

User manual

MELAdoc[®] Labeller



EN

Dear customer,

We thank you for your confidence demonstrated by the purchase of this MELAG product. As an owner-run and operated family concern founded in 1951, we have a long history of successful specialization in hygiene products for practice-based use. Our focus on innovation, quality and the highest standards of operational reliability has established MELAG as the world's leading manufacturer in the instrument reprocessing and hygiene field.

You, our customer are justified in your demand for the best products, quality and reliability. Providing **“competence in hygiene”** and **“Quality – made in Germany”**, we guarantee that these demands will be met. Our certified quality management system is subject to close monitoring: one instrument to this end is our annual multi-day audit conducted in accordance with EN ISO 13485. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

Contents



1 General guidelines	4
Symbols used	4
Formatting rules	4
Disposal	4
2 Safety	5
3 Product description	6
Intended use	6
Scope of delivery	6
Views	6
4 Commissioning	8
Inserting the label roll	8
Removing jammed labels	10
Setting the maximum storage duration and ID	11
Correcting the print position	12
Replacing the inking roller	13
5 Approval and documentation	14
Process approval	14
Batch approval	14
Approval of the sterile material	15
Documentation system	15
Storing sterile material	15
6 Spare parts and consumables	16

1 General guidelines




Please read this user manual carefully before commissioning the product. The manual includes important safety instructions. Failure to comply with the safety instructions can result in injury and/or damage to the product. Use the product only for the purpose specified in these instructions. 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.

Symbols used

Symbol	Description
	Draws your attention to a situation, which if not avoided, could result in damage to the practice fittings or the device.
	Draws your attention to important information.

Formatting rules

Symbol	Description
	Prerequisites for the following handling instruction.
	Refer to the glossary or another text section.
	Information for safe handling.

Disposal

MELAG products are synonymous for long-term quality. When you eventually need to decommission your MELAG product after many years of operation, dispose of it and any spare parts that are no longer used properly.

The packaging protects the product against transport damage. The packaging materials have been selected for their environmentally-friendly and recycling properties and can be recycled. Returning the packaging to the material flow reduces the amount of waste and saves raw materials.

2 Safety



When using the product, comply with the following safety instructions as well as those contained in subsequent chapters. Use the product only for the purpose specified in these instructions. Failure to comply with the safety instructions can result in injury and/or damage to the product.

Commissioning

- After unpacking the product, check it for transport damage.

Normal operation

- Avoid temperatures above 60 °C in order not to change the shape and state of the product.

Storage and transport

- Store and transport the product frost-free.
- Store the product protected from moisture.

3 Product description

Intended use

MELAdoc is used for labelling medical devices, providing documentation and ensuring the traceability of approval decisions.

Scope of delivery

- MELAdoc Labeller
- User manual
- Label roll
- Inking roller

Views

View from the side (right)



- 1 Setting wheels (maximum storage duration and ID)
- 2 Release button (on both sides)
- 3 Label printing trigger
- 4 Label roll cover

View from the front



5 Inking roller cover

View from below



6 Pressure roller
7 Feed roller cover

4 Commissioning

Inserting the label roll



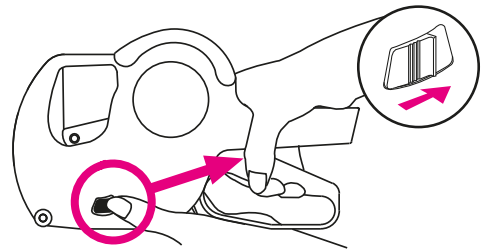
NOTICE

Material damage due to unsuitable consumables

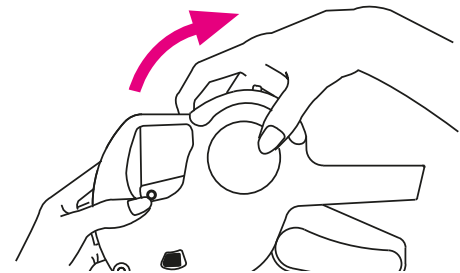
Consumables not approved by MELAG can cause functional impairments and damage to the product.

