MELAG

Operating Manual

MELA*doc* Label Printer

Dear doctor,

With your purchase of MELA*doc*, you have acquired a device which only a few years ago was not to be found in a doctor's or dentist's practice. The majority of your colleagues would doubtless have dismissed it as a "bureaucratic inanity."
The situation has changed fundamentally.

Hygiene standards for doctor's and dental practices have become very strict. It is especially important to observe the recommendations from the Robert Koch Institute "Hygiene requirements for the treatment of medical products," and §4 clause.2 of the Medical Devices Operations Ordinance, which requires that the "operator" (i.e. yourself) "…prepares the instruments in a suitable and validated procedure which ensures its verifiable success…"

Compliance with these requirements will be verified. The Infections Protection Act gives government authorities the right to subject practices to rigorous inspection without any grounds for suspicion. Health authorities, local authorities etc. are making increased use of this right in the form practice inspections, usually announced in advance.

Using MELA*doc* and the corresponding labels means that you are able to label sterile equipment in terms of its sterilization date, expiry date, batch number and clearance of the sterilized product, and enables you to fulfil all the valid legal requirements.

Your MELAG team

Operating Manual MELA*doc* Label Printer

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Contents

Chapter 1 – What does the MELAdoc do?

MELA*doc* serves the: **Documentation of the clearance decision**
Labelling the medical product
Traceability.

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 procedure clearance, batch clearance and clearance of the sterilized equipment.

1. **Documentation of the procedure clearance**
2. **Documentation of the batch clearance**
3. **Labelling and clearance of the sterilized equipment**
4. **Storage**
5. **Post-application documentation**

Documentation of the procedure clearance

Daily routine inspection and commissioning of large steam sterilizers is described in DIN 58946-6:2002. The norm for the operation of small steam sterilizers is currently being formulated. We recommend:

A 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 (automatically with MELAG Euroklav®, Vakuklav® and Cliniklav®25),
- Cooling water provision, electricity provision
- Printer paper

Steam penetration test

- For large steam sterilizers: Bowie&Dick test.
- For small steam sterilizers of the class “B”: Helix test.
- For small steam sterilizers of the class “S”: Follow manufacturer’s instructions. For the MELAG Euroklav®, you can use a Bowie&Dick test on porous basis of e.g. 3M.

Background: Daily routine inspection using a Bowie&Dick test is described in DIN 58946-6:2002 (operating large steam sterilizers). The norm design for the operation of small steam sterilizers is oriented around the norm for large steam sterilizers. Differing from this, for class “B” autoclaves instead of the Bowie&Dick test, we recommend a Helix test according to EN 867-5.

Documentation of the batch clearance

Batch clearance assesses and documents the success of the sterilization procedure.

Assessing the success of the process

- The success of the sterilization procedure is assessed using the protocol print out, the autoclave display or a software output.
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A log print-out requires written evaluation. The print-out can be signed or a label can be affixed to the rear side.

Controlling the batch indicators added

- The use of an indicator system increases process reliability. The MELA*control*® Helix test body can be used as a batch indicator for class “B“ autoclaves or large steam sterilizers.

Batch indicators can increase reliability. For further validation of the success of the sterilization procedure we recommend adding batch indicators (e.g. MELAcontrol). 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.

Documentation of the (daily) procedure clearance in the batch control sheet, consisting of label, entry and signature.

Labelling and clearance of the sterilized equipment

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

Visual control

- The transparent sterilization packaging must be undamaged and dry. The container must be closed securely or sealed with sterilization 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 sterilization-tape used must have coloured successfully.

Labelling the sterile equipment

- The sterile equipment is 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.

Storage

- **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. When opening the packaging, dust and microorganisms deposited on the packaging during the storage time can fall on the instruments, thus contaminating them. An ideal storage time can thus not be generally specified.

- **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.

-

- **Damage to the sterilization packaging** usually follows isolated events and is not a factor of time. Primary and secondary packaging may only be opened immediately prior to use. Remove all dust on the packaging before doing so.

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- **Primary packaging** is the sealed packaging system surrounding the medical product and holding it sealed from all germs (DIN EN 868-1:1997-05).

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- **Secondary packaging** is the packaging containing one or more medical products, each of which enclosed in its own primary packaging (DIN EN 868-1:1997-05).

- **Responsibility** for maintaining the specified storage requirements and times rests with the facility operator.

