EMP Pro

User Manual

www.fagronlab.com

Fagron lab

Dear FagronLab™ user, dear Compounder
thank you for choosing the EMP technology.

You have purchased a quality system for advanced pharmaceutical compounding.
Please read the following operation manual carefully.
For more information and compounding recommendation consult our homepage

www.fagronlab.com
www.fagron.com

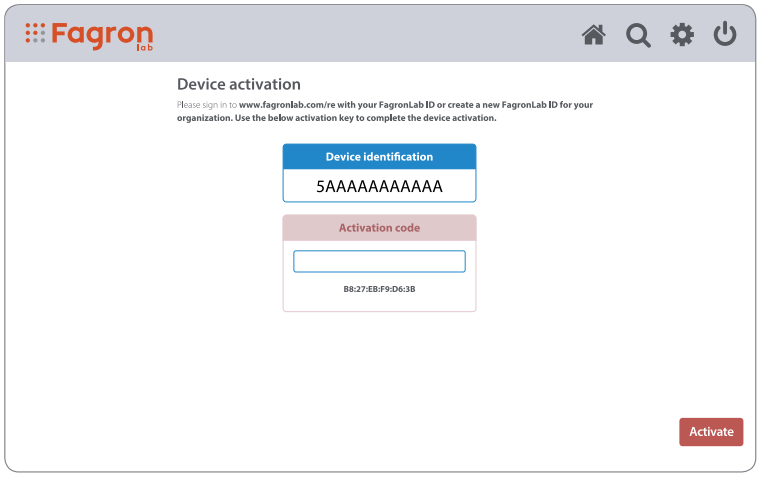
For additional support, operation handling and all other questions regarding
the technology please feel free to contact your local Fagron company or dealer.

Enjoy the successful production of quality assured compounding.

Your
FagronLab™
Compounding Support Team

Contents

Quick Start



How to register your EMP Basic device

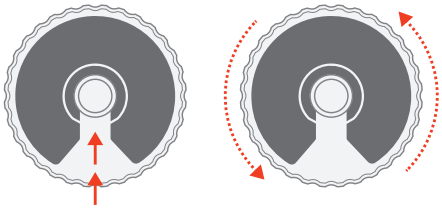
- Go to **www.fagronlab.com/re**
- Enter the 12 digit serial number
- Enter the activation code on your device

Display handling

- Touch screen reacting to pressing directly the respective symbols with your finger
- Main display displaying the mixing programs
- After selecting the program, scan of the jar size via the integrated camera or manual input by selecting "**Jar size**".

Lift arm with quick-lock coupling

- Hold the FagronLab™ logo on top of the jar to the front; insert the mixing shaft directly from the front into the lift arm
- Insert the mixing unit from below
- Fix the jar with a slight turn counterclockwise (about a quarter turn) into the lift arm and push the start button.



1. Installation information

The EMP Pro weighs 36,8 lbs (16,7 kg).

Select a suitable location for the EMP Pro.

- Solid, horizontal surface
- Away from direct airflow from air conditioning systems, heaters, open windows or fans
- No direct sunlight, keep the temperature steady between 15 - 30ºC (59 - 86ºF) and maximum humidity of 80%
- Clean, dry and dust-free

Remove all components from the cardboard box.
Check to ensure that the following components are included in your shipment:

- 1x EMP Pro mixing device
- Standard mixing Blades 1 - 5
- 1x Power cable
- 1x Disposable Blade starter kit I
- 1x Operating instructions

Note

- Please contact the FagronLab™ support team at your local Fagron or official dealer in case components are missing or arrived damaged.
- To ensure proper return without additional costs please, hold on to the original cardboard box and packing material of the **EMP Pro**.
- The warranty lapses if the original packing materials are not used for return deliveries.

2. Initial operation

- If the device is exposed to cold weather conditions, please allow the device to acclimatize for approx. 30 minutes, this will prevent humidity and condensation from interfering with the device's proper operation.
- The socket outlet is located on the rear of the **EMP Pro**. First connect the power cord to the socket outlet and then plug the power cord into the power outlet.
- The power button is also the emergency button. It is located on the rear of the device.
- Use the power button to turn on the **EMP Pro**. Now the device is ready for operation.

1 Touch - Display

2 Automatic, replaceable lift arm with quick-lock coupling

Power button/emergency button 1

3x RS232 ports 2

Socket outlet 3

4 4x USB ports

4 RJ45 port

3. The Unguator technology - Competence from the start

The **FagronLab™** product line is based on the Unguator Technology originally patented by Gako Konietzko GmbH, Germany. The core of the technology is to comply with requirements of prescribed semisolid formulations. It consists of the patented arrangement of the Mixing Blade and the jar that serves as both, a hygienic mixing jar and a hygienic dispensing jar.

The principle of the preparation method using technology in the closed FagronLab™ mixing system is quick and easy to learn, true to the motto:

"learning by doing"

A little experience will make it easy to prepare all semisolid formulations, though it may seem rather complicated at first. Using the technology enables the pharmacy to better prepare prescription ointments in a shorter period of time, compared to the conventional methods. For the first time, it is possible to not only standardize ointments, but validate them, too.

3.1 FagronLab™ mixing devices

The current FagronLab™ mixing devices - **EMP Basic**, **EMP Standard** and **EMP Pro** - are useful and advanced improvements. The FagronLab™ mixing devices feature a high safety standard. They were audited for safety by TŰV Rheinland, Germany.

The devices are manufactured by Gako International GmbH, Schesslitz - Germany. With increased product quality, product uniformity and reproduction of ointments prepared individually and in batches were vastly improved.

Method of ointment preparation	Pharmaceutical quality	Uniformity of ointment	Lift arm	Mixing parameters (rpm, mixing time)
Mortar and Pestle	●●○○	●○○○	—	Individually
EMP Basic	●●●○	●●●○	Manual guided lift	Individually programmable
EMP Standard	●●●○	●●●○	Automatic	Individually programmable
EMP Pro	●●●●	●●●●	Automatic	Fully automatic

Tab: Quality improvements with increasing automation

3.2 EMP Basic

- The **EMP Basic** ensures a GMP suitable preparation of semi-solid compounds up to 500 ml.
- The lift by hand is much easier through the guided lift arm with integrated quick-lock coupling.
- Jar size, mixing time and ten mixing speeds can be set on the **EMP Basic**.

3.3 EMP Standard

- The **EMP Standard** ensures a GMP suitable preparation of semi-solid compounds up to 500 ml
- The integrated quick-lock coupling allows for faster attachment of the mixing unit into the lift mount
- The lift arm works automatically so the mixing time can be used for e. g. documentation
- Jar size, mixing time and ten mixing speeds can be set with the **EMP Standard**.

3.4 EMP Pro

- The **EMP Pro** is the complete solution for the pharmacy
- The **EMP Pro** will not only support GMP compounding of semi-solid preparations up to 2000 ml. It also will be useful for additional compounding needs in the pharmacy
- Another beneficial feature will make stirring in medicine bottles possible
- Integrated standard mixing programs (suspension, emulsion, gel, etc.) with default mixing parameters makes the production of semi-solid compounds a lot easier. It is possible to rescale an already created mixing program to a different jar size to ensure the constant quality of the compound. This feature is time saving because there is no need to recalculating the parameters for an existing mixture. The optimized mechanics and electronics ensure a quiet operation
- In addition, the **EMP Pro** is preloaded with a database of several mixing parameters for semi-solid NRF formulations. This will optimize the manufacturing of NRF and NRF similar formulations and increase the compound quality
- The **EMP Pro** is equipped with several ports and ready for potential interconnection with electronic scales, printers (label, paper), keyboard and networking.

3.5 FagronLab™ assortment

As well as the FagronLab™ devices, the FagronLab™ assortment underlies further and new developments. All FagronLab™ accessories are compatible with all current and former available FagronLab™ mixing devices.

FagronLab™ stirrer

The FagronLab™ stirrer are the FagronLab™ Standard Mixing Blade (SMB) and the FagronLab™ Disposable Blade (Disp. Blade). The stirrers are steadily guided up and down inside the jar. Their unique design results in a tight contact between the mixing blade and the inside wall of the jar, which serves, primarily, for distributing the substances during the mixing process.

The lubrication effect of the ointment and the foundation generally protects the jars and the stirrer against abrasion. Discolorations of the mixing blade are mostly irreversible and therefore harmless. All SMB and Disp. Blade shafts are dishwasher safe.

