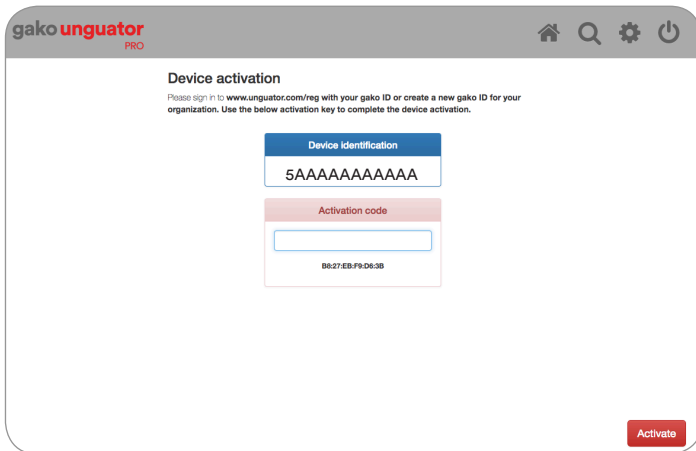


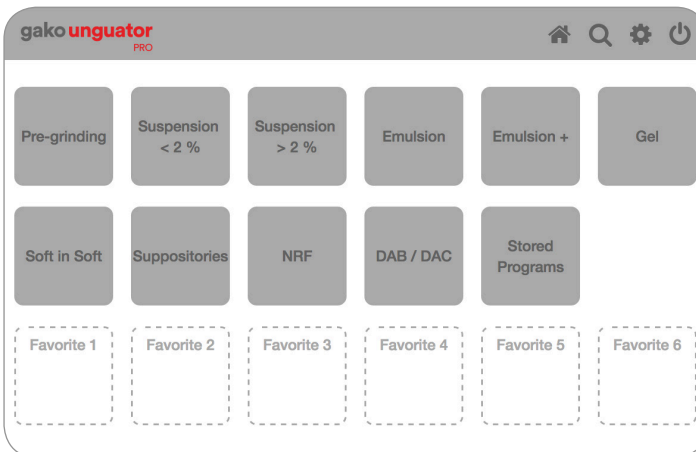
Quick - Start



How to register your gako unguator PRO device

Go to unguator.com/reg
Enter the 12 digit serial number
Enter the activation code on your device

--> review chapter 3

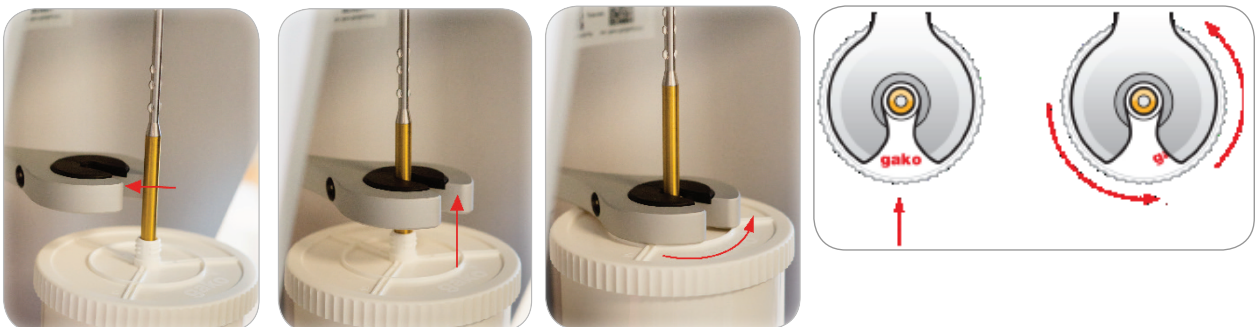


Display handling

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“

--> review chapter 3

Lifting arm with quick-lock coupling



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

--> review chapter 4

Dear gako unguator user,

thank you for choosing the Unguator Technology. You 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.unguator.com

For additional support, operation handling and all other questions regarding the Unguator Technology please feel free to contact us by

E-Mail: contact@unguator.com

Enjoy the successful production of quality assured compounding ointments.

Your

gako **competence center**

Table of content

Installation Information / Initial Operation

The Unguator Technology - Competence from the start

- gako unguator Mixing Devices
- gako unguator Assortment

Display Handling

- Initial Operation
- Compounding with the gako unguator PRO
- Additional mixing programs
- Aborting the mixing process
- Updating the gako unguator PRO

Compounding guidelines for the Unguator Technology

- Preparing the gako unguator Mixing Unit
- Weighed Portion of the Formulation
- The Mixing Process
- Mixing Programs
- Requirements for the Components of a Formulation
- After the Mixing Process is Complete

General Notes on the gako unguator Mixing System

- Patent Protection
- Identification Number ID
- Error codes
- Operation Errors
- Cleaning the gako unguator BASIC

Service and Warranty

- Notes on Malfunctions
- Manufacturer's Service and Warranty in Germany
- Notes on Safety
- Technical Data of the gako unguator BASIC
- Distribution, Manufacturing and Customer Service
- Warranty Certificate

Documents

- Manufacturer's Certificate

Index of Pictures

Installation Information / Initial Operation

gako unguator PRO front
gako unguator PRO rear

The Unguator Technology - Competence from the start

gako unguator BASIC / EMP
gako unguator PRO
gako unguator Standard Mixing Blade
gako unguator Disposable Blade
gako unguator Disposable Blade Shaft
gako unguator Jars
AirDynamic / Spindle
Certificate of analysis gako unguator jar
jar label gako unguator jar
gako unguator Varionozzles
gako unguator Applicator short
gako unguator Applicator long
gako unguator Spindle
gako unguator Coupling
gako unguator AirDynamic
gako unguator ExactDose

Display Handling

gako unguator PRO rear
display gako unguator PRO
display country selection
display Device activation
device registration
gako-ID Login / Register I
gako-ID Login / Register II
Device activation
display start screen
display mixing progress
display summary mixing process

Compounding guidelines for the Unguator Technology

quick-lock Coupling

General Notes on the gako unguator Mixing System

Identification Number - ID
quick-lock Coupling

Index of Tables

The Unguator Technology - Competence from the start

quality improvements with increasing automation

Compounding guidelines for the Unguator Technology

value chart rotation speed

General Notes on the gako unguator Mixing System

number / jar size correlation

letter / time correlation

number / rpm correlation

error codes

Operation Errors / Stirrer

Operation Errors / Jar

Operation Errors / Common Errors

Service and Warranty

Technical Data of the gako unguator PRO

Installation Information

The gako unguator PRO weighs 36,8 lbs (16,7 kg).

Select a suitable location for the gako unguator 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°- 30° C (59°- 86°F) 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:

- gako unguator PRO mixing device
- Standard mixing Blades 1 - 5
- Power cable
- Disposable Blade starter kit I
- Operating instructions

Please contact the gako support team by E-mail contact@unguator.com 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 gako unguator PRO.

