FagronLab™ BLIST-Rx

User Manual

www.fagronlab.com

Fagron lab

Contents

1. Performance and Main Features

The **FagronLab™ BLIST-Rx™** is a thermo-sealing device developed for individually packing capsules and tablets in blister trays, protecting the compounding from air, humidity, and contamination until the administration. At default parameters (148 °C ± 5 °C and 2000 ms.), the device can seal blister trays composed of various materials, including an aluminum lid with an aluminum or a plastic body.[1] The device also allows changing the default parameters if desired.

Advantages and Properties

- Suitable for sealing wide-range blister trays.
- Automatic temperature stabilizer prevents overheating.
- Suitable with all capsule sizes.
- Convenient tablet sizes: Ø 8 mm and 13 mm.
- Precise time settings between 100 - 25,500 milliseconds (ms.) in 1 ms increments.
- Temperature settings between 100 - 170°C.
- Up to 15 capsules and 20 tablets sealing.
- Low power consumption (250 W).
- User-friendly and quick operation.
- For substances with decomposition temperature < 120°C.

1.1. Blistering Process

The **FagronLab™ BLIST-Rx™** uses a flat plate blister welding method, enabling effective blister sealing within seconds. Once the device is activated, the integrated welding plate gradually increases in temperature until it reaches the desired level, typically taking just a few minutes. Meanwhile, once the **FagronLab™ BLIST-Rx™ tray**, a pre-welded blister tray, is loaded with the compound, it is inserted into the **FagronLab™ BLIST-Rx™ holder**.

Afterward, the **FagronLab™ BLIST-Rx™ holder** is inserted into the device by sliding it through the blister holder slide. Subsequently, the heated welding plate closes over the **FagronLab™ BLIST-Rx™ holder**, enabling to seal the blister pack through heat transfer. The duration of this process depends on the predetermined stop-time established before the operation and typically takes only a few seconds.

Due to the heat application over 100 °C ± 5 °C, it is essential to note that a temperature increase within the cavity is anticipated. In default, the temperature in the blister cavity can reach approximately 120°C. However, since thermal application of the device is limited to only a few seconds and typically longer durations are required for thermal degradation to begin, the **FagronLab™ BLIST-Rx™** is generally compatible with many substances. The thermal degradation temperature of APIs can be checked mainly from Safety Data Sheets (SDS) and pharmacopeias. The decomposition temperatures of some common substances are shown in Table 1.

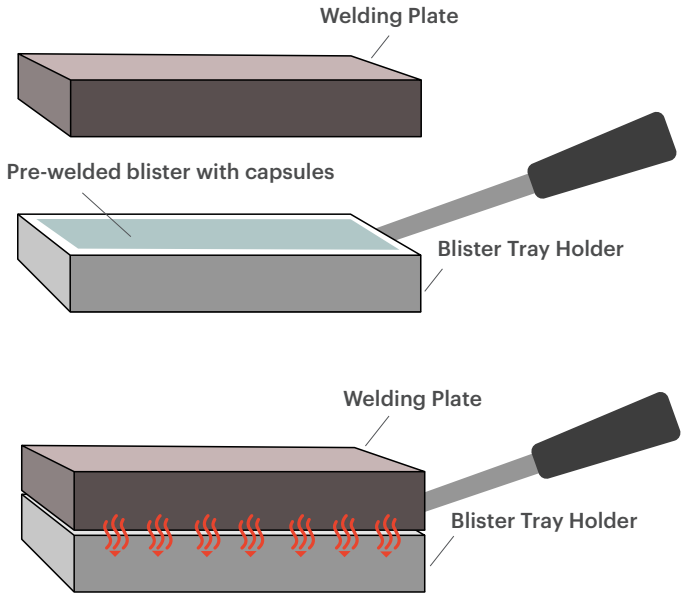


Figure 1. Working mechanism of the FagronLab™ BLIST-Rx™.

