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MELAG
competence in hygiene

Operating Manual

MELA*doc*®

Label Printer



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General notes

Please read this Operating Manual before you start operation of the label printer. The instructions include important information.

Make sure to keep the Operating Manual near to the product.
It represents a component of the product.

About this manual

Symbols used

Symbol	Explanation
	Indicates a situation which if not avoided could entail damage to the instruments, the practice equipment or the device.
	Draws your attention to important information.

Formatting rules

Symbol	Explanation
see Chapter 2	Reference to another text section within this manual.
Fig. 1/(3)	Reference to a detail in a figure – in the example, to part no. 3 in figure 1.

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1 Description of the device

Intended Use

MELA*doc* serves the:

- Labelling the medical product
- Documentation of the clearance decision
- Traceability

Views



1) Wheel for setting date
2) Release button to open
3) Label ejection
4) Hinged top section
5) Label printing trigger

Figure 1: Side view of the label printer

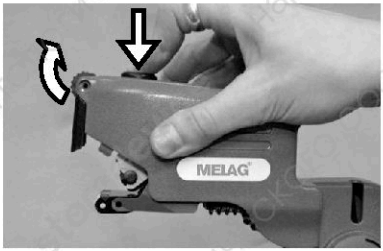
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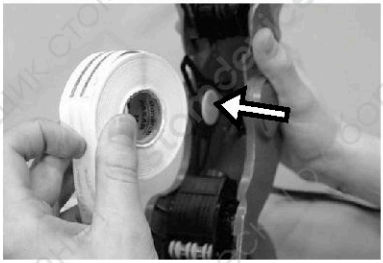
2 Operation

Inserting the label roll

1. Press the black release button located on the housing and open the upper section of the label printer backwards.



2. Remove the new label roll from its packaging.
3. Extend around 18 cm and dispose the first 12 labels.
4. Push the roll into the bracket until it clicks into position.

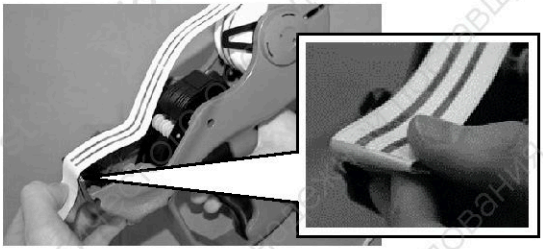


5. Lay the free label strip c. 15 cm over the label guide.
   The first label on the strip must finish directly on the guide.

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6. Kink the label strip and hold it in position whilst closing the top section.

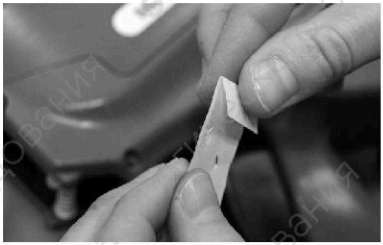


7. Close the label printer. Hold it in position to avoid the label strip from being pulled back into the inside and being slipped to the sides.



8. Kink the free end of the label strip downwards.

   This makes it easier to feed the free label strip into the label printer as will be described.



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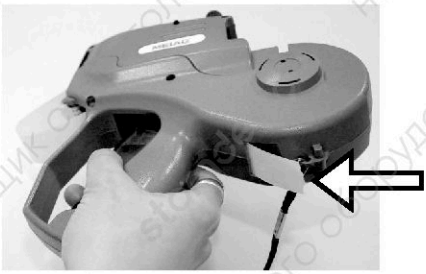
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9. Guide the hanging label strip below into the opening of the lower shaft located underneath the white guide roll and push in as far as is possible.



10. Press the trigger repeatedly, until the strip has been fully taken in and has left the rear shaft.

    Continue pushing the label strip if necessary so that the label feed grabs.



11. Remove the first printed label issued from the guide. It will have been printed over several times.

    The label printer is now ready to print.

