FagronLab™ PM140

User Manual

www.fagronlab.com

Fagron lab

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1. An All-in-One Solution: FagronLab™ PM140

For pharmacists who are looking for a simple, fast, and affordable solution for mixing, wet milling and deaeration, the **FagronLab™ PM140** is a revolutionary device that combines those multiple functionalities to standardize the compounding process, ensuring safety, quality, and efficacy for compounded preparations while saving time and money for the pharmacy (Figure 1).

Moreover, it can be used on its own or in a combined workflow with other compounding equipment, such as the **FagronLab™ EMP*** or other devices required for the preparation of semi-solid formulations.

Figure 1. FagronLab™ PM140 device.

1.1. Mechanism of Action

Due to its ingenious mechanism, the preparation inside the PM jar (mixing jar) simultaneously spins and rotates around an axis in opposite planetary motion while keeping all the components at an angle of 40°. This promotes a centrifugal force caused by the rotational movement making particles in the mixture move toward the edges of the PM jar. As a result, the mixing process can be conducted in an enclosed environment without blades (Figure 2), reducing the number of items to be cleaned afterwards and enabling the pharmacist to **mix** and **deaerate** formulas within a simple one-step process (a process in less than 60 seconds). A natural and incidental temperature rise may occur during extended operation of the device. This warming is not controlled or designed to provide heating, nor does it serve any functional purpose in melting or maintaining the physical state of formulations.

The device's low-temperature rise, even over extended periods, ensures safe usage with formulations containing thermolabile substances.

For optimal results, we are continuously developing suitable accessories including jars and dispensers for the **FagronLab™ PM140** (see section 3. Accessories). The PM jars and dispensers provide a closed environment to reduce microbial contamination and eliminate spilling and spreading problems. They can be used in negative pressure cabinets to prevent hazardous drug exposure. The disposable ones that are also used as primary packages, help avoiding material loss that would otherwise occur during the transfer step from the preparation cup into the package.

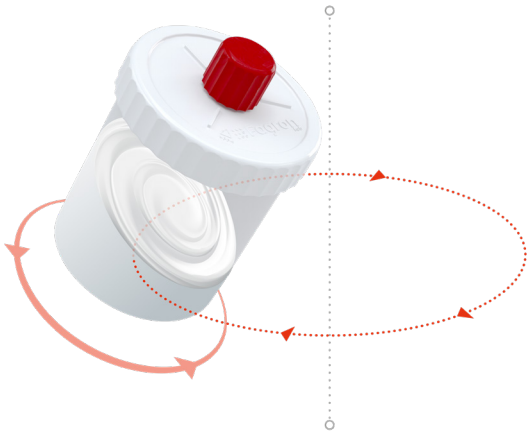


Figure 2. The working mechanism of FagronLab™ PM140.

* **FagronLab™ EMP** is a product line of fully automatic, semi-automatic, and manual versions devices, designed for mixing and the homogenization of semi-solid preparations (gels, creams, ointments, and suppositories) using blades.

1.2. Application and Use

Mixing

FagronLab™ PM140 is a user-friendly and practical device that allows the preparation of formulas in less than a minute, in a closed mixing jar, with no need for mixing blades (Figure 3). The studies conducted by our laboratories show the content uniformity in all portions of the formulations produced. The standardized mixing allows for greater stability of emulsions, therefore eliminating formulation issues such as creaming, sedimentation, flocculation, and coalescence. An adequate homogenization also ensures correct rheological properties, such as the formulation's viscosity and flow.

Figure 3. Mixing process using the FagronLab™ PM140.

* External heating must be applied for melting previously to the mixing step (for example, using a hot-water bath).

Deaeration

FagronLab™ PM140 deaerates emulsions and gels in just 45 seconds, ensuring the removal of macrobubbles from those formulations (Figure 4).

Thermal considerations

As the **FagronLab™ PM140** is not designed for melting, it does not incorporate heat-emitting parts or a thermal insulation system to mitigate ambient temperature changes, so direct use for the melting process is not recommended. For the formulations requiring heat treatment, it is necessary to apply external heat to conduct the melting process. This approach also ensures compounding standardization by fixing the parameters.