Table 1. The decomposition temperatures of some substances used in oral dosage forms.[2,3,4,5]

API	Function in oral dosage forms	Decomposition temperature
Caffeine	API	178 - 200 °C
Calcium carbonate	Diluent, bulking agent, opacifier, API	> 750 °C
Dextrin	Diluent, binder, plasticizer	178 °C
Fructose	Diluent, flavor	102 - 105 °C
Mannitol	Diluent, flavor	140–220 °C
Sodium bicarbonate	Disintegrant, API	270 °C
Sucrose	Binder, flavor	160 - 186 °C
Talc	Diluent, lubricant, adsorbant, dissolution retardant	800 °C
Vanillin	Flavor	284 - 285 °C

1.2. Application and Use

When operated at default parameters, the **FagronLab™ BLIST-Rx™** can effectively and securely seal both uncoated and coated tablets, as well as hard and soft capsules, into the blister trays. However, it is essential to note that due to the heat treatment applied to the aluminum lid of the blister tray during the sealing process, direct contact between the dosage form and the welding plate must be avoided. Therefore, it is crucial to select the appropriate blister tray size by the capsule size, so that the dosage form fits conveniently into the cavity.

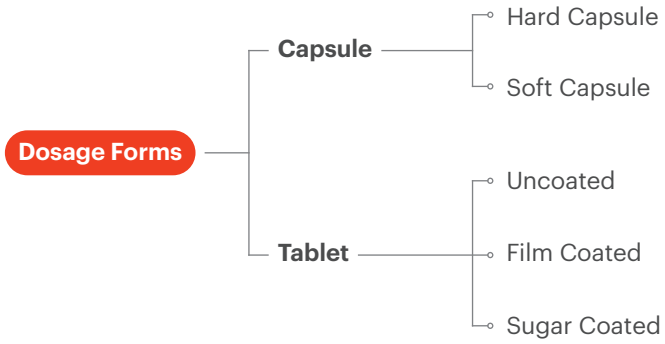


Figure 2. The dosage forms that can be sealed in the FagronLab™ BLIST-Rx™ trays with using FagronLab™ BLIST-Rx™.

Figure 3. FagronLab™ BLIST-Rx™.

2. Technical Information

Model	The FagronLab™ BLIST-Rx™
Dimensions (L x W x H)	24.35 X 36.15 X 25.31 cm
Weight (kg)	9
Electrical Requirements	230 VAC, 50 / 60 Hz
Power Consumption (W)	250
Minimum Temperature	100°C ± 5°C
Maximum Temperature	165°C ± 5°C
Default Temperature	148°C ± 5°C
Default Temperature Range	10°C
Default Maximum Pressure Time	2000 ms.

3. Accessories

3.1. FagronLab™ BLIST-Rx™ Trays

The **FagronLab™ BLIST-Rx™ trays** are partially pre-welded blister trays with a thickness of 0.25 mm, comprising a thermoformed rigid PVC body and a hard-tempered aluminum lid. The thermoformed rigid PVC has a low water-vapor transmission rate, meaning a material that protects the compounding from contamination, moisture, and air, which are well-known triggers and accelerators of oxidation. Additionally, individual packing breaks contact between each dosage unit, preventing the spread of reactive radicals generated through this reaction to the other dose units. Thus, it maintains the stability of the compounding during shelf-life. The high chemical resistance of the **FagronLab™ BLIST-Rx™ tray**, as well as its flexural strength and excellent thermoformability[1], make it an excellent choice for packaging.

Advantages

- More environmentally friendly and cost-efficient as it contains 84% less aluminum.
- Dose tracking and improved treatment compliance.
- Reduced cross-contamination during storage.
- Low water-vapor permeability.
- Dose separation, providing stability maintenance.
- Easy to carry because of its lightweight (0.3 g).
- Tamper evidence.
- Optional personalization by printing.
- Compliance with current Good Manufacturer Practices (cGMP)[6], Food and Drug Administration (FDA)[7], European Pharmacopoeia (Ph. Eur.)[8,9], United States Pharmacopeia (USP)[10] and Japanese Pharmacopoeia (JP)[11] quality standards.

