

Operating Instructions and Production Recommendations





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Please look over the operating instructions carefully, in particular the notes on safety, before operating the UNGUATOR® e/s. After a certain period of use, it may make sense to study the operating instructions more closely for selected information.

Installation notes:

Select a suitable location for the UNGUATOR® e/s. CAUTION! The UNGUATOR® e/s weighs almost 21 lbs.

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, level surface
- Away from direct air flow from air conditioning systems, heaters, open windows or fans
- Removed from direct insolation, extreme humidity or temperature fluctuations
- Clean, dry and dust-free

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

- UNGUATOR® e/s
- Operating instructions

Please contact customer service at SMS Elap GmbH & Co. KG. 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® e/s in for service.

You will find the power switch „O/I“ at the rear of the UNGUATOR® e/s on its base. This is also the emergency switch. Please check now that the UNGUATOR® e/s power switch is set to off. Connect the power cord to the socket outlet. You may now switch the UNGUATOR® e/s on using the power switch. It is now ready for operation and should show the default settings 2 minutes mixing time and speed step „5“ on the display.



1 UNGUATOR® Mixing System

The UNGUATOR® Mixing System consists of UNGUATOR® Technology, the UNGUATOR® mixing machines and further UNGUATOR® line products.

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 aim we continue to search for efficient improvements in addition to periodic quality controls. This objective is actively supported by application of vast know-how of the inventor of the UNGUATOR® Mixing System, pharmacist Albrecht Konietzko.

1.1 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 principle of the preparation method using UNGUATOR® Technology in the closed UNGUATOR® Mixing System is quick and easy to learn. Despite the almost countless number of possible combinations of ingredients used in a pharmacy, there is no need here to offer or list instructions for preparation. 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.

1.2 UNGUATOR® Mixing Machines

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

Notes on production	Pharmaceutical quality	Homogeneity of ointment	Stroke guidance	Mixing parameters (speed, mixing time)
Mortar and pestle	++	+	(-)	(individual)
UNGUATOR® B/R	+++	++	individual	individually adjustable
UNGUATOR® e/s	+++	+++	automatic	individually programmable
UNGUATOR® 2100	++++	++++	automatic	fully automatic

Tab. 1-1: Quality improvement with increasing automation



1.2.1 UNGUATOR® B/R

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

1.2.2 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.

1.2.3 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 his or her own mixing programs into the device and a maximum of 180 additional programs can be stored.



Fig. 1-1: UNGUATOR® B/R

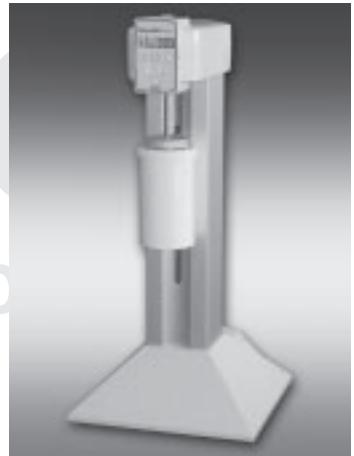


Fig. 1-2: UNGUATOR® e/s



Fig. 1-3: UNGUATOR® 2100

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.

1.3 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.

1.3.1 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 comminution 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, particularly when using the UNGUATOR® e/s and the UNGUATOR® 2100, 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.



Fig. 1-4: UNGUATOR® SMB

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.



Fig. 1-5: UNGUATOR® Disp. Blade

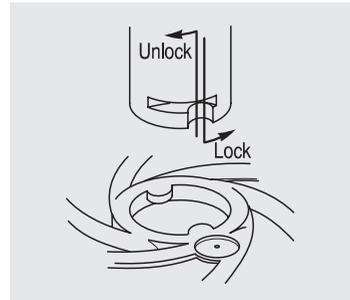


Fig. 1-6: Handling the UNGUATOR® Disp. Blade

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 should be picked up with the weak end of the shaft and thrown away. 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. On the weak end of the shaft, the range of UNGUATOR® Jar sizes that can be used (15-100 ml and 200 ml respectively) for the application is marked for orientation.

1.3.2 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.



Fig. 1-7: UNGUATOR® Jars

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 100 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.

The UNGUATOR® Jar comes 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 are dispensed using the movable jar bottom and always close to the life, The UNGUATOR® Jar solves

the problem of the unsightly contents in traditional porcelain vessels use previously. Evaporation, the 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.

Analysenzertifikat UNGUATOR® - KRUK EINWEGGEFÄSS VOR GE CHARGEN-NR.: 7202/05P ARTIKEL-NR.: 340 VERSA PZN: 0702570 VERPACKI Geprüft nach ZL-Verp.-Vorschri Lichtdurchlässigkeit : e Partikelgehalt : e Farbbeständigkeit : e Dichtigkeit : e Mikrobiologie : e gez.: Grieser (Ltr. Qualitäts: G-A-K-O Konietzko GmbH	Certificate of Analysis Date May 6, 2007 UNGUATOR® - JAR DISPOSABLE / DO NOT RINSE BEFORE USAGE CH.No.*: 7202/05P00 NOMINAL-/ FILLING VOL.: 100/140 ml PRODUCT No.: 340 SHIPPING UNIT: 500 units PZN**: 0702570 PACKING UNIT: 10 units Examined acc. to the central lab. packing regulations : DK II/94 Translucency : confirmed Particle Concentration : confirmed Color Fastness : confirmed Dichtigkeit : confirmed Microbiology : confirmed signed: Grieser (head of quality assurance) G-A-K-O Konietzko GmbH * 96049 Bamberg
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* Internal Registration No. ** Pharmaceutical Ref. No.

