

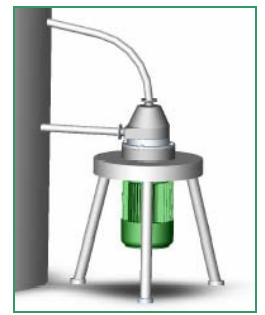
# High Shear In-Line Mixer User's guide

Technical Description

Installation

Operating Instructions

Maintenance



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# I. Introduction

## I.1 General

The High Shear In-Line Mixer is especially designed for the aseptic process in the pharmaceutical and biotech industry. The design represents the culmination of more than 25 years of engineering and design experience with this type of equipment. The aseptic design concept, on which it is based, will greatly improve the serviceability, cleanability and sterilizability of your mixing process.

The fact that the High Shear Mixer Rotor is driven by magnetic forces eliminates drive shafts through the vessel wall. Any possibility for seal leakage to occur is totally eliminated. This is a unique technical advantage of the High Shear In-Line Mixer. An added feature of this design is the ease of service when it is required.

The aseptic design of the High Shear In-Line Mixer represents a major improvement.

- It totally eliminates the possibility for entrapment of air pockets inside the Rotor and Housing.
- The CIP-process is made safer and more effective.
- The SIP-process is made easier to perform.
- All wet surfaces are made drainable.

**IMPORTANT:** The manual, as well as the enclosed documents and addendums must be read carefully before installation and start-up. All warnings and prohibitions must be considered. Also, particular attention and complete understanding must be made of section #2- Safety. Negligence to do so can result in personal injuries and or material damage.

## I.2 Warrantee

NovAseptic AB. offers comprehensive after-sales services. If any major defect develops, the High Shear In-Line Mixer should be returned immediately for service or repair.

Repair under warrantee will be in effect without charge for up to 1 year from the date of purchase.

The mixer must only be shipped suitably packed and with the prior approval of NovAseptic AB or their accredited representatives. All boxes, packing slips and correspondence should refer to the RGA number provided by NovAseptic.

The nature of the defect should be described in detail with the model and serial number of the mixer component noted in any accompanying correspondence.

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**NOTE!** The warranty will not be valid if any types of modifications have been made to the delivered original High Shear In-Line Mixer.

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## I.3 Technical Service

Spare parts and advice regarding operation of your NA-Mixer can be obtained from your local appointed agent or NovAseptic AB.

NovAseptic AB  
Rödjans Väg 7  
SE-449 34 Nödinge, Sweden

Phone: +46 (0)303-97520

Fax: +46 (0)303-96079

[info@novaseptic.se](mailto:info@novaseptic.se)

[www.novaseptic.com](http://www.novaseptic.com)

## 2. Safety

All High Shear In-Line Mixers are supplied as components and are intended to be mounted onto process vessels before use. The High Shear In-Line Mixers must not be modified in any way or run beyond their limits specified in this manual or addendums to this. The High Shear In-Line Mixer can only be used with liquids compatible with the material in the mixer specified in the Product Specification Sheets.

Each warning and prohibition is marked in the manual with symbols as below:

### 2.1 Signs used in this manual



**WARNING:**

**Negligence to this warning can result in personal injuries and or material damage**



**PROHIBITION:**

**Ignoring these prohibitions will definitely cause damage to personnel and or components**

### 2.2 Warnings



**People carrying any electrically controlled medical devices (pacemakers etc.) should not be involved in the close handling of the magnetic mixers.**



**Certain magnetic cards can be damaged in close contact with the above-mentioned magnetic parts.**



**Always use the High Shear In-Line Mixer connected to a vessel.**



**The magnetic items (High Shear Rotor and Outer Driving Head) should on a routine basis be checked against foreign material that can get magnetically stuck to their surfaces.**



**It is important to check that correct / equal sizes are used as complete units.**



**Never install any components (dip-tubes, sensors, etc.) in the immediate vicinity of any rotating parts.**



**To avoid burns stay away from all heated parts as well as the Drive Unit.**

## 2.3 Prohibitions



Before any kind of maintenance work with the High Shear In-Line Mixer, make sure that the vessel, (piping system), etc. where the mixer is installed, is at atmospheric pressure, cooled down to max 25 °C, totally drained from liquids or gases and not showing any trace of other dangerous products.



Be aware that standard motors are not explosion proof.

It is the **customer's responsibility to check the safety** of the High Shear In-Line Mixer each time it is used in a new application. It should be checked with regard to:

- External loads due to traffic, wind, seismic activity etc.
- Reaction forces and moments that result from any supports, attachments, piping etc.
- Corrosion and erosion, fatigue etc.
- Decomposition of unstable fluids

### 3. Description

The High Shear In-Line Mixer is available in one model and size. It is designed to be used in liquid process vessels mainly in pharmaceutical/biotechnology industries and for liquid products.

