

Operating Instructions and Production Recommendations



UNGUATOR® 2100

*Dear UNGUATOR® user,
thank you for choosing the UNGUATOR® Mixing Technology,
a quality system
for advanced prescription compounding.*

*Please read the operations manual carefully.
For additional information about the use
and operation of the
UNGUATOR® Mixing Technology,
please feel free to contact us at
contact@unguator.com*

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1. Installation information

Select a suitable location for the UNGUATOR® 2100.

CAUTION! The UNGUATOR® 2100 weighs 36.7 lbs (16.7 kg). It is recommended to have an assistant while carrying and moving the equipment to the final destination.

Ensure that there is enough space to operate the UNGUATOR® e/s. This must include sufficient space around the UNGUATOR® e/s to provide good ventilation.

Select a suitable environment:

- Solid, horizontal surface
- Away from direct air flow from air conditioning systems, heaters, open windows or fans.
- Keep the temperature between 15°- 30° C (59°- 86°F) and maximum humidity of 80%.
- Clean, dry and dust-free.

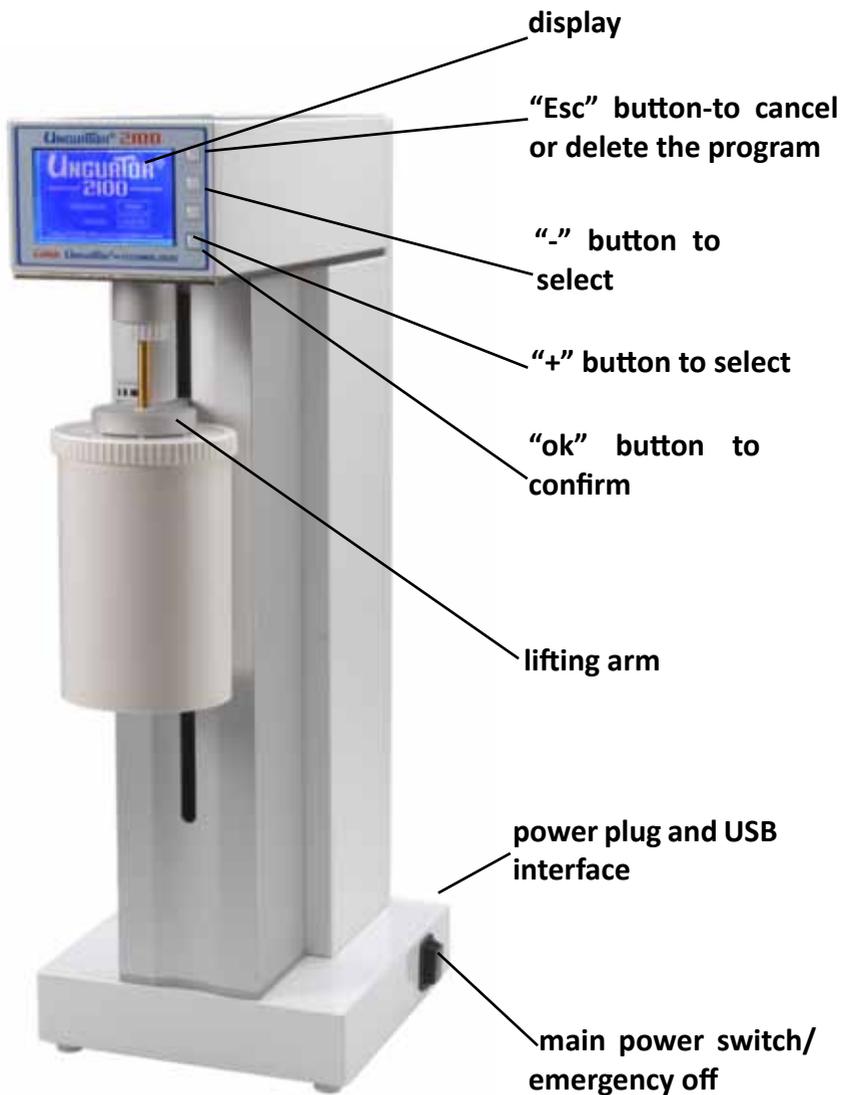
Remove all components from the cardboard box. Check to ensure that the following components are included in your shipment:

- UNGUATOR® 2100 mixing device
- Power cable
- Operating instructions

Please contact your responsible UNGUATOR® dealer and/or supplier immediately in case that components are missing or arrived damaged. Afterwards, we will not accept any claims regarding missing or defect items, they will be for your account!

Please hold on to the original cardboard box and packing material in case you have to send your UNGUATOR® 2100 in for service.

UNGUATOR 2100



Pic. 1. UNGUATOR® 2100

2. Initial operation

The interfaces for the power cord and USB-cable are located on the rear side of the UNGUATOR® 2100. The power “O/I” switch is also the emergency switch and is located at the bottom right side. Please check that the power switch of the UNGUATOR® 2100 is switched off. First connect the power cord to the UNGUATOR® 2100 and then to the socket outlet. You may now switch on the UNGUATOR® 2100 using the power switch. The device is now ready for operation.

3. Display operation

The control panel with four buttons: “Esc”, “-”, “+” and “ok” for manual control or command input and a display are located on the front of the UNGUATOR® 2100. The start screen will appear on the display after switching on the UNGUATOR® 2100 using the power switch.



Pic. 2: Display with splash screen

The start screen shows the current number of preparations and the version of the Microprocessor software stored.

4. Language menu



Pic. 3: Language set up

it the “Esc” key to move from the start screen to the language menu. The “+” and “-” keys will get you to the next or previous language setting. Enter “OK” to confirm your selection and move back to the start screen.

5. UNGUATOR® Technology

The UNGUATOR® Technology reduces the mechanical preparation of formulation ointments to the least common denominator. The core of UNGUATOR® Technology consists of the patented arrangement of the UNGUATOR® Mixing Blade adapted to the requirements of prescription ointments and the UNGUATOR® Jar that serves as both a hygienic mixing jar and a hygienic dispensing jar.

The principle of the preparation method using UNGUATOR® Technology in the closed 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 they 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 conventional methods that were used prior to the invention (1994). For the first time, it is possible to not only standardize ointments, but also validate them.

5.1 UNGUATOR® mixing machines

The current UNGUATOR® mixing machines - UNGUATOR® B/R, UNGUATOR® e/s, UNGUATOR® 2100 and UNGUATOR Q - are useful and advanced improvements on the first UNGUATOR® launched in 1994. They are designed for a working capacity of approx. 500 work hours which corresponds to approximately 15,000 to 20,000 preparations.

The UNGUATOR® mixing machines feature a high safety standard and were tested by TÜV-Rheinland, Germany for safety. The devices are manufactured under license and maintained by defined service partners.

Product quality, product uniformity and reproducibility of ointments prepared individually and in batches were improved with the increasing automation of the UNGUATOR® units starting with the individual model B/R- through e/s-, Q- and 2100 model.

| Method of ointment preparation | Pharmaceutical Quality | Uniformity of ointment | Lifting arm | Mixing parameters |
|--------------------------------|------------------------|------------------------|-------------|---------------------------|
| Mortar and pestle | ++ | + | - | manual |
| UNGUATOR® B/R | +++ | ++ | Manual | manually adjustable |
| UNGUATOR® e/s | +++ | +++ | automatic | individually programmable |
| UNGUATOR® Q | ++++ | ++++ | automatic | fully automatic |
| UNGUATOR® 2100 | ++++ | ++++ | automatic | fully automatic |

Tab. 1: Quality improvement with increasing automation

5.1.1 UNGUATOR® B/R

The UNGUATOR® B/R is the basic machine with controlled mixing motor and manual jar guidance.



Pic. 4: UNGUATOR® B/R

5.1.2 UNGUATOR® e/s

The UNGUATOR® e/s machine was developed for efficient individual and batch preparations. The automated stroke enables the user to leave the UNGUATOR® e/s during the mixing process to serve a customer for instance or to prepare the next formulation at the same time.



Pic. 5: UNGUATOR® e/s

The precisely set sensor for the automatic oscillation arm will always ascertain at each upward or downward stroke the exact position of the UNGUATOR® Jar bottom or lid. This guarantees that the UNGUATOR® Jar is always accessible to the UNGUATOR® Mixing Blade despite the inevitable vertical motion during the mixing process. If the stroke length of the first stroke was taken as a constant value, then the active ingredient weighed out in the lower region of the UNGUATOR® Jar might not be included in the mixing process by the UNGUATOR® Mixing Blade, getting „lost“ at the bottom. The lifting technique of the UNGUATOR® Mixing System prevents this from happening, so that the result of the mixing process is not just a homogeneous ointment, but also one with the desired ratio of active ingredients.

5.1.3 UNGUATOR® 2100

The UNGUATOR® 2100 shows all the advantages of its predecessors and can therefore automatically control the mixing parameters for each UNGUATOR® Jar size and different types of ointments. The user may program individual mixing parameters with a maximum of 180 additional programs can be stored. The UNGUATOR® 2100 can be connected to a PC via an USB interface.

An integrated microprocessor measures the actual revolutions of the UNGUATOR® Mixing Blade carried out by the UNGUATOR® 2100. This guarantees that the selected mixing program will always be identical, even for paste-like preparations which usually might demand more power from the mixing motor. This makes it easy to develop new ointments, cosmetics, etc. using the UNGUATOR® 2100, since only the composition changes and not the mixing program. As a result, ointments can now finally be reliably reproduced in smaller quantities.

The adjustable stroke speed, or the speed of the upward or downward motion of the automated oscillation arm, is another unique feature of the UNGUATOR® 2100. This allows the UNGUATOR® Mixing Blade to rotate at lower speed while the UNGUATOR® Jar quickly travels up and down, or vice versa. This new function is particularly useful using a low rotating speed of the UNGUATOR® Mixing Blade since it allows the UNGUATOR® Mixing Blade to mix an ointment homogeneously with a slow stroke.

5.1.4 UNGUATOR® Q

The UNGUATOR Q is the result of continuous improvement of the UNGUATOR® e/s from the year 2003.

It combines both the mixing functions of the UNGUATOR® e/s and the operating concept of the UNGUATOR® 2100. The basic functionality of the e/s - System, with the setting parameters of the mixing rotation speed and time are retained. A significant innovation in the UNGUATOR® Q is the possibility of scaling one mixing program already created to another jar size. This enables a constant quality of the recipes and as a consequence has a tremendous time saving result, since recalculation can be time consuming and complex.



Pic. 6: UNGUATOR® 2100



Pic. 7: UNGUATOR® Q

5.2 UNGUATOR® Assortment

Appart from the UNGUATOR® Standard Mixing Blade (SMB), the UNGUATOR® Disposable Blade (Disp. Blade) and the UNGUATOR® Jars, the UNGUATOR® Assortment provides additional and useful components. These include dosing aids such as the UNGUATOR® Varionozzles and UNGUATOR® Applicators, removal or transfer aids such as the UNGUATOR® Spindle, the UNGUATOR® Coupling and the patented AirDynamic® PumpballSystem. All UNGUATOR® products are compatible with all currently available UNGUATOR® Mixing devices.