3.2. FagronLab™ BLIST-Rx™ Holder

The **FagronLab™ BLIST-Rx™ holder** is a tool made from stainless steel that holds the **FagronLab™ BLIST-Rx™ tray** with the desired dosage forms to be sealed inside while the sealing process is carried out by the hot welding plate attached inside the device. Thanks to its durable structure, it is resistant to high temperatures and can be washed in the dishwasher.

Advantages

- Durable structure to scratches.
- Resistant to high temperatures.
- High thermal conductivity, providing quick heat up and cool down.
- Suitable to be cleaned in the dishwasher.
- Available in 7 types designed to accommodate tablets and capsules.

Table 3 shows the capacity and compatibility of the **FagronLab™ BLIST-Rx™ trays** and the **FagronLab™ BLIST-Rx™ holders**. They can also be matched through the names since they are self-explanatory. For example, the **FagronLab™ BLIST-Rx™ holder** 15 00-0 A has 15 cavities and is used with a blister tray suitable for both capsule sizes 00 and 0 (Figure 4).

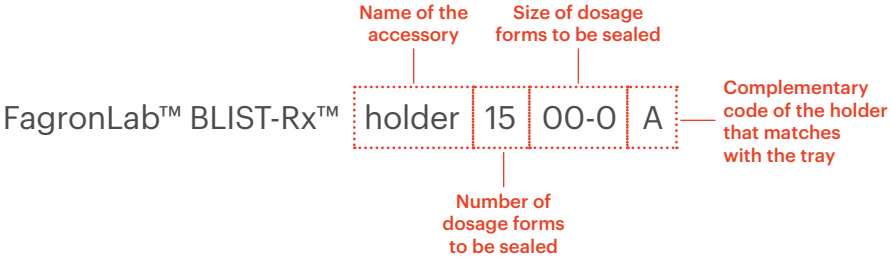


Figure 4. Self-explanatory name of the FagronLab™ BLIST-Rx™ accessories.

Table 3. The classification of the FagronLab™ BLIST-Rx™ holders.

Model		Capacity	Suitable tray	
FagronLab™ BLIST-Rx™ holder 15 00-0 A		15 Capsules	FagronLab™ BLIST-Rx™ tray 15 00-0 A Size: 00-0	
FagronLab™ BLIST-Rx™ holder 15 3-4 B		15 Capsules	FagronLab™ BLIST-Rx™ tray 15 3-4 B Size: 3-4	
FagronLab™ BLIST-Rx™ holder 10 000-00 C		10 Capsules	FagronLab™ BLIST-Rx™ tray 10 000-00 C Size: 000-00	
FagronLab™ BLIST-Rx™ holder 20 Ø8 D		20 Tablets	FagronLab™ BLIST-Rx™ tray 20 Ø8 D Size: Ø8 mm	
FagronLab™ BLIST-Rx™ holder 12 Ø13 E		12 Tablets	FagronLab™ BLIST-Rx™ tray 12 Ø13 E Size: Ø13 mm	
FagronLab™ BLIST-Rx™ holder 15 0-1-2 F		15 Capsules	FagronLab™ BLIST-Rx™ tray 15 0-1-2 F Size: 0-1-2	
FagronLab™ BLIST-Rx™ holder 10 0-1-2-3-4 G		10 Capsules	FagronLab™ BLIST-Rx™ tray 10 0-1-2-3-4 G Size: 0-1-2-3-4	