The external heat can be directly administered to the substances within the FagronLab™ PM jar 125 mL HV+LV (see 3.2. FagronLab™ PM jar 125 mL HV+LV) through a hot water bath, as the jar can withstand temperatures of up to 85°C (Figure 5). Thus, any external heating step is carried out in a closed environment, protecting the substances from external contaminants such as water vapor. The closed PM jar 125 mL HV+LV is then inserted directly into the FagronLab PM140 for mixing and deaeration.

This eliminates the need to transfer substances from a melting vessel to the FagronLab™ PM jar, preventing any substance loss.

The device does not provide controlled heating and does not prevent re-solidification; any slight warming during operation is incidental and non-regulated.

Figure 4. Deaeration process using the FagronLab™ PM140.

Figure 5. External heating of the FagronLab™ PM jar 125 mL HV+LV in a hot water bath.

Wet Milling

The preparation of colloidal solutions and suspensions is effortlessly streamlined by the **FagronLab™ PM140** through a one-step process that integrates mixing, de-aeration, and wet milling. This is achieved by utilizing the innovative FagronLab™ MillBottle (see 3.3. FagronLab™ MillBottle), enabling milling whole tablets, capsules or capsule contents, and bulk powders (Figure 6). For suspension preparation, simply place the whole tablets, capsules, or powdered APIs into the FagronLab™ MillBottle in the required formulation amount. Add the necessary quantity of water or liquid suspension base and securely close the lid of the FagronLab™ MillBottle. After inserting the FagronLab™ MillBottle into the FagronLab™ PM140, set the time and start the operation. As the base generates a centrifugal force during high-speed operation, medications added to the bottle crush against the strips inside this bottle. This milling process reduces particle size, dispensing particles in the base and achieving a homogeneous preparation.

Beyond its role as a mixing and milling vessel, this patent-pending bottle also serves as a storage and dispensing container for the final compounded formulation. The operational procedure is simple: Place all components into the FagronLab™ MillBottle, set the time, and initiate the operation.

Figure 6. FagronLab™ MillBottle.

1.3. Key Features

Single-Step Process

FagronLab™ PM140 combines mixing, wet milling, and deaeration processes in a single step. This enables the preparation of various dosage forms with a single device, simplifies the compounding process, and saves time while ensuring high quality formulations.

Time-Saving

The high mixing speed of **FagronLab™ PM140** is fixed to 2800 rpm, allowing the preparation of formulations in less than 60 seconds.

Dosage Accuracy

In volume-dependent doses, as in HRT creams, a reliable mixing process that deaerates the formulation improves API distribution and ensures dosage accuracy for each application.

Material-Loss Prevention

In traditional mixing processes, material loss occurs during the transfer to the final package after mixing. Even if the exact amounts are calculated and weighed, the compounded preparation is never completely transferred from the mortar into the package, especially when working with semi-solid dosage forms. To prevent material loss, the **FagronLab™ PM140** is designed to mix the formulation in a disposable FagronLab™ PM jar, also used as a final package to be delivered to the patient.

Conservation of Resources

The **FagronLab™ PM140** contributes to water conservation, as it does not require subsequent washing and rinsing steps of spare parts such as blades and mixing rods.

Low-Maintenance

The **FagronLab™ PM140** is distinguished by quality materials that allow for a low-maintenance and durable service, improving cost-efficiency. Due to its compact and functional design, the device can be easily integrated into lab furniture or used on the workbench. It also eliminates issues when compounding colored ingredients, such as coloring the blades or wearing them out by changing color and avoiding cross-contamination in a hormone preparation through the edges.

Compounding Hazardous Drugs

The term “hazardous drug” (HD) was first described by the American Society of Health-System Pharmacists (ASHP) in 1990 and has also been used by Occupational Safety and Health Administration (OSHA) for compounds that display the following characteristics: genotoxicity; carcinogenicity; teratogenicity or loss of fertility; and severe toxic manifestations at low doses in experiments with animals or treated patients. An API is considered hazardous if it features one or more of these characteristics, and new APIs with structure and toxicity profiles that mimic those of hazardous APIs are also classified as HDs.