The SMB and mixing shaft of the disposable blades are coated with titanium nitride, which makes them more resistant towards chemical and physical influences.

Assignment of the FagronLab™ stirrer

Ensure to use the correct stirrer for the corresponding jar. Selecting the wrong shaft may cause failure messages with the automated devices. Also ensure that the right shaft is used when working with the Disp. Blade. Both available shafts are marked for use with sizes 15 - 100 ml or 200 ml in the FagronLab™ jar. They have to be combined with the correct Disp. Blade. While the same Disp. Blade is used for the 100 ml and 200 ml jar sizes, it still needs a different shaft for each. See also the operation instructions that come with the disposable blade shafts.

Flowing recess of the FagronLab™ SMB

The flow-adapted shape of the SMB generally cleans itself during the rotating penetration of the ointment. Depending on ointment's ingredients', compatibility of weighted formulation and also if the jar is considerably under filled (e.g. large volumes of powder), unmixed ingredients may adhere to the SMB in recesses of flow. These remnants should be transferred into the jar using a spatula when about half of the mixing time is complete.

The air should be diminished again, by pushing the bottom of the jar up, following this process. When using the Disp. Blade, however there are no recesses of flow and no remedial work is generally required.

Warming

The warmth that develops from the friction between the stirrer and the inside wall of the jar is generally desired. Decreased viscosity increases the wettability of powders and accelerates the penetration of potential powder pockets. Even the emulsifying ability of fats and oils benefits by warming.

A temperature of 54ºC / 129ºF was the maximum taken after 6 minutes of mixing a highly pasty preparation made of vaseline and zinc oxide at full speed.

This temperature increase is generally safe for the substances used in the pharmaceutical field. Ointments of low viscosity only heat slightly. Volatile substances such as ethereal oils or alcohol do not evaporate from the closed mixing unit.

Cleaning the FagronLab™ stirrer

The stirrer is normally cleaned with a paper towel and, if necessary, held under hot water faucet and then dried with a paper towel. The stirrers can also be cleaned in the dishwasher.

The FagronLab™ devices as well as the FagronLab™ line of products should never be treated with sharp-edged objects or abrasive cleaning agents.

FagronLab™ Standard Mixing Blade (SMB)

The FagronLab™ SMB's are adjusted to the size of each individual FagronLab™ jar. For jar size 100 ml and 200 ml use the same SMB, also the 300 ml and 500 ml jars share a SMB. Before each use make sure the SMB used has the correct length, and the blades are clean prior using them (e.g. cleaning with isopropanol 70%).

The SMB is suitable for the production of all kinds of formulations. We recommend especially for suspension ointments and pre-grinding the use of the standard mixing blade.

FagronLab™
Standard Mixing Blade

FagronLab™
Disposable Blade

FagronLab™
Disposable Blade Shaft

FagronLab™ jar

The FagronLab™ jar is both, a mixing and a dispensing jar, and is therefore designed as a disposable jar. The jar guarantees evaporation free and contamination free preparation in an air reduced mixing space.

The FagronLab™ jar lid closes the jar tightly to prevent evaporation and therefore loss of active ingredients. Used as a dispensing jar, the jar corresponds to the guidelines for quality assurance from the German Chamber of Pharmacists ("Apothekerkammer"). With its small dispensing opening, comparable to a tube and without an environmental contamination surface, the jar guarantees the minimization of negative quality interference demanded by section 13, ApBetrO (Pharmacy Operation Regulations); including those caused by germs on fingers when dispensing the ointment. Therefore, the user can remove very hygienically the ointment from the jar.

FagronLab™ Disposable Blade (Disp. Blade)

The FagronLab™ Disp. Blade is suitable for all FagronLab™ devices. The one time use mixing blade is connected to the disp. blade shaft by pushing it down and twisting the blade counterclockwise, it can be disconnected after the mixing process with a clockwise turn.

The material contact in the ointment is three times higher due to the three times amount of blades when using the Disp. Blade compared to the SMB at the same mixing speed. The counter rotating twist of the mixing blades causes intensive material vibration, therefore a better distribution in the material to be mixed and achieves good product quality faster than using the SMB. However, we recommend using the same mixing time as for the SMB.

In the obligated process of final quality control the mixing blade can be removed and discarded or left inside the jar. Cleaning is limited to the Disp. Blade shaft. We also recommend using the Disp. Blade for substances that may discolor the regular blade. This type of stirrer also comes with different shaft lengths. Every shaft is imprinted on its thinner end with the associated range of jar sizes, 15 - 100 ml and 200 ml. Disp. Blades are specially suitable for compounding emulsion, gels and "soft in soft" formulations. For suspension ointments and pre-grinding is recommended the use of SMB.

Additionally, it is possible to open the jar by unscrewing the lid and removing compound remainders. The jar is resistant to hot-water baths and microwaves with temperatures maximum of 85ºC / 185ºF. Higher temperatures may alter the tightness of the jar and the sliding ability of the jar bottom might be negatively impacted. The jar material could become brittle at temperatures below 0ºC / 32ºF.

Jars are available in following sizes: 15 - 20/33 ml, 30/42 ml, 50/70 ml, 100/140 ml, 200/280 ml, 300/390 ml, 500/600 ml, 1000/1250 ml and 2000/2600 ml (rated volume/filling volume). The standard color of the jar housing is white and the lid red. The 300 ml, 500 ml, 1000 ml und 2000 ml jar come only with white lids.

Note

- All jars come sealed in plastic packaging.
- Cleaning or disinfection prior usage could put the certified low microbiological contamination at risk.
- We would recommend storing the jar in its plastic packaging after opening for protection against possible dust contamination.
- A large applicator is standardly delivered with a 200 ml jar as pushing aid.

The jar sizes 300 to 2000 ml are particularly well suited as storage and transfer vessels for semisolids and other preparations. Since the contents dispensed using the movable jar bottom are always close to the lid, jars solve the problem of the unsightly contents in traditional porcelain vessels used previously.

Evaporation, formation of crust, contamination and oxidation processes can thereby be avoided to a great extent. Furthermore, the contents of the jar can be moved close to the lid after dispensing using the spindle or the AirDynamic.

As long as the housing of a 300 ml to 2000 ml jar is meant to remain in the pharmacy it can be cleaned in a dishwasher.

AirDynamic/Spindle

Note

- Low microbiological contamination has to be ensured before reuse though.
- The movable bottom of the jar is not suitable for the dishwasher and the sealing lip of the jar lid may be destroyed after repeated mixing.
- The corresponding jar lids or jar bottoms can be ordered as spare parts in sets of five and used for the economical reuse of the body.

The jar is subject to periodic inspections in accordance to the guidelines of the Bundesapothekerkammer “Examination and Storage of primary packaging material”. A certificate of analysis is issued after batch-defined examinations. After a visual receiving inspection the manufacturer’s test certificate (certificate of analysis) is retained for the documentation of primary packing materials as stipulated. This certificate is affixed to the plastic packaging of the jar. If required, it can be removed and added to the stipulated documentation.

VPE/pu: 10
Ch-B/Lot.No: 5AAAAAAAARYD
Art.-Nr./PCN: AT1000000267
PZN: 11602883 BLOZ: 1234567
PPN: 1111602883
Prüfdatum/date of control: 1/1/2016

Fagron lab 100

Made in Germany

4 251208 800060

Detailliertes Analysenzertifikat/detailed certificate of analysis: fagronlab.com/coa
Geprüft nach Arzneibuch (entspricht) / tested according to pharmacopoeia (complies)
manufactured for Fagron Group by Gako International GmbH, D-96110 Scheßlitz
which is certified according **DIN EN ISO 9001:2015**
Gezeichnet/signed: Glöckner (Leiter Qualitätswesen/Head of Quality)

Analysenzertifikat
Certificate of analysis

Made in Germany
Detailliertes Analysenzertifikat/detailed certificate of analysis: fagronlab.com/coa

manufactured for Fagron Group by
Gako International GmbH, D-96110 Scheßlitz
which is certified according
DIN EN ISO 9001:2015

