

# 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® 2100. 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® 2100. CAUTION! The UNGUATOR® 2100 weighs 36,75 lbs. We recommend you to ask a second person for assistance when lifting the device or when transporting it.

Ensure that there is enough space to operate the UNGUATOR® 2100. This must include sufficient space around the UNGUATOR® 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® 2100
- Power cord
- 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® 2100 in for service.

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

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

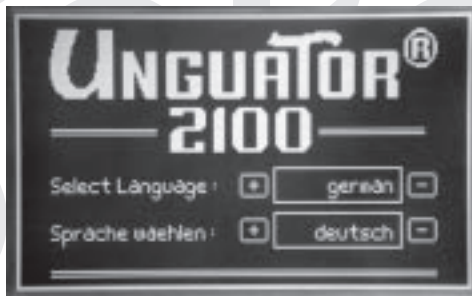


will appear on the display after switching on the UNGUATOR® 2100 using the power switch.



*Fig. 0-1: Display*

The start screen will then display the current preparation number and the version of the software stored on the microprocessor. Hit the “Esc” button to move from the start screen to the language menu.



*Fig. 0-2: Language menu*

Use the “+” and “-” buttons will get you to the next or previous language setting. Enter “Ok” to confirm your selection and move back to the start screen.

# 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

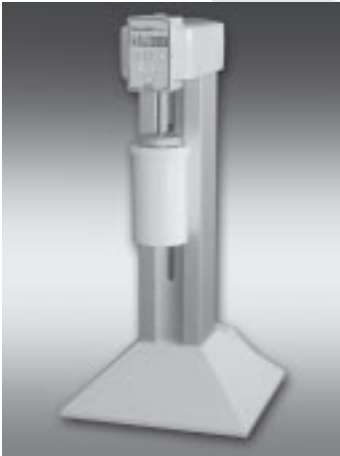
The UNGUATOR® B/R is the basic machine with a controlled mixing motor and manual Jar guidance.



*Fig. 1-1: UNGUATOR® B/R*

### 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.



*Fig. 1-2: UNGUATOR® e/s*

The precisely set sensor for the automatic oscillation arm will always ascertain at each upward or downward stroke the exact position of the UNGUATOR® Jar Bottom or lid. This guarantees that the UNGUATOR® Jar is always accessible to the UNGUATOR® Mixing Blade despite the inevitable 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. 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.



*Fig. 1-3: UNGUATOR® 2100*

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)

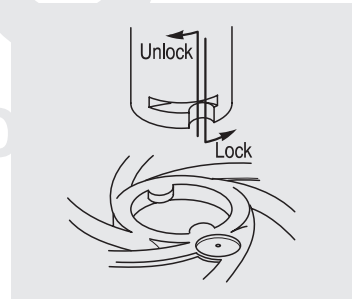
UNGUATOR® Disp. Blade is suitable for all UNGUATOR® devices. The Mixing Blade of the UNGUATOR® Disp. Blade is connected to the UNGUATOR® Disp. Blade shaft by twisting the blade counterclockwise and can be disconnected after the mixing process with a clockwise turn.

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.



*Fig. 1-5: UNGUATOR® Disp. Blade*



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

### 1.3.2 UNGUATOR® Jar

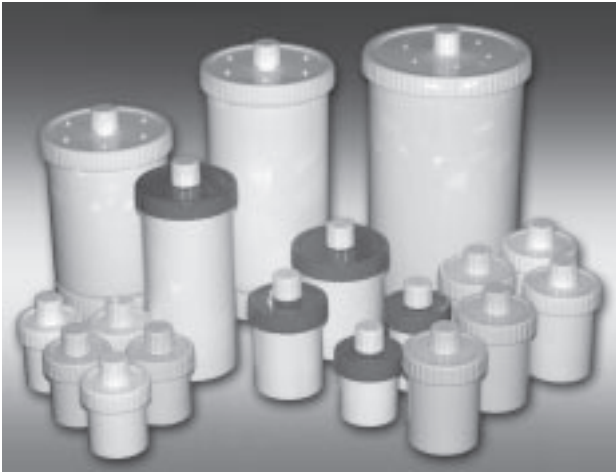


Fig. 1-7: UNGUATOR® Jars

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 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

<p>Analysenzertifikat  <b>UNGUATOR® - KRUK</b>          EINWEGGEFÄSS VOR GE          CHARGEN-NR.: 7202/05P          ARTIKEL-NR.: 340 VERSA          PZN: 0702570 VERPACKU          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</p>	<p>Certificate of Analysis          Date May 6, 2007  <b>UNGUATOR® - JAR</b>          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</p>
--	--

\* Internal Registration No.      \*\* Pharmaceutical Ref. No.