5.2.1 UNGUATOR® Mixing Blade (MB)

The UNGUATOR® Standard Mixing Blade and the UNGUATOR® Disposable Blade are designated as the UNGUATOR® MBs. The UNGUATOR® MBs are steadily guided up and down inside the UNGUATOR® Jar. Their special design results in a tight contact between the mixing blade and the inside wall of the UNGUATOR® Jar, which serves, primarily, for the comminuting of the substances during the mixing process. Additionally forced mixing in the whole mixing space is achieved through the shape and vibration of substances while preparing the ointment.

The lubricating effect of the foundation ointment protects the UNGUATOR® Jars and the UNGUATOR® MB against abrasion. Discolorations of the mixing blade are mostly irreversible and therefore harmless. All UNGUATOR® MBs are dishwasher safe.

UNGUATOR® Standard Mixing Blade (SMB)



Pic.. 8: UNGUATOR® SMB

UNGUATOR® SMBs are adjusted to the size of each individual UNGUATOR® Jar. While the UNGUATOR® SMBs for 100 and 200 ml and for the 300 and 500 ml jars have the same mixing blade diameter, their shaft length differs. This must be taken into consideration especially when using the devices with automatic stroke lead, since the use of the wrong length may cause problems with the automated stroke.

Always make sure the UNGUATOR® MB being used is the right length, and that it is clean prior to use. (For example with isopropanol 70%)

The UNGUATOR® SMB is suitable for the production of all recipes. For suspension ointments and glass cleaning operations, we recommend the use of the UNGUATOR® Disp. Blade.

UNGUATOR® Disposable Blade (Disp. Blade)

The UNGUATOR® Disp. Blade is suitable for all UNGUATOR® devices. The mixing blade of the UNGUATOR® Disp. Blade is connected to the UNGUATOR® Disp. Blade shaft by twisting the blade counterclockwise and can be disconnected after the mixing process with a clockwise turn.

The material contact in the ointment is three times as high as when using the Disp. Blade compared to the UNGUATOR® SMB at the same mixing speed. The counter rotating twist of the mixing blades causes intensive material vibration in the material to be mixed and achieves good product quality faster than using the UNGUATOR® SMB. We do however recommend using the same mixing time as for the UNGUATOR® SMB.



Pic. 9: UNGUATOR® Disposable Blade

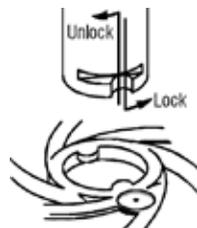
In the process of final quality control the mixing blade can be picked up and discarded with the small end of the shaft, or left inside the jar. Cleaning is limited to the UNGUATOR® Disp. Blade shaft. We recommend using the UNGUATOR® Disp. Blade for substances that may discolor the regular blade. This type of UNGUATOR® MB also comes with different shaft lengths.

The range of UNGUATOR® Jar sizes that can be used for the application is marked for orientation on the weak end of the shaft (15-100 ml and 200 ml respectively).

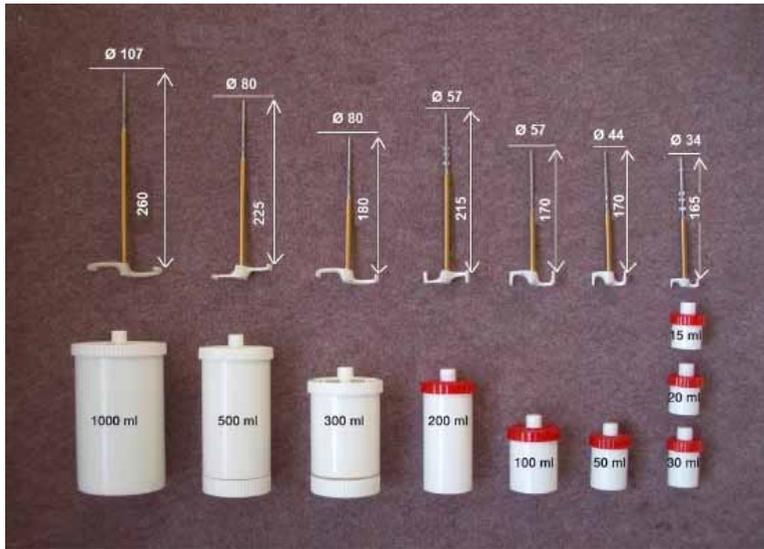
Assignment of the UNGUATOR® MB

Please take care to use the correct UNGUATOR® MBs for the corresponding UNGUATOR® Jar (Pic.11). Mix-up may cause failure messages.

Please, also take care to ensure that the right shaft is used with the UNGUATOR® Disp. Blade. Both shafts available are marked for use with sizes 15–100 ml or 200 ml in the UNGUATOR® Jar. They have to be combined with the correct UNGUATOR® Disp. Blade, and while the same UNGUATOR® Disp. Blade is used for the 100 and 200 ml UNGUATOR® Jar sizes, it needs a different shaft for each. See also the operating instructions that come with the shafts.



Pic. 10: Handling the UNGUATOR® disp. Blade



Pic. 11: Assignment of the UNGUATOR® SMB with different length of shafts

Flowing recesses of the UNGUATOR® SMB

The flow-adapted shape of the UNGUATOR® SMB generally cleans itself during the rotating penetration of the ointment. Unmixed ingredients may adhere to recesses of flow of the UNGUATOR® SMB depending on ointment's ingredients' compatibility of weighted formulation and also if the UNGUATOR® Jar is considerably under filled (e.g. large volumes of powder). These remnants should be transferred into the UNGUATOR® Jar using a spatula when about half of the mixing time is complete. The air should be decreased again following this process. When using the UNGUATOR® Disp. Blade, however, there are no recesses of flow and no remedial work is required.

Heating

The heat that develops from the friction between the UNGUATOR® MB and the inside wall of the UNGUATOR® Jar is required. Decreased viscosity increases the wettability of powders and accelerates the penetration of potential powder pockets. Even the emulsifying readiness of fats and oils is benefited by heat. 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 [2]. Volatile substances such as ethereal oils or alcohol do not evaporate from the closed UNGUATOR® Mixing System.

Cleaning the UNGUATOR® MB

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

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

5.2.2 UNGUATOR® Jar

The UNGUATOR® Jar is both the mixing and the dispensing jar and is therefore designed as an expendable or disposable jar. The UNGUATOR® Jar guarantees evaporation-free and contamination-free preparation in the air-reduced mixing space.

The UNGUATOR® Jar Lid closes the UNGUATOR® Jar to ensure no loss of active ingredients.

Used as a dispensing jar, the UNGUATOR® 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 UNGUATOR® guarantees the minimization of negative quality interference demanded by section 13, ApBetrO (Pharmacist Operating Regulations); including those caused by germs on the fingers when dispensing the ointment. Consequently, the user can remove the prescription ointment from the UNGUATOR® Jar very hygienically.

The UNGUATOR® Jar is resistant to hot-water baths and microwaves with temperatures below 85°C/185°F. Higher temperatures may alter the tightness of the UNGUATOR® Jar and the displaceability of the bottom (“push-up process might be negatively impacted”).

The UNGUATOR® material becomes brittle at temperatures below 0°C/32°F.

UNGUATOR® Jars are available in the following sizes: 15/28 ml, 20/33 ml, 30/42 ml, 50/70 ml, 100/140 ml, 200/280 ml, 300/390 ml, 500/600 ml and 1000/1250 ml (rated volume/filling volume). The standard color for the UNGUATOR® Jar housing is white and the UNGUATOR® Jar Lid is red. The 300 ml, 500 ml and 1000 ml UNGUATOR® Jars come with white lids. In addition, the 20 ml to 200 ml UNGUATOR® Jars are available in the pastel colors pink, light yellow, light blue and turquoise. Furthermore, UNGUATOR® Jars from 20 to 200 ml can be ordered with UNGUATOR® Jar Lids in the special colors green, blue and white. Upon special demand and defined quantity, UNGUATOR® Jars from 20 to 200ml may also be ordered in customized colors.



Pic. 12: UNGUATOR® Jar

All UNGUATOR® Jars come sealed in plastic packaging. Cleaning or disinfection prior usage could put the certified asepsis at risk. We would recommend storing the UNGUATOR® Jars in its plastic packaging after opening for protection against possible dust contamination. The UNGUATOR® Jar sizes 300 to 1000 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, The UNGUATOR® Jar solves 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 UNGUATOR® Jar can be moved close to the lid after spatula dispensing using the UNGUATOR® Spindle or the AirDynamic® Pumpball System.

| | |
|---|-----------------|
| Analysenzertifikat / Certificate of Analysis | Dat. 01.03.2012 |
| UNGUATOR® Kruke / Jar | |
| EINWEGEFÄSS VOR GEBRAUCH NICHT SPÜLEN | |
| DISPOSABLE / DO NOT RINSE BEFORE USAGE | |
| NENN- / FÜLL- / NOMINAL- / FILLING -VOL.: 50/70 ml | |
| PZN: 0471975 * INHALT / PACKING UNIT: 10 ST / pcs | |
| ART. / PROD.-NR.: 808 CHARGE: 1234/56P78 | |
| Geprüft nach ZL-Verp.-Vorschrift: DK II/94 | |
| Examined acc. to central lab. pack. regul.: DK II/94 | |
| Lichtdurchlässigkeit / Opaqueness | :OK |
| Partikelgehalt / Particle Concentration | :OK |
| Farbbeständigkeit / Color Fastness | :OK |
| Dichtigkeit / Seal Integrity | :OK |
| Mikrobiologie / Microbiology | :OK |
| gez./signed: Grieser (head of quality assurance) | |
| GAKO® * www.unguator.com | |



Pic. 10: Certificate of Analysis for the UNGUATOR® jar of 50 ml

The body of the UNGUATOR® Jar sizes 300 to 1000 ml can be cleaned in a dishwasher as long as it has not left the pharmacy. Asepsis has to be ensured before reuse though. The movable bottom of the UNGUATOR® Jar is not suitable for the dishwasher and the sealing lip of the UNGUATOR® Jar Lid may be destroyed after repeated mixing. The corresponding UNGUATOR® Jar Lids or jar bottoms can be ordered in sets of five and used for the economical reuse of the body.

The UNGUATOR® Jar is subject to periodic inspections in accordance to the German ZL packing regulation DK II/94. All plastic materials, which come into contact with food are made with the legal requirements of the plastic Regulation (EU) N° 10/2011 and Regulation (EU) N° 1935/2004 (in their current form).