*All parts described below have their own ID-No. and size code, which correspond to the actual documentation.*

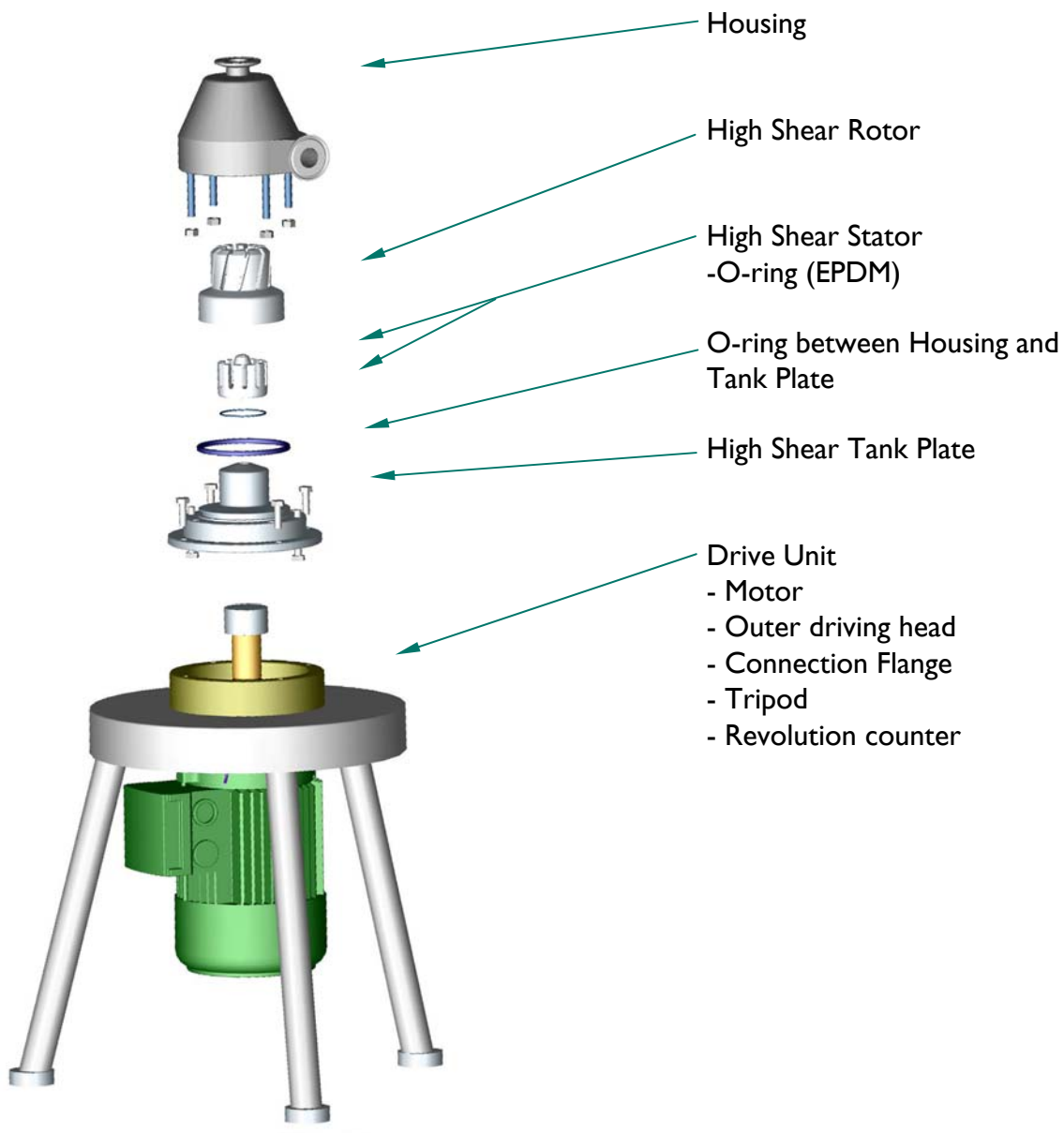


Fig.3.1 Exploded view High Shear In-Line Mixer



### 3.1 High Shear In-Line Housing

All High Shear In-Line Housing consist of the following parts:

- Inlet with TC-connection
- Outlet with TC-connection
- Housing with inner radial slots
- Screws for assembly
- Nuts for assembly

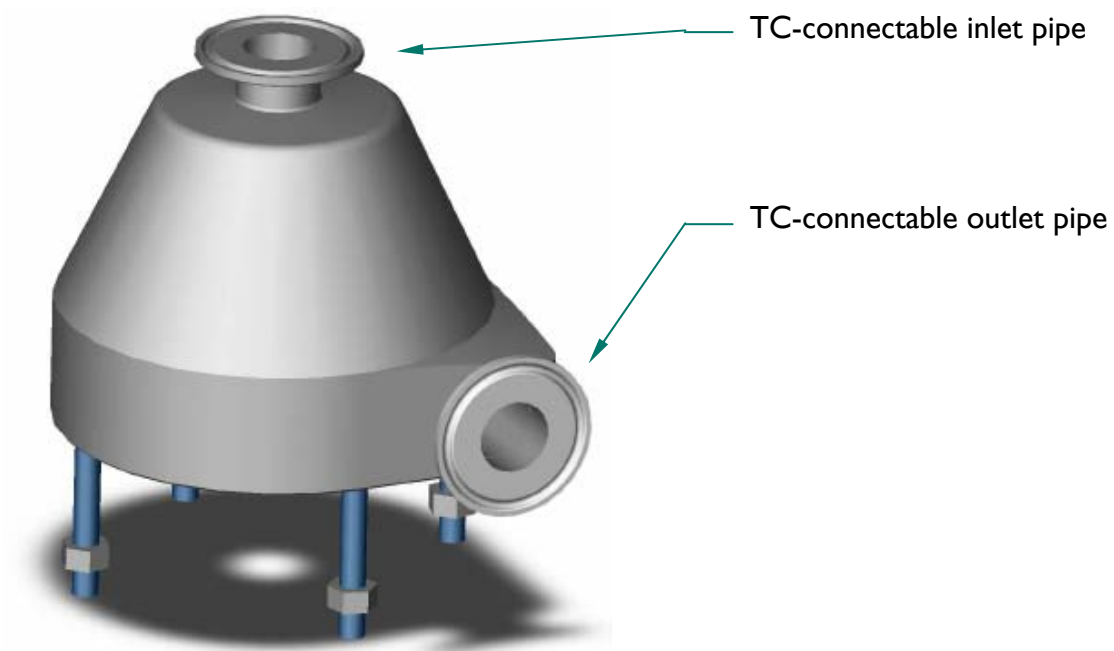


Fig.3.1.1 High Shear In-Line Housing

Each High Shear In-Line Housing is marked with individual ID No. and heat number.

