

UNGUATOR[®] TECHNOLOGY

NEW Q



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1. Instalation information

Select a suitable location for the **UNGUATOR**® QMS.

CAUTION! The **UNGUATOR**® QMS weighs almost 30 lbs. It is recommended to have an assistant while carrying and moving the equipment.

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

Select a suitable environment:

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

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

- **UNGUATOR**® QMS
- Power Cable
- Operation manual
- Standard Mixing Blade 1-7
- Disposable Blade Start set

Please contact your **UNGUATOR**® responsible dealer and/or supplier in the event that components are missing or damaged. Contact information is at the end of these operating instructions.

Keep the cardboard box and the packing material in case you have to send the **UNGUATOR**® QMS in for service.

The **UNGUATOR**® QMS

Fig. **UNGUATOR**® QMS

2. Initial Operation

On the back of the **UNGUATOR**® QMS you will find the interface for the power cord. The power switch "O/I" is also the emergency switch and it is located at the bottom of the machine to the

right. Initially check if the power switch of the Unguator® is switched off. Second, connect the power cable to the device, and finally connect the power cable to the socket.

During cold weather condition, plan in advance 30 minutes to allow the UNGUATOR® QMS to acclimatize.

Now you can turn the power switch of the UNGUATOR® QMS on using the "I / O". The device is ready to be used.

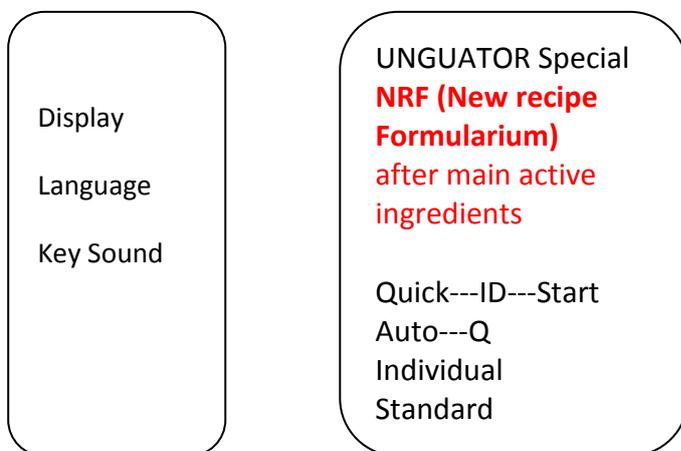
3. Display-operation

In the front part of the UNGUATOR® QMS there is a panel with the four keys "Esc", "-", "+" and "ok" for manual control or command input, and a screen. After turning the UNGUATOR® QMS with the power button a start screen appears in the display.

Fig. 1: Display Start Menu

The start screen displays the current number of preparations and the version stored in the microprocessor software. By pressing any key the "Start Menu" will appear.

4. Menu guide



In the right part of the UNGUATOR® QMS Display you will find a panel with the four keys "Esc" "+" "-" and "OK".

By operating the key "+" or "-" you start from the Start menu and move on. Pressing the key "OK" you can choose an option and confirm it. Pressing the key "Esc" you move a step back.

More choices

figure 2: selection Menu "Display" "Language" "Key Sound"

Pressing the key "Esc" you will go to the "Start Menu" in the settings menu. Here you can change the Background color of the display, change the operating language and activate the sound or cancel it.

Changes in the language or in the color background can take a few seconds because a large amount of data in the memory needs to be read. Pressing the key "Esc" you will reach again the "Start Menu".

You will find descriptions of the "Start menu" programs in this manual in chapter 6.4 "The recipe programs" section.

5. UNGUATOR®Technology

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 mixing system consists of the UNGUATOR® Technology, the UNGUATOR® mixing machines and the whole line of UNGUATOR® assortment.

The principle of the preparation method using UNGUATOR® Technology in the closed UNGUATOR® Mixing System is quick and easy to learn. The motto here is:

Learning by doing

A little experience will make it easy to prepare ointments though they may seem rather complicated at first. Using UNGUATOR® Technology enables the pharmacy to better prepare prescription ointments in a shorter period of time compared to the preparation methods that were common until 1994. For the first time, it is possible to not only standardize ointments, but validate them too. To find recommendations for mixing and sample recipes, visit www.unguator.com.

5.1 UNGUATOR® Mixing Machines

The current UNGUATOR® mixing machines - the UNGUATOR® B/R, the UNGUATOR® e/s, the UNGUATOR® 2100, and the Unguator QMS - are useful and advanced improvements on the first UNGUATOR® from 1994. They are designed for a performance of approximately 15,000 to 20,000 prescriptions.

The UNGUATOR® Mixing Machines feature a high safety standard and were tested by TÜV-Rhineland for their safety. They are manufactured under license and maintained by SMS Elap GmbH & Co. KG in Zella Mehlis, Germany.

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 B/R through the e/s, QMS to the 2100.

Bowls and pestle	++	+	-	individual
Unguator BR	+++	++	individual	individually adjustable
Unguator e/s	+++	+++	automatic	individually programmable
Unguator QMS	++++	++++	automatic	automatically
Unguator 2100	++++	++++	automatic	automatically

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.

5.1.2 UNGUATOR® e/s

The UNGUATOR® e/s lift-off machine was developed for efficient individual and batch preparation. 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 preparation.

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 displacement motion during the mixing process. If the stroke length of the first stroke was taken as a constant value, then the active ingredient weighed in into 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 has all 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 the mixing programs into the device and a maximum of 180 additional programs can be stored. The UNGUATOR® 2100 can be connected to and controlled by a PC via a USB interface. This makes programming even easier, making the number of programs that can be stored practically unlimited.

An integrated microprocessor measures the actual revolutions of the UNGUATOR® Mixing Blade carried out by the UNGUATOR® 2100. This guarantees that the mixing program called up will always be identical, also for paste preparations which 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 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 by slow stroke.

5.1.4 UNGUATOR® QMS

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

It combines the mixing functions of the UNGUATOR® e/s with 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® QMS 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 very complicated and complex.

Additionally, you will find in the UNGUATOR® QMS a stored database, which shows you various mixing recommendations for semi-solid formulations, which are provided in the NRF. This will open the possibility to optimize the preparation of NRF and similar NRF recipes and increase the formulas quality.