The warranty lapses if the original packing materials are not used for return deliveries.

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 gako unguator 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 gako unguator PRO. Now the device is ready for operation.



pic.: gako unguator PRO front



pic.: gako unguator PRO rear

The Unguator Technology - Competence from the start

The core of the gako unguator Technology is to comply with the requirements of prescription ointments it consists of the patented arrangement of the gako unguator. Mixing Blade and the gako unguator Jar that serves as both, a hygienic mixing jar and a hygienic dispensing jar.

The principle of the preparation method using gako unguator Technology in the closed gako unguator Mixing System is quick and easy to learn, true to the motto:

learning by doing

A little experience will make it easy to prepare ointments though it may seem rather complicated at first. Using the Unguator Technology enables the pharmacy to better prepare prescription ointments in a shorter period of time, compared to the conventional methods that were used prior to the invention (1994). For the first time, it is possible to not only standardize ointments, but validate them, too. Mixing parameters and examples of formulation are found at www.unguator.com

gako unguator Mixing Devices

The current gako unguator Mixing Devices - gako unguator BASIC, gako unguator EMP and gako unguator PRO - are useful and advanced improvements over the first Unguator Device, launched in 1994.

The gako unguator Mixing Devices feature a high safety standard. The devices are manufactured and maintained by Gako Deutschland GmbH, Scheßlitz.

With increased automation; of the gako unguator units from B/R, e/s, 2100 and QMS to BASIC, EMP and PRO; 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	Lifting arm	Mixing Parameters (rpm, mixing time)
Mortar and Pestle	++	+	-	individually
gako unguator BASIC	+++	+++	manual guided lift	individually programmable
gako unguator EMP	+++	+++	automatic	individually programmable
gako unguator PRO	++++	++++	automatic	fully automatic

tab.: quality improvements with increasing automation

gako unguator BASIC

The gako unguator BASIC ensures a GMP suitable preparation of semi-solid compounds up to 500 ml.

The lift by hand is much easier through the guided lifting arm with integrated quick-lock coupling.

Jar size, mixing time and ten mixing speeds can be set on the gako unguator BASIC.

gako unguator EMP

The gako unguator EMP 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 lifting arm.

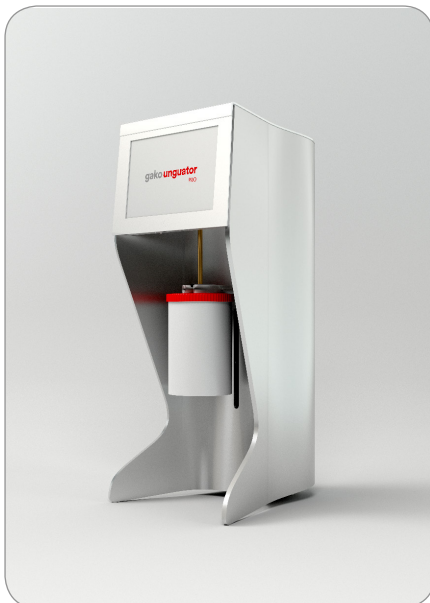
The lifting arm works automatically so the mixing time can be used for e. g. documentation.

Jar size, mixing time and ten mixing speeds can be set with the gako unguator EMP.



pic.: gako unguator BASIC / EMP

gako unguator PRO



pic.: gako unguator PRO

The gako unguator PRO the complete solution for the pharmacy.

The gako unguator 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 (soon available).

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, is the gako unguator PRO 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 gako unguator PRO is equipped with several ports and together with the optional gako software ready for potential interconnection with electronic scales, printers (label, paper), keyboard and networking.

gako unguator Assortment

As well as the gako unguator Devices, the gako unguator Assortment underlies further and new developments. All gako unguator accessories are compatible with all current and former available gako unguator Mixing Devices.

gako unguator Stirrer

The gako unguator Stirrer are the gako unguator Standard Mixing Blade (SMB) and the gako unguator Disposable Blade (Disp. Blade). The stirrer 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 gako unguator 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 gako unguator 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 gako unguator 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 54°C/129°F was the maximum taken after 6 minutes of mixing a highly pasty preparation made of vaseline and zinc oxide aa 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 gako unguator 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 gako unguator devices as well as the gako unguator line of products should never be treated with sharp-edged objects or abrasive cleaning agents.

- gako unguator Standard Mixing Blade (SMB)

The gako unguator SMB's are adjusted to the size of each individual gako unguator 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.



pic.: gako unguator Standard Mixing Blade

- gako unguator Disposable Blade (Disp. Blade)



pic.: gako unguator Disposable Blade

The gako unguator Disp. Blade is suitable for all gako unguator 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.



pic.: gako unguator Disposable Blade Shaft

gako unguator Jar

The gako unguator 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 gako unguator 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.

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 85°C/185°F. 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 0 °C/32 °F.



pic.: gako unguator Jars

Jars are available in the 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 2000/2600ml (rated volume/filling volume).

The standard color of the jar housing is white and of the jar lid red. The 300 ml, 500 ml, 1000 ml und 2000 ml jar come only with white lids. In addition, the 20 ml to 200 ml jars are available in the pastel colors pink, light yellow, light blue and turquoise.

Furthermore, jar from 20 to 200 ml can be ordered with jar lids in the special colors green, blue and white.

Customized jar colors are also possible if demanded.

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.



pic.: AirDynamic / Spindle

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.

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.

A detailed certificate is available for download at www.unguator.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 gako unguator 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. It is possible to extract an exact amount of 0.5 ml.

gako unguator Varionozzles



pic.: gako unguator Varionozzles

The gako unguator Varionozzles with inner diameters of 1, 2 or 4 mm can be pressed into the regular nozzle of any gako unguator 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)

gako unguator Applicators

The gako unguator Applicators reduce the extracted quantity of low-viscosity formulations and are particularly helpful in cases where the ointment must be precisely applied.

- gako unguator Applicator short

The gako unguator Applicator short with a diameter of 1mm is obligatory for nose and ear ointments.



pic.: gako unguator Applicator short

- gako unguator Applicator long

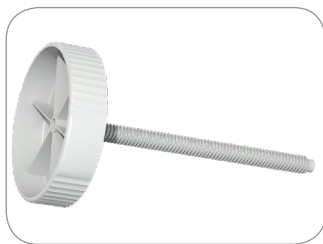


pic.: gako unguator Applicator long

The gako unguator 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 gako unguator 200 ml Jar to help pushing up the bottom of this jar size in full.

gako unguator Spindle



pic.: gako unguator Spindle

The gako unguator Spindle serves as a dispensing system for gako unguator 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 content of the jar.