### 3.2 High Shear Rotor

All High Shear Rotor consist of the following parts:

- Rotor body, with a ring of permanent encapsulated magnets
- Female ceramic bearing
- High precision slots corresponding to the teeth in the Stator

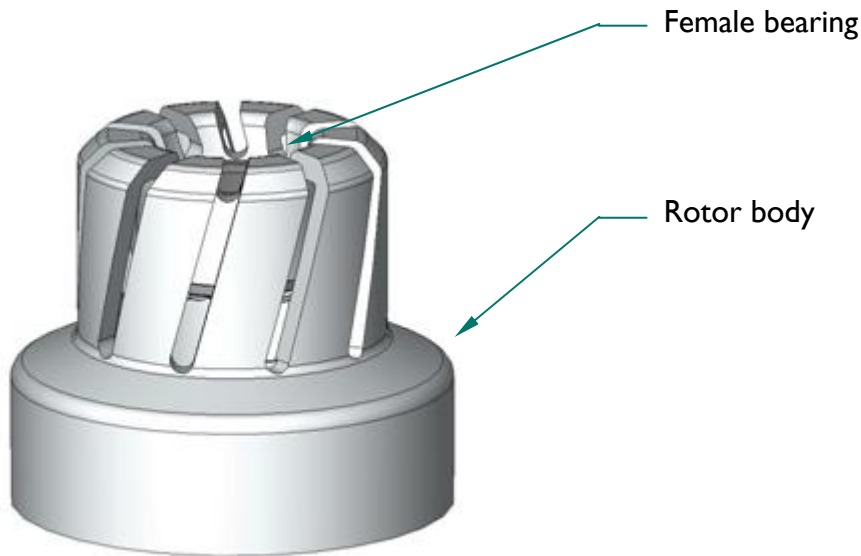


Fig.3.2.1 High Shear Rotor

The High Shear Rotor is designed to operate in aseptic pharmaceutical processes. Therefore, they are designed free from pits, crevices, cavities, hidden areas, etc. and are manually and electro-polished to a high degree of smoothness.



**The magnetic forces must be kept away from any contaminating magnetic particles that will be attracted by the magnetic fields.**



**Avoid operating temperature >135 °C.**



**The High Shear Rotor surface is manufactured with high demands on surface quality and tolerances. It must, therefore, be handled with great care to prevent damage to its functionality and cleanability.**



**The High Shear Rotor may corrode if used with non compatible liquids or substances. This can lead to failure.**

### 3.3 High Shear Stator

All High Shear Stator consist of the following parts:

- A stainless steel support with a connection thread to the High Shear Tank Plate, and a groove for the o-ring, on the bottom and sharp teeth produced with high precision to generate high shear forces when the Rotor with corresponding slots passes the teeth.
- One solid piece of bearing material (Silicon Carbide) that is fixed into the stainless steel support. The bearing material is hard and brittle with a bearing surface that is ground and polished to precise tolerances.

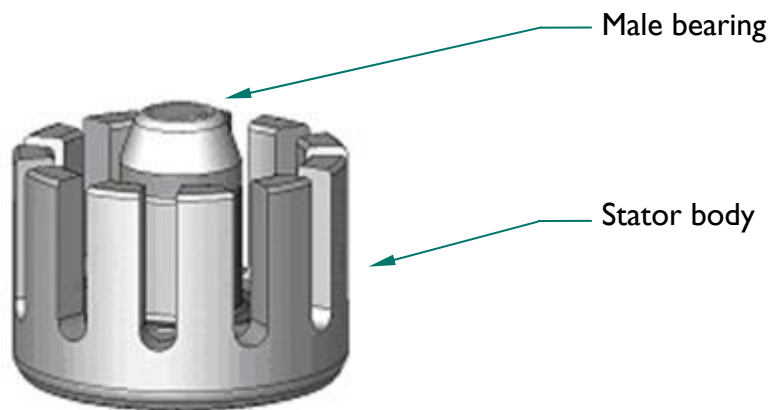


Fig.3.3.1 High Shear Stator



When connecting and disconnecting the bearing from the High Shear Tank Plate, do not use any grip tools other than NA recommended tools on the bearing surfaces.



Hard hits and incorrect handling will definitely break the bearing material.



**The High Shear Stator surface is manufactured with high demands on surface quality and tolerances. It must, therefore, be handled with great care to prevent damage to its functionality and cleanability.**



**The High Shear Stator may corrode if used with non compatible liquids or substances. This can lead to failure.**

### 3.4 High Shear Tank Plate

The High Shear Tank Plate is made from one uniform piece of material, and includes:

- Connection thread for High Shear Stator
- O-Ring between tank plate and In-Line housing
- Jack Screws
- Connections for In-Line housing
- Connections for In-Line Drive Unit

Each High Shear Tank Plate is marked with an individual ID No. and heat number.