Fig. 1-8: Certificate of analysis for the 100 ml UNGUATOR® Jar

1.3.3 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 as a mnemonic aid:

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



Fig. 1-9: UNGUATOR® Varionozzles

1.3.4 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.



Fig. 1-10: UNGUATOR® Applicator short and long

1.3.5 UNGUATOR® Spindle

The UNGUATOR® Spindle serves as a dispensing system for the 200 ml or 500 ml UNGUATOR® Jar. The spindle has to be removed by rotating it clockwise on the new UNGUATOR® Jars that come with UNGUATOR® Spindles. 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).

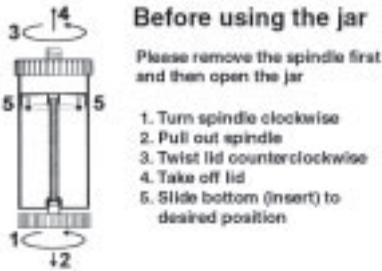


Fig. 1-11: Note on operation 1 for the UNGUATOR® Spindle

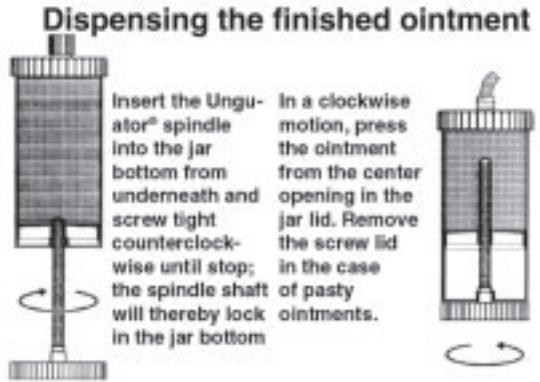


Fig. 1-12: Note on operation 2 for the UNGUATOR® Spindle



Fig. 1-13: UNGUATOR® Spindle

Air can be diminished by placing the UNGUATOR® Jar onto the formulation table and using both hands to move the jar against the table. The formulation can be transferred into small UNGUATOR® Jars with the aid of the UNGUATOR® coupling.

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. One turn dispenses approx. 20 ml of the contents of UNGUATOR® Jar.

Caution! If the movable bottom is accidentally perforated or the spindle locks onto the insert permanently then the UNGUATOR® Jar may only serve as dispensing or storage vessel and cannot be used for the mixing process.

1.3.6 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 that the UNGUATOR® Mixing System remains uncontaminated 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.

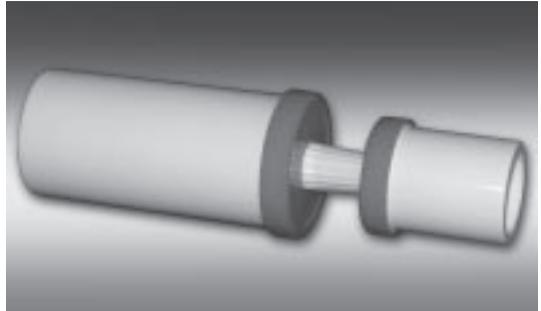


Fig. 1-15: UNGUATOR® Coupling

In addition to the UNGUATOR® Coupling, required for transfer from a 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.



*Fig. 1-14:
Transfer using a 200 ml UNGUATOR® Jar*

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

1.3.7 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 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® using the pump ball, the pressure thus generated moves the movable bottom upward. Thanks to the AirDynamic®



Fig. 1-16: AirDynamic® System

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 formulation viscosity.

1.4 Quality Verification

The production site for all UNGUATOR® products is certified in accordance with DIN EN ISO 9001. Periodic quality controls not only guarantee the outstanding but also most notably the lasting quality of the UNGUATOR® Mixing System.

- UNGUATOR® Applicators, couplings and jars are made of polypropylene (PP) and the UNGUATOR® Varionozzles of polyethylene (PE),
- The head of the UNGUATOR® SMB is made of polyoxymethylene (POM) and the mixing blades of the UNGUATOR® Disp. Blade of polyamide (PA).
- The shaft of the UNGUATOR® MB is made of stainless steel (quality: 1.4301) and hardened through titan nitration (gold-colored).
- The materials and pigments deployed are physiologically safe.
- All priceable UNGUATOR® line products (UNGUATOR® Jar, Disp. Blade, Applicator and Varionozzle) can be found under UNGUATOR® ... since the designations start with UNGUATOR® in the EPDS and the German "Hilfstaxe" (a database of approx. 340.000 medicines and other pharmaceutical products).



