



SAMIX® U1000



Original Instruction Manual

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1 Basic comments

1.1 General specifications

The SAMIX® U1000 is manufactured by SAMIX GmbH, and its safety has been checked by the TÜV Rheinland.

For safe operation, and to avoid personal injuries and material damage,

- the instruction manual must be read carefully and understood,
- the instruction manual must always be available at the mixer and observed.

The current instruction manual describes the structure, operating principle, and handling of the SAMIX® U1000 mixer.

1.2 Intended use

The SAMIX® U1000 mixer is solely intended for the manufacture of pharmaceutical and cosmetic products.

1.3 Foreseeable misuse

The following usage is considered foreseeable misuse:

- operation of mixing blades without jar
- implementing the mixing process with the "Manual" program, whereby the shaft of the mixing blade is not properly engaged in the bayonet mount of the device
- no coaxial guidance of the jar to the device

1.4 Limits of operating range

SAMIX® devices are designed for operation in a normal room atmosphere. An ambient temperature of 15 - 30 °C and relative air humidity below 80% are recommended.

1.5 Manufacturer's warranty

As a customer, you also receive explicit warranty rights from the manufacturer with the enclosed manufacturer's warranty. Please note the details in the enclosed documentation.

1.6 Scope of delivery

Check your purchase for completeness immediately upon receipt. The scope of delivery includes:

- SAMIX® U1000
- Accessories
- Instruction manual

When checking for completeness, please also observe the information in the enclosed document "Installation Qualification (IQ)".

If there are parts missing or damaged, please contact the manufacturer.

1.7 Manufacturer's Customer Service

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98544 Zella Mehlis
Germany

www.samix.com
info@samix.com

Tel.: +49 3682 455 0
Fax: +49 3682 455 200

2 Safety

2.1 Structure of safety notices

The safety notices in this document are marked with safety symbols and designed in accordance with the SAFE principle. They contain information on the type and source of danger, possible consequences, as well as measures to prevent the danger.



DANGER

Warns against an accident which occurs when the instructions are not followed. The accident leads to serious, possibly life-threatening, injuries or death, for e.g. by touching high-voltage electrical units.



WARNING

Warns against an accident which occurs when the instructions are not followed. The accident leads to serious, possibly life-threatening, injuries or death, for e.g. by touching high-voltage electrical units.



CAUTION

Warns against an accident which occurs when the instructions are not followed. The accident may cause minor injuries, for e.g. burns, wounds, incisions or bruises.



ATTENTION

Warns against possible material damage.



NOTICE

Important general information.



NOTICE

Important information on environment protection.

2.2 General safety notices



WARNING

Risk of injury from rotating parts and during the automatic lifting function!

Do not touch rotating parts! Keep long hair, ties, scarves, etc., away from rotating parts and the lifting mechanism.

Only use mixing blades with the SAMIX® U1000 in jars or mixing bowls which have been firmly screwed in.

In the event of an emergency, immediately switch off the device using the power switch or disconnect the connector!



WARNING

Risk of injury from handling hazardous substances!

Do not operate SAMIX® devices in a dangerous atmosphere. Observe the relevant safety regulations when handling hazardous substances (for e.g. combustible liquids such as alcohol)!



WARNING

Risk of injury (Protective conductor resistance)

Do not replace the removable power cord by inadequately dimensioned power cords.



NOTICE

If the device has been disconnected from the mains while performing a mixing program, or the mixing process was mechanically interrupted, the mixing process has to be repeated. The mixing program is not continued after the interruption.

Also observe the following information in order to avoid material damage:

- Only connect SAMIX® devices to appropriately grounded sockets with 230 V or with country-specific nominal voltage which have been installed in accordance with DIN VDE 0100.
- Acclimatize the SAMIX® U1000 to room temperature for roughly 30 minutes before the initial operation or after a prolonged storage time in cold rooms.
- SAMIX® devices are designed for operation in a normal room atmosphere. Only operate the SAMIX® devices at an ambient temperature of 15 - 30 °C and relative humidity below 80%.
- Only operate the mixing blade in jars or mixing bowls which have been fastened with screws.
- Do not immerse SAMIX® devices in water.
- Only allow skilled electricians to install or remove electrical parts.



NOTICE

If SAMIX® devices are not used in accordance with this instruction manual or with products not supplied or recommended by the manufacturer, the warranty becomes null and void and the intended protection may be affected.

2.3 Safety devices

The SAMIX® U1000 has an electronic overload protection. If the device is overloaded, the current program stops. One of the fault messages "Mixing engine overload" or "Lifting engine overload" appears on the display.

3 Technical description

3.1 Technical data

Name	Value
Mains connection	100 - 240 V; 50 - 60 Hz
Overall power consumption	600 W
Power consumption (mixing engine)	550 W
Power consumption (lifting engine)	50 W
Type of operation	Continuous operation S1
Protection class	I
Protection type	IP X0
Adjusting knob	infinitely variable control (electronic) (120) 250 - 2500 rpm, 120 rpm only in the „Combination mix“ program as lowest speed
Time setting	program-controlled
PC connection	USB - Standard B
SAMIX® jar size	15 - 1000 ml (nominal volume)
Weight	16.7 kg
Dimensions (L x B x H in mm)	356 x 221 x 642
Conformity sign	CE sign

Tab. 1: Technical data

3.2 Product range

The SAMIX® product range includes:

- Standard mixing blade (SMB)
- Disposable blade (DSP)
- Jars
- Dosing aids (vario nozzles, applicators and ExactDose)
- Removal or filling aids (spindle, coupling and the SAMIX® jar pump with a nominal volume from 300 ml)

All SAMIX® products are compatible with each other.

3.2.1 Mixing blade

Due to the even upward and downward movement of the SAMIX® jar (see section „3.2.2 Jars“), a consistent mix of the substances is achieved with use of the mixing blade (SMB or DSP).



NOTICE

Do not use mixing blades which are bent or defective in any other way.

Wetting the SAMIX® jar and the SAMIX® mixing blade with an ointment base protects the plastic parts against abrasion and wear. Discoloration of the mixing blade is generally harmless.



NOTICE

Mixing blades cannot be placed in the microwave.

Cleaning the mixing blade



ATTENTION

Risk of material damage!

SAMIX® devices and products cannot be treated with sharp objects or abrasive cleaning agents.

1. First clean the mixing blade with cellulose.
2. Wash the mixing blade under hot water or in the dishwasher.

Standard mixing blade (SMB)

Standard mixing blades (see Fig. 1) are adjusted to the respective jar (see section „3.2.3 Assignment of mixing blades to the jars“).

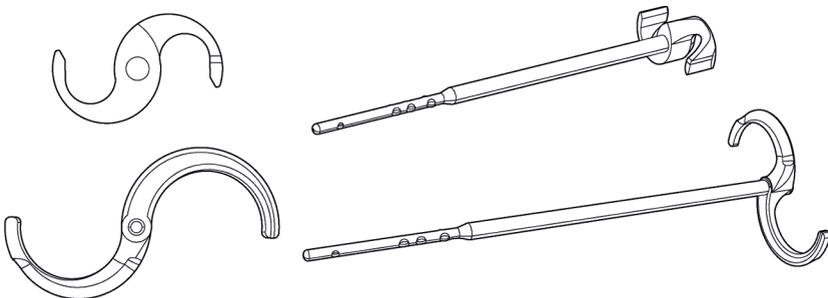


Fig. 1: Standard mixing blade (SMB)

Before use, check whether

- the mixing blade is the right length and size
- the mixing blade is clean. If necessary, disinfect the mixing blade (for e.g. with 70% isopropyl alcohol).

Disposable blade (DSP)



NOTICE

In the case of substances with strong colors, it is recommended to use the disposable blade.

Disposable blades (see Fig. 2) are adjusted to the respective jar (see section „3.2.3 Assignment of mixing blades to the jars“).

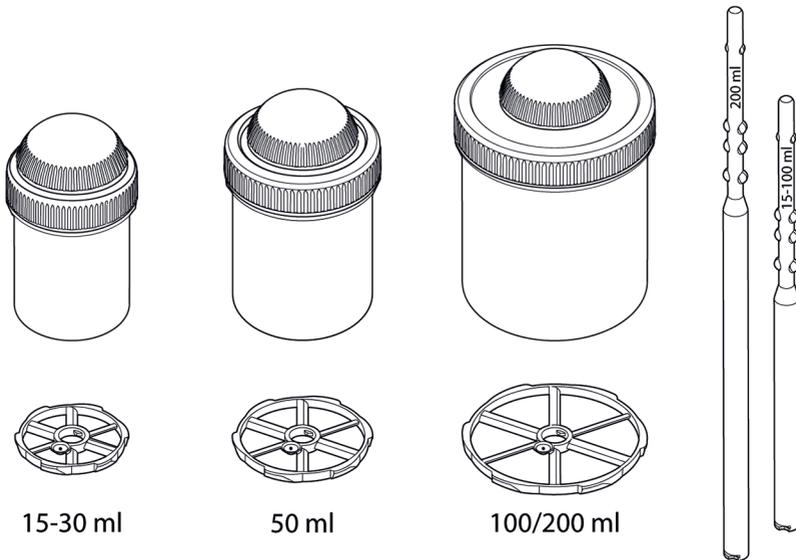


Fig. 2: Disposable blade (DSP): Overview

The DSP are supplied in dispensers, which allow individual removal with the shaft. Before the mixing process, apply gentle pressure to the mixing blade of the DSP and turn it in an anticlockwise direction with the shaft of the DSP.



NOTICE

Ensure correct orientation in accordance with Fig. 3. The injection point faces upwards, the slanted outer contours face downwards.

After the mixing process, the shaft of the DSP is disconnected from the mixing blade of the DSP by turning in a clockwise direction (see Fig. 3).

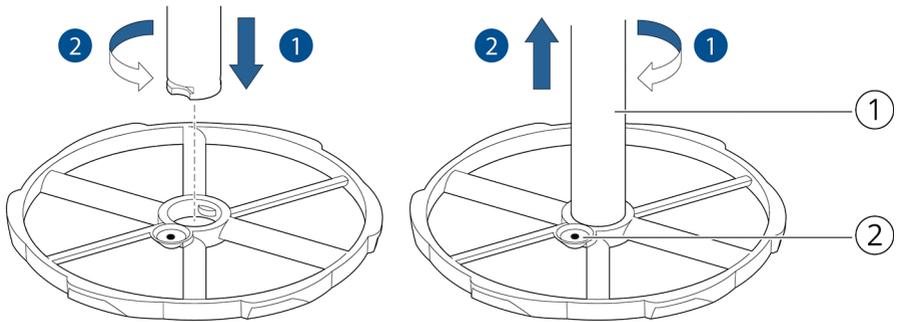


Fig. 3: Disposable blade (DSP): Assembly and disassembly

1 DSP shaft

2 Injection point



NOTICE

The cleaning is restricted to the shaft of the DSP.

3.2.2 Jars

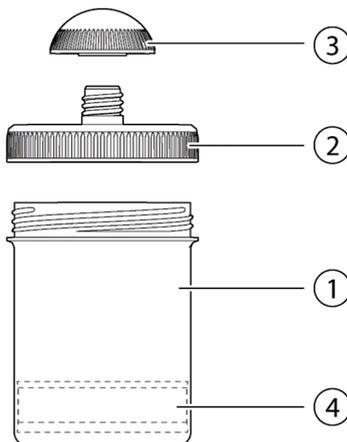


Fig. 4: Jar

1 Jar housing

3 Jar cap

2 Jar lid

4 Jar base (movable)

Jars (see Fig. 4) have a movable base and can be mixing and dispensing containers. The jar lid seals the jar without a loss of the active ingredients. As mixing containers, jars guarantee manufacture in the air-reduced mixing chamber free of evaporation and contamination. As dispensing containers, jars correspond to the quality assurance guideline of the German Chamber of Pharmacists. The small dispenser opening without an environmental contamination area guarantees the minimization of negative quality effects (for e.g. by finger germs) as required by § 13 ApBetrO for the dispensing of the ointment or cream from the jars.



NOTICE

A jar is a disposable container and cannot be rinsed before use. Otherwise, the inspected sterility is jeopardized.

SAMIX® jars are supplied in the following sizes:

Nominal volume (filling volume)	Nominal volume (filling volume)	Nominal volume (filling volume)
15 (28) ml	50 (70) ml	300 (390) ml
20 (33) ml	100 (140) ml	500 (600) ml
30 (42) ml	200 (280) ml	1000 (1250) ml

Tab. 2: Jar sizes

Jars are supplied sealed in a film sleeve.



NOTICE

Also after the beginning of the film sleeve it is recommended to store non-used jars in the film sleeve to protect against possible dust contamination.