5.2 UNGUATOR® Assortment

In addition to the UNGUATOR® Standard Mixing Blade (SMB), the UNGUATOR® Disposable Blade (Disp. Blade) and the UNGUATOR® Jar, all essential for preparing ointments using the UNGUATOR® Mixing System, the UNGUATOR® assortment includes other additional and very 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® System. All UNGUATOR® products are compatible with each other.

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 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)

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 used is the right length, and that it is clean prior to use. **(For example with isopropanol 70%)**

UNGUATOR® Disposable Blade (Disp. Blade)

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.

In the process of final quality control the mixing blade can be picked up and discarded with the weak end of the shaft, or left in the recipe. Cleaning is confined 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.

A mark is found on the weak end of the shaft to indicate the range of UNGUATOR® Jar sizes that can be used (15-100 ml and 200 ml respectively) for the application.

Assignment of the UNGUATOR® MB

Please take care to use the correct UNGUATOR® MBs for the corresponding UNGUATOR® Jar (Fig. 9). Mix-up may trigger fault messages with UNGUATOR® devices with a semiautomatic stroke feature.

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.

Niches of Flow on the UNGUATOR® SMB

The flow-adapted shape of the UNGUATOR® SMB generally cleans itself during the rotating penetration of the ointment. Unmixed constituents may adhere to niches of flow of the UNGUATOR® SMB depending on ointment constituents' compatibility sequence of weighted sample but also if the UNGUATOR® Jar is considerably underfilled (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 niches 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 desired as a rule. Decreased viscosity increases the wettability of powders and speeds the penetration of powder pockets. Even the emulsifying readiness of fats and oils is promoted by heat.

54 °C/129 °F was the maximum temperature measured after 6 minutes of mixing the highly pasty preparation made of Vaseline and zinc oxide aa under full speed. This temperature increase is generally safe for the substances employed 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 dispensing pulp and, if necessary, held under a hot water jet and then dried with dispensing pulp. UNGUATOR® MBs can also be cleaned in a dishwasher.

The UNGUATOR® devices as well as the UNGUATOR® line products should never be treated with sharp-edged objects or chafing 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 (Apothekenkammer) [11]. 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 Rules); 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 (temperatures less than 85 °C/185 °F). Higher temperatures (e.g. rinsing machines) can change the tightness of the UNGUATOR® Jar and the displaceability of the bottom (“push-up” jars).

The UNGUATOR® material becomes brittle at temperatures below 0 °C/32 °F. UNGUATOR® Jars are available in 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 request, the UNGUATOR® Jars can be produced in specific color.

The UNGUATOR® Jars come sealed in plastic wrap. Cleaning or disinfection prior to use could put the tested sterility at risk. We would recommend storing the remaining UNGUATOR® Jars in the plastic wrap 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® System.

The housing of the UNGUATOR® Jar sizes 300 to 1000 ml can be cleaned in a dishwasher as long as it has not left the pharmacy.

Sterility 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 housings.

The UNGUATOR® Jar is subject to periodic inspection in accordance with ZL packing regulation DK II/94. 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) after visual receiving inspection be retained. This certificate is affixed to the plastic wrapping in which the UNGUATOR® Jars are packed. It may be removed from the plastic wrapping as needed and added to the records.

Fig. 11: Certificate of Analysis for the (e.g. 50ml) UNGUATOR® jar.

Notes on Dispensing Ointment

Each customer should be given specific dispensing instruction when being given ointment in an UNGUATOR® Jar. The use of the UNGUATOR® Spindle should be explained for large UNGUATOR® Jars. Low-viscous ointments should be fitted with an UNGUATOR® Applicator or an UNGUATOR® Varionozzle to reduce the dispensed volume. Medium-viscous ointments can be easily emptied through the small opening of the UNGUATOR® Jar. For very viscous ointments (such as zinc paste) it may be harder to press through this opening, even when using the Spindle.

The ointment can also be dispensed with a spatula, as with the traditional jar with lid, when the UNGUATOR® Jar Lid is removed. If the UNGUATOR® Jar Lid has been removed, the ointment should be pushed up close to the lid after the dispensing. With larger UNGUATOR® Jars, this occurs with the help of the UNGUATOR® Spindle or the AirDynamic® System.

The diameter of the dispensing opening allows simple dosing of the quantity of ointment to be applied using approximate values. *The dispensing openings in the screw lid of each UNGUATOR® Jar has the 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 when weighing-in concentrated active substances or regular comminutions from the UNGUATOR® Jar.

To obtain an exact dosing especially for highly effective formulations (e.g. hormone cream) the UNGUATOR® Precise Dosing System (pds) 0.5 or 1.0 should be used. With the pds it is possible to extract an exact amount of 0.5 ml and/or 1.0 ml.

5.2.3 UNGUATOR® Varionozzles

The UNGUATOR® Varionozzles with inner diameters of 1, 2 or 4 mm can be pressed into the dispensing opening of the UNGUATOR® jar lid. They reduce the opening size, making it possible to safely dose even low-viscous formulations. The viscosity of the finished product normally specifies the diameter of the UNGUATOR® Varionozzles. The softly rounded surface allows ointment to be pleasantly distributed on the 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)

5.2.4 UNGUATOR® Applicators

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

UNGUATOR® Applicator short

The UNGUATOR® Applicator short with an opening diameter of 1 mm is obligatory for nose and ear ointments.

UNGUATOR® Applicator long

The UNGUATOR® Applicator long with an opening diameter of 2 mm allows formulations to be introduced into large orifices of the body or probes. Moreover, the UNGUATOR® Applicator long is also available as a sliding aid together with the 200 ml UNGUATOR® Jar.

5.2.5 UNGUATOR® Spindle

The UNGUATOR® Spindle serves as a dispensing system for the 300 ml or 500 ml UNGUATOR® Jar. With new UNGUATOR® Jars that come with UNGUATOR® Spindles, the spindle has to be removed by rotating it clockwise. The bottom can be slid up and down when the UNGUATOR® Spindle is screwed in 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 formulation table and using both hands to move the jar against the table.