2 General Guidelines for the UNGUATOR® Mixing System

2.1 Preparing the UNGUATOR® Mixing System

The UNGUATOR® Mixing System consists of an UNGUATOR® Jar, an UNGUATOR® MB and the formulation constituents 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 Bottom 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 removed from the UNGUATOR® Jar housing by pulling with a slight counterclockwise turn. The UNGUATOR® Jar Lid will be moved in Mixing Blade direction. Both parts, i.e. the UNGUATOR® MB and UNGUATOR® Jar lid are put down or possibly tared on the balance together with the UNGUATOR® Jar housing.

2.2 Weighing in the Formulation Constituents

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

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% AND SUSPENSION > 2% as well as GEL

and SUPPOSITORIES. Powder mixings fall under NORMAL since their mixing process is similar. 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 jar the UNGUATOR® Jar 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.

2.2.1 Emulsion

Emulsifying semisolid substances with water at room temperature

Example: Eucerin c. aqua aa

We recommend using the UNGUATOR® Disp. Blade.

Emulsification can be more difficult using refrigerated foundations. Emulsification can be sped up by heating the water to be added; however, often the heat that develops inside the Jar during the mixing process may already be sufficient. Adapted emulsifiers can, after consultation with the physician, promote stability and the formation of emulsion or reverse phase separation. For instance, liquor carbon. detergens in vaseline emulsifies better containing a small portion of lanolin or wool fat ointment (unguentum alcoholum lanae).

2.2.2 Emulsion +

Emulsifying of semisolid substances to be melted.

Examples: Emulsific. aquosa, Lanette, Cera

We recommend using the UNGUATOR® Disp. Blade.

Emulsions should always be heated then when UNGUATOR® Jars of 300 ml to 500 ml are employed with UNGUATOR® B/R or e/s.

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



1. Addition of hot water
2. Covering with cold water – heat up to 200 ml in the hot-water bath = 85 °C/ 185 °F.
3. Covering with cold water – careful heating in the microwave.

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.

Emulsification can be more difficult when using refrigerated foundations. Adapted emulsifiers can, after consultation with the physician, promote stability and the formation of emulsion or reverse phase separation. For instance, liquor carbon. detergens in vaseline emulsifies better containing a small portion of lanolin or wool fat ointment (unguentum alcoholum lanae).

2.2.3 Normal

Mixing semisolid substances from low-viscous to paste state

Examples: Ready-made pharmaceutical ointment with foundation(s), concentrated active substances with foundation(s), liquid active ingredients in foundation(s).

First the foundation ointment should be weighed in into the UNGUATOR® Jar. Then the remaining constituents should be weighed.

2.2.4 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 means of a pregrind program in the case of a suspension with a content of less than 2 % active ingredients. For pregrinding, the solids with a low foundation content are weighed into the UNGUATOR® Jars. 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.

The “scratching and grinding check” on the ball of one’s thumb familiar from traditional preparation methods is often enough. Pasting should be repeated depending on the results of inspection.

Pregrinding has the advantage that ingredients are distributed fairly evenly along the UNGUATOR® Jar wall, and homogenize quickly with the remaining formulation constituents added, even in large UNGUATOR® Jars.

After the pre-ground ingredients have been pasted, the remaining foundation and all other remaining formulation constituents can be weighed in.

2.2.5 Suspension > 2%

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

Examples: Zincum oxydatum, acidum salicylicum, urea in aqueous foundation

We recommend using the UNGUATOR® SMB.

The preparation of a pre-ground substance is can be skipped for suspensions with more than 2 % content of active ingredients in favor of mixing time extension. First of all, the foundation should be rendered on weighing-in. Then the liquid constituents should be weighed in. Finally, the solid constituents are filled into the UNGUATOR® Jar. In so doing, ensure that these are placed into recesses and covered with foundation ointment. This will avoid direct contact with the UNGUATOR® MB and achieve better homogeneity.

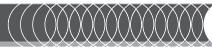
2.2.6 Gel

Mixing gel.

Example: Hydroxypropyl cellulose 400

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

Gel preparations are mixed, with several intervals, at high speed during the required swell time thus preventing agglomerations and slightly reducing soaking time. Principle-related, trapped air will normally clear after the preparation is allowed to settle for a while.



2.2.7 Suppositories

Dispersion of suppository blends after heating.

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

The heating of fat suppository foundations 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 drier or an infrared lamp should the mass have re-solidified. Preparation with approx. +5 ... 10 % recommended.

2.2.8 Powder

Mixing powder to fill capsules.

Using the standard Normal program will achieve good mixing results for microfine powder with a high proportion of lubricious Aerosil (silicic acid). We recommend the use of UNGUATOR® Disp. Blade for UNGUATOR® Jars up to 200 ml. The UNGUATOR® SMB will provide excellent results for the UNGUATOR® Jar sizes 300, 500 and 1000 ml.

To minimize the grinding noise along the sealing lip in the UNGUATOR® Jar Lid when mixing powder, the lip may be widened a bit using the shaft of the UNGUATOR® MB or vaseline or paraffinum liquidum may be applied to the shaft of the UNGUATOR® MB. The powder can be evenly distributed from the dispensing opening using the capsule filling device.

