

Sterimixer and Sanimixer

STD0016EN00

APPLIES TO: Steridose products Sterimixer[®]-Low-Shear SMO/SMA, Sterimixer[®]-Medium-Shear SMMS, Sterimixer[®]-ATEX, Sanimixer.

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1. IMPORTANT SAFETY INFORMATION

1.1. Introduction

1.1.1. Purpose of this manual


Read this manual carefully before installing and using the product. Improper use of the product can cause personal injury and damage to property, and may void the warranty.


 **NOTICE:** Save this manual for future reference


1.2. Safety terminology and symbols


1.2.1. Hazard levels and indications

The following symbols are used to indicate hazard levels.

 **DANGER:** Indicates a hazardous situation which, if not avoided, will result in death or serious injury.

 **WARNING:** Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

 **CAUTION:** Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury, or, a situation that might lead to serious damage to the product or components.

 **NOTICE:** Indicates: A potential situation which, if not avoided, could result in undesirable conditions or contains tips to enhance the performance or facilitate the installation of the product.

1.2.2. Hazard categories

Hazard categories can either fall under hazard levels or let specific symbols replace the ordinary hazard level symbols.

 **ELECTRICAL HAZARD:**

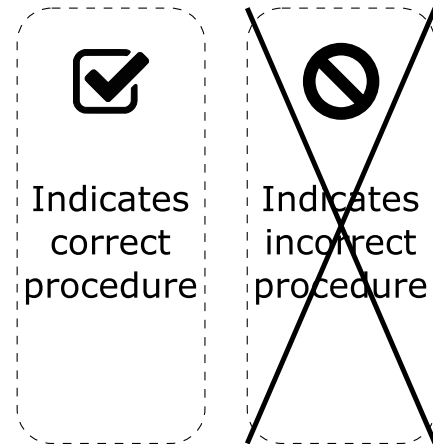
 **STRONG MAGNETIC FIELDS HAZARD:**

 **CORROSIVE AGENTS HAZARD:**

 **HAZARD FOR WEARERS OF CARDIAC PACE-MAKER:**

1.2.3. Other symbols used

In situations where confusion could arise, the icons below are used to distinguish between the right and the wrong procedure.



1.3. General safety


1.3.1. General statement

Undertaking any work covered by this manual may either directly or indirectly create risks to the safety and health of the person undertaking the work or the Sterimixer/Sanimixer and/or its components while the work is being undertaken.


It is the responsibility of the user to ensure that appropriate controls and precautions are identified and applied in relation to the work covered by this document in accordance with relevant statutory, legal and industry requirements to protect the health and safety of the persons undertaking the work.

Neither this document, nor its use, in any way absolves the user from their responsibility to ensure that the controls and precautions referred to in this chapter are implemented.

If, by undertaking any work covered by this document, you become aware of any Steridose product design related feature which could create risk to a person undertaking work or to the Sterimixer/Sanimixer and/or its components please contact Steridose immediately.

 **CAUTION:** You must observe the instructions contained in this manual. Failure to do so could result in physical injury, damage or delays.

1.4. User safety

 **WARNING:** This manual cannot replace specific knowledge and adequately trained personnel needed for installing and handling equipment for professional use, such as this product.

1.4.1. General safety rules

These safety rules apply:

- Always keep the work area clean
- Pay attention to the risks presented by gas and vapors in the work area
- Avoid all electrical dangers. Pay attention to the risks of electric shock or arc flash hazards
- Always bear in mind the risk of pinching fingers, electrical accidents and burn injuries.

1.4.2. Safety equipment

Use safety equipment according to the company and local regulations.

1.4.3. Electrical connections

Electrical connections must be made by certified electricians in compliance with all international, national, state and local regulations. For more information about requirements see the relevant sections dealing specifically with electrical connections (if applicable).

1.4.4. Hazardous liquids

The product is designed for use in liquids that can be hazardous to your health.



WARNING: Make sure that all personnel who work with hazardous liquids use suitable protective equipment.

1.4.5. Specific operational hazards

Specific operational hazards are listed under its respective section.

1.4.6. Specific hazards while performing maintenance

Specific hazards while performing maintenance on the product are listed under its respective section.

2. HANDLING

Upon receipt always:

- Check the packing slip against the goods received.
- If delivered with a drive unit, check that the drive unit specification and technical information are included.
- Inspect the packaging for signs of damage in transit.
- Carefully remove the packaging. Pay special attention to cavities and make sure they are free of packaging material.
- Inspect the Sterimixer/Sanimixer for any visible signs of damage. Pay special attention to make sure the bearings do not show any sign of cracks.
- Report any damage to the carrier.

Approximate weight of the different components of the Sterimixer/Sanimixer is specified in table 1:



STRONG MAGNETIC FIELDS HAZARD: The Sterimixer/Sanimixer impeller and magnetic rotor include strong magnets with the associated risk of pinching fingers and permanently damaging magnetic cards (e.g. credit cards) if being close to these components.



HAZARD FOR WEARERS OF CARDIAC PACEMAKER: The Sterimixer/Sanimixer impeller and magnetic rotor include strong magnets thus personnel equipped with pacemaker shall not handle these components.



CAUTION: Ensure that suitable lifting equipment is chosen and correctly used.



CAUTION: If the Sterimixer/Sanimixer is not to be installed immediately, the Sterimixer/Sanimixer should be repacked in the original package and stored in a suitable

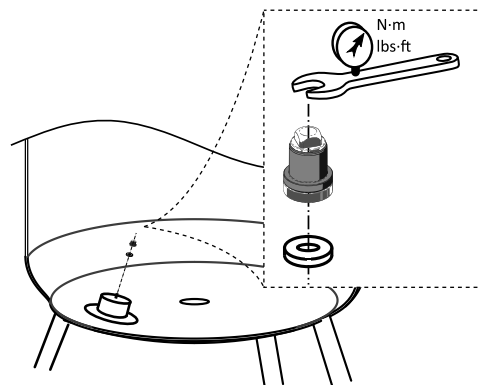


Figure 1 Mounting the bearing unit on the weld plate in the vessel. The figure shows the bearing unit and the PTFE-washer. Use a torque wrench (refer to table 2 for recommended torque).

able storage after receipt and inspection. The following should be considered with regards to storage:

The storage shall be a clean, dry location free from vibration. If stored in a moist or dusty atmosphere, further protect the Sterimixer/Sanimixer with a suitable cover.