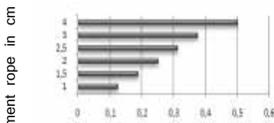
A certificate of analysis is issued after batch-defined examinations. The documentation of primary packaging materials at the pharmacy stipulates that the manufacturer's test certificate (certificate of analysis) is retained after receiving visual inspection. This certificate is affixed to the plastic packaging of the UNGUATOR® Jars. It may be removed from the plastic packaging as needed and added to the records.

Notes on Dispensing Ointment

Each customer should be given specific instructions at how to apply the UNGUATOR® Jars when speaking to the individual client. The use of the UNGUATOR® Spindle should be explained for large UNGUATOR® Jars, size 300/500 ml. Low viscosity ointments should be equipped with an UNGUATOR® Applicator or an UNGUATOR® Varionozzle to reduce the dispensed volume. Medium viscosity ointments can easily be extracted through the regular opening of the UNGUATOR® Jar. Very pasty ointments (e.g. pasta zinc) may not necessarily be pressed through the regular opening, even by using a spindle.

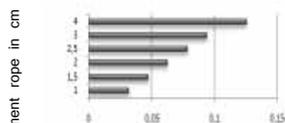
In this case, once the UNGUATOR® Jar lid has been removed, the ointment can be extracted with the help of a spatula, similar to handling conventional jars with a regular lid. If the UNGUATOR® Jar Lid has been removed, the ointment should be pushed up close to the lid after each dispensing process, using the UNGUATOR® Spindle or the AirDynamic® System.

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 UNGUATOR® Jar has a diameter of 8mm. The varionozzles or applicators reduce the diameter to 4, 2 or 1 mm. The approximate values represented in the following diagrams may also be helpful to weight out concentrated active substances or regular trituration from the UNGUATOR® Jar.



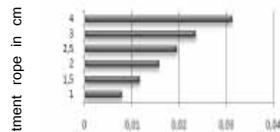
Quantity of ointment in ml
 Pic. 14: Dispensing with regular UNGUATOR® varionozzle

Length of ointment rope in cm



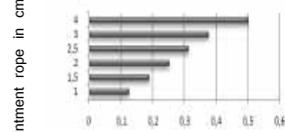
Quantity of ointment in ml
 Pic. 15: Dispensing with UNGUATOR® 1mm varionozzle or UNGUATOR® applicator short

Length of ointment rope in cm



Quantity of ointment in ml
 Pic. 16: Dispensing with UNGUATOR® 2mm varionozzle or UNGUATOR® applicator long

Length of ointment rope in cm



Quantity of ointment in ml
 Pic. 17: Dispensing with UNGUATOR® varionozzles 4 mm

Length of ointment rope in cm

5.2.3 UNGUATOR® Varionozzles

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



Pic 18: UNGUATOR® Varionozzles 1, 2, 4 mm

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)

5.2.4 UNGUATOR® Applicators

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

UNGUATOR® Applicator short

The UNGUATOR® Applicator short with a diameter of 1mm is obligatory for nose and ear ointments. The UNGUATOR® Applicator short comes with a cap to close the applicator.



Pic. 19: Applicator short UNGUATOR®

UNGUATOR® Applicator long



Pic. 20: Applicator long UNGUATOR®

The UNGUATOR® Applicator long with a diameter of 2 mm allows formulations to be introduced into large orifices of the body or probes. Moreover, the UNGUATOR® Applicator long also comes inside each UNGUATOR® 200 ml. Jar to help pushing up the bottom of this jar size in full. The UNGUATOR® Applicator long is generally available both with and without cap.

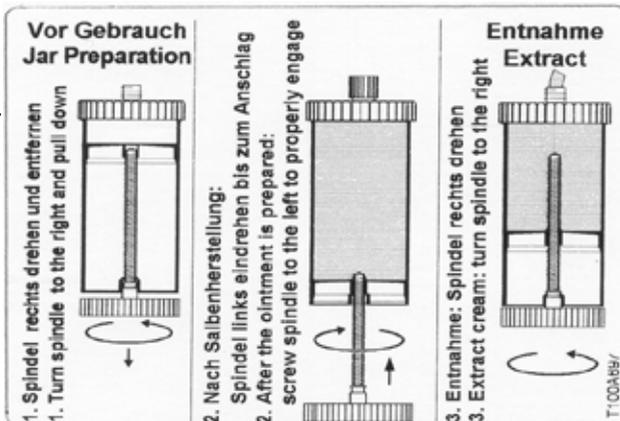
5.2.5 UNGUATOR® Spindle

The UNGUATOR® Spindle serves as a dispensing system for UNGUATOR® jar sizes 300 ml or 500 ml UNGUATOR® Jars that come with UNGUATOR® Spindles. The spindle has to be removed by rotating it clockwise prior the mixing process. The bottom can be slid up and down when the UNGUATOR® Spindle is screwed slightly (1/2 to max. 1 turn) counterclockwise without perforating the movable bottom (a slight resistance can be felt before the bottom is perforated).

Air can be decreased by placing the UNGUATOR® Jar onto the table and using both hands pushing the jar against the table.

Before giving the UNGUATOR® Jar to the customer, the UNGUATOR® Spindle must be screwed in the UNGUATOR® Jar counter clockwise from the bottom till it locks into place. The UNGUATOR® Spindle must be turned clockwise to extract the ointment. To remove the ointment the UNGUATOR® Spindle must be twisted to the right. One turn dispenses approx. 20 ml of the contents of the UNGUATOR® Jar.

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



Pic. 21: How to operate the UNGUATOR® Spindle



Pic. 22: UNGUATOR® Spindle

5.2.6 UNGUATOR® Coupling



Pic. 23. UNGUATOR® Coupling

The UNGUATOR® Coupling connects two UNGUATOR® Jars by the threads of their dispensing openings and is very useful when preparing ointments in larger batches. Transferring a formulation from a larger UNGUATOR® Jar into a smaller UNGUATOR® Jar using the UNGUATOR® Coupling will ensure hygiene from the mixing process to the end user.

The 200 ml UNGUATOR® Jar becomes a convenient transfer device to smaller UNGUATOR® Jars when their UNGUATOR® Jar bottoms are carefully pressed towards the work surface using an UNGUATOR® Applicator (long) screwed on a 30 ml UNGUATOR® Jar.

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

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

5.2.7 AirDynamic® Pumpball System

The AirDynamic® Pumpball System optimizes batch preparation within the closed system:

- Contamination-free transfer
- Contamination-free storage



Pic. 24: UNGUATOR® AirDynamic® Pumpball system

The AirDynamic® Pumpball System has been designed to apply with UNGUATOR® Jars from size 300 ml to 1000 ml to extract mixtures. An adapter connected to a pumpball is affixed to the center hole on the body's bottom of the UNGUATOR® Jar with an air-tight connection.

By pumping air into the lower chamber of the UNGUATOR® Jar using the pumpball, the pressure thus generated moves the bottom upward. Thanks to the AirDynamic® Pumpball System, even thick pastes can be dispensed via the small dispensing opening in the screw cap or transferred to small UNGUATOR® Jars using the

UNGUATOR® Coupling. The material outlet velocity depends on viscosity which may be reduced through heating.

The air pressure that had developed in the lower chamber of the UNGUATOR® Jar can be relieved by opening the valve screw. This is mandatory after the transfer process using the UNGUATOR® Coupling **before the smaller UNGUATOR® Jar is removed**. Otherwise this may result in considerable contamination of the immediate environment, depending on the formulation viscosity.

6. General Guidelines for the UNGUATOR® Technology

6.1 Preparing the UNGUATOR® Mixing System

The UNGUATOR® Mixing System consists of an UNGUATOR® Jar, an UNGUATOR® MB and the components of the formulation to be mixed.

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

Second, the UNGUATOR® MB is inserted into the UNGUATOR® Jar housing, sliding the UNGUATOR® Jar down. The UNGUATOR® Jar lid is then slid onto the UNGUATOR® MB standing in the UNGUATOR® Jar housing and pressed down firmly using both thumbs. Ensure that the sealing lip of the UNGUATOR® Jar lid opening is not damaged by the bayonet noses because the ointment may otherwise rise on the UNGUATOR® MB shaft during the mixing process.

Third, the UNGUATOR® MB is carefully removed from the UNGUATOR® Jar and the UNGUATOR® Jar lid will be moved all the way in the direction of the Blade. Both parts, i. e. the UNGUATOR® MB and the UNGUATOR® Jar lid are put down or possibly tarde on the balance together with the UNGUATOR® Jar.

6.2 Weighed portion of the formulation

Generally, oily, greasy, aqueous and pulverized ingredients can be weighed out into the UNGUATOR® Jar all at the same time. It is however advantageous to consider certain general procedures to optimize the mixing results. Generally, know-how gained from the traditional procedures to prepare ointments is very helpful when using the UNGUATOR® Mixing System. As already mentioned at the beginning of the operating instructions, true to the

motto:

learning by doing

Listed below are the seven different general procedures used to produce the routine standard formulations in pharmaceutical preparation of ointments: EMULSION, EMULSION +, NORMAL, SUSPENSION<2%, SUSPENSION>2% as well as GEL and SUPPOSITORIES. Due to the rapid heat generation, powder mixtures should be processed only at very low speed. 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 base on the UNGUATOR® Jar Bottom is first carefully placed around the sealing lip. This enhances the leak tightness of the UNGUATOR® Jar when it is filled. For UNGUATOR® Jars of 200 ml and up an active ingredient proportion of less than 5 %, of the active ingredient can be filled alternating with the foundation ointment over two or more levels to speed up vertical intermixture.

6.3 The mixing process with the UNGUATOR® 2100

The UNGUATOR® 2100 is the result of continuous improvements of the UNGUATOR® Technology of the year 2000.

The integrated programmable microprocessor that automates the UNGUATOR® 2100 Mixing System turns the device into a universal machine for the production of formula-tions!

The UNGUATOR® 2100 operates with 2 quiet, high duty; permanent motors and is an intelligent ointment stirring machine for recipes of 15-1000ml. When preparation type and size of the UNGUATOR® Jar have been selected, the microprocessor controls the mixing parameters for uniform and reproducible product quality.

Unlike its predecessor, the speed of the lifting motor can be increased or reduced on the UNGUATOR® 2100. This means that the oscillation arm will move up and down faster or slower. For mixing processes that are carried out at low mixing motor speed, homogeneity of the substances by thoroughly mixing them can be optimized thanks to a slow upward or downward stroke of the UNGUATOR® Mixing System.

In addition to the formulations such as emulsions, suspensions, gels or suppositories common in a pharmacy, where the mixing processes have already been preprogrammed in the closed system for all UNGUATOR® Jar sizes, the user can also mix combination mixtures, i.e. liquids, in the open vessel using the UNGUATOR® 2100 at 120 to 600 rpm.