2.2.9 General Notes

Powder and active crystalline ingredients

Frequently the active substances needed should, in contrast to commercially available concentrates, be prepared in a UNGUATOR® Jar for storage or reuse as regular comminution at appropriate concentration and weighed in directly from the jar whenever required.

Powder

Powders should be used as microfine substances, if possible. Powders should be weighed in after the liquid constituents to ensure better wetting. For substances with a low proportion of powder, we recommend pregrinding by pasting the powder in a bit of foundation in the UNGUATOR® Jar, as already described above.

Crystalline Active Ingredients

We recommend pulverizing active crystalline ingredients in the mortar prior to weighing-in 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 after heating supported by mixing (e.g., urea with water, resorcinol with glycerin). 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. Some cases may require post-processing using an ointment mill. Afterwards, the ointment should be homogenized using an UNGUATOR®.

Waxes, Hydrophilic Ointment, etc.

Pour either 85 °C/185 °F warm water alone or containing the remaining heated constituents over Cera, Lanette N, etc. in the UNGUATOR® Jar. If the mixing temperature expected is higher than that of the melting temperature of the receiver, it will melt during the mixing process.

Pour water over the substances and heat them either in a hot-water bath (= 85 °C/ 185 °F) or in the microwave, then mix them using the UNGUATOR®. Please note that the UNGUATOR® MB cannot go into the microwave. 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 pregrind ingredients using the whole fatty phase and a low portion of water with a pregrind program. The remaining water can then be filled into the UNGUATOR® Jar in additional steps when the mixing process is interrupted. The advantage of pregrinding, where the ground ingredients are distributed 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.



2.3 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 AirDynamic® 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 diminuation.

Air diminuation 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 diminuation be repeated after 15 seconds of the mixing process.

When pregrinding 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 diminuation need be carried out before pegrinding.

At this point of the mixing process, device-specific settings will need to be implemented and the UNGUATOR® Mixing System connected to the UNGUATOR®. These procedures are exhaustively described in chapter 3.

2.4 The Mixing Process

Extending the mixing time and increasing the speed of the mixing motor will improve the product quality of the ointment. Please see chapter 3 for more detailed information and device-specific settings.

2.5 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 or, 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 on temporarily. Large UNGUATOR® Jars will be fitted with a spindle or the AirDynamic® System. Here too, as in the mixing process, air diminuation 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. There is a document template for this purpose at the end of these operating instructions.



3 The Mixing Process Using the UNGUATOR® e/s

The UNGUATOR® e/s is an improved version of the UNGUATOR® e from 1994. It represents an improvement first ever UNGUATOR® from 1994 with an added automated lifting device, and programmable mixing time and speed. The “e” in the name stands for the electronics necessary for the respective automated processes, resulting in the simplicity of ointment preparation and the elegance of the UNGUATOR® e/s. Due to its powerful and robust mixing motor, the UNGUATOR® e/s guarantees safe, clean and fast preparation of ointments, resulting in the “s” in its name.

Before using the UNGUATOR® e/s, ensure the power switch “ON/OFF” located on the base at the rear of the UNGUATOR® e/s is turned off. We recommend switching the UNGUATOR® e/s off when not in use.

In addition to automated processes, the UNGUATOR® e/s also allows for manual mixing like its predecessors. Use the “AUTO/HAND” button when the device is switched on to select manual or automatic operation. The current setting is indicated on the display where either the triangle above the “AUTO” for auto mode or beneath “HAND” for manual operation lights up. The oscillating arm of the UNGUATOR® e/s will automatically move to the corresponding position when operating mode is changed.

When automatic manual stroke operation has been selected, preset mixing time and speed step should be selected. A dot in the respective number field indicates the parameter that can be changed via the „plus“ and „minus“ buttons. 2 minutes of mixing time and „5“ for the speed step are the default values.

The mixing time can be set anywhere from one second up to 9 minutes and 55 seconds, and the mixing motor is adjustable from “0” to “9” in 10 steps.

See the table below for the exact speed of each step measured in revolutions per minute (rpm).

The actual mixing process can begin after the mixing time and speed parameter have been set.

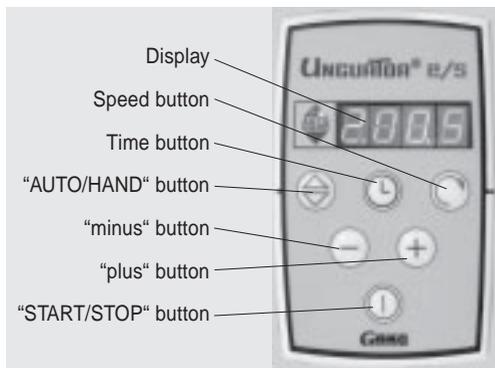


Fig. 3-1: Control panel of the UNGUATOR® e/s

Step	Speed		Step	Speed
0	720 rpm		5	1630 rpm
1	900 rpm		6	1810 rpm
2	1080 rpm		7	1990 rpm
3	1260 rpm		8	2160 rpm
4	1440 rpm		9	2340 rpm

Tabella 3-1: Value table of the speed steps

This is described in the two following subsections Operating Mode “AUTO” and Operating Mode “HAND”.