- Only use consumables approved by MELAG.

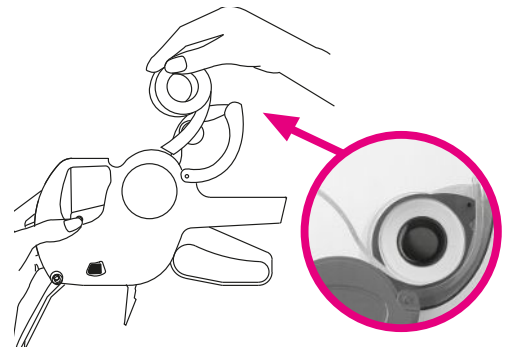
1. Hold the labeller horizontally in one hand.
2. Open the feed roller cover by pulling back both release buttons simultaneously with the other hand.



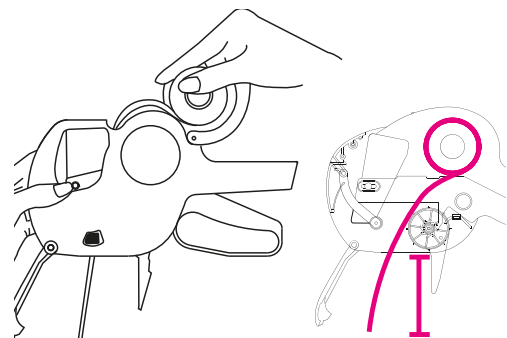
3. Open the label roll cover.



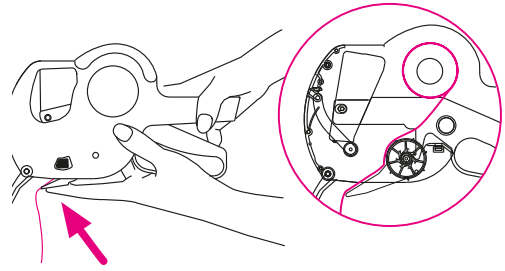
4. Insert a label roll into the cover with the loose end pointing inwards.



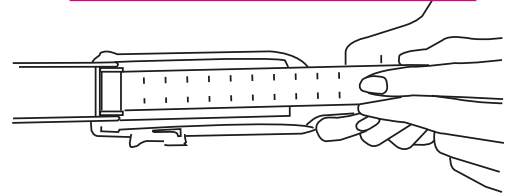
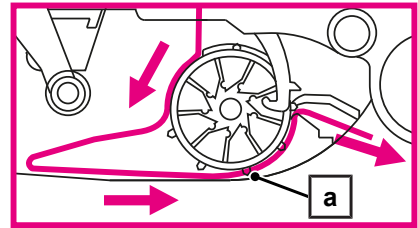
5. Insert the label strip into the inside of the labeller and pull it about 10 cm out of the lower housing cover.



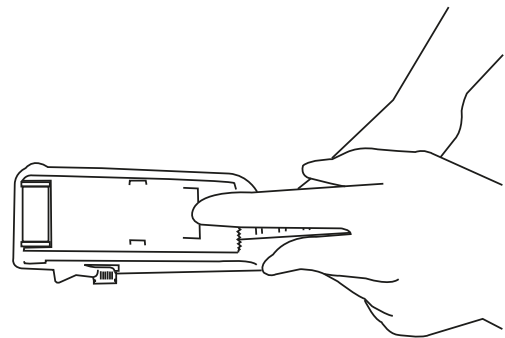
6. Fold in the fixation. You should hear and feel it click into place.



7. Guide the label strip under the feed roller towards the trigger. The holes of the strip must lie on the lugs (pos. a) of the feed roller.