Users already familiar with UNGUATOR® Technology will recognize many of the functions from the UNGUATOR® B, B/R, and e/s in the “DIRECT” program. This program allows for mixing process with both manual stroke and automated stroke where the mixing parameter speed of the mixing motor and the mixing time may still be changed during the mixing process.

Up to 180 mixing programs can be stored in the machine using the “MANUAL” program. Each of these 180 programs allows the user to change numerous mixing parameters. Users can the addition of a free spin motion program for each of these 180 programs.

The single mixing stages are defined by the mixing parameters of lifting motor speed and mixing motor speed in addition to the number of strokes or duration of the mixing stage. 360,000 settings per mixing stage are possible due to the various values of the mixing parameters. This results in a practically unlimited variety of optional programs that can be used to mix an ointment using the “MANUAL” program.

The UNGUATOR® 2100 has a USB interface. Using a PC and with the aid of the UNGUATOR® Assist Software, the UNGUATOR® 2100 can be controlled and any number of mixing programs can be changed and stored. The database makes label printing easy.

The UNGUATOR® 2100 will automatically assign an identification number to each finished preparation. This serves to document the mixing process, making it reproducible, and is shown on the display.

6.4 Standard formulation programs

The 7 standard formulation programs EMULSION+, EMULSION, NORMAL, SUSPENSION < 2% and SUSPENSION > 2% as well as GEL and SUPPOSITORIES can be selected from the main menu “SELECT MIX TYPE:” With few exceptions, the procedure is identical for all of these standard formulations and they are described below.

First select one of the standard formulation programs using the “+” and “-” buttons. Confirm the selection with the “ok” button. Next on the menu “SELECT UNGUATOR® JAR:” will appear. Select the UNGUATOR® Jar size using the “+” and “-” buttons and confirm using the “ok” button. The oscillation arm will automatically move to its starting position. The user will be prompted then to mount the UNGUATOR® Jar or the UNGUATOR® mixing unit. The UNGUATOR® MB shaft of the prepared UNGUATOR® Mixing System is run upward through the opening of the oscillation arm. Then the male thread of the UNGUATOR® Jar Lid is screwed into the oscillation arm. Pressing the “ok” button will initiate the mixing process after the UNGUATOR® Mixing System has been screwed tightly onto the oscillation arm.



Pic. 25. Main menu “Selecting Mixing Type”

The remaining time of the respective mixing program stage will show on the upper part of the display in minutes or seconds and the current speed of the mixing motor is indicated in percent. A progress bar illustrates the overall mixing progress on the lower part of the display. The automatic free spin program will complete the mixing process.

With the mixing process finished, the display of the UNGUATOR® 2100 will indicate the mixing parameters that have been run through. These are mixing time, number of revolutions of the UNGUATOR® MB, number of strokes and the identification number of the preparation. In addition, the number of the preparation and the software of the UNGUATOR® 2100 will display. Hitting the “ok” button will get you back to the start screen.

To remove the UNGUATOR® Mixing System, screw off the UNGUATOR® Jar Lid. The UNGUATOR® Mixing System is removed from the bayonet holder by twisting the UNGUATOR® MB shaft counterclockwise. Then the UNGUATOR® Mixing System can be removed by pulling downward. Hitting the “ok” button will get you back to the start screen.

6.4.1 Emulsion

(Emulsifying semisolid substances with water at room temperature).

Example: Eucerin c. aqua aa

Up to 200ml. we recommend using the UNGUATOR® Disp. Blade.

Cold stored foundations make the emulsification more difficult. Heating up the liquid to be added may accelerate the emulsification. Sometimes the heat that occurs during the mixing process inside the jar may already be sufficient and formation of emulsions.

6.4.2 Emulsion +

(Emulsifying of semisolid substances to be melted).

Examples: Emulsific. aquosa, Lanette, Cera

Up to 200ml. we recommend using the UNGUATOR® Disp. Blade.

Emulsions should always be heated then when UNGUATOR® Jars of 300 ml to 500 ml are used.

Melting semisolid substances using max. 85°C/185°F hot water can be achieved by three methods:

1. Addition of hot water ($\leq 85^{\circ}\text{C}/185^{\circ}\text{F}$)
2. Covering with cold water – heat up to 200 ml in the hot-water bath $\leq 85^{\circ}\text{C}/185^{\circ}\text{F}$.
3. Covering with cold water – careful heating in the microwave (mind max. temperature)

To attain an even structure, heated emulsions should be stirred until they have cooled to room temperature with a few intervalled strokes using a water jacket or by using cooling phases at medium speed during which the UNGUATOR® Jars are placed in the refrigerator, if necessary.

6.4.3 Normal

(Mixing semisolid substances from low-viscous to pasty).

Examples: Off-the-shelf pharmaceutical ointments with base(s), concentrated active substances with base(s), liquid active ingredients in base(s)

First the ointment base should be weighed out into the UNGUATOR® Jar. Then the remaining constituents should be added accordingly.

6.4.4 Suspension <2%

(Mixing semisolid substances with a portion of microfine, agglomerated, optionally fine-grained solid substances of less than 2 %).

Examples: Cortisones, antibiotics, fungicides, metronidazole

We recommend using the UNGUATOR® SMB.

If there is no concentrated active substance, we recommend a pregrinding process e.g. by use of a pregrind program in the case of a suspension with a content of less than 2% active ingredients. For pregrinding, the solids with low base content are weighed out into the UNGUATOR® Jar. The movable bottom remains in the lowest position, in order to make use of the full capacity of the jar including both lid and bottom areas for the dispersion process. The degree of dispersion reached by pregrinding should be checked to ensure that no active substance particles or

agglomerates are too large, either microscopically or using a strong magnifying glass. Usually, the spreading on a glassplate (e.g. object slide) is sufficient to prevent inhomogeneity. Eventually the pregrinding process needs to be repeated depending on the examination.

Due to a high speed grinding process a warming of the formulation up to 50°C (122°F) may occur. Since this warming may not be suitable for some of the substances (e.g. metronidazole), we recommend continuously checking the temperature.

In order to gently work the substances, making use of these programs, the rpm and lifting speed can be individually selected and adjusted.

The relatively large surface of the UNGUATOR® SMB benefits the formation of an agglomerate grinding process. This can be quickly homogenized with the rest of the base even when using larger UNGUATOR® Jar sizes. After finalizing the pregrinding process both the remaining base and all substances will be weighed in.

6.4.5 Suspension >2%

(Mixing semisolid substances with a portion of microfine, agglomerated, optionally finegrained solid substances of more than 2 %).

Examples: Zincum oxydatum, acidum salicylicum

We recommend using the UNGUATOR® SMB.

For suspensions with ingredient content above 2% pregrinding is not required. For preparation please add 50% of the required base in the UNGUATOR® jar first and then include the micronized solid parts. Add the remainder of the base on top of the ingredients in order to avoid remaining powder sticking to the blades.

6.4.6 Gel

(Mixing of gel).

Example: Hydroxypropyl cellulose 400

We recommend using the UNGUATOR® Disp. Blade for up to 200 ml.

Basic gel approaches are mixed, with several intervals, at high speed during the required swell time thus preventing agglomerations and slightly reducing soaking time. Principlerelated, trapped air will normally clear after the preparation would settle for a while.

6.4.7 Suppositories

We recommend using the UNGUATOR® Disp. Blade for up to 200 ml.

The heating of fat suppository base ointment may be carried out using an infrared lamp over the open UNGUATOR® Jar. An UNGUATOR® Applicator aids the precise filling of the suppository forms. It may be reheated using a hair dryer or an infrared lamp. A batch of approximately 5 to 10% is recommended.

6.4.8 Powder

(Mixing powder to fill capsules).

We recommend using the UNGUATOR® Disp. Blade for sizes up to 200 ml.

Excellent mixing results will be achieved when using microfine powder with a high content of lubricious aerosil, which is considered as “Soft in Soft” preparation. Please select low rpm (level 0/650 rpm), preferably applying the manual “Hand” mode (changing from “Auto” to “Hand”). Please have the mixing time extended accordingly.

To minimize the grinding noise along the sealing lip of the UNGUATOR® Jar Lid when mixing powder, the lip may be widened a bit using the shaft of the UNGUATOR® MB.

The powder can be evenly distributed from the dispensing opening using the capsule filling device.

6.4.9 “Direct” Program



Pic. 26: Menu “DIRECT PREPARATION:”

First select the “DIRECT” program using the “+” and “-” buttons in the main menu. Confirmed selection with the “ok” button and the menu “SELECT UNGUATOR® JAR:” will show. Select UNGUATOR® Jar size using the “+” and “-” buttons and confirm using the “ok” button, then the “DIRECT PREPARATION:” menu will be displayed.

First select one of the six possible speed steps of the lifting motor that determine the speed of the oscillation arm using the “+” and “-” buttons and confirm with the “ok” button. Speed steps “01” to “05” stand for

slow to fast upward and downward stroke of the automated oscillation arm (see 3.2.1). The speed of the lifting motor can not be changed during the mixing process. The automated movement of the oscillation arm is suspended when selecting speed step “0” and the oscillation arm is moved into its full down position before the mixing process starts which allows for a manually guided stroke.

6.4.9.1 Automated stroke

Once the automated stroke has been selected, the user may, depending on the size of the UNGUATOR® Jar, choose from up to 10 different speed steps of the UNGUATOR® MB using the “+” and “-” buttons and confirm this with the “ok” button. The last of the selectable mix parameters is mixing time which may be between 10 seconds and 2 hours. Change mixing time with the “+” and “-” buttons.

After mixing time is confirmed with the “ok” button, the oscillation arm will automatically move to its starting position. Now the user will be prompted to mount the UNGUATOR® Jar or the UNGUATOR® Mixing Unit.

The UNGUATOR® MB shaft of the prepared UNGUATOR® Mixing System is run upward through the opening of the oscillation arm. Then the male thread of the UNGUATOR® Jar Lid is screwed into the oscillation arm. Be sure the UNGUATOR® Mixing System has been screwed tightly onto the oscillation arm. Pressing the “ok” button will initiate the mixing process.

The remaining mixing time and the current speed of the UNGUATOR® MB are displayed throughout the entire mixing process. The UNGUATOR® MB speed and mixing time parameter can be changed during mixing using the “+” and “-” buttons. Selection of the mixing parameters to be changed is made using the “ok” button. Once the mixing time is over, the UNGUATOR® 2100 will automatically run the free spin program.

With the mixing process finished, the display of the UNGUATOR® 2100 will indicate the mixing parameters that have been run through. These are mixing time, number of revolutions of the UNGUATOR® MB, number of strokes and the identification number of the preparation. In addition, the number of the preparation and the software of the UNGUATOR® 2100 will display.

To remove the UNGUATOR® Mixing System, screw off the UNGUATOR® Jar Lid from the oscillation arm (clockwise). The UNGUATOR® Mixing System is removed from the bayonet holder by twisting the UNGUATOR® MB shaft counterclockwise. Then the UNGUATOR® Mixing System can be removed by pulling downward. Hitting the “ok” button will get you to the start screen.

