICATES A POTENTIAL HAZARD BECAUSE OF HIGH TEMPERATURE.

#### Symbols on the machine

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	This symbol indicates a potential hazard because of high temperature.		
Œ	Machine compliant to applicable directives.		
X	Waste disposal in accordance with Directives 2002/95/EC, 2002/96/EC and 2003/108/EC.		
<b>.</b>	Consult the user manual		

# ENGLISH

#### **1.1. APPLICABLE EUROPEAN** DIRECTIVES

pose any hazard for the operator if used according to the instructions. The product complies with the following applicable European Directives: 2006/95/EC for reconciliation of the Member State legislations related to low-voltage equipment

2004/108/EC for reconciliation of the Member State legislations related to electromagnetic compatibility; 2006/42/EC for reconciliation of the member state legislations related to machines.

The product described in this manual has been constructed to the highest safety standards and does not

#### **1.2. INTENDED USE**

The machine is intended for professional use and must only to be used for the purpose for which it was designed, that is, heat sealing and cutting of rolls of paper/polypropylene laminate for sterilization.



NOTE THE MACHINE MAY NOT BE USED WITH ROLLS OF MATERIALS OTHER THAN THOSE INDICATED ABOVE.



WARNING USE OF THE MACHINE IS STRICTLY RESERVED FOR QUALIFIED PERSONNEL. IT MAY NOT BE USED OR HANDLED BY INEXPERT AND/OR UNAUTHORISED PERSONS FOR ANY REASON WHATSOEVER.

	1.3. PU	RPOSE OF	THE MA
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	NOTE THE INFORMATION CONTAINED IN THIS MANUAL IS SUBJECT TO CHANGE WITHOUT PRIOR NOTICE.
<b>B</b>	THE MANUFACTURER IS NOT RESPONSIBLE FOR DIRECT, INDIRECT, ACCIDENTAL OR CONSEQUENTIAL DAMAGES OR ANY OTHER DAMAGES RELATING TO THE PROVISION/ USE OF THIS INFORMATION.
	NO PART OF THIS DOCUMENT MAY BE REPRODUCED, ADAPTED OR TRANSLATED IN ANY FORM OR BY ANY MEANS WITHOUT THE PRIOR WRITTEN PERMISSION OF THE MANUFACTURER.
	FOR CORRECT INTERPRETATION OF THE INSTRUCTIONS CONTAINED IN THIS MANUAL, THE ITALIAN VERSION SHALL BE VALID AS ORIGINAL TEXT.
- Gener - Prope - Safe a	ose of this manual is to provide instructions for: ral knowledge of the product; r installation; and efficient use; nent of the instruments and/or materials to be sterilized.

The appendix contains:

- The technical characteristics of the product;
- The maintenance operations;
- Analysis of the problems and their resolution;
- \_ Other documentation.

The product must always be used according to the procedures described in this manual and never for purposes other than those specified herein.



MANUAL

WARNING THE USER IS RESPONSIBLE FOR FULFILLING THE LEGAL OBLIGATIONS RELATING TO INSTALLATION AND USE OF THE PRODUCT. IF THE PRODUCT IS IMPROPERLY INSTALLED, USED OR MAINTAINED, THE MANUFACTURER SHALL NOT BE HELD RESPONSIBLE FOR ANY FAILURE, MALFUNCTION, PERSONAL OR PROPERTY DAMAGE.

In order to prevent hazardous situations with possible personal or property damage, please observe the precautions given in this manual; in particular:

- only use the recommended cleaning products;
- do not pour water or other liquids or substances onto the machin;
- do not use the machine in the presence of explosive gases or vapours;



<u>HAZARD</u> BEFORE CARRYING OUT ANY MAINTENANCE OPERATION, ALWAYS DISCONNECT THE POWER CABLE PLUG FROM THE POWER SOCKET.

ensure that the electric system is earthed in compliance with the laws and/or regulations in force;

do not remove any label or plate; if necessary, ask for new ones;

only use genuine spare parts.