Before giving the UNGUATOR® Jar to the customer, the UNGUATOR® Spindle must be screwed into the UNGUATOR® Jar counterclockwise from the bottom till it locks into place. The UNGUATOR® Spindle must be turned clockwise to dispense ointment. To remove the ointment the UNGUATOR® Spindle must be twisted to the right. One turn dispenses approx. 20 ml of the contents of 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 cannot be used for the mixing process.

5.2.6 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 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® System may also be used. Dispensing and transferring a formulation via the dispensing opening in the UNGUATOR® Jar Lid from the 1000 ml UNGUATOR® Jar is practically only possible using the AirDynamic® 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® System

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

- Contamination-free transfer
- Contamination-free storage

The AirDynamic® System has been designed to use UNGUATOR® Jars from 300 ml to 1000 ml for dispensing mixtures. An adapter connected to a pump ball is affixed to the center hole on the housing bottom of the UNGUATOR® Jar with an air-tight connection.

By pumping air into the lower chamber of the UNGUATOR® Jar using the pump ball, the pressure thus generated moves the movable bottom upward. Thanks to the AirDynamic® 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 surroundings, all depending on the viscosity of the formulation.

5.2.8 UNGUATOR® Precise Dosing System (pds)

The UNGUATOR® Precise Dosing System (pds) is especially developed to extract the semi solid preparation with high effectiveness of the ingredients, such as corticosteroids, antibiotics and hormones. It helps the patient to use the preparation of high effectiveness of the ingredients with more precision and to follow the correct specification of the pharmacist.

The UNGUATOR® dispenser is available in two different versions:

- The UNGUATOR® pds with 0, 5, allows the extraction of the exact dosage of 0.5ml of the prepared prescription directly from the UNGUATOR® Jar.
- The UNGUATOR® pds with 1, 0 allows the extraction of the exact dosage of 1,0ml of the prepared prescription directly from the UNGUATOR® Jar.

Other advantages of the UNGUATOR® pds are the piston seals, which compared to linear seals that are used in other dosing systems, only allow the extraction with bigger and massive pressure. In addition, the pds allows the patient a better conformity, for the application is easy to be explained, illustrated and executed.

Application:

Please note that the UNGUATOR® pds can only work correctly when there is not entrapped air in the filled basis.

The UNGUATOR® Precise Dosing System (pds) can be coupled to any UNGUATOR® Jar. It just has to be screwed onto the small opening of the UNGUATOR® Jar and it may remain on the jar, replacing the white cap, until the jar is empty.

To extract semi-solid preparations, turn the white UNGUATOR® pds in one direction until you notice a relevant resistance and then you can extract, by pressing the movable bottom of the UNGUATOR® jar, exactly 0.5 or 1.0 ml of the preparation.

For a further removal of semi-solid preparations, turn the UNGUATOR® pds once again into the opposite direction and extract, by pressing the movable bottom of the UNGUATOR® jar, exactly 0.5 or 1.0 ml of the preparation.

6 Preparation of the UNGUATOR® Technology

6.1 Preparation of UNGUATOR® mixing system

The UNGUATOR® Mixing System consists of a UNGUATOR® jar, a UNGUATOR® MB and the components of the formula to be mixed.

First, the UNGUATOR® jar cap (white smaller cap) and subsequently the UNGUATOR® jar cover (large red or colored cap) of the UNGUATOR® jar are unscrewed.

Second, the UNGUATOR® MB is introduced in the UNGUATOR® Jar housing and with it the UNGUATOR® jar bottom is pushed straight down. The UNGUATOR® Jar cover is pushed into the UNGUATOR® MB located in the UNGUATOR® Jar and pressed with two thumbs down. Please observe that the sealing lip of the UNGUATOR® Jar cover opening is not damaged by the noses of the UNGUATOR® MB otherwise the ointment may lift through the UNGUATOR® MB piston during the stirring process.

Third, the UNGUATOR® MB is carefully pulled out of the UNGUATOR® Jar housing and the UNGUATOR® Jar cover moved in the direction of the mixing blades. Both the UNGUATOR® MB and the UNGUATOR® Jar cover are stored, or possibly tared on the scale together with the UNGUATOR® jar housing.

After the initial weighing of the formula components, the UNGUATOR® MB, together with the UNGUATOR® Jar cover are loosely screwed on the UNGUATOR® Jar housing. By pushing the UNGUATOR® Jar bottom with the thumb or, for example, large UNGUATOR® Jars with the UNGUATOR® Spindle or with the UNGUATOR® AirDynamic® Pump Ball System the air between the UNGUATOR® Jar cover and the UNGUATOR® Jar housing is freed. This process is called **Air Diminution**.

Subsequently the UNGUATOR® Mixing System is firmly screwed.

Air diminution will 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.

It is recommended, mainly in the case of large quantities of powder, that air diminution be repeated after 15 seconds of the mixing process.

6.2 Weighing the ingredients of the formula

Generally, oily, greasy, aqueous and pulverized constituents can be weighed in into the UNGUATOR® Jar at the same time. It is however advantageous to heed certain general procedures to optimize the mixing results. Generally, know-how gained from the traditional

preparation of ointments is very helpful when using the UNGUATOR® Mixing System. As already mentioned at the beginning of the operating instructions, the motto for use is:

Learning by doing

The stored stirring programs allow you to prepare the most relevant galenic formulas in a pharmacy.

In the following, these standard formulations will be defined and the recommended procedure on weighing in 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 foundation ointment 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 %, 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

The UNGUATOR® QMS is the result of continuous improving of the UNGUATOR® Technology.

The integrated programmable microprocessor that automates the UNGUATOR® QMS Mixing System completely turns the device into a universal machine for the production of formulation!

The UNGUATOR® QMS works with 2 quiet high duty permanent motors and is an intelligent ointment stirring machine for recipes and Defektur of 15-500 ml. You can work in the ranges of 0 to 2400 rpm and produce homogeneous recipes. It is also possible to set intervals and gives you the opportunity to interrupt the formula manufacturing in a controlled manner.

After selecting a program and the size of the UNGUATOR® Jar a microprocessor controls the mixing parameters for a consistent and reproducible product quality.

After the completion of each preparation the UNGUATOR® QMS automatically assigns an identification number. It is used for simple documentation and the accurate reproduction of the mixing process and will appear at the display after the mixing process.