Gezeichnet/signed: Glöckner
(Leiter Qualitätswesen/Head of Quality)

en: Only material and color components which correspond to the German Consumer Goods Ordinance (BedGgstVO), the regulation (EC) No. 1935/2004 and the FDA regulations (21CFR177.1520, 4/2012) are used for this product. Quality control is performed in accordance with the Pharmacopoeias DAB, Ph. Eur., USP and JP. Detailed certificate of analysis available: fagronlab.com/coa **This product can be used without cleaning.**

pl: Wszystkie surowce i barwniki odpowiadają niemieckiemu rozporządzeniu dotyczącym konsumentów i towarów (BedGgstVO), europejskiemu rozporządzeniu (WE) nr. 1935/2004 oraz regulacjami FDA (21CFR177.1520, 4/2012). Kontrola jakości odbywa się zgodnie z Farmakopei DAB, Ph. Eur., USP i JP. Szczegółowe informacje: fagronlab.com/coa **Produkt ten może być stosowany bezpośrednio bez oczyszczenia.**

pt: Este produto utiliza apenas componentes com materiais e cores de acordo com o regulamento de bens de consumo alemão (BedGgstVO), o Regulamento (CE) N.o 1935/2004 e os regulamentos da FDA (21CFR177.1520, 4/2012). O controlo de qualidade é realizado em conformidade com as Farmacopeias DAB, Ph. Eur., USP e JP. Certificado de análise detalhado, disponível em fagronlab.com/coa **Este produto pode ser utilizado de imediato sem limpeza prévia.**

fr: Ce produit utilise exclusivement des composants (matériaux et couleurs) qui suivent la réglementation en vigueur en Allemagne (BedGgstVO), en Europe (règlement (CE) No 1935/2004 et aux États-Unis (21CFR177.1520, 4/2012). Le contrôle de la qualité est effectué en conformité avec les Pharmacopées DAB, Ph. Eur., USP et JP. Certificat d'analyse détaillée disponible: www.unguator.com/coa. fagronlab.com/coa **Ce produit peut être utilisé sans nettoyage préalable.**

sl: Za izdelke se uporabljajo samo materiali in barvne komponente, ki ustrezajo nemškemu odloku o potrošniškem blagu (BedGgstVO), uredbi (ES) št. 1935/2004 in predpisih organa FDA (21CFR177.1520, 4/2012). Nadzor kakovosti se izvaja v skladu s farmakopejami DAB, Ph. Eur., USP in JP. Podrobno potrdilo o analizi je na voljo: unguator.com/coa fagronlab.com/coa **Izdelek se lahko uporablja neposredno brez predhodnega čiščenja**

es: En este producto se utilizan exclusivamente componentes (materiales y colores) de acuerdo con la Ordenanza Alemana de Bienes de Consumo (BedGgstVO), el Reglamento (CE) No 1935/2004 y la directriz de la FDA (21CFR177.1520, 4/2012). El control de calidad se realiza de acuerdo con las farmacopeas DAB, Ph. Eur., USP y JP. El certificado de análisis detallado está disponible en: fagronlab.com/coa **Este producto se puede utilizar directamente sin limpieza**

de: Für dieses Produkt werden nur Material- und Farbkomponenten verwendet, die der BedGgstVO, der Verordnung (EG) Nr. 1935/2004 und der FDA-Richtlinie (21CFR177.1520, 4/2012) entsprechen. Die Qualitätskontrolle wird gemäß den Arzneibüchern DAB, Ph. Eur., USP und JP durchgeführt. **Dieses Produkt kann ohne Reinigung direkt verwendet werden.**

cs: Pro výrobu tohoto produktu byly použity pouze materiály a barvy, které odpovídají německým vyhláškám o spotřebním zboží (BedGgstVO), nařízení (ES) č 1935/2004 a předpisům FDA (21CFR177.1520, 4/2012). Kontrola kvality je prováděna podle lékopisů DAB, Ph. Eur., USP a JP. Podrobné certifikáty o analýze je dotupné na: fagronlab.com/coa **Tento produkt může být použit bez dalšího mytí.**

sk: Pre výrobu tohto produktu boli použité iba materiály a farby, ktoré zodpovedajú nemeckým vyhláškam o spotrebnom tovare (BedGgstVO), nariadenia (ES) č 1935/2004 a predpisom FDA (21CFR177.1520, 4/2012). Kontrola kvality je vykonávaná podľa liekopisov DAB, Ph. Eur., USP a JP. Podrobné certifikáty o analýze je dotupné na: fagronlab.com/coa **Tento produkt môže byť použitý bez ďalšieho umývania.**

Certificate of analysis FagronLab™ jar

Ch-B/Lot.No: 5AAAAAAAARGD
PCN: AT1000000267
1/1/2016 - 1/1/2018
PZN: 11602883 BLOZ: 1234567
fagronlab.com/coa

manufactured for Fagron Group by
Gako International GmbH, D-96110 Scheßlitz
which is certified according
DIN EN ISO 9001:2015

Fagron lab 100

Made in Germany

Jar label FagronLab™ jar

A detailed certificate is available for download at **www.fagronlab.com/coa**

A label is attached to each jar, which provides jar size, serial number (S/N), product number (PCN), date of packing, date of expiration and PPN. We recommend for a complete documentation to attach the jar label of the used jar onto the manufacturing record.

Notes on dispensing ointment

Each customer should be given specific instructions with an empty jar at how to use the jars. The use of the spindle should be explained for large jar, size 300 and 500 ml. Low viscosity ointments should be equipped with an applicator or a varionozzle to reduce the dispensed volume. Medium viscosity ointments can be easily extracted through the regular opening of the jar. Very pasty ointments (e.g. pasta zinc) may not necessarily be pressed through the regular opening, even by using a spindle.

In this case, the ointment can also be removed, similar to handling conventional jars with a regular lid, by removing the lid and with the help of a spatula. If the jar lid has been removed, the ointment should be pushed up close to the lid after each dispensing process. In larger jars by using the spindle or the AirDynamic.

The diameter of the dispensing nozzle allows simple dosing of the quantity of ointment to be applied using approximate values. The regular dispensing nozzle in the screw lid of each FagronLab™ jar has a diameter of 8 mm. The varionozzles or applicators reduce the diameter to 4, 2 or 1 mm. To ensure an exact dosage of highly active compounds, it is recommended to use the ExactDose Adapter. It is possible to extract an exact amount of 0.5 ml.

FagronLab™ varionozzles

The FagronLab™ varionozzles with inner diameters of 1, 2 or 4 mm can be pressed into the regular nozzle of any FagronLab™ jar. They reduce the opening size, making it possible to safely dose even low viscosity formulations. The viscosity of the finished product normally specifies the diameter of the varionozzles. The softly rounded surface allows ointment to be pleasantly spread directly onto skin.

The coloring was selected corresponding to the wavelength of light:

- 4 mm: red (long-wavelength light)
- 2 mm: yellow
- 1 mm: blue (short-wavelength light)

FagronLab™ applicators

The FagronLab™ applicators reduce the extracted quantity of low-viscosity formulations and are particularly helpful in cases where the ointment must be precisely applied.

FagronLab™ applicator short

The FagronLab™ applicator short with a diameter of 1 mm is obligatory for nose and ear ointments.

FagronLab™ applicator long

The FagronLab™ applicator long with a diameter of 2 mm allows formulations to be introduced into large orifices of the body or probes. In addition, the applicator long also comes inside each FagronLab™ 200 ml jar to help pushing up the bottom of this jar size in full.

FagronLab™ spindle

The FagronLab™ spindle serves as a dispensing system for FagroLab™ jar sizes 300 ml or 500 ml. Extract the spindle from the jar. Push carefully the bottom of the jar with a disinfected SMB (if not available, with a disinfected spatula) all the way down. Air can be diminished by placing the jar with slightly open lid loosely onto a spindle and pushing the bottom upwards. Before giving the jar to the customer, the safety adapter needs to be removed and the spindle must be screwed in the jar counter clockwise from the bottom until it locks into place. The spindle must be turned clockwise to extract the ointment. One turn dispenses approx. 20 ml of the contents of the jar.

Warning

- If the movable bottom is accidentally perforated or the spindle is permanently locked in the bottom of the jar, the jar may only serve as dispensing or storage vessel and can no longer be used for the mixing process.

FagronLab™ coupling

The FagronLab™ coupling connects two FagronLab™ jars by their screw threads of their dispensing openings and is very useful when preparing ointments in larger batches. Transferring a formulation from a larger jar into a smaller jar using the coupling will ensure hygiene from the mixing process to the end user. The 200 ml jar becomes a convenient transfer device to smaller jars when their jar bottoms are carefully pressed towards the work surface using an applicator, long screwed on a 30 ml jar. The jar coupling is available as FagronLab™ jar coupling 15 - 1000 ml and also as FagronLab™ jar coupling 2000 ml.

