MELAG
competence in hygiene

User Manual

MELA*doc*

Labeller

EN

MELA*doc* Tutorial:

Information about the video tutorial on the back side or on www.melag.com/en/multimedia

Table of contents

1 Description of the device

General notes

Please read this user manual before you start operation of the product. The user manual includes important information.

Make sure that you always have access to digital or printed version of the user manual.

Should the manual no longer be legible, is damaged or has been lost, you can download a new copy from MELAG download centre at www.melag.com.

Safety

- After unpacking the product, check it for transport damage.
- Only use original MELAG consumables and accessories. The use of foreign parts may result in damage and loss of warranty.
- Store and transport the product and its accessories frost-free.
- Store the product and its accessories protected from moisture..

Intended use

MELAdoc serves for:

- labelling the medical product
- documentation of the clearance decision
- traceability

Scope of delivery

Please check the scope of delivery before using the product.

- MELAdoc Labeller
- User Manual
- Label roll
- Ink roller

Views

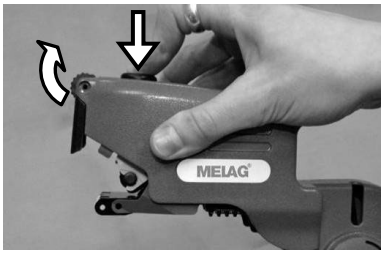
1. Wheel for setting date
2. Release button to open
3. Label ejection
4. Hinged top section
5. Label printing trigger

2 Operation

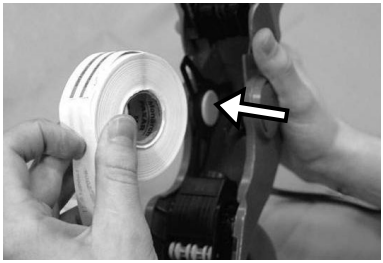
Inserting the label roll

NOTICE
Only use original accessories and consumables. Other accessories and consumables not approved by MELAG may cause functional impairments and damage to the product.

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

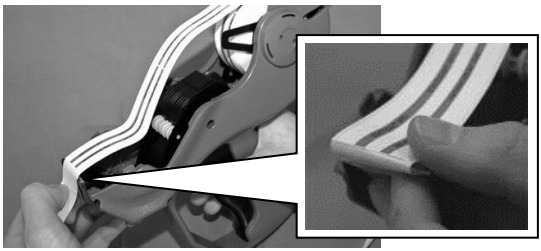


2. Remove the new label roll from its packaging.
3. Extend approx. 18 cm and dispose the first 12 labels.
4. Push the roll into the bracket until it clicks into position.



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

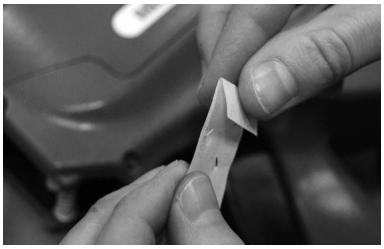
6. Kink the label strip and hold it in position whilst closing the top section.



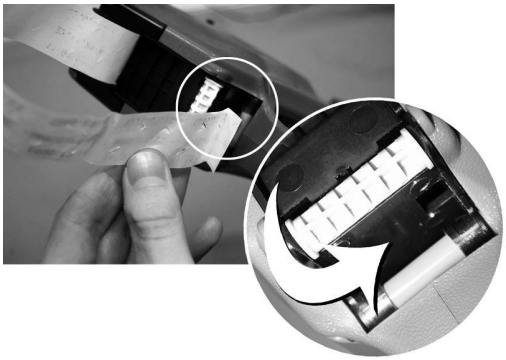
7. Close the labeller. Hold it in position to avoid the label strip from being pulled back into the inside and being slipped to the sides.

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

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



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.