6.4 The recipe programs

6.4.1 UNGUATOR® Special

Under the menu “UNGUATOR® Special” you can find predefined stirring programs for selected recipes from the DAB, DAC and stem preparations. Additionally, you can call up stirring programs for pharmacy exclusive cosmetics brand Kamia®.

Scroll with "+" or "-" through the various stirring programs and select an item with "OK".

For each predefined recipes you will find the main ingredients and comments regarding the characteristics of this recipe. In parallel there is a choice of the recommend UNGUATOR® MBs (SMB or Disp. Blade) listed so you can get the best result of your recipe.

In addition, recipes with ingredients that need to be grounded, a grounding process is recommended. Once you run a mixing program with recommended grounding process, you will be asked if you have already performed the grounding process. With a negative answer you will automatically be forwarded to the programs stored in the standard grounding process and can proceed directly to the selection of jar sizes.

After successful completion of grounding process, select again the desired mixing program from the menu UNGUATOR® Special and confirm this time that you have carried out the grounding process.

Following is the choice of the mixing jar sizes with „+“ or „-“ which you confirm with "OK".

After each completed run through the mixing process the UNGUATOR® QMS generates an identification number which contains all the mixing parameters. Now you can save them, document or discard. Saving the recipe enables you to give an individual name to it. Rejecting the identification number does not allow it to be called up again and it is therefore lost. The initial mixing and their parameters remain kept.

If the stirring is interrupted the UNGUATOR® QMS does not create an identification number. You may continue stirring under your own responsibility or start the process from the beginning.

6.4.2 NRF (New recipe Formularium) by main active ingredient

In the program **"NRF (New recipe Formularium) by main active ingredient"** you will find predefined stirring programs stored for semi-solid NRF formulas. The selection of the program is done on basis of the main active agent in the recipe.

Scroll with „+“ or „-“ through the various mixing programs and select an item with "OK".

For each predefined recipe you will find the main ingredients and comments regarding the characteristics of this recipe. In parallel there is a choice of the recommend UNGUATOR® mixing blades (SMB or Disp. Blade) listed so you can get the best result for your recipe.

In addition, recipes with ingredients that need to be grounded, a grounding process is recommended. Once you run a mixing program with recommended grounding process, you will be asked if you have already performed the grounding process. With a negative answer you will automatically be forwarded to the programs stored in the standard grounding process and can proceed directly to the selection of the jar sizes.

After successful completion of grounding process select again the desired mixing program from the menu UNGUATOR® Special and confirm this time that you have carried out the grounding process.

Following comes the choice of the mixing jar sizes with „+“ or „-“ which you confirm with “OK”.

After each completed run through the mixing process the UNGUATOR® QMS generates an identification number which contains all the mixing parameters. Now you can save them, document or discard. Saving the recipe enables you to give an individual name to it. Rejecting the identification number does not allow it to be called up again and it is therefore lost. The initial mixing and their parameters remain kept.

If the stirring process is interrupted the UNGUATOR® QMS does not create an identification number. You may continue stirring under your own responsibility or start the process from start.

6.4.3 Quick-ID-Start

In the program “Quick Start ID” you can quickly enter a mixing program known or previously created by you using a known identification number. It is allowed to transfer a mixing program to other jar sizes without having to calculate it. This “scaling” is done based on the entered identification number and the specified jar size.

Enter a known identification number of e.g. a pre-established or documented formula.

(Fig: Program “Quick-ID-Start”)

The first position of the UNGUATOR® identification number gives information about the jar size, whereby each jar size is assigned to a number:

(Graphic: Number-Jar size-assignment)

Choose to start with "+" or "-" the specified UNGUATOR® jar size and confirm with “OK”.

From a jar size of 100ml and bigger the indication “You have chosen a jar size which speed range is defined differently due to quality assurance reasons” appears. All previous settings of the ID will be lost". This is safety built in by the manufacturer to optimize the force acting on the material of the jars and the mixing blades in case of larger UNGUATOR® jars being used.

Now introduce the identification number by entering the rotation speed and the duration of each stage for the six possible stirring stages.

The time is specified in uppercase and lowercase letters, whereby each letter is assigned to a specific time value:

(Graphic: Letters-Time-Assignment)

Set with "+" or "-" the desired time interval and confirm with “OK”.

The input of the rotation speed is carried out with the numbers 0 - 9, in which each number is assigned to a specific rotation speed:

(Graphic: Number-Mapping Velocity-Assignment)

Set with "+" or "-" the desired rotation speed and confirm with "OK".

With this option you can set up to 6 stirring stages. With "Esc" you can go back to the previous step and edit it again. By confirming the previous ID stage, you have confirmed the entry of the identification number.

If the entered identification number is less than the previously given 6 stirring stages, then you can stop entering earlier. To do this, set the time with 0 using "+" or "-" after your last stirring. Once you have confirmed this with "OK" then the remaining stirring stages are also automatically set to 0.

At next follows another query of the desired jar size. If you wish to produce the same jar size with the entered identification number again, then confirm the proposed size jar with "OK".

If you have entered an identification number for a specific jar size but would like to produce a recipe of different size, then choose the actual jar size with "+" or "-" and confirm with "OK". The UNGUATOR® QMS scales all entered stirring parameters automatically for the chosen jar size. The scaling is limited with at least 5 seconds and maximum 10 minutes per stirring stage. Smaller or bigger time intervals cannot be displayed.

Note: As a user you are responsible for the quality of the formula to be delivered. Please always check the quality of the recipe before its delivery.

After each completed run through the stirring process the UNGUATOR® QMS generates an identification number which contains all the mixing parameters. Now you can save them, document or reject. Saving the recipe enables you to give an individual name to it. Rejecting the identification number does not allow it to be called up again and it is therefore lost. The initial mix and their parameters remain kept.

If the stirring process is interrupted the UNGUATOR® QMS does not create an identification number. You may continue stirring under your own responsibility or start the process from the beginning.

6.4.4 Auto-Q

With the program "Auto-Q" you can start a stirring process directly without calling up a pre-stored mixing program.