In addition to the coupling, required for transferring from a 300 ml or 500 ml jar into a smaller jar, both the spindle and the AirDynamic may also be used. Dispensing and transferring a formulation via the regular jar nozzle from a 1000 ml and 2000 ml jar is practically only possible using the AirDynamic.

We recommend transferring the formulation after mixing as soon as possible, since the formulation is still warm and less viscous.

FagronLab™ AirDynamic

The FagronLab™ AirDynamic optimizes batch preparation within the closed system:

- Contamination-free transfer
- Contamination-free storage

It is designed for FagronLab™ jar sizes from 300 to 2000 ml for hygienic transfer of the compound. The jar is attached to the base plate of the AirDynamic with the central hole at the bottom of the jar housing. By closing the easy-lock system on the side of the base plate, the jar is attached airtight.

By pressing the pump ball, with its valve screw closed, air is pumped into the lower chamber of the jar. The thus generated pressure pushes the movable bottom up. Thanks to the AirDynamic, even thick pastes can be dispensed via the small dispensing opening in the screw cap or transferred to small jars using the coupling. The material outlet velocity depends on viscosity which may be reduced through warming. The air pressure that has developed in the lower chamber of the jar can be relieved by opening the valve screw. This is mandatory after the transfer process using the coupling before the smaller jar is removed. Otherwise this may result in considerable contamination of the immediate environment, depending on the formulation viscosity.

FagronLab™ ExactDose adapter

The FagronLab™ ExactDose Adapter allows the exact dosage of 0.5 ml paste, gel, cream or ointment for topical or transdermal therapy. The adapter will be screwed onto the jar after the mixing process is finished. Insert the red set screw with a little pressure into the transparent part of the ExactDose Adapter. The coloured ball inside the ExactDose Adapter lays on its lowest position when the red set screw is horizontally positioned.

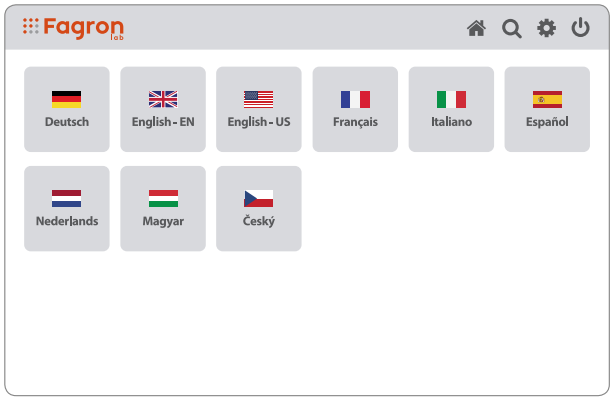
With pushing the jar bottom upwards the ExactDose chamber will be filled with the exact amount of compound and the coloured ball will be pushed up to its highest position. With a 180 degree turn of the set screw the coloured ball will be in the lowest position again, the compound will be extracted by pushing the jar bottom upwards and the chamber will be filled again with compound for the next dosage extraction.

4. Display handling

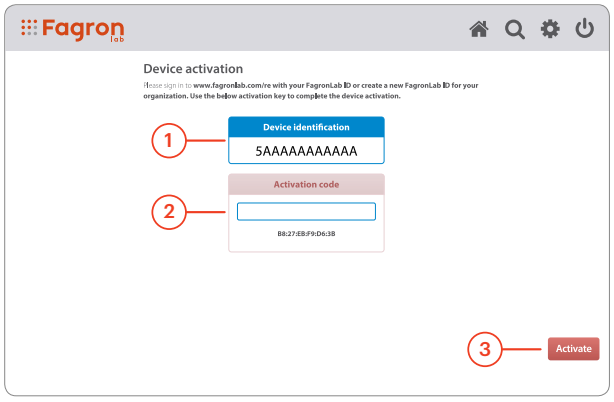
4.1 Initial operation

- The socket outlet is located on the rear of the **EMP Pro** (1). Located above, is the power button (2), which is also the emergency button. Ensure that the power button of the **EMP Pro** is in its off position. First connect the power cord to the socket outlet and then plug the power cord into the power outlet
- Connect the keyboard, delivered with your device, with one of the USB ports (3) of the **EMP Pro**
- Use the power button to turn **EMP Pro**, the device boots and is ready for operation.

- After booting the touch-screen shows the device type "**EMP Pro**".



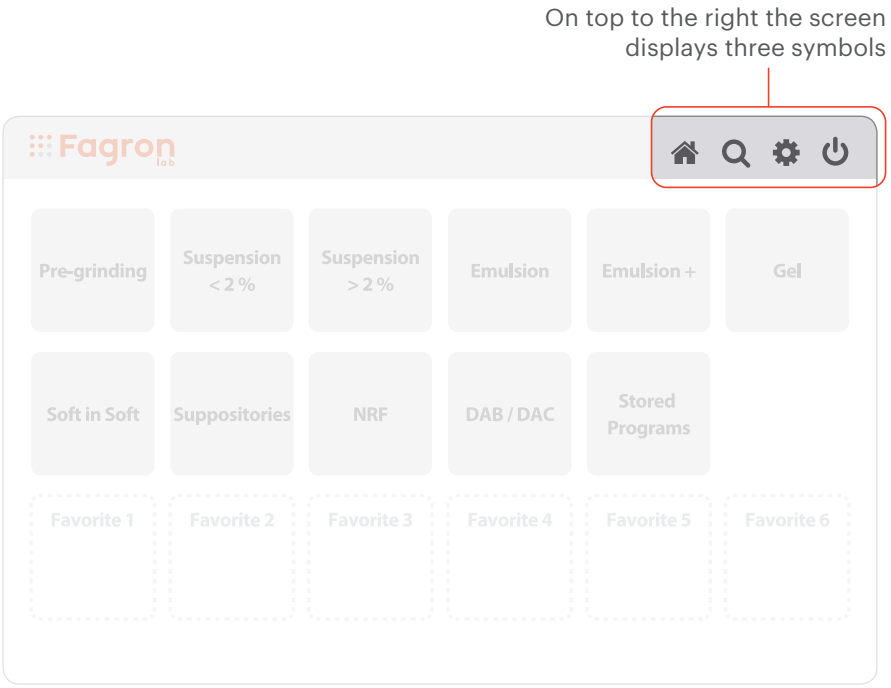
- On initial operation, the reference for the online registration at **www.fagronlab.com/re** will be displayed.



- Enter the 12 digit serial number (1) online at **www.fagronlab.com/re** to register the new device. Then the activation code will be provided to activate the **EMP Pro**
- Click with a finger onto the input mask (2) showing on the touch-screen and enter, using the keyboard, the activation code
- Confirm the activation by taping the "**Activate**" button (3) with a finger.

4.2 Compounding with the EMP Pro

- Located on the front of the **EMP Pro** is the touchscreen to control the device
- After booting the touchscreen shows the device type "**EMP Pro**"
- Followed by displaying the current number of preparations. After a few seconds, it forwards to the next screen.



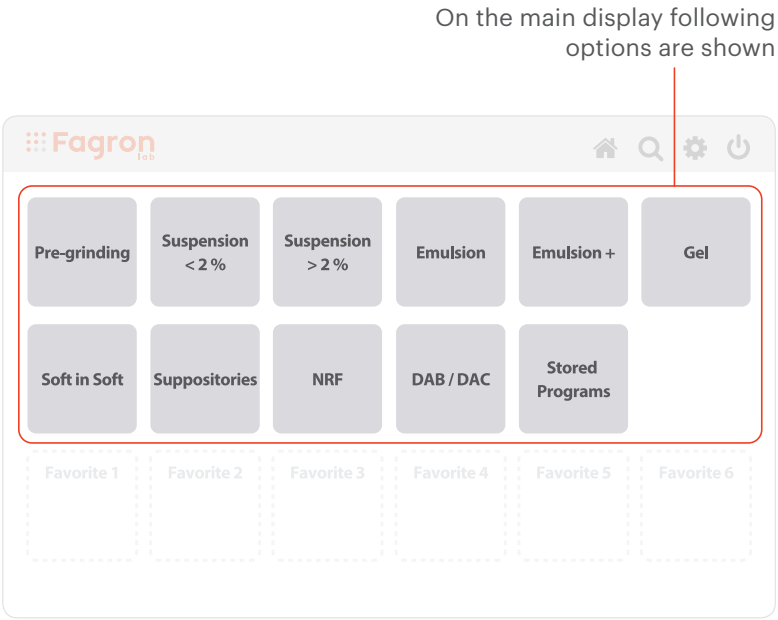
Home
Redirects to the start screen

Magnifying glass
Formulation search function

Gear
Settings, with the following options available

- **Information:** Displays the technical information of the EMP Pro (device type, softwareversion, current number of preparations, MAC address, device identification)
- **Language:** Change the language setting
- **Shutdown:** The device shuts down and can be turned off with the power button afterwards
- **Reset:** The EMP Pro sets back to the factory settings. Please only perform this action after being instructed by the technical service of the Fagron (fs@fagronlab.com).
- **Network:** To manage the network and proxy settings.