According to the United States Pharmacopoeia (USP), pharmacists can be potentially exposed to HDs while compounding when:

- Weighing or mixing components;
- Crushing or splitting tablets or opening capsules;
- Pouring oral or topical liquids from one container to another;
- Constituting or reconstituting powdered or lyophilized HDs;
- Withdrawing or diluting injectable HDs from parenteral containers;
- Expelling air or HDs from syringes;
- Contacting HD residues present on Personal Protective Equipment (PPE) or other garments;
- Deactivating, decontaminating, cleaning, and disinfecting areas contaminated with or suspected to be contaminated with HDs;
- Maintenance activities for potentially contaminated equipment and devices.

FagronLab™ PM140 decreases the risk of exposure to HDs as it works in a closed environment provided by the FagronLab™ PM jars. Additionally, the FagronLab™ PM jars can be placed in negative pressure cabinets, which increases safety for the compounding of HDs.

Volume-Adjustable Jar

For the preparation of smaller batches than 100 mL, FagronLab™ PM jar 100 mL HV enables the reduction of the jar volume by pushing the bottom upwards after the operation. This eliminates the requirement of acquiring multiple jar sizes and additional jar holders/adaptors to accommodate them with the device. Additionally, it minimizes air contact by removing excess space, resulting in improved quality.

2. Technical Parameters

Model	FagronLab™ PM140
Width (mm)	205
Height (mm)	295
Depth (mm)	265
Weight (kg)	17.3
Table-Top Model	Yes
Electrical requirements	100 VAC - 230 VAC, 50 / 60 Hz
Power Consumption (W)	250
Feed Line	3 x 1.5 mm^2
On-Time	%15
Fuse Protection	2 x 4 AT
Revolutions	2800 rpm
Time-range	Seconds 10, 20, 30, 40, 50, 60, 90
	Minutes 2, 3, 4, 5, 10, 15

3. Accessories

3.1. FagronLab™ PM jar 100ml HV

FagronLab™ PM jar 100 mL HV is a sterile and disposable jar composed of polypropylene, and it is specifically designed to be used in the deaeration and mixing processes of high viscosity (HV) gels, creams, and ointments. Although its capacity is up to 100 mL, the internal nominal volume is 140 mL. This extra volume is necessary to allow the particles to move through the process, and promote its features. This PM jar presents a movable bottom. After the preparation, the remaining volume can be eliminated by pushing the bottom upwards, reducing air contact and its mixing capacity. The mixing capacity is also compatible with **FagronLab™ EMP** devices, enabling it to be used with low-soluble APIs and to prepare suspension formulas. It, therefore, eliminates the need to transfer the compound from the EMP jar to the **FagronLab™ PM jar 100 mL HV**. Since the FagronLab™ PM jars are made of a disposable material, they can also be used as a primary package to deliver to the patient, reducing the tools to be cleaned, saving time, and avoiding material loss during the transfer phase.

3.2. FagronLab™ PM jar 125ml HV+LV

The **FagronLab™ PM jar 125 mL HV+LV** is a disposable jar with a fixed bottom, designed mainly for mixing low-viscosity and more fluid formulations - but it can also be used for other preparations like creams, ointments, and gels. The capacity of this PM jar is 125 mL with a 180 mL nominal volume. When the device is operated at room temperature, the content can reach up to 45 °C. In case the prescription requires a higher temperature, the external heat can be applied to the **FagronLab™ PM jar 125 mL HV+LV**, up to 85 °C by using a hot water bath.

Table 1. Comparing FagronLab™ PM jars.

Accessory	FagronLab™ PM jar 100 mL HV	FagronLab™ PM jar 125 mL HV+LV
Internal Nominal Volume	140 ml	180 ml
Maximum capacity for Mixing	100 ml	125 ml
Bottom	Movable	Closed
Sterility	STERILE|EO*	STERILE|EO*
Applications	Deaeration Mixing	Deaeration Mixing
EMP Suitability	Suitable	Not-suitable
Suitable Dosage Forms	• Ointment • Cream • Gel	• Ointment • Cream • Gel • Lotion • Suppository • Insert • Mucosal films
Usability as Dispensing Primary Packaging	Applicable	Applicable

* **STERILE|EO**: Sterilized with ethylene oxide.