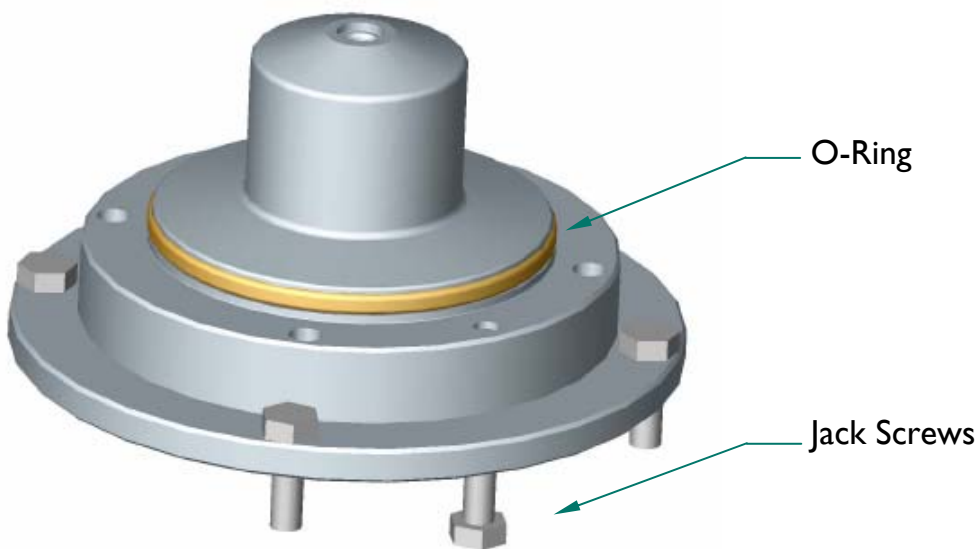


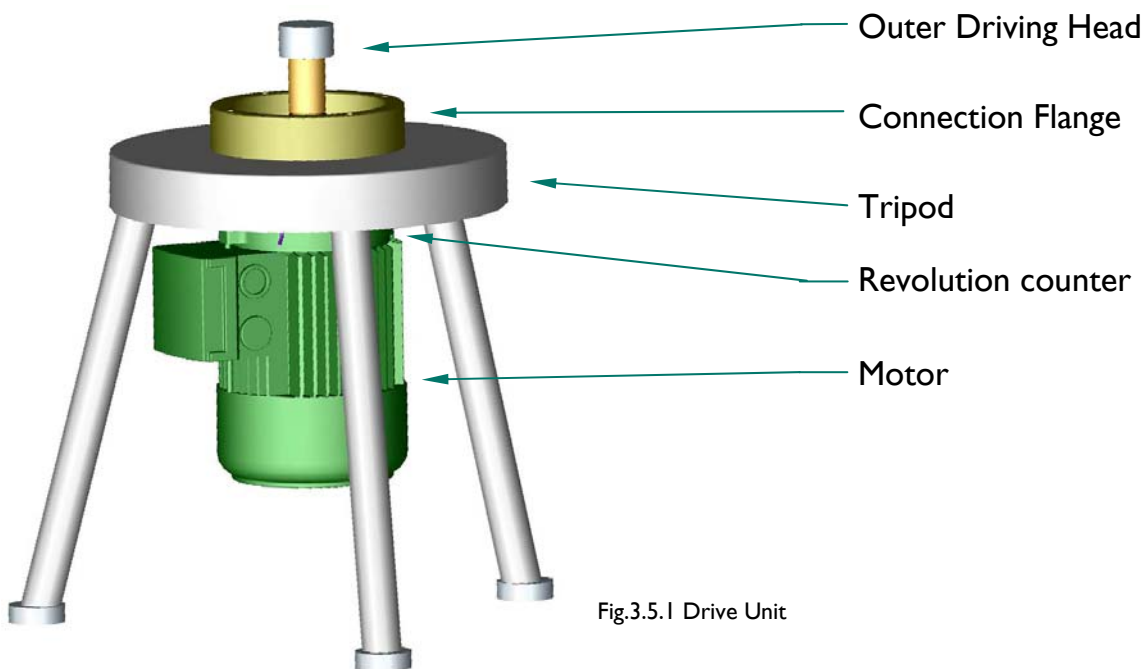
Fig.3.4.1 Tank Plate

## 3.5 Drive Unit

The Drive Units consists of the following parts:

- Tripod
- Motor
- Connection Flange
- Outer Driving Head
- Adapter
- Revolution counter

The Drive Unit is supplied as a factory assembled unit and needs no preparation before installation. For motor data, see High Shear In-Line Mixer documentation.