3.1 Operating Mode “AUTO”

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 button “Start/Stop” will initiate the mixing process after the UNGUATOR® Mixing System has been screwed tightly into the oscillation arm.

The oscillation arm will automatically move upward and the UNGUATOR® MB will then be coupled to the bayonet receptor of the mixing motor. A sensor will ensure that a UNGUATOR® MB has been inserted and will immediately switch off if the UNGUATOR® Mixing System has not been fixed to the oscillation arm correctly or at all. The mixing process will continue once the UNGUATOR® is detected by the sensor.

The programmed mixing time will be completed at the set speed step with steady up and down movement of the UNGUATOR® Mixing System. The mixing time and speed parameters can also be changed during the mixing process using the same procedure for initial programming of the mixing process.

Freespin can be done when mixing time is complete, and is indicated by “FSP” on the display. The oscillation arm moves downward till the mixing blade hits the UNGUATOR® Jar Lid, then the mixing motor is accelerated to speed step “9”. The UNGUATOR® MB now cleans itself via high-speed rotation close to the lid, a process referred to as freespin motion. Almost all ointment is removed from the UNGUATOR® MB and mixing is complete. The display now indicates total mixing time including reset times.



To remove the UNGUATOR® Mixing System, first screw off the UNGUATOR® Jar Lid. The UNGUATOR® Mixing System is then removed from the bayonet receptor by twisting the UNGUATOR® MB shaft counterclockwise. Then the UNGUATOR® Mixing System can be removed by pulling it downwards.

3.2 Operating Mode “HAND“

The pre-prepared UNGUATOR® Mixing System is inserted into the bayonet receptor of the UNGUATOR® e/s 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.

The bayonet receptor will grip immediately when the UNGUATOR® e/s is switched on using the “Start/Stop” button. It will now run from the first revolution until the mixing process is complete. The programmed mixing time will be completed at the set speed step. The mixing time and speed parameters can also be changed during the mixing process.

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, while holding the UNGUATOR® Mixing System tightly with at least one hand.

The UNGUATOR® Mixing System can be switched to freespun as a special step with manual stroke movement. Press the “Start/Stop” before the mixing process is complete to switch to freespun. This will interrupt the mixing process, and the display will prompt for freespun by showing “FSPA”.

The UNGUATOR® Mixing System needs to be removed from the UNGUATOR® e/s and the UNGUATOR® Jar Lid slightly untwisted as if for air diminuation. The UNGUATOR® Jar bottom is then pushed into the full down position using the UNGUATOR® MB. Then the UNGUATOR® Jar Lid is retightened. The UNGUATOR® Mixing System should now be inserted back into the bayonet receptor of the UNGUATOR® e/s from below and pushed up as far as it will go. Now push the “Start/Stop” button again, and the UNGUATOR® MB can now clean itself by means of high-speed rotation in a position close to the lid. This is referred to as freespun. Most of the ointment is removed from the UNGUATOR® MB and the mixing process is complete. The display will show the total mixing time incl. the reset times after the freespun is finished.

The UNGUATOR® Mixing System is removed from the bayonet holder by twisting the UNGUATOR® MB shaft counterclockwise and then pulling it out in downward direction.

3.3 General Notes on Operation

The UNGUATOR® e/s is to be operated as described in chapter 2:

1. Preparing the UNGUATOR® Mixing System
2. Weighing in the formulation constituents
3. Preparing the mixing process – air diminuation
4. The mixing process
5. After the mixing process is complete

For paste preparations the mixing process should be started using the default speed setting, viz. step “5”. The speed should then be increased after a couple of strokes. The minimum quantity of strokes should not be less than 50 at maximum speed of the mixing motor to ensure an optimal mixing result. Keep in mind that the required mixing time will increase with the size pressing the “Start/Stop” button. The display will then show the mixing time up to this point stage. Air could then be reduced after a large volume of powder has been added, for example. The device will reboot when the “Start/Stop” button is pressed again.

The operation mode “HAND” should only be selected for UNGUATOR® Jars in sizes 15 to 100 ml. UNGUATOR® Jars from 200 to 500 ml should either be guided using both hands or, even better, guided in operation mode “AUTO”.

A thermo safety element will switch off the mixing function of the UNGUATOR® e/s at signs of excessive stress, e.g. due to the repeated preparation of ointments over a short period of time and in large UNGUATOR® Jars. Should this occur, we recommend switching off the UNGUATOR® e/s using the power switch or pulling the power plug. Wait 30 minutes before switching the machine back on.

