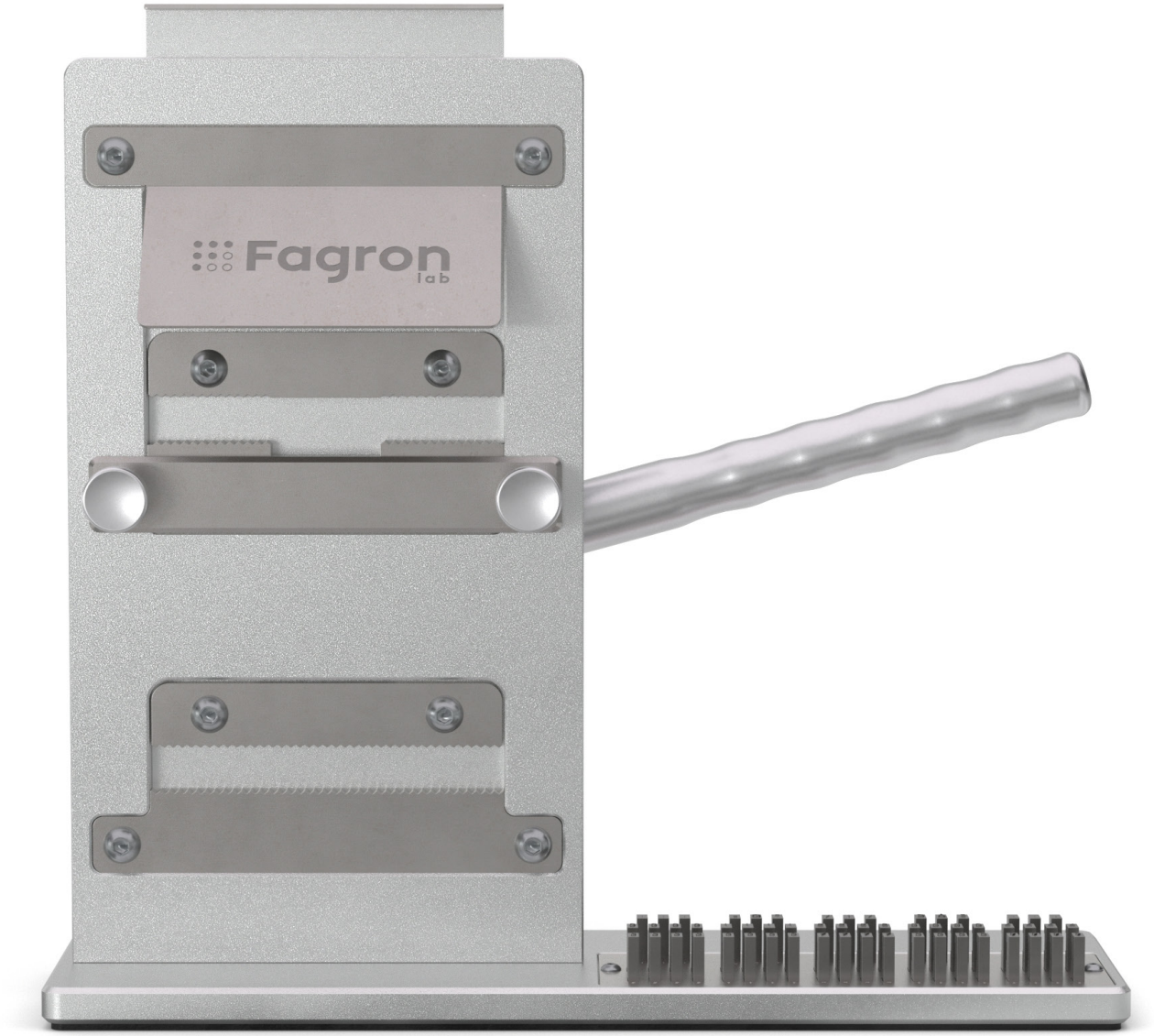


FagronLab™ LEV-Rx™

User Manual

www.fagronlab.com

Fagron lab

Contents

1. Performance and Main Features

FagronLab™ LEV-Rx™ is a versatile, manually operated device designed for compounding pharmacies and small-scale pharmaceutical production. This all-in-one unit combines sealing and embossing functions to provide a professional finish across various packaging formats, including aluminum tubes, blister trays, sachets, and cardboard boxes.