Caution! 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.

gako unguator Jar Couplings



pic.: gako unguator Jar Couplings

The gako unguator Jar Couplings connect two gako unguator Jars by their screw threads of their dispensing openings and they are very useful when preparing ointments in larger batches. Transferring a formulation from a larger jar into a smaller jar using the jar couplings 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.

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.

gako unguator AirDynamic



pic.: gako unguator AirDynamic

The gako unguator AirDynamic optimizes batch preparation within the closed system:

- Contamination-free transfer
- Contamination-free storage

The AirDynamic has been designed to apply with jars from size 300 ml to 2000 ml to extract compounds. An adapter connected to a pump ball is fixed to the center hole on the body's bottom of the jar with an air-tight connection.

By pumping air into the lower chamber of the jar using the pump ball, the pressure thus generated moves the bottom upward.

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 had 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.

gako unguator ExactDose

The gako unguator ExactDose allows the exact dosage of 0.5 ml paste, gel, cream or ointment for topical or transdermal therapy.

The ExactDose 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.

The coloured ball inside the ExactDose 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.



pic.: gako unguator ExactDose

Display handling

Initial operation



pic.: gako unguator PRO rear

The socket outlet is located on the rear of the gako unguator PRO①. Located above, is the power button ②, which is also the emergency button. Ensure that the power button of the gako unguator 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 gako unguator PRO.

Use the power button to turn gako unguator PRO, the device boots and is ready for operation.

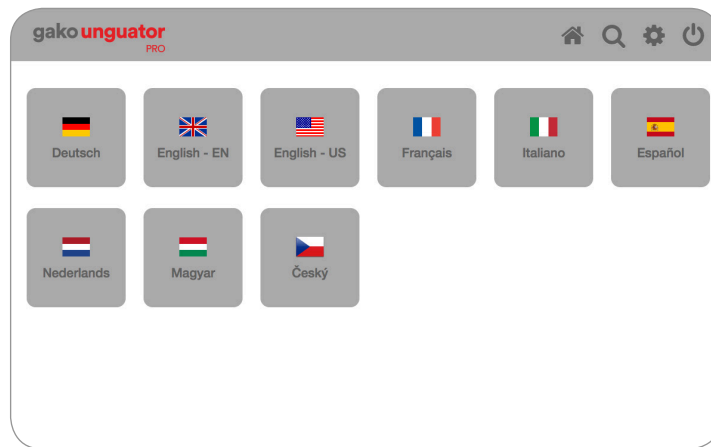
After booting the touch-screen shows the device type “gako unguator PRO”.



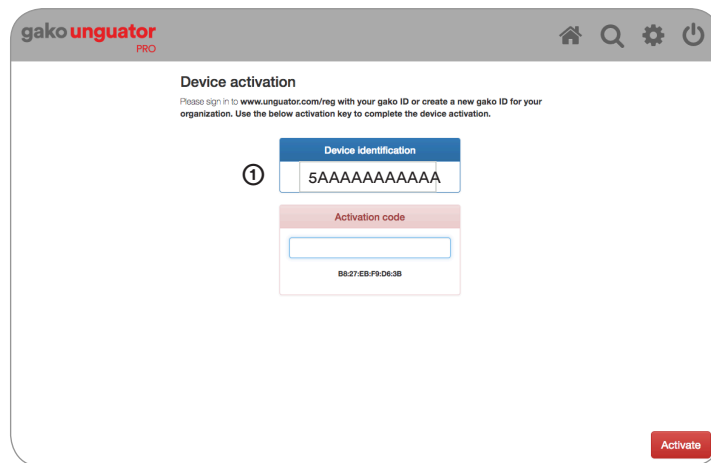
pic.: display gako unguator PRO

On initial operation, after the country selection, the reference for the online registration at unguator.com/reg will be displayed.

Registration

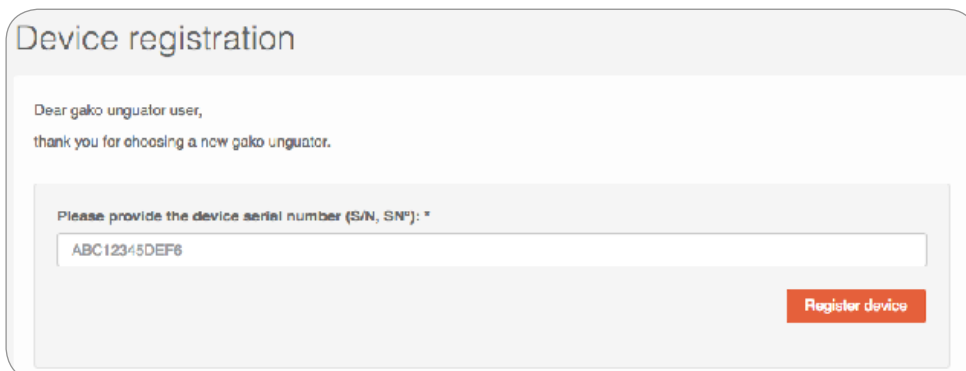


pic.: display country selection



pic.: display device activation

To register the new device enter the 12 digit serial number ① online at unguator.com/reg and confirm the registration by clicking on „register device“.



pic.: device registration

Following, sign in with an existing gako-ID (left side) or register, by entering the required data (right side).

The screenshot shows the 'gako-ID Login / Register' page. It features a header with the text: 'Dear gako unguator user, The gako ID is a personal account, which allows you to access all gako services. With only one gako ID and one password, you can manage and use your gako devices, your gako software and other peripherals you would like to connect to the gako software. You only need one gako ID, so before creating a new one, please consider whether it would be better to use an existing.' Below this, there are two main sections: 'Login' and 'Register'. The 'Login' section has fields for 'gako-ID / E-Mail *' (containing 'max.mustermann@example.com') and 'Password *' (containing '123456789'). The 'Register' section has fields for 'First given name *' (containing 'Max'), 'Surname *' (containing 'Mustermann'), 'E-Mail *' (containing 'max.mustermann@example.com'), 'Password *' (containing '123456789'), and 'Repeat password *' (containing '123456789'). At the bottom of each section are 'Login' and 'Register' buttons respectively.

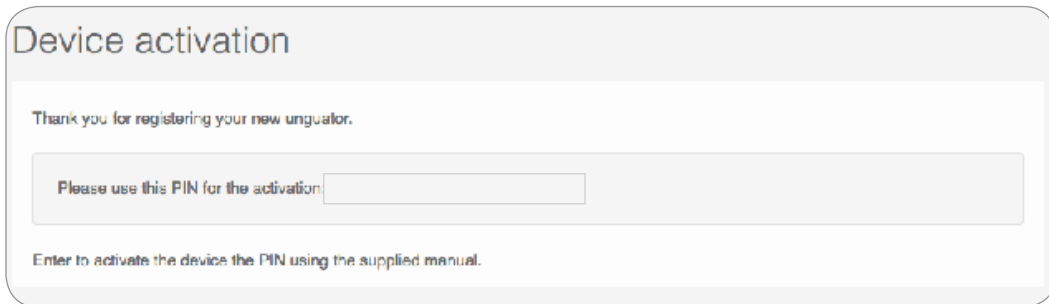
pic.: gako-ID Login / Register I

To register, enter the required information on the second input screen. Following, confirm the terms of use (check the first box below the input field). The other check boxes are optional.