Choose to start with "+" or "-" the specified UNGUATOR® jar size and confirm with "OK". From a jar size of 100ml and larger the maximum rotation speed is limited. This is a safety measure built in by the manufacturer to optimize the force acting on the material of the jars and the mixing blades.

Subsequently enter a preliminary total stirring duration with "+" or "-". This may be a maximum of 10 minutes at the beginning. Confirm this with "OK".

Next, enter the desired preliminary rotation speed. With "OK" you can confirm that rotation speed and the stirring process starts.

During the stirring process you may modify the stirring duration with "+" or "-". With "OK" you will move to the rotation speed set-up. This can be modified with "+" or "-". As soon a new rotation speed is detected for longer than 3 seconds, this speed will be automatically set and the stirring process will be adjusted accordingly. A new stirring level will be opened. With "OK" you will go back to the time setting menu.

This way it is possible to adjust 6 different stirring levels. Since each of the 6 stirring levels are 10 minutes long, the total stirring duration takes maximal 60 minutes.

After each completed run through the stirring process the UNGUATOR® QMS generates an identification number which contains all the mixing parameters. Now you can save them, document or reject. Saving the recipe enables you to give an individual name to it. Rejecting the identification number does not allow it to be called up again and is therefore lost.

In case more than 6 stirring levels are entered or if the stirring process is interrupted the UNGUATOR® QMS does not create an identification number. You may continue stirring under your own responsibility or start the process from the beginning.

6.4.5 Individual

The archive of your individually created and stored stirring programs can be found under the menu "Individual".

With "+" or "-" you can browse a list in alphabetical order and confirm the choice with "OK".

Following is the choice of the mixing jar sizes with „+“ or „-“ which you confirm with "OK".

The UNGUATOR® QMS scales all entered stirring parameters automatically for the chosen jar size.

The scaling is limited with at least 5 seconds and maximum 10 minutes per stirring stage. Smaller or bigger time intervals cannot be displayed.

Note: As a user you are responsible for the quality of the formula to be delivered. Please always check the quality of the recipe before its delivery.

After each completed run through the stirring process the UNGUATOR® QMS generates an identification number which contains all the mixing parameters. Now you can save them, document or reject. Saving the recipe enables you to give an individual name to it. Rejecting the identification number does not allow it to be called up again and is therefore lost. The initial mix and their parameters remain kept.

If the stirring process is interrupted the UNGUATOR® QMS does not create an identification number. You may continue stirring under your own responsibility or start the process from the beginning.

If you wish to modify or edit your individual recipe, choose the desired program with "+" or "-" and hold the "OK" button longer than 3 seconds. Now you can modify the designation of the recipe. To save it, please press the "OK" button longer than 3 seconds.

To delete your individual recipe, choose the desired program with "+" or "-" and hold the "ESC" button longer than 3 seconds. Now you can modify the designation of the recipe. Following will appear a security inquiry, which you may accept or reject.

6.4.6 Standard

In the program "Standard" you can choose the standard recipe program, based on the galenic dosage form of the recipe to be manufactured. The application of the "NRF main active ingredients" and the "UNGUATOR® Special" programs are recommended for complicated recipes or compositions with sensitive ingredients.

With "+" or "-" you can browse the given programs and confirm the choice with "OK".

Following comes the choice of the mixing jar sizes with „+" or „-" which you confirm with the "OK" key.

Grinding Program

The grinding program serves to moisten solids in the preparation of suspensions with an active substance content <2%, allowing a homogeneous distribution of the active ingredient in the foundation.

As an example, the incorporation of corticosteroids, antibiotics, fungicides or hormones in a foundation is showed. In order to ensure a homogeneous processing, please use the UNGUATOR® standard stirring blade.

For preparation, place approximately 30% of the foundation in the UNGUATOR® jar and bed in the micronized ingredients. The ingredient must be involved in the foundation in order to avoid remaining powder sticking to the blades.

The movable bottom stays at the lower position during the grinding process in order to utilize the complete inner wall of the UNGUATOR® jar as grinding surface.

Please control the recipe for agglomerates or qualitative abnormalities after the grinding process. If required, the grinding can be repeated.

After the pre-grinding, further recipe components can be added and the foundation can be filled up to the desired final volume.

Further processing of the recipe is carried according to the galenic nature of the composition.

Suspension <2%

The program "Suspension <2%" allows you to prepare a recipe with the complete initial weight of a foundation after a grinding process.

Suspension>2%

With the program "Suspension >2%" it is possible to homogeneously incorporate solid parts with a content >2% in a foundation.

As an example, the incorporation of Zinc oxide, salicylic acid or bismuth gallate in a foundation is demonstrated. In order to obtain a homogeneous processing please use the UNGUATOR® SMB.

For suspensions with ingredient content above 2% it is not required to prepare a pre-grinding.

For preparation please add 50% of the required foundation in the UNGUATOR® jar and bed in the micronized solid parts. Add the remainder of the foundation on top of the ingredients in order to avoid remaining powder sticking to the blades.

For recipes with a higher content of solids, e.g. pastes, it is possible that the recipe is warmed up during the stirring process. This increase in temperature can be reduced once using a cooled foundation or a cooling sleeve.

In case you are handling a temperature sensitive recipe, we recommend using the programs "NRF main active ingredient" and "UNGUATOR® Special".

In addition it is possible to make a gentle stirring program with "Quick-ID-Start" program.

Emulsion

The program "Emulsion" allows to incorporate liquids at room temperature into water absorbing foundations.

As example, the incorporation of a preparation of water-containing hydrophilic ointment or hydrous "wool wax alcohol" ointment in a foundation is demonstrated. In order to obtain a homogeneous processing please use the UNGUATOR® disp. blade up to 200ml. For larger quantities it is possible to use the UNGUATOR® SMB.

For preparation please add the complete foundation in the UNGUATOR® jar so that it covers the entire base of the jar.

Subsequently add the required content of liquid or solution at room temperature to it.

Cold stored foundations may difficult the emulsification in some cases. Heating up the liquid to be added may accelerate the emulsification.

Emulsion +

The program "Emulsion +" allows the preparation of recipe foundations and creams out of individual components with integrated cold stirring program.

As example the preparation of the DAC base cream or cooling ointment DAB is demonstrated. In order to obtain a homogeneous processing, please use the UNGUATOR® disp. blade up to 200ml. For larger quantities it is possible to use the UNGUATOR®SMB.