Storage length according to DIN 58953-8 from October 2003:

Sterilized material packaging	**Packaging type**	**Storage period**	
		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.	Sterilized material in primary or secondary packaging	Serves provision for immediate use.[2] To be avoided as method of storage	6 months, although no longer than expiry date[3]

1) On shelves in rooms which do not correspond with room class 1 as defined by DIN 1946-4 (Ventilation air conditioning) 1999-03, table 2

2) Immediate use means application / use of the product within a maximum of 2 days / 48 hours.

3) Experience has shown that exceeding the storage period when using this type of package is not to be recommended for both practical and economical reasons.

Chapter 2 – Batch documentation

Batch documentation completes the batch clearance.

The documentation in the batch control sheet is to be completed with a label, entries and a signature. An unsuccessful clearance must also be documented.

Staff number
Sterilizer number
Batch number

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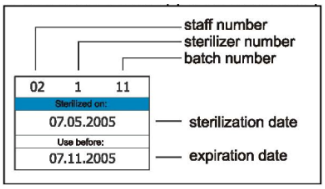
2 10 01 / Sterilized on: 07.05.2005 / Use before: 07.11.2005	Program / Load	Sterilization successful?	Batch indicator (MELA*control*®) results OK?	Approval granted?	Signature
	Universal OP I, unwrapped	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No	Su.
2 10 02 / Sterilized on: 07.05.2005 / Use before: 07.11.2005	- " -	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No	Su.
2 10 03 / Sterilized on: 07.05.2005 / Use before: 07.11.2005	- " -	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No	Su.
2 10 04 / Sterilized on: 07.05.2005 / Use before: 07.11.2005	- " -	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No	Su.
5 / Sterilized on: / Use before:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
6 / Sterilized on: / Use before:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
7 / Sterilized on: / Use before:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
8 / Sterilized on: / Use before:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	