4. Functions and Use

4.1. Installation

1. Connect the device to the power supply.

2. Turn the device on by pressing the "**ON/OFF**" switch.

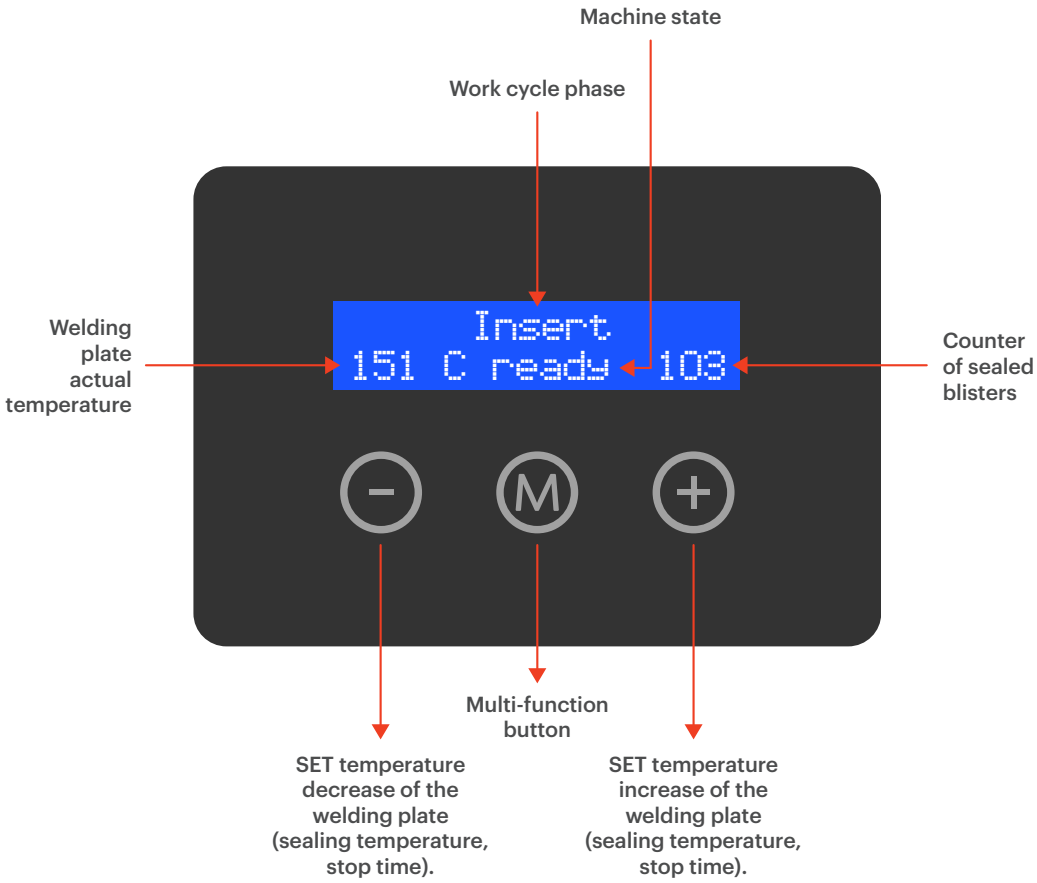
3. Once you switch the machine on, the display will present the name of the device.

4. Afterwards, it automatically starts heating the welding plate to default temperature.

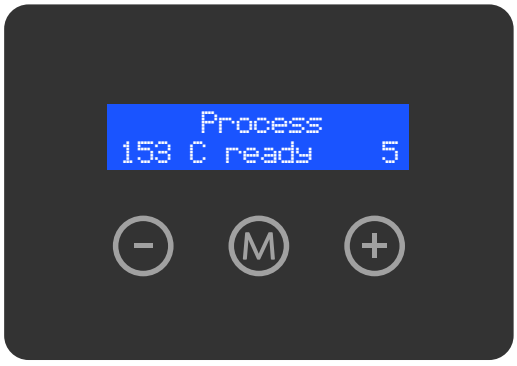
5. Once the temperature has reached the set-up temperature, the display will indicate "**ready**". In this phase, the sealing parameters can be adjusted from the "**Menu**" (see 4.4. Settings).