**Do not make any adjustments on any screws or bolts.**



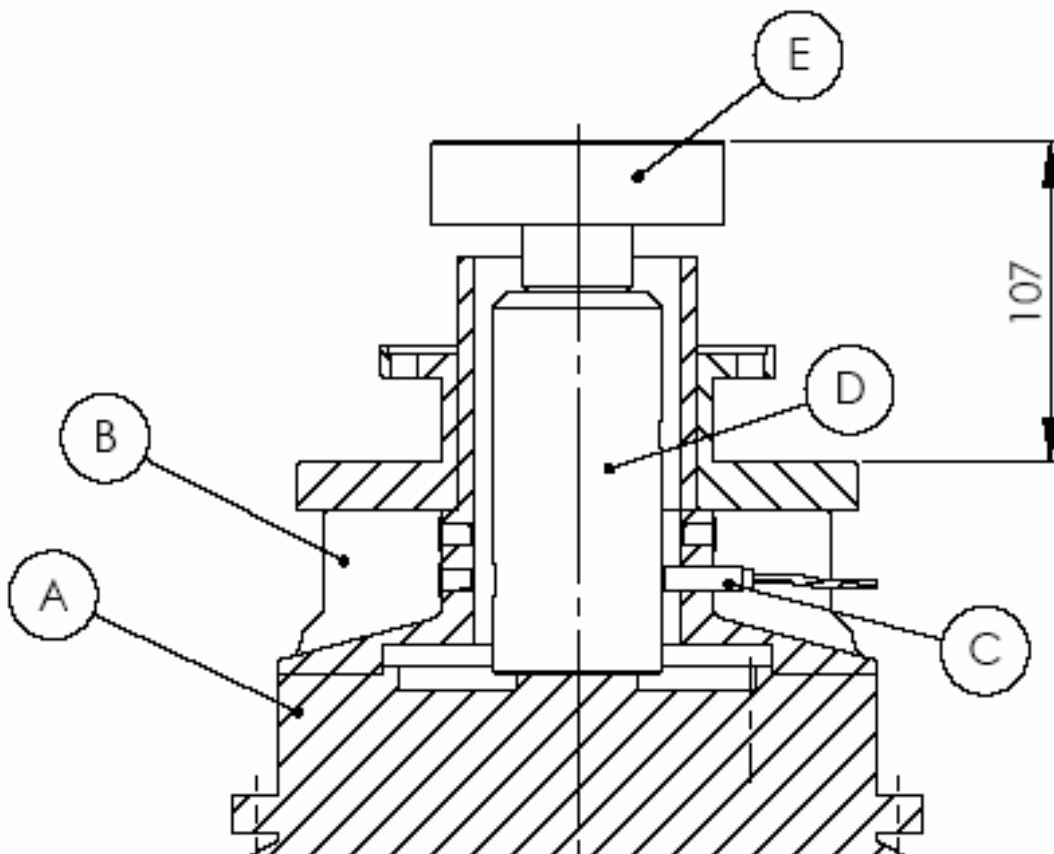
**Protect the Outer Driving Head and shaft from damage. If this part becomes misaligned and put out of position, it will lead to malfunction of the mixer.**

### 3.6 Revolution Counter

The HSI Mixer has an optional Revolution Counter, which measures the number of revolutions of the motor shaft.

#### Installation guide

The Revolution Counter (C) is placed on the motor flange (B). The sensor receives signals from a shaft adapter (D) on the motor shaft. This enables measurement of motor rotation (A) speed and rotor (E) speed.



### 3.7 Dimensions and Weights

These statements refer to standard mixers with a standard drive motor and a standard High Shear In-Line Mixer.

Weight: Shows the approx. weight of the High Shear In-Line Mixer and Drive Unit.

Dimensions: Shows the approx. dimensions of standard Drive Units

HS Size	HS-Housing	HS-Rotor	HS-Stator	HS-Tank Plate	Drive Unit with Tripod	Drive Unit		
	Weight (Kg)	Weight (Kg)	Weight (Kg)	Weight (Kg)	Weight (Kg)	X (mm)	Y1* (mm)	Y2* (mm)
<b>T60</b>	4,0	0,9	0,3	3,3	25,0	600	458	518

\*Dimension Y is without extension.

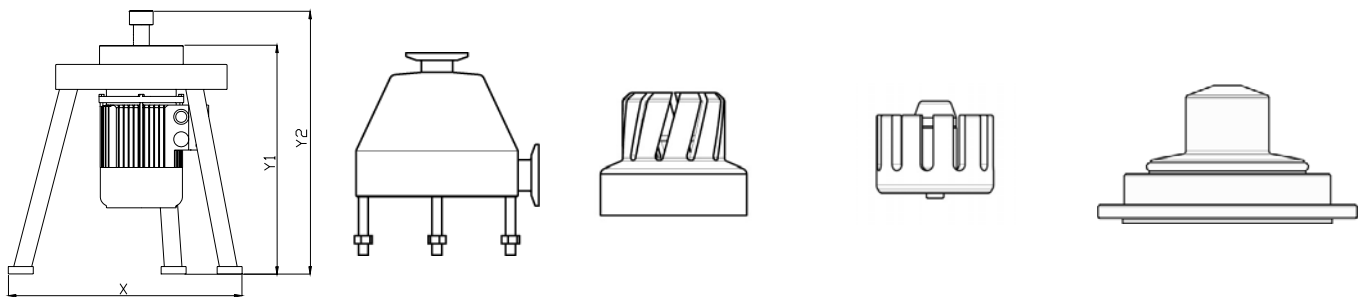


Fig.3.7.1

For more detailed information regarding dimensions and weights for the High Shear Rotor and Drive Unit, please refer to High Shear In-Line Mixer Product Specification Sheets.

### 3.8 Noise level and Vibrations

For detailed design data regarding noise level and vibrations, see motor data in the High Shear In-Line Mixer documentation and applied standards.

#### 3.8.1 Noise level

Noise levels; measured using the method prescribed by ISO 1680 Standards, are within the maximum levels specified by Standards CEI 2-24 / IEC 34-9. The final noise level with the High Shear In-Line Mixer mounted in the system must be analyzed before the complete installation is declared in conformity with the machine directive

#### 3.8.2 Vibrations and balancing

All rotors are balanced with half key and fall within the vibration standards of class N, as specified by Standard CEI 2-23 / IEC 34-14. The final vibrations with the High Shear In-Line Mixer mounted in the vessel must be analyzed before the complete installation is declared in conformity with the machine directive.

## 4. Transport and Handling

### 4.1 Transport

The High Shear In-Line Mixer **must not** be transported without being packed securely to avoid damage during transport or storage.

Keep the High Shear Housing, Rotor, Stator, Tank Plate and Drive Unit in their packing as long as possible in order to protect the equipment from dirt, blows or other impacts.

### 4.2 Handling

When the High Shear In-Line Mixer is received and unpacked, take precautions to prevent scratching the polished surfaces with any tools. Be aware that any contact between the stainless material and other non-stainless materials will result in a material contamination that can lead to corrosion spots.