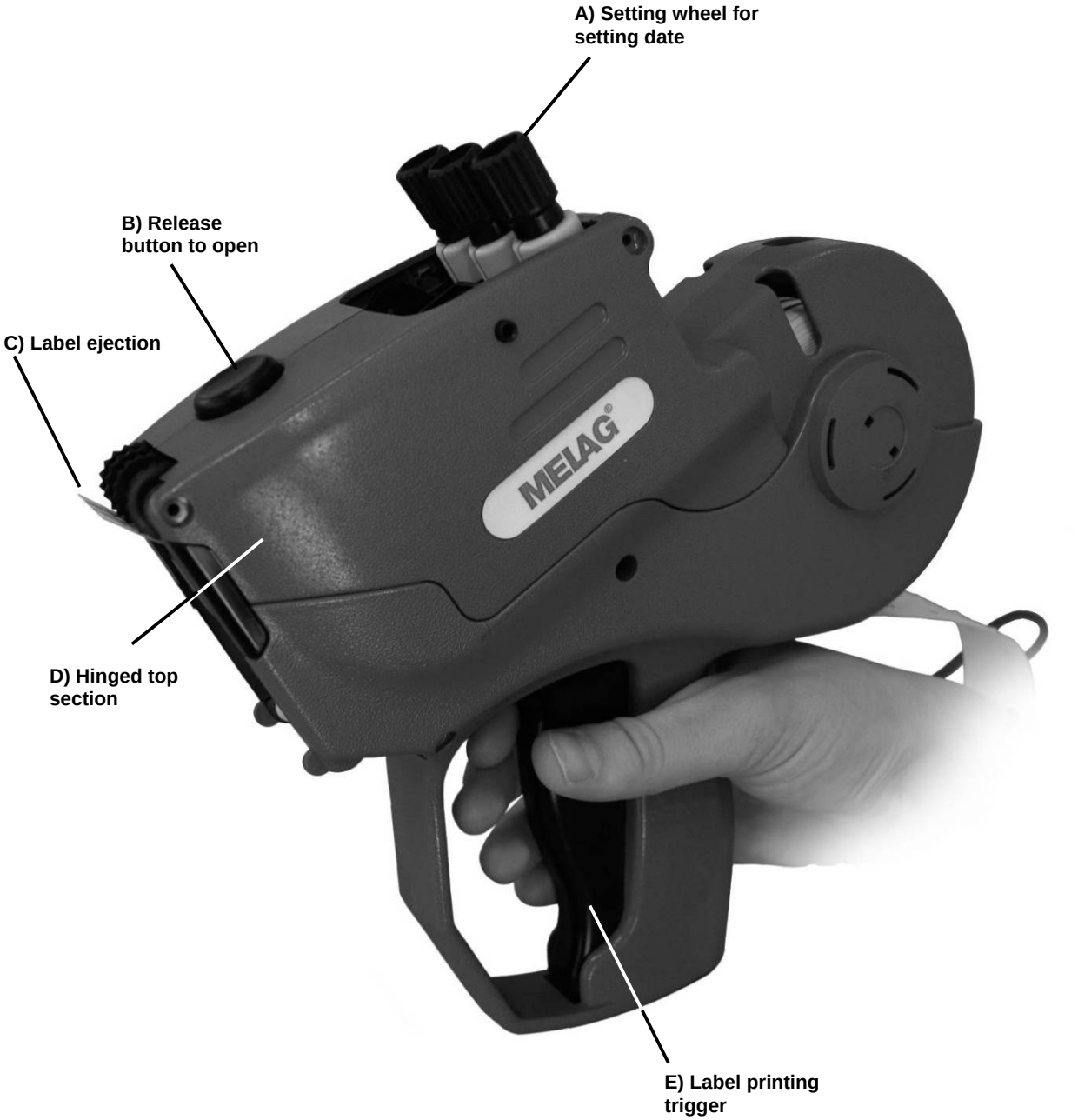


Post-application documentation

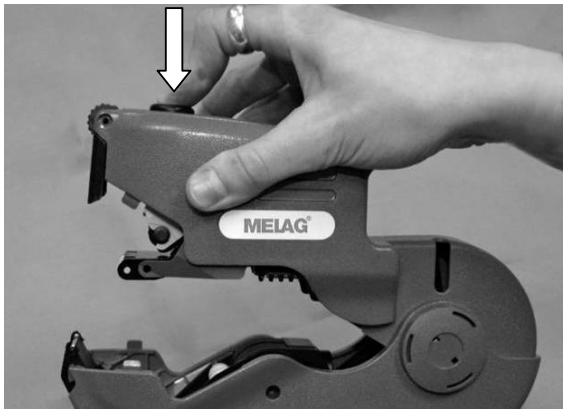
After use of the medical product, the labels can be removed from the packaging and fixed to the operation protocol or in the patient records. This enables traceability via the patient records from the application to sterilization process.

Chapter 3 – Commissioning

Overview – Assembly of the label printer

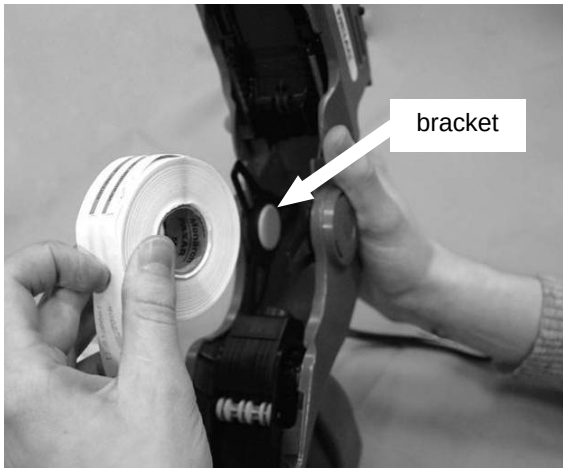


Inserting the label roll



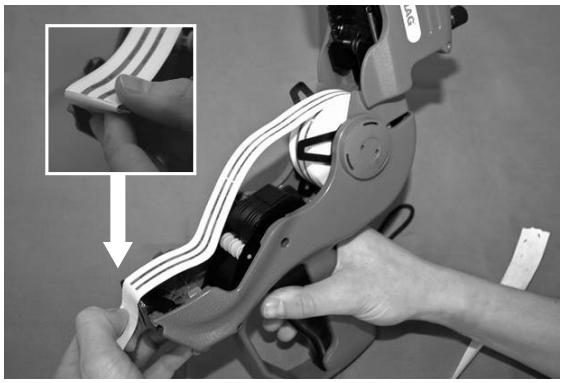
Opening the label printer

Press the black release button (see page 8, overview, B)) located on the housing and open the upper section of the label printer backwards.