6.4.9.2 Manual stroke

Once the manual stroke has been selected, the user may, depending on UNGUATOR® Jar size, select up to 10 different speed steps for the UNGUATOR® MB using the “+” and “-” buttons and confirm this using the “ok” button. The last of the selectable mix parameters is mixing time which may be between 10 seconds and 2 hours. Use the “+” and “-” buttons to change mixing time.

After mixing time is confirmed with the “ok” button, the oscillation arm will automatically move to its starting position. Now the user will be prompted to mount the UNGUATOR® Jar or the UNGUATOR® mixing unit.

The already prepared UNGUATOR® Mixing System is inserted into the bayonet receptor of the UNGUATOR® 2100 from below and pushed up as far as it will go. The UNGUATOR® Jar Lid and the UNGUATOR® Jar housing should both be held in one hand simultaneously.

When the “ok” button on the UNGUATOR® 2100 is pressed, the bayonet receptor will grip immediately and hold until the mixing process is complete. The programmed mixing time is run through at the speed step set. The remaining mixing time and the current speed of the UNGUATOR® MB display throughout the entire mixing process. During the mixing process, the UNGUATOR® MB speed and mixing time parameters can be changed via the “+” and “-” buttons. Select the mixing parameter(s) to be changed and confirm via the “ok” button.

We recommend moving the UNGUATOR® Jar up and down steadily from the stop on the UNGUATOR® Jar Bottom to the stop on the UNGUATOR® Jar Lid every second.

The free spin program can also be selected in this operating mode. In free spin, the UNGUATOR® MB is positioned close to the lid and the UNGUATOR® MB will perform a “self-cleaning” process through high-speed rotation.

With the mixing process finished, the UNGUATOR® 2100 display will indicate the mixing parameters that have been run through. These are mixing time, number of revolutions of the UNGUATOR® MB, number of strokes and the identification number of the preparation. In addition, the number of the preparation and the software of the UNGUATOR® 2100 will display. The UNGUATOR® Mixing System is removed from the bayonet receptor by twisting the UNGUATOR® MB shaft counterclockwise and then pulling it out in downward direction. Hitting the “ok” button will get you to the start screen.

6.4.10 “Combination mix”

The sequence of the “COMBINATION MIX” program serves to speed up the dissolving process or that of a chemical reaction in a medium of constant good flow properties. It is done without reciprocating motion.

First select the “COMBINATION MIX” program in the main menu using the “+” and “-” buttons. Confirm with the “ok” button. The oscillation arm will automatically move into the full down position and the display will prompt the user to mount the mixing tools. These consist of the UNGUATOR® Jar Lid of a 1000 ml UNGUATOR® Jar, a vessel with the combination mix and a UNGUATOR® SMB or Disp. Blade appropriate for the vessel. Ensure that the overall diameter of the UNGUATOR® MB is smaller than the inside diameter of the vessel.

The UNGUATOR® Jar Lid should be tightly screwed upside-down above the oscillation arm, with the threads facing upward. The vessel will be placed, together with the reaction mixture and the UNGUATOR® SMB, onto the mounted UNGUATOR® Jar Lid. Then the UNGUATOR® SMB should be inserted into the bayonet receptor of the UNGUATOR® 2100, moved up as far as it goes, then twisted clockwise.

Confirm the assembly by hitting the “ok” button and the user will be prompted to move the oscillation arm into mixing position. The oscillation arm can be moved upward by pressing the “+” button and downward by pressing the “-” button. Confirm with “ok” once the desired mixing position has been reached.

The speed of the UNGUATOR® MB can be changed using the “PARAMETERS SELECT:” menu using the “+” and “-” buttons. Select speeds between 120 and 600 rpm in 12 steps and confirm using the “ok” button. Then the mixing time parameters can be set using the “+” and “-” buttons. Available mixing times are between 2 minutes and 2 hours.

Start the mixing process by confirming the mixing time using the “ok” button. The remaining mixing time and the speed of the UNGUATOR® MB display throughout the entire mixing process.

After the mixing process has been completed, the user will be prompted to move the oscillation arm into the retrieval position using the “+” and “-” buttons. We recommend the full down position of the oscillation arm for easy retrieval. Please keep in mind though that this means the UNGUATOR® SMB could drop out of the bayonet receptor upon the slightest touch. This is why the UNGUATOR® SMB should be twisted loose from the bayonet holder in counterclockwise direction, then pulled out downward and placed into the vessel with the reaction mixture prior to moving the oscillation arm into its retrieval position. Confirm with “ok” once the retrieval position has been reached.

When the mixing process is complete, the UNGUATOR®



Pic. 27: Combination mix”

2100 display will indicate the mixing parameters that have been run through. These are mixing time, number of revolutions of the UNGUATOR® MB, number of strokes and the identification number of the preparation. In addition, the number of the preparation and the software of the UNGUATOR® 2100 will display.

The vessel with the reaction mixture and the UNGUATOR® MB should be removed and the UNGUATOR® Jar Lid screwed off of the oscillation arm. Hitting the “ok” button will get you to the start screen.

6.4.11 “Manual” Program

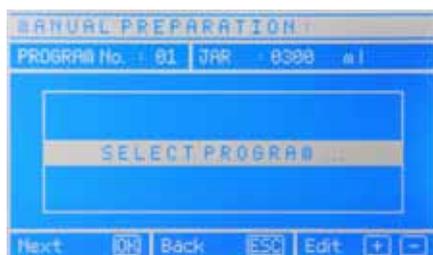
Generally speaking, ointments prepared individually and in batches in a pharmacy can be optimally prepared using the standard formulation programs. The individual programming with the “MANUAL” program is first and foremost meant for study and research purposes but also for mixing processes that have to be run under stringently controlled conditions or do not require the quality-assuring energy input of the standard formulation programs. The preparation of concentrated active substances or the preparation of subcomponents but also preparations following a given graduated scheme and emulsions may require these mixing processes

The “MANUAL” program allows for the storage of 180 different mixing programs.

Each UNGUATOR® Jar size is assigned to 20 mixing programs. Using a PC and appropriate software, the number of mixing programs that can be stored is practically unlimited.

A mixing program consists of a re grind program (1–3 = enabled; 0 = disabled), a main mixing program subdivided into 16 mixing stages and a ree spin program (1 or 2 = enabled; 0 = disabled). So each main program can be preceded by a pre grind program and be followed by a free spin program.

First select the “MANUAL” program using the “+” and “–” buttons in the main menu. Confirm with the “ok” key and the “UNGUATOR® JAR SELECTION” menu will show. Select UNGUATOR® Jar size using the “+” and “–” buttons and confirm with the “ok” button, and



Pic. 28. Menu “SELECT PROGRAM”



Pic. 29: Main menu “MANUAL PREPARATION”

the “PROGRAM SELECT:” menu will show.

First select the “MANUAL” program using the “+” and “-” buttons in the main menu. Confirm with the “ok” key and the “UNGUATOR® JAR SELECTION” menu will show. Select UNGUATOR® Jar size using the “+” and “-” buttons and confirm with the “ok” button, and the “PROGRAM SELECT:” menu will show.

Select one of the programs “01” to “20” for the respective sizes of UNGUATOR® Jar selected in the previous step using the “+” and “-” buttons. Confirm with the “ok” button and a new menu will show on the display. This is the main “MANUAL PREPARATION” menu.

Here the user can select among “USE”, “INDICATE”, “EDIT” and “DELETE” options in the main “MANUAL PREPARATION” menu using the “+” and “-” buttons. The menu option selected must be confirmed with the “ok” button.

6.4.11.1 “Use” a manual preparation

The oscillation arm will automatically move into its starting position. Now the user will be prompted to mount the UNGUATOR® Jar or the UNGUATOR® mixing unit. The UNGUATOR® MB shaft of the prepared UNGUATOR® Mixing System is run upward through the opening of the oscillation arm. Then the male thread of the UNGUATOR® Jar Lid is screwed into the oscillation arm. Pressing the “ok” button will initiate the mixing process after the UNGUATOR® Mixing System has been screwed tightly onto the oscillation arm.

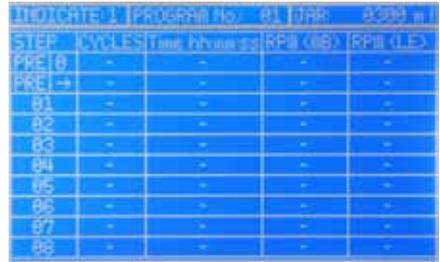
The upper part of the display shows the current speed of the mixing motor in percent during the mixing process. A progress bar illustrates the overall mixing progress on the lower part of the display

When the mixing process is complete, the UNGUATOR® 2100 display will indicate the mixing parameters that have been run through. These are mixing time, number of revolutions of the UNGUATOR® MB, number of strokes and the identification number of the preparation. In addition, the number of the preparation and the software of the UNGUATOR® 2100 will display.

To remove the UNGUATOR® Mixing System, screw off the UNGUATOR® Jar Lid. The UNGUATOR® Mixing System is removed from the bayonet receptor by twisting the UNGUATOR® MB shaft counterclockwise. Then the UNGUATOR® Mixing System can be removed by pulling downward. Hitting the “ok” button will get you to the start screen.

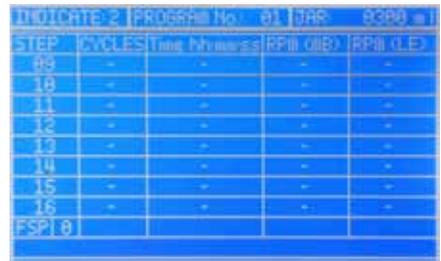
6.4.11.2 “Indicate” a manual preparation

The “Indicate” menu option allows the user to get a quick general idea about the currently stored mix parameters of the mixing program selected. The tabulated data can be retrieved with the two screens “INDICATE: 1” and “INDICATE: 2”. When selecting the “Indicate” menu option, the “INDICATE: 1” screen will display first, which, in addition to program number and Jar size selected, also displays the current mix parameters stored on the UNGUATOR® 2100, strokes and mixing time respectively as well as the speed of the UNGUATOR® MB and the lifting motor of the pre grind program as well as the first 8 mixing stages.



| STEP | CYCLES | Time | Number of strokes | RPM (MB) | RPM (L.E.) |
|-------|--------|------|-------------------|----------|------------|
| PREI0 | - | - | - | - | - |
| PREI→ | - | - | - | - | - |
| 01 | - | - | - | - | - |
| 02 | - | - | - | - | - |
| 03 | - | - | - | - | - |
| 04 | - | - | - | - | - |
| 05 | - | - | - | - | - |
| 06 | - | - | - | - | - |
| 07 | - | - | - | - | - |
| 08 | - | - | - | - | - |

Pic. 30: Screen “INDICATE: 1”



| STEP | CYCLES | Time | Number of strokes | RPM (MB) | RPM (L.E.) |
|-------|--------|------|-------------------|----------|------------|
| 09 | - | - | - | - | - |
| 10 | - | - | - | - | - |
| 11 | - | - | - | - | - |
| 12 | - | - | - | - | - |
| 13 | - | - | - | - | - |
| 14 | - | - | - | - | - |
| 15 | - | - | - | - | - |
| 16 | - | - | - | - | - |
| FSP10 | - | - | - | - | - |

Pic. 31: Screen “INDICATE: 2”

Change to “INDICATE: 2” screen by hitting the “ok” button. One may return to the “INDICATE: 1” screen using the same procedure.