The surface of the High Shear Housing, Rotor, Stator and Tank Plate are manufactured with high demands on surface quality and tolerances. It must, therefore, be handled with great care to prevent damage to preserve its functionality. When the High Shear Rotor has been taken out from the vessel and is not in use, it should be placed on a table according to fig.4.2.1, preferably on a soft material or stored in its original packing materials. Since the High Shear Rotor and the Outer Driving Head on the Drive Unit are highly magnetized, avoid contact with magnetic particles and other magnetized material. Do not place the High Shear Rotor onto its lower base magnetized ring.

To avoid damaging the rotating shaft and the outer driving head, the High Shear In-Line Mixer Drive Unit should always be put in such a position, that there is no risk for the Drive Unit to flip over and thereby damage the Outer Driving Head when it is not installed in the vessel, see fig. 4.2.1.

By putting the Drive Unit according to fig. 4.2.1 you will also avoid having the magnetic Outer Driving Head from contacting particles that may damage the functionality of the mixer.

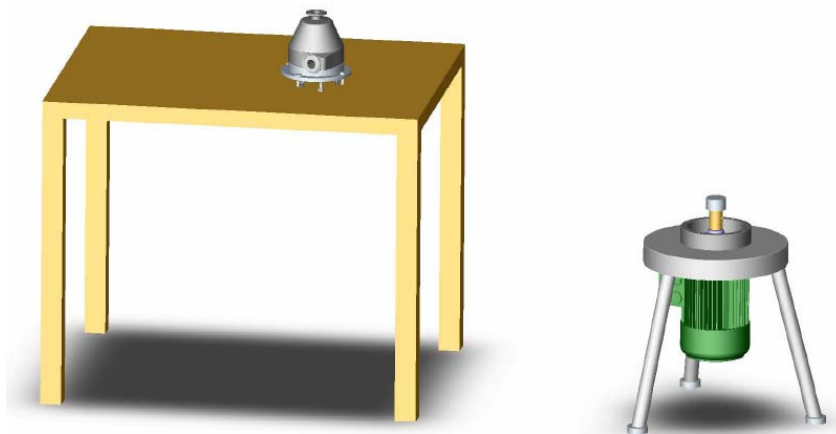


Fig. 4.2.1



## 5. Installation

Do not install the High Shear Rotor, Stator or the Drive Unit into a new process system before it has been properly cleaned. New process systems will always carry a heavy burden of foreign material that must be removed before the system can be taken into use. These materials could contain magnetic particles that will be caught by the magnetic fields of the High Shear Rotor.

Keep the High Shear Housing, Rotor, Stator and Tank Plate in the transport wrapping until they are to be installed in the process vessel. If they have become dirty during handling, a cleaning procedure, as described in section 6.3.3, must be performed.



**Before any kind of maintenance work, make sure the vessel has been cooled down, emptied, depressurized and ventilated from any possible gases or any traces of dangerous products. Disconnect all media during maintenance work.**

### 5.1 Electrical Installation

*When a Control Unit delivered by NovAseptic is used, the manual for the Control Unit must be carefully followed.*

All incoming power must be equipped with an emergency stop (near to its unit) and an on/off switch with locking possibilities. Use only cables with correct voltage and current ratings. To ensure that it does not create any interference, the cables are recommended to be shielded. It's also important that the electrical equipment is well ground.



**NOTE!** Make sure that the electric cables between the Drive Unit and connecting cabinet are of such length, that it is possible to dismount and take the Drive Unit away from the vessel.

To set the speed within its limits it is required to have a speed control device installed, as:

- o AC-motor Frequency converter, with adjustable acceleration/ retardation-time

**AC-MOTOR (Alternating Current)**

Connection according to the switchboard diagram. Changing two connection wires can reverse the direction of rotation.

To protect winding against overloading, a motor protection must be used.

The overload function must be set to the correct rated current to the respective voltage, see rating plate / technical data sheet.

Make sure that the electric cover and the conduit entries are properly in place after installation.

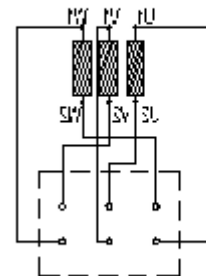


Fig. 5.1.1

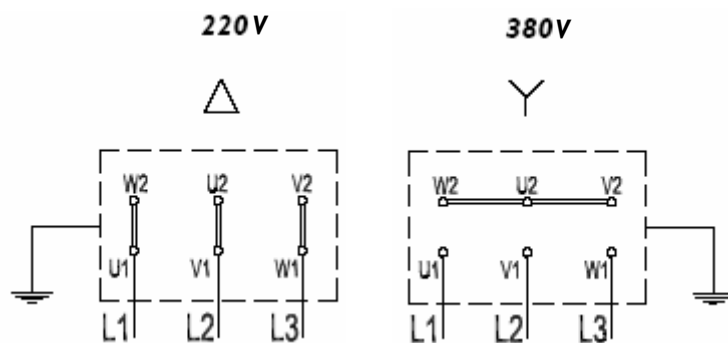


Fig. 5.1.2

**USA**

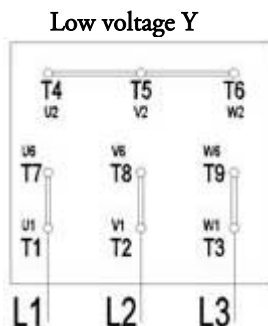


Fig. 5.1.3

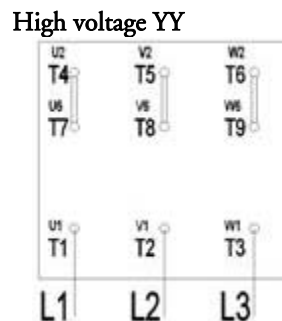


Fig. 5.1.4

## 5.2 Revolution Counter

Product Specification Sheets for the Revolution counter will be delivered with the documentation for the Drive unit.