					WAR	NING			
	FAILURE	TO	OBSERVE	THE	ABOVE	INSTRUCTIONS	SHALL	RELIEVE	THE
<u> </u>	MANUFAC	TURE	ER OF ANY A	ND ALL	RESPON	SIBILITY.			



**NOTE** UPON RECEIPT, CHECK THAT THE PACKAGING IS SEALED AND INTACT.

#### 2. CONTENTS OF THE PACKAGING

After opening the packaging, check that:

The contents match the order specifications (see the delivery document)

There is no evident damage.

#### 2.1. DIMENSIONS AND WEIGHT

Dimensions and weight	Millseal+ evo
Height	260 mm
Width	600 mm
Depth	300 mm
Total weight	8.5 kg



<b>R</b>	<b>NOTE</b> IF THE PRODUCT DELIVERED IS INCORRECT OR PARTS ARE MISSING OR DAMAGED IN ANY WAY, IMMEDIATELY INFORM THE DEALER AND THE COURIER THAT MADE THE DELIVERY PROVIDING ALL RELATED DETAILS.





<u>NOTE</u>

THE WARRANTY CERTIFICATE MUST BE FILED AT THE CUSTOMER TOGETHER WITH

THE PURCHASE INVOICE OF THE PRODUCT.

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2.2. DESCRIPTION OF THE CONTENTS

#### 3. PRODUCT PRESENTATION

**Millseal+evo** is an innovative automatic heat sealing machine that allows you to seal large volumes of bags cut to size with a simple command.

In a few easy steps this revolutionary product allows you to set the length and number of bags, start the automatic procedure without an operator, and finally collect the pre-sealed bags in the large removable container provided, ready for subsequent use.

These performance features, together with the elegant and compact design make **Millseal+evo** a musthave partner for all professionals in the healthcare field.

#### 3.1. MAIN PERFORMANCE CHARACTERISTICS

**Millseal+ evo** is an electronically-controlled heat sealing machine that produces a sealing strip of 12 mm, suitable to withstand the sterilization processes of modern autoclaves that work with fractionated pre-vacuum, and ensures package sterility over time.

The automatic temperature adjustment allows effective heating control in the sealing area, providing high and constant performance.

The solid structure in plastic and aluminium, together with the ergonomic and essential shape offer a high level of hygiene, reduced weight and dimensions and excellent stability during use. All this with the aim of providing a product suited to the daily needs in the medical field.



**NOTE** FOR THE DESCRIPTION OF THE SAFETY DEVICES, REFER TO THE APPENDIX (TECHNICAL CHARACTERISTICS).

Proper installation is the <u>first</u> and essential operation to be carried out to ensure <u>correct</u> operation of the heat sealing machine. This will also help prevent malfunctions or damage to the machine.



## 3.2. FUNCTIONS AND DIMENSIONS



#### 4. INSTALLATION

Please scrupulously observe the warnings given further on in this section.



#### 4.1. GENERAL PRECAUTIONS

- Install the heat sealing machine on a <u>flat surface</u> leaving an adequate space for the handling operations and for sufficient ventilation.
- Check that the support tray is sufficiently robust to support the weight of the machine and of the roll (16 kg max.);
- Do not install the machine near sinks in order to prevent contact with water or liquids which may cause short-circuits or potentially hazardous situations for the operator;
- Do not install in humid or poorly ventilated environments;
- Do not install in environments where there are flammable and/or explosive gases or vapours;
- Install the machine in such a way that the power cable is not kinked or squeezed along its path up to the
  power socket.

#### 4.2. ELECTRICAL CONNECTION

The machine must be connected to an earthed mains socket of adequate capacity for machine power absorption, in accordance with the regulations in force. The socket must be appropriately protected upstream by an electric panel equipped with a differential magnetothermal switch.

Connect the power cable provided to the power socket on the rear of the machine.



NOTE EXCLUSIVELY USE THE POWER CABLE PROVIDED WITH THE MACHINE. THE USER IS RESPONSIBLE FOR PLUG REPLACEMENT IF NECESSARY. CONNECT THE POWER CABLE DIRECTLY TO THE MAINS SOCKET. DO NOT USE

EXTENSIONS, ADAPTERS OR OTHER ACCESSORIES.