Type of formulation	Size of the UNGUATOR® Jar			
	15 to 20 ml	30 to 100 ml	200 to 300 ml	500 ml
Emulsion / +	01:30	02:00	03:00	04:00
Normal	01:00	01:30	02:30	03:30
Suspension < / > 2 %	02:00	02:30	04:00	05:00
Suppositories	01:00	01:30	02:45	03:30

Tabelle 3-2: Minimum values for mixing time at speed step 9 in min:sec



Type of formulation	Size of the UNGUATOR® Jar			
	15 to 20 ml	30 to 100 ml	200 to 300 ml	500 ml
Emulsion / +	03:10	04:10	06:45	08:15
Normal	02:10	03:10	05:45	07:15
Suspension < / > 2 %	04:10	05:15	08:15	10:20
Suppositories	02:10	03:10	05:45	07:15
Gel	25 min 6 times 10 strokes each with 5 breaks á 04:30 at 1750 rpm			

Tabella 3-3: Minimum values for mixing time at speed step 5 in min:sec

Type of formulation	Size of the UNGUATOR® Jar			
	15 to 20 ml	30 to 100 ml	200 to 300 ml	500 ml
Emulsion / +	10:10	13:30	22:00	27:00
Normal	06:45	10:10	18:40	23:45
Suspension < / > 2 %	13:30	16:55	27:00	33:45
Suppositories	06:45	10:10	18:40	23:45

Tabella 3-4: Minimum values for mixing time at speed step 1 in min:sec

Any irregularities are indicated a fault message on the display. The meaning of the individual fault messages are listed in the table below.

Fault display	Fault remedy	Possible causes of fault
FE 0	Hit the “Start/Stop” button, oscillation arm moves to the next end position	Switching the device on and off during a work phase or temporary blackout
FE 1	Remove jar and hit the “Start/Stop” button, Oscillation arm moves to the desired position	change-over between the operating modes, when a mixing unit has locked in place or switching on the device when a mixing mixing unit has locked in place
FE 2	Hit the “Start/Stop” button, FE 0 displays	Oscillation arm does not move or very slowly
FE 8	Hit the “Start/Stop” button, snap in jar - reboot	No mixing unit locked in place when in “HAND” mode
FE 9	Oscillation arm will automatically return to home position	No mixing unit attached to oscillation arm in “AUTO” mode
FE 9	Remove jar and hit the “Start/Stop” button	No mixing unit snapped in or released in “AUTO” mode
FE A	Hit the “Start/Stop” button, possibly switch off device	Temporary motor overload

Table 3-5: UNGUATOR® e/s error messages

Error messages will also occur if UNGUATOR® MBs are used that do not match the respective size of the UNGUATOR® Jar or if the end position of the previous mixing process has been left at the beginning of the mixing process rather than the start position required for the new mixing process.

Incorrect operation or environmental influences may cause problems not listed in the error list. If this occurs, switch off the device or pull the power plug. The UNGUATOR® e/s may then be switched on again after period of 10 seconds.



4 General Notes on the 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.

4.1 References

The advantages of the UNGUATOR® Mixing System vs. traditional production methods with a mortar and pestle have been described in the literature several times:

- GMP-compatible ointment formulation possible in pharmacies [2], [4].
- Ointment formulation can be standardized [4], [8].
- Better homogeneity [2], [4], [9].
- Improved microbiology [3], [8].
- Risk of contamination strongly reduced during production: Hygienic production in a closed system, no transfer into a separate dispensing jar [2], [3], [4], [8].
- Hygienic product extraction, low risk of contamination through the user [2], [3], [4], [8].
- Improved product quality in improved packaging guaranteed extended product durability [3], [4].

4.2 Notes on the Mixing Process

This subchapter serves to clarify frequently asked questions and clear up possible misunderstandings. Adhering to the following tips will help eliminate possible error sources quickly and efficiently.

4.2.1 Assignment of the UNGUATOR® MB

Please take care to use the correct UNGUATOR® MBs for the corresponding UNGUATOR® Jar (cf. Fig. 4-1). Mix-up may trigger fault messages with UNGUATOR® devices with a semiautomatic stroke feature.

Please 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,

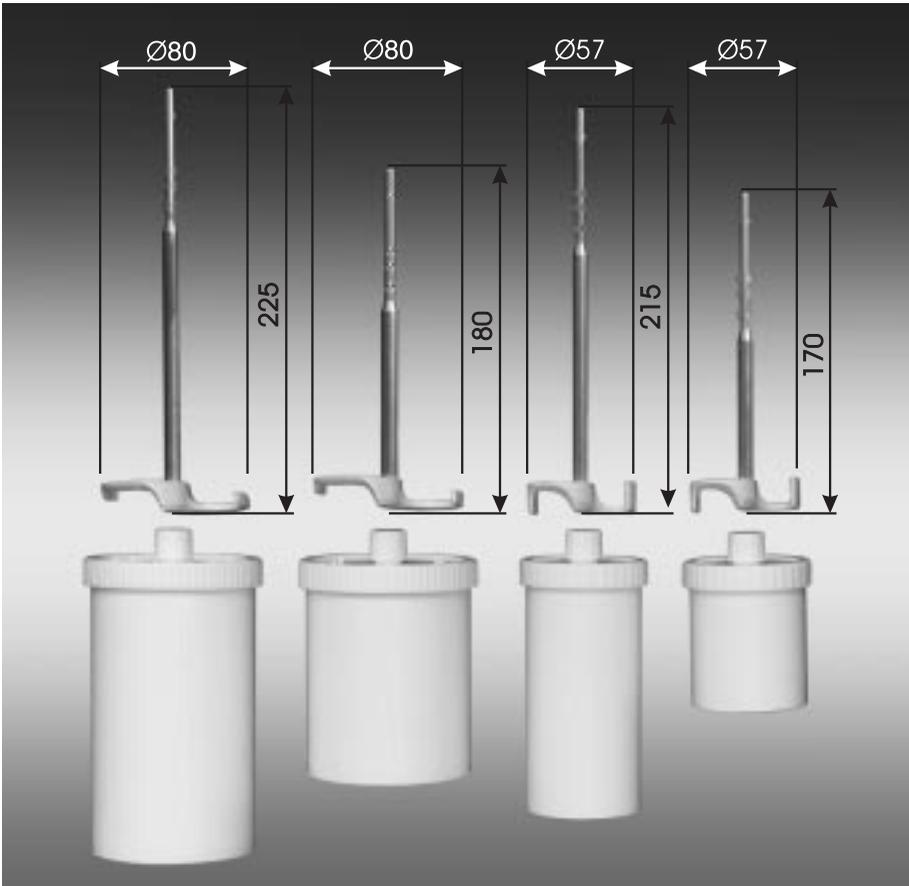
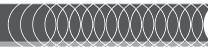