The screenshot shows the second part of the registration process. It features a 'Register' section with the following fields: 'Pharmacy / Company *' (containing 'Muster-Apotheka'), 'Address *' (containing 'Straße, Hausnummer'), 'Wohnung, Stockwerk, usw.' (containing 'Wohnung, Stockwerk, usw.'), 'Weitere Adressinformationen', 'Zip code / City *' (with sub-fields for 'PLZ' and 'Ort'), and 'Country *'. Below these fields is a warning icon (a triangle with an exclamation mark) and three checkboxes: 'Terms of Service *' (with a sub-note: 'With your registration you agree to our Terms of Use, our Privacy Policy as well as our Terms for Cookies & Online-Advertisement'), 'Announcements' (with a sub-note: 'Receive announcements, recommendations and updates for products, services, software updates and more from gako.'), and 'Offers from gako and partners' (with a sub-note: 'Receive recommendations, new product releases, special offers, exclusive offers and more.'). A 'Complete' button is located at the bottom right.

pic.: gako-ID Login / Register II

The registration is complete after confirming the process by clicking the „finish“ button. The activation code for the gako unguator PRO is displayed.



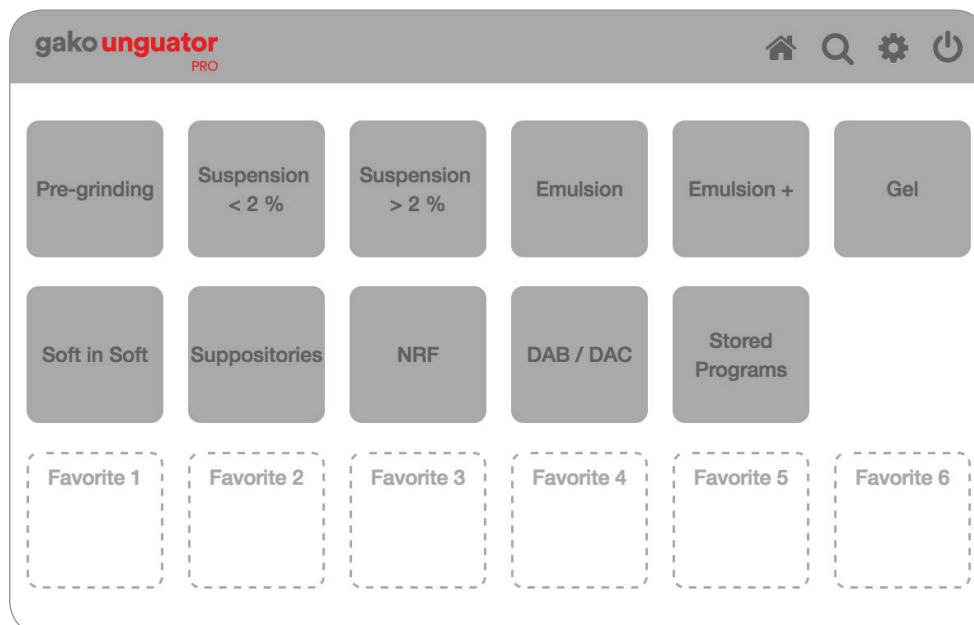
pic.: Device activation

Tap with the finger the input field on the touch display of the gako unguator PRO and enter the activation code by using the connected keyboard.
Confirm the activation by taping the „activation“ button with a finger.

Compounding with the gako unguator PRO

Located on the front of the gako unguator PRO is the touchscreen to control the device. After booting, the touchscreen shows the device type „gako unguator PRO“, the serial number of the device, the current software version and the current number of preparations.

After a few seconds, it forwards to the start screen.



pic.: display start screen

On top to the right the screen displays four symbols.

- Home: redirects to the start screen
- Magnifying glass : formulation search function
- Gear : settings, following options are available
 - Information: Displays the technical information of the gako unguator PRO (device typ, software version, 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 gako unguator PRO sets back to the factory settings. Please only perform this action after being instructed by the technical service of the Gako International GmbH (gis@gako-int.com)
 - Network: To manage the network and proxy settings
- On/Off-Button: Shuts the gako unguator PRO directly down to be turned off with the power button.

On the main display following options are shown:

Stored mixing programs

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

Additional options are available:

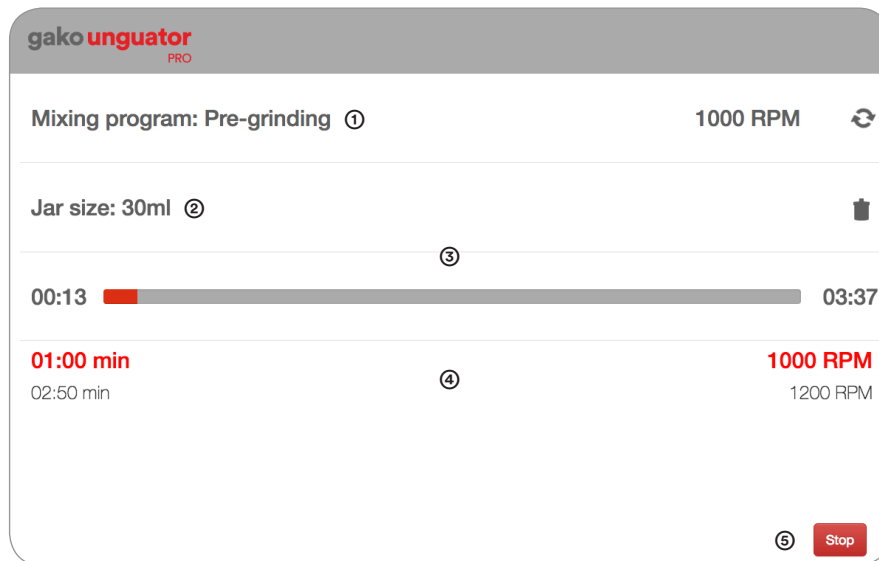
- DAB / DAC
- NRF
- custom programs

To select the program press the communicating program button. The lifting 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 lifting arm. The visual description shows the easy mounting of the jar into the quick-lock coupling. By selecting „start“ on the lower right, the lifting arm moves automatically into the start position, the stirrer shaft locks and the mixing process starts. During the mixing process the progress of the mixing program is displayed.