3. INSTALLATION AND START-UP

NOTICE: Refer to the Steridose welding manual on www.steridose.com for correct installation of the Sterimixer/Sanimixer weld plate. The remainder of this manual concerns the installation of a Sterimixer/Sanimixer with the weld plate correctly welded in place in the tank.

3.1. Mounting of the bearing unit

The bearing materials used are either Tungsten Carbide (TC), Silicon Carbide (SiC) or Dri-amond™ (diamond coated SiC), which are very hard but brittle materials. It is therefore important that the bearing is protected from physical impact damage. It is also of the utmost importance that the bearing surfaces are kept free from particles to avoid damage or disturbances of the bearing function during operation.



CAUTION: Before the bearing unit and the impeller are to be mounted, the vessel, pipes and other installed parts must be thoroughly cleaned from dirt and in particular loose metal particles (can occur in new vessels, where machined stainless steel particles might have acquired magnetic properties). Wetted Sterimixer/Sanimixer components can otherwise be permanently damaged. Ensure the vessel has been allowed to cool down, drained, depressurized and ventilated from possible gasses or vapours.

Carefully fit the bearing unit together with the PTFE washer to the weld plate and tighten to a proper torque (Table 2). Make sure that the PTFE washer is centered correctly. Steridose have designed a tool for this purpose that facilitates mounting the bearing unit in hard-to-access places. See section 3.3.

Mixer size	Impeller weight (kg (lb))	Standard ^a drive unit weight (kg (lb))
60	0.6 (1.3)	3.3 (7.3)
85/100	1.0 (2.2)	7 (15.4)
85/140	1.2 (2.6)	7 (15.4)
120/150	2.9 (6.4)	15 (33.1)
120/190	3.0 (6.6)	21 (46.3)
120H	4.9 (10.8)	24 (52.9)
210/275	10 (22)	48 (105.8)
210/350	10.5 (23.1)	55 (121.3)
SMMS 85	0.9 (2)	8.2 (18)
SMMS 120	2.5 (5.5)	30.2 (67)
Sanimixer 500	1.2 (2.6)	7 (15.4)
Sanimixer 3 000	3.0 (6.6)	21 (46.3)
Sanimixer 7 000	4.9 (10.8)	24 (52.9)
Sanimixer 10 000	4.9 (10.8)	24 (52.9)
Sanimixer 30 000	10.5 (23.1)	55 (121.3)

■ **Table 1** Approximate weights for different Sterimixer/Sanimixer components.

^a note ATEX, XP and stainless steel motors are not 'standard'

👉 **NOTICE:** A used PTFE washer should never be reinstalled, please replace the PTFE washer with a new one each service.

⚠️ **CAUTION:** Do not over-torque the bearing unit assembly.

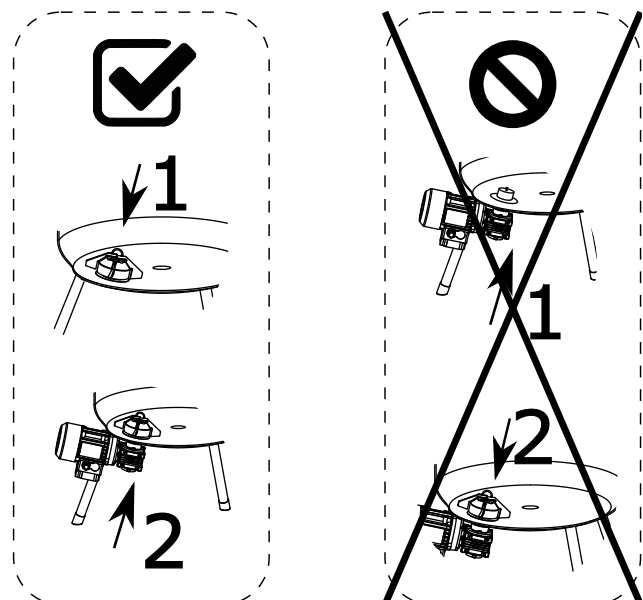
3.2. Mounting the impeller

The impeller is to be mounted before the drive unit and the magnet rotor are installed. Failure to do so will cause a sudden attraction between the mounted rotor and the impeller, causing the latter to violently hit the bearing assembly, with likely bearing damage to occur.

⚠️ **CAUTION:** Before mounting the impeller, make sure that the drive unit is NOT mounted on the vessel.

👉 **NOTICE:** To facilitate mounting and dismounting the impeller, Steridose has developed an optional 'Magnet Lowering Device' that allows the magnet rotor to be lowered without disassembling the complete drive unit from the vessel. Refer to www.steridose.com or your local Steridose representative for more information.


Carefully position the impeller onto the bearing unit and spin by hand to ensure that the impeller runs freely. Steridose have designed a tool for this purpose that facilitates mounting the impeller in hard-to-access places. See section 3.3.



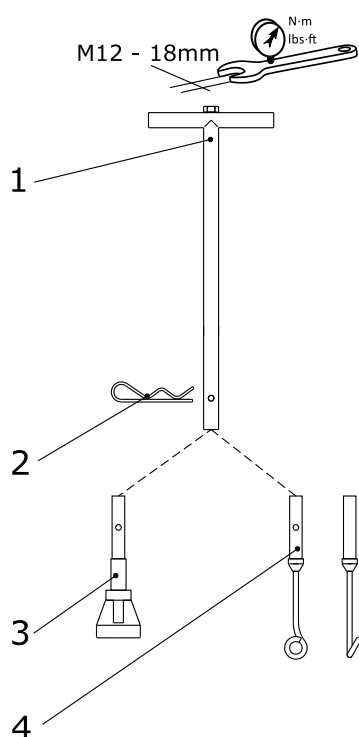
■ **Figure 2** The impeller is to be mounted before the drive unit and the magnet rotor are installed.