3.3. FagronLab™ MillBottle

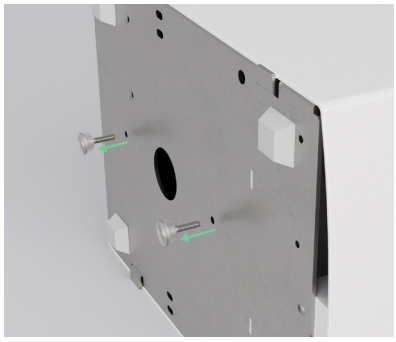
The **FagronLab™ MillBottle** is a graduated polyethylene bottle with a mixing capacity of 150 ml and an internal nominal volume of 220 ml, designed to compound colloidal solutions and suspensions in a closed environment. Its patent-pending design enables the wet milling of whole tablets, capsules, capsule contents, and bulk powders in water or a liquid suspension base while simultaneously engaging in mixing and deaeration without using the FagronLab™ PM jar holder. The high speed capability of the **FagronLab™ PM140** makes it also suitable for both high and low-viscosity liquid vehicles as well as powder suspending agents.

The semi-transparent orange color of the bottle allows for easy liquid volume measurement while protecting the substances from UV-light exposure.

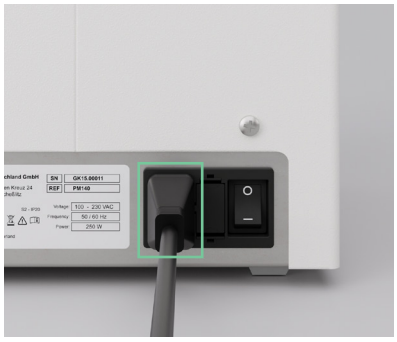
In addition to its function as a mixing and wet milling vessel, this unique bottle doubles as the primary packaging for these preparations, eliminating the need for an extra packaging step. It is delivered to pharmacies in a single, ready-to-use packaging, ensuring the protection of the **FagronLab™ MillBottle** from dust, dirt, and contamination during storage.

4. Functions and Use

4.1 Installation



1.
Remove the safety screws from the bottom, turn the device back to its rubber feet, open the cover and remove the cardboard tube.



2.
Connect the device to the local power supply using the provided power cord.

3.
Turn the device on using the power switch at the back of the device.
I → ON **O** → OFF

4.2. Operation

4.2.1. Operation with the FagronLab™ PM jar

1.
After turning the device on, and when the lid is closed, the LED light is flashing.

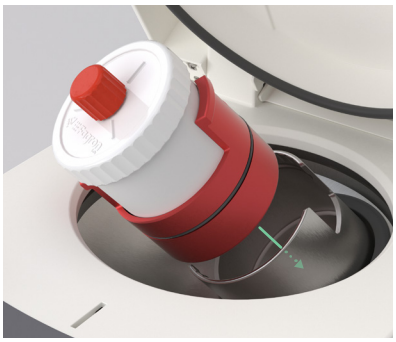
2.
Open the lid to insert the FagronLab™ PM jar.

3.
Select the time (min/sec).

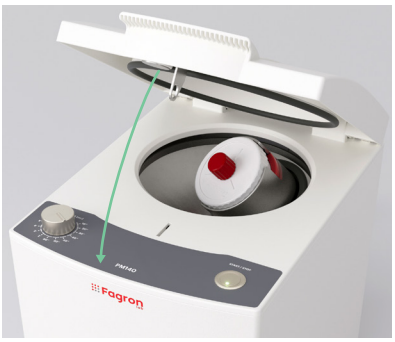
4.
Put the FagronLab™ PM jar holder on the table.

5.
Insert the FagronLab™ PM jar in the FagronLab™ PM jar holder.

6.
Turn the FagronLab™ PM jar slightly clockwise to ensure it is placed inside the FagronLab™ PM jar holder completely.

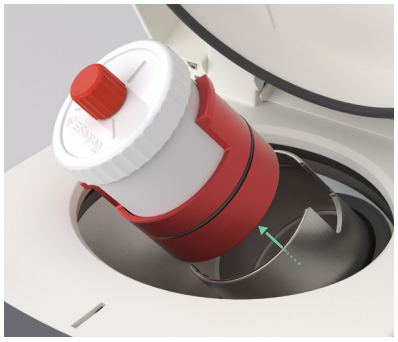


7.
Place the FagronLab™ PM jar with the FagronLab™ PM jar holder into the well. Make sure the FagronLab™ PM jar lid is completely closed, the shape is complementary with the well and the FagronLab™ PM jar is pushed all the way down.