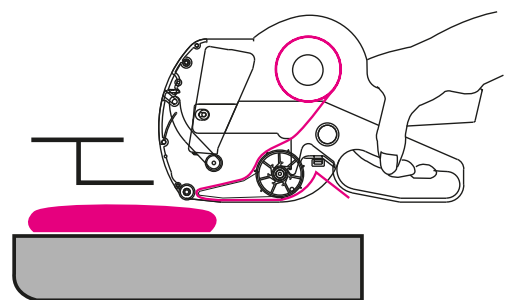


8. Close the feed roller cover. You should hear and feel it click into place. Make sure that the label strip is tight against the feed roller.



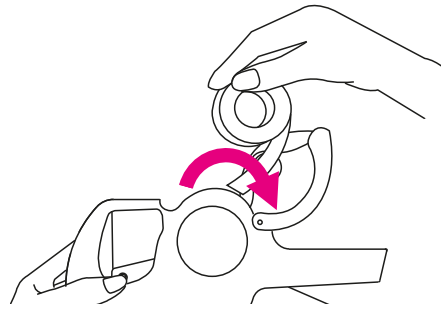
9. Press the labeller trigger three times to adjust the print position on the label strip.

10. Apply the labels to the desired position on the product by pressing the pressure roller onto the product while pressing the trigger.

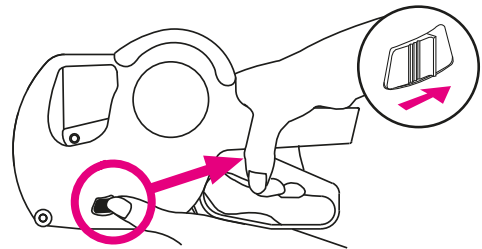


Removing jammed labels

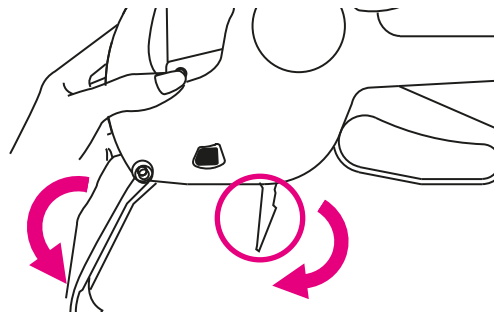
1. Open the label roll cover and remove the label roll.



2. Remove all loose labels in the interior of the labeller.
3. Close the label roll cover.
4. Hold the labeller horizontally in one hand.
5. Open the feed roller cover by pulling back both release buttons simultaneously with the other hand.



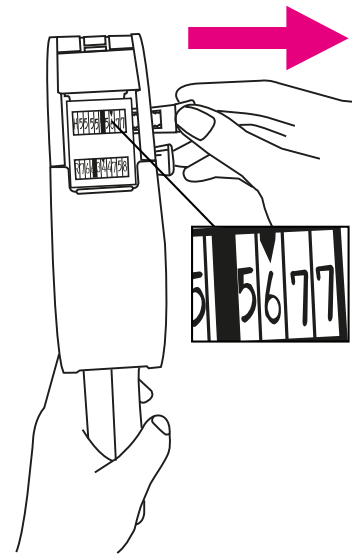
6. Remove all labels that have become stuck in the interior of the labeller.
7. If necessary use a commercial label remover to remove adhesive residues.
8. Fold in the fixation and then close the cover of the feed roller.



9. Insert the label roll into the labeller, see [Inserting the label roll](#) [▶ page 8].

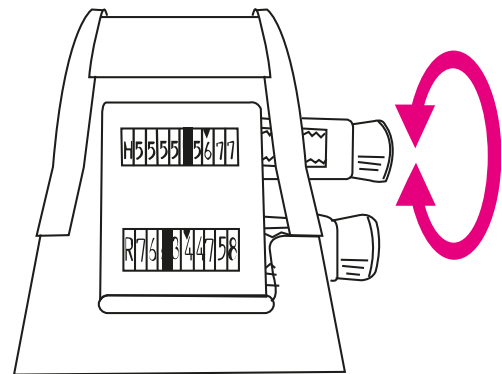
Setting the maximum storage duration and ID