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

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.

### 1.3.3 UNGUATOR® Varionozzles

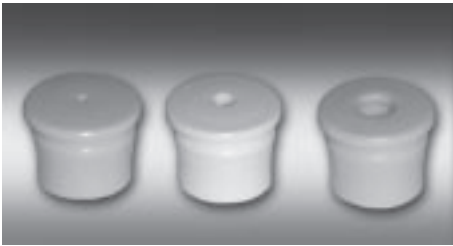


Fig. 1-9: UNGUATOR® Varionozzles

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)

### 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.



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



Moreover, the UNGUATOR® Applicator long is also available as a sliding aid together with the 200 ml UNGUATOR® Jar.

### 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).

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.



Fig. 1-13: UNGUATOR® Spindle

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.

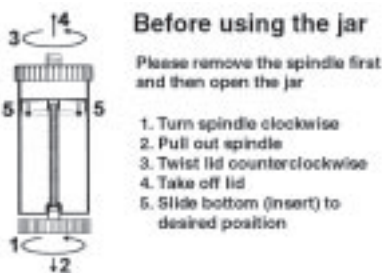


Fig. 1-11: Note on operation 1 for the UNGUATOR® Spindle

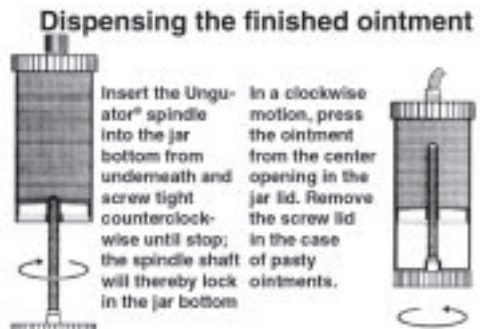
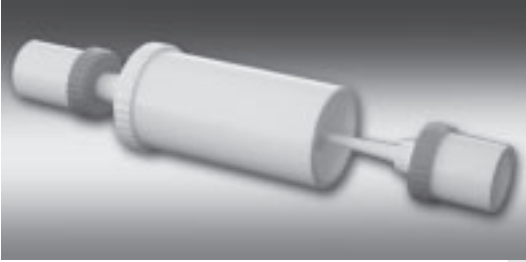


Fig. 1-12: Note on operation 2 for the UNGUATOR® Spindle

**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.

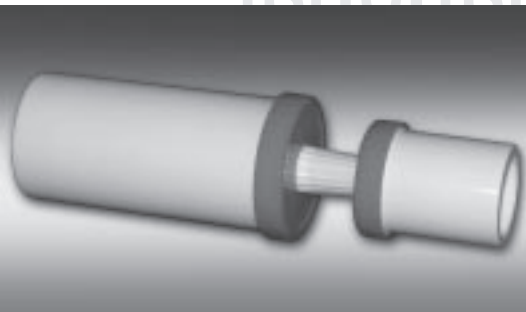
### 1.3.6 UNGUATOR® Coupling



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

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.



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® 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.



*Fig. 1-16: AirDynamic® System*

## 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 pregrinding e.g. by means of a pasting 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 pasting 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 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 pre-grinding 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 pre-grind ingredients using the whole fatty phase and a low portion of water with a pasting program. The remaining water can then be filled into the UNGUATOR® Jar in additional steps when the mixing process is interrupted. The advantage of pre-grinding, 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® 2100**

The UNGUATOR® 2100 is the result of continuous improvement of the first ever UNGUATOR® 2000 from the year 2000. Thanks to a programmable microprocessor that completely automates the mixing process, it represents a great improvement over the UNGUATOR® e from 1997.