The remaining data for the mixing program are represented on the “INDICATE: 2” screen. These are the corresponding mix parameters of mixing stages 9 to 16 and those of the free spin program. As on the “INDICATE: 1” screen, the mixing program number and Jar size can also be read. Hitting the “Esc” button will from either the “INDICATE: 1” or “INDICATE: 2” screen with return you to the main “MANUAL PREPARATION” menu.

6.4.11.3 “Edit” a manual preparation

The “EDIT” menu option is the core of the “MANUAL” program. Here users can edit both the pre grind and free spin program and mix the parameters of the speed of the lifting and mixing motor as well as number of strokes or mixing time of the 16 mixing stages.

First select the pasting program by using the “+” and “-” buttons, and confirm with the “ok” button. The following programs are available: pasting “00”, which means the “01” mixing stage starts directly, skipping pasting, and programs “01” to “03”. The mixing parameters of the individual pasting programs are shown in Tab. 2.

| PRE Prog.-No. | FSP Prog.-No. | Strokes | Speed of the MB in rpm | Speed of the lifting motor in rpm |
|---------------|---------------|---------|------------------------|-----------------------------------|
| 00 (disabled) | 00 | 0 | 0 | 0 |
| 01 (enabled) | 01/02 | 6 | 1500 | 2200 |
| | 01/02 | 20 | 2000 | 1500 |
| 02 (enabled) | 01/02 | 4 | 1500 | 2200 |
| | 01/02 | 10 | 1500 | 1500 |
| 03 (enabled) | 01/02 | 4 | 1500 | 800 |
| | 01/02 | 10 | 2000 | 1500 |

Tab. 2 Mixing parameters of the grinding programs from “00” to “03”

The free spin program can be set after pre grind program selection is confirmed with the “ok” button. The options available here are the free spin “00” motion program, i.e. end of mixing process without free spin, or free spin program “01” or “02”, i.e. the UNGUATOR® MB will “cleanitself” before the end of the mixing process by means of high-speed rotation in a position close to the lid in the free spin program. Confirm this select too by hitting the “ok” button.

| FSP Prog.-No | Time In min:sec | Suitable jar size Volume in ml | Speed of the MB In rpm |
|---------------|-----------------|--------------------------------|------------------------|
| 00 (disabled) | 0:00 | - | 0 |
| 01 (enabled) | 0:03 | 15...200 | 2500 |
| 02 (enabled) | 0:03 | 300...1000 | 2000 |

Tab. 3: Parameters of the rotation from “00” to “02”

One of the 16 mixing stages can be directly selected on the “Prog. Stage” line using the “+” and “-” buttons. Confirm the mixing stage selected with the “ok” button. This will call up the selection of mixing parameters. Exactly like in the previous selection processes, the various mixing parameters, speed of the lifting motor and the UNGUATOR® MB and number of strokes or duration of the mixing time can be changed using the “+” and “-” buttons in each case and are to be confirmed with the “ok” button. It is also possible to select or confirm individual mixing parameters by hitting the “Esc” button, but here the selection does not jump to the following but to the previous data record.

Since the number of strokes and the mixing time depend directly on each other, the user may either pre-select the number of strokes or the mixing time. So if the number of strokes is determined within a mixing stage and the mixing time is set afterward, then the data record of mixing parameter number of strokes will be deleted again and the record of mixing parameter mixing time will be stored.

| Step | Speed of the lifting motor in rpm |
|------|-----------------------------------|
| 01 | 800 |
| 02 | 1500 |
| 03 | 2200 |
| 04 | 2900 |
| 05 | 3600 |

| Step | Speed of the MB in rpm | Max. jar size allowed (Nominal volume in ml) |
|------|------------------------|--|
| 01 | 250 | 1000 |
| 02 | 500 | 1000 |
| 03 | 750 | 1000 |
| 04 | 1000 | 1000 |
| 05 | 1250 | 1000 |
| 06 | 1500 | 1000 |
| 07 | 1750 | 1000 |
| 08 | 2000 | 1000 |
| 09 | 2250 | 200 |
| 10 | 2500 | 50 |

Tab. 4: Steps of velocity available for the mixing and lifting motor

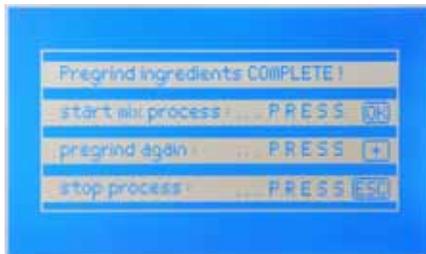
When all mixing parameters of the 16 mixing stages have been confirmed with the “ok” button, the user is returned to the “MANUAL PREPARATION” menu. The user may also leave the “Change” menu backwards by confirming all mixing parameters hitherto set using the “Esc” button. The microprocessor will immediately accept all changes that were made during the navigation through menu option “Change” as a change of the existing mixing program and store it under the number of the program selected. Here it does not matter if the menu option was properly exited using the “ok” button or by termination through the “Esc” button. The UNGUATOR® 2100 will not prompt for storage of the new settings at any time but will overwrite the old ones with the new data records directly upon change. Please check the changed data at the “Indicate” menu option prior to initiating the mixing process.

6.4.11.4 “Delete” a manual preparation

Selecting the “Delete” menu option will irrevocably delete the complete data record of the mixing program currently selected. This means that all the mixing parameters of all 16 mixing stages will be set to “0” and the pre grind program as well as the free spin program will be set to “00” or “disabled”. In the event that the menu option “Delete” was selected, the UNGUATOR® 2100 will ask once more whether the selected mixing program should be really deleted. Confirm using the “ok” button or abort using the “Esc” button.

6.4.11.5 Pregrind program

While the pre grind program is running, the lower part of the display shows „PREGRINDING ACTIVE“. The mixing process is interrupted after the pre grind program has ended and the display shows the following prompt (Picture 30: After the pre grinding program).



Pic. 32: After finishing the pregrinding program

The user has now the option of detaching the UNGUATOR® Mixing System from the oscillation arm and the bayonet receptor and removing it by pulling it downward. Pre grinding results can be checked by opening the UNGUATOR® Jar Lid. Depending on the result of the quality check, either the mixing process can be continued, the pre grind program run through once more, or the mixing process terminated.

Hit the “ok” button to continue the mixing process. The oscillation arm will automatically move into its starting position. The remaining formulation constituents can now be weighed in, the UNGUATOR® Jar closed tight again and the UNGUATOR® Mixing System screwed into the oscillation arm. Then restart the mixing process by hitting the “ok” button.

The “+” button can be pressed to re-run the pre grind program. The oscillation arm will automatically move into its starting position. The UNGUATOR® Jar needs to be reclosed and the UNGUATOR® Mixing System screwed into the oscillation arm. Confirm pre grind program restart by hitting the “ok” button. The user will again see the prompt shown in the display after the pre grind program has finished.

The “Esc” can be pressed to reject or abort the mixing process. The UNGUATOR® 2100 will then return to the start screen.

6.4.11.6 Number of strokes

One upward motion and one downward motion of the UNGUATOR® Mixing System taken together is one stroke. In addition to mixing motor speed, the number of times the UNGUATOR® MB covers the path from the lid to the bottom and back again is of critical importance for vertical intermixture. We recommend using at least 50 strokes for a good vertical intermixture regardless of UNGUATOR® Jar size at max. Mixing motor speed.

6.4.11.7 Mixing time

The option of setting the mixing time has been designed solely for special tasks in the field of research or for users with adequate know-how. This is because the variable speed of the lifting motor and the influence on final product quality is unreadable for the unpracticed user. Tab. 3–4 and Tab. 3–6 give reference values for this.

6.4.11.8 Minimum mixing times for the “Direct” and “Manual” programs

The following tabulated reference values can be derived for ointment preparation using the “DIRECT” and “MANUAL” programs. These minimum values are stated as [min/sec] and dependant on the size of the UNGUATOR® Jar, type of ointment, and speed of the mixing motor as variables.

Size of the UNGUATOR® Jar

| Type of formulation | 15 30 ml. | 50 a 100 ml. | 200 a 300 ml. | 500 ml. | 1000 ml. |
|---------------------|-----------|--------------|---------------|---------|----------|
| Suspension | 02:00 | 02:30 | 04:30 | 06:10 | 08:15 |
| Normal S/S | 01:40 | 02:10 | 04:00 | 05:10 | 07:10 |
| Emulsion | 02:00 | 02:20 | 04:10 | 05:30 | 07:40 |
| Suppositories | 01:40 | 02:10 | 04:00 | | |

Tab. 5: Minimum values for the mixing time at 2500 rpm in min:s

Size of the UNGUATOR® Jar

| Type of formulation | 15 20 ml. | 30 a 100 ml. | 200 a 300 ml. | 500 ml. | 1000 ml. |
|---------------------|--|--------------|--|---------|----------|
| Suspension | 03:00 | 03:50 | 06:45 | 09:30 | 09:40 |
| Normal S/S | 02:30 | 03:20 | 06:10 | 07:50 | 08:25 |
| Emulsion | 03:00 | 03:50 | 06:30 | 08:30 | 08:50 |
| Suppositories | 02:30 | 03:20 | 06:10 | | |
| Gel | 4x1 min. with 1500 U/min And pause after 5 mins. | | 4x1 min. with 1500 U/min And pause after 5 mins. | | |

Tab. 6: Minimum values for the mixing time at 1750 rpm in min:s

6.4.11.9 Selecting the UNGUATOR® Jar size

The selection of the UNGUATOR® Jar size was designed to protect the UNGUATOR® 2100 from overloads. For example, the maximum speed of the UNGUATOR® MB was limited to 2000 rpm when a 1000 ml UNGUATOR® Jar has been selected.

6.4.12 Requirements for the ingredients of a prescription

Powder

(Mixing powder to fill capsules).

We recommend using the UNGUATOR® Disp. Blade for sizes up to 200 ml.

Excellent mixing results will be achieved when using microfine powder with a high content of lubricious aerosil, which is considered as “Soft in Soft” (S/S) preparation. Please select low rpm (level 0/650 rpm), preferably applying the manual “Hand” mode (changing from “Auto” to “Hand”). Please have the mixing time extended accordingly.