Equipped with an integrated embossing kit, the **LEV-Rx™** enables users to apply critical product information—such as batch numbers, expiration dates, and custom markings—directly onto packaging materials. By ensuring clear, permanent identification, the device supports product traceability, enhances regulatory compliance, and contributes to packaging safety and efficiency.

Features

- Manual, all-in-one device for sealing and embossing
- Designed for compounding pharmacies and small-scale production
- Suitable for aluminum tubes, blister trays, sachets, and cardboard boxes
- Includes standard embossing kit for:
  - Batch numbers
  - Expiration dates
  - Custom markings
- Ensures traceability and regulatory compliance
- Produces a professional, durable finish
- Supports product safety and clear identification

2. Applications

FagronLab™ LEV-Rx™ offers a tailored application designed to meet specific needs, whether for sealing or embossing the selected package. Figure 1 provides a clear overview, illustrating which application is suitable for each type of packaging, ensuring optimal functionality and performance.

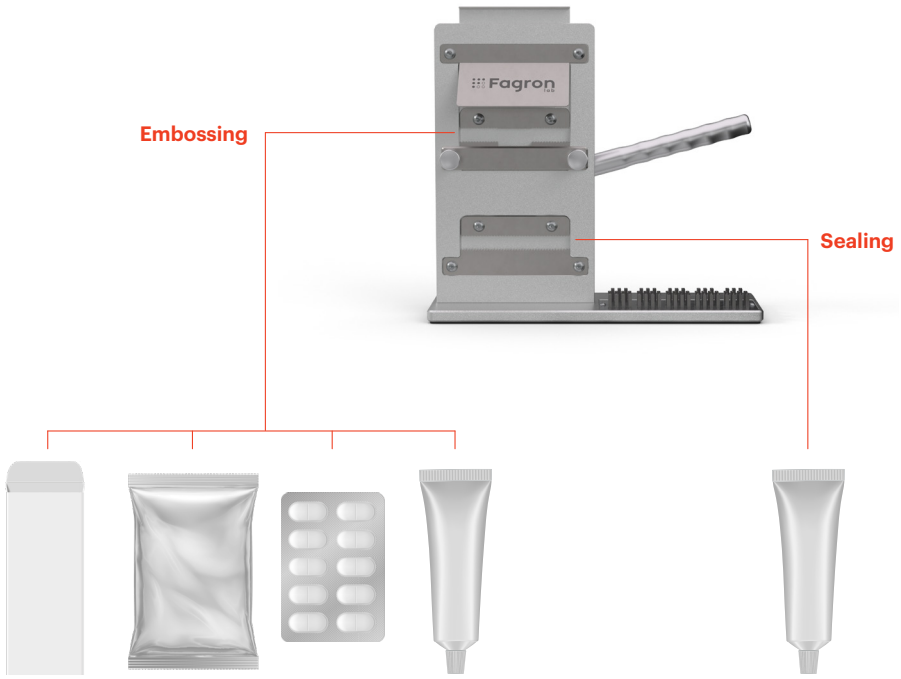
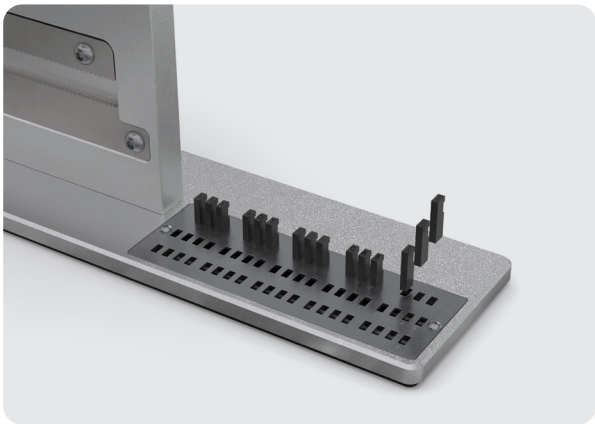


Figure 1. Application overview of FagronLab™ LEV-Rx™.