The UNGUATOR® 2100 operates with two silent PM motors for continuous load and is an intelligent universal machine for individual and small batch preparation from 15 to 1000 ml. When preparation type and size of the UNGUATOR® Jar have been selected, the microprocessor controls the mixing parameters for uniform and reproducible product quality.

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

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

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

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

The single mixing stages are defined by the mixing parameters of lifting motor speed and mixing motor speed in addition to the number of strokes or duration of the mixing stage. 360,000 settings per mixing stage are possible due to the various values of the

mixing parameters. This results in a practically unlimited variety of optional programs that can be used to mix an ointment using the “MANUAL” program.

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

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

### 3.1 Standard formulation Programs



Fig. 3-1: Main menu “SELECT MIX TYPE”

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

First select once of the standard formulation programs using the “+” and “-” buttons. Confirmed selection with the “ok” button. Next on the menu “SELECT UNGUATOR® JAR:” will appear. Select UNGUATOR® Jar size selected using the “+” and “-” buttons and confirm using the “ok” button. The oscillation arm will automatically move to its starting position. The user will be prompted then to mount the UNGUATOR® Jar or the UNGUATOR® mixing unit.

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

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



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

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

### 3.2 Program “DIRECT”

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



Fig. 3-2: Menu “DIRECT PREPARATION”

First select one of the six possible speed steps of the lifting motor that determine the speed of the oscillation arm using the “+” and “-” buttons and confirm with the “ok” button. Speed steps “01” to “05” stand for slow to fast upward and downward stroke of the automated oscillation arm (see 3.2.1). The speed of the lifting motor can not be changed during the mixing process. The automated movement of the oscillation arm is suspended when selecting speed step “0” and the oscillation arm is moved into its full down position before the mixing process starts which allows for a manually guided stroke (see 3.2.2).

#### 3.2.1 Automated Stroke

Once the automated stroke has been selected, the user may, depending on the size of the UNGUATOR® Jar, choose from up to 10 different speed steps of the UNGUATOR® MB using the “+” and “-” buttons and confirm this with the “ok” button.

The last of the selectable mix parameters is mixing time which may be between 10 seconds and 2 hours. Change mixing time with the “+” and “-” buttons.

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

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

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

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

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

### **3.2.2 Manual Stroke**

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



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

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

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

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

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

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

The UNGUATOR® Mixing System is removed from the bayonet receptor by twisting the UNGUATOR® MB shaft counterclockwise and then pulling it out in downward direction. Hitting the “ok” button will get you to the start screen.

### **3.3 Program “COMBINATION MIX”**

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



Fig. 3-3: *Combination mix in the UNGUATOR® 2100*

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

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

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

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

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



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

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

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

### 3.4 Program “MANUAL”

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

The “MANUAL” program allows for the storage of 180 different mixing programs. Each UNGUATOR® Jar size is assigned to 20 mixing programs. Using a PC and appropriate software, the number of mixing programs that can be stored is practically unlimited.



Fig. 3-4: Menu “SELECT PROGRAM...”

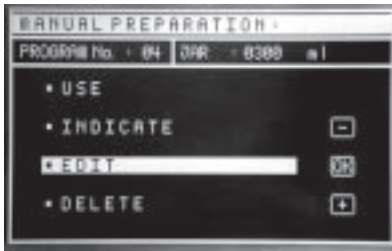


Fig. 3-5: Main menu “MANUAL PREPARATION”

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

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

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

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

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

### 3.4.1 Menu Option “USE”

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

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



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

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

### 3.4.2 Menu Option “INDICATE”

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

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

STEP	NO	EST	TIME	REV	SP	DIR	SP	DIR
00	-	-	-	-	-	-	-	-
01	-	-	-	-	-	-	-	-
02	-	-	-	-	-	-	-	-
03	-	-	-	-	-	-	-	-
04	-	-	-	-	-	-	-	-
05	-	-	-	-	-	-	-	-
06	-	-	-	-	-	-	-	-
07	-	-	-	-	-	-	-	-
08	-	-	-	-	-	-	-	-