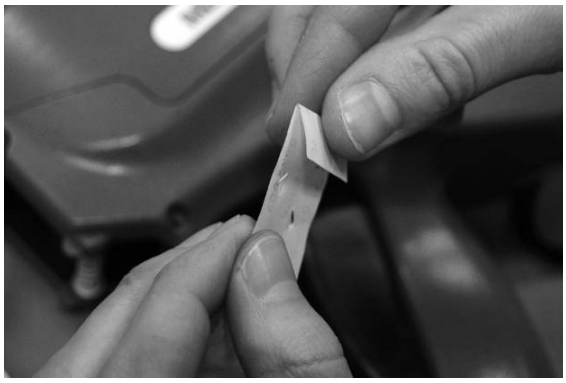
Inserting the label roll:

1. Remove the new label roll from its packaging; extend around 18 cm and dispose of the first 12 labels.
2. Push the roll into the bracket until it clicks into position.



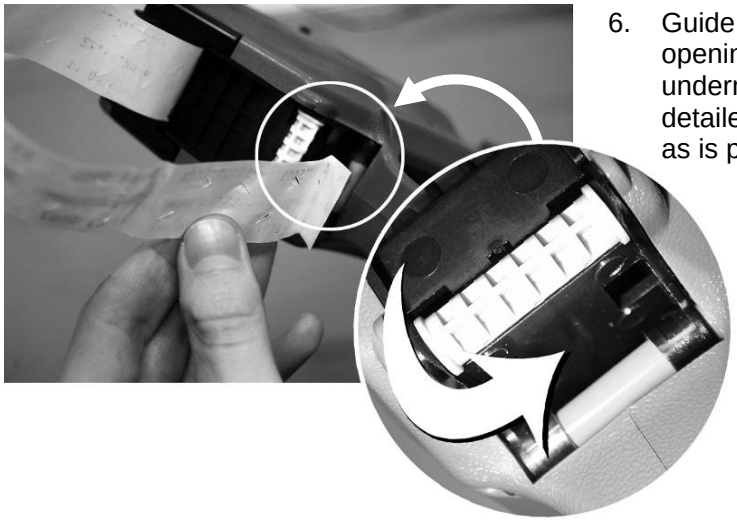
3. Lay the free strip over the label guide and extend it c. 15 cm. The first label on the strip must finish directly on the guide. To ensure an improved grip at this point, kink the strip (see detail left) and hold it in position whilst closing the top section.

4. Close the label printer. Ensure that the strip is held in position so that it is not pulled into the machine. This is important to ensure faultless central pressure.



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

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



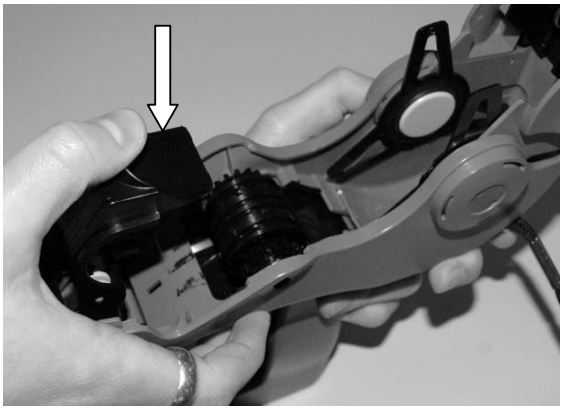
6. Guide the hanging strip below into the opening of the lower shaft located underneath the white guide roll (see detailed diagram left) and push in as far as is possible.

7. Press the trigger (page 8, overview, E)), until the strip has been fully taken in and has left the rear shaft (see diagram left).

   The label strip may require feeding by hand so that it is drawn in.

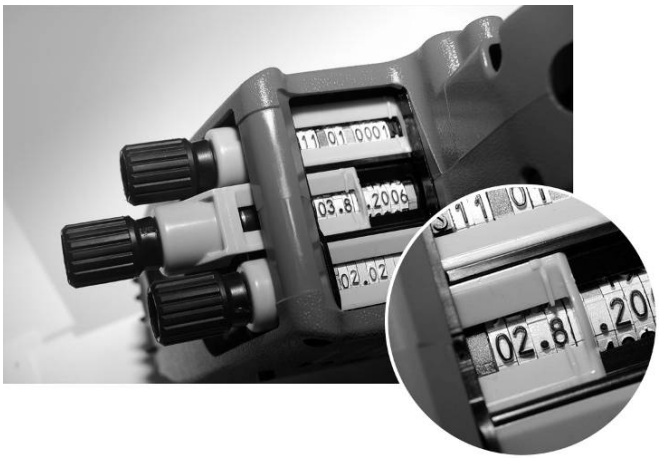
8. The first printed label issued from the guide needs to be removed. It will have been printed over several times. The MELA*doc* is now ready to print.