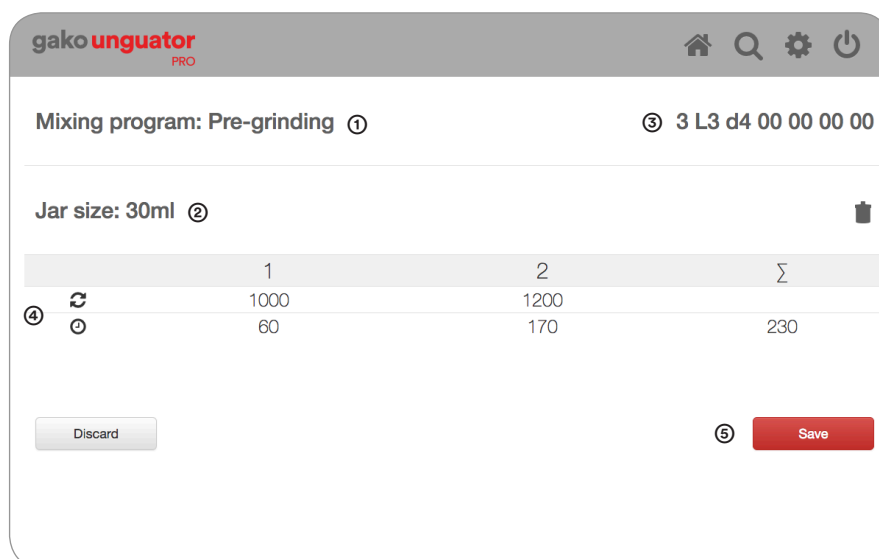
pic.: display mixing process

Following parameters are displayed:

- mixing program ①
- jar size ②
- time (passed and remaining) ③
- list of mixing time and mixing level ④
- “Stop” button to abort the mixing process ⑤

After the mixing process is finished the free spin program starts, the stirrer will be mostly clean, the mixing process is finished and the lifting 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.



pic.: display summary mixing process

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.

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 touch-screen 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

It gives the option to save often used formulations 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 5). 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 favorite by pushing the star behind the formulation and it will be displayed on the start screen. The favorite 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.



Aborting the mixing process

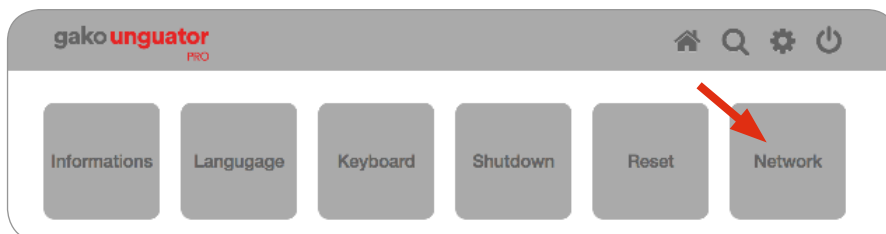
To abort the mixing process, press the „Stop“ button on the lower right on the screen. Following, select „cancel“ on the lower left (the mixing process ends immediately) or „free-spin“ on the lower right (performs the free-spin). The touch-screen will show the start screen. When aborting the mixing process, no ID-number is issued.

Updating the gako unguator PRO

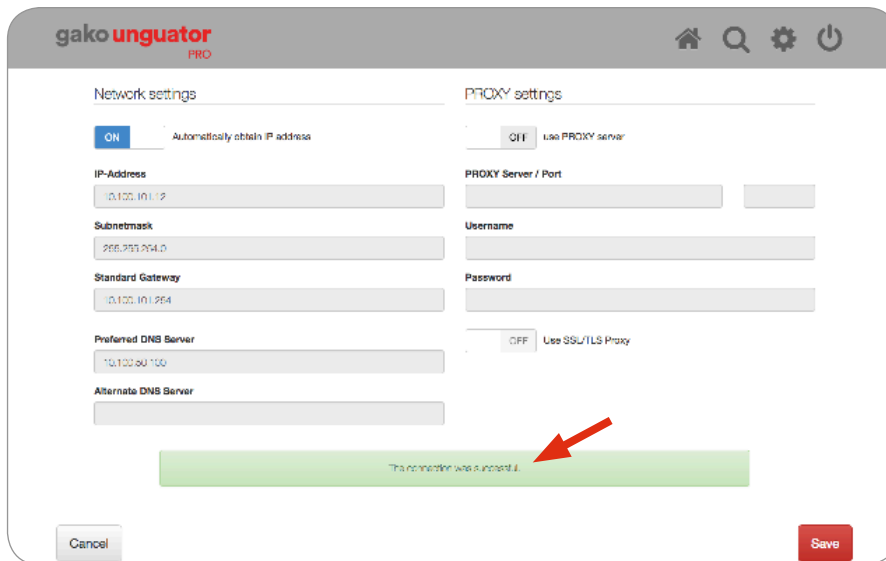
The gako unguator PRO can perform automated free online updates. Just connect the device by using the RJ45-port on the back with the network. If the device is connected, it will check every reboot for the current software version. If a new software version is available, the information appears and the update can be downloaded. If the update is not performed, the information appears every reboot.

Instructions to connect the gako unguator PRO with the internet

- Shutdown your device  and/or turn it off
- Connect your device with the ethernet cable with your local network
- Turn on your device and check if your device is connected to the internet via  settings menu and network