Fig. 3-6: Screen “INDICATE: 1”

STEP	NO	EST	TIME	REV	SP	DIR	SP	DIR
09	-	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-
13	-	-	-	-	-	-	-	-
14	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-	-
FSP	10	-	-	-	-	-	-	-

Fig. 3-7: Screen “INDICATE: 2”

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

### 3.4.3 Menu Option “EDIT”

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

First select the pasting program by using the “+“ and “-“ buttons, and confirm with the “ok“ button. The following programs are available: pasting “00“, which means the “01“ mixing stage starts directly, skipping pasting, and programs “01“ to “03“. The mix parameters of the individual pasting programs are shown in Tab. 3-1.

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

Tab. 3-1: Mix parameters of the pasting programs “00“ bis “03“

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

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

Tab. 3-2: Parameters of the freespin motion programs “00“ bis “02“

One of the 16 mixing stages can be directly selected on the “Prog. stage“ line using the “+“ and “-“ buttons. Confirm the mixing stage selected with the “ok“ button. This will call up the selection of mixing parameters. Exactly like in the previous selection processes, the various mixing parameters, speed of the lifting motor and the



UNGUATOR® MB and number of strokes or duration of the mixing time can be changed using the “+” and “-” buttons in each case and are to be confirmed with the “ok” button. It is also possible to select or confirm individual mixing parameters by hitting the “Esc” button, but here the selection does not jump to the following but to the previous data record.

Step	Speed of the lifting motor in rpm	Step	Speed of the MB in rpm	max. permitted Jar size (Nominal volume in ml)
01	800	01	250	1000
02	1500	02	500	1000
03	2200	03	750	1000
04	2900	04	1000	1000
05	3600	05	1250	1000
		06	1500	1000
		07	1750	1000
		08	2000	1000
		09	2250	200
		10	2500	50

*Tab. 3-3: Available speed steps of the lifting motor and the MB*

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

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

### 3.4.4 Menu Option “Delete”

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

## 3.5 General Notes on Operation

The general notes on operation contain clearly arranged procedures or explanations that either concern all or several UNGUATOR® 2100 mixing programs. This includes the procedure for the pregrind program, the explanation of the number of strokes and mixing time mixing parameters, information on maximum mixing times in the “DIRECT” and “MANUAL” programs as typical values. This chapter will also answer the questions: “Why do I have to select the size of the UNGUATOR® Jar, what is the effect of the “Esc” button, when do I press what button and what does the identification number stand for?” The last subchapter gives notes on operating errors and solving them.

### 3.5.1 Pregrind Program



Fig. 3-8: After finishing the pregrind program

While the pregrind program is running, the lower part of the display shows „PREGRINDING ACTIVE“. The mixing process is interrupted after the pregrind program has ended and the display shows the following prompt (Fig. 3-8).

The user has now the option of detaching the UNGUATOR® Mixing System from the oscillation arm and the bayonet receptor and removing it by pulling it downward. Pregrinding results can be

checked by opening the UNGUATOR® Jar Lid. Depending on the result of the quality check, either the mixing process can be continued, the pregrind program run through once more, or the mixing process terminated.

Hit the “ok” button to continue the mixing process. The oscillation arm will automatically move into its starting position. The remaining formulation constituents can now be



weighed in, the UNGUATOR® Jar closed tight again and the UNGUATOR® Mixing System screwed into the oscillation arm. Then restart the mixing process by hitting the “ok” button.

The “+” button can be pressed to re-run the pregrind program. The oscillation arm will automatically move into its starting position. The UNGUATOR® Jar needs to be re-closed and the UNGUATOR® Mixing System screwed into the oscillation arm. Confirm pregrind program restart by hitting the “ok” button. The user will again see the prompt shown in Fig. 3-8 on the display after the pregrind program has finished.