Removing jammed labels



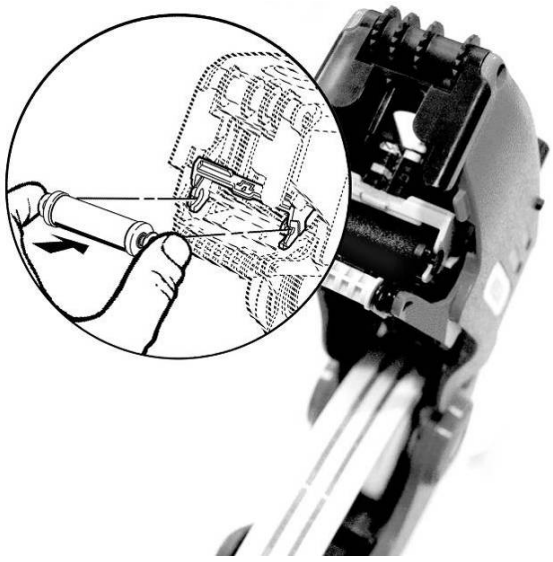
1. Open the MELAdoc (see page 9, Opening the label printer) and pull out the label roll.
2. Remove all loose labels in the interior of the label printer.
3. Open the label guide upwards and to the left as shown in the diagram on the left. In this way you can access and remove the jammed labels.
4. Shut the label guide.
5. If necessary, use a standard label remover to remove adhesive residue.
6. The label roll can then be returned to the MELA*doc* label printer.

Setting the date



7. Pull out the setting wheel to change the personal number, date etc.
8. Move the marker (see detailed diagram) to the position to be changed. Turning the black wheel sets the desired value.
9. After having set the value, return the wheel to its starting position.

Inserting the inking roller



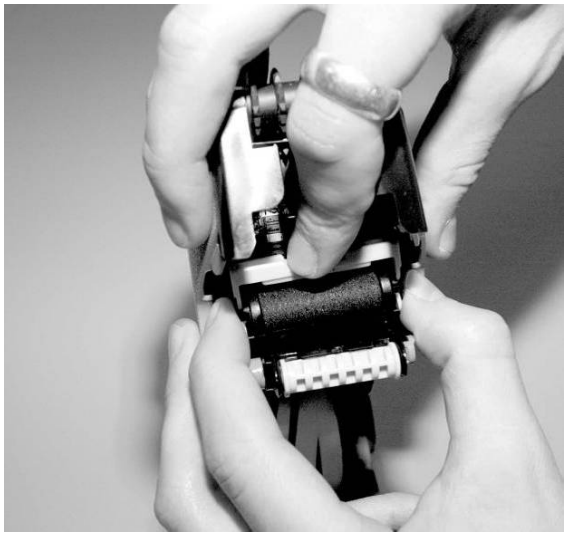
Open the device to insert the inking roller (see page 9, **Opening the label printer**)

1. Open the packaging of the inking roller and remove it.
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.

ⓘ Note!