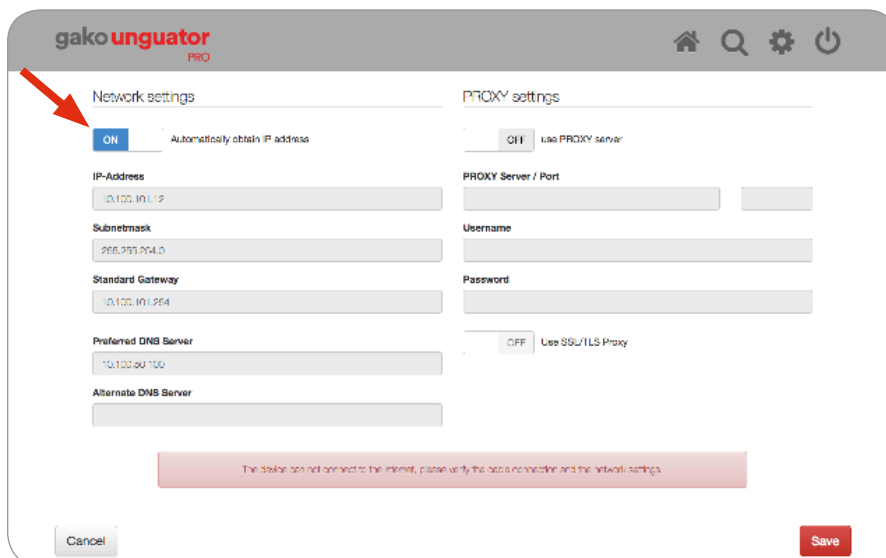


pic.: Display setting menu



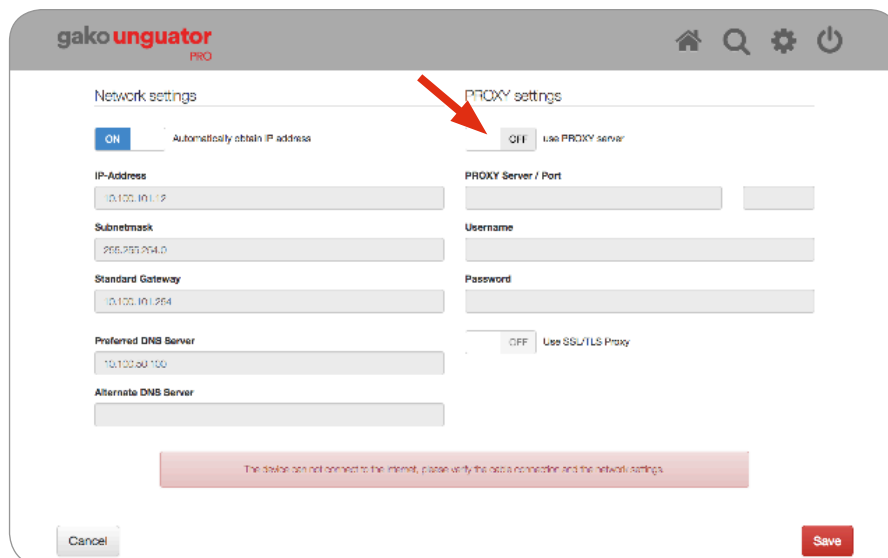
pic.: Display network setting - connection successful

- If the connection could not be successfully established, changes have to be made at the IP address or PROXY-Server settings. If you are not sure and do not know how, please contact your network administrator
- If you need a static IP address as well as other customized settings like the subnet mask and the standard gateway, turn off the button „automatically obtain IP address“ and adjust the according settings:



pic.: Display automatically obtain IP address

- After confirming the changes with the „save“ button, the changes are directly applied and tested. The notification below should change to green and display that the connection is established
- If the notification is still red, check the implemented changes and check those again with the „save“ button until the settings are correct
- If you use a PROXY-Server in your network to connect to the internet, turn on the button „use PROXY-Server“ and adjust the according settings:



pic.: Display use PROXY-Server

- After confirming the changes with the „save“ button, the changes are directly applied and tested. The notification below should change to green and display that the connection is established
- If the notification is still red, check the implemented changes and check those again with the save button until the settings are correct

If there is still a problem connecting your device to the internet, check again if the ethernet cable is correctly plugged in at the device and also at your network. Restart your device again and check if a connection to the internet could be established via the network settings.

If further problems connecting the device with the internet are occurring, please contact your network administrator or our technical support at

contact@unguator.com

Compounding guidelines for the Unguator Technology

Preparing the gako unguator Mixing Unit

The gako unguator Mixing Unit consists of a gako unguator Jar, a gako unguator stirrer and the components of the formulation to be mixed.

First, the jar cap (small white 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 jar lid down.

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.

The Mixing Process

The gako unguator PRO is the result of continuous improvements of the Unguator Technology.

The integrated, programmable microprocessor automates the mixing process with the gako unguator PRO completely, providing an universal device for pharmaceutical compounding!

The gako unguator PRO uses two quiet, high performance, permanent motors and is an intelligent ointment mixing device for compounds from 15-20 to 2000 ml. It works in the range from 0 to 2400 rpm and manufactures homogeneous compounds.

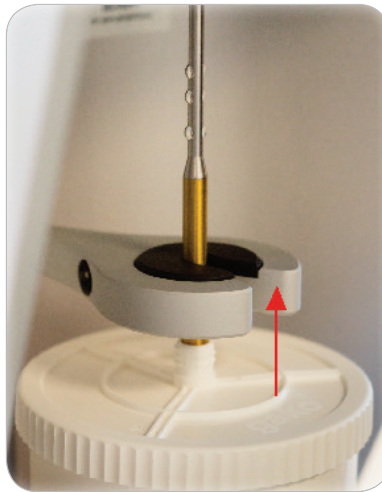
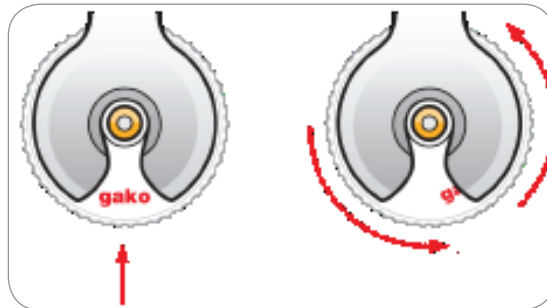
After selecting a program, the jar size can be scanned or manually entered and the mixing unit mounted into the quick-lock coupling.

With every finished mixing process the gako unguator 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 in the display after the mixing process.

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

tab.: value chart rotation speed

Quick-lock Coupling



pic.: quick-lock Coupling

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

Push the start button on the display, the lifting 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 lifting 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 lifting arm will move the mixing unit into the removal position for an easy extraction.

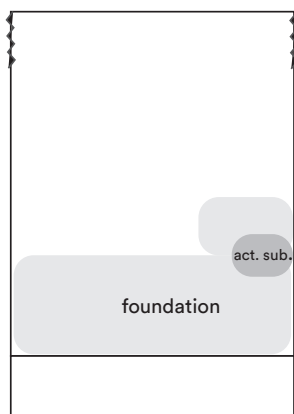
With every finished mixing process the gako unguator PRO will automatically issue an identification number (ID). The identification number will simplify documentation and exact reproduction of the mixing process and will be shown in the display after the mixing process.

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 15 % of the foundation (based on the total amount of the preparation) ground-covering in the jar and place the micronized active substances sideways into the jar. The active substance has to be covered by again 15% of the foundation (based on the total amount of the preparation) in order to avoid powder residue sticking on the blade.

Afterwards the jar bottom should be pushed up until resistance is felt 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 blades 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 so 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 *

The mixing parameters „Emulsion *“ allow the cold stirring of formulation bases and creams from molten individual components.

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 85 °C / 185 °F 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 gako unguator 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 gako unguator 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 gako unguator 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” semisolid substances from low-viscous to pasty can be mixed together.

As an example, combining two foundation.

To ensure a homogeneity we recommend applying disp. blades for for low-viscous and the standard mixing blades for high-viscous foundation.

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.

As an example, metronidazole, chlorhexidine gluconate, Linola®.

Therefore with suspension ointments < 2 % first use the “pre-grinding” parameters and for the main mixing process the mixing parameters “specialties”

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 weighed out to fuse, may be placed inside a jar, doused with heated aqueous or oily phases of the formulation components (< 85 °C / 185 °F) 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 (< 85°C / 185 °F) or carefully observed in a microwave oven. In order to avoid overpressure in the jar remove the white 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!