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

### **3.5.2 Number of Strokes**

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

### **3.5.3 Mixing Time**

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

### **3.5.4 Minimum Mixing Times for the “DIRECT” and “MANUAL” Programs**

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

Type of formulation	Size of the UNGUATOR® Jar				
	15 to 20 ml	30 to 100 ml	200 to 300 ml	500 ml	1000 ml
Emulsion / +	01:30	02:00	03:00	04:00	04:45
Normal	01:00	01:30	02:30	03:30	04:15
Suspension < / > 2 %	02:00	02:30	04:00	05:00	06:00
Suppositories	01:00	01:30	02:45	03:30	04:15

*Tabella 3-4: 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	1000 ml
Emulsion / +	03:10	04:10	06:45	08:15	09:45
Normal	02:10	03:10	05:45	07:15	08:45
Suspension < / > 2 %	04:10	05:15	08:15	10:20	12:25
Suppositories	02:10	03:10	05:45	07:15	08:45
Gel	25 min 6 times 10 strokes each with 5 breaks á 04:30 at 1750 rpm				

*Tabella 3-5: 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	1000 ml
Emulsion / +	10:10	13:30	22:00	27:00	31:45
Normal	06:45	10:10	18:40	23:45	28:25
Suspension < / > 2 %	13:30	16:55	27:00	33:45	40:40
Suppositories	06:45	10:10	18:40	23:45	28:25

*Tabella 3-6: Minimum values for mixing time at speed step 1 in min:sec*

### 3.5.5 Selecting UNGUATOR® Jar Size

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

### 3.5.6 “Esc” Button

The mixing process will be aborted when the “Esc” button is pressed. Further action is shown on the display.

The UNGUATOR® 2100 will either return to the previous menu return to the previous line when the “Esc” button has been pressed.



### 3.5.7 Pressing Buttons

Both the UNGUATOR® 2100 software and hardware has been designed so that any button may be pressed at any time without damaging any UNGUATOR® 2100 component.

### 3.5.8 Identification Number

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

The first two digits represent the type of ointment:

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

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

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

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

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

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

00 = no pasting program
01 = 1 pasting program run through
02 = 2 pasting programs run through
etc.

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

0 = with interruption
1 = without interruption

For instance, the identification number 090504021 stands for a mixing process using the no. 04 manual mixing program with a 100 ml UNGUATOR® Jar, where two pasting programs were run and without interruption.

### 3.5.9 Operating Errors

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

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

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

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

The UNGUATOR® MB should not press too deeply into the UNGUATOR® Jar so that the oscillation arm can guide it up to the stop of the bayonet receptor. For this reason we recommend manually pulling up the UNGUATOR® MB as far as it will go after screwing in the UNGUATOR® Mixing System, if necessary.

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

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

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



shaft taper. The selection of the wrong UNGUATOR® MB can also cause this operating error, please see below.

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

Shortening of the stroke range by pushing up the UNGUATOR® Jar Bottom will change the selected size of the UNGUATOR® Jar for the UNGUATOR® 2100. The mixing process may now be started again by selecting the correct UNGUATOR® Jar size. The movable bottom does not have to be pushed up to execute the pregrind program.

If the material to be mixed is a paste, comes cold from the refrigerator or the UNGUATOR® MB has to penetrate a larger volume of not freely flowing solid substances such as zinc oxide or sulfur, then the elevated load might be greater than the mechanical switch-over counterforce. This means that the UNGUATOR® MB cannot make the stroke to its full height at the beginning of the mixing process and changes the stroke direction before it has reached the UNGUATOR® Jar Lid of the UNGUATOR® Jar Bottom. Here we recommend a manually assisted push up at the first full stroke when working with large UNGUATOR® Jars (500 and 1000 ml, possibly even 300 ml) or briefly heating up the material to be mixed in the microwave to reduce viscosity.