Bearing unit size	Torque (Nm (in-lb))
60/75 ; 85/100-140 ; Sanimixer 500	6 (53)
120/150 - 190 ; 120H/220 ; 210/275-350 ; Sanimixer 3 000 - 30 000	20 (177)

■ **Table 2** Torque values for mounting the male bearing unit on the weld plate.

Bearing unit size	Tool size 
60 ; 85 ; 120H & Sanimixer 500; 7 000; 10 000	8 mm
120 ; 210 ; Sanimixer 3 000 & 30 000	14 mm

■ **Table 3** Tool sizes required for mounting the male bearing on the weld plate.



■ **Figure 3** Components of the bearing and impeller mount tool. 1: handle and rod, 2: hair-pin-type lock, 3: bearing mount tool, 4: impeller mount tool.

3.3. Use of the bearing / impeller installation tool (Option).

To change the impeller and male bearing in applications where it is difficult to access the tank, a special *bearing and impeller mount tool* can be used. It consists of the following parts (see figure 3):

1. Handle
2. Hair-pin-type lock
3. Bearing mount tool
4. Impeller mount tool

To facilitate mounting of the male bearing it is recommended to apply a small amount of suitable grease on

the PTFE washer. This prevents the PTFE washer from loosening from the bearing unit during mounting.

The bearing and impeller mount tool are ordered separately.

3.4. Mounting and dismounting the drive unit

The drive unit consists of a motor (either AC, DC or Air driven), gearbox, flange and rotor (some differences occur depending on type of drive and size).

Be certain that you can handle the weight of the drive unit. Take a firm grip of the gearbox to balance the weight of the drive unit and to minimize the risk of damage caused by crushing when dismounting. Use appropriate lifting device for the larger models, SM 120/190 and larger.

3.4.1. Mounting the drive unit

There are two different ways of attaching the drive unit to the flange of the vessel, depending on Sterimixer/Sanimixer size, by a bayonet coupling or by a threaded joint.

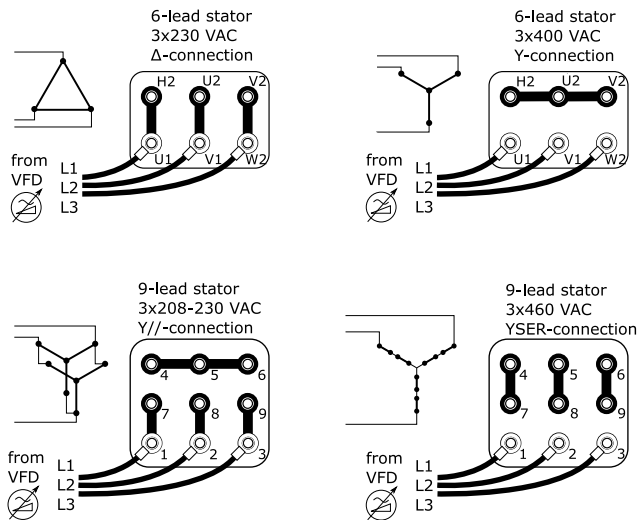
Ensure the magnetic rotor is not damaged and properly aligned preventing physical contact with the weld plate upon installation and operation.

60/75; 85/100 - 140; SMMS 85 - 120; Sanimixer 500

1. Lift up the drive unit and let the welding plate's screws pass through the slots in the drive unit flange.
2. Turn the drive unit counter clockwise into position.
3. Lock the drive unit in position by tightening the locking nuts.

120/150 -190; SMMS 120; Sanimixer 3 000

1. Lift up the drive unit and let the welding plate's screws pass through the slots in the drive plate.
2. Turn the drive unit counter clockwise into position.
3. Lock the drive unit in position by tightening the locking nuts.



■ **Figure 4** The most common wiring alternatives for Steridose-supplied electric motors.

120H/220 ; 210/275-350; Sanimixer 7 000 - 30 000

1. Lift up the drive unit and let the flange screws pass through the holes in the drive unit flange.
2. Lock the drive unit by tightening the locking nuts.

3.4.2. Dismounting the drive unit

Dismount the drive unit by following the mounting instructions in reverse order.

3.5. Connection to main power



WARNING: Electrical connections must be made by certified electricians in compliance with all international, national, state and local regulations.



CAUTION: Never use the Sterimixer/Sanimixer (drive unit) without a Variable Frequency Drive (VFD).



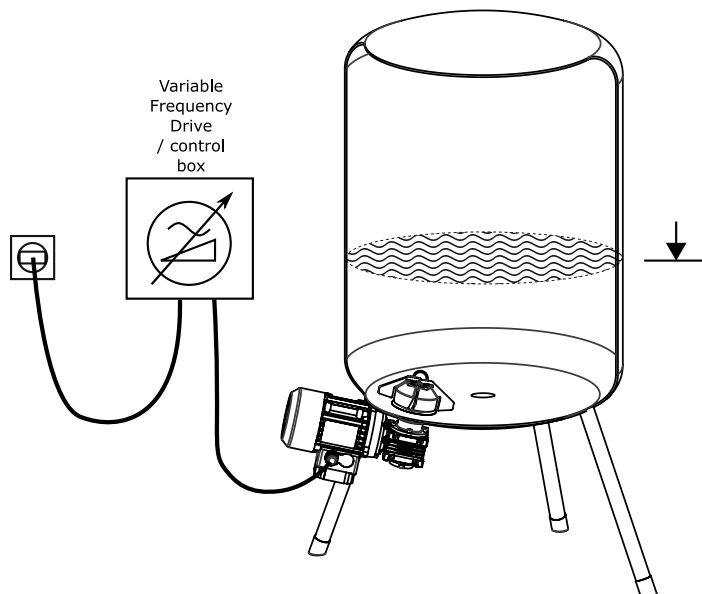
NOTICE: If a control box is used, the drive unit is connected to the control box, which in turn is connected to the external power supply.