On/Off-button
Shuts the EMP Pro directly down to be turned off with the power button



Stored mixing programs

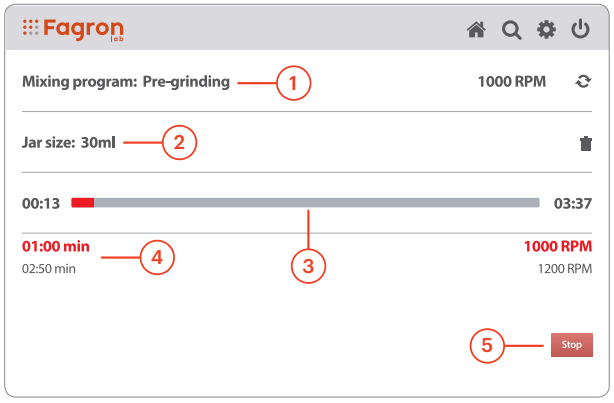
- Pre-grinding
- Suspension < 2%
- Suspension > 2%
- Emulsion
- Emulsion +
- Gel
- Soft in Soft
- Suppositories

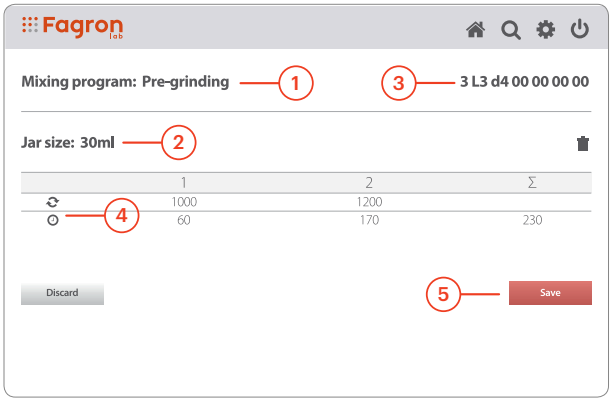
Additional options are available

- DAB / DAC
- NRF
- Custom programs

To select the program press the communicating program button. The lift arm moves into the mounting position. The integrated camera will be activated and displayed on the screen. Scan the QR-code on the left side of the jar label, the device will recognize the jar size. By pressing the button "**Jar size**", the jar size can be entered manually by selecting the communicating jar size.

Following, the mixing unit is mounted into the lift arm. The visual description shows the easy mounting of the jar into the quick-lock coupling. By selecting "**Start**" on the lower right, the lift arm moves automatically into the start position, the stirrer shaft locks and the mixing process starts.





- During the mixing process the following parameters are displayed:

1. Mixing program
2. Jar size
3. Time (passed and remaining)
4. List of mixing time and mixing level
5. "**Stop**" button to abort the mixing process

After the mixing process is finished the free spin program starts, the stirrer will be mostly clean, the mixing process is finished and the lift arm will move to the removal position. The mixing blade unlocks and the mixing unit can be removed.

- A summary of the mixing process is displayed
- It shows the used mixing program (1), the jar size (2), the ID-Number (3) and a precise breakdown of the mixing levels and mixing time (4) and their sum (5)
- The identification number (ID-Number, review chapter 5) helps for an easier documentation and reproducible product quality. We recommend to record the ID Number on the manufacturing record.

4.3 Additional mixing programs

DAB / DAC

DAB/DAC Standard formulation are stored and selectable. Scroll through the list of selected formulation by using the buttons on the lower right. A formulation can be selected and/or marked as favorite (push the star behind the formulation, it will be filled). This is recommended for often used DAB/DAC formulation. The favorite can always be removed by another push onto the star (the star will not be filled).

The search function in the top part of the touchscreen will search directly for a certain DAB/DAC Formulation and can be selected by pushing it.

The following steps are comparable using the standard mixing programs.

NRF

NRF formulations are stored and selectable. Scroll through the list, sorted by NRF-Numbers, by using the buttons on the lower right. A formulation can be selected and/or marked as favorite (push the star behind the formulation, it will be filled). This is recommended for often used NRF formulation. The favorite can be always removed by another push onto the star (the star will not be filled).

The search function in the top part of the touch screen will search directly for a certain NRF Formulation and can be selected by pushing it.

The following steps are comparable using the standard mixing programs.

Stored programs

There is the option to save often used formulation or formulation manufactured following certain criteria. Select “**Stored programs**”. All saved programs are displayed as a list, select the desired program.

To add a mixing program, select “**New program**” and the input mask is available. Attach the supplied keyboard using a USB port on the rear of the device. Tab the upper input field and enter the name of the formulation. In the lower input field enter the 13 digit ID-Number, which defines the mixing parameters by level and time (review chapter 6). Confirm the parameter by selecting “save” in the lower right, the formulation is stored in the list “**Stored programs**”.

Again, a formulation can be marked as favourite by pushing the star behind the formulation and it will be displayed on the start screen. The favourite can always be removed by another push onto the star (the star will not be filled).

The following steps are comparable using the standard mixing programs.

4.4 Aborting the mixing process

To abort the mixing process press the “**Stop**” button on the lower right on the screen.

Following, select “**Cancel**” on the lower left (the mixing process ends immediately) or “**Free-spin**” on the lower right (performs the free-spin).

The touch-screen will show the start-screen. When aborting the mixing process, no ID-number is issued.

5. Compounding guidelines for the technology

5.1 Preparing the FagronLab™ mixing unit

The FagronLab™ mixing unit consists of a FagronLab™ jar, a FagronLab™ stirrer and the components of the formulation to be mixed.

First, the jar cap (small red screw cap) of the jar and then the jar lid (large red, white or coloured screw cap) must be unscrewed from the jar.

Second, the stirrer is inserted into the jar housing and used to slide the jar bottom straight down. The jar lid is then slid onto the stirrer standing in the jar housing and pressed down firmly using both thumbs. Ensure that the sealing lip of the jar lid opening is not damaged by the bayonet noses, because the ointment may otherwise rise up the stirring shaft during the mixing process.

Third, the stirrer is carefully removed from the jar and the jar lid will be moved all the way in the direction of the blade. Both parts, i. e. the stirrer and the jar lid are put down or possibly tare on the scale together with the jar.

After weighing out the formulation components into the jar, the lid including the stirrer has to be screwed on. Afterwards move the lid with a slight twist, about a half centimeter, to open it a tad. By pushing the bottom up with the thumb or for large jars, with help from an applicator, the spindle or AirDynamic the air will escape between the jar lid and the jar housing. This process is called air diminution.

Air diminution will prevent ointment exudation at the sealing zones of the jar through reduction of any overpressure that may have developed. The mixing result is also optimized since there is no trapped air. Then the mixing unit should be closed by tightly screwing the jar lid down.

5.2 Weighed portion of the formulation

Generally, oily, greasy, aqueous and pulverized components can be weighed out into the jar all at the same time. However, it is advantageous to consider certain general procedures to optimize the mixing results. Generally, know-how gained from the traditional preparation of ointments is very helpful when using the mixing device. As already mentioned at the beginning of the operating manual, true to the motto: ***learning by doing***

The mixing programs are general procedures used to produce the routine standard formulations in pharmaceutical preparation of compounds.

In the following, these standard formulations will be defined and the recommended procedure on weighing described. This will produce a code of practice for orientation. This does not exclude other possible methods for optimization.