It is possible to melt the individual components up to 85°C directly in the UNGUATOR® jar since the UNGUATOR® direct jar is resistant to water bath and microwaves.

Given this, add all the recipe's components including the water phase in the UNGUATOR® jar and heat up the mixture in the microwave at lower power and open lid. The control with a thermometer is to be done in short intervals in order to avoid overheating the recipe.

In case the foundation to be prepared does not contain water it is possible to liquefy the components to be melted on a water bath directly in the UNGUATOR® jar.

In order to improve the cold stirring process of the UNGUATOR® QMS it is possible to fix a cooling sleeve to the jar or repeat the stirring process for larger batches.

Soft in Soft (Normal)

With the program "Soft-in-Soft" it is possible to mix together half solid substances from low viscosity to pasty.

As an example, the processing of recipe concentrates in ointment foundation or mixing of two foundations is showed. In order to obtain a homogeneous processing it is possible to use the UNGUATOR® SMB or the UNGUATOR® disp. blade.

For preparation please add 50% of the ointment foundation in the UNGUATOR® jar and weigh the required quantity of the required substance. Cover the weighed recipe substance with the rest of the foundation. For jar sizes above 200ml it is possible to make the layering several times, in order to ensure a faster mixing of the recipe.

Gel

The program "Emulsion" allows the quick and homogenous preparation of gels and viscous solutions and facilitates the processing of source materials in liquid and half solid foundations.

For example, the preparation of ultra sound gels, electrode gels or antiperspirant gels are showed. Also it is possible to process source materials such as Betonite or Aerosol in half solid foundations.

In order to obtain a homogeneous processing it is possible to use the UNGUATOR® disp. blade. For larger quantities please use the UNGUATOR® SMB.

For preparation please weigh the liquid phase in the UNGUATOR® jar. Soluble solids can be added directly to the jar and then dissolved. Subsequently the source material is spread over.

In case the source material is processed in a half solid foundation, it is possible to bed in the source substance between two foundation layers. This way it is possible to achieve a faster distribution of the source materials in the foundation.

After each completed run through the stirring process the UNGUATOR® QMS generates an identification number which contains all the mixing parameters. Now you can save them, document or reject. Saving the recipe enables you to give an individual name to it. Rejecting the identification number does not allow it to be called up again and is therefore lost. The initial mix and their parameters remain kept.

If the stirring process is interrupted the UNGUATOR® QMS does not create an identification number. You may continue stirring under your own responsibility or start the process from the beginning.

6.4.7 Hand

The program "hand" gives you the possibility to make a recipe without the automatic stroke that the UNGUATOR® QMS produce. In this case, the stroke is made manually by the user.

With the "hand" program you can start a process directly without a pre-stored mixing program.

To begin, choose with the "+" or "-" key the desired size of the UNGUATOR® jar and confirm with the key "OK". From a jar size of 100ml and large the maximum rotation speed is limited. This is a safety measure built in by the manufacturer to optimize the force acting on the material of the jars and the mixing blades.

Subsequently enter a preliminary total stirring duration with "+" or "-". This can be a maximum of 10 minutes. Confirm this with "OK".

In the following step, select the desired preliminary rotation speed with "+" or "-". With "OK" you can confirm the initial rotating speed and the lifting arm moves to its lowest position in order to be manually handled.

The prepared mixing unit can now be inserted into the UNGUATOR® QMS receiving bayonet. The UNGUATOR® jar lid will simultaneously be covered with the UNGUATOR® jar housing and the mixing process may start by pressing the "OK" key.

The UNGUATOR® mixing unit will now evenly and in moderate tempo move up and down from the bottom of the UNGUATOR® jar till the top of the UNGUATOR® lid.

During the stirring process you may modify the mixing time with "+" or "-". With "OK" you will move to the rotation speed set-up. This can be modified with "+" or "-". Pressing the "OK" key you will be lead back to the time option.

Due to the possibility of having Individual stroke the program "Hand" creates no identification number.

For a UNGUATOR® jar of 200ml and bigger we recommend the use of the automatic UNGUATOR® QMS stroke. With this you can prevent a jam of the stirrer or the damage of the used material.

6.5 Mixing time

When creating and individual mixing with the programs "Auto-Q" and "Quick-ID- Start", it is recommended a minimum mixing time for the chosen recipe. After each composition and size of the recipe, different minimum times are given in which a recipe should be mixed.

The time given for the indicated rotation speed is oriental, and should be adjusted after each modification of the rotation speed.

Size of the UNGUATOR® Jar				
Type of formulation	15-30 ml	50-100 ml	200-300 ml	500 ml
Suspension	02:00	02:30	04:30	06:10
Soft in soft	01:40	02:10	04:00	05:10
Emulsion	02:00	02:20	04:10	05:30

Tab 5: Minimum values for mixing time by 2150 U/min:s

Size of the UNGUATOR® Jar				
Type of formulation	15-30 ml	50-100 ml	200-300 ml	500 ml
Suspension	03:00	03:50	06:45	09:30
Soft in soft	02:30	03:20	06:10	07:50
Emulsion	03:00	03:50	06:30	08:30

Tab 6: Minimum values for mixing time by 1650 U/min:s

6.6 Selecting the UNGUATOR® Jar size

The maximum rotational speed is limited for jars sized 100ml and bigger. This is a safety built in by the manufacturer to optimize the force acting on the material of the jars and the mixing blades in case of larger UNGUATOR® jars are used.

6.7 Requirements for the ingredients of a prescription

Powder

Basically, powders should be used as microfine substances.

To ensure a better wetting of powders in aqueous recipes, the micronized substances should only be weighed in after the liquid ingredients or be embedded in the basis cream.

With solids below 2%, we recommend performing a Grinding program with approximately 30% of base ointment. (Referred in chapter 6.4 Recipe programs – Grinding Program)

Crystalline substances

Before weighing into the UNGUATOR® Jar, crystalline active ingredients must be pulverized in a mortar, this will avoid a complex post-process, for example, using a mill.

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

For melting ingredients

The ingredients to be melted can be in the UNGUATOR® Jar, with the heated aqueous or oily phase of the recipe ($\leq 85^{\circ}\text{C}$) doused and melted.