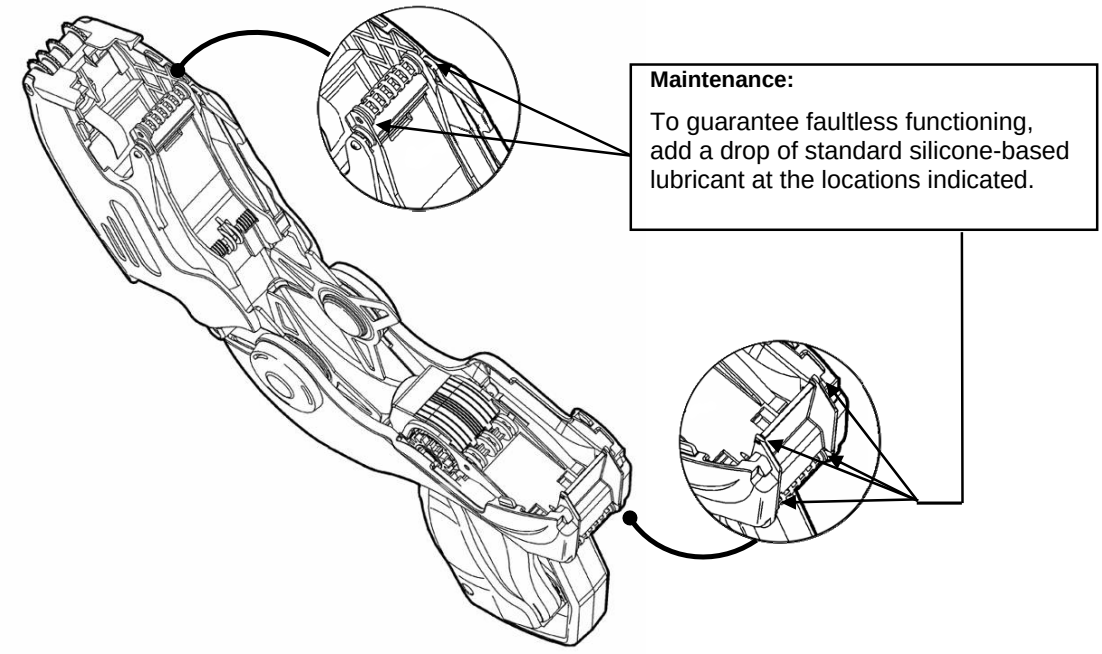
Do not touch the inking roller at any point other than at its both ends. Otherwise, the ink will colour.

Removing the inking roller



Before removing the inking roller, it is necessary to open the label printer.

1. Open the MELA*doc* label printer as described above.
2. Hold the inking roller by its ends as depicted. 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.
3. The empty inking roller can be disposed as domestic waste.



Measures for use - example

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Stamp of practice / Date / Signature of practice owner

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10829 Berlin
Tel: 030-555-555-555
Fax: 030-555-555-555

01.05.2005
Dr. Bauer

A few organizational measures are necessary for the operation of MELA*doc* 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.