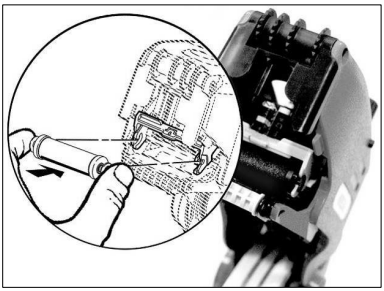
    The labeller is now ready to print.

Inserting the ink roller

NOTICE
Only use original accessories and consumables. Other accessories and consumables not approved by MELAG may cause functional impairments and damage to the product.

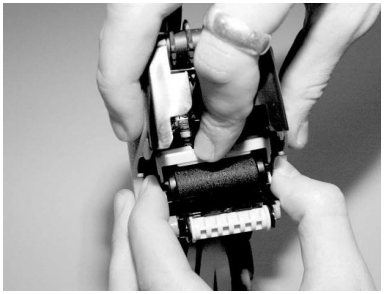
PLEASE NOTE
Do not touch the inking roller at any point other than at its both ends. Otherwise, the ink will colour.

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



Removing the ink roller

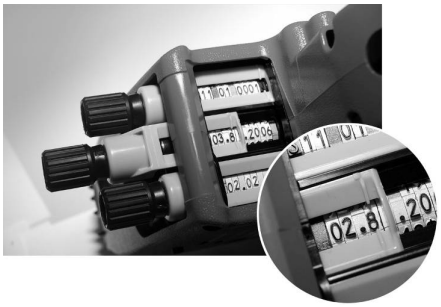
1. Open the labeller as described above.
2. Hold the ink roller horizontal by its ends as depicted.



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

Setting the date

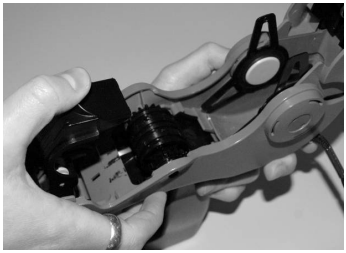
1. Pull out the setting wheel to change the personal number, date etc.



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 labeller as described above.
2. Remove all loose labels in the interior of the labeller.
3. Open the label guide upwards. 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 labeller.

3 Batch approval and documentation

Batch approval

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

The approval procedure consists of the steps:

1. Procedure approval,
2. Batch approval
3. Approval of the sterile material

Documentation of the procedure approval

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

Visual check

Visual check of the sterilization chamber, the door seal, door lock, and where necessary, further checks in accordance with the manufacturer’s instructions.

Inspection of the operating materials

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

Using batch control systems

For further validation of the success of the sterilization procedure MELAG recommends adding batch indicators.

The use of a batch control system increases process reliability. The test body system (e.g. MELAcontrol Helix) can be used as batch indicator for following steam sterilizers:

- steam sterilizers with type “B” cycles
- steam sterilizers with type “B” cycles, of which the scope of supply covers the treatment of hollow bodies
- large steam sterilizers in accordance with EN 285

Batch documentation

Documentation of the batch approval

The batch documentation completes the batch approval and assesses and documents the success of the sterilization.

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

Assessing the success of the process

The success of the sterilization procedure is assessed by the sterilization log or the steam sterilizer 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.

Checking 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 approval of the sterile material

Every single sterilization package must be checked and approved after successful sterilization.

Visual check

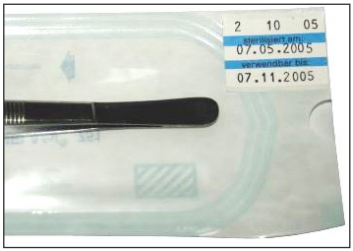
The transparent sterilization package must be intact and dry. The container must be closed securely or sealed with indicator tape, so that any early opening during the storage time can be recognized easily. Also check the labelling of the container (information regarding the contents).