1. Pull out the setting wheels until the small arrow mark points to the number or symbol to be adjusted.



2. Turn the black wheel to set the desired value.

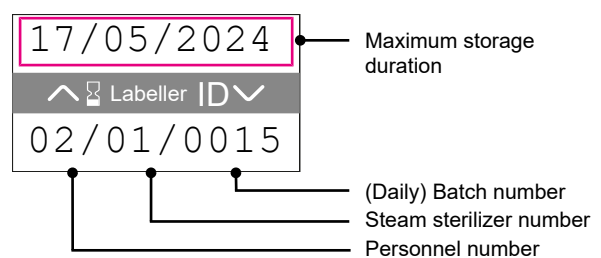
- **Black numbers and symbols on a white background** show the desired arrangement of the individual characters as printed on the label.
- **Black numbers and symbols on a black background** show the mirror-inverted embossing for label printing (must not be visible).
- A **yellow, white or black background without numbers and symbols** shows a blank space.



3. After setting, slide the wheels back to the starting position.

Maximum storage duration

- ▶ Specify the date until when the sterile packed instrument may be used. This allows you to check whether the maximum storage duration has already been exceeded.

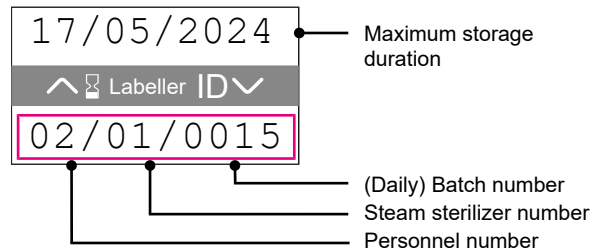


ID

PLEASE NOTE

MELAG recommends taking organisational measures to ensure that all practice employees are aware of the meaning of the ID on the label, see [Documentation system](#) [▶ page 15].

- ▶ Determine the meaning and sequence of the ID yourself. In our example, the coding contains the personnel, steam sterilizer and batch number from left to right.

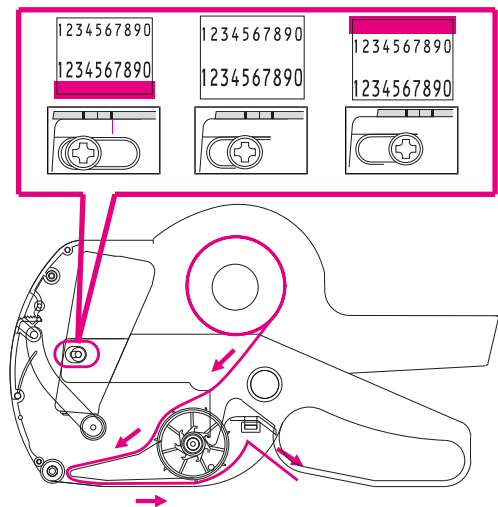


Correcting the print position

PLEASE NOTE

Only change the print position of the numbers and symbols if they are not correctly aligned in the delivery state.

1. Loosen the screws on both sides of the printing unit.



2. Correct the position.
3. Tighten the screws of the printing unit.

Replacing the inking roller



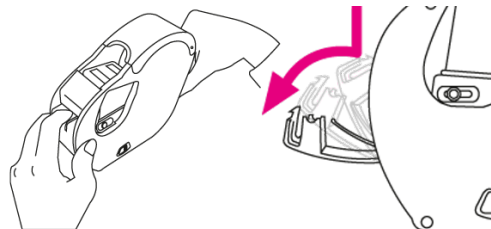
NOTICE

Material damage due to unsuitable consumables

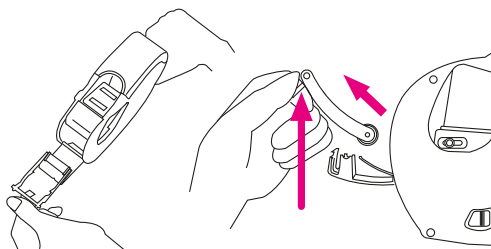
Consumables not approved by MELAG can cause functional impairments and damage to the product.