4.2. Display

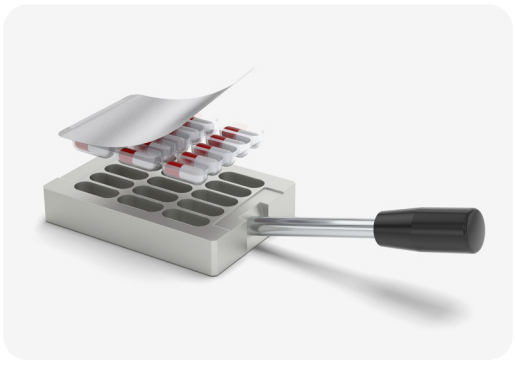
Once the **FagronLab™ BLIST-Rx™** is ready to use, the display shows the following commands and information.



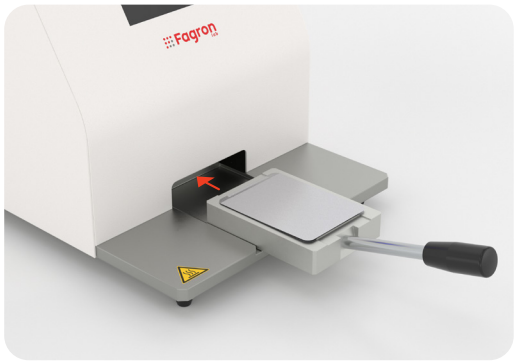
4.3. Blister Sealing



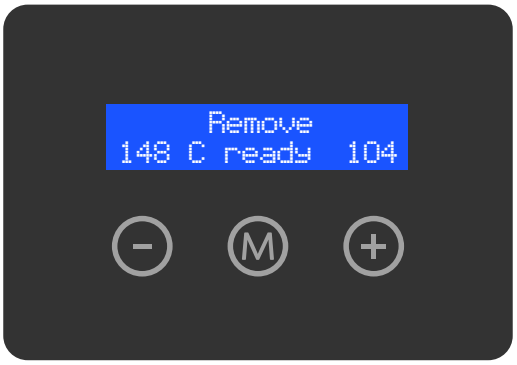
1. When the welding plate reaches the set temperature, the "**ready**" notice appears on the display.



2. Place the FagronLab™ BLIST-Rx™ tray on the FagronLab™ BLIST-Rx™ holder, welded side up, and fill it with the dosage forms to be sealed.



3. Insert the FagronLab™ BLIST-Rx™ holder into the machine from the holder slide, until it stops mechanically.



2. The sealing cycle starts automatically after inserting the FagronLab™ BLIST-Rx™ holder. Once it is finished, the “remove” notice will appear on the display. The system will update the counter of sealed blisters.

4.4. Settings

The default sealing parameters listed below, have been optimized for the **FagronLab™ BLIST-Rx™ trays**.

- The sealing temperature (TEMPERATURE) is around 148 °C ± 5 °C.
- Max pressure time (STOP TIME) 2000 ms.
- Temperature range (TEMP RANGE) ±5 °C.

Although it is possible to modify these parameters, it is recommended to remain as default for sealing blister trays consisting of an aluminum lid and either an aluminum or plastic body. It should be noted that any temperature change could compromise the correct blister sealing and functioning of the blistering machine.

To access the menu, hold the "**M**" button for approx. 5 sec. The display returns to the home screen in 60 seconds if any button is touched. To switch between the settings, push the "**M**" button once. The settings return to default when the device is rebooted.

4.4.1. Temperature

Upon accessing the set-up menu, the display will present the screen showing the set temperature value (Figure 5). Using the "**+**" and "**-**" buttons, you can adjust the set temperature, which the machine will reach each time it is powered on.

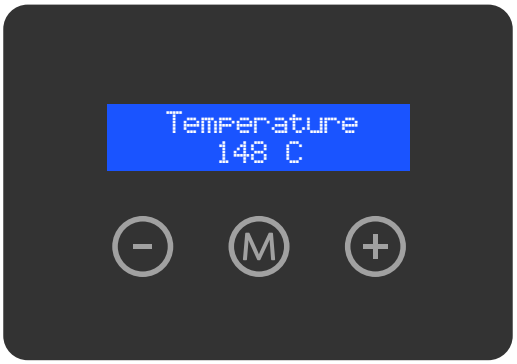


Figure 5. Sealing temperature set-up menu.