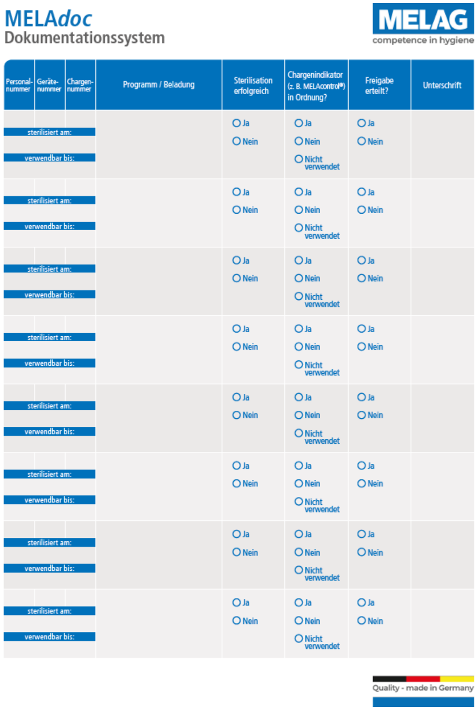
Checking the process indicators

The process indicators on the transparent sterilization package or the indicator tape used must be completely coloured.

Labelling sterile materials

The sterile materials are approved 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 package.





MELAdoc
Dokumentationssystem

MELAG
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Personal-nummer	Geräte-nummer	Chargen-nummer	Programm / Beladung	Sterilisation erfolgreich	Chargenindikator (z. B. MELAcontrol®) in Ordnung?	Freigabe erteilt?	Unterschrift
sterilisiert am: verwendbar bis:				O Ja O Nein	O Ja O Nein O Nicht verwendet	O Ja O Nein	
sterilisiert am: verwendbar bis:				O Ja O Nein	O Ja O Nein O Nicht verwendet	O Ja O Nein	
sterilisiert am: verwendbar bis:				O Ja O Nein	O Ja O Nein O Nicht verwendet	O Ja O Nein	
sterilisiert am: verwendbar bis:				O Ja O Nein	O Ja O Nein O Nicht verwendet	O Ja O Nein	
sterilisiert am: verwendbar bis:				O Ja O Nein	O Ja O Nein O Nicht verwendet	O Ja O Nein	
sterilisiert am: verwendbar bis:				O Ja O Nein	O Ja O Nein O Nicht verwendet	O Ja O Nein	
sterilisiert am: verwendbar bis:				O Ja O Nein	O Ja O Nein O Nicht verwendet	O Ja O Nein	
sterilisiert am: verwendbar bis:				O Ja O Nein	O Ja O Nein O Nicht verwendet	O Ja O Nein	

Quality - made in Germany

Post-application documentation

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

Storing sterile material

The maximum storage time is dependent on the packaging and the storage conditions. Please observe the regulatory requirements for the storage period of sterile materials (in Germany e.g. DIN 58953, Part 8 or the DGSV guidelines) as well as the following listed criteria:

- ✓ *Comply with the maximum storage duration in accordance with the packaging type. Comply with the manufacturer's information on the packaging.*
- ✓ *Do not store the sterile material in the reprocessing room.*
- ✓ *Store the sterile material in a dust-protected environment e.g. in a closed instrument cabinet.*
- ✓ *Store the sterile material in an environment protected against moisture.*
- ✓ *Store the sterile material in an environment protected against excess temperature variations.*

MELAG

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Dokumentationssystem

Für den Einsatz von MELA*doc* müssen in der Praxis organisatorische Maßnahmen getroffen werden.

MELAG empfiehlt von diesen Formblättern Kopien zu machen, diese auszufüllen und sichtbar auszuhängen.

Praxisstempel / Datum / Unterschrift Praxisinhaber

1. Lagerdauer

Das Sterilgut darf bis zu _____Monaten nach der Aufbereitung in unserer Praxis gelagert werden.
Die Verwendung des Sterilguts muss spätestens zum letzten Tag der Lagerfrist erfolgen!

Nach Ablauf der Lagerfrist darf das Sterilgut unter folgenden Bedingungen verwendet werden:

- Das Sterilgut wurde staub- und kontaminationsgeschützt in einem Schrank, einer Schublade oder in einem separaten Lagerraum gelagert.
- Das Sterilgut wurde während der gesamten Zeit trocken gelagert.
- Die Verpackung des Sterilguts ist unbeschädigt.