### Technical information

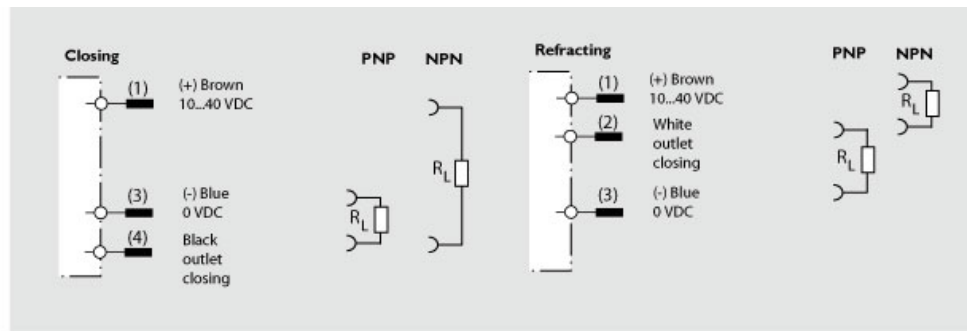
Supply voltage	10...40 VDC, $\pm 10\%$ reverse connection protection
Current consumption	Max 13 mA
Control output	200 mA, open collector, short-circuit protection
Sensing object	Metal
Indicator	Indication of operation LED yellow
Ambient Temperature	-40...70°C (with no icing)
Enclosure rating	IP67, IEC 60529
Material	Coating: Stainless Steel (M8) Sensor house: Plastic (PBT)
Weight	270g
Component	



M8  
2 = refracting  
4 = closing



M12  
2 = refracting  
4 = closing



### 5.3 Commissioning of Drive Unit

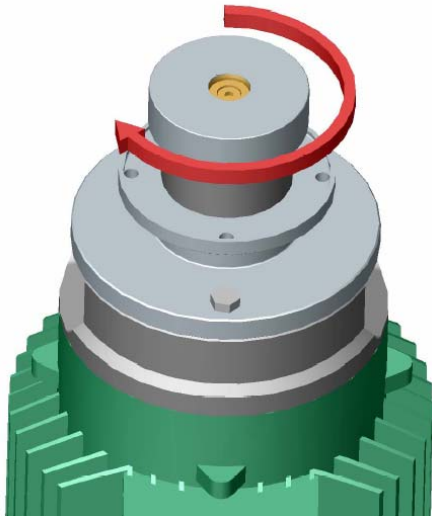


Fig. 5.3.1

After installation, it is very important to check that the motor is running in proper rotation, direction which means **-CLOCKWISE**, seen from above. If not, the High Shear Rotor may come off the Stator and cause damage to the Housing or the Stator may unscrew from the Tank Plate. To perform this test, the Drive Unit should be placed on the floor or on a table and driven at as low speed as possible without Tank Plate mounted.

1. Install the Drive Unit to a frequency converter, see chapter 5.1, electrical installation
2. Rotation direction. The proper rotation direction is clockwise see fig 5.3.1.



Contact with the outer driving head when rotating without cover can lead to personal injury.



Incorrect rotation direction may cause damage to the vessel and High Shear In-Line Mixer.



Incorrect rotation direction may unscrew the High Shear Stator during operation causing malfunction and damage.

When commissioning the Drive Unit according to the above mentioned instruction has been performed, the Unit should be lowered to its disconnection position. At the final installation, the instructions should be followed according to the chronological order described in this manual.

## 5.4 Installing the High Shear Stator on Tank Plate

1. Unscrew the jack screws on the Tank Plate.

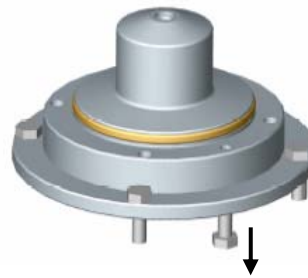


Fig.5.4.1

2. Check O-ring on stator.

Check that the sealing o-ring is properly in place according to fig 5.4.2.

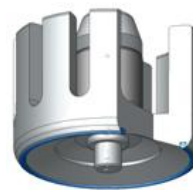


Fig.5.4.2

3. Mount Stator with High Shear In-Line mounting tool for stator.

Screw the Stator clockwise into the thread in the High Shear Tank Plate. Tighten the Stator to steel/steel contact.

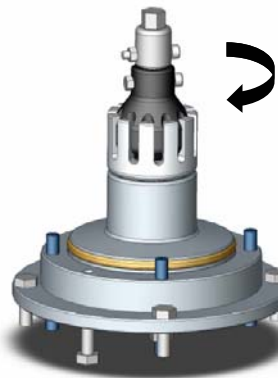


Fig.5.4.3

G20-005
20 Nm [14.8 lbf <sup>t</sup> ]



Make sure that it is aligned to the centerline of the High Shear Tank Plate, and can be screwed without any resistance.

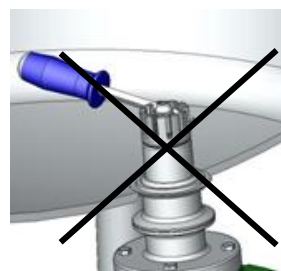
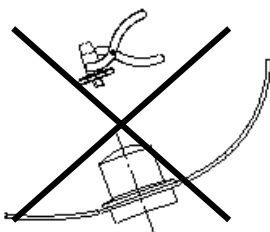


Fig.5.4.4

Never use any grip tools or other tools to mount the Stator, then the High Shear Stator mounting tools. It will definitely damage the surface and can break the bearing.