Crystalline active ingredients

We recommend pulverizing active crystalline ingredients in a mortar prior adding into the UNGUATOR® Jar.

Should a solvent for the active crystalline ingredient be part of the formulation, the ingredients may then also be dissolved in the UNGUATOR® Jar. For example, urea with water. Then the remaining formulation ingredients can be added. The crystalline substance may also dissolve during the mixing process if the solvent is an ingredient of the ointment base.

Waxes, hydrophilic ointment, etc.

Either pour warm water alone ($\leq 85\text{ }^{\circ}\text{C}/185\text{ }^{\circ}\text{F}$) or the heated remaining ingredients constituents over Cera, Lanette N, etc. in the UNGUATOR® Jar,

or

pour water in the substances and heat them either in a heated-water bath ($\leq 85\text{ }^{\circ}\text{C}/185\text{ }^{\circ}\text{F}$) or carefully observed in a microwave oven. Formulations without water containing components may be melted already directly inside the UNGUATOR® Jar by placing the jar in the water bath.

Please note that the UNGUATOR® MB must not go in a microwave oven. Furthermore, isolated areas of heat concentration may develop when heating in a microwave. To avoid this, we recommend coarsely blending the content of the jar during heating using a spatula at intervals. Please also keep in mind that a microwave will only heat aqueous substances. Generally it is sufficient to homogenize heated mixtures in three cooling intervals of six minutes each and apply 10 strokes each using the UNGUATOR® at high speed. Homogenization of solid substances takes slightly longer. The cooling time and hence the cooling interval can be shortened in the refrigerator or by using a water jacket. The UNGUATOR® MB should remain in the UNGUATOR® Jar during the cooling phase.

For emulsions, it makes sense in some cases to pregrind ingredients using the whole fatty phase and a low portion of water by a pregrinding. The remaining water can then be filled in the UNGUATOR® Jar in additional steps when the mixing process is interrupted. The advantage of pregrinding, where the basic ingredients are mixed evenly along the UNGUATOR® Jar wall, is a relatively fast bonding of the liquid constituents. This in turn assures an increased tightness of the sealing lips, even for large UNGUATOR® Jars and extended mixing processes.

6.5 Preparing the mixing process

Together with the UNGUATOR® Jar Lid, the UNGUATOR® MB should be loosely screwed onto the UNGUATOR® Jar housing after the formulation constituents have been weighed in. By pushing up the UNGUATOR® Jar Bottom with a thumb or, for large UNGUATOR® Jars, with the UNGUATOR® Spindle or the Air Dynamic® System, the air will escape between the UNGUATOR® Jar Lid and the UNGUATOR® Jar housing. Then the UNGUATOR® Mixing System should be tightly screwed down. This process is called air diminution.

Air diminution will not only prevent ointment exudation at the sealing zones of the UNGUATOR® Jar through reduction of any overpressure that may have developed. The mixing result is also optimized since there is no trapped air. We recommend, mainly in the case of intermingling large quantities of powder, that air diminution be repeated after 15 seconds of the mixing process.

When pre grinding by pasting the solids with some foundation in the UNGUATOR® Jar, we recommend positioning the movable UNGUATOR® Jar Bottom as far downward as possible. This will guarantee that the large surface area of the inside wall of the UNGUATOR® Jar also including the lid and bottom can be used for dispersion between the friction surfaces of the UNGUATOR® MB and the inside surface area of the UNGUATOR®

Jar housing. Consequently, no air diminution need be carried out before pre grinding. At this point of the mixing process, device-specific settings will need to be implemented

and the UNGUATOR® Mixing System connected to the UNGUATOR®.

6.6 After the mixing process is complete

The UNGUATOR® Mixing System is released and removed from the UNGUATOR® oscillation arm once the mixing process is finished. Unscrew the UNGUATOR® Jar Lid from the oscillation arm and/or twist the UNGUATOR® MB shaft counterclockwise. This will only require a quarter turn, which may already have happened when releasing the jar from the oscillation arm. For this reason, we recommend holding the UNGUATOR® Mixing System tightly with one hand when removing it from the UNGUATOR®.

In the next step, the UNGUATOR® Jar Lid is opened and the UNGUATOR® MB removed. Since this is also an opportunity execute a quality check, the UNGUATOR® Jar Lid should also be opened after mixing when using the UNGUATOR® Disp. Blade. Practice has proved that if the surface of the ointment looks smooth and if the minimum defined mixing time has elapsed, homogeneity inside the UNGUATOR® Jar in fall can be expected.

Push the UNGUATOR® MB out of the UNGUATOR® Jar Lid. The ointment on the mixing blade can be fallen off into the UNGUATOR® Jar using a spatula. When using the UNGUATOR® Disp. Blade, the mixing blade can be removed from the UNGUATOR® Jar and disposed or left inside the UNGUATOR® Jar. Leaving the blade inside the jar will have no effect on dispensing the ointment through the UNGUATOR® Jar Lid. Removal of the 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 UNGUATOR® Jar Lid is screwed back onto the UNGUATOR® Jar body and equipped with an UNGUATOR® Varionozzle as needed. Then a UNGUATOR® Jar Lid together with an UNGUATOR® Applicator is screwed on. Large UNGUATOR® Jars will be equipped with a spindle or the AirDynamic® System. Also in this case, like in the the regular mixing process, air diminution should be repeated. A “squirting out” of the ointment when first dispensed can be prevented by eliminating cavities that may have developed during the mixing process. The UNGUATOR® Jar Lid or the UNGUATOR® Applicator may now be fasten in place.

A label may be attached on the UNGUATOR® Jar prior forwarding to the client, preferably together with a short illustration of how to use and apply UNGUATOR® dispensing system. It is also a good idea to record the individual mixing parameters together with the results according to the final validation.

7. General notes on the UNGUATOR® Mixing System

In its quality regulations for processing any semisolid preparation, the German Chamber of Pharmacists is recommending to apply for dispensing and mixing a jar having a small dispensing nozzle since the year 2000.

7.1 Patent protection

The UNGUATOR® Mixing System consists of UNGUATOR® Technology, the UNGUATOR® mixing machines and various UNGUATOR® assortment.

The UNGUATOR® Mixing System, and UNGUATOR® Technology and the AirDynamic® Pumpball System integrated therein are inventions of the pharmacist Albrecht Konietzko from Bamberg in Germany. The UNGUATOR® Technology and the AirDynamic® Pumpball System are patented in selected countries. UNGUATOR® and AirDynamic® are registered trademarks exclusively available from the company GAKO®.

The 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 UNGUATOR® Mixing System.

7.2 Identification number

The 9-digit identification number used to unmistakably mark preparations has the following structure:

The first two digits represent the type of ointment:

| | |
|---------------------|----------------------|
| 01 = Emulsion + | 06 = Gel |
| 02 = Emulsion | 07 = Suppositories |
| 03 = Normal | 08 = Direct |
| 04 = Suspension <2% | 09 = Manual |
| 05 = Suspension >2% | 00 = Combination mix |

The third and fourth digits stand for the size of the UNGUATOR® Jar:

| | |
|------------|----------------------|
| 01 = 15ml | 06 = 200ml |
| 02 = 20ml | 07 = 300ml |
| 03 = 30ml | 08 = 500ml |
| 04 = 50ml | 09 = 1000ml |
| 05 = 100ml | 00 = Combination mix |

The fifth and sixth digits stand for the MANUEL mixing program:

00 = no manual mixing program
01 = Manual mixing program no. 01
02 = Manual mixing program no. 02
etc.

The seventh and eighth digit stands for the number of pasting programs:

00 = no pregrinding program
01 = 1 pregrinding program performed
02 = 2 pregrinding programs performed
Etc.

The ninth or last digit stands for an interruption of the mixing process:

0 = mixing process interrupted
1 = without interruption

For instance, the identification number 090504021 stands for a mixing process using the “Manual” mixing program with a “100 ml” UNGUATOR® Jar, with “Manual mixing program n° 04” and two pregrinding performances.

7.3 Operating errors

The quality assurance of optimized ointment production using the UNGUATOR® 2100 requires that operating errors be registered and displayed. If a problem occurs the display will show the following error indication:

“Mixing tool not locked”, “Jar disengaged”, “Wrong Jar size”, “Lifting motor overload”, and “Mixing motor overload”.

If necessary switch the device off after an operating error. The UNGUATOR® 2100 will normally function again after the device is switched off and the operating error corrected.

The UNGUATOR® 2100 has been test-operated, centered, aligned and tested using the UNGUATOR® MB included. As a rule, any UNGUATOR® MBs delivered after 1996 are compatible with the UNGUATOR® 2100. UNGUATOR® MBs that are bent in the plastic region or shaft are not suitable. UNGUATOR® MBs other than those supplied with the UNGUATOR® 2100 may cause problems on coupling. We recommend contacting customer service should this occur.

The UNGUATOR® MB should not press too deeply into the UNGUATOR® Jar so that the oscillation arm can guide it up to the stop of the bayonet receptor. For this reason we

recommend manually pulling up the UNGUATOR® MB as far as it will go after screwing in the UNGUATOR® Mixing System, if necessary.

The Jar connected to the UNGUATOR® 2100 is not an UNGUATOR® Jar. This Jar has to be replaced with an UNGUATOR® Jar.

A UNGUATOR® Jar Lid was screwed onto the UNGUATOR® Jar aslant and the UNGUATOR® MB cants on automatic insertion. The operating error can be remedied by unscrewing the UNGUATOR® Jar followed by its correct placement on the UNGUATOR® Jar.

In the event that the oscillation arm was pulled too far out of its “starting position”, the shaft of the UNGUATOR® MB may not be centered in the holder after running through a complete stroke. This can be fixed manually, but please take care to only grasp the shaft taper. The selection of the wrong UNGUATOR® MB can also cause this operating error, please see below.

Size selection of the UNGUATOR® Jar does not correspond with the actual size at which mixing takes place.

Shortening of the stroke range by pushing up the UNGUATOR® Jar Bottom will change the selected size of the UNGUATOR® Jar for the UNGUATOR® 2100. The mixing process may now be started again by selecting the correct UNGUATOR® Jar size. The movable bottom does not have to be pushed up to execute the pre grind program. If the material to be mixed is a paste, comes cold from the refrigerator or the UNGUATOR® MB has to penetrate a larger volume of not freely flowing solid substances such as zinc oxide or sulfur, then the elevated load might be greater than the mechanical switch-over counterforce. This means that the UNGUATOR® MB cannot make the stroke to its full height at the beginning of the mixing process and changes the stroke direction before it has reached the UNGUATOR® Jar Lid of the UNGUATOR® Jar Bottom. Here we recommend a manually assisted push up at the first full stroke when working with large UNGUATOR® Jars (500 and 1000 ml, possibly even 300 ml) or briefly heating up the material to be mixed in the microwave to reduce viscosity.