NOTICE

SAMIX® jars are subject to regular checks in accordance with ZL packaging regulation DK II/94. An analysis certificate is issued after batch-defined inspections. The documentation of primary packaging material in the pharmacy includes the retention of the manufacturer's inspection certificate (analysis certificate) after a visual incoming test. This is adhered to the film sleeve containing the jars. It can be removed from the film sleeve and kept with the documentation.



NOTICE

SAMIX® jars are designed for one-off use. Multiple usage as a mixing container is not permitted for hygienic and technical reasons.

3.2.3 Assignment of mixing blades to the jars



NOTICE

An incorrect assignment of the mixing blades to the jars can trigger fault messages or mean that the incorrectly prepared mixing unit cannot be screwed into the oscillation arm.

Standard mixing blade (SMB)

Ensure correct assignment of the mixing blades to the corresponding jars. The SMB for jars with a nominal volume of 100, 200, 300 and 500 ml have the same diameter of the mixing blade, but differ in the length of the shaft (see Fig. 5).

Disposable blade (DSP)

There are also different shaft lengths for DSP. The two available DSP shafts are marked for the use of jars with a nominal volume between 15 and 100 ml or 200 ml, and must be combined with the respective DSP. For jars with a nominal volume of 100 and 200 ml, the same DSP are used but with different shafts.



NOTICE

Also observe the operating instructions enclosed with the mixing blade shafts.

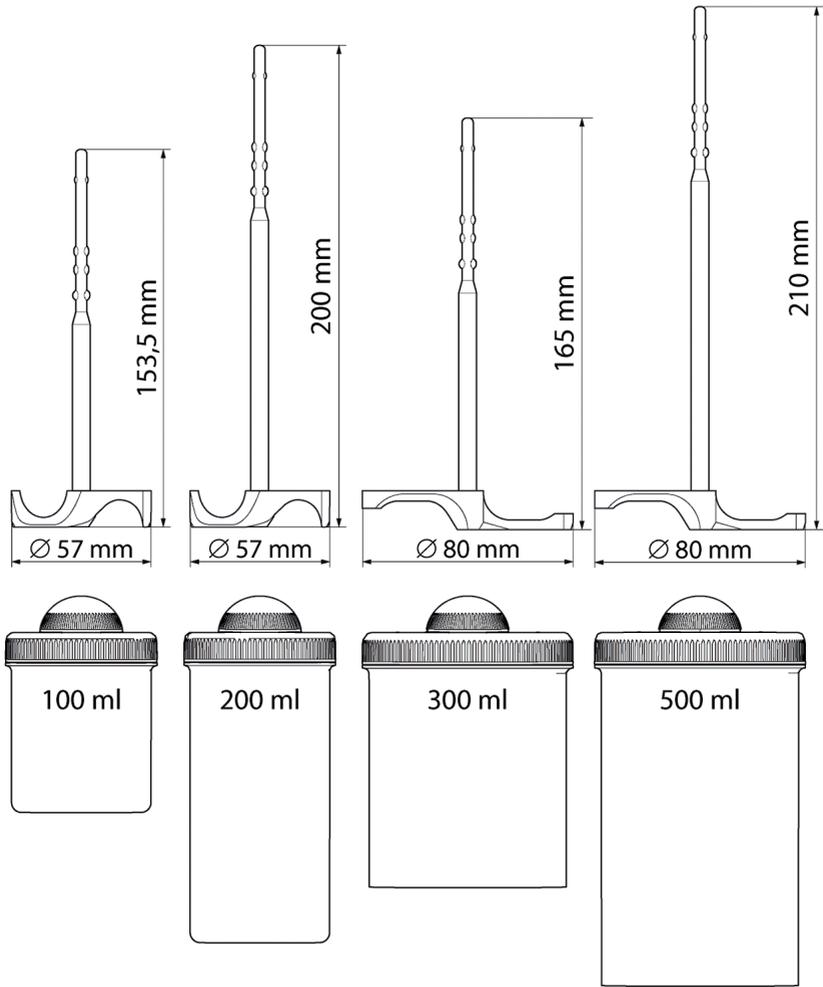


Fig. 5: Assignment of the standard mixing blade with different shaft lengths

4 Transportation, packaging and storage

4.1 Transportation



CAUTION

Risk of crushing when lifting and transporting the SAMIX® U1000.

It is recommended to call on the assistance of a second person when lifting and transporting the SAMIX® U1000.

The SAMIX® U1000 is sent in a cardboard box.

4.2 Packaging

Store the packaging (cardboard box and inserts) in case you have to send in the SAMIX® U1000.

4.3 Storage

Protect the SAMIX® U1000 against direct sunlight, extreme humidity and huge temperature fluctuations.

Store the SAMIX® U1000 at an ambient temperature between +15 °C and +30 °C and relative humidity below 80%.

5 Initial operation



CAUTION

Risk of crushing when lifting and transporting the SAMIX® U1000.

It is recommended to call on the assistance of a second person when lifting and transporting the SAMIX® U1000.

5.1 Site selection

Choose a suitable location for the SAMIX® U1000. Observe the following information:

- Position the SAMIX® U1000 on steady, even ground.
- Ensure that there is enough space for the operation of the SAMIX® U1000. The power switch and mains connector must be easily accessible.
- SAMIX® devices satisfy the safety standards for laboratory equipment. Choose a location for the device which prevents handling by unauthorized people.
- Ensure good ventilation in the area of the SAMIX® U1000.
- Choose a location away from the direct air flow of air conditioning systems, heaters, open windows, or fans.
- Protect the SAMIX® U1000 against direct sunlight, extreme humidity (max. 80%), and high temperature fluctuations. An ambient temperature between +15 °C and +30 °C is recommended.
- Keep the SAMIX® U1000 clean, dry, and dust-free.



NOTICE

When checking for suitable erection conditions, please also observe the information in the enclosed document "Installation Qualification (IQ)".

5.2 Initial operation



ATTENTION

Risk of material damage from condensation inside the device!

Acclimatize the SAMIX® U1000 to room temperature for roughly 30 minutes before the initial operation, in the case of low temperatures, or after a prolonged storage time in cold rooms.

1. Check the supply connections. Observe the information in the enclosed document "Installation Qualification (IQ)".



CAUTION

Risk of injury from unexpected startup of the device!

Before connecting the SAMIX® U1000, check that the power switch at the pedestal is switched off on the right side of the device.

The interfaces for the power cord and a USB cable are located on the back of the SAMIX® U1000.

2. Connect the power cord to the SAMIX® U1000.
3. Connect the power cord to the socket.
4. If necessary, connect the USB cable to a PC.

The device is now ready for operation.



NOTICE

In the event of an emergency, the SAMIX® U1000 can be shut down by switching off the device with the power switch or disconnecting the power cord from the socket.

5.3 Function check

Perform a function check in accordance with the details under "Function check or initial operation" in the enclosed document "Installation Qualification (IQ)".



NOTICE

The operation of the SAMIX® U1000 using the control panel and display is described in detail in chapter „6 Operation“.

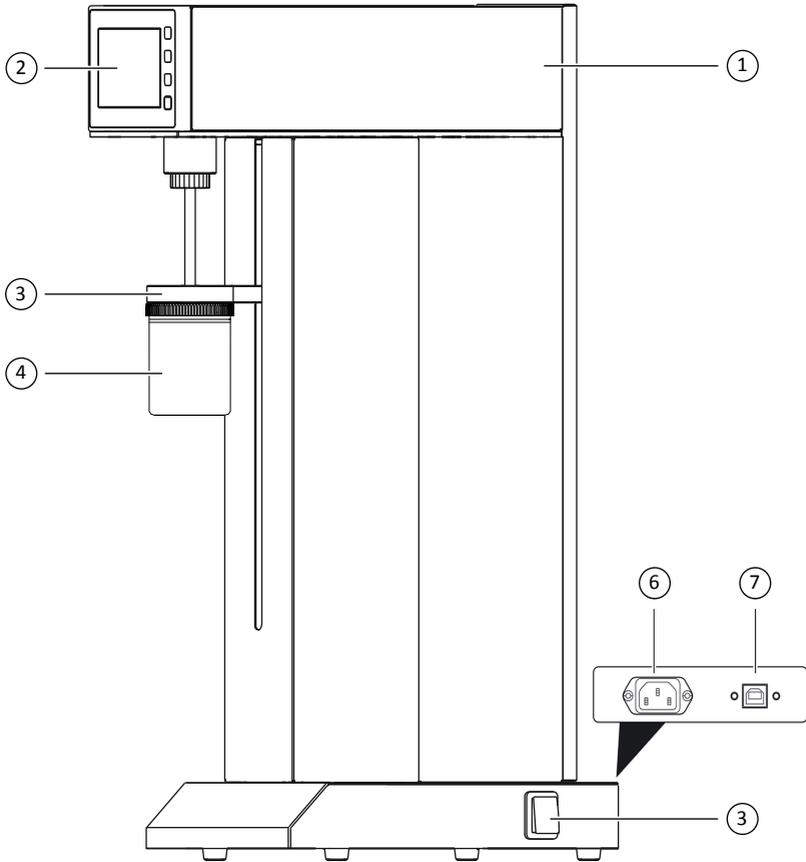


Fig. 6: SAMIX® U1000

- | | | | |
|---|---------------------------|---|------------------|
| 1 | Drive head | 5 | Power switch |
| 2 | Control panel and display | 6 | Mains connection |
| 3 | Oscillation arm | 7 | USB connection |
| 4 | Mixing unit | | |

6 Operation

6.1 Control panel and display

Menu guidance

For manual control of the SAMIX® U1000, there is a display and control panel with the four buttons "ESC", "-", "+", and "OK" on the front of the device.

The menu guidance using the display is effected using the buttons on the control panel.

Button	Function
ESC	Return to the previous screen
+ / -	Selection of individual menu items
OK	Confirmation of a selection and switch to the next screen

Tab. 3: Functions of buttons on control panel

Start screen

After switching on the SAMIX® U1000 with the power switch, the start screen appears on the display. Here the current number of preparations and the version of the software stored on the microprocessor are displayed.



Fig. 7: Control panel and display with start screen

Language menu

Switch from the start screen to the language menu by pressing the "ESC" button.

In the language menu you can switch to the next or previous language setting using the "+" or "-" buttons.



Fig. 8: Language menu

Return to the start screen by confirming the selection with "OK".



NOTICE

Further operation of the SAMIX® U1000 using the control panel and display for the mixing process is described in section „6.4 The mixing process“.

6.2 Preparation of mixing unit

A SAMIX® mixing unit consists of

- jar,
- mixing blade,
- the components to be mixed.

Prepare the mixing unit for the mixing process as follows:

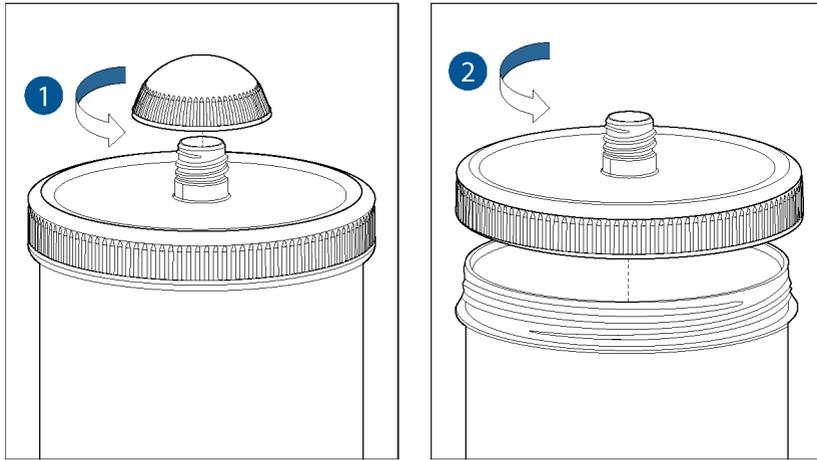


Fig. 9: Unscrew jar cap and jar lid



NOTICE

Observe the correct assignment of the mixing blades to the jars (see section „3.2.3 Assignment of mixing blades to the jars“).



NOTICE

Ensure you do not break the sealing lip of the jar lid opening with the noses of the mixing blade shaft when inserting the mixing blade in the jar lid. Otherwise, ointment elements (mainly liquid) may draw up at the shaft of the mixing blade during the mixing process.