#### 4.3. PRODUCT PREPARATION

#### 1. Carefully take the material out of the package.

2. Fit the roll supports (A) in their housings. Tighten the screws (B) using the Allen wrench (C) provided.



3. Place the paper roll tube (D) on the supports (A) checking that the pins (E) in the supports (A) slide into place in the holes at the ends of the tube.



4a. Fit the support tray (F), holding it in vertical position, into the slots (G) and push it to the left (as indicated by the arrow). Turn the tray downwards until it is in the support position.



Horizontal tray position: manual bag production and finishing.



**4B.** Raise the tray (F) by about  $45^{\circ}$  and move it fully to the right (as indicated by the arrow).



Lower the tray so that the tabs indicated in the figure slide into the slots, and move it with your hands following the slots (see figure).



Inclined tray position: automatic bag production.





#### 4.4. FITTING THE PAPER ROLL

- Fit the paper roll onto the paper roll tube;
- Place the tube with the paper roll on the housings in the supports (as described in the paragraph above), oriented in such a way that the paper strip unwinds from the top and the polypropylene film is visible;
- Finally, fit the centring devices so that they sit against the paper roll.



#### 4.5. BAG CONTAINER ASSEMBLY

Take the bag container out of the packaging, fully open it and assemble it following the folds (see the figures).

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Fasten the bag container to the heat sealing machine as shown in the figure.



Finally, refit the tray in inclined position.



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A

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#### 5. MANUAL MODE

#### 5.1. PREPARATION (SAME AS FOR AUTOMATIC OPERATION MODE)

For manual bag production, you need to arrange the tray in horizontal position (see paragraph 4a).

- Turn on the machine with the switch (A) found on the rear of the machine.
- The front green LED (B) flashes.
- The heating element is powered and the temperature gradually increases.
   When it reaches the optimal value for proper sealing, the front green LED stays on permanently emitting an acoustic signal.



#### 5.2. INSERTING THE PAPER

- The pushbutton panel will not be operational until the machine has reached the operating temperature.
- Feed the edge of the paper (D) into the rear slot (C) taking care to rest it on the rubber-coated roller.
- Holding the edge of the paper (D) in place, feed the paper forward by pressing the button 🙆 (value up).
- Using the buttons 🚺 (value up) and 💟 (value down), pull out the paper for the desired length.
- It is advisable to prepare a bag that fits the length of the instrument plus 8 cm to allow proper sealing of the edge.



### 5.3. SEALING ONE END AND CUTTING

- Pull out the paper for the desired length.
- Press the button (sealing and cutting) to seal and cut.
- The green LED flashes for the time required to seal and cut the bag. When the operation is complete, the front LED stops flashing and an acoustic signal indicates the end of the process. The bag is now sealed at one end.



5.4. RESUMING AND FINISHING THE BAG (SAME AS FOR AUTOMATIC OPERATION MODE)

AUTOMATIC MODE

6.1. MEMORY SETTING

- Raise the arch of the extractor (C).
- Insert the instrument on the open side of the bag observing the warnings given under "Preparing the material" (see Section 7).
- Insert the unsealed end of the bag in the front slot (A) for a few centimetres until the end of the bag is aligned with the upper slot (B).
- press the button (Sealing) to seal the bag.
- Wait for the acoustic signal and extract the completely sealed bag.



- The paper length adjustment warning light comes on.

Pull out the paper to the desired length based on the indications displayed, using the buttons (value up) and (value down).

THE MAXIMUM LENGTH OF THE BAG IS 50 cm

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of ba	LED indicating that the number of bags has been memorised comes on Set the nugs using the buttons (value up) and (value down).
	NOTE THE MAXIMUM NUMBER OF BAGS SETTABLE IS 99.
the n	s one of the two buttons $(P1)$ or $(P2)$ depending on which one of the two memories you wish to nachine automatically and independently reproduces the memorised program associated wit bination set (number and length of bags).
Ð	NOTE YOU CAN USE 2 ROLLS OF THE SAME WIDTH SIMULTANEOUSLY.
1)	NOTE THE MACHINE IS SUPPLIED WITH TWO PRESET VALUES ASSOCIATED WITH THE BUTTONS P1 AND P2.
R P	NOTE THE MEMORIES SET BY THE USER REMAIN SET EVEN AFTER THE MACHINE HAS BE TURNED OFF.
rð.	NOTE THE MEMORIES SET BY THE USER REMAIN SET EVEN AFTER THE MACHINE HAS BE