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).

After the Mixing Process is Complete

After finishing the mixing process the mixing unit will be released and can be removed from the lifting arm. Unscrew the jar from the lifting 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 gako unguator Dispensing System.

After completion of every single process the gako unguator 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 gako unguator mixing parameters are an assistance in the right handling of the Unguator Technology. The manufacturing with the gako unguator devices lies in the responsibility of the pharmaceutical personal.

General Notes on the gako unguator Mixing System

Patent Protection

The gako unguator Mixing System consists of the gako unguator Technology, the gako unguator Mixing Machines and various gako unguator assortment.

The mixing system, the Unguator Technology, also the integrated gako unguator AirDynamic and gako unguator ExactDose therein are inventions of the pharmacist Albrecht Konietzko from Bamberg in Germany. The Unguator Technology, the AirDynamic und ExactDose are patented in selected countries.

gako unguator, AirDynamic and ExactDose are registered trademarks and designated exclusively for devices and accessories only available from the company Gako Deutschland GmbH.

The gako unguator Mixing System from the Gako Deutschland GmbH is the original.

The gako unguator Mixing System with its versatile and comprehensive line products captivates with its simplicity. Everything the pharmacist needs for the production of pharmaceutical ointments and cosmetics is covered by the mixing system. The Gako Deutschland GmbH is not only working to ensure continuation of the quality of gako unguator Products, it is also constantly improving the present standard.

To achieve this, steady quality controls are in place using the comprehensive know-how from the inventor of the mixing system, pharmacist Albrecht Konietzko, also research for reasonable improvements and enhancements which will improve user friendliness of the gako unguator mixing system.

Identification Number ID

The 13-digit Identification Number used to unmistakably mark preparations has the following structure:



5 A1 A4 B6 G7 E8 M8

pic.: Identification Number - ID

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:

gako unguator jar	1	2	3	4	5	6	7	8	9	0
Jar size in ml	15	20	30	50	100	200	300	500	1000	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:

	A	B	C	D	E	F	G	H	I	J	K	L	M
mm:ss	0:05	0:10	0:15	0:20	0:25	0:30	0:35	0:40	0:45	0:50	0:55	1:00	1:05
	N	O	P	Q	R	S	T	U	V	W	X	Y	Z
mm:ss	1:10	1:15	1:20	1:25	1:30	1:35	1:40	1:45	1:50	1:55	2:00	2:05	2:10
	a	b	c	d	e	f	g	h	i	j	k	l	m
mm:ss	2:20	2:30	2:40	2:50	3:00	3:10	3:20	3:30	3:40	3:50	4:00	4:20	4:40
	n	o	p	q	r	s	t	u	v	w	x	y	z
mm:ss	5:00	5:20	5:40	6:00	6:25	6:50	7:15	7:40	8:05	8:30	9:00	9:30	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	0	1	2	3	4	5	6	7	8	9
Rpm	300	600	800	1000	1200	1400	1650	1900	2150	2400

tab.: number/rpm correlation

Due to high rotation speed the levels 8-9 are not suitable for manufacturing in the jar sizes 300 ml and 500 ml, the levels 7-9 are not suitable for the 1000ml jar and the levels 6-9 are not suitable for the 2000ml jar.

Error codes

	Error	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.	<ul style="list-style-type: none"> • Check if the jar is screwed in straight or if the stirrer is bend. • The gako unguator Stirrer is not straight in the gako unguator 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.	<ul style="list-style-type: none"> • tap the home button (house upper right corner) and restart • shut down the gako unguator PRO using the On/Off-button (upper right corner) and restart the device

tab.: error codes

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

Operation Errors

gako unguator Stirrer

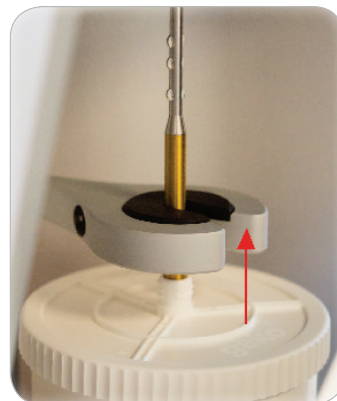
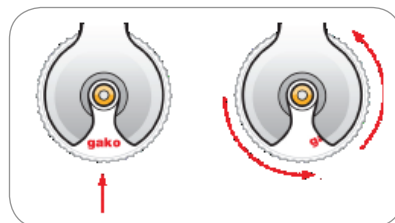
	Error	Troubleshooting
1	The stirrer used is not compatible with the gako unguator PRO.	The stirrer used is not an original gako unguator stirrer. The gako unguator PRO has only been tested, centered and aligned with original gako unguator stirrers. All stirrers delivered after the year 1996 are compatible with the gako unguator PRO.
2	There are problems while coupling the stirrer with the gako unguator PRO.	<ul style="list-style-type: none"> • The gako unguator Stirrer is bent or damaged! Replace it with an intact stirrer! • The gako unguator Stirrer is not straight in the gako unguator jar. Straighten the stirrer.
3	The gako unguator 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

gako unguator Jar

	Error	Troubleshooting
1	The jar connected to the gako unguator PRO is not a gako unguator jar.	The jar has to be substituted for a gako unguator jar.
2	The gako unguator 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.	<ul style="list-style-type: none"> 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 lifting arm.	<ul style="list-style-type: none"> The jar is not an original gako unguator Jar. Always use an original gako unguator Jar. Please observe the correct handling of the quick-lock coupling (see description below)

tab.: Operation Errors / Jar



pic.: quick-lock Coupling

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

Common Errors

	Error	Troubleshooting
1	The compound rises up the stirrer shaft.	<ul style="list-style-type: none"> • 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

Cleaning the gako unguator PRO

Always unplug the gako unguator 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 gako unguator PRO, keep the device turned off and inform customer service. An unauthorized opening of the gako unguator PRO device is not permitted.

Service and Warranty

Notes on Malfunctions

If the gako unguator 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 gako unguator device cannot 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.

Manufacturer's Service and Warranty in Germany

The manufacturer will accept, independent from the obligations of the vendor against the buyer, a warranty period of twenty-four (24) months from the date of purchase.