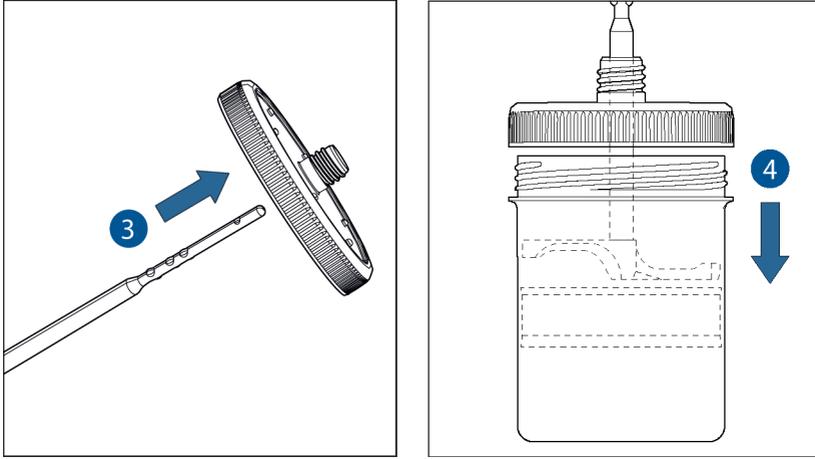


Fig. 10: Insert mixing blade and press down jar base



NOTICE

Press down the base of the jar before weighing in ingredients or filling as far as the stop. Otherwise, you cannot necessarily place elements (especially particularly light components) in the jar.

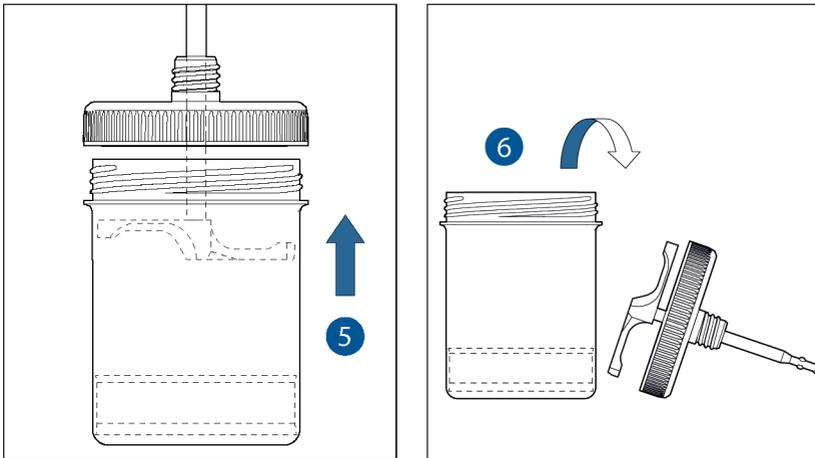


Fig. 11: Remove jar lid with mixing blade and set down

You can now weigh in the recipe components in the jar.

6.3 Preparation of mixing process

Proceed as follows after weighing in the recipe components:

1. Gently screw the mixing blade and the jar lid on the jar housing.
2. Push the jar base upwards using your thumbs so that air escapes between the jar lid and jar housing.

With this air reduction, any overpressure in the jar is released and the escaping of the ointment at the sealing areas of the jar during the mixing process is prevented. The mixing result is also optimized by avoiding air pockets.



NOTICE

If the air is not released from the jar, an air column forms on the inside when mixing the ointment, meaning the mixing blade cannot clean itself. In this case, unmixed components may remain adhered to the mixing blade.

3. Firmly screw down the mixing unit.



NOTICE

Screw the jar lid onto the jar. If the jar lid is screwed on at an angle, the mixing blade tilts upon automatic entry into the bayonet guide.



NOTICE

When incorporating large powder amounts, it is recommended to repeat the air release after approximately 15 seconds of mixing.

6.4 The mixing process

6.4.1 Switching on, selecting the preparation

Switching on the SAMIX® U1000

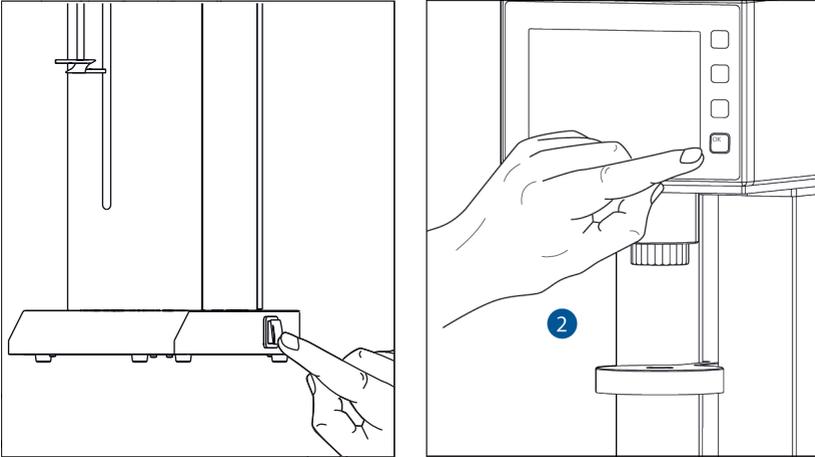


Fig. 12: Switch on the SAMIX® U1000 using the power switch and press "OK"

The main menu "Select mix type" appears on the display with the following programs (see Fig. 13):

- 7 standard recipe programs: Emulsion +, Emulsion, Normal, Suspension <2%, Suspension >2%, Gel, Suppositories
- "Direct" program
- "Combination mix" program
- "Manual" program

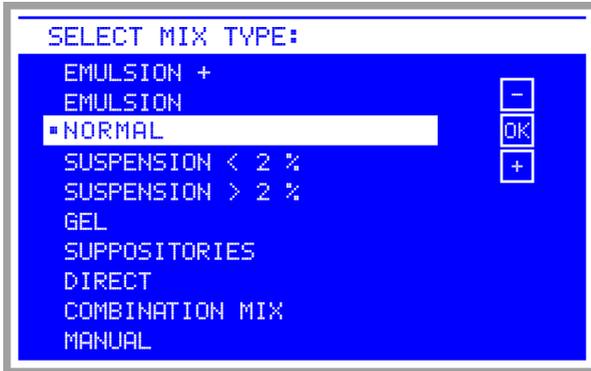


Fig. 13: "Select mix type" main menu

Select program

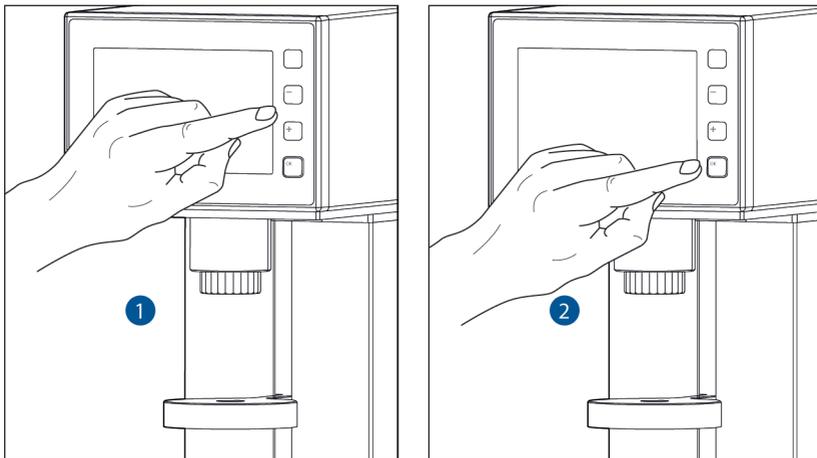


Fig. 14: Define the type of preparation using "-" and "+" and confirm selection with "OK"

6.4.2 Mixing process for standard recipe programs

After selecting one of the 7 standard recipe programs for the mixing process, the "Select jar size" menu appears on the display.

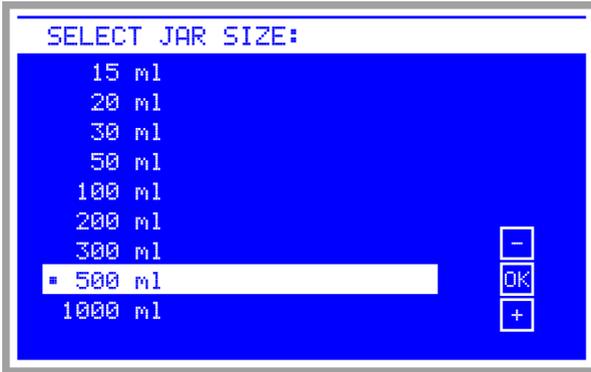


Fig. 15: "Select jar size" menu



NOTICE

Ensure that the selection of the jar size via the display corresponds to the actual size of the jar used.

Using the "-" and "+" buttons select the size of the jar for the mixing process and confirm the selection with "OK".

The oscillation arm automatically moves to the start position. The following screen is shown on the display:

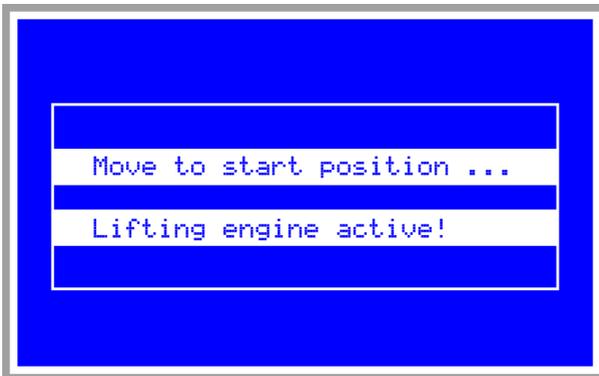


Fig. 16: "Move to start position" screen

Now mount the mixing unit. Proceed as follows:

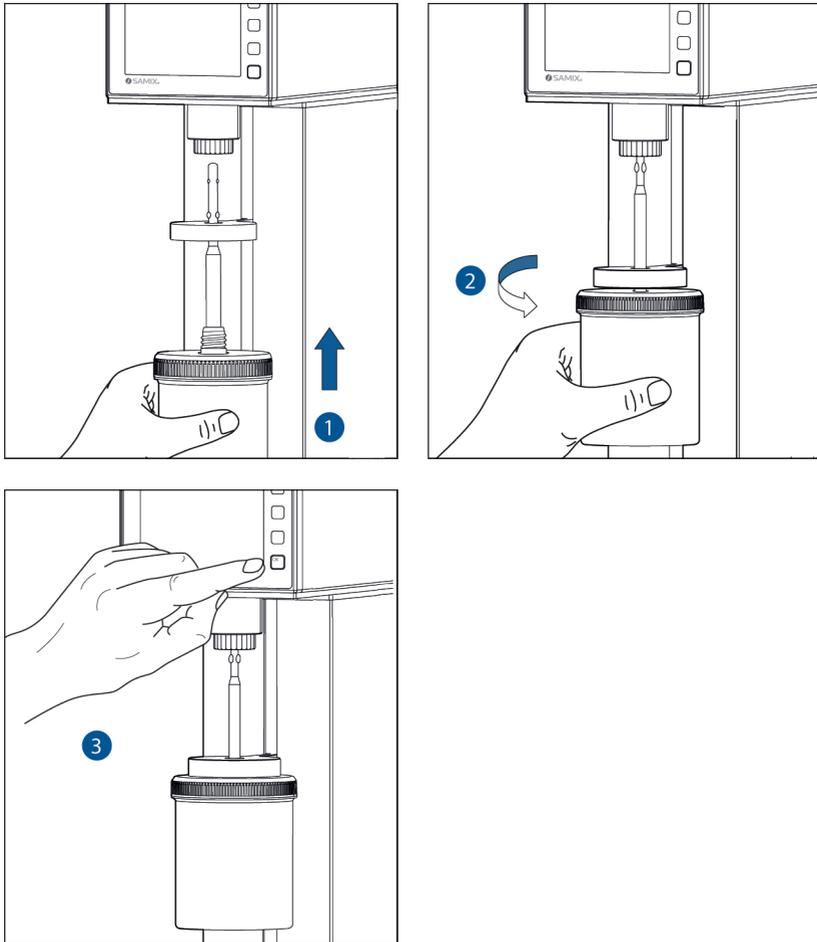


Fig. 17: Mount the mixing unit at the oscillation arm and start the mixing process using "OK"

The oscillation arm is automatically moved up and the bayonet mount grips the mixing blade. The mixing process begins and the recipe is automatically mixed according to the programmed specifications for the preparation (mixing time, speed of mixing engine, speed of lifting engine).



NOTICE

If the mixing unit was not secured at the oscillation arm or was secured incorrectly, a fault message appears („8.2 Fault messages“).

During the mixing process the time left of the respective mixing program level is shown on the display in minutes and seconds, and the current speed of the mixing engine is also shown as a percentage (see Fig. 18). A progress bar also shows the time of the entire mixing process.