An electrical drawing/wiring diagram is supplied with the motor (drive unit) and control box upon delivery when applicable. Technical information for the motor (drive unit) and the control box is found within the documentation enclosed with the equipment. The most common wiring alternatives for Steridose-supplied electric motors are summarized in figure 4.

3.6. Installation check and calibration

3.6.1. Verifying the impeller direction of rotation

1. Submerge the impeller completely in water to ensure there is a film of liquid between the male bearing unit and the impeller's female bushing.
2. Set the speed potentiometer/regulator to zero.



■ **Figure 5** General arrangement of tank, control box for start up

3. For DC-drive applications - Start the Sterimixer/Sanimixer and carefully increase to a low speed (max 50 rpm).
4. For AC-drive applications - The Sterimixer/Sanimixer starts at low speed.
5. Visually check the direction of rotation for the impeller, which should be *clockwise* when seen from above. If the Sterimixer/Sanimixer rotates counter clockwise, refer to section 6.
6. Stop the Sterimixer/Sanimixer immediately after completed verification.



CAUTION: Dry operation of the Sterimixer/Sanimixer will damage the bearings.

3.6.2. Calibration of the Sterimixer/Sanimixer

The most important parameters in maintaining proper operation and thereby a long operational life for the Sterimixer/Sanimixer are pre-set on delivery (applies only to Steridose-supplied control boxes). The pre-set parameters include acceleration time (ramp-up), deceleration time (ramp-down), maximum speed, and minimum speed.

Acceleration time and maximum speed will depend heavily on the application. Ensure that the minimum and maximum speed parameters can cover the entire range of operation for the unit during process and cleaning. Depending on the impeller design, required speed during cleaning may be considerably lower than process, or vice-versa (see also section 4.5).

The maximum speed shall not exceed the specified maximum speed specified for each Sterimixer/Sanimixer size. The minimum speed shall not be lower than the minimum speed specified for each model, refer to table 4.

For verification of the speed of the Sterimixer/Sanimixer, use the impeller monitor sensor (IMS) or a hand tachometer.

Mixer size	Minimum speed (rpm) ^a	Maximum speed (rpm)
60/75 - 120/150	50	450
120/190 - 210/350	50	350
SMMS 85	50	1 200
SMMS 120	50	1 800
Sanimixer 500	50	450
Sanimixer 3 000 - 30 000	50	350

■ **Table 4** Minimum and maximum speed for different sizes of mixers.

^a Applies to AC motors

The maximum speed of the Sterimixer/Sanimixer is achieved at frequencies above the nominal frequency (50/60Hz) of the motor. The frequency at maximum speed is usually in the interval from 80Hz to 100Hz.

Factory-supplied Sterimixer/Sanimixer motors are of the 4-pole AC (alternating current) type (exception 60/75 is equipped with 2-pole AC motor). They are coupled to gear boxes with reduction 5:1 or 7.5:1 depending on mixer size and type of drive unit (standard IEC, IEC ATEX, NEMA XP, NEMA Stainless Steel, etc). Approximate speeds for motor/gearbox combinations are listed in table 5.

4. OPERATION

WARNING: The Sterimixer/Sanimixer is only to be operated when mounted in a vessel, thus avoiding impact damage and loose objects from becoming entangled in the rotating parts.

CAUTION: Do not run the Sterimixer/Sanimixer dry.

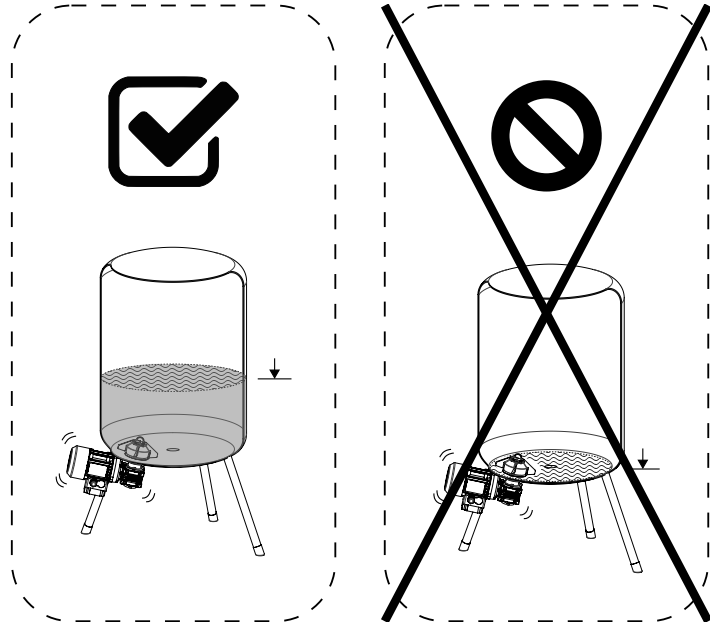
4.1. Allowed operating temperature range

Component	Temperature range
Impeller	0 - 140°C (32 - 284°F) ^a
Bearing unit	0 - 140°C (32 - 284°F)
Drive unit ambient temperature	
All sizes	-25 - +40°C (-13 - +104°F)

^a The permanent magnets in the impeller withstand temperatures up to +225 °C (autoclave cleaning)

4.2. Allowed pressure range

Weld plate size	Design pressure range
All sizes	-1 - +7 bar g (-14.5 - +101.5 psig)



■ **Figure 6** Sterimixer/Sanimixer should never be allowed to run dry.

4.3. Chemical compatibility

The impeller and bearing are not to be exposed to strong chemicals. Nominal pH range for tungsten carbide (TC) bearings is 2 - 14 but silicon carbide (SiC) bearings can be used in a pH range from 0 to 14. In addition to these materials Steridose offers Dri-amond™ bearings. Dri-amond™ bearings feature a pure crystalline diamond film coating that is deposited in the silicon carbide structure. This results in a lower coefficient of friction and greater survivability under dry-running conditions.

Refer to table 6 or contact Steridose for further assistance.