#### 6.2. RECALLING FROM MEMORY

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7.	PREPARING THE MATERIAL	The sterilization process may be considered effective, reliable and repeatable provided that the instruments and the materials in general are first appropriately treated and then correctly positioned in the sterilization chamber. These requirements shall be observed in particular when handling <u>bagged items</u> .
		It should be stressed that organic residues or deposits of substances used in medical practice are inevitably receptacles for microorganisms and may thwart the steam sterilization process.
		Incorrectly arranging the load makes it difficult and sometimes impossible for the steam to circulate on the material and/or to penetrate the cavities with inevitable consequences.
		We therefore provide some <u>basic</u> indications regarding these aspects below, leaving it up to the user to decide how best to operate.
7.1.	HANDLING THE MATERIAL	<ul> <li>In handling and moving contaminated materials, it is advisable to take the following precautions:</li> <li>Always wear rubber gloves of adequate thickness.</li> <li>Wash your hands with a germicidal detergent with the gloves on.</li> <li>Always use a tray to transport the instruments.</li> <li>Never transport the instrument holding them in your hands.</li> <li>Be careful with any sharp or cutting parts to prevent the risk of infections.</li> <li>Separate the items that need not be subjected to sterilization or which are unable to withstand the process.</li> <li>After handling, thoroughly wash your hands still with the gloves on.</li> </ul>
7.2.	CLEANING THE INSTRUMENTS	All the materials and/or instruments to be subjected to sterilization must be thoroughly clean and without any kind of residue (organic and inorganic matter, paper fragments, cotton swabs or gauze, scale, etc.).
		Otherwise, the sterilization process might be ineffective and the sterilizer and the instruments irreparably damaged.
		<ul> <li>For effective cleaning:</li> <li>After use, <u>immediately</u> rinse the instruments under a jet of running water.</li> <li>Separate the instruments by type of material (carbon steel, stainless steel, brass, aluminium, chromium, etc.) to prevent oxidoreduction phenomena.</li> <li>Clean the instrument with an ultrasound device containing a mixture of water and disinfectant solution, carefully following the manufacturer's recommendations.</li> <li>Thoroughly rinse and check that they are perfectly clean; if necessary, repeat the washing cycle or clean the instruments by hand.</li> <li>Dry them thoroughly.</li> </ul>
		Before sterilization, consult the instructions provided by the manufacturer of the instrument/material and check for any incompatibility.
		Strictly follow the operating procedures of the detergent or disinfectant products and the instructions for use of the instrument washing and automatic lubrication devices.
7.3.	PACKING AND POSITIONING THE LOAD	Using paper bags for autoclaves allows optimal sterilization and preservation of the sterility conditions over time.
		Follow these guidelines:
		<ul> <li>Bag the instruments individually or make sure that they are made of the same material.</li> <li>Close the bag using the heat sealing machine.</li> <li>Do not use metal stitches, pins or similar that do not guarantee sterility over time.</li> <li>Arrange the bags in such a way as to prevent the formation of air pockets that hinder correct steam penetration and removal.</li> <li>If possible, arrange the bags vertically using a suitable support.</li> <li>Never lay the bags over each other.</li> </ul>

#### **APPENDIX A - TECHNICAL FEATURES**

#### SUMMARY TABLE

Device	Heat sealing machine
Model	Millseal+ evo
Manufacturer	Mocom s.r.l. Via Saliceto, 22 40013 CASTEL MAGGIORE (BO) - ITALIA
Power supply voltage	220-240 V~
Mains frequency	50-60 Hz
Mains fuses (5 x 20 mm)	T 3.15 A - 250V
Nominal power	150 W
Insulation class	Class I
Installation category (IEC 61010-1)	Cat. II
Operating environment (IEC 61010-1)	Indoors
	Temperature: +15°C TO +35°C
Ambient operating conditions	Relative humidity: 80% (max), without conden- sate
Outside dimensions (without roll) (L x D x H)	474 x 374 x 200 mm
Net weight	8.5 kg
Sealing type	Continuous cycle at constant temperature
Heating element nominal operating temperature	180°C
Sealing band height	12 mm
Maximum sealing width	300 mm
Sealable material	Paper/polypropylene laminates
Maximum roll diameter	200 mm
Maximum roll width	300 mm
Paper/polypropylene laminate orientation	Polypropylene film facing up

The identification data label is applied at the base of the machine.