2. Sterilisatoren

Autoklaven-Nr.*	Typ	Hersteller	Seriennummer	Bemerkung
10				
20				
30				
40				
50				

*Bitte kennzeichnen Sie die Geräte, wenn mehrere Sterilisatoren in der Praxis vorhanden sind.

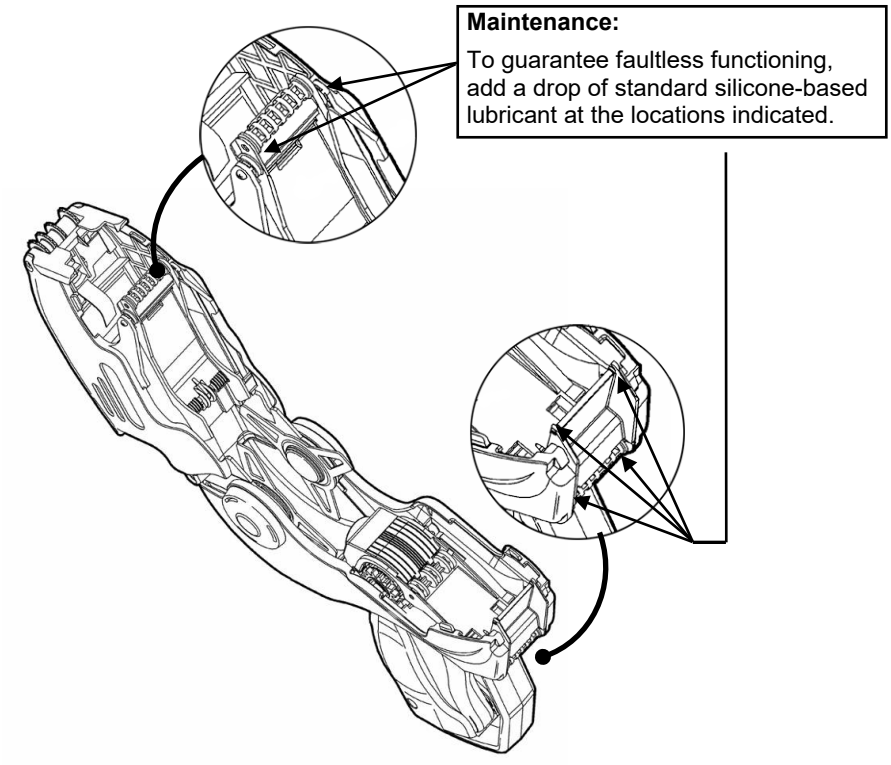
3. Zur Freigabe berechtigte Personen

Personal-Nr.	Name, Vorname	Unterschrift
1		
2		
3		
4		
5		
6		
7		
8		

Figure: Measures for use

The form can be downloaded from the MELAG website (Service/Download Center).

4 Maintenance



5 Appendix – Accessories

NOTICE
Only use original accessories and consumables. Other accessories and consumables not approved by MELAG may cause functional impairments and damage to the product.

Category	Article	Art. no.
Accessories and consumables	MELAdoc labels (DE, 4500 pcs.) incl. ink roller	ME01096
	MELAdoc labels (EN, 4500 pcs.) incl. ink roller	ME01097
	MELAdoc labels (FR, 4500 pcs.) incl. ink roller	ME01098
	MELAdoc labels (IT, 4500 pcs.) incl. ink roller	ME01099
	Ink roller for MELAdoc	ME01094
For the documentation	MELAdoc documentation sheets for steam sterilizer (1000 pcs., in German)	ME01091

Notes

MELA*doc* Tutorial:

Learn how to replace the label roll and ink pad of the label printer.

Please scan the QR code to watch the video on **www.melag.com/en/multimedia**

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Original instructions

Your stockist:

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