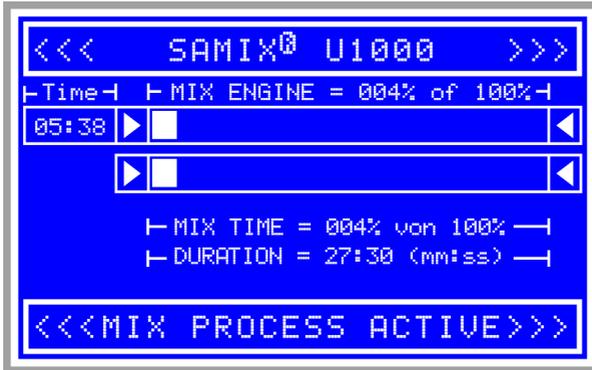


Fig. 18: "Mix process active" screen

i NOTICE
 You can interrupt the mixing process by pressing the "ESC" button.

After the mixing time has lapsed, the SAMIX® U1000 automatically performs the so-called "free spin motion". The mixing blade is cleaned of ointment to the greatest possible extent by this high-speed rotation.

The mixing process is completed after the free spin motion. The mixing process data is shown on the display.

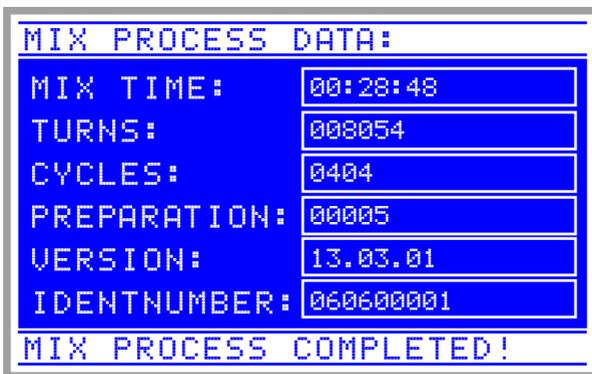


Fig. 19: "Mix process data" screen

You can now remove the mixing unit and if necessary switch off the SAMIX® U1000 (see section „6.5 Switching off and removing the mixing unit“).

6.4.3 Mixing process in "Direct" program

After selecting the "Direct" program for the mixing process, the "Select jar size" menu appears on the display.

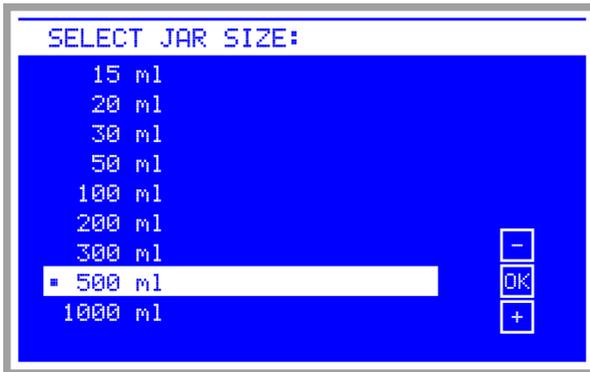


Fig. 20: "Select jar size" menu



NOTICE

Ensure that the selection of the jar size via the display corresponds to the actual size of the jar used.

- Using the "-" and "+" buttons select the size of the jar for the mixing process and confirm the selection with "OK".

The "Direct preparation" menu appears on the display.



Fig. 21: "Direct preparation" menu

- In the "Direct preparation" menu select the speed setting of the lifting engine using the "-" and "+" buttons and confirm the selection with "OK".



NOTICE

The lifting engine has the speed settings 01 (3600 rpm) and 00 (0000 rpm).

Upon selection of the speed setting "00", the automated arm movement is suspended. The oscillation arm is moved to the lowermost position before the start of the mixing process, thus enabling manual lifting.

Manual lifting is only intended for jars with a nominal volume up to 200 ml.

3. In the "Direct preparation" menu select a speed setting for the mixing engine of the mixing blade using the "-" and "+" buttons and confirm the selection with "OK".



NOTICE

Depending on the size of the jar, you can choose between up to 10 different speed settings for the mixing engine.

4. In the "Direct preparation" menu define the mixing time for the mixing process using the "-" and "+" buttons and confirm the selection with "OK".



NOTICE

The mixing time can be set between 10 seconds and 2 hours.

The oscillation arm automatically moves to the start position for one of the two options:

- Mixing with automatic lifting
- Mixing with manual lifting

Mixing with automatic lifting

Mount the mixing unit as follows for mixing with automatic lifting:

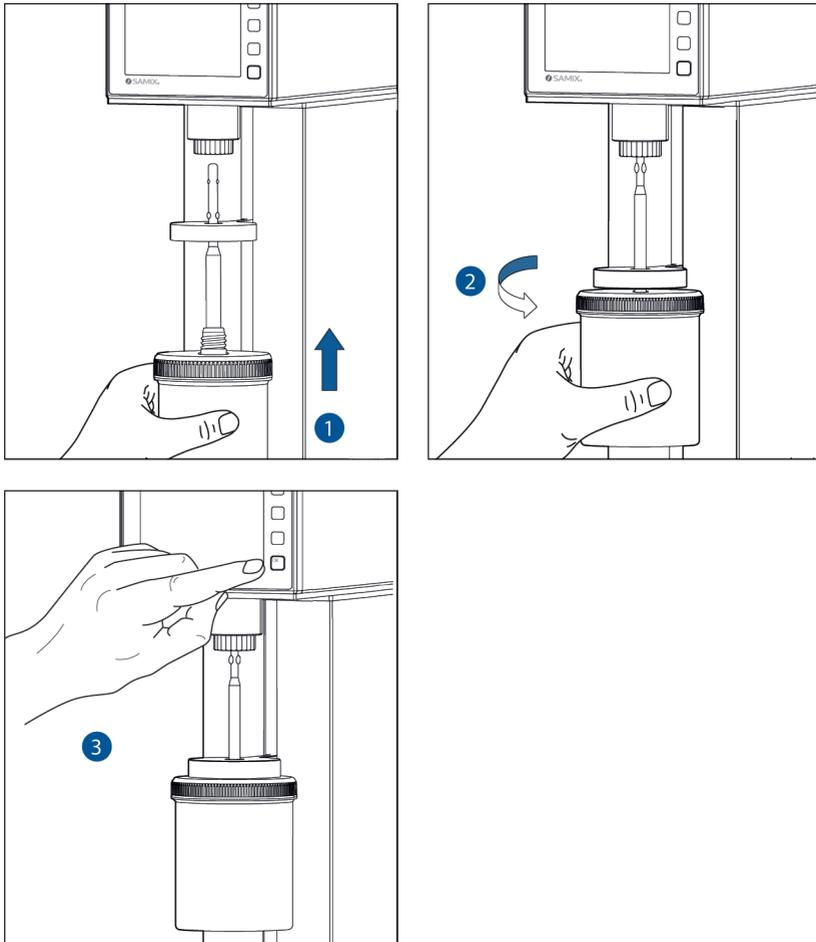


Fig. 22: Mount the mixing unit at the oscillation arm and start the mixing process using "OK"

The oscillation arm is automatically moved up and the bayonet mount grips the mixing blade. The mixing process begins and the recipe is automatically mixed according to the programmed specifications for the preparation (mixing time, speed of mixing engine, speed of lifting engine).



NOTICE

If the mixing unit was not secured at the oscillation arm or was secured incorrectly, a fault message appears („8.2 Fault messages“).

During the mixing process the time left and the current speed of the mixing engine are shown on the display (see Fig. 23).

i NOTICE
 The speed setting of the mixing engine and the mixing time can also be changed during the mixing process using the "-" and "+" buttons (see Fig. 23). Confirm the change of the corresponding mixing parameter using the "OK" button.



Fig. 23: "Change mixing parameters" screen

i NOTICE
 You can interrupt the mixing process by pressing the "ESC" button.

After the mixing time has lapsed, the SAMIX® U1000 automatically performs the so-called "free spin motion". The mixing blade is cleaned of ointment to the greatest possible extent by this high-speed rotation.

The mixing process is completed after the free spin motion.

The mixing process data is shown on the display (see Fig. 19).

You can now remove the mixing unit and if necessary switch off the SAMIX® U1000 (see section „6.5 Switching off and removing the mixing unit“).

Mixing with manual lifting

Mount the mixing unit as follows for mixing with manual lifting:



CAUTION

Risk of injury from unsteady holding of mixing unit during the mixing process!
Firmly hold the mixing unit with at least one hand during the entire mixing period.



ATTENTION

Risk of material damage!

In order to avoid a destruction of the hollow shaft, the SAMIX® mixing blade shaft must be inserted fully in the device. The bayonet noses can no longer be visible, only the gold-colored coating.



NOTICE

Manual lifting is only intended for jar sizes up to 200 ml.

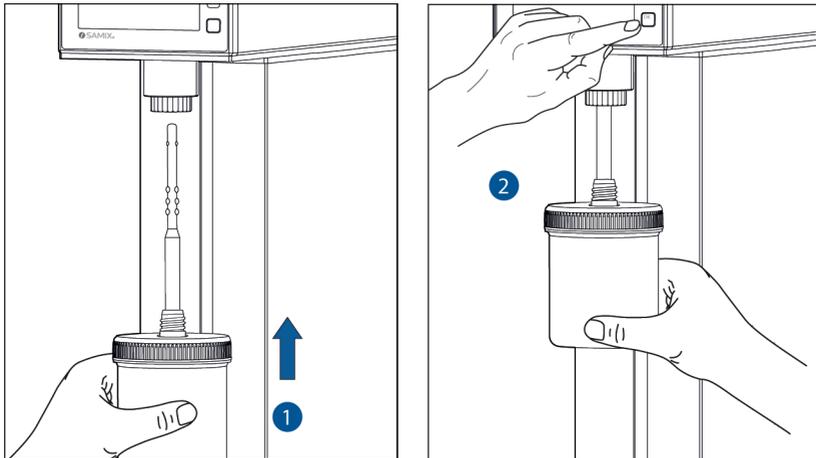


Fig. 24: Mount the mixing unit and start the mixing process using "OK"

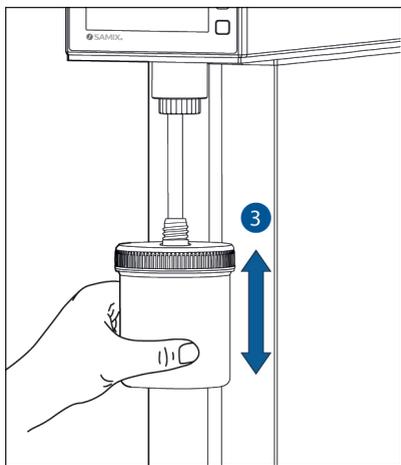


Fig. 25: Guide the jar up and down



NOTICE

The bayonet mount takes effect by pressing the "OK" button. This status remains until the end of the mixing process.

The recipe is automatically mixed for the defined period at the set speed.

During the mixing process the time left and the current speed of the mixing engine are shown on the display (see Fig. 26).



Fig. 26: "Mix process active" screen

**NOTICE**

The speed setting of the mixing engine and the mixing time can also be changed during the mixing process using the "-" and "+" buttons (see Fig. 23). Confirm the change of the corresponding mixing parameter using the "OK" button.

**NOTICE**

You can interrupt the mixing process by pressing the "ESC" button.

**NOTICE**

In order to achieve an optimal mixing result, you should perform at least 50 strokes. The required mixing time increases with the size of the jar.

The "Process finished" screen is shown.

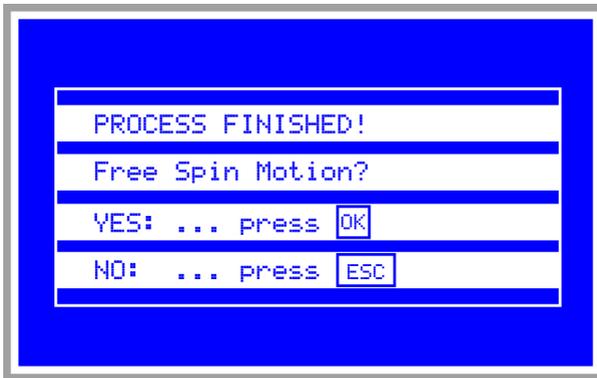


Fig. 27: "Process finished" screen

**CAUTION**

Risk of injury from unsteady holding of mixing unit during the free spin motion!
Firmly hold the mixing unit with at least one hand during the free spin motion.

You can now:

- perform the free spin motion program by pressing the "OK" button
- end the mixing process without a free spin motion by pressing the "ESC" button

During the so-called "free spin motion", the mixing blade is cleaned of ointment to the greatest possible extent by high-speed rotation.

The mixing process data is shown on the display after the mixing process is completed (see Fig. 28).