3. Installation

Before using the device, ensure the **LEV-Rx™ Plate** is securely attached on the device. This step is essential, as the **LEV-Rx™ plate** creates the pre-sealing position. Use the Allen key and the two screws included in the packaging to ensure a tight and secure attachment.



Additionally, please take the **LEV-Rx™ embossing letters** and place them into the dedicated position. The magnetic surface will hold the letters securely in place during operation, allowing to make quick and easy adjustments during use.

4. Technical specifications and components

Model	FagronLab™ LEV-Rx
Material	Aluminum / Stainless steel
Embossing Holder	Aluminum
Letter material	Coated steel
Size (W x H x L) (cm)	29.5 x 27.5 x 9.0
Weight (kg)	2,5
Packaging Weight (g)	0,9
Embossing kit	Embossing holder and letters
Maximum tube size (mm)	60
Maximum blister tray/sachet/ cardboard box size (mm)	95

5. Safety Precautions

- **Use Personal Protective Equipment (PPE)** eg, gloves, safety glasses.
- **Keep your hands and fingers away** from the embossing and sealing areas when using the lever.
- **Ensure device stability** by placing it on a firm, leveled surface during operation.
- **Ensure that the embossing letters** are covered while operating the device.

6. Operation Procedures

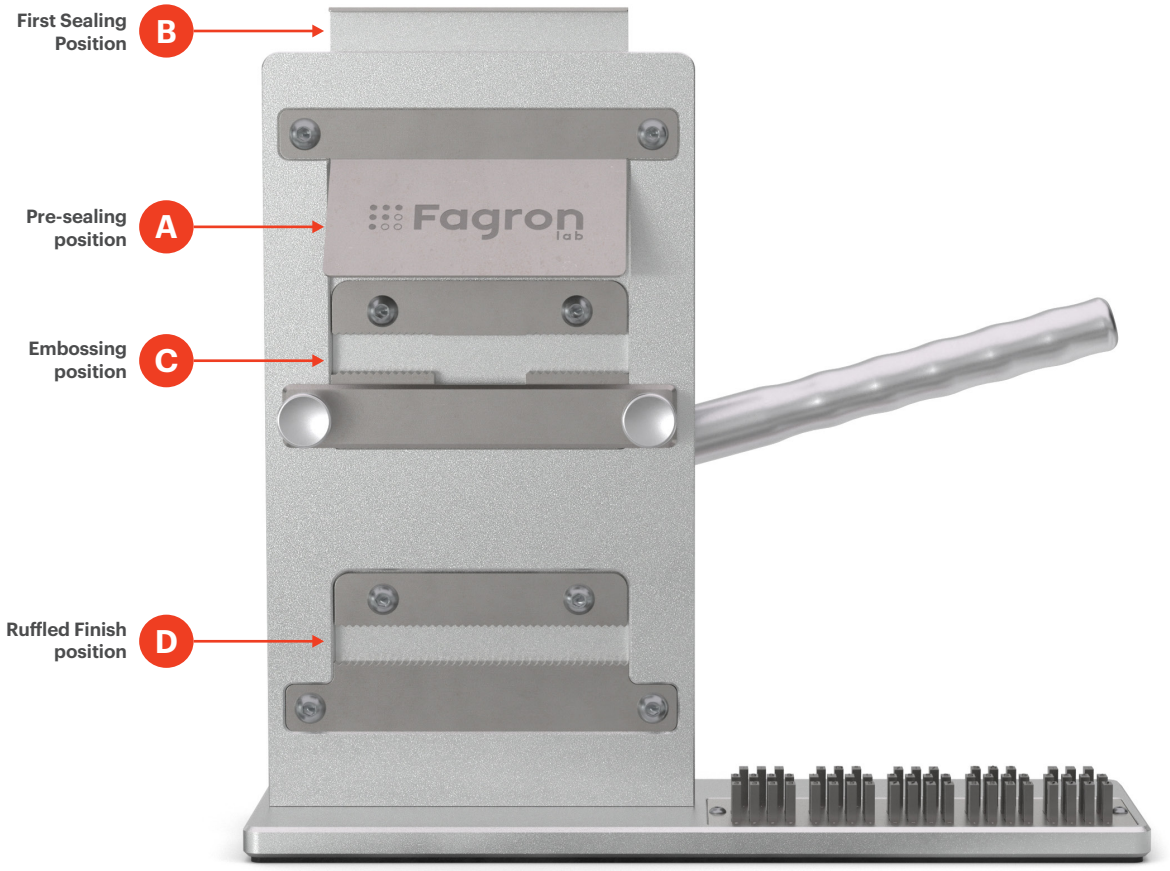
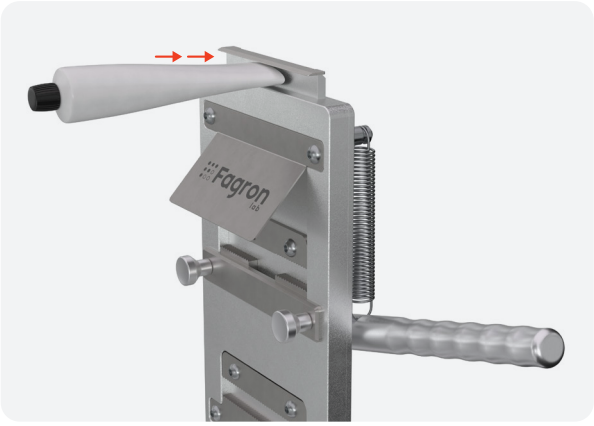