8.
Close the lid.

9.
Press **START/STOP** button. The device automatically starts the operation, then stops after the mixing process is completed.



10.
After the operation is completed, open the lid to remove the FagronLab™ PM jar.

11.
Place the FagronLab™ PM jar holder on the table.

12.
By holding the FagronLab™ PM jar holder, take the FagronLab™ PM jar out of it while turning slightly clockwise and pulling out.

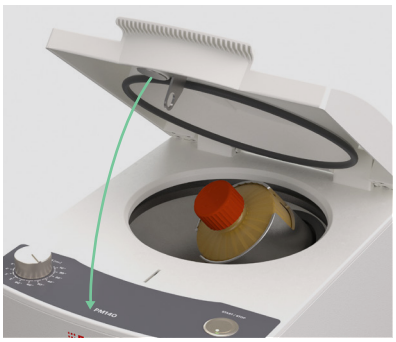
4.2.2. Operation with the FagronLab™ MillBottle

1.
After turning the device on, and when the lid is closed, the LED light is flashing.

2.
Open the lid to insert the FagronLab™ MillBottle.

3.
Select the time (min/sec).

4.
Place the FagronLab™ MillBottle into the well. Make sure the FagronLab™ PM lid is completely closed, its shape is complementary with the well and it is pushed all the way down.



5.
Close the lid.

6.
Press **START/STOP** button. The device automatically starts the operation, then stops after the mixing process is completed.

7.
After the operation, open the lid to remove the FagronLab™ MillBottle.

Should the compounding not exhibit homogeneity at the conclusion of the operation, it is possible that the operation time was too short. Follow the same steps to repeat the mixing process and ensure thorough homogenization.

5. Safety Shutdown

- The safety shutdown protects individuals from injury and the device from damage.
- Any attempt against the opening of the lid during mixing procedures leads to an immediate safety shutdown, which may lead to mechanical damage to the device and requires customer service support.
- Mixing procedures are immediately interrupted and stopped when pressing **STAR / STOP button**.

6. Maintenance

6.1. Cleaning

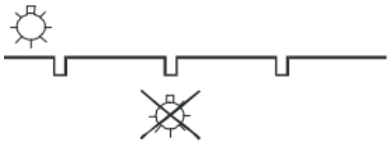
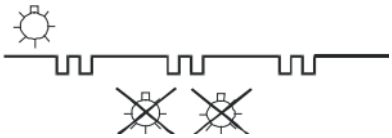
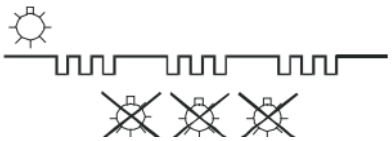
- Clean the surface with a soft fabric or cloth soaked with warm water and a non-abrasive household cleaning agent.
- Afterward, wipe the surface with another soft fabric or cloth soaked with warm water and clear it.
- In the end, rapidly wipe the entire surface with a dry cotton cloth or towel.
- Heavy scaling may be cleaned with a standard liquid cleanser.
- 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.
- Use mild surface disinfectants.
- Do not use thermal disinfection.

6.2. Operational Error

Error	Troubleshooting	Solution
Insufficient mixture quality.	Short mixing time.	Adjust mixing-time.
	The expiry date of the mixture passed.	Observe expiry date.
Uncombined powder after mixing.	Humid powder.	Store the powder according to the manufacturer's instruction.
Uncombined mixture.	Mixing time set too short.	Set longer mixing time.
Residues in the FagronLab™ PM jar holder.	The FagronLab™ PM jar is not closed properly.	Close the FagronLab™ PM jar properly.
The FagronLab™ PM jar cannot be lifted easily from the FagronLab™ PM jar holder.	Expansion due to long operation.	Wait for it to cool down.

6.3. Technical Error

Errors are indicated by a flashing LED light on the start button. They could be reset by pressing the start button or restarting the device. If the error continues, the LED light will flash again. The device does only work after eliminating the error.