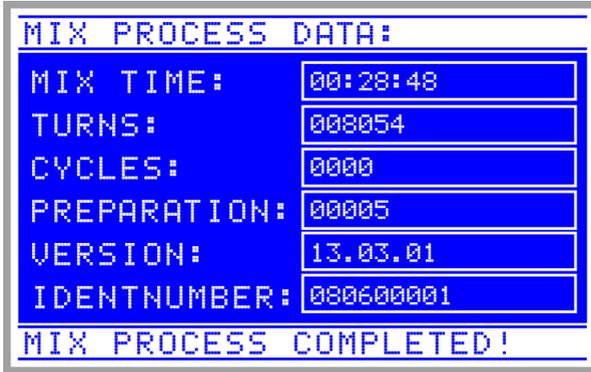


Fig. 28: "Mix process data" screen

Remove the mixing unit after the mixing process is completed:

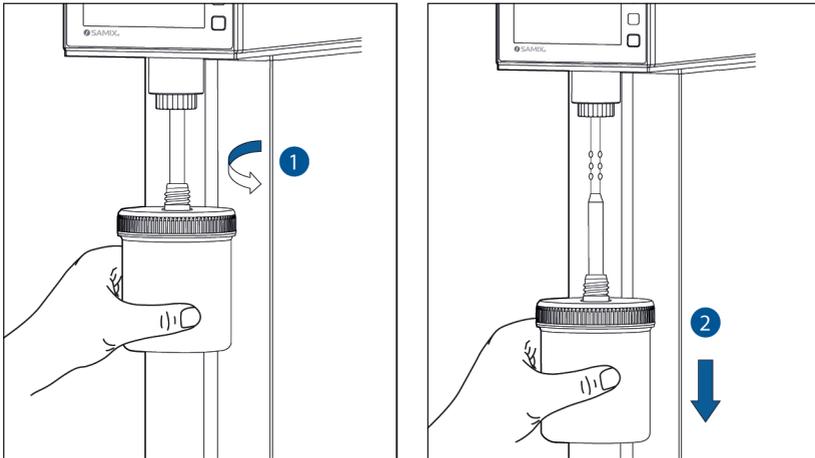


Fig. 29: Remove mixing unit

Press the "OK" button to return to the start screen and if necessary switch off the power switch.



NOTICE

In the event of a prolonged period of non-usage, it is recommended to switch off the SAMIX® U1000.

6.4.4 Mixing process in "Combination mix" program

The "Combination mix" program is used to accelerate a dissolution process or a chemical reaction in a medium with constantly good flow properties, and is effected without a lifting movement of the mixing unit.

The mixing unit for the "Combination mix" program consists of

- mixing bowl
- jar lid of jar with nominal volume of 1000 ml,
- a mixing blade suitable for the mixing bowl,
- the components to be mixed.



NOTICE

Note that the outer diameter of the mixing blade must be smaller than the inner diameter of the mixing bowl.

After selecting the "Combination mix" program for the mixing process, the oscillation arm automatically moves to the lowermost position.

Now mount the mixing unit:



NOTE

Ensure that there is no mixing blade in the bayonet mount.

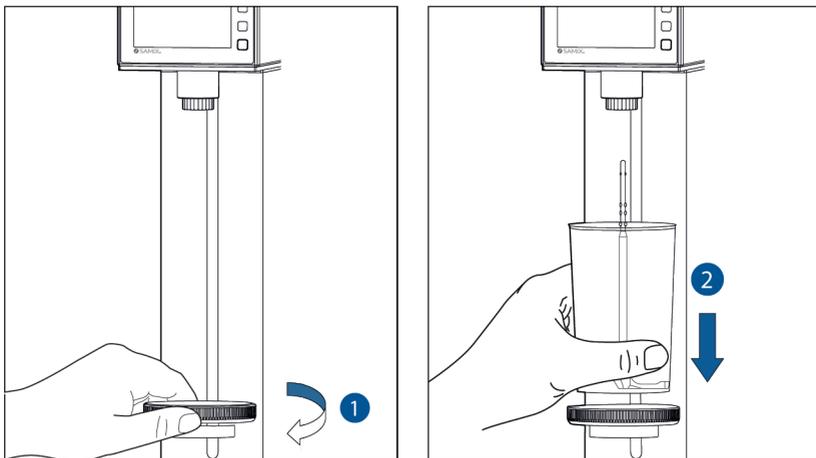


Fig. 30: Screw the jar lid on to the oscillation arm and position mixing bowl with mixing blade



ATTENTION

Risk of material damage!

In order to avoid a destruction of the hollow shaft, the SAMIX® mixing blade shaft must be inserted fully in the device. The bayonet noses can no longer be visible, only the gold-colored coating.

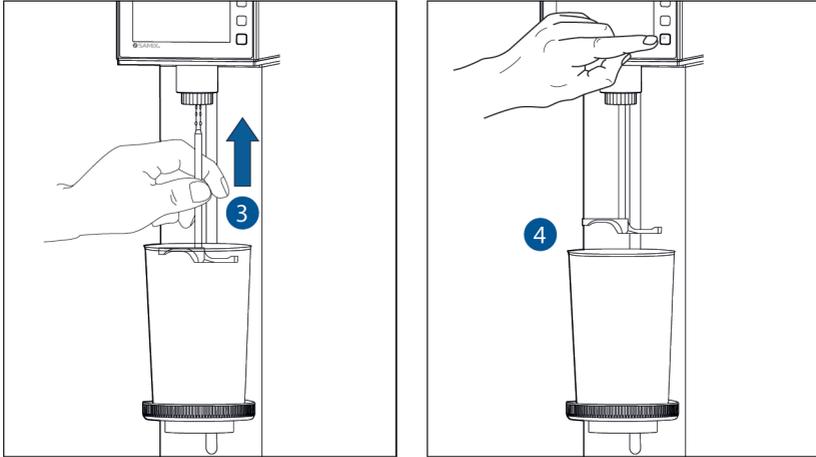


Fig. 31: Mount mixing blade and confirm assembly with "OK"



NOTICE

Push the mixing blade as far as the stop in the bayonet holder and turn it in clockwise direction until it engages.

The mixing blade may fall from the bayonet mount upon gentle contact.

The "Move oscillation arm to mix position" screen appears.

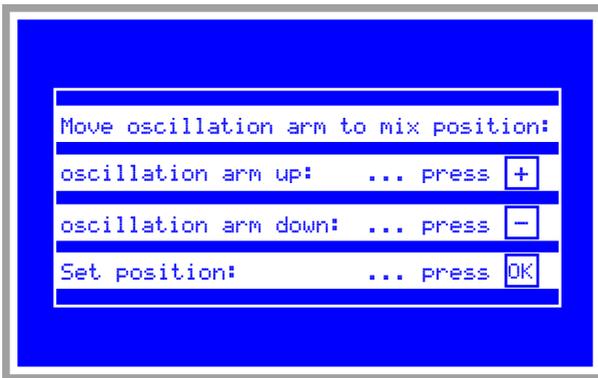


Fig. 32: "Move oscillation arm to mix position" screen

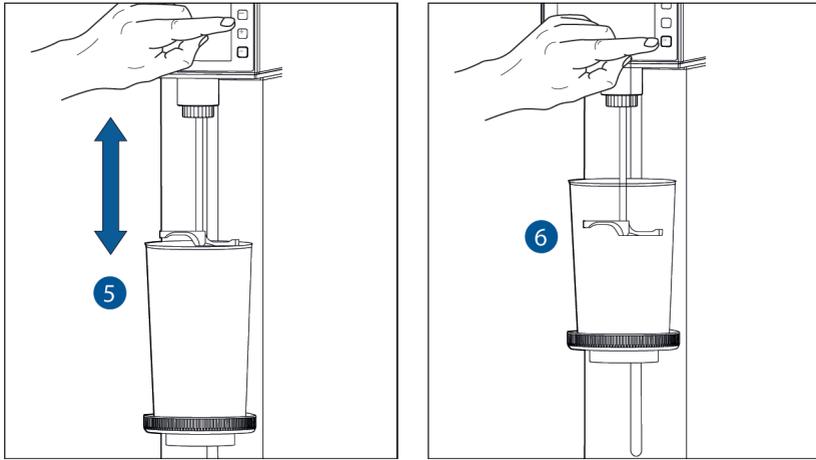


Fig. 33: Move oscillation arm to mixing position with "-" / "+"; confirm mixing position with "OK"

The "Parameters" menu appears on the display.



Fig. 34: "Parameters" screen - Select mixing speed

Define the mixing parameters "Mixing speed" and "Mixing time" as follows:

1. In the "Parameters" menu select the speed setting of the mixing blade using the "-" and "+" buttons and confirm the selection with "OK".



NOTICE

You can choose speeds between 120 and 600 rpm in increments of 12 rpm.

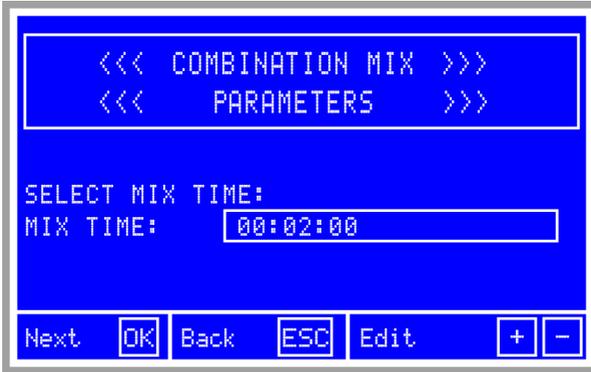


Fig. 35: "Parameters" screen - Select mixing time

2. Using the "-" and "+" buttons specify the mixing time for the mixing process and confirm the selection with "OK".



NOTICE

The mixing time can be set between 2 minutes and 2 hours.

The mixing process starts.

During the mixing process the time left and the current speed of the mixing engine are shown on the display (see Fig. 36).



Fig. 36: "Combination mix active" screen

**NOTICE**

You can interrupt the mixing process by pressing the "ESC" button.

After the mixing process is completed, the "Move oscillation arm to unmount" menu is shown on the display.

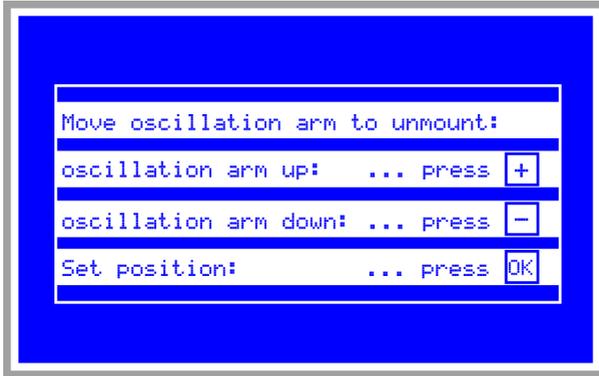


Fig. 37: "Move oscillation arm to unmount" screen

Remove the mixing unit after the mixing process is completed:

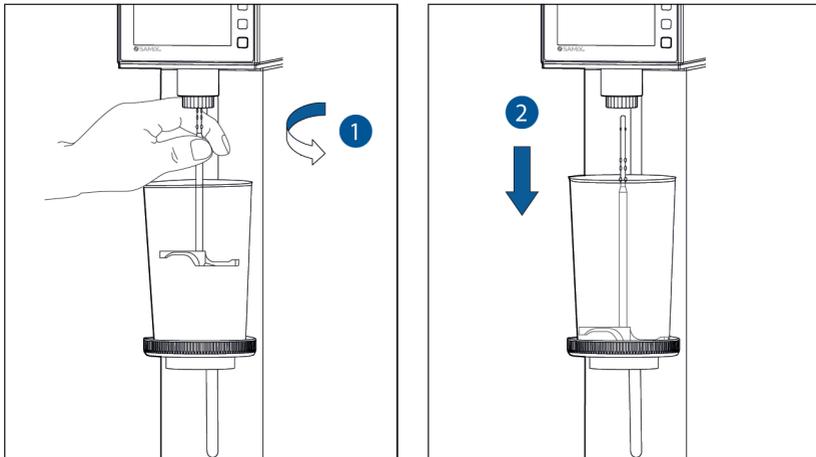


Fig. 38: Loosen mixing blade from bayonet mount and place in mixing bowl

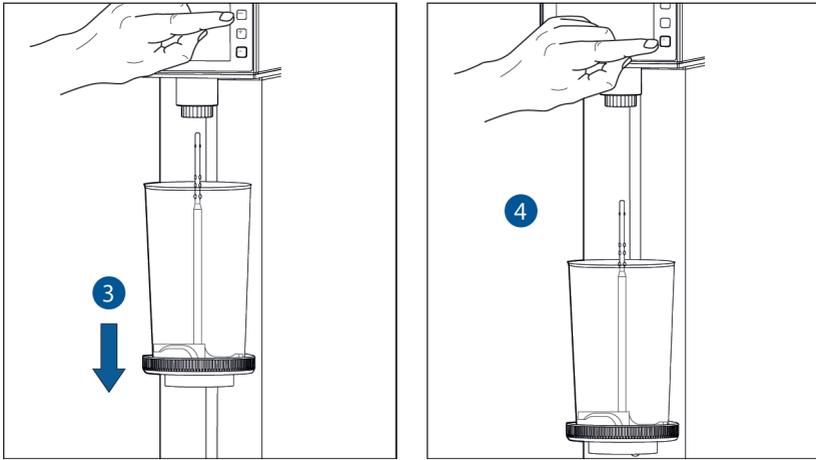


Fig. 39: Move oscillation arm to disassembly position using the "-" button; confirm with "OK"

The mixing process data is shown on the display after the mixing process is completed.