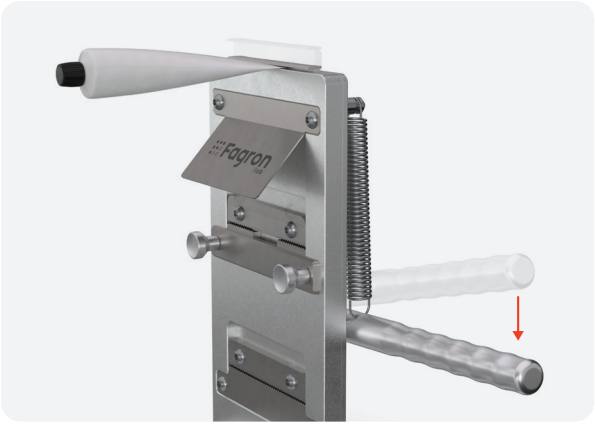
Figure 2. FagronLab™ LEV-Rx™.

6.1 Sealing Procedure FagronLab™ LEV-Rx

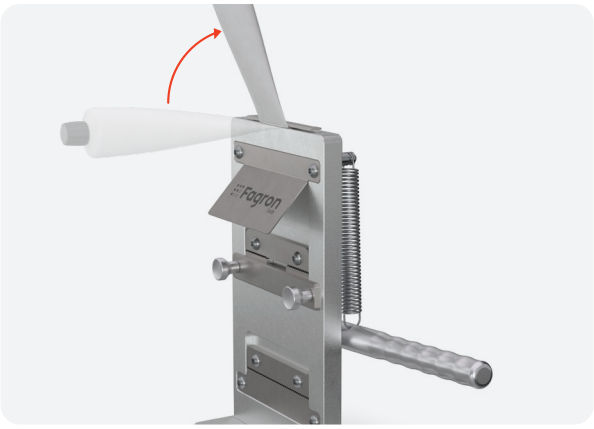
1. **Position the Tube in Area A (Pre-sealing position)**
   Place the tube into **Position A**. Slightly press the tube diagonally upwards to prepare it for the sealing process. This step helps align the tube for proper closure.



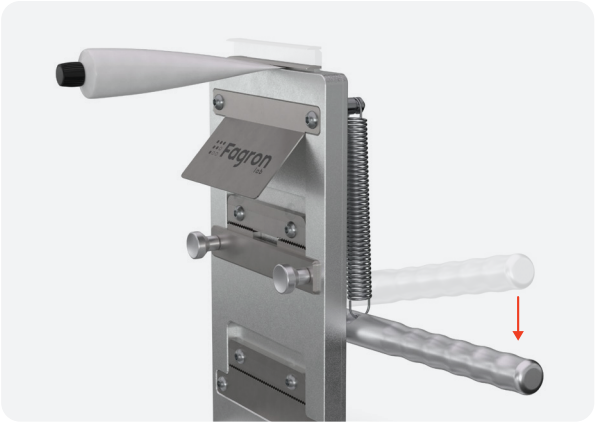
2. **Position the Tube in Area B (First Sealing Position)**
   Place the tube in **Area B**, where the **Closing Die** is located. This is the first sealing position.