#### SAFETY DEVICES

The heat sealing machine is equipped with the following safety devices. A brief description of these devices and their function is given below:

- **Mains fuses** (see the data in the summary table). Machine protection against internal electrical faults. Action: power failure.
- Finger-trap prevention design.
   Protection against accidentally finger trapping during operation.
- Automatic Stand-By system.

When the machine has not been used for 30 minutes, it goes into standby mode, reducing the temperature of the heating element. The automated device protects against the risk of overheating caused by failing to turn off the machine

after use and at the same time saving considerable energy.

- Protected cutting blade.
   Exclusive design with a cutting blade totally inaccessible from the outside.
- Paper repositioning system.

The paper edge is moved back from the sealing area 10 seconds after positioning, if the button is not pressed. This prevents overheating with consequent paper deformation if you unintentionally leave the machine during the sealing and cutting operation.

#### **APPENDIX B - MAINTENANCE**

#### GENERAL

The machine does not need any particular maintenance; we only recommended that the user regularly clean it.

Always strictly follow the procedures given below.

If replacing parts of the machine, order and use ONLY GENUINE SPARE PARTS.





Clean the outside of the machine with a soft cotton cloth moistened with water and neutral detergent.

	ļ	NOTE
		NOTE - DO NOT USE PRODUCTS CONTAINING ISOPROPYL ALCOHOL (2-PROPANOL, ISOPROPANOL);
		- DO NOT USE PRODUCTS CONTAINING SODIUM HYPOCHLORITE (BLEACH); - DO NOT USE PRODUCTS CONTAINING PHENOLS.
L		- Bo Nor Beer Robboro Bonnaining Thended.

Thoroughly dry the surfaces and remove any resistant residue.

Always bear the following general warnings in mind:

- Do not clean the machine with direct jets of pressurised or sprayed water. Any infiltration into internal electrical components might irremediably compromise its functioning.
- Do not use abrasive sponges, metal brushes (or other aggressive materials) or metal cleaning products (both solid and liquid).

Regularly, or whenever you notice difficulties in cutting the paper, replace the blade. Contact the Technical Service.

Regularly, or when you notice imperfect sealing, replace the silicone sealing counter-element. Contact the Technical Service.

The fuses are housed in the fuse carrier compartment, above the power cable socket.

- Pull out the power plug.
- Remove the fuse carrier using a screwdriver.
- Replace the fuse with one of the same kind (see Appendix A).



In accordance with Directives 2002/95/EC, 2002/96/EC and 2003/108/EC, regarding reduced use of dangerous substances in electrical and electronic devices as well as waste disposal, do not dispose of the devices in the household waste but collect them separately. When individually purchasing a new machine of an equivalent type, the machine that has come to the end of its lifetime should be returned to the dealer for disposal. As regards reuse, recycling and other forms of recovery of the above mentioned waste, the manufacturer carries out the functions defined in the individual national legislations.

Appropriate separate waste collection for subsequent machine recycling, reatment and disposal respectful of the environment contributes to preventing possible negative effects on the environment and health and encourages recycling of the materials which make up the machine. The crossed-out bin symbol on the device indicates that the product must be collected separately from other waste at the end of its useful life.