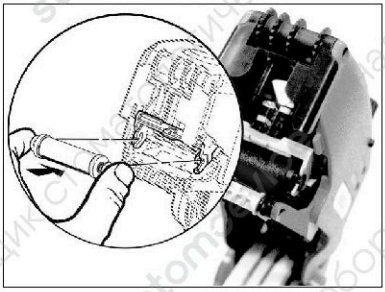
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Inserting the inking roller

1. Remove the new label roll from its packaging.
2. Hold the inking roller horizontal by its ends as depicted.
3. Insert the inking roller in the bracket using a little pressure until it clicks.



PLEASE NOTE

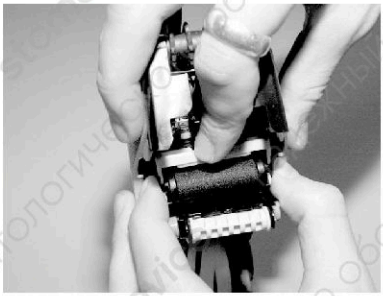
Do not touch the inking roller at any point other than at its both ends. Otherwise, the ink will colour.

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Removing the inking roller

1. Open the label printer as described above.
2. Hold the inking roller horizontal by its ends as depicted.



3. Depress the lever-shaped ejector button with the small arrow. This releases the ends of the inking roller from its anchoring and it can be removed.
4. Dispose the inking roller in the domestic waste.

Setting the date

1. Pull out the setting wheel to change the personal number, date etc.



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2. Move the marker to the position to be changed.
3. Turning the black wheel to set the desired value.
4. After having set the value, return the wheel to its starting position.

Removing jammed labels

1. Open the label printer as described above.
2. Remove all loose labels in the interior of the label printer.
3. Open the label guide upwards. In this way you can access and remove the jammed labels.



4. Shut the label guide.
5. If necessary use a commercial label remover to remove adhesive residues.
6. Return the label roll into the label printer.

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3 Batch clearance and documentation

Batch clearance

Instrument preparation ends with the documented clearance for storage and use (according to RKI: “Hygiene requirements for the treatment of medical products”). The respective clearance decisions may only be carried out by authorized and expert personnel and must be documented.

The clearance procedure consists of the steps:

1. Procedure clearance,
2. Batch clearance,
3. Clearance of the sterilized equipment

Documentation of the procedure clearance

Daily routine inspection and commissioning of steam sterilizers is described in DIN 58946-7.

Visual inspection

Visual inspection of the autoclave chamber, the door seal, door lock, and where necessary, further checks in accordance with the manufacturers instructions.

Inspection of the operating materials

Quality of the feed water, cooling water provision, electricity provision and available output media for the log output.

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Using batch control systems

For further validation of the success of the sterilization procedure we recommend adding batch indicators.

The use of a batch system increases process reliability. The Helix test body (e.g. Helix test body MELA*control*) can be used as batch indicator for "class B" autoclaves.

Batch documentation

Documentation of the batch clearance

The batch clearance ends with the batch documentation and assesses the success of the sterilization procedure.

Documentation of the (daily) procedure clearance is carried out by filling out the batch control sheet, the labels, entries and signature. An unsuccessful clearance must also be documented.

Assessing the success of the process

The success of the sterilization procedure is assessed by the sterilization log or the autoclave display message.

A sterilization log requires written evaluation. The sterilization log can be printed and signed or a label can be affixed to the rear side.

Controlling the batch indicators added

The impossibility of making a certain prediction of the likely appearance of a successfully coloured indicator after five or more years (return discolouration), means that it is necessary to make a written record of the successful colour change. It is not necessary to store the indicators.

Labelling and clearance of the sterilized goods

Every sterilization package must be controlled and cleared after successful sterilization.

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Visual control

The transparent sterilization packaging must be undamaged and dry. The container must be closed securely or sealed with indicator tape, so that any early opening during the storage time can be recognized easily. Also check the labelling of the container (information regarding the contents).