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

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

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

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

## 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].

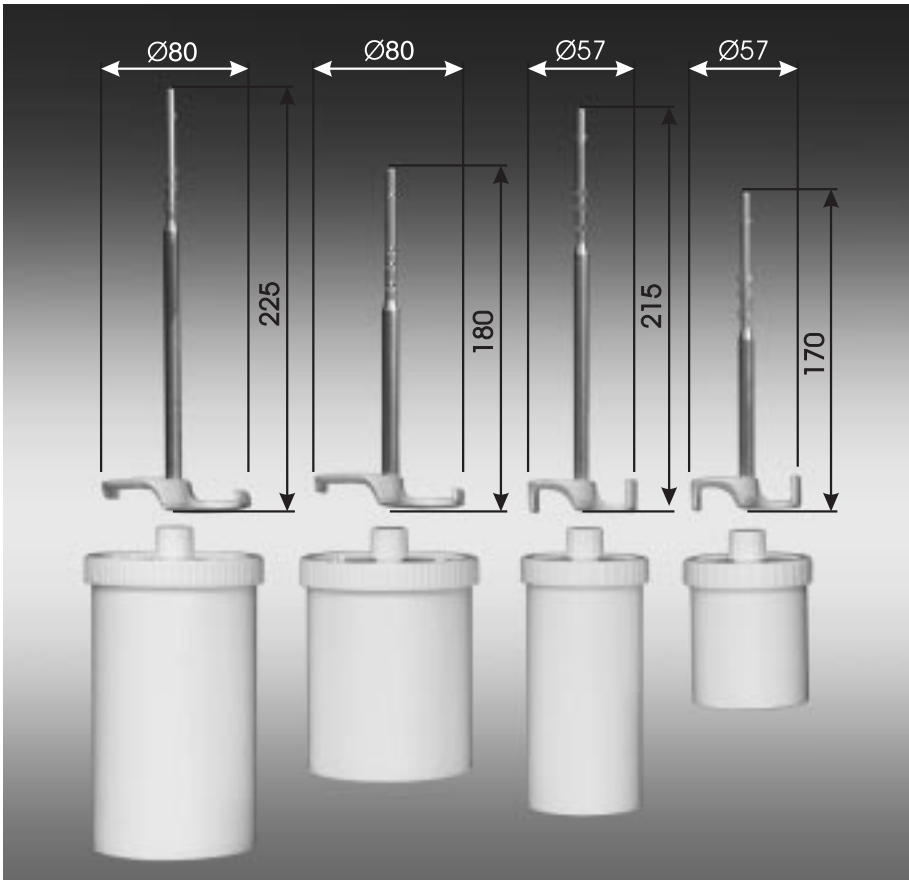
### 4.2 Notes on the Mixing Process

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.

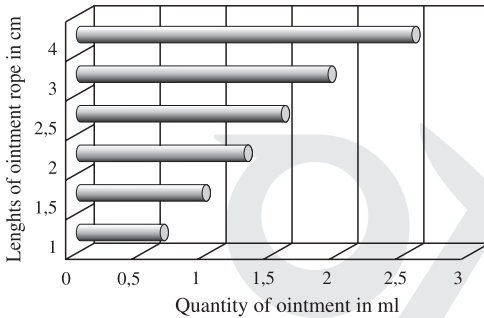
The user failed to diminish air again or to mount a UNGUATOR® Varionozzle or UNGUATOR® Applicator before dispensing. This will cause the user to first push the air out of the opening and the ointment will follow in a gush [1].

### **4.3 Notes on Dispensing Ointment**

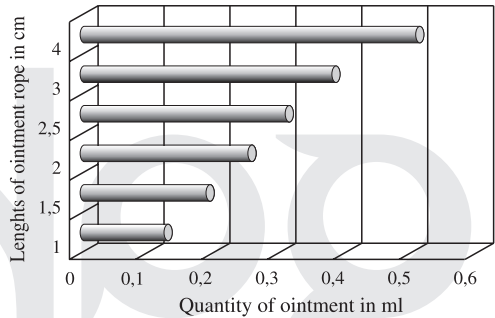
Each customer should be given specific dispensing instruction when being given ointment in an UNGUATOR® Jar. The use of the UNGUATOR® Spindle should be explained for large UNGUATOR® jars. Low-viscous ointments should be fitted with an UNGUATOR® Applicator or an UNGUATOR® varionozzle to reduce the dispensed 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.