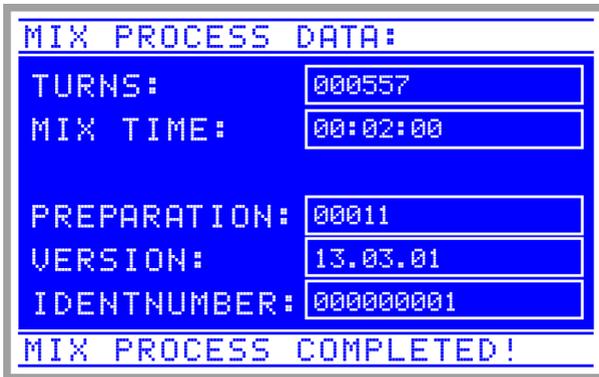


Fig. 40: "Mix process data" screen

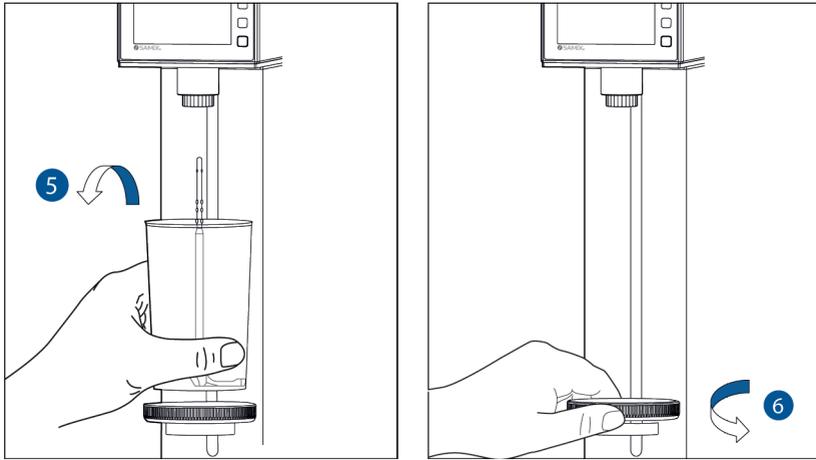


Fig. 41: Remove mixing bowl with mixing blade and unscrew jar lid from oscillation arm

Press the "OK" button to return to the start screen and if necessary switch off the power switch.



NOTICE

In the event of a prolonged period of non-usage, it is recommended to switch off the SAMIX® U1000.

6.4.5 Mixing process in "Manual" program

In the "Manual" program you can create individual mixing programs and store up to 180 mixing programs, whereby you can assign up to 20 mixing programs to each jar size.

A mixing program consists of a pregrinding program, a main mixing program, and a free spin motion program.

- You can choose between three pregrinding programs (selection "1" to "3") or decide on no pregrinding program (selection "0").
- You can divide the main mixing program into 16 mixing levels.
- You can choose between two free spin motion programs (selection "1" or "2") or decide on no free spin motion (selection "0").

After selecting the "Manual" program for the mixing process, the "Select jar size" menu appears on the display.

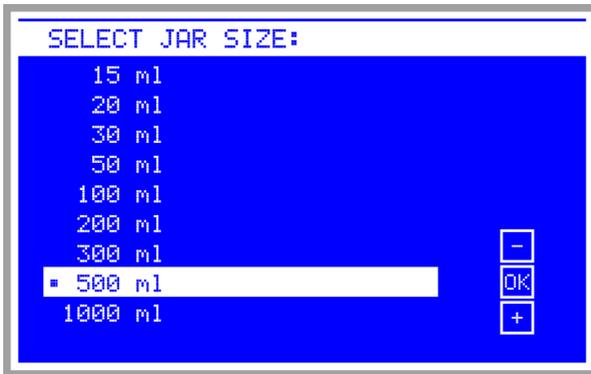


Fig. 42: "Select jar size" menu



NOTICE

Ensure that the selection of the jar size via the display corresponds to the actual size of the jar used.

1. Using the "-" and "+" buttons select the size of the jar for the mixing process and confirm the selection with "OK".

The "Select program" menu appears on the display (see Fig. 43).

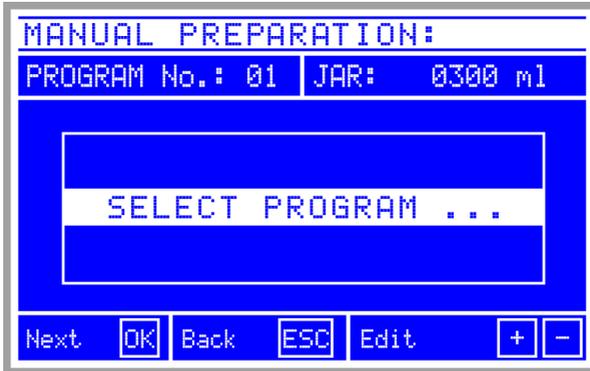


Fig. 43: "Select program" screen

2. Using the "-" and "+" buttons select one of the programs "01" to "20" for the selected jar size and confirm the selection with "OK".

The "Manual preparation" main menu appears on the display.

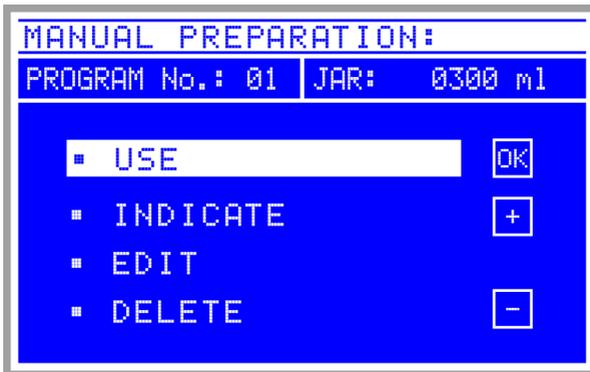


Fig. 44: "Manual preparation" screen

Here you can choose between the following menu items:

- "Use": The selected mixing program is carried out.
- "Indicate": The settings of the selected mixing program are shown.
- "Edit": You can change the selected mixing program.
- "Delete": The selected mixing program is deleted.

3. Using the "-" and "+" buttons select a menu item and confirm the selection with "OK".

"Use" menu item

After selecting the "Use" menu item, the oscillation arm automatically moves to the start position.

Now mount the mixing unit. Proceed as follows:

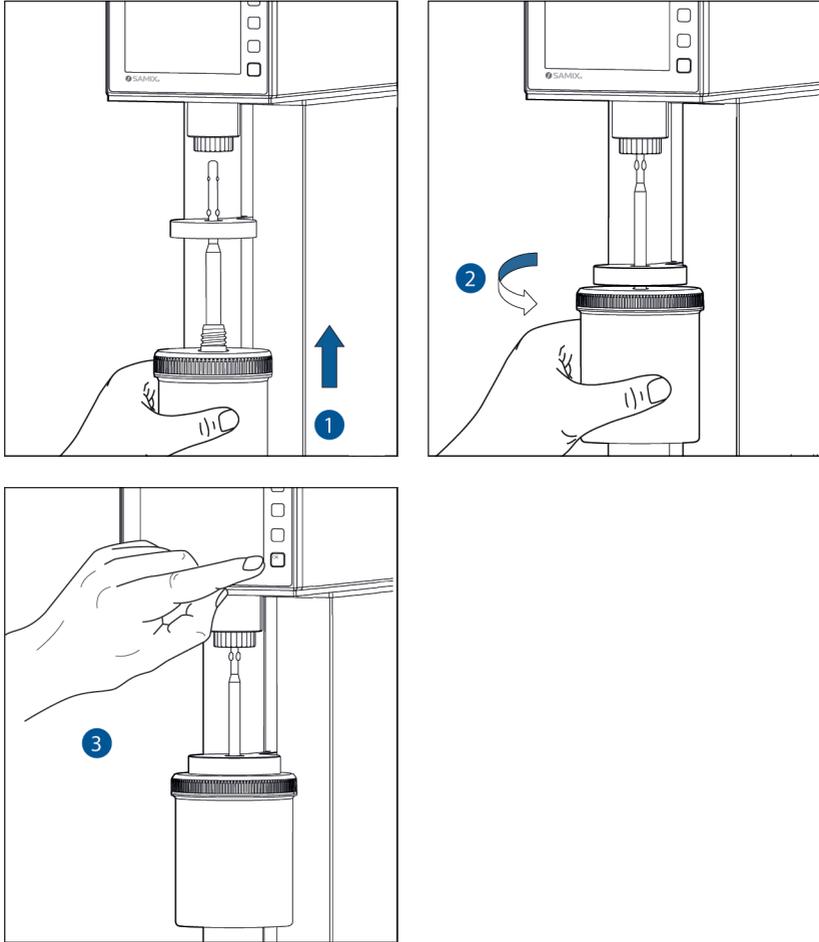


Fig. 45: Mount the mixing unit at the oscillation arm and start the mixing process using "OK"

The oscillation arm is automatically moved up and the bayonet mount grips the mixing blade. The mixing program starts and the recipe is automatically mixed according to the programmed specifications for the preparation.

**NOTICE**

If the mixing unit was not secured at the oscillation arm or was secured incorrectly, a fault message appears („8.2 Fault messages“).

During the mixing process the progress of the selected mixing program, as well as the current speed of the mixing engine, are shown on the display.

**NOTICE**

You can interrupt the mixing process by pressing the "ESC" button.

**NOTICE**

In order to achieve an optimal mixing result, at least 50 strokes should be performed. The required mixing time increases with the size of the jars.

The mixing process data is shown on the display after the mixing process is completed (see Fig. 19).

You can now remove the mixing unit and if necessary switch off the SAMIX® U1000 (see section „6.5 Switching off and removing the mixing unit“).

If a pregrinding program is in progress, "Pregrinding active" appears in the lower area of the display.

After the pregrinding program is completed the mixing process is interrupted and "Pregrind ingredients complete" is shown on the display.

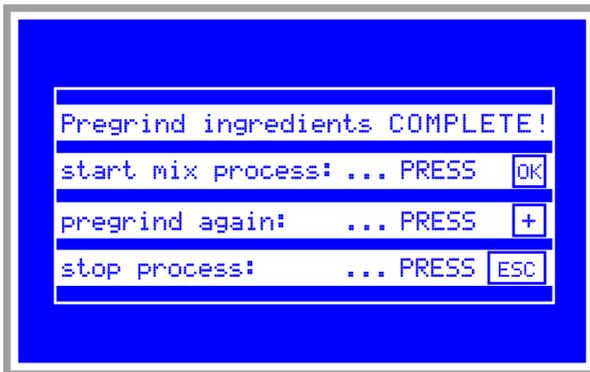


Fig. 46: "Pregrind ingredients complete" screen

You can now check the quality of the pregrinding. Proceed as follows:



ATTENTION

Risk of material damage!

Remove the mixing unit downwards from the oscillation arm in order to avoid damage to the oscillation arm or the mixing shaft.



NOTICE

After the mixing unit has been removed from the oscillation arm, it is useful to turn the mixing unit in an anticlockwise direction in order to remove the mixing blade from the bayonet mount.