For mixtures with high liquid content, ensure that the ointment foundation on the jar bottom is first carefully placed around the sealing lip. This enhances the leak tightness of the jar. For jars of 200 ml and up an active substance proportion of less than 5"%, the active ingredient can be filled alternating with the foundation ointment over two or more levels to speed up vertical intermixture.

Solid components should be inserted on the side of the jar and covered with foundation. This will prevent the solid materials to adhere onto the stirrer.

5.3 The mixing process

The **EMP Pro** is the result of continuous improvements of the technology.

The integrated, programmable microprocessor automates the mixing process with the **EMP Pro** completely, providing an universal device for pharmaceutical compounding!

The **EMP Pro** uses two quiet, high performance permanent motors and is an intelligent ointment mixing device for compounds from 15 - 20 to 2000 ml. After selecting a program, the jar size can be scanned or manually entered and the mixing unit mounted into the quick-lock coupling.

With every finished mixing process the **EMP Pro** will automatically issue an identification number (ID). The identification number will simplify documentation and exact reproduction of the mixing process and will be shown on the display after every mixing process.

Level	Rotation speed (rpm)
0	300
1	600
2	800
3	1000
4	1200
5	1400
6	1650
7	1900
8	2150
9	2400

Tab: Value chart rotation speed

Quick-lock coupling

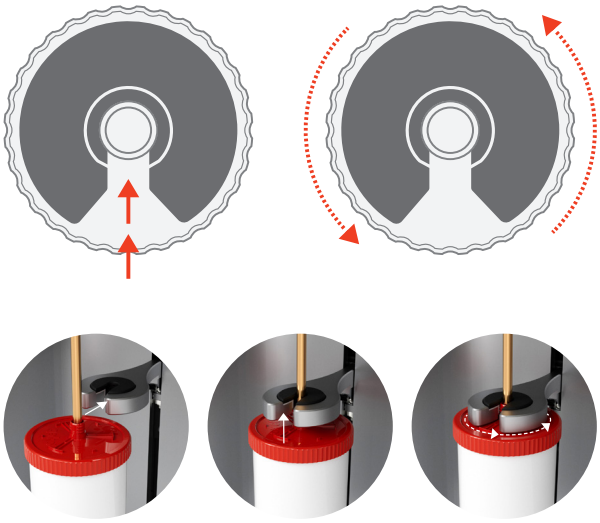
Hold the FagronLab™ logo, on top of the jar, to the front. Load the stirring shaft directly from the front into the lift arm. Push the mixing unit up and with a slight turn counterclockwise (about a quarter turn) fix the mixing unit into the lift arm.

Push the start button on the display, the lift arm including the mixing unit moves up, locks and the mixing process starts.

After the mixing process is finished the free spin program will be initiated.

The lift arm will move down until the MB will touch the lid. The mixing motor will accelerate up to level 9. The MB will be mostly clean, the mixing process is finished and the lift arm will move the mixing unit into the removal position for an easy extraction.

With every finished mixing process the **EMP Pro** will automatically issue an identification number (ID). The identification number will simplify documentation and exact reproduction of the mixing process and will be shown on the display after every mixing process.



5.4 Mixing programs

Pre-grinding

The pre-grinding process serves to wetten solids in the preparation of suspension with an active substance content < 2%, allowing a homogeneous distribution of active substances in an ointment foundation.

As an example, the incorporation of corticoids, antibiotics, fungicides or hormones in an ointment foundation. In order to ensure a homogenous distribution, we recommend using the standard mixing blade.

First, load approximately 30% of the foundation ground-covering in the jar and cover the micronized active substances with foundation. The active substances have to be covered in the foundation in order to avoid powder residue sticking on the blade.

The jar bottom should be pushed up as far as possible to prevent incorporating air.

Please inspect the preparation for agglomerates or qualitative abnormalities after the pre-grinding process is completed. If required, the pre-grinding process may be repeated. Further processing of the compound should be prepared by using the program "**Suspension < 2%**".

Suspension < 2%

After finalising the pre-grinding process, both the remaining foundation and all active substances will be weighed in. Therefore move the jar bottom by using a spatula all the way down to add the remaining components.

To incorporate air as little as possible push the movable jar bottom up until resistance is felt.

Suspension > 2%

With the mixing program "**Suspension > 2%**" solid substances of more than 2% can be incorporated into foundation.

As an example, the incorporation of zinc oxide, salicylic acid or bismuth gallate in foundation. To ensure a homogeneous distribution we recommend using the standard mixing blade.

For suspensions with ingredient content above 2% pre-grinding process is not required.

In preparation, add 50% of the required foundation ground-covering into the jar and the micronized solids to the middle. Add the remainder of the base on top of the ingredients in order to avoid remaining powder sticking to the blades. The jar bottom should be pushed up as far as possible to prevent incorporating air.

Compounds with a higher content of solids, e.g. pastes, warming of the compound during the mixing process may occur. This temperature rise may be reduced applying cooled foundation or using a cooling cuff.

Emulsion (Solution ointment)

With the mixing program "**Emulsion**" liquid components can be incorporated into hydrophilic foundations at room temperature.

As an example, the preparation of aqueous hydrophilic ointment, aqueous lanolin alcohol ointment or eucerin c. aqua aa. To ensure a homogenous distribution we recommend applying disp. blades for jar sizes up to 200 ml and the standard mixing blade for larger batches.

First, weigh out the entire amount of required foundation ground-covering inside the jar. Then add the required amount of liquid or solution by room temperature. The jar bottom should be pushed up as far as possible to prevent incorporating air. In some cases emulsifying refrigerated foundations can cause difficulties. In this case the process of emulsification can be accelerated by adding the required liquid warmed.

Emulsion +

With the mixing program "**Emulsion+**" liquid components can be incorporated into a melted foundation and cooling down parameters. As an example, the preparation containing emulsific. aquosa, lannette or cera.

To ensure a homogenous distribution we recommend applying disp. blades for jar sizes up to 200 ml and the standard mixing blades for larger batches. The jar is heat resistant up to 85ºC / 185ºF and can be used in a hot-water bath or microwave. The melting components can be melted directly in the jar. If there is no water in the formulation, the components can be melted directly in the jar on a hot-water bath.

Formulation containing an aqueous phase can be melted in a hot-water bath or the microwave, leave the regular nozzle open and set the microwave to a low power setting. The temperature control with a thermometer should take place in short intervals to make sure the compound is not overheating.

To support the cool down process with the **EMP Pro** a cooling cuff can be used around the jar and the mixing process for larger jar sizes can be repeated.

Gel

With the mixing program "**Gel**" gelling agents can be incorporated into fluids or semi-solid foundation.

As an example, the preparation of ultrasonic contact gel, hydroxypropyl cellulose 400.

Also incorporation gelling agents like bentonite or Aerosil into a semi-solid foundation.

To ensure a homogenous distribution we recommend applying disp. blades for jar sizes up to 200 ml and the standard mixing blades for larger batches. The fluid component will be weighed out first into the FagronLab™ jar. Soluble active substances can be administered directly into the jar and dissolved. The gelling agent will be dispersed on top of the liquid component.

If the swelling agent will be incorporated into a semi-solid foundation, the gelling agent can be covered between two foundation layers. This will obtain a faster dispersion of the gelling agent into the foundation.

Suppositories

With the mixing program "**Suppositories**" suppositories compounds mixtures can be dispersed.

The suppositories foundation can be warmed in a water bath directly in a transparent jar and afterwards stirred with the FagronLab™ to the soft melting point. An applicator long aids in the precise filling of the suppository mould. For a batch approximately 5 % to 10% added allowance is recommended.

Soft in Soft

With the mixing program "**Soft in Soft**" semi-solid substances from low-viscous to pasty can be mixed together. As an example, combining two foundations. To ensure a homogeneity we recommend applying disp. blades for low-viscous and the standard mixing blades for high-viscous foundations.

NRF

The menu option "**NRF**" is loaded with mixing programs for selected semi-solid NRF formulations.

DAB / DAC

The menu option "**DAB/DAC**" is loaded with mixing programs for selected DAB, DAC formulation and standard preparations.

Stored Programs

The menu option "**Stored Programs**" gives the possibility to enter the mixing time and the mixing speed in six different mixing parameters to create an individual mixing program. It is also possible to enter the mixing program using a known or before created ID number.