4.4. Operational limits

4.4.1. Lubrication principle

During operation of the Sterimixer/Sanimixer a liquid film of the process fluid is generated between the male and female bearing, aided by the rotation of the impeller, providing cooling and lubrication of the bearings. In addition to this, for the SMA-type impeller, a negative pressure is created on the backside of the impeller wings, the processed liquid will be transported from the inside of the impeller through the holes to the outside of the impeller.

To avoid dry running the speed has to be adjusted in accordance to the level in the tank. This will depend on the following:

- The diameter of the tank.
- The shape of the bottom of the tank.
- The viscosity; as viscosity increases, the flow through the impeller decreases.

The above are process and installation parameters, not mixer parameters. Specific maximum speed for an application is not dictated by the mixer, but by the combination of mixer, tank, process fluid and purpose of mixing.

Frequency (Hz)	Motor speed (rpm)	Impeller speed (rpm) ^a		
		5:1 (60/75 - 120/150)	7.5:1 (120/190 - 210/350)	n/a (SMMS)
10	275	55	37	275
20	550	110	73	550
30	825	165	110	825
40	1100	220	147	1100
50	1375	275	183	1375
60	1650	330	220	1650
70	1925	385	257	1925
80	2200	440	293	
90	2475	495	330	
100	2750	550	367	

■ **Table 5** Approximate impeller speeds for certain motor/gearbox combinations at different frequencies

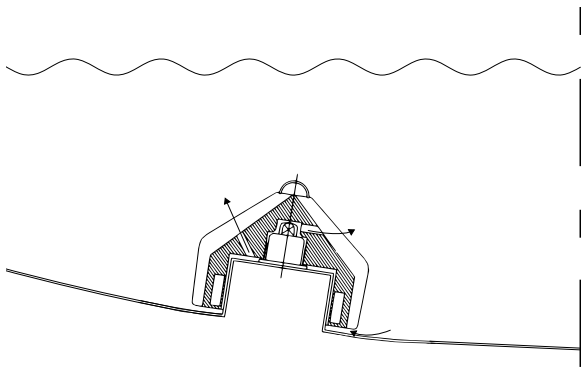
^a Applies to standard IEC drive unit, for other types (IEC ATEX, NEMA XP, NEMA Stainless Steel, etc) this may vary.

Bearing material ^a	Tungsten Carbide	Silicion Carbide	Dri-amond™
Chemical compatibility	pH range 2-14 ^b	Best - inert	Same as silicon carbide
Ease of installation and handling	Best	Harder than tungsten carbide, but more brittle	Somewhat better than silicon carbide
Survivability under dry-running conditions	Good	Poor	Best - lowest coefficient of friction

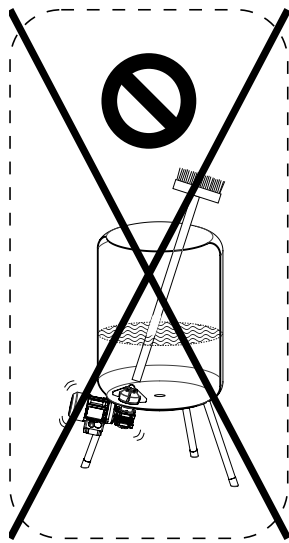
■ **Table 6** Comparison of bearing materials.

^a The use of dissimilar materials in male and female bearings is not recommended

^b Exact value depends on particular fluid properties, temperature and exposure time.



■ **Figure 7** The bearing lubrication principle of the SMA type impeller.



■ **Figure 8** Never insert foreign objects in the vessel when the mixer is operational.

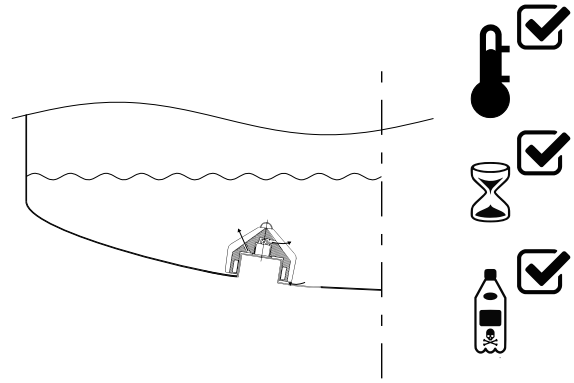
4.5. Further operational advice

The impeller is factory cleaned prior to delivery. However, before it is put into service it must be cleaned in an appropriate manner so that it is free from foreign particles, followed by CIP and/or SIP cycles as required by the application.

The operational parameters are pre-set in the control box (applies only to Steridose-supplied control boxes). In extreme working conditions, uncoupling of the magnetic coupling can occur, i.e. the motor rotates, but not the impeller. To avoid any uncoupling of the magnetic coupling, the acceleration time (ramp up) and the maximum rpm should be adjusted to conform to the specific application.

For a Sterimixer/Sanimixer supplied without a control box, soft manual start of the motor is required to prevent the magnetic coupling becoming uncoupled. A suitable acceleration time up to the maximum rpm can be anything from ten seconds to a couple of minutes depending on the application.

CAUTION: Never insert foreign objects in the vessel when the mixer is operational.



■ **Figure 9** Successful cleaning of the impeller relies on a combination of the self-cleaning flow through design of the SMA-type impeller, the cleaning-agent used and respecting the prescribed time and temperature.

4.5.1. Cleaning guidance for SMA-type impeller equipped Sterimixers

The Sterimixer is designed for optimum performance in cleaning in place (CIP) without any need for dismounting. The flow channels in the impeller provide a process fluid flow through the bearings. In order to achieve this, the impeller should be covered with fluid and rotated at a certain minimum speed. The flow of the process fluid through the flow channels is very much determined by the rotational speed of the impeller.

The result of the cleaning is dependent on many parameters such as temperature, time, and chemical composition of the cleaning agent, mechanical conditions, speed and the type of product to be removed.

The cleaning usually consists of several cycles e.g. pre-rinse, cleaning with base and/or acid cleaning agents, main rinse following acid or base cleaning, and a final rinse.