3. **Press the Lever (First Seal)**
   Press down the lever to apply pressure and crimp the end of the tube. Hold the lever down to secure the tube in the closed position.



4. **Move the Tube Backward**
   While keeping the lever in the position, **gently move the tube backward** by hand to ensure even sealing along the crimped edge.

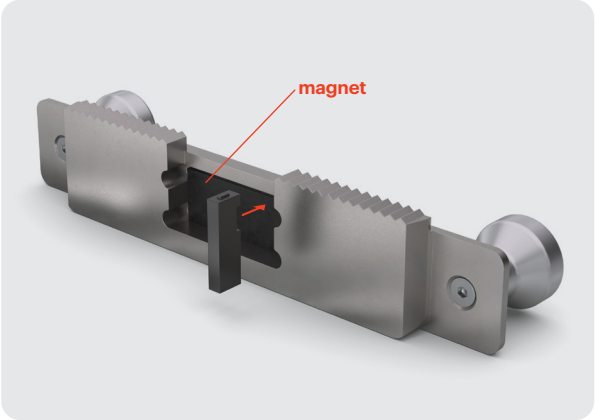


5. **Repeat the Process**
   Release the lever and return it to its starting position. Move the tube slightly forward, re-positioning it in **Area B**, and then **press down** the lever again, applying the same steady pressure. Hold the lever down while moving the tube backward again to create a strong, secure seal.

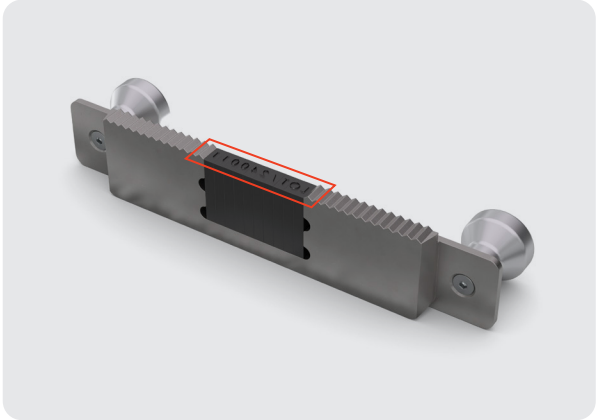
6. **Final Sealing in Area D (Creating Ruffled Finish)**
   After achieving the initial seal, move the tube to **Area D**, where the ruffling die is located. **Press down** the lever one last time to create the ruffled finish. This ensures that the tube is fully sealed with a professional, secure closure.

7. **Inspect the Seal**
   Release the lever and return it to the starting position. Remove the tube and inspect the sealed end to ensure it is properly sealed with a consistent ruffled finish.

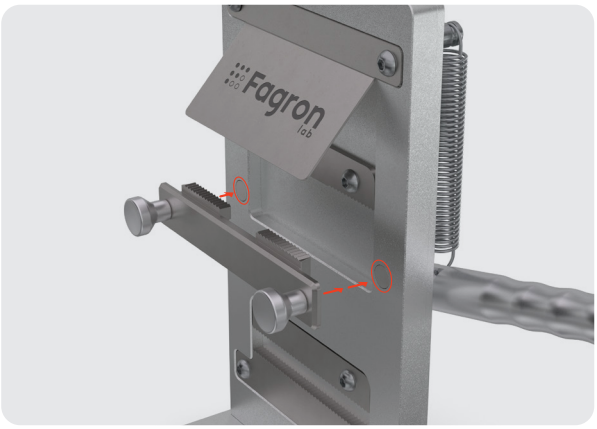
6.2 Embossing Procedure (Area C) FagronLab™ LEV-Rx