Error	Troubleshooting	Solution
The device is not running, no LED light.	Defective fuse.	Check the fuse and replace it if necessary.
	ON/OFF switch in off-state.	Activate the ON/OFF switch.
Flashing LED	The lid has not been opened after switching on the device (with a closed lid).	The lid circuit is not yet activated. Open and close the lid.
	The lid has not been opened before the further mixing process.	Open and close the lid.
	The device cover does not close properly after pressing the start button.	Close the lid, press the start button.
The device is not running, no LED light.	Defective fuse.	Check the fuse and replace it if necessary.
Rapidly Flashing LED	Device activated too long.	Let the device cool down.
	Overheating	Let the device cool down
Flash Mode: *ON 100ms / OFF 100ms, 5 Hz*		
1 x Flashing LED 	Defective locking.	Contact your local supplier.
	Missing locking signal.	Contact your local supplier.
Flash Mode: *ON 2000ms / OFF 300ms / ON 2000 ms*		
2 x Flashing LED 	Defective incremental decoder.	Contact your local supplier.
Flash Mode: *ON 2000ms /* ***OFF 300ms*** */ ON 300 ms /* ***OFF 300ms*** */ ON 2000ms*		
3 x Flashing LED 	The defective motor control unit.	Contact your local supplier.

Flash Mode: *ON 2000ms /* ***OFF 300ms*** */ ON 300 ms /* ***OFF 300ms*** */*
ON 300 ms / ***OFF 300ms*** */ ON 2000ms*

7. Transportation and Storage

The **FagronLab™ PM140** weighs approximately 17.3 kg and should only be stored on flat, leveled surfaces capable of supporting the device's weight. The device is attached to the base plate with safety screws for protection during transportation, and the cardboard tube is inserted into the PM jar holder. Transporting the device should avoid collisions.

NOTE: Do not store the device in wet or extremely damp locations.

8. Warranty

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

Annex I. 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 mixing device
Product type:	FagronLab™ PM140
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 61010-2-051:2016-02
DIN EN IEC 61326-1:2022-11
DIN EN 61000-4-2:2009-12
DIN EN 61000-4-4:2013-04
DIN EN 61000-4-5:2019-03
DIN EN 61000-4-8:2010-11
DIN EN IEC 61000-4-11:2019-08
DIN EN 55011:2022-15

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

Dipl.-Wirtsch.-Ing. Matthias Konietzko, MBA

01.11.2022

Annex II. IQ/OQ

Functional Test FagronLab™ PM140

Assessment	Conclusion	
	OK	Not OK
Check the device label for readability.		
Check device location for stability and suitability.		
Check the device location for drafts, direct sunlight, extreme humidity, or temperature fluctuations.		
Check the device location for cleanliness, dryness, and freedom from dust.		
Check the accessibility to the power plug and power switch.		
Check the power supply for suitability and country-specific nominal voltage and frequency.		
Handling by unauthorized persons is excluded.		
Operation instructions in the user manual are available.		
Turn the device upside down and remove the safety screws from the bottom.		
Turn the device back to its rubber feet and open the lid.		
Remove the cardboard tube from the device and close the lid.		
Connect the device to the local power supply using the provided connection cable.		
Switch the power button on the back side of the device to “I”.		
Check if the red light keeps flashing after turning it on.		
Prepare a FagronLab™ PM jar adding a base cream or gel and close the lid of the jar to test deaeration (both the FagronLab™ PM jar 100ml HV and FagronLab™ PM jar 125ml HV+LV can be used).		
Place the FagronLab™ PM jar holder on the table, insert the FagronLab™ PM jar into the FagronLab™ PM jar holder, and turn the jar slightly clockwise. It is normal to be tight.		
Is the FagronLab™ PM jar inserted in the FagronLab™ PM jar holder?		
Place the FagronLab™ PM jar with the FagronLab™ PM jar holder into the well. Make sure the FagronLab™ PM jar lid is completely closed, the shape is complementary with the well and the jar is pushed down.		
Is the FagronLab™ PM jar fully inserted into the well?		
Close the lid of the device and set the time to 30 seconds from the button.		
Does the button move properly?		
Press “START”.		
Does the device start operation?		
Is the operation time the same as the set time?		
Does the device stop operating automatically?		
Open the lid of FagronLab™ PM140 and remove the FagronLab™ PM jar with the FagronLab™ PM jar holder.		
Is the FagronLab™ PM jar holder removed?		
Put the FagronLab™ PM jar holder on the table.		

Date **Signature**

Notes

Notes

References

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