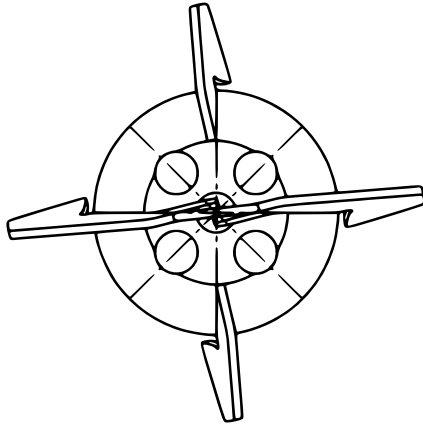
NOTICE: To achieve the optimal cleaning effect the impeller should be covered with cleaning agent and rotating.

Example of CIP procedure for SMA-type impeller:

1. Drain the vessel of process fluid.
2. Close the outlet and fill with cleaning agent having the fluid level above the impeller with at least 150 - 200 mm.
3. A suitable speed is approximately 300 rpm with filled vessel (depending on the size).
4. Normal cycle time is 5 - 20 minutes.

NOTICE: The exact operational conditions for CIP must be validated for each individual application.

NOTICE: The cleaning method described above does not remove any magnetic particles. Due to the strong magnets inside the impeller all magnetic particles will be stuck inside the impeller. To have these removed,



■ **Figure 10** SMO-type impeller with openings that expose the bearing surfaces and weld plate during the cleaning cycle.

the impeller must be removed and cleaned separately. Magnetic particles stuck to the impeller may cause discoloration of the impeller surface.



CORROSIVE AGENTS HAZARD: Many cleaning agents are corrosive. Please exercise adequate care when handling.

4.5.2. Cleaning guidance for SMO/SMMS/Sanimixer-type impeller

This section provides general guidelines for CIP procedures for Sterimixer with SMO style impellers, Sterimixer SMMS and Sanimixer.

The bearing assembly on a SMO/SMMS/Sanimixer-type impeller head is exposed. When directing flow from a spray ball to the impeller head, the bearing surfaces will get in contact with the CIP fluid.

The openings on top of the SMO-type impeller head also allow the CIP fluid to hit the weld-plate under the impeller, please refer to Figure 10. In order to hit all surfaces, the impeller head needs to rotate at low speed during the CIP cycle (e.g. 100 rpm).

The cleaning procedure can be divided in two steps:

4.5.3. Step 1: CIP solution cleaning

Start CIP solution flow through the sprayball at the recommended flow rate. Open the tank outlet valve completely to allow full drainage. Operate mixer at low speed (around 50-100 rpm).

Ensure that the sprayball flow is hitting the impeller head. Typically, coverage test with riboflavin (usually performed during FAT) will provide evidence that the impeller head is fully wetted by the cleaning solution.

The duration of the cycle depends on the application and requires to be validated by swabbing vessel and mixer surfaces.

4.5.4. Step 2: WFI (water for injection) flushing

Repeat step 1 using WFI (water for injection) through the sprayball.

4.6. Guidance for sterilizing Sterimixer/Sanimixer

The Sterimixer/Sanimixer are designed for optimum performance in steaming in place (SIP) without any need for dismounting. The selection of method from those listed below depends on the individual conditions.



CAUTION: The permanent magnets in the impeller and the rotor withstand temperatures up to +225 °C. Never expose these parts to higher temperatures. The drive unit and gearbox shall not be exposed to ambient temperatures above +40 °C.



NOTICE: Use caution when exposing to temperatures over +135 °C as this may decrease the life expectancy of the elastomeres used in the bearing assembly.

A certain delay in the rise of temperature between the inside of the impeller and the vessel is caused by the mass of the impeller head. This delay is influenced by:

- Sterimixer/Sanimixer size: the larger the Sterimixer/Sanimixer, the longer the delay.
- Sterilization method: steam sterilization gives the shortest delay. Hot air sterilization gives the longest delay.

When evaluating sterilization temperature one should focus on the location that is most likely to have the lowest temperature (typically this would be on the inside, in the impeller cavity). A thermal element should be used if the system is sterilized in a hot air oven or autoclave. For applications with SIP/SHW where the impeller rotates, the validation should be carried out by biological tests.

4.6.1. Steaming in place (SIP)

Example of SIP procedure:

- To remove any condensation, the impeller may be rotated at a low speed (i.e. 50 rpm) for a few seconds, approximately every five minutes.
- When the sterilization temperature in the vessel has been achieved, the periodic rotation of the Sterimixer/Sanimixer shall be stopped.

4.6.2. Super heated water sterilization in place (SHW)

The vessel and the mounted drive unit are sterilized with super heated water. Example of SHW procedure:

- The vessel is filled with WFI (water for injection) to a suitable level.
- During heating, sterilization and cooling the Sterimixer/Sanimixer should rotate.
- Vortices (suction whirlpools) must not arise. The water level and speed control this.
- During the emptying phase the Sterimixer/Sanimixer must not rotate.

4.6.3. Sterilization in autoclave or hot air oven

Dismount the drive unit as per section 3.4.2.



CAUTION: The vessel and the impeller (without the drive unit) must be sterilized in an upright position in an autoclave or hot air oven to prevent the impeller sliding off the bearing. To prevent this, a magnetic drive dummy can be installed to avoid any risk of damage and hold the impeller in place.

4.7. Specific information for the use of Sterimixer/Sanimixer in ATEX applications

4.7.1. Use of Sterimixer/Sanimixer in tanks with Ex zone 0 or 1

Mixers are generally defined in the Machinery Directive as incomplete machinery, which are to be installed in another machine (hence delivered with Declaration of incorporation, in accordance with Machinery Directive 2006/42/EC, Annex IIB). That is how the mixer becomes a machine and it is then to be assessed by the tank supplier if it is compliant with the regulations regarding safety (Machinery Directive) and with regards to explosion protection (ATEX Directive 94/9/EC). Only then can a CE mark be granted.