Specialties

With the mixing parameters "**Specialties**" surface-active or sensitive active substances or force sensitive foundations can be processed. Therefore with suspension ointments < 2% first use the "**Pre-grinding**" parameters and for the main mixing parameters "specialties".

5.5 Requirements for the components of a formulation

Powder

Generally, powders should be used as microfine and micronized substances. In order to ensure better wetting of powders in aqueous compounds, micronized substances should be added after any liquid components or covered with foundation.

For a solids content less than 2%, we recommend applying the pre-grinding process together with approx. 30% of the ointment foundation (review pre-grinding).

Crystalline active substances

We recommend pulverizing active crystalline ingredients in a mortar prior adding into the jar to avoid complex post processing (e.g. ointment mill). Should a solvent for the active crystalline component be part of the formulation, the ingredient may then also be dissolved in the jar, for example urea with water.

Then the remaining formulation component/s can be added. If the solvent is in sufficient amounts a component of the ointment foundation the crystalline substance may dissolve during the mixing process.

Components to be melt

Components, that have been weigh out to fuse, may be placed inside a jar, douse with heated aqueous or oily phases of the formulation components (< 85ºC / 185ºF) to melt the content in full.

In case this process does not sufficiently melt all the components, the formulation inside the jar might be heated in a warm water bath (< 85ºC / 185ºF) or carefully observed in a microwave oven. In order to avoid overpressure in the jar remove the red cap of the jar lid.

Formulations, without water containing components, may be melted directly inside the jar by placing the jar in a warm water bath. Please be aware that stirrers must not go into the microwave oven! Furthermore, due to irregular mixing of oily and water phases, reaching the melting point might happen with a delay, since only aqueous phases will be heated by microwaves.

Please consider also the operation manual of the used microwave oven! An excessive temperature rise for both, jar and its content, must be avoided all the time! The cooling time and the cooling interval can be decreased by using a refrigerator or a cooling cuff. The stirrer should remain in the jar during the cooling phase.

Thermolabile substances

Active substances or components with thermolabile characteristics should be processed with caution. To protect the substances, we recommend a maximum speed of 1200 rpm (level 4). To control the frictional heat, a cooling cuff can be used or a cool down interval in a refrigerator if required.

5.6 After the mixing process is complete

After finishing the mixing process the mixing unit will be released and can be removed from the lift arm. Unscrew the jar from the lift arm, this will only require a quarter turn clockwise.

In the next step, the jar lid should be opened and the stirrer removed. Since this is also an opportunity, execute an organoleptic quality check, the jar lid should also be opened after mixing when using the Disp. Blade.

Practice has proven that if the surface of the compound looks smooth and consistent, complying with the minimum defined mixing time, homogeneity inside the jar also can be expected for the entire product.

Afterwards slide the stirrer out of the jar lid. The ointment on the stirrer can be cleaned off into the jar by using a spatula. When using the Disp. Blade, the stirrer can be removed from the jar and disposed, or left inside the jar.

Leaving the blade inside the jar will have no effect on dispensing the ointment through the jar lid. Removal of the disposable mixing blade is recommended, particularly when giving the ointment to elderly clients, since it might otherwise cause confusion if the ointment is traditionally dispensed.

The jar lid is screwed back onto the jar body and equipped with a varionozzle as needed. Then the little cap or a applicator will be loosely screwed on. Large jars will be equipped with a spindle or the AirDynamic. Move the finished compound close to the lid to prevent a “squirting out” of the ointment when first dispensed. A large applicator is standardly delivered with a 200 ml jar as pushing aid. Jars 300 ml up to 2000 ml use a spindle or the AirDynamic. The little cap or the applicator may now be fasten in place.

A label may be attached on the jar prior forwarding to the client, preferably together with a short illustration of how to use and apply the FagronLab™ dispensing system.

After completion of every single process the **EMP Pro** issues automatically an identification number (ID). The display shows the ID and it conducts an easier documentation and an exact reproduction of the mixing process.

The FagronLab™ mixing parameters are an assistance in the right handling of the technology. The manufacturing with the FagronLab™ devices lies in the responsibility of the pharmaceutical personal.

6. General notes on the FagronLab™ mixing system

6.1 Identification number ID

The 13-digit identification number used to unmistakably mark preparations has the following structure:

5 A1 A4 B6 G7 E8 M8

The first number of the identification number provides information about the jar size, whereby each jar size is assigned to one of the following numbers:

FagronLab™ jar	Jar size in ml
1	15
2	25
3	30
4	50
5	100
6	200
7	300
8	500
9	1000
0	2000

Tab: Number/jar size correlation

As from the second position the mixing time and the rotation speed in 6 mixing stages are represented. The time specification is represented with large - and lowercase letters, in which each letter correlates to a defined time value:

Letter	mm:ss
A	0:05
B	0:10
C	0:15
D	0:20
E	0:25
F	0:30
G	0:35
H	0:40
I	0:45
J	0:50
K	0:55
L	1:00
M	1:05
N	1:10
O	1:15
P	1:20
Q	1:25
R	1:30
S	1:35
T	1:40
U	1:45
V	1:50
W	1:55
X	2:00
Y	2:05
Z	2:10

Letter	mm:ss
a	2:20
b	2:30
c	2:40
d	2:50
e	3:00
f	3:10
g	3:20
h	3:30
i	3:40
j	3:50
k	4:00
l	4:20
m	4:40
n	5:00
o	5:20
p	5:40
q	6:00
r	6:25
s	6:50
t	7:15
u	7:40
v	8:05
w	8:30
x	9:00
y	9:30
z	10:00

Tab: Letter/time correlation

The input of the rpm is assigned to the numbers 0 - 9, in which each number correlates to a defined rpm value:

Level	Rotation speed (rpm)
0	300
1	600
2	800
3	1000
4	1200
5	1400
6	1650
7	1900
8	2150
9	2400

Tab: Number/rpm correlation

6.2 Error codes

Error	Cause	Troubleshooting
Error 1	The stirrer lock detached during the mixing process.	Restart the mixing process.
Error 2	The locking attempt cannot lock the stirrer (after 5 tries no success), it might be blocked.	Check if the jar is screwed in straight or if the stirrer is bend. The FagronLab™ stirrer is not straight in the FagronLab™ jar. Straighten the stirrer.
Error 3	The set jar size does not match the used jar size (the used jar is bigger).	The used jar size must match the set jar size.
Error 4	The stirrer blocks (The device tries to fix it itself).	The device needs to restart.
Error 5	The software communication was temporary interrupted.	Tap the home button (house upper right corner) and restart. Shut down the EMP Pro using the On/Off button (upper right corner) and restart the device.

Tab: Error codes

6.3 Operation errors

FagronLab™ stirrer

Error	Cause	Troubleshooting
1	The stirrer used is not compatible with the EMP Pro.	The stirrer used is not an original FagronLab™ stirrer. The EMP Pro has only been tested, centered and aligned with original FagronLab™ stirrers. All stirrers delivered after the year 1996 are compatible with the EMP Pro.
2	There are problems while coupling the stirrer with the EMP Pro.	The FagronLab™ stirrer is bent or damaged! Replace it with an intact stirrer!
		The FagronLab™ stirrer is not straight in the FagronLab™ jar. Straighten the stirrer.
3	The FagronLab™ stirrer does not penetrate completely in the mixture, since the formula is to pasty, firm, or in powder form.	To ensure the complete mixing of the recipe, you can for example, warm cold recipe substances in room temperature or assist pasty mixtures by hand. Further help is usually no longer necessary.

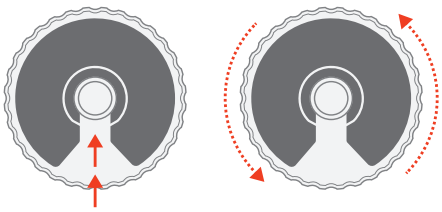
Tab: Operation errors/stirrer

FagronLab™ Jar

Error	Cause	Troubleshooting
1	The jar connected to the EMP Pro is not a FagronLab™ jar.	The jar has to be substituted for a FagronLab™ jar.
2	The FagronLab™ jar lid was screwed alsant onto the jar and the stirrer cants on automatic insertion.	Open the jar and screw the lid on correctly.
3	At first time extraction the ointment leaks out in a gush.	Diminish air before the first time extraction.
4	Liquid leaks out on the bottom of the jar.	The bottom of the jar was not completely covered with foundation all the way to the rim of the jar bottom. Ensure to cover the sealing lip of the bottom with foundation.
		After using the jar in a water bath, water accumulated in the cavity on the bottom side of the jar. The water cannot penetrate into the jar itself through the sealing lip, remove the excess water with a paper towel.
5	The jar does not attach into the lift arm.	The jar is not an original FagronLab™ jar. Always use an original FagronLab™ jar.
		Please observe the correct handling of the quick-lock coupling (see description below)

Tab: Operation errors/jar

- Hold the FagronLab™ logo, on top of the jar, to the front
- Load the stirring shaft directly from the front into the lift arm.
- Push the mixing unit up and with a slight turn counterclockwise (about a quarter turn) fix the mixing unit into the lift arm.