Controlling the treatment indicators

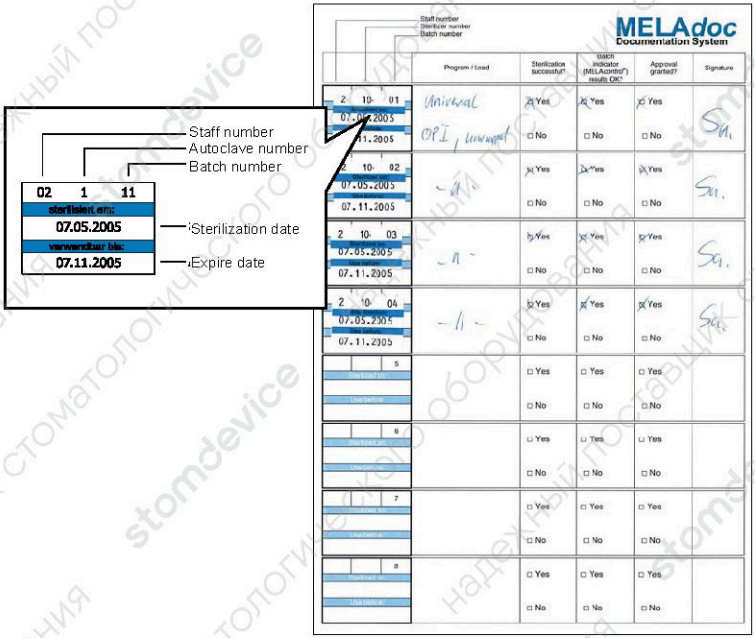
The treatment indicators on the transparent sterilization packaging or the indicator tape used must have coloured successfully.

Labelling the sterile goods

The sterile goods are cleared by adding a label. It is possible that individual items in a batch cannot be cleared e.g. due to damage to the individual transparent sterilization packaging.



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Post-application documentation

After use of the medical product, the labels can be removed from the packaging and fixed to the operation protocol or in the patient records. This enables traceability via the patient records from the application to sterilization process.



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Storage length for sterile medical products

Terms

Sterile barrier system

DIN EN ISO 11607-2:2006 replaces the terms "packaging", "end packaging" and primary packaging" with the single term "sterile barrier system."
A sterile barrier system is the minimum level of packaging facilitating successful sterilization, serving as a micro-biological barrier and permitting aseptic provision.

Protective packaging

The protective packaging is designed to provide the sterile barrier system with protection up until its final application.

Packaging system

The sterile barrier system and protective packaging combine to form the packaging system.

Peel test

A procedure to determine the peeling characteristics of paper/plastic composite material in accordance with DIN EN 868-5, Appendix E.

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Guidelines for the storage period of sterile medical products according to DIN 58953-8 from October 2010

This standard applies to the delivery, storage, commissioning, transport and provision (including the packaging and marking necessary for these ends) of all sterile medical products to be used in healthcare institutions such as hospitals, dental and medical practices.

This standard applies to all medical products delivered in a sterile state and which are to be handled in such a manner so as that their quality is maintained until coming to aseptic application.

According to DIN 58953-8 section 7.1.1, responsibility for compliance with the specified storage requirements and period is lies with the operator of the institution.

According to section 7.2, loss of sterility is dependent less on the length of the storage time as from external influences during storage, as well as transport and handling. An ideal storage time can thus not be generally specified. **Table 1** only makes recommendations regarding the storage length of sterile medical products.

The following requirements apply to the storage of sterile medical products:

- The rooms must be dry, cool and easy to clean.
- The rooms must not be accessible to everyday activity.
- We recommend protected storage in cupboards or drawers.

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Table 1: Storage length for sterile medical products

Packaging type	Storage period	
Sterile barrier system	***Unprotected storage***[1)]	***Protected storage***
Paper bag in accordance with DIN EN 868-4 and heatable, self-sealing transparent bag and tubing of paper and plastic composite film in accordance with DIN EN 868-5, or other equivalent packaging.	Serves provision for immediate use[2)]. Should be avoided as a method of storage.	6 months, not longer than the expiry date
Packaging system (a combination of a sterile barrier system and sterile packaging)	5 years, as far as the manufacturer has not determined an alternative expiry date.	

1) On shelves in rooms which do not correspond with room class 1 as defined by DIN 1946-4:2008-12 (Ventilation and air conditioning).
2) Immediate use means application / use of the product within a maximum of 2 days / 48 hours.

Specification of a suitable storage time is to be taken from the hygiene plan. Responsibility for the storage conditions and length rests with the practice operator.