The reversing force of approx. 6.7 to 11.2 lbs (30 ...50 N) for the oscillation arm has been purposely selected low as safety precaution. If reversing force is higher or inappropriately sensitively controlled, this can result in injuries due to force or the possible destruction of glass vessels located underneath.

Irreversible software faults caused by current transients or strong electromagnetic fields in the vicinity can only be remedied by customer service.

For functionally testing reason the UNGUATOR® 2100 has to be switched off at first. The device can be switched on again after 20 seconds. No UNGUATOR® MB can be attached to the device during start up or reboot. It is best to change the UNGUATOR® Jar size when performing a function test, and running a mixing process with a filled UNGUATOR® Jar of 30 or 50 ml size for example.

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

7.4 Potential sources of nonconformances

- The UNGUATOR® Jar bottom was not pressed fully down to the stop position prior to weighing out or filling. First and foremost, it is not imperative to accommodate specifically light constituents in an UNGUATOR® Jar of equal weight although the filling volume is 40 % more than the rated volume. Please use the next largest UNGUATOR® jar for the mixing.
- The air was not removed before the mixing precess of semisolid preparations from the UNGUATOR® Jar. Then the mixing blade centrifuges the ointment against the UNGUATOR® Jar wall, forming an air column inside in which the UNGUATOR® MB cannot clean itself and unmixed constituents may adhere to the UNGUATOR® MB.
- The UNGUATOR® Jar bottom has not been moved up. The penetrating UNGUATOR® MB will generate an overpressure at high rate of speed that cannot be compensated when the movable bottom yields. Thus the overpressure may cause mixed material, mainly liquid constituents, to squeeze out of the seals on the threaded UNGUATOR® Jar Lid, between UNGUATOR® Jar bottom and UNGUATOR® Jar body and along the shaft of the UNGUATOR® MB [1].
- The sealing lip on the UNGUATOR® Jar bottom does not retain liquids during the emulsifying process. Before starting the mixing process, particularly for large amounts of liquids, the region round the sealing lip of the UNGUATOR® Jar bottom should be carefully brushed with foundation so as to improve its sealing quality.
- The sealing lip of the UNGUATOR® Jar Lid has been damaged by the shaft tappets of the UNGUATOR® MB upon perforating the lid. This will cause ointment to creep up the shaft.
- The UNGUATOR® Jar Lid is not tightened correctly and not held during the manually guided stroke. This may cause the UNGUATOR® Jar Lid to unscrewed during the mixing process, resulting in a large mess.
- The user failed to remove air again or to mount a UNGUATOR® Varionozzle or UNGUATOR® Applicator before dispensing. This will cause the user to first push the air out of the opening and the ointment will follow in a gush [1].

7.5 Quality assurance of the ointments

Simple test methods convincingly demonstrate the good homogenizing capability of the UNGUATOR® Mixing System. Perform a homogeneity test when receiving the UNGUATOR® device and document the results. After a year or when needed you can repeat the test.

Use a recipe with a colored substance, for example iron oxide (micronized) or Sudan Red and work this in a semi-solid base. You can spread out the finished recipe in a glass plate or in a microscope slide and check under the microscope the solids distribution and the grain size.

For a short-term statement about the solids distribution in the formula basis, you can test in different levels of the UNGUATOR® Jars and examine these as described.

8. Service and warranty

8.1 Notes on malfunctions

If the UNGUATOR® device does not work, it may be due to a little thing that you may be able to correct yourself. Before you take the unit for repair, please follow instructions below:

- If the 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.
- Should faults or damage occur, please also read the manufacturer's notes on the machines' metal foot.
- Please note the machine type, serial number and the occurring error message and contact your local UNGUATOR® dealer and/or certified UNGUATOR® service partner.

8.2 Notes on maintenance

- To preserve gears and motor for continuous untroubled operation, the UNGUATOR® e/s should either be sent to your representative in your individual country (please contact your UNGUATOR® dealer) or to SMS Elap GmbH & Co. KG after 20,000 preparations or after five (5) years for maintenance.
- After-sales service and maintenance service will be billed for expenses and wearing parts at reasonable price according to the cost estimate within the warranty period as well.
- Upon request an UNGUATOR® loaner may be provided for a one-time charge that can be used while your UNGUATOR® is away for maintenance and repair.

8.3 Notes on safety

- UNGUATOR® devices must only be connected to grounding type receptacles with 230V/50Hz(cps); 120V/60Hz(cps) or rated country specific voltage installed according to the regulations of DIN VDE 0100.
- 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 commissioning and/or after extended storage time in cold rooms.
- UNGUATOR® power switch and cable must be easily accessible.
- Do not immerse UNGUATOR® devices in water
- UNGUATOR® devices should only be operated by authorized persons.
- Only operate the UNGUATOR® MB with correctly attached UNGUATOR® jars or in a plastic beaker provided for a reaction mixture.
- Do not touch rotating parts.
- Keep long hair, ties and cables away from rotating parts.
- During the automatic lifting function of the UNGUATOR®: always keep long hair, parts of the body or objects away from the lifting mechanism. Immediately turn off the power switch in an emergency or pull the power plug.
- Always keep the air vents on the driving head/back or underside of the devices free when using the device.
- Using the UNGUATOR® devices not according to these operating instructions or with line products that the manufacturer did not deliver or recommend may impair safety and will void the warranty!
- 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).
- 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.



8.4 Technical data of the UNGUATOR® 2100

| | |
|-----------------------------------|--|
| Electrical requirement | 90...265 V / 45...65 cps |
| Total power consumption | 600 W |
| Power consumption (mixing motor) | 550 W |
| Power consumption (lifting motor) | 50 W |
| Operating mode | Continuous Operation S1 |
| Safety class | I |
| Type of protection | IP 21 |
| Speed controller | in 10 steps electronic controlled |
| Timer | continuous electronically |
| PC connection | USB - Standard B |
| Software | www.unguatorassist.com |
| UNGUATOR® Jar sizes | 15...1000 ml |
| Weight | 36,75 lbs) |
| Dimensions (L x W x H in mm) | 356x 221 x 642 |
| Testing certifications | CE, TÜV GS |

8.5 Quality and material

Manufacturing facilities for the UNGUATOR® line of products is certified according to DIN EN ISO 9001:2008. Regular quality control, ensures both outstanding and sustainable quality of the UNGUATOR® Mixing Technology.

- The UNGUATOR® Applicators, Couplings and Jars, are made out of Polypropylen (PP) and the regular UNGUATOR® Varionozzles of Polyethylen (PE).
- The UNGUATOR® SMB is made out of Polyoximethylen.
- The UNGUATOR® Disp. MB is made out of Polyamid.
- The shaft of the UNGUATOR® MB is made of NIRO-Stainless steel (quality standard: 1.4301) and hardened titanium-nitride (golden color). The utilized material and pigments are physiologically classified as safe.

9. References

The advantages of the UNGUATOR® Mixing Technology and -System compared to conventional manufacturing methods with mortar and pestle are frequently mentioned in the literatures below:

- Preparation of GMP-compliant ointments in the pharmacy is possible [2], [4]
- Formulations for ointment is standardized [4], [8]
- Excellent homogeneity [2], [4], [9]
- Improved microbiology [3], [8]
- Risk of contamination is greatly reduced in the preparation process: hygienic production in a closed system, no transfer to a separate container [2], [3], [4], [8]
- Hygienic extraction of the formulation, minimum threat of contamination by the user [2], [3], [4], [8]
- Enhanced product quality in an improved packaging ensures longer product shelf life [3], [4]

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11. Manufacturer's Certificate/ Declaration of Conformity

for plastic materials, which come into contact with food.

| Article ¹⁾ | | Material ²⁾ | |
|--------------------------|-----------------------------|-------------------------|----------|
| | | standard | cosmetic |
| UNGUATOR® Jar cap | Polypropylene, natural | white | colored |
| UNGUATOR® Jar lid | Polypropylene, natural | red, white, green, blue | colored |
| UNGUATOR® Jar body | Polypropylene, natural | white | colored |
| UNGUATOR® Jar bottom | Polypropylene, Polyethylene | - | - |
| UNGUATOR® Jar bottom cap | Polypropylene, natural | white | white |

1) The licensed manufacturer, SMS ELAP GmbH & Co. KG, D-98544 Zella-Mehlis is DIN EN ISO 9001:2000 certified

additional UNGUATOR® products

| | | |
|--|------------------------|-------------------|
| UNGUATOR® Spindle | Polypropylene, natural | white |
| UNGUATOR® Applicator long with cap | Polypropylene, natural | white |
| UNGUATOR® Applicator short with cap | Polypropylene, natural | white |
| UNGUATOR® Coupling | Polypropylene, natural | white |
| UNGUATOR® Varionozzle blue, yellow, pink | Polypropylene, natural | blue, yellow, red |
| UNGUATOR® Disp. Blade | Polyamide, white | - |
| UNGUATOR® SMB | Polyoxymethylene | - |

2) Declarations of conformity for materials and color concentrates of the materials vendors are deposited at the licensed manufacturer.

All products listed are manufactured according to the legal requirements of plastic Regulation (EU) No 10/2011 and (EU) No 1935/2004 (in their current version).

For applications according to formal specification both the overall and specific migration are under the legal limits of 10mg/dm³, according to Regulation (EU) No 10/2011.

The materials and raw materials used comply with Regulation (EU) No 10/2011. The following monomers and additives, which are subject to a specific migration limit (SML), are included according to suppliers in the used materials:

| Material: | | |
|--------------------|-----------------|--|
| Polypropylen natur | - | |
| Polyamid | Caprolactam: | SML(T) = 15 mg/kg |
| Polyethylen | Ref.-Nr. 68320: | SML = 6 mg/kg |
| | Ref.-Nr. 89040: | SML = 25 mg/kg (calculated as Zn salt) |
| Polyoxymethylen | - | |

| Color concentrate: | | |
|--------------------------|-----------------|-------------------|
| white | Ref.-Nr. 46880: | SML = 6 mg/kg |
| white (SMB) | Formaldehyd: | SML = 15 mg/kg |
| | 1,3-Dioxolan: | SML = 5 mg/kg |
| | Trioxan: | SML = 5 mg/kg |
| white (disposable blade) | Caprolactam: | SML(T) = 15 mg/kg |
| other colors | - | |

Compliance with these specific migration limit is certified by the polymer manufacturers.

The traceability of Regulation (EC) No 1953/2004 of the product is ensured by the lot number and the application of manufacture.

Specification for intended use: Kind / types of food or procedures for which the material is suitable:
aqueous media acidica media

issued by GAKO® Germany - production control (as of January 2013)

issued by GAKO® Germany - production control

The certificate has been produced electronically and is valid without a signature

12. Distribution, manufacturing and customer service

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Web: www.unguator.com

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