- Deficiencies that can be related to faults in the material or manufacturing defects will be remedied free of charge within the warranty period
- Gako Deutschland GmbH must be informed of necessary warranty repairs
- A cost estimate can be obtained for service repairs. For sent in gako unguator Devices a 7 workdays resend period after receiving or approval a cost estimate is assured (only Germany)
- The warranty will lapse should the gako unguator device be sent NOT in its original cardboard box and packing. Please hold on to the original packaging of the gako unguator EMP materials to avoid additionally costs for a proper return
- gako unguator devices are included in the warranty. Gako unguator Assortment are excluded
- The warranty claim will lapse should an unauthorized party have tampered with the device.
- Damages caused by improper use as well as force majeure or other external influences are excluded from any warranty claims
- The parts replaced at maintenance and repair will become property of Gako Deutschland GmbH
- Claims beyond the free rectification of faults, e.g. indemnification cannot be made within the warranty period
- For warranty claims the warranty certificate with date of purchase, the dealer's stamp and signature, or the receipt has to be presented together with the warranty certificate
- Repairs within warranty will be exclusively carried out by Gako Deutschland GmbH or by authorized Gako Deutschland GmbH service partners
- Repairs to the gako unguator can only be performed by Gako Deutschland GmbH and certified service partners since the adjustment from electronics and mechanics requires special equipment
- After-sales service and maintenance service are billed for expenses and wear parts at reasonable price, according to the cost estimate within the warranty period as well

- Upon request a gako unguator Loaner may be provided for a one-time charge that can be used while your gako unguator is away for maintenance and repair

Notes on Safety

- gako unguator Devices must only be connected to grounding type receptacles with 230 V / 50 Hz(cps); 120 V / 60 Hz(cps) or rated country specific voltage installed according to the regulations of DIN VDE 0100
- gako unguator Devices have been designed for operation under normal room atmospheric conditions. Recommended values: Ambient temperature between 15 - 30 °C / 59 - 86 °F 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 gako unguator 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 gako unguator Devices in water
- Electronic parts should just be dis- and assembled by a certified service partner
- Only operate the gako unguator Stirrer inside a closed gako unguator Jar
- **Do not touch rotating parts**
- Keep long hair away from rotating parts
- **During the automated lifting of the gako unguator 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 gako unguator Devices not according to these operating instructions or with line products that the manufacturer did not deliver or recommend may impair safety.
- gako unguator 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).
- gako unguator 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.

Technical Data of the gako unguator PRO

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	continuous operation S1
Safety class	I
Type of protection	IP 20
Connection	4 USB-Ports 3 RS232-Ports 1 RJ45-Port
Rotational speed controller	in 10 steps electronic controlled
Timer	program-controlled
gako unguator Jar sizes	15-20 ml - 2000 ml
Weight	36 lbs / 16,5 kg
Dimensions (LxWxH in mm)	339 x 293 x 670
Testing certifications	CE

tab.: Technical Data of the gako unguator PRO

Certificate of Conformity



The certificate is available at the Gako Deutschland GmbH, D-96110 Scheßlitz.

The manufacturer of all the gako unguator products, the Gako Deutschland GmbH, D-96110 Scheßlitz, is DIN EN ISO 9001:2015 certified.

gako

Gako Deutschland GmbH
96110 Scheßlitz / Germany

Dipl.-Wirtsch.-Ing. Matthias Konietzko

Distribution, Manufacturing and Customer Service

Gako Deutschland GmbH
Am Steinernen Kreuz 24
96110 Scheßlitz, Germany

Tel: +49 (0) 89/ 1222 387 200
Fax: +49 (0) 89/ 1222 387 201
E-Mail: contact@unguator.com
Web: www.unguator.com

Distribution and Delivery Conditions

International distribution of the gako unguator Assortment is generally regulated and monitored by Gako Deutschland GmbH, Germany. Gako Deutschland GmbH works with selected distribution partners in defined territories on a global basis.

If generic or copied products being distributed under the registered trademark gako unguator, please contact us immediately following the Gako Deutschland GmbH contact details previous mentioned.

Your courtesy and support helps to prevent losses in terms of intellectual property, quality and customer satisfaction.

Customer Service

With all inquiries about technical data, service, warranty, customer service or replacement parts contact the customer service from Gako Deutschland GmbH directly.

Gako Deutschland GmbH
gako **competence center**
Am Steinernen Kreuz 24
96110 Scheßlitz, Germany

Tel: +49 (0) 89 1222 387 200
Fax: +49 (0) 89 1222 387 201
Email: contact@unguator.com
Web: www.unguator.com



WARRANTY CERTIFICATE

for the

gako unguator
BASIC

gako unguator
EMP

gako unguator
PRO

Date of registration: _____

Serial number: _____

Stamp and signature

The manufacturer will accept, independent from the obligations of the vendor against the buyer, a warranty period of twenty-four (24) months from the date of registration.

gako

Gako Deutschland GmbH

Am Steinernen Kreuz 24
D-96110 Scheßlitz
Germany

Tel.: +49 (0) 89 1222 387 200
Fax: +49 (0) 89 1222 387 201



Manufacturer's certificate

The entire gako unguator assortment is exclusively produced from materials and color components that meet the requirements for

the German **consumer goods ordinance (BedGgstVO)** from 10th of April 1992 (revised version from 23th of November 1997, last amendment from 24th of June 2009),

the **Database BfR Recommendations on Food Contact Materials**

the **legal specifications regulation (EU) Nr. 10/2011 (Kunststoff-Verordnung)** as well as the **regulation (EC) Nr. 1935/2004** (in their current version)

and the **EU-Guideline 2002/95/EG (ROHS)**.

Product	Material ¹⁾	Colour concentration ¹⁾	
gako unguator Jar ²⁾		standard	cosmetic
gako unguator Jar Cap	polypropylene natural	white	coloured
gako unguator Jar Lid	polypropylene natural	red, white, green, blue	coloured
gako unguator Jar Body	polypropylene natural	white	coloured
gako unguator Jar Bottom	polypropylene / polyethylene	-	-
gako unguator Jar Bottom Cap	polypropylene natural	white	white
Additional gako unguator assortments			
gako unguator Spindle	polypropylene natural	white	
gako unguator Applicator long	polypropylene natural	white	
gako unguator Applicator short with Cap	polypropylene natural	white	
gako unguator Coupling	polypropylene natural	white	
gako unguator Varionozzle blue, yellow, pink	polyethylene from 02/2019: thermoplastic elastomer	blue, yellow, red	
gako unguator SMB/Disp. Blade Shaft	stainless steel, titanium nitride (coating)	-	
gako unguator SMB	polyoxymethylene white	-	
gako unguator Disp. Blade	polyamide white	-	
gako unguator ExactDose	polypropylene natural	white, light blue, red	

1) Conformity declarations for materials and colour concentrates are deposited at Gako Deutschland GmbH.

2) With detailed certificate of analysis according to guideline from the Federal Union of German Associations of Pharmacists (Bundesapothekerkammer) "Examination and Storage of primary packaging material "Prüfung und Lagerung der Primärpackmittel" 13th of November 2013) as download at unguator.com/coa and the shortened certificate of analysis on the plastic packaging.

gako

Gako Deutschland GmbH
96110 Scheßlitz / Germany

Matthias Konietzko

Dipl.-Wirtsch.-Ing. Matthias Konietzko
01.02.2020