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MELAdoc
Documentation System

Stamp of practice / Date / Signature of practice owner

Dr. M Baker
Brausebachstraße 35
10829 Berlin
Tel 030-555-555-55
Fax 030-555-555-555

18.09.2006

A few organizational measures are necessary for the operation of MELAdoc equipment in a medical practice. We recommend that you make copies of these forms, fill them out, and hang them in plain view in your practice.

1. Duration of permissible storage time of sterilized objects

Up to 6 months after sterilization, sterilized objects may be stored in our practice and used, under the condition that the following conditions are met:

a) The packages with sterilized objects are stored in a closed cabinet or drawer – or in a separate room for the storage of sterile objects – where they are sufficiently protected from dust and all other forms of contamination.
b) Storage conditions are dry throughout the entire storage period
c) The packaging of the sterile objects is not broken or damaged in any way.

2. Designation of sterilizers

Important: Be sure to designate your systems accordingly if more than one sterilizer is in operation in your medical practice.

Autoclave no.	Type	Manufacturer	Serial number	Remarks
10	Vacuklav30-B	MELAG	0530-B1000	
20	Vacuquick14-B	MELAG	0514-B1000	short cycle
30				
40				
50				

3. Persons who are authorized to provide approval clearance of sterilized items

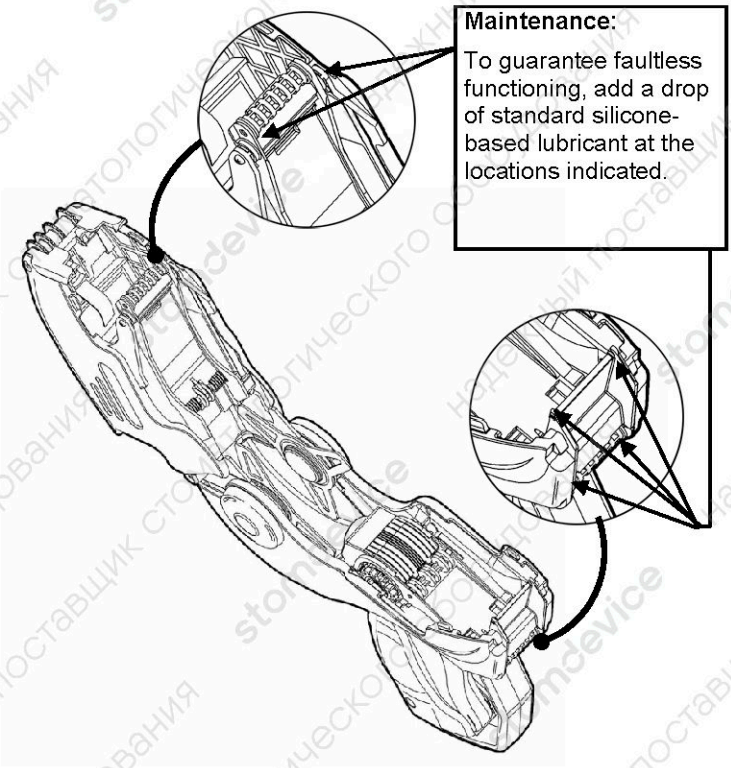
Staff number	Last name, first name	Signature
1	Hawkins, Esmeralda	
2	Summer, Joy	
3	Linley, Sabrina	
4		
5		
6		
7		
8		

Figure 2: Measures for use – example

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4 Maintenance



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5 Appendix – Accessories

Article	Description	Order no.:
MELA*doc* labels	Replacement rolls (6 pcs.) with 750 labels, incl. 1 inker roller	01096
Inker roller	For MELA*doc* label printer	01094
MELA*doc* documentation sheets	MELA*doc* Documentation sheets, 10 blocks à 100 sheets	01091
MELA*control* Batch control system	Consisting of 1 Helix test body and 250 indicator strips	01080

*Exclusively available from a specialist stockist

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MELAG Medizintechnik oHG

Geneststraße 6-10
10829 Berlin
Germany

E-Mail: info@melag.de

Web: www.melag.de

Responsible for content: Technical Office

Subject to technical alterations

Your stockist:

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