4.7.2. Magnetic mixers in Ex zones

The magnetic mixer is an assembly, consisting of:

- The atmosphere side components, the weld plate welded to the bottom of the containment shell and the drive unit
- The components in the tank, impeller and bushing unit

The magnetic mixer components inside the tank are not in an Ex zone, as long as these components are covered by fluid (the Ex zone is by definition only the gas space above the fluid). The mixer must therefore be covered with fluid when in operation.

The mixer must be installed so that when sufficient coverage is not achieved, the drive is switched off automatically by an interlocking safety circuit.

If the impeller is not rotating, the assembly parts located in the tank may also be in Ex zone 0 (e.g. when emptying). In this operating state, the mixer does not have its own source of ignition. The mixer shall not be allowed to restart until the impeller inside the vessel is properly covered with liquid.

4.7.3. Safety systems

In Ex zone 0, a *double safety system* is to be used. Therefore, the fluid level in the tank must be monitored by a measuring system with the ignition prevention level 2 (IPL2). In general, two independent systems (such as level measurement and limit switch) are used (in Ex zone 1, one directive-compliant system is sufficient).

Measuring systems with high safety integrity level (SIL) are to be used.

As an additional security element for Ex zone 0, a speed sensor is supplied (NAMUR), which measures the actual speed of the mixing impeller. When the difference between measured speed and the frequency converter's set value speed, exceeds 10 %, the drive is to be disabled (interlocking). In this case the magnetic field between the inner and outer magnetic rotor is broken, indicating a malfunction.

4.7.4. Assessment

Components outside of the tank are in Ex zone 1 (or 2) and are delivered with the corresponding ATEX declaration of conformity from the manufacturer (Ex II 2G b/c de IIC T4).

The 'machine' (mixer tank) with all hardware mounted is finally to be assessed with regards to policy compliance (for Ex zone 0 by a notified body).

4.7.5. General

Only genuine parts from the supplier must be used to achieve the level of protection stated.

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Type denomination Sterimixer, Sterimixer-SMMS, Sanimixer

General This incorporation manual applies to the Sterimixer/Sanimixer fitted in applications covered by the ATEX directive 94/9/EC. Note that applicable health and safety regulations with regards to processed media shall be considered by the end-user. The electrical motor, gear-box and impeller monitor (optional) shall be installed and operated as per the manufacturers' instructions supplied with the Sterimixer/Sanimixer.

Protection class  II 2 G c Tx

Type of protection EN 13463-1:2001 'c' 'k'

Safety zones applicable Zone 1 & 2

Maximum surface temperature The maximum surface temperature of the Sterimixer/Sanimixer is very much dependant on the temperature of the media processed by the mixer.

4.7.6. Safety instructions specific to ATEX installations



CAUTION: Please note that all safety instructions in other parts of this manual equally apply to ATEX installations. Please familiarize yourself with all relevant sections.

General By design, Sterimixer/Sanimixer bearings are sliding rotary motion devices. For the proper function, the bearings depend on the presence of cooling and lubrication by the process fluids to limit frictional heat generation. Poor lubrication and poor cooling of the bearings will cause temperatures in excess of allowable limits. To prevent this from happening, the following must be avoided:

- The Sterimixer/Sanimixer operates without any process fluid in the vessel.
- The Sterimixer/Sanimixer operates with a too low level of process fluid.
- The Sterimixer/Sanimixer operates at too high speed.
- The Sterimixer/Sanimixer operates with a fluid having too high viscosity reducing the flow through the bearings.

Chemical compatibility To prevent hazardous reaction between processed fluid and materials of construction the materials of construction shall be ensured to be suitable for the application. The Sterimixer/Sanimixer incorporates different materials of construction being specified in the technical documentation.

Start-up Before start-up of the Sterimixer/Sanimixer the following shall be controlled and verified:

- The Sterimixer/Sanimixer being correctly installed as per section 3.
- Materials of construction chosen are suitable for the application.
- The application is within operating parameters originally specified.

Assembly The Sterimixer/Sanimixer shall be assembled as per section 3.

Disassembly The Sterimixer/Sanimixer shall be disassembled as per section 3.

Maintenance In addition to section 5 the following should be observed:

Frequency	Action
Zone 1 daily, Zone 2 weekly	Verify the function of any alarms applied. Check for unusual noise or vibrations.
Every two years or 9000 hours of operation, whichever comes first	Replace the Sterimixer/Sanimixer with a new or professionally refurbished Sterimixer/Sanimixer. A used Sterimixer/Sanimixer can usually be refurbished, it is therefore essential to handle the mixer with care to prevent unnecessary damage. Life time of the Sterimixer/Sanimixer depends on the application, so shorter service intervals may apply.

4.7.7. Special conditions which by experience have proven likely to occur

- If the Sterimixer/Sanimixer is to be used within another application than originally intended there will

be a risk of chemical incompatibility in between the processed fluid and the materials of construction creating a possible hazard. Each and every application shall be assessed individually to ensure the safety conditions are maintained.

- If the Sterimixer/Sanimixer is subjected to poor lubrication this will create excessive wear and heat and subsequently premature failure.
- If the Sterimixer/Sanimixer is incorrectly installed conditions could very likely be similar to poor lubrication creating excessive wear and heat and subsequently premature failure. It is therefore important that the operator is properly trained and familiar with all procedures.
- If the Sterimixer/Sanimixer is operated beyond its operating limits severe damage might occur subsequently creating a failure. It is essential that the operator has received specific training together with the full understanding of the Sterimixer/Sanimixer and the education related thereto.
- If the weld plate has been incorrectly fitted to the vessel, deformation can cause contact with the impeller and/or magnetic rotor.
- Worn out bearings will cause physical contact in between the impeller and the weld plate. Specified maintenance shall be performed.
- Through poor handling the magnetic rotor can be misaligned causing physical contact between magnetic rotor and weld plate. Always ensure the magnetic rotor to be correctly aligned upon installation.
- If the impeller is subjected to excessive torque it might uncouple the magnetic coupling. Ensure compliance with operational limits and set-up specification.
- Fluids with high viscosity and/or containing particles can possibly clog the impeller's flow channels reducing the cooling and lubricating flow. The applications shall therefore be validated to ensure proper function.
- Incorrect direction of rotation can cause the impeller to decouple from the magnetic coupling. Ensure proper direction of rotation as described in section 3.6.1.