#### CLEANING

**REPLACING THE CUTTING** 

SEALING COUNTER-ELEMENT

**REPLACING THE FUSES** 

DISPOSAL AT THE END OF

LIFE

BLADE

**REPLACING THE** 

#### **APPENDIX C - ERROR CODES**

The list of ERROR codes and the relative messages shown on the display are listed in the table below:

CODE	ALARM DESCRIPTION	SUGGESTED SOLUTION
E0	PTC open (at power on) or sealing error (V1.4)	Contact the Technical Service Network
E1	Motor 1 overcurrent error (paper insertion roller)	Check that nothing hinders roller rotation (e.g. paper jammed or wires wound around the roller)
E2	Motor 2 overcurrent error (sealing)	Check that nothing hinders sealing bar closure (e.g. objects inserted in the sealing area).
E3	Motor 3 overcurrent error (paper cutting)	Check that nothing hinders movement of the cutting blade carriage (e.g. jammed paper)
E4	Motor 4 overcurrent error (paper extraction roller)	Check that nothing hinders roller rotation (e.g. paper jammed or wires wound around the roller)
E5	Motor 1 disconnected error (paper insertion roller)	Contact the Technical Service Network
E6	Motor 2 disconnected error (sealing)	Contact the Technical Service Network
E7	Motor 3 disconnected error (paper cutting)	Contact the Technical Service Network
E8	Motor 4 disconnected error (paper extraction roller)	Contact the Technical Service Network
E9	Paper cutting and/or jam error (V1.4)	Check that nothing hinders movement of the cutting blade carriage (e.g. jammed paper)

1P	NOTE CONTACT THE TECHNICAL SERVICE NETWORK PROVIDING THE MACHINE MODEL AND SERIAL NUMBER.
	THIS DATA IS INDICATED ON THE FACTORY PLATE ON THE LOWER PART OF THE MACHINE.

#### **APPENDIX D - TROUBLESHOOTING**

If your heat sealing machine does not function properly, check the following before contacting the Technical Service:

PROBLEM	POSSIBLE CAUSE	SUGGESTED SOLUTION
	The power plug is not inserted in the socket.	Properly insert the plug.
	No power to the power socket.	Check the cause of the power failure and correct it.
The heat sealing machine does not turn on.	The magnetothermal and/or differential switches of the system are off.	Set the switches to ON.
	The mains fuses have burned.	Replace the fuses (see Appendix C - Maintenance).
	The LED is not working.	Contact the Technical Service Network.
	Electronic board faulty.	
	Insufficient pressure in the sealing area.	Contact the Technical Service Network.
Insufficient bag sealing	Silicon rubber profile damaged.	
indunitient bug dealing.	The heating element does not reach the opera- ting temperature.	
Bag difficult to cut.	Blade worn.	Contact the Technical Service Network.
Paper jam during operation.	Paper edge wrinkled.	Turn off the machine, manually remove the paper from the rear, check that no scraps of paper have remained in the sealing area and if so remove them, cut the edge of the damaged paper with scissors, restart the machine and re-insert the paper.
	Fault in the feed system.	Contact the Technical Service Network.
Failed paper extraction.	Arch raised.	Lower the arch.

#### NOTE SHOULD THE PROBLEM PERSIST, CONTACT THE TECHNICAL SERVICE NETWORK INDICATING THE MODEL AND SERIAL NUMBER OF THE HEAT SEALING MACHINE.

THIS DATA IS INDICATED ON THE FACTORY PLATE ON THE LOWER PART OF THE MACHINE.

#### Warning for the operator

WARNING	CAUSE	ACTION
Green flashing LED.	The machine is in the warm-up phase.	Wait for the machine to warm up.
Green LED permanently ON.	The machine is ready for use.	-
The green LED flashes briefly every 5 seconds.	The machine has gone into stand-by after it has not been used for 30 minutes.	Press one of the buttons to restore normal operation.
The red and green LEDs flash simultaneously.	The machine signals a fault in the heating system.	Turn off and restart the machine. If the fault recurs, contact the Technical Ser- vice Network.
The red LED flashes + a beep is sounded.	Action aborted.	
	The button is not enabled.	
The red and green LEDs come on alternately.	Electrical problem.	Turn off and restart the machine. If the fault recurs, contact the Technical Ser- vice Network.
The red and green LEDs are permanently on simultaneously.	Mechanical problem.	Turn off and restart the machine. If the fault recurs, contact the Technical Service Network.