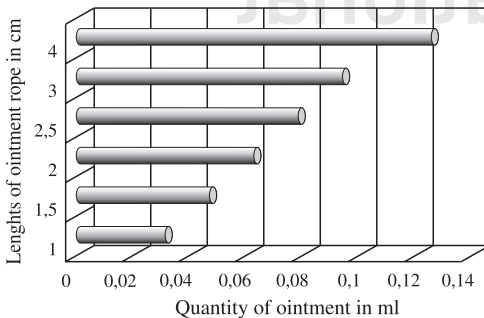
The diameter of the dispensing opening allows simple dosing of the quantity of ointment to be applied using approximate values. The dispensing openings in the screw lid of the UNGUATOR® Jars all have the same diameter. The Varionozzles or Applicators reduce the diameter to 4, 2 or 1 mm. The approximate values represented in the following diagrams may also be helpful when weighing-in concentrated active substances or regular comminutions from the UNGUATOR® Jar.



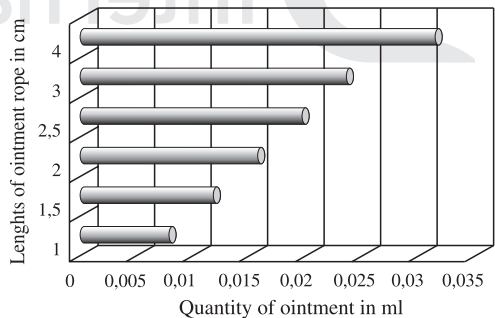
**Fig. 4-2:**  
*Opening of the UNGUATOR® Jar Lid*



**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.
- 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® 2100 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.



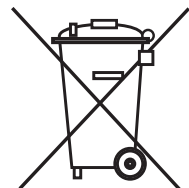
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## 7 Notes on Safety

- 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® 2100

Electrical requirement	90...265 V / 45...65 cps
Total power consumption	600 W
Power consumption (mixing motor)	550 W
Power consumption (lifting motor)	50 W
Operating mode	Continuous Operation S1
Safety class	I
Type of protection	IP 21
Speed controller	in 10 steps electronic controlled
Timer	program controlled
PC connection	USB - Standard B
Software	<a href="http://www.unguatorassist.com">www.unguatorassist.com</a>
UNGUATOR® Jar sizes	15 ... 1000 ml
Weight	36.75 lbs
Dimensions (L x W x H in mm)	356 x 221 x 642
Testing certifications	TÜV GS



# Manufacturer's Certificate

All **UNGUÄTOR®** 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 <sup>1)</sup>	Material <sup>2)</sup>	Color concentrate <sup>2)</sup>	
<b>UNGUÄTOR®</b> Jar <sup>3)</sup>		Standard	Cosmetic
<b>UNGUÄTOR®</b> Jar cap	Polypropylene, natural	white	colored
<b>UNGUÄTOR®</b> Jar lid	Polypropylene, natural	red, white, green, blue	colored
<b>UNGUÄTOR®</b> Jar housing	Polypropylene, natural	white	colored
<b>UNGUÄTOR®</b> Jar bottom	Polypropylene / Polyethylene	-	-
<b>UNGUÄTOR®</b> Jar bottom cap	Polypropylene, natural	white	white
Further <b>UNGUÄTOR®</b> line items			
<b>UNGUÄTOR®</b> Spindle	Polypropylene, natural	white	
<b>UNGUÄTOR®</b> Applicator <b>long</b> with cap	Polypropylene, natural	white	
<b>UNGUÄTOR®</b> Applicator <b>short</b> with cap	Polypropylene, natural	white	
<b>UNGUÄTOR®</b> Coupling	Polypropylene, natural	white	
<b>UNGUÄTOR®</b> Varionozzle blue, yellow, pink	Polypropylene, natural	blue, yellow, red	
<b>UNGUÄTOR®</b> SMB	Polyoxymethylene white	-	
<b>UNGUÄTOR®</b> 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

# GAKO

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# gako

International

GAKO International GmbH  
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D-80637 München  
Germany

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fax: +49 (0) 89 / 15 88 14 85  
email: [info@unguator.com](mailto:info@unguator.com)  
web: [www.unguator.com](http://www.unguator.com)

### 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® 2100

Date of purchase: \_\_\_\_\_

Ser. no.: \_\_\_\_\_

Stamp and signature:

gako  
International

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S|M|S

gako  
International



gako  
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