If this process is not sufficient, in order to melt all ingredients the recipe in the UNGUATOR® Jar can be heated in a water bath ($\leq 85^{\circ}\text{C}$) or carefully in the microwave.

With recipes with no aqueous portion, the ingredients to be melted can be directly in the UNGUATOR® Jar in the water bath melted.

Please note that the UNGUATOR® MB cannot go into the microwave! Furthermore, isolated areas of heat concentration may develop when heating in a microwave.

Please note the essential instructions of your microwave oven. A high heating of both the UNGUATOR® jar and the content should in every case be avoided.

The cooling time and the cooling interval can be reduced with a cooling jacket or in a refrigerator. The UNGUATOR® MB should remain the UNGUATOR® Jar while the cooling process.

Thermolabile substances

Active ingredients or substances with thermolabile properties should be handled with caution. For the protection of the substances, we recommend a maximum rotation speed of 1500U/min. Control the result of the created frictional heat and cool according to the requirements with a cooling jacket or with cooling in a refrigerator.

6.8 After the Mixing Process is complete

The UNGUATOR® Mixing System is released and removed from the UNGUATOR® holder when the mixing process is complete. 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 to undertake an organoleptic quality check, the UNGUATOR[®] Jar Lid should also be opened after mixing when using the UNGUATOR[®] Disp. Blade. Practice has established that if the surface of the ointment looks smooth and even and if the minimum specifications for the mixing times have been adhered to, then homogeneity inside the UNGUATOR[®] Jar can be assumed.

Push the UNGUATOR[®] MB out of the UNGUATOR[®] Jar Lid. The ointment on the mixing blade can be wiped 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 of, or left in the UNGUATOR[®] Jar.

Leaving the blade in 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 users, since it might otherwise cause confusion if the ointment is traditionally dispensed.

The UNGUATOR[®] Jar Lid is screwed back onto the UNGUATOR[®] Jar housing and outfitted with an UNGUATOR[®] Varionozzle as needed. Then a UNGUATOR[®] Jar Lid or an UNGUATOR[®] Applicator is loosely screwed. Large UNGUATOR[®] Jars will be fitted with a spindle or the AirDynamic[®] System. Here too, as in the 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 can now be screwed down tightly.

A pre-printed label is affixed to the UNGUATOR[®] Jar before it is given to the customer, possibly with a short explanation of the UNGUATOR[®] dispensing system.

It is also a good idea to document the stroke and mixing parameters along with the results of the final check.

7. General recommendations on UNGUATOR[®] Mixing System

In its quality guideline for the production of semisolid preparations, the German Chamber of Pharmacists has recommended a closed system and delivery in dispensing containers with small dispensing opening since the year 2000.

7.1 Patent Protection

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

The UNGUATOR® Mixing System, and UNGUATOR® Technology and the AirDynamic® System integrated therein are inventions of the pharmacist Albrecht Konietzko from Bamberg in Germany. UNGUATOR® Technology and the AirDynamic® System are patented in selected countries. UNGUATOR® and AirDynamic® are protected trademarks and exclusively refer to devices and line products from GAKO Konietzko GmbH or under license of GAKO International GmbH.

The UNGUATOR® Mixing System from GAKO Konietzko GmbH is the original.

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. To continue to ensure that this remains so, GAKO Konietzko GmbH consistently strives to both maintain and improve the quality of the UNGUATOR® Mixing System.

To achieve this, there is a constantly quality control using the extensive know-how of the inventor of the UNGUATOR mixing system, the pharmacist Albrecht Konietzko, after meaningful improvements and enhancements that makes the UNGUATOR® mixing system easier to be handled.

7.2 Identification Number

The 13 digit identification number to clearly identify each preparation has the following construction:

(Fig.: program "Quick Start -ID -")

The first position the UNGUATOR® identification number gives information about the size of the jar, in which each jar's size has one number assigned:

(Graphic: --- --- Number-jar's size- assignment)

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 has certain value assigned:

(Graphic: Letter--- Time --- letter assignment)

The input of the rotation speed is assigned with the numbers 0-9, in which each number is assigned a certain rotation speed:

(Graphic: Number - Rotational speed - assignment)

7.3 Operating Errors

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

“Mixing tool not locked in place”, “Lifting motor overload” “Mixing motor overload”,

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

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® QMS 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 that cannot be remedied using the above information.

UNGUATOR® Mixing Blades

The UNGUATOR® QMS is tested with the attached UNGUATOR®MB, centered, and aligned.

All UNGUATOR® MB delivered after 1996 are compatible with the UNGUATOR® QMS. Please do not use any bent or damaged UNGUATOR® MB. Other UNGUATOR® MB used, rather than the ones supplied with the UNGUATOR® QMS may cause problems of coupling. If this is the case, we recommend contacting the customer center.

The UNGUATOR® MB should not be pressed too deep in the UNGUATOR® Jar, thus the lifting arm can stop at the bayonet. For this reason we recommend that possibly after screwing the UNGUATOR® mixing unit, the UNGUATOR® MB should by hand be drawn to the top until it stop.

Error: The UNGUATOR® Jar cannot be screwed in the lifting arm because the shaft of the UNGUATOR® MB is too long.

Solution: The used UNGUATOR® MB must be replaced with the appropriate UNGUATOR® MB with the correct shaft length. 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.

Error: The lifting arm is unintentionally moved with the hand too far from the Starting position and the shaft is no longer aligned in the entrance.

Solution: the shaft can be conducted with the hand to the entrance. The shaft touches the narrowing and is lead into the entrance.

Error: The UNGUATOR® MB does not penetrate completely in the mixture, since the formula is to pasty, firm, or in powder form.

Solution: The reverse power of the lifting arm is from 3 to 5kp intentionally low selected to avoid violation or material damages. For this reason, the UNGUATOR® QMS registers the resistance and the return of the stroke direction. To ensure the complete mixing of the recipe, you can for example, warm cold recipe substances in room temperature or assist pasty mixtures with the hand. A repeated support is usually no longer necessary.

UNGUATOR® Jars

Error: The jar connected to the UNGUATOR® QMS is not an UNGUATOR® Jar.