4.7.8. Essential accessories

There are no additional important accessories required for the use of Sterimixer/Sanimixer apart from those being presented in this installation and operation manual.

4.7.9. Drawings and diagrams

No special drawings or diagrams are required for the safe operation of the Sterimixer/Sanimixer apart from those being presented in this installation and operation manual.

4.7.10. Maintenance and service

The Sterimixer/Sanimixer requires a minimum of maintenance. Regular inspection of all parts, and any consequent action is usually sufficient. See section 5.

5. MAINTENANCE

A used Sterimixer/Sanimixer can usually be refurbished, it is therefore essential to handle the mixer with care to

prevent unnecessary damage. Life time of the Sterimixer/Sanimixer depends on the application, so shorter service intervals may apply.



WARNING: Ensure the Sterimixer/Sanimixer is in a safe state before performing any service.

Before performing maintenance and service ensure;

- the impeller and vessel are fully cleaned from any process fluid and that no process fluid can enter the vessel during maintenance.
- the vessel is fully vented from any possible gases.
- the vessel is depressurised.
- the main power is switched-off and cannot be accidentally switched on during maintenance.
- the vessel has been cooled to a temperature below 50°C (or a limit set by local regulations).

5.1. Routine maintenance during start up/running in

Following maintenance schedule should be performed at start up and/or running in of the Sterimixer/Sanimixer.

- Remove and check the impeller.
- If particles are stuck to the impeller they have to be removed.
- Due to the strong magnets inside the impeller all magnetic particles will get stuck inside the impeller. Therefore, check the inside of the impeller in particular.
- The impeller must not be scratched or in any way damaged. If it has been damaged, the impeller and bearing must be replaced. The impeller can be sent to Steridose for refurbishment.

5.1.1. At least once a year - interval dependent on application

The following maintenance schedule should be performed at least once a year. Note that the interval will be highly dependent on the application.

- Remove and check the bearing and the impeller for signs of surface damage and general wear of the bearings.
- Change the bearing and the impeller if the surface is coarse or uneven, scratched or if fragments have been knocked out from the bearing. The impeller can be sent to Steridose for refurbishment.
- Change the PTFE washer when dismantling the bearing.
- Make a general inspection of the motor, gearbox and other Sterimixer/Sanimixer parts. Make sure the gearbox is not leaking oil.
- ATEX application specific advice can be found in section 4.7

5.1.2. General guidelines on bearing wear

Actual wear of the impeller bearing and the male bearing unit will depend on the application. Impeller bearings can in many cases be replaced as part of an impeller refurbishment. This refurbishment can only be done at the Steridose factory or authorized Steridose service center.

Male bearing units cannot be refurbished, they must be replaced when worn.

The outline of a bearing wear assessment is as follows:

1. Measure the inner diameter of the impeller bearing, $ID =$
2. Measure the outer diameter of the male bearing unit, $OD =$
3. Calculate the difference $ID - OD =$ and check that the difference does not exceed 0.14 mm. If the measured value exceeds the 0.14 mm, send in your impeller and bearing unit in for evaluation and repair.

6. TROUBLESHOOTING

Refer to table 7.

Fault	Possible cause	Action
The mixer does not start	Fault in power supply	Check power supply
The impeller does not rotate	Male bearing or magnetic drive not mounted	Dismount the drive unit, detach the impeller and mount the male bearing, impeller and magnetic drive
Insufficient power	Motor connected incorrectly	Check wiring diagram and wiring
Poor mixing	a) The impeller does not rotate at the maximum speed b) Impeller rotating in the wrong direction	a) Increase speed, pay attention to the guidelines in section 3.6.2. b) Check the drive installation AC: phase reverse power cables DC: pole reverse power cables AIR: swap the air supply and outlet hoses. Verify the impeller rotates clockwise when seen from above
The mixer does not reach the required maximum rpm	Incorrectly set parameters in the VFD (Variable Frequency Drive)	Adjust and calibrate the VFD
Slow and inefficient compressed air driven motor	Clogged motor housing	Flush with paraffin as per motor supplier's maintenance instructions
Noise from the mixer	a) Impeller has rotated without fluid between the male and female bearing b) Worn out bearings c) Missing male bearing d) Mechanical interference (contact) between impeller and weld plate e) Mechanical interference (contact) between magnet rotor and weld plate	a) Stop the mixer. Do not restart until the fluid level covers the impeller b) Replace the bearing and the impeller c) see b) d) Reinstall the weld plate correctly e) Realign the magnet rotor
Noise from the drive unit (first discard that this is not 'normal noise' amplified by the vessel acting as a soundboard)	a) New drive unit has not been allowed to run in b) Gearbox problems. Running insufficiently lubricated	a) Run the drive unit for a couple of hours to see if the noise disappears b) Refer to gearbox supplier maintenance manual
Magnetic coupling disconnected	a) Acceleration too rapid b) Speed too high for the application	a) Adjust acceleration b) lower speed.
Insufficient cleaning of the impeller	Poor fluid flow through the impeller a) Due to low fluid level b) Due to low speed c) Due to high speed d) Magnetic particles	a) Increase fluid level b) Increase speed c) Reduce speed and the formation of vortices d) Magnetic particles are not removed during normal cleaning. The impeller must be removed and cleaned separately

■ **Table 7** Troubleshooting.

About us

Steridose is a global company and our world headquarters are located in Tumba, Sweden. We are highly specialized in the design, development and manufacturing of magnetic coupled mixers and radial diaphragm valves.

Steridose is part of the Velcora group, with regional offices in key locations around the world.

Steridose is represented in important certifying and standards organizations, most notably and relevant to the pharmaceutical industry, ASME BioProcessing Equipment standards committee (BPE). We help develop the standards and Good Manufacturing Practices that minimize risk for process interference.

Steridose partners with the best distributors and representatives in the industry all over the world. Together we become the perfect mix; a premium product with global references combined with local presence for product and application support.



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