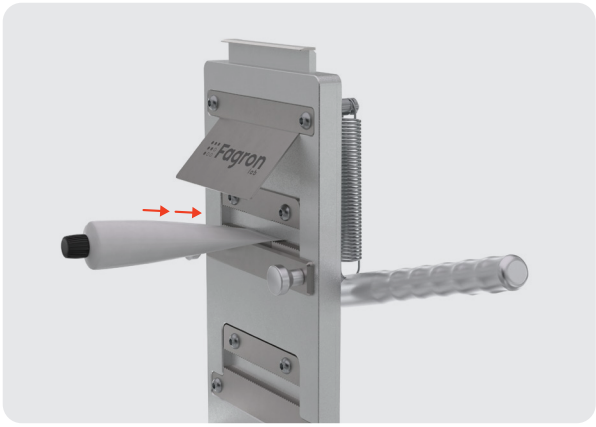
1. **Correct letter placement**
   Ensure that each letter is placed in the correct direction and securely positioned in the embossing holder. As the embossing letters are mirrored, they must be placed **from right to left**. The system is designed with a special structure to prevent the letters from being embossed upside down.



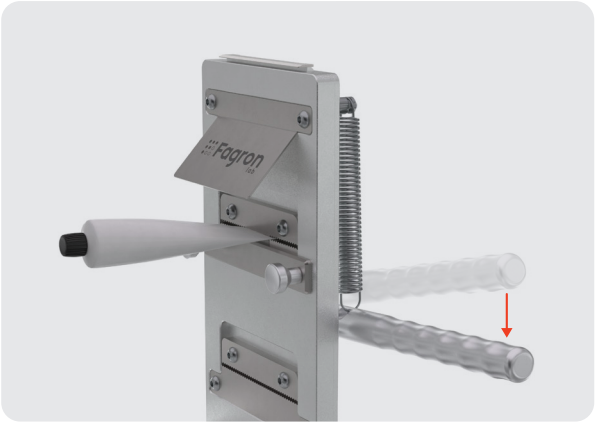
2. **Prepare the Embossing Holder**
   Place the desired letters (e.g., LOT number, expiration date, or other relevant information) into the embossing holder. If necessary, a dedicated character (|) may be used to shorten the marking, positioning it on both the left and right sides



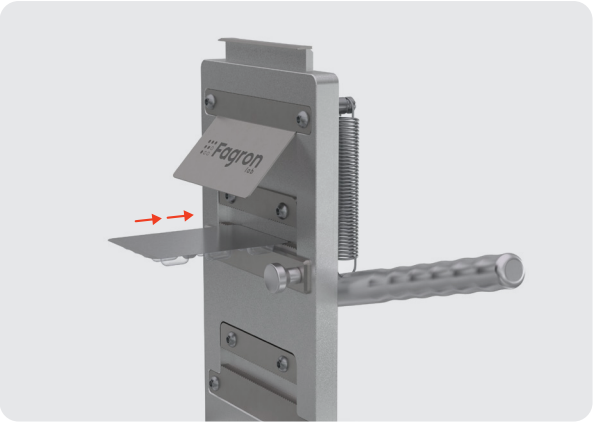
3. **Attaching the embossing holder to the device**
   To attach the embossing holder to the device, align it with the magnetic surface on the device. The magnets will securely hold the embossing holder in place, ensuring stable positioning during operation.



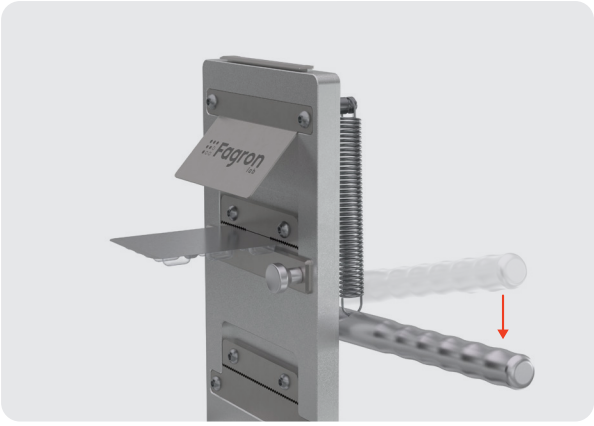
4. **Tube embossing (a)**
   After sealing the Tube in **Area B**, move the tube directly to **Area C** for embossing. This area is designed to imprint critical details onto the tube.