Fig. 4-1: Assignment of the UNGUATOR® SMB with different length of shaft

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.

4.2.2 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 diminished again following this process. When using the UNGUATOR® Disp. Blade, however, there are no niches of flow and no remedial work is required.

4.2.3 Heating

The heat that develops from the friction between 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. For instance, aqueous hydrophilic ointments can be produced using the “cold method” using wool fat ointment and water aa. or also ungt. emulsific. pre-emulsified with a small amount of water (approx. 10 %) and water ad 70 %.

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.

4.2.4 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.

4.2.5 Possible Error Sources to be Avoided

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.

The air was not diminished 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 housing 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 is 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 untwist during the mixing process, resulting in a large mess.

The user failed to diminish 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].

4.3 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. Principle-related, very pasty ointments cannot be pressed through this opening, even using the spindle.



Here the ointment can be dispensed with a spatula, as from 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 dispensing this way and for large UNGUATOR® Jars, using 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 the UNGUATOR® Jars all have the same diameter. 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.

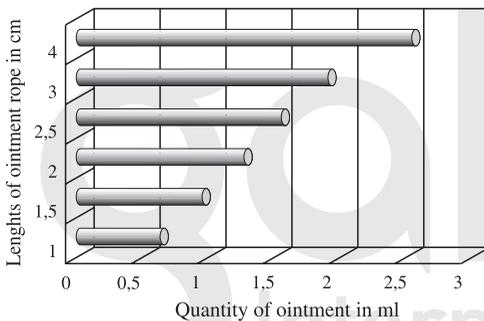


Fig. 4-2:
Opening of the UNGUATOR® Jar Lid

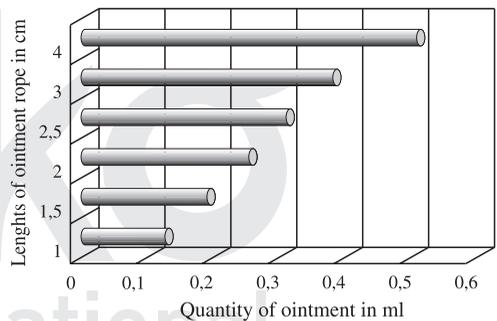


Fig. 4-3:
Opening of the UNGUATOR® Varionozzle 4 mm

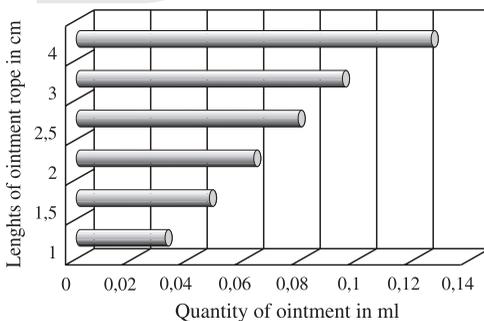


Fig. 4-4:
Opening of the UNGUATOR® Varionozzle 2 mm or of the UNGUATOR® applicator long

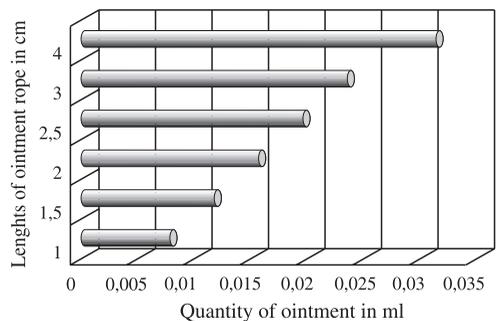


Fig. 4-5:
Opening of the UNGUATOR®-Varionozzle 1 mm or of the UNGUATOR® applicator short

4.4 Quality Assurance of the Ointments

Simple test methods convincingly demonstrate the good homogenizing capability of the UNGUATOR® Mixing System. The test is performed using analog formulations with colored powders such as iron oxide (red/hydrophilic, yellow/hydrophobic) or Sudan red and riboflavin [2] or methylene blue [4]. Here the examination of ointment streaks from various levels of the mixing jar using a magnifying glass or microscope have demonstrated the success of the mixing process, as has viewing one or more sections of an “ointment block” that can be pressed out of the UNGUATOR® Jar as a whole after it was placed into a freezer overnight. “Mixing up” such analog formulations not only ensures that UNGUATOR® Mixing System is being used correctly: it also allows our customers to build up trust in the modern UNGUATOR® Technology and the quality associated with it.