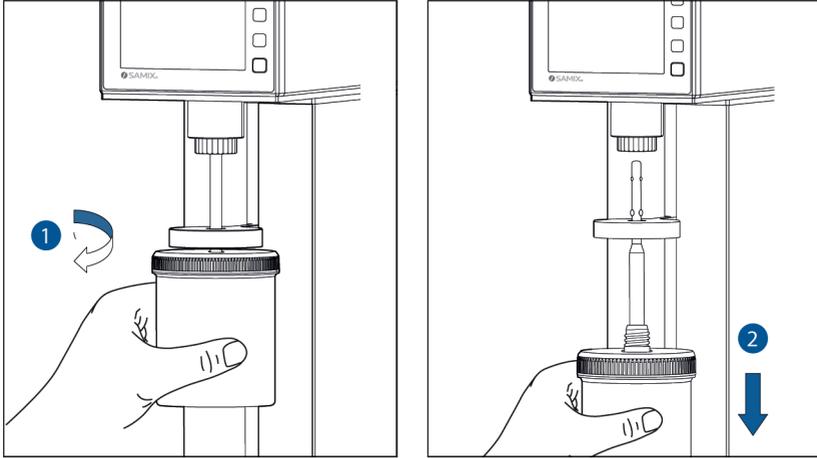


Fig. 47: Unscrew the mixing unit from the oscillation arm and remove mixing unit

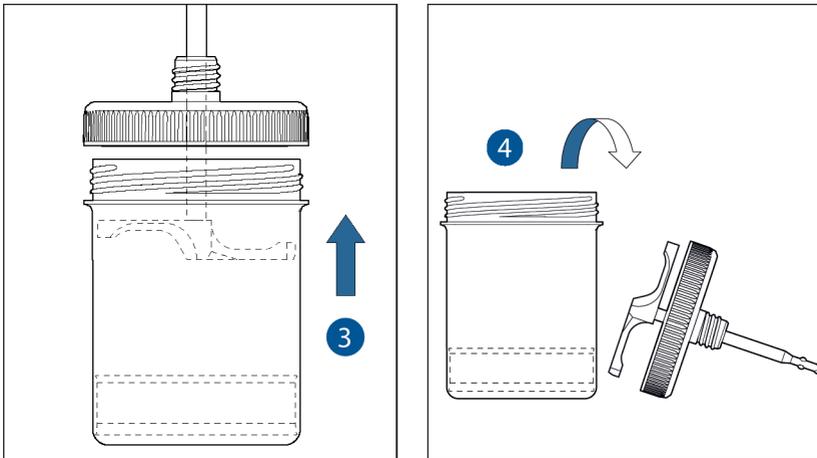


Fig. 48: Unscrew jar lid and set down mixing blade with jar lid

Check the quality of the pregrinding.

Depending on the result of the quality control, you have the following options:

- continue the mixing process by pressing the "OK" button
- repeat the pregrinding program by pressing the "+" button
- cancel the mixing process by pressing the "ESC" button and return to the start screen

The oscillation arm automatically moves to the start position after pressing the "OK" button. Now weigh in the remaining recipe components. Perform air reduction and close the mixing unit. Then screw the sealed mixing unit back into the oscillation arm and confirm with "OK" (see Fig. 45). The mixing process is started.

The oscillation arm automatically moves to the start position after pressing the "+" button. Close the mixing unit. Then screw the sealed mixing unit back into the oscillation arm and confirm with "OK" (see Fig. 45). The pregrinding program is repeated.

"Indicate" menu item

After selecting the "Indicate" menu item the view "Indicate 1" appears on the display. The following details are shown here:

- the number of the selected mixing program
- the jar size
- the mixing parameters currently stored (number of strokes, mixing time, as well as speed of mixing blade) for the pregrinding program and the first 8 levels of the main mixing program

INDICATE:1		PROGRAM No.:01		JAR: 0050 ml
STEP		CYCLES	Time hh:mm:ss	RPM (MB)
PRE	2	004	-	1500
PRE	->	010	-	1500
	01	-	00:02:00	0750
	02	-	-	-
	03	-	-	-
	04	-	-	-
	05	-	-	-
	06	-	-	-
	07	-	-	-
	08	-	-	-

Fig. 49: "Indicate 1" screen

Switch to the view "Indicate 2" by pressing the "OK" button.

INDICATE:2		PROGRAM No.:01		JAR: 0050 ml	
STEP	CYCLES	Time hh:mm:ss	RPM (MB)		
09	-	-	-		
10	-	-	-		
11	-	-	-		
12	-	-	-		
13	-	-	-		
14	-	-	-		
15	-	-	-		
16	-	-	-		
FSP	1	-	00:00:03	2500	

Fig. 50: "Indicate 2" screen

The following details are shown here:

- the number of the selected mixing program
- the jar size
- the mixing parameters currently stored (number of strokes, mixing time, as well as speed of mixing blade) for levels 9 to 16 of the main mixing program and the free spin motion

Switch back to the view "Indicate 1" by pressing the "OK" button.

Press the "ESC" button to return to the main menu "Manual preparation".

"Edit" menu item

Here the mixing parameters (number of strokes, mixing time, as well as speed of mixing blade) both for the pregrinding and free spin motion programs, as well as for all levels of the main mixing program, can be defined.



NOTICE

All changes you make during navigation through the menu item "Edit" for a selected mixing program are stored without a prompt under the number of the selected program.

It is therefore recommended to check the data of a modified mixing program before starting the mixing program under the menu item "Indicate".

After selecting the "Edit" menu item a view with all setting parameters appears on the display. Using the "-" and "+" buttons select a parameter and confirm the selection with "OK".

You can choose between the following program levels:

- pregrinding program
- free spin motion program
- one of the 16 levels of the main mixing program in the line "Prog. level"

All selections for the individual program levels are made using the "-" and "+" buttons and are confirmed with "OK".

The mixing parameters of the pregrinding programs are defined as follows:

Pregrinding program no.	Strokes	Speed of mixing blade
00 (inactive)	0	0 rpm
01 (active)	15	1000 rpm
	30	1250 rpm
02 (active)	14	1500 rpm
03 (active)	4	1500 rpm
	10	2000 rpm

Tab. 4: Mixing parameters of the pregrinding programs "00" to "03"

The mixing parameters of the free spin motion programs are defined as follows:

Free spin motion program no.	Time [min:s]	suitable jar size (nominal volume)	Speed of mixing blade
00 (inactive)	0:00	-	0 rpm
01 (active)	0:03	15 to 200 ml	2500 rpm
02 (active)	0:03	300 to 1000 ml	2000 rpm

Tab. 5: Mixing parameters of the free spin motion programs "00" to "02"

For a selected level of the main mixing program the following parameters can be changed using the "-" and "+" buttons and the selection can be confirmed with "OK":

- Speed of the mixing blade
- Mixing time



NOTICE

The individual parameters can also be confirmed by pressing the "ESC" button. In this case, however, the previous dataset is selected and not the next dataset.

Speed setting	Speed of the mixing blade	Nominal volume of the max. permissible jar size	Speed setting	Speed of the mixing blade	Nominal volume of the max. permissible jar size
01	250 rpm	1000 ml	06	1500 rpm	1000 ml
02	500 rpm	1000 ml	07	1750 rpm	1000 ml
03	750 rpm	1000 ml	08	2000 rpm	1000 ml
04	1000 rpm	1000 ml	09	2250 rpm	200 ml
05	1250 rpm	1000 ml	10	2500 rpm	50 ml

Tab. 6: Speed setting of the mixing engine

Return to the "Manual preparation" main menu using one of the following two options:

- after selecting or confirming all mixing parameters of the 16 mixing levels with the "OK" button
- by confirming all mixing parameters set up to now with the "ESC" button

"Delete" menu item

After selecting the "Delete" menu item, you are asked to confirm the deletion of the mixing program. You now have the following options:

- Press "OK" to permanently delete the entire dataset of the selected mixing program.
- Press "ESC" to cancel the deletion process.

Then return to the "Manual preparation" main menu.



NOTICE

During the deletion process the mixing parameters of all 16 levels of the main mixing program are set to "0". Pregrinding and free spin motion programs are set to "00" (inactive).

6.5 Switching off and removing the mixing unit



ATTENTION

Risk of material damage!

Remove the mixing unit downwards from the oscillation arm in order to avoid damage to the oscillation arm or the mixing shaft.



NOTICE

After the mixing unit has been removed from the oscillation arm, it is useful to turn the mixing unit in an anticlockwise direction in order to remove the mixing blade from the bayonet mount.

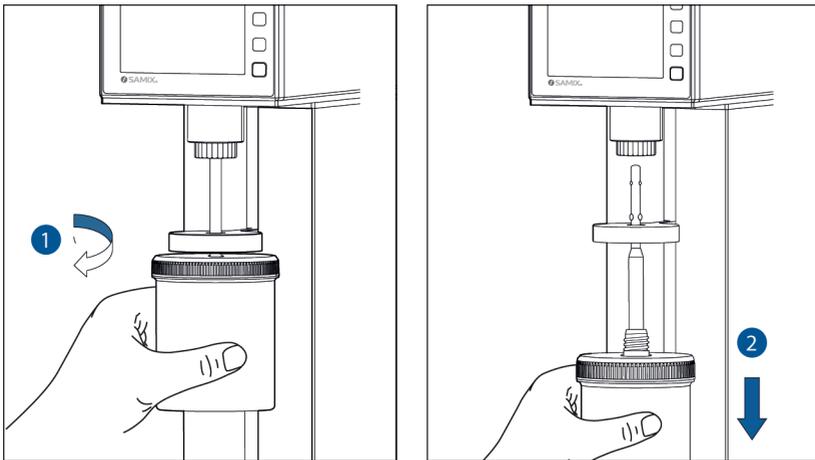


Fig. 51: Unscrew the mixing unit from the oscillation arm and remove mixing unit

Press the "OK" button to return to the start screen and if necessary switch off the power switch.



NOTICE

In the event of a prolonged period of non-usage, it is recommended to switch off the SAMIX® U1000.

6.6 Final operations

Proceed as follows after the removal of the mixing unit:

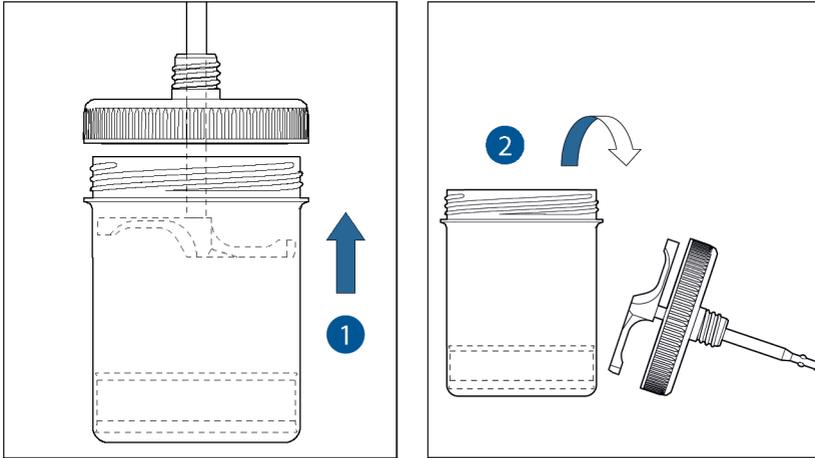


Fig. 52: Unscrew jar lid and set down mixing blade with jar lid

Check the surface of the ointment.

If the surface of the ointment looks smooth and consistent, it has been proved in practice that the consistency of the ointment was also achieved in the inside of the jar. In this case continue as described in Fig. 53.

If the surface of the ointment is not consistent, repeat the steps from the sections „6.3 Preparation of mixing process“ and „6.4 The mixing process“.

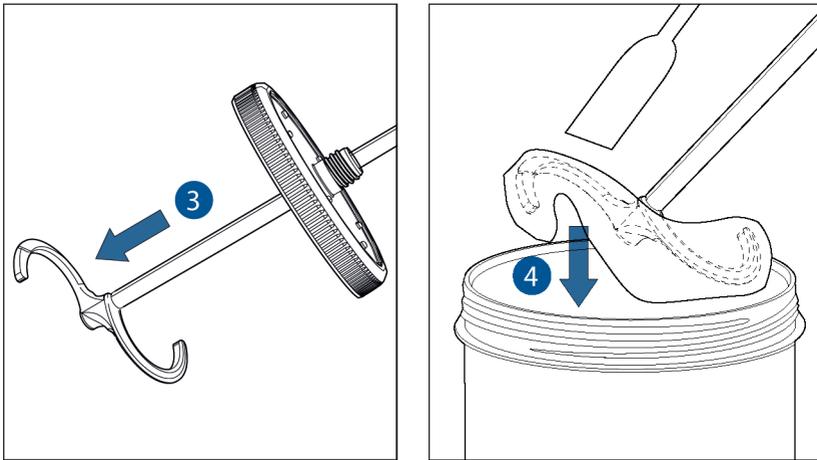


Fig. 53: Push the mixing blade from the jar lid and scrape off ointment using a spatula

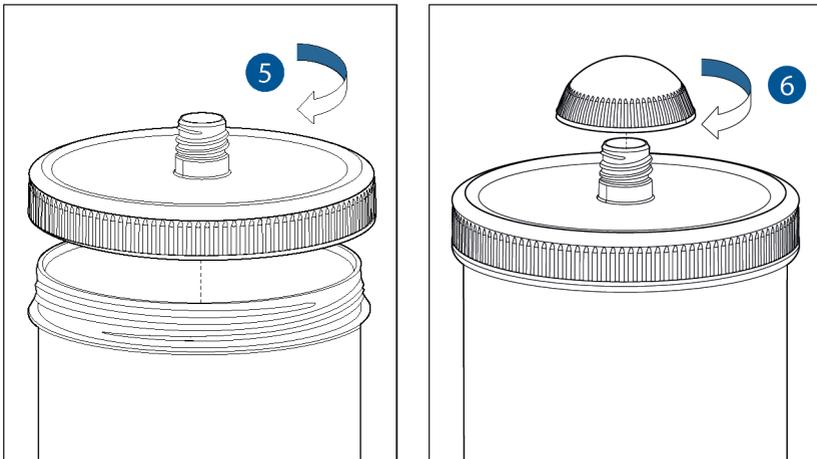


Fig. 54: Screw back on the jar lid tightly and the jar cap gently



NOTICE

You can also have the jar lid with a SAMIX® vario nozzle.