- Only use consumables approved by MELAG.

1. Fold the inking roller cover downwards.
NOTICE! The ink on the inking roller can cause stains on textiles that cannot be washed out.

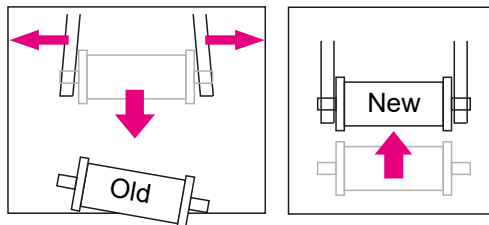


2. Remove the inking roller holder from the cover.



3. Release the old inking roller from the inking roller holder by pulling it out.

4. Insert a new inking roller by pressing it into the inking roller holder.



5 Approval and documentation

Instrument reprocessing ends with documented approval for storage and use (according to RKI¹⁾: “Hygiene requirements for the reprocessing of medical devices”). The respective approval can only be given by authorised and competent personnel.

The approval procedure consists of the steps:

1. Process approval
2. Batch approval
3. Approval of the sterile material

Process approval



PLEASE NOTE

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

Batch approval

Assessing the success of the process

The display on the steam sterilizer or the sterilization log in MELAtrace is used to determine the success of sterilization. A sterilization log requires written evaluation. The documentation sheet for steam sterilizers can be used for this purpose. Labels, entries and signatures are recorded here.

Use and control of batch indicators

For further validation of the success of the sterilization process, MELAG recommends adding batch indicators. The use of a test system (e.g. MELAcontrol Helix) increases process reliability. It can be used as a batch indicator for the following steam sterilizers:

- Steam sterilizers with type B cycles
- Steam sterilizers with type S cycles, of which the scope of supply covers the reprocessing of hollow bodies
- Large steam sterilizers in accordance with EN 285

The batch indicators must have changed colour completely. The successful colour change must be recorded in writing. It is not necessary to store the indicators.

Documentation of batch approval

The batch approval ends with the batch documentation. It documents the success of sterilization and contains the assessment by the specialist personnel.

MELAG recommends the documentation sheet for steam sterilizers (art. no. ME01091) for manual batch approval. For automated batch approval, MELAG recommends the MELAtrace software.

¹⁾ RKI is the abbreviation for “Robert Koch Institute”. The Robert Koch Institute is the central institution for the detection, prevention, and control of diseases, especially infectious diseases in Germany.

Approval of the sterile material

Visual check

After successful sterilization, each individual sterilization package and each individual sterile container must be checked. The transparent sterilization package must be undamaged and dry. The container must be closed securely or sealed with an indicator tape, so that any early opening during the storage time can be recognized.

Checking the process indicators

The process indicators of the transparent sterilization package must have changed colour completely.

Labelling and approval of the sterile material

Every sterilization package must be cleared after successful sterilization. The sterile material is approved by adding a label. It is possible that individual products in a batch cannot be approved, e.g. due to damage to the transparent sterilization package.

Post-application documentation

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

Documentation system

Organisational measures must be taken for the use of MELAdoc so that all practice employees are informed about the meaning of the labeller ID on the label, see [Setting the maximum storage duration and ID](#) [▶ page 11]. MELAG recommends copying the [form provided](#) in the MELAG download centre for your documentation system, filling it in and displaying it publicly.

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.
- 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.

6 Spare parts and consumables



NOTICE

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Consumables not approved by MELAG can cause functional impairments and damage to the product.

- Only use consumables approved by MELAG.

You can obtain the specified articles and an overview of further accessories from your stockist.

Category	Article	Art. no.
Spare parts and consumables	Labels for MELAdoc Labeller (6000 pcs. incl. inking roller)	ME01088
	Inking roller for labeller	ME01069
For the documentation	MELAdoc documentation sheets for steam sterilizers (1000 pcs.)	ME01091



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Original instructions

Responsible for content: MELAG Medizintechnik GmbH & Co. KG
We reserve the right to technical alterations

Your stockist