4.4.2. Maximum Pressure Time (Stop Time)

The maximum pressure time is the fraction of the entire work cycle´s duration. Within this period, the machine holds the welding plate on the **FagronLab™ BLIST-Rx™ holder** in the max pressure position.

After entering the menu shown in Figure 5, press the "**M**" button once to access the Stop Time Settings. Then, the display switches to the screen in Figure 6, indicating the value of the stop-time in ms. The stop time can be adjusted by pressing the "**+**" and "**-**" buttons to increase or decrease the value.

Figure 6. Maximum pressure time set-up menu.

4.4.3. Temperature Range

The system is designed to hold the temperature value in a particular range and prevent overheating during sealing cycles, regulating the heating system's switch on and off. This menu allows you to set the temperature range of the welding plate when added or subtracted to the temperature set-up.

To access this menu, press the "**M**" button twice after entering the set-up menu and reaching the screen depicted in Figure 5. Once the screen shown in Figure 7 appears, you can adjust the stop-time by pressing the "**+**" and "**-**" buttons to increase or decrease the value.

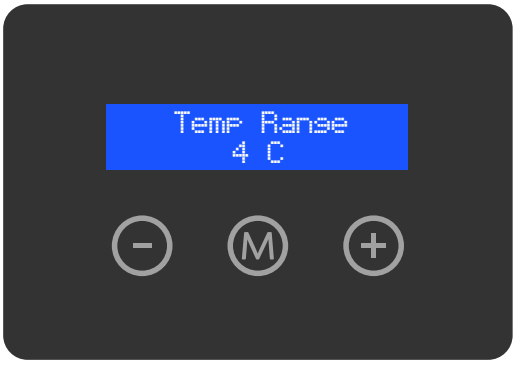


Figure 7. The menu of temperature range set-up.

4.4.4. Temperature Calibration

Our technicians use the menu shown in Figure 8 to align the actual temperature of the welding plate to the one shown on display. Using the buttons "**+**" and "**-**", increasing or decreasing the temperature to align it to the one read on an external thermometer is possible. This operation must be executed by experts and trained personnel only. Please note that this value is pre-set at our premises, and we suggest not changing it.

Figure 8. The temperature calibration set-up menu.

5. Attention

- The operator's safety and health must be protected by ensuring the room has ample natural light, appropriate artificial lighting, and proper ventilation. The lighting of the room must comply with the laws in the country where the machine is installed and guarantee good product visibility.
- Do not insert objects other than the **FagronLab™ BLIST-Rx™ holder** inside the blister machine to prevent damage to the device and external objects.
- Do not insert your fingers inside the **FagronLab™ BLIST-Rx™ holder** after sealing since the temperature of the plate can exceed 100 °C both during the heating and sealing steps.
- If you are unsure that the **FagronLab™ BLIST-Rx™ holder** is cold, use protective gloves. Since it can be melted and stuck to the hand due to the high temperature, do not use plastic laboratory gloves.
- If you do not use the device long, disconnect it from the power supply.

6. Maintenance

6.1. Cleaning

- Clean the surface with a soft fabric or cloth soaked in warm water and a non-abrasive household cleaning agent. Afterward, clean the surface with another soft fabric or cloth soaked in warm water. In the end, rapidly wipe the entire surface with a dry cotton cloth or towel.
- Do not use scratching sponges or abrasive cleaning agents such as nitro or synthetic resin thinner.
- Since it may cause irreparable damage, ensure no fluids enter the device.
- Do not wet the electronic components.
- Do not use thermal disinfection.

6.2. Operational Errors

The operational errors observed while using the FagronLab™ BLIST-Rx™ are listed with their solutions below.