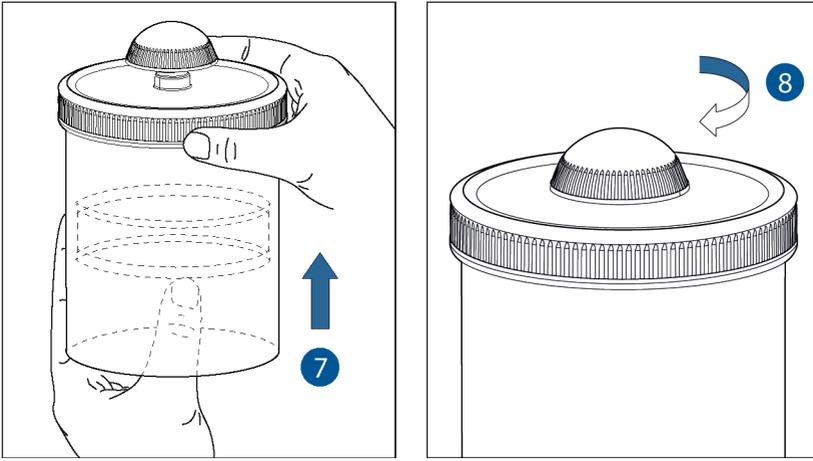


Fig. 55: Reduce air and firmly screw on jar cap



NOTICE

The air reduction before the discharge of the jar serves to remove any air-filled areas arising during the mixing process. If no air reduction is performed, during the first withdrawal the operator first pushes the air and then the ointment from the jar opening in a gushing movement.

Stick the label on the sealed jar and give the jar to the operator.



NOTICE

It is recommended to document the lifting and mixing parameters, as well as the result of the final check.

6.7 Identification number

The 9-digit identification number for clear identification of the respective preparation has the following structure:

The first two digits represent the ointment type:

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

Tab. 7: Assignment of digit sequence to ointment type

The third and fourth digits represent the size of the jar (nominal volume):

Digit sequence	Jar size (nominal volume)	Digit sequence	Jar size (nominal volume)
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" program

Tab. 8: Assignment of digit sequence to jar size

The fifth and sixth digits represent the "Manual" mixing program:

- 00 = no manual mixing program
- xx = manual mixing program xx

The seventh and eighth digits represent the number of pregrinding programs:

- 00 = no pregrinding program
- xx = xx pregrinding programs completed

The last digit represents an interruption to the mixing process:

- 0 = with interruption
- 1 = no interruption

An ointment with the identification number 090504021 was mixed with the "Manual" program no. 04 in a 100 ml SAMIX® jar, whereby two pregrinding programs were completed and the mixing process was not interrupted.

7 Maintenance and repair

7.1 Service and warranties in Germany

Regardless of the obligations of the seller vis-a-vis the purchaser, the manufacturer assumes a warranty in accordance with the specifications in the enclosed documentation.

The Technical Service Department for SAMIX® mixers can be reached at:

SAMIX GmbH
Am Köhlersgehäu 50
98544 Zella Mehlis
Germany

www.samix.com
info@samix.com

Tel.: +49 3682 455 0
Fax: +49 3682 455 200



NOTICE

Repairs carried out under warranty are only performed by SAMIX GmbH.



NOTICE

In the case of faults needing repair, send the entire SAMIX® U1000 device to SAMIX GmbH. Use the material of the original packaging or request packaging material from SAMIX GmbH when sending in the device.

In addition, observe the following information for services:

- A quote can be obtained for service repairs.
- For SAMIX® devices sent in, a return deadline of 6 working days following receipt or confirmation of the quote is promised.
- Mixing blades and jars, as well as other SAMIX® products, are not covered under the warranty.
- The warranty claim becomes null and void if unauthorized operations or procedures have been performed on the device. Damage arising from improper use or as a result of force majeure or other external influences is not covered under the warranty.
- The parts replaced during maintenance and repair become the property of SAMIX GmbH.
- Claims beyond the free troubleshooting, for e.g. damages, cannot be asserted within the framework of the warranty.
- A warranty claim only exists if proof of purchase can be demonstrated.

**NOTICE**

Please note the information and details in the enclosed documentation.

7.2 Maintenance

**NOTICE**

The SAMIX® U1000 is serviced solely by the personnel of SAMIX GmbH.

The inspection and maintenance work to be performed for documentation within the framework of a QM system can be obtained from customer service upon request.

**NOTICE**

When utilizing services, send the entire SAMIX® U1000 device to SAMIX GmbH.

Use the material of the original packaging or request packaging material from SAMIX GmbH when sending in the device.

Observe the following information:

- Services are also invoiced within the warranty period for costs and wear parts.
- Upon request, a replacement device is provided for the duration of the service work in return for a one-off rental charge.

**NOTICE**

Please note the information in the enclosed documentation for warranty cases.

7.3 Cleaning



WARNING

Electrical hazard from direct contact with live parts!

Always remove the connector from the socket before cleaning the SAMIX® U1000.



ATTENTION

Risk of material damage!

Do not open the housing of the SAMIX® U1000 without authorization.

Do not use any aggressive cleaning substances or abrasive cleaners for cleaning.

Ensure that no liquid enters the device. If liquid ends up in the inside of the SAMIX® U1000, disconnect the device from the power supply and inform customer service.

Proceed as follows for daily cleaning of the device:

1. Disconnect the connector from the socket.
2. Wipe the surfaces of the device using a damp cloth (wet with mild soapy water).
3. Dry the surfaces of the device using a soft, dry cloth.



NOTICE

To disinfect, you can spray the display of the SAMIX® U1000 using a suitable cleaning agent (for e.g. containing 70% isopropyl alcohol) and wipe.

8 Fault causes/troubleshooting

8.1 Instructions in the event of faults

Fault	Troubleshooting
The SAMIX® U1000 cannot be switched on.	Check whether there is supply voltage and the connector of the mains supply line is correctly connected to the device and the socket.
You have switched off the SAMIX® U1000 as a result of the fault messages "Mixing engine overload" or "Lifting engine overload".	The device is overloaded. Press "OK".

Tab. 9: Faults and troubleshooting

i NOTICE
 In the event of irregularities, a fault message is shown on the display. Information on the cause of the fault and troubleshooting can be found in section „8.2 Fault messages“.

i NOTICE
 An incorrect assignment of the mixing blades to the jars can trigger fault messages.

After the device is switched off and the operating fault has been eliminated, the SAMIX® U1000 works again normally.

Following troubleshooting perform a function check in accordance with the details under "Function check or initial operation" in the enclosed document "Installation Qualification (IQ)".

If device functional faults cannot be eliminated, contact customer service. Irreversible software errors caused by overvoltage or strong electromagnetic fields in the surrounding area can also only be eliminated by customer service.

In the case of serious faults, note the device type and contact the manufacturer.

i NOTICE
 In the case of faults needing repair, send the entire SAMIX® U1000 device to SAMIX GmbH. Use the material of the original packaging or request packaging material from SAMIX GmbH when sending in the device.

i NOTICE
 The inspection and maintenance work to be performed for documentation within the framework of a QM system can be obtained from customer service upon request.

8.2 Fault messages

Fault display	Possible cause of fault	Troubleshooting
Mixer not fixed!	The mixing blade shaft is not engaged in the bayonet mount or no mixing unit is mounted.	Press "OK" and mount the mixing tool again so that the mixing blade shaft engages in the bayonet mount.
Jar not fixed	The mixer came loose from the bayonet mount, the hollow shaft may be worn. No mixing unit is secured or engaged at the oscillation arm.	Press "OK" and mount the mixing unit properly so that the mixing blade shaft engages in the bayonet mount.
Wrong jar size	An incorrect jar size was used.	Press "OK" and use the correct size SAMIX® jar.
	The jar used is not a SAMIX® jar.	Press "OK" and use the correct size SAMIX® jar.
Lifting engine overload	The lifting engine is temporarily overloaded.	Press "OK", if necessary heat substances used.
Mixing engine overload	The mixing engine is temporarily overloaded.	Press "OK", if necessary heat substances used or select a slower speed.

Tab. 10: Fault messages

8.3 Possible fault sources to avoid

Potential faults	Possible consequences	Troubleshooting
The incorrect mixing blade is used.	The mixing blade shaft is too long and the jar cannot be screwed into the oscillation arm.	Use a mixing blade with a suitable shaft length (see section „3.2.3 Assignment of mixing blades to the jars“).
The incorrect mixing blade is used.	The mixing blade shaft cannot be centered in the holder after performing a full stroke.	Use a mixing blade with a suitable shaft length (see section „3.2.3 Assignment of mixing blades to the jars“).
Defective (for e.g. bent) mixing blades or other mixing blades than those supplied are used.	The mixing blade does not engage or engages only partly in the bayonet mount.	Only use intact SAMIX® mixing blades with appropriate shaft length (see section „3.2.3 Assignment of mixing blades to the jars“).
The mixing blade is operated with the device without a jar or mixing bowl.	Risk of injury upon contact with the rotating mixing blade.	Only use mixing blades with the SAMIX® U1000 in jars or mixing bowls which have been firmly screwed in.
When inserting the mixing blade in the jar lid, the sealing lip of the jar lid opening breaks with the noses of the mixing blade shaft.	Ointment elements (mainly liquid) may draw up at the shaft of the mixing blade during the mixing process.	When inserting the mixing blade in the jar lid, do not break the sealing lip of the jar lid opening with the noses of the mixing blade shaft.
The base of the jar is not pushed down as far as the stop before weighing in the ingredients.	All recipe components cannot be housed in the jar, although the filling volume is on average 40% larger than the nominal volume.	Press down the base of the jar fully before weighing in the ingredients. Use the next biggest jar.
For the manufacture of low-viscose preparations, the sealing lips of the jar base are not wet with an ointment base.	Mixed material may emerge at the jar base during preparation.	Wet the sealing lips of the base with ointment to support the sealing effect.
The air is not removed from the jar before the mixing of semi-solid preparations.	An air column forms on the inside of the jar when mixing the ointment, meaning the mixing blade cannot clean itself. Unmixed elements may remain stuck on the mixing blade.	Perform air reduction before the mixing process.
The air is not removed from the jar before the mixing of liquid preparations.	During mixing overpressure arises which cannot be reduced by pushing base down the movable base. As a result, ointment can draw up on the shaft of the mixing blade during the mixing process.	Perform air reduction before the mixing process.
The jar lid is screwed onto the jar at an angle.	The mixing blade tilts upon automatic entry into the bayonet mount.	Screw the lid onto the jar properly and tightly.

Potential faults	Possible consequences	Troubleshooting
The oscillation arm is pulled too far from the defined starting position by hand.	The mixing blade shaft is not centered in the holder after performing a full stroke.	Take hold of the mixing blade shaft at the taper and manually guide it into the holder.
The mixing unit is not held firmly with at least one hand during the entire mixing period in the case of a manual lifting process.	Risk of injury as a result of unstable holding of the mixing unit during the entire mixing process in the case of manual lifting process.	Firmly hold the mixing unit with at least one hand during the entire mixing period in the case of manual lifting process.
Substances with extreme viscosity are used.	The fault messages "Mixing engine overloaded" or "Lifting engine overloaded" appear on the display.	Press "OK", if necessary heat substances used or select a slower speed.
No air reduction is performed before handover of the jar to the operator.	The air reduction serves for pushing out any air-filled spaces arising during the mixing process. During the first withdrawal the operator first pushes the air and then the ointment from the jar opening in a gushing movement.	Perform air reduction before the handover of the jar to the operator. If necessary, use a vario nozzle or an applicator.

Tab. 11: Possible fault sources to avoid

9 Waste disposal



NOTICE

SAMIX® devices cannot be disposed of with general household waste. At the end of their service life, send SAMIX® devices to the available return and collection systems.

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