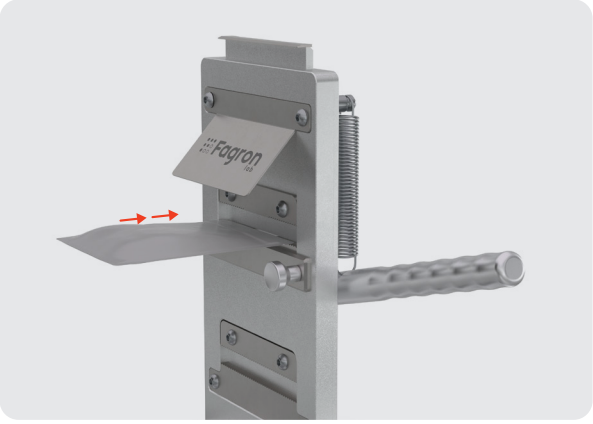
5. **Tube embossing (b)**
   Once the Tube is positioned in **Area C**, press down the lever. This will apply pressure to the embossing die, transferring the marking. (e.g., 10-letter LOT number, expiration date). The embossing should be crisp, readable, and located in the correct position.



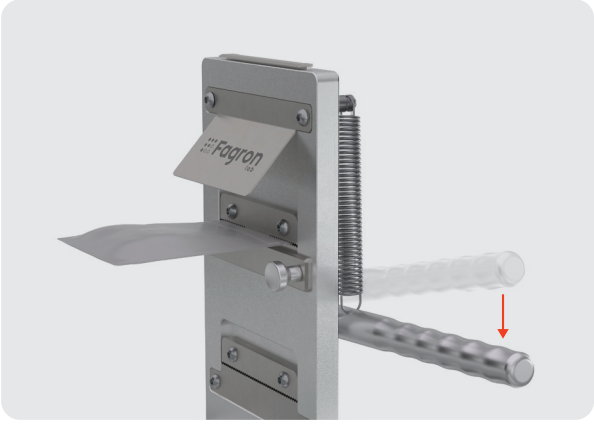
6. Blister Tray embossing (a)
Place the Blister Tray, with the plastic surface facing the embossing letters, directly into **Area C**, where the embossing die is located. For optimal results, it is recommended to perform this step immediately after sealing, while the blister tray is still warm.



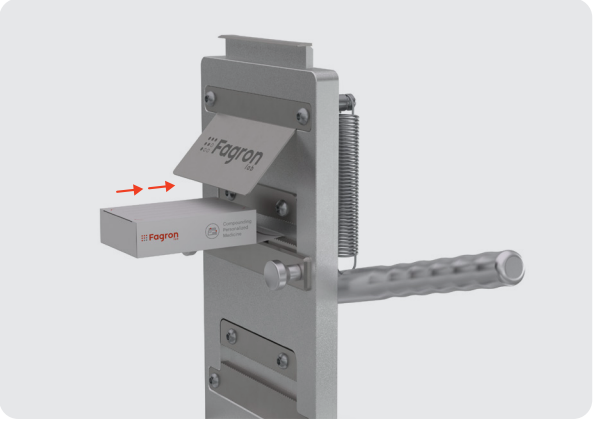
7. Blister Tray embossing (b)
Once the Blister Tray is positioned in **Area C**, press down the lever. This will apply pressure to the embossing die, transferring the marking.



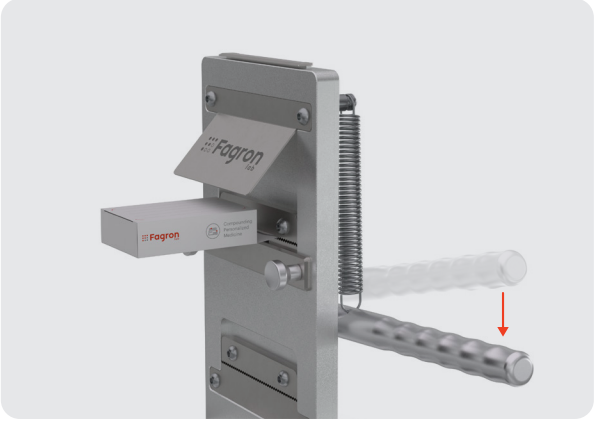
8. Sachet embossing (a)
Place the sachet directly into **Area C**, where the embossing die is located.