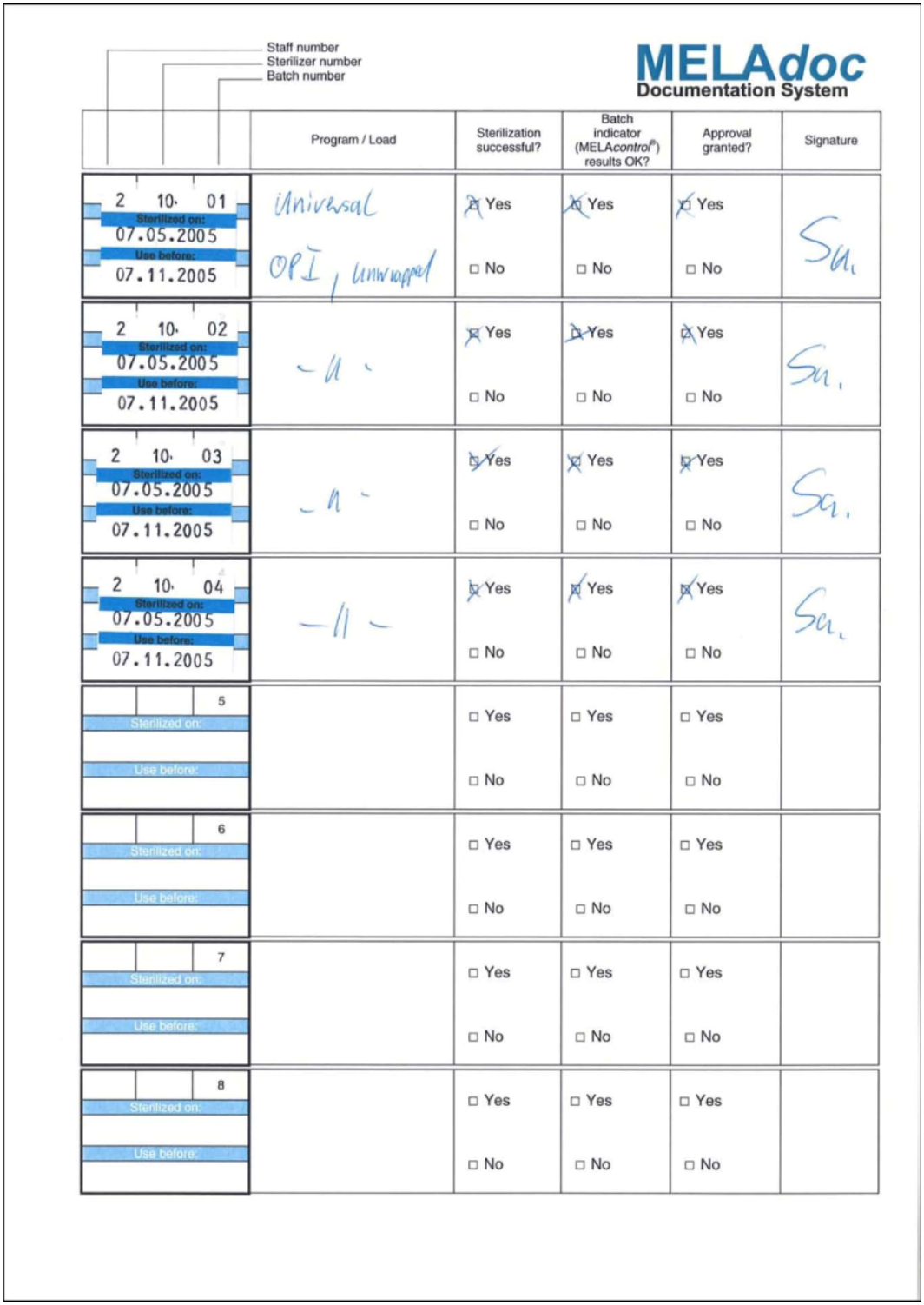
2. Designation of sterilizers

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	Hawkins
2	Summer, Joy	Summer
3	Linley, Sabrina	Linley
4		
5		
6		
7		
8		



Staff number
Sterilizer number
Batch number

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Staff number / Sterilizer number / Batch number	Program / Load	Sterilization successful?	Batch indicator (MELAcontrol®) results OK?	Approval granted?	Signature
2 10 01 Sterilized on: 07.05.2005 Use before: 07.11.2005	universal OPI, unwrapped	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No	Sm.
2 10 02 Sterilized on: 07.05.2005 Use before: 07.11.2005	-"-	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No	Sm.
2 10 03 Sterilized on: 07.05.2005 Use before: 07.11.2005	-"-	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No	Sm.
2 10 04 Sterilized on: 07.05.2005 Use before: 07.11.2005	-"-	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No	Sm.
5 Sterilized on: Use before:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
6 Sterilized on: Use before:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
7 Sterilized on: Use before:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
8 Sterilized on: Use before:		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	

Glossary

Bowie&Dick test
Checks and simulates the steam penetration of a 7kg textile package. A load of this size is usually not permitted for small steam sterilizers Moreover, experience shows that small steam sterilizers are more often used to sterilize hollow articles than textiles. Of greater practical relevance for hollow bodies is verification using a steam penetration test (Helix test). The Helix test sets greater requirements for the autoclave than the Bowie&Dick test. For the Helix-Test, MELAG recommends the
MELA*control*® (Article No. 01080).

Vacuum test
In accordance with DIN 58946-6:2002, this test must be carried out for large steam sterilizers on a monthly basis, as far as the manufacturer has not prescribed shorter test intervals (e.g. daily). With small steam sterilizers, this test only serves the purpose of trouble shooting when errors occur (e.g. upon a failed Helix test). As long as the manufacturer has not issued any further specifications, the test should not be performed on a daily basis.

Empty chamber sterilization
This procedure removes any condensate remaining in the steam conduits of a large steam sterilizer from the previous day. This also serves to pre-warm the sterilizer. Whether empty chamber sterilization is necessary is determined by the respective manufacturer. MELAG autoclaves do not require empty chamber sterilization.

Indicators
The impossibility of making a certain prediction of the appearance (return discolouration) of a coloured indicator (Helix test or Bowie&Dick test) after five or more years means that it is necessary to make a written record of the successful colour change. It is not necessary to store the indicators used.

Appendix - Accessories

MELA*doc* labels

6 replacement rolls with 750 labels, including an inking roller (Article No. 01096*).

MELA*doc* documentation sheets

1 block contains 100 sheets. We recommend using a single sheet per day and per autoclave. (Article No. 01091).

MELA*control*® – Batch control system

MELA*control*® is a test system for the purpose of batch control and testing the functioning of the fractionation of a pre-vacuum of a “class B“ autoclave or a MELAG Cliniklav®25 in accordance with EN 867-5.

The practice set consists of 1 test body (Helix) and 250 indicator strips (Article No. 01080*).

*** Exclusively available from a specialist stockist**

www.melag.com