Solution: The jar has to be substituted for an UNGUATOR® jar.

Error: The UNGUATOR® jar lid is wrongly screwed on the UNGUATOR® jar and the UNGUATOR® MB tilted at automatic hub.

Solution: The UNGUATOR® jar should be unscrewed and correctly screwed together.

Error: The UNGUATOR® Jar Bottom was not pressed fully down to the stop position prior to weighing in or filling.

Solution: Particularly specific slight components are not compelling accommodate in the same weight UNGUATOR® jar although the filling volume is in the average 40% more as the nominal volume. Please use the next largest UNGUATOR® jar for the mixing.

Error: The air was not diminished before the mixing process of semisolid preparations from the UNGUATOR® Jar.

Solution: 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.

Error: the air has not been decreased before the stirring of fluid preparations from the UNGUATOR® jar.

Solution: Through the high rate of speed of UNGUATOR® MB and overpressure is generated and it cannot be compensated when the movable bottom yields. Thus, the overpressure may cause mixed material, mainly liquid constituents, to squeeze through the seals of the jar along the shaft of the UNGUATOR® MB.

Error: In recipes with a large amount of liquids components and cold emulsions the UNGUATOR® Jar Bottom does not retain liquids during the emulsifying process.

Solution: With cold emulsions, the basis cream must cover the complete UNGUATOR® Jar Bottom and along the lower jar wall until it is well distribute. When you prepare large quantity of liquids, for example the production of gels, it is important to use the appropriate mixing program. Those programs are constructed in order to avoid an excessive stirring speed and excess pressure on the UNGUATOR® jar.

Error: The sealing lip on the UNGUATOR® Jar Bottom does not retain liquids during the emulsifying process.

Solution: Please be aware that when setting up the UNGUATOR® jar lid with the UNGUATOR® mixing shaft, the sealing lip is not damaged by the tabs of the shaft. Reduce the air before the mixing process and use the appropriate mixing program.

Error: The user failed to decrease 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.

7.4 Quality assurance of the ointments

Simple test methods convincingly demonstrate the good homogenizing capability of the UNGUATOR® Mixing System. A homogeneity test is performed when receiving the UNGUATOR® device and the results documented. After a year or at demand you can repeat the test. Use a recipe with a colored substance. For example iron oxide (micro-fine) or Sudan Red and work this in a semi-solid basis.

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 rehearse 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.
- Please note the machine type and the occurring failure and contact your local UNGUATOR® dealer and/or certified UNGUATOR® service partner.

8.2 Manufacturer's Service and Warranty

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 of the device. Please retain the packaging material or request its replacement from your respective representative in your individual country (please contact your local UNGUATOR® dealer)

- Deficiencies that can be related to faults in the material or manufacturing defects will be remedied free of charge within the warranty period.
- The respective representative in your individual country (please contact your UNGUATOR® dealer) must be informed of necessary warranty repairs. A cost estimate can be obtained for service repairs.
- UNGUATOR® MBs and UNGUATOR® Jars along with further UNGUATOR® line products are excluded from warranty.
- The warranty claim will lapse should an unauthorized party have interfered 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 SMS Elap GmbH & Co. KG.
- Claims beyond the free rectification of faults, e.g. indemnification cannot be made within the framework of warranty.
- Claim of warranty will only be granted if the warranty certificate bearing date of purchase, dealer's stamp and signature or the purchase receipt in connection with the warranty certificate is provided.

- Repairs within the framework of warranty will be exclusively carried out by SMS Elap GmbH & Co. KG or companies authorized by it.
- To preserve gears and motor for further undisturbed operation, the UNGUATOR® QMS should be sent to your respective representative in your individual country after 20,000 preparation or five (5) years for maintenance. (please contact your UNGUATOR® dealer)
- 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.

9 Bibliography

10 Notes on Safety

- UNGUATOR® devices must only be connected to grounding-type receptacles with 230 V 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 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.
- Do not immerse UNGUATOR® devices in water
- UNGUATOR® power switch and power cord must be easily accessible.
- UNGUATOR® devices should only be operated by authorized persons.
- Only operate the UNGUATOR® MB with screwed-on UNGUATOR® Jar or in reaction mixture glassware
- Do not touch rotating parts.
- Keep long hair, ties and cables away from rotating parts
- During the automatic lifting function of the UNGUATOR® 2100: 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. Warranty expires!
- 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.

- Overload protection in the Unguator B/R: after 5 minutes of mixing operation, 30 minutes pause.
- 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 useful life.

11 Technical Data of the UNGUATOR® Q

- General total output: 300W
- Total output of mixing motor: 250W
- Total output of lifting motor: 50W
- Operating type : constant load S1
- Protection class I
- Type of protection: IP 20
- Engine speed governor : regulated in 10 speed level
- Time setting: program-controlled and/or in steps
- UNGUATOR® jar sizes: 15 -500ml
- Weight: 13,6 kg
- Dimensions (LxWxH in mm): 320 x 220 x 600
- Certification mark : TÜV-GS
- min/max rpm: 600 -2400
- replacable SD-card (Torx 20 required)
- service intervall recommended after 20,000 preparations

1 KB5: 30 minutes interval after 5 minutes of mixing operation. Be aware of warnings!

As to KB 5: Maximum load capacity will not be reached during normal operation. It is defined by 5 minutes' mixing of pasta zinc in the UNGUATOR® 100 ml and 30 minutes cooling interval. A safety element may switch off the device in the case of overload condition, e.g. at 3 ointment preparations in the 500 ml UNGUATOR® Jar in quick succession

12. Distribution, manufacturing and customer service

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Distribution and Terms of Delivery

Distribution of UNGUATOR® line products is exclusively made through wholesale firms that either have a marketing agreement with GAKO® Konietzko GmbH, GAKO® Direkt GmbH or GAKO International GmbH. In Germany, the UNGUATOR® line products are also directly marketed by GAKO® Direkt GmbH. The General Delivery Terms either of GAKO® Konietzko GmbH, GAKO® Direkt GmbH or GAKO International GmbH shall apply.

Customer Service

Please contact the service department of SMS Elap GmbH & Co. KG directly with all questions pertaining to technical details, maintenance, warranty, customer service or spare parts.