Error	Troubleshooting	Solution
The device does not switch on.	The device is not correctly connected to the plug.	Connect the device to the plug.
	There are problems with the main line.	Check the supply line.
The sealing cycle does not start.	The device is switched off.	Turn on the device.
	The sensor that detects the FagronLab™ BLIST-Rx™ holder is broken.	Contact customer service.
	The fuse is broken.	Contact customer service.

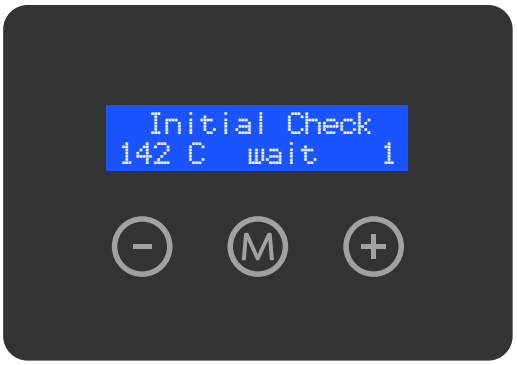
6.3. Unlock The FagronLab™ BLIST-Rx™ Holder

In case the **FagronLab™ BLIST-Rx™ holde**r is stuck in the switched-on machine, the following steps should be applied.

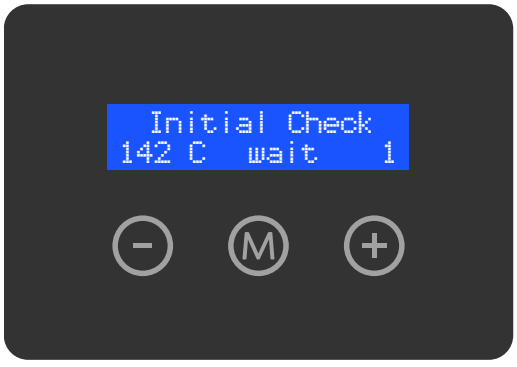
1. Restart the device from the "**ON/OFF**" switch. Then, press and hold the "**+**" button to let draw back the welding plate. Once you release the button, the welding plate will stop.

2. Try to pull out the FagronLab™ BLIST-Rx™ holder. If the plate is still stuck, push again the button "**+**", and try again.

3. Once the FagronLab™ BLIST-Rx™ holder is out, the display will show the message above.



4. Push the "**+**" button again to automatically return the welding plate to the initial position. In this phase, the machine will heat the welding plate, and it will warn the operator to "**wait**" until the reach of the set work conditions.



5. When the device is ready to use again, the message on the left is shown on the display. Then, it can be used according to the directions given in Section 4.4.

7. Transportation and Storage

The **FagronLab™ BLIST-Rx™** weighs approximately 9 kg and should only be stored on flat, leveled surfaces capable of supporting the device's weight. The device should provide sufficient space for using, maintaining, and using any peripheral equipment.

8. Warranty

This device is under warranty and free from defects in materials and workmanship, under regular use and service, for 12 months from the invoice date (excluding consumable accessories). The warranty is extended only to the original purchaser. Warranty is not valid on a device that improper installation, improper connections, misuse, accident, or abnormal conditions of operation have damaged. If the warranty has expired, Fagron will still be responsible for repair with relative charges. **For claims under warranty, please contact your local supplier**.

9. Declaration of Conformity

Declaration of Conformity

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

CE

Product: Laboratory sealing device incl. accessories
Product type: FagronLab™ Blist-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 2014 / 35 / EU of the European Parliament and of the Council
26th February 2014
on the harmonisation of the laws of the Member States relating to the making available of electrical equipment designed for use within certain voltage limits on the market

Directive 2014 / 30 / EU of the European Parliament and of the Council
26th February 2014
on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)

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

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

DIN EN 61010-1:2020-03
DIN EN IEC 61326-1:2022-11
DIN EN 50561-1 Berichtigung 1:2018-12
DIN EN IEC 61000-3-2:2019-12
DIN EN 61000-3-3:2020-07

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.

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01.11.2022

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Together
we create the future
of personalizing medicine.

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