9. Sachet embossing (b)
Once the Sachet is positioned in **Area C**, press down the lever. This will apply pressure to the embossing die, transferring the marking.



10. Cardboard Box embossing (a)
Place the Cardboard Box directly into **Area C**, where the embossing die is located.



11. Cardboard Box embossing (b)
Once the Cardboard Box is positioned in **Area C**, press down the lever. This will apply pressure to the embossing die, transferring the marking.

7. Cleaning and Maintenance

To maintain the **FagronLab™ LEV-Rx** in optimal working conditions, it is essential to clean the device after each use. This helps prevent product buildup, contamination, and ensures consistent performance during future applications.

- Always use a soft, lint-free cloth or microfiber cloth to prevent scratches.
- Use only **pharmaceutical-grade disinfectants** that are effective against bacteria, viruses, and fungi. Make sure the disinfectant is compatible with the materials of the device (e.g., stainless steel, aluminium) and follow manufacturer recommendations for dilution and contact time.
- **Do not soak** or use excessive amounts of disinfectant or water. Damp cloths should be used instead to wipe down surfaces to avoid moisture buildup, which could affect the mechanical parts.
- Ensure that the **LEV-Rx™ embossing kit** is cleaned and disinfected after each use. Use a **soft brush** or cloth with a disinfectant solution to maintain clear.
- Do not scrub the surface to avoid any damage.
- After each cleaning and disinfection session, **inspect the device** for any signs of wear, corrosion, or damage. Make sure that all moving parts are free of residue as necessary to maintain optimal performance.

8. Transportation and Storage

- When not in use, store the device in a **cool**, **dry place** to prevent exposure to extreme temperatures, humidity, or moisture. The original packaging is designed to protect the device from dust, dirt, and external contaminants, so it should remain sealed or placed in a designated storage area that is free from direct sunlight or excessive heat.
- Always transport the **FagronLab™ LEV-Rx** in its **original packaging** to ensure the device is securely protected during transit. The packaging is specifically designed to cushion the device, prevent damage, and minimize the risk of impact or scratches. This helps prevent any damage to the mechanical components, embossing kit (for the PRO version), or the device frame.

9. Warranty

The **FagronLab™ LEV-Rx** is covered by a **24-month warranty**, ensuring that the device is free from defects in materials and workmanship under normal use and service. The warranty is valid only for the original purchaser and does not cover damage resulting from improper installation, misuse, accidents, abnormal operating conditions, or failure to follow the recommended cleaning and maintenance procedures. After the warranty period, **Fagron** will still offer repair services, subject to charges for parts, labor, and shipping. For warranty claims, please contact your local supplier.

Declaration of Conformity

Gako Deutschland GmbH
Is certified according
DIN EN ISO 9001:2015 &
DIN EN ISO 50001:2018

CE

Product: Aluminum tube closer & batch/date embosser
Product type: FagronLab™ LEV-Rx™

Manufacturer: Gako Deutschland GmbH
Am Steinernen Kreuz 24
96110 Scheßlitz/Germany

The manufacturer declares the conformity of the designated product with the following European guideline:

Directive 2006 / 42 / EC of the European Parliament and of the Council
17th May 2006
on machinery, and amending Directive 95/16/EC (recast)

Regulation (EC) No 1935 / 2004 of the European Parliament and of the Council
27th October 2004
on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

Commission Regulation (EC) No 2023/2006
22nd December 2006
on good manufacturing practice for materials and articles intended to come into contact with food.

The conformity of the designated product has been proven by the complete compliance of the following directions:

DIN EN ISO 12100-1:2013-08

For the intended use the designated product meets the requirements from European, US, British and Japanese Pharmacopeia and ROHS ((EU) 2015/863 and 2011/65/EU) regulations.

The product has been examined regarding the compliance of the direction/standards mentioned above.

gako

Gako Deutschland GmbH
96110 Scheßlitz / Germany

Karamperis Aris, Product manager, Gako

22.05.2025

Together
we create the future
of personalizing medicine.

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