Common errors

Error	Cause	Troubleshooting
1	The compound rises up the stirrer shaft.	The sealing lip from the lid is damaged. Replace the lid with an intact one.
		The air was not diminished before the mixing process. Repeat the compounding and diminish the air correctly before the mixing process.
		The foundation is known to rise (eg. Linola®, hydrophilic cream). Refrigerate the foundation prior the compounding and diminish the air correctly.
2	A suspension ointment is not homogeneous mixed.	For the mixing process a Disp. Blade was used not the SMB. Always use the SMB for suspension ointments. The wide blades of the stirrer together with the inner wall of the jar breaks down agglomerate and the active substance dispenses homogenic.
3	The finished compound is at the organoleptic final quality control inhomogeneous.	Instead of micronized solid substances crystalline substances are used. To ensure homogeneity use the ointment mill or micronized solid substances.

Tab: Operation errors/common errors

Note

- Please contact customer service for any malfunctions cannot be remedied using this information.

6.4 Cleaning the EMP Pro

- Always unplug the **EMP Pro** from the wall outlet before performing a cleaning.
- Do not use aggressive cleaning agents or abrasive cleaners.
- For cleaning, we recommend daily wiping the surface with a damp cloth with mild detergent and immediately drying it with a dry cloth. For disinfecting, the display can be lightly sprayed and wiped with isopropanol 70%.
- Make sure that no liquids enter the device. If liquids enter the interior of the **EMP Pro**, keep the device turned off and inform customer service. An unauthorized opening of the **EMP Pro** device is not permitted.

7. Service and warranty

7.1 Notes on malfunctions

If the FagronLab™ device does not work, it may be due to a small problem that can be simply corrected. Before taking the unit for repair, please follow the instructions below:

- If the FagronLab™ device can not be switched on, please check to ensure that there is electricity available and that the plug of the power cord has been correctly connected to the device and the socket
- In any case of problems or damage of the device, please also mind the manufacturer's notes on the machines' metal foot.

7.2 Notes on safety

- FagronLab™ devices must only be connected to grounding type receptacles with 230V / 50Hz (cps); 120 V / 60Hz (cps) or rated country specific voltage installed according to the regulations of DIN VDE 0100
- FagronLab™ devices have been designed for operation under normal room atmospheric conditions. Recommended values: Ambient temperature between 15 - 30ºC / 59 - 86ºF and relative air humidity less than 80%
- The device should be allowed to acclimatize for approx. 30 minutes at initial commissioning and/ or after extended storage time in cold rooms
- The **EMP Pro** should be placed to ensure easy access to the power switch and power cable also to avoid use by unauthorized persons
- Do not immerse FagronLab™ devices in water
- Electronic parts should just be dis- and assembled by a certified service partner
- Only operate the FagronLab™ stirrer inside a closed FagronLab™ jar
- Do not touch rotating parts
- Keep long hair away from rotating parts
- During the automated lifting of the **EMP Pro**: always keep long hair, body parts or objects away from the lifting mechanism. Immediately turn off the power switch in case of an emergency or pull the power plug
- Using the FagronLab™ devices not according to these operating instructions or with line products that the manufacturer did not deliver or recommend may impair safety
- FagronLab™ devices have not been designed for operation under hazardous conditions. Heed the relevant safety regulations when handling hazardous substances (e.g. combustible liquids such as alcohol or similar substances)
- FagronLab™ devices correspond to the safety standards for laboratory equipment. They have to be positioned to prevent any interference or use by unauthorized persons
- The device must not be disposed of in ordinary domestic waste. Please deliver the device to the available collecting and recycling systems at the end of its life cycle.

7.3 Technical data of the EMP Pro

FagronLab™ jar	Jar size in ml
Electrical requirement	100 - 115 V / 220 - 240 V
Total power consumption	223 W
Power consumption (mixing motor)	169 W
Power consumption (lifting motor)	54 W
Operating mode	continous operation S1
Safety class	I
Type of protection	IP 20
Connection	4x USB-Ports, 3x RS232-Ports, 1x RJ45-Port
Rotational speed controller	in 10 steps electronic controlled
Timer	program-controlled
FagronLab™ jar sizes	15-20 ml - 2000 ml
Weight	44.1 lbs / 20 kg
Dimensions (LxWxH)	339 x 293 x 670 mm
Testing certifications	CE

8. Manufacturing and Customer Service

The **EMP Pro** is certified:
Certificate of Conformity

CE

The certificate ist available at the license holder, Gako Konietzko GmbH, D-96049 Bamberg.
The license manufacturer of FagronLab™ products, the Gako International GmbH, D-96110 Schesslitz, is DIN EN ISO 9001:2015 certified.

For inquiries regarding FagronLab™ technology products please refer to your local Fagron company or official dealer.

Customer Service
With all inquiries about technical data, service, warranty, customer service or replacement parts contact the customer service of your local Fagron company or official dealer.

8.1 Installation qualification (IQ)

Company (Pharmacy)

Device identification

Serial number (SN): .....

Date of purchase: .....

Assessment	OK	not OK
Examination of readability of the labels on the device		

Considering appropriate installation conditions

Assessment	OK	not OK
Stable, flat surface, observe product weight		
Suitable space for the device and unobstructed access to the power cord and power switch		
No direct air flow (windows, heating, fans, air conditions)		
No direct sunlight		
No extreme humidity or temperature fluctuations		
Clean, dry, dust-free		
Correctly installed, earthed socket with 220 Vor country-specific nominal voltage and required grid frequency		
Before initial operation acclimate the device for 30 minutes at room temperature		
Excludes device handling by unauthorized persons		
Observe the operation manual and manufacturer's recommendations		

Testing initial operation

Assessment	OK	not OK
Place the device securely		
Establish the power supply, connect the device with the power outlet		
Turn on the FagronLab™ EMP device with the power switch		
The display shows the device type “FagronLab™ EMP”		
The display shows the number of current number of preparations “mixed <<---->>”		
The display shows “IQ - Mode >> >>”		
Attach the test mixing unit (review chapter 4) into the quick-lock coupling (review chapter 5)		
The compounding button starts the IQ-Mode		
The display shows all the levels during IQ-Mode		
The display shows IQ-Mode “OK”		
Remove the test mixing unit (review chapter 5)		
Jump between configuration options with the Compounding button		
Use the +/- buttons to decrease and increase the jar size		
With changing the jar size mixing time and mixing parameters are adjusting		
Use the +/- buttons to decrease and increase the mixing time		
Use the +/- buttons to change the mixing level from 0 to 9		
Observe the operation manual		

	Date	Signature
Performance of the test		
Approval by pharmacist		

8.2 Operation qualification (OQ)

Company (Pharmacy)

Device identification

Serial number (SN): .....

Date of purchase: .....

Assessment	OK	not OK
Examination of readability of the labels on the device		

Functional testing

Assessment	OK	not OK
The device is securely placed		
Power is supplied		
Turn on the FagronLab™ EMP device with the power switch		
The display shows the device type “FagronLab™ EMP”		
The display shows the number of current number of preparations “mixed <<---->>”		
The display shows “OQ - Mode >> >>”		
Attach the test mixing unit (review chapter 4) into the quick-lock coupling (review chapter 5)		
The compounding button starts the OQ-Mode		
The display shows all the levels during OQ-Mode		
The display shows OQ-Mode “OK”		
Remove the test mixing unit (review chapter 5)		
Observe the operation manual		

	Date	Signature
Performance of the test		
Approval by pharmacist		

Together
we create the future
of personalizing medicine.

Fagron BV
Fascinatio Boulevard 350
3065 WB Rotterdam
The Netherlands

T +31 88 33 11 288
F +31 88 33 11 210
www.fagronlab.com

Fagron lab