5 Service and Warranty

5.1 Notes on Malfunctions

If UNGUATOR® device is not functioning, it may be due to something small that you can remedy yourself. Please read and apply the tips below before returning the device for repair:

- 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.
- If the UNGUATOR® e/s was switched off due to overload, please check to see whether the power plug has been pulled out or the device has been switched off and that a 30 minutes cooling phase has been adhered to.
- Replace a defective connecting cable with a rubber-sheathed cable with a polychloroprene HO5 RN F sheathing.
- The UNGUATOR® e/s carbon brushes may be worn after an operating period of approx. 500 work hours. They will be replaced in the course of maintenance work periodically carried out by SMS Elap GmbH & Co. KG.
- Should faults or damage occur, please also read the manufacturer's notes on the underside of the base

5.2 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 for the device. Please retain the packaging material or request its replacement from your respective representative in your individual country (please contact your UNGUATOR® dealer) or SMS Elap GmbH & Co. KG to avoid damage in shipping.

- Deficiencies that can be related to faults in the material or manufacturing defects will be remedied free of charge within the warranty period.
- Either the respective representative in your individual country (please contact your UNGUATOR® dealer) or SMS Elap GmbH & Co. KG 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® e/s should either be sent to your respective 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.

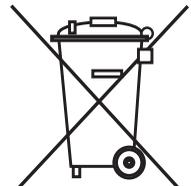


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7 Notes on safety

- 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.
- UNGUATOR® devices should only be operated by authorized persons.
- UNGUATOR® power switch and power cord must be easily accessible.
- Do not immerse UNGUATOR® devices in water.
- Always pull the power plug before opening UNGUATOR® devices.
- Have electric parts removed or installed by professionals only.
- Only operate the UNGUATOR® MB with screwed-on UNGUATOR® Jar or in reaction mixture glassware.
- Do not touch rotating parts.
- Keep long hair 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.
- 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 useful life.





8 Technical data of the UNGUATOR® e/s

Electrical requirement	230 V / 50 cps; 120 V / 60 cps
Total power consumption	270 W
Power consumption (mixing motor)	220 W
Power consumption (lifting motor)	50 W
Operating mode	KB 5 ¹
Safety class	I
Type of protection	IP 21
Speed controller	in 10 steps electronic controlled
Timer	continuous electronically
UNGUATOR® Jar sizes	15 ... 500 ml
Weight	20.44 lbs
Dimensions (L x W x H in mm)	300 x 300 x 650
Testing certifications	TÜV GS

¹ KB5: 30 minutes interval after 5 minutes' mixing operation. Heed warning notices!

As to KB 5: Maximum load capacity will not be reached during normal operation. It is defined by 5 minutes' mixing of pasta zinci in the UNGUATOR® 100 ml jar at 2000 RPM 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 200 ml UNGUATOR® Jar in quick succession.

Manufacturer's Certificate

All **UNGUATOR®** plastic line items
are exclusively produced from materials and color components that meet the
preconditions for the

**Regulation on Consumer Articles of the Federal Republic of Germany dated
4/10/1992,**

**the recommendation of the Federal Public Health Department (BGA) from
1993 for objects in contact with foodstuffs
and the
EU Directive 2002/95/EC (RoHS).**

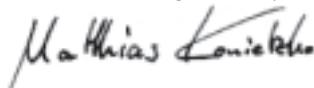
Article ¹⁾	Material ²⁾	Color concentrate ²⁾	
UNGUATOR® Jar ³⁾		Standard	Cosmetic
UNGUATOR® Jar cap	Polypropylene, natural	white	colored
UNGUATOR® Jar lid	Polypropylene, natural	red, white, green, blue	colored
UNGUATOR® Jar housing	Polypropylene, natural	white	colored
UNGUATOR® Jar bottom	Polypropylene / Polyethylene	-	-
UNGUATOR® Jar bottom cap	Polypropylene, natural	white	white
Further UNGUATOR® line items			
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® SMB	Polyoxymethylene white	-	
UNGUATOR® Disp. Blade	Polyamide white	-	

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

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

3) With certificate of analysis according to ZL Packing Instruction DK II / 1994 on the packaging hose.

GAKO Konietzko GmbH
D-96049 Bamberg / Germany



Dipl.-Wirtsch.-Ing. Matthias Konietzko
Production control



10 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 or GAKO International GmbH. In Germany, the UNGUATOR® line products are also directly marketed by GAKO Konietzko GmbH. The General Delivery Terms either of GAKO Konietzko 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.

SMS Elap GmbH & Co. KG
Service-Center UNGUATOR®
Am Köhlersgehäu 50
D-98544 Zella-Mehlis
Phone: +49 3682 / 455 199
Fax: +49 3682 / 455 206

S|M|S

WARRANTY CERTIFICATE

for the

UNGUATOR® e/s

Date of purchase: _____

Ser. no.: _____



Stamp and signature:

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Service-Center UNGUATOR®
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