The Tank Plate must be clean and completely dry, before the installation of the High Shear Stator. Make sure that the stator also is completely dry. Ignoring this warning can result in material damage.



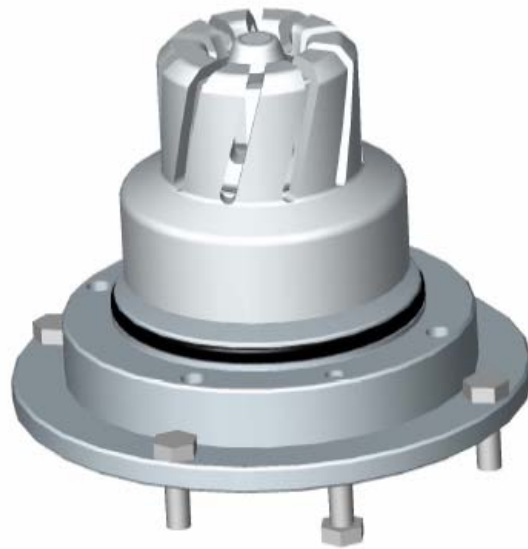
The High Shear Tank Plate thread must be cleaned before installation of the High Shear Stator. If the thread is not cleanable please contact NovAseptic AB.

## 5.5 Installing the High Shear Rotor



Never install the High Shear Rotor on the Stator with the Drive Unit connected to the Tank Plate. The powerful magnetic forces can cause severe damage to the bearing.

1. Inspect the Rotor so that it does not contain any foreign particles, especially on the magnetic part.
2. Mount the High Shear Rotor by hand.
3. Position the High Shear Rotor very carefully and place it properly aligned onto the High Shear Tank Plate. Do not drop the Rotor onto the male bearing. The bearing surfaces are very brittle and can be easily destroyed.
4. Rotate it by hand or with the mounting tool to ensure that it will rotate without any scratching.



A special tool should be used to mount the High Shear Rotor. Without the correct mounting tool, the material may be damaged.

## 5.5 Installing the High Shear Housing on the Tank Plate



Never install the High Shear Housing while the Drive Unit is connected. The powerful magnetic forces can cause severe damage to the bearing.

1. Make sure that the O-ring gasket is placed correctly in the slot on the Tank Plate.
2. Carefully place the Housing in the Tank Plate.
3. Tighten the nuts to 20 Nm.

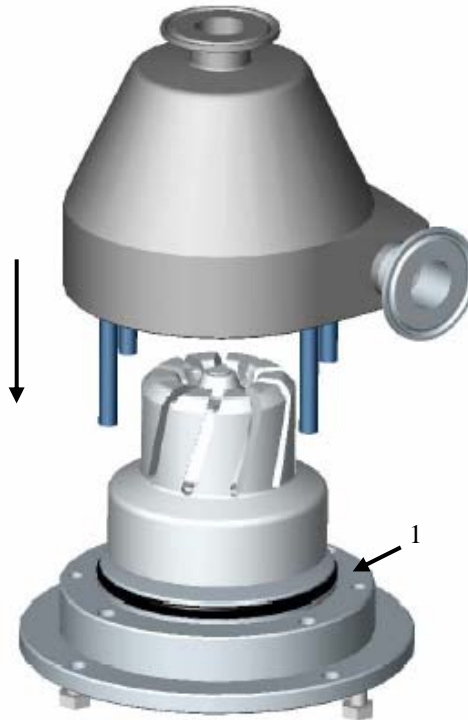


Fig.5.5.1

## 5.7 Installing the In-Line Housing unit on Drive Unit

Follow enclosed installation instructions for the Drive Unit:



### Mounting

The High Shear Rotor and Stator and Housing are to be mounted on the Tank Plate before the Drive Unit is attached to avoid damage to the bearing surfaces. This ensures that no bearing damage can occur by the significant magnetic forces pulling the Rotor to the magnets of the Drive Unit.

### High Shear In-Line T60

1. Insert the High Shear Housing unit on the High Shear Drive Unit.



**Warning! Powerful magnets on Drive Unit.**  
Operators might injure themselves, us precaution.

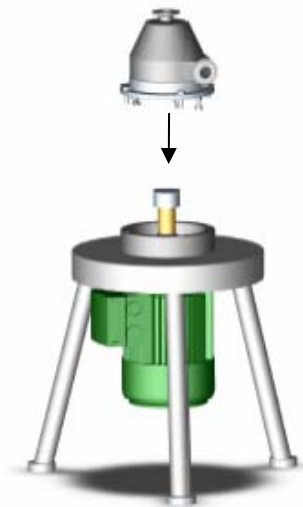


Fig.5.7.1

2. Connect the In-Line Housing to the Drive Unit flange and secure with screws.
3. Connect the inlet and outlet pipe with TC-clamps.



Fig.5.7.2

### Disassembly of mixer system

The above-mentioned procedures in chapters 5.5, 5.6 and 5.7 shall be followed in reversed order for dismantling the High Shear In-Line Mixer.



### Dismounting

The In-Line Housing unit must be dismounted before the High Shear Rotor can be lifted from the Stator.



## 5.8 Start-up

### Before and during Start-up



The Housing must be filled up with enough liquid and the air vented of, trough the inlet pipe to get liquid to cover the High Shear Rotor.

Dry operation will immediately cause damage to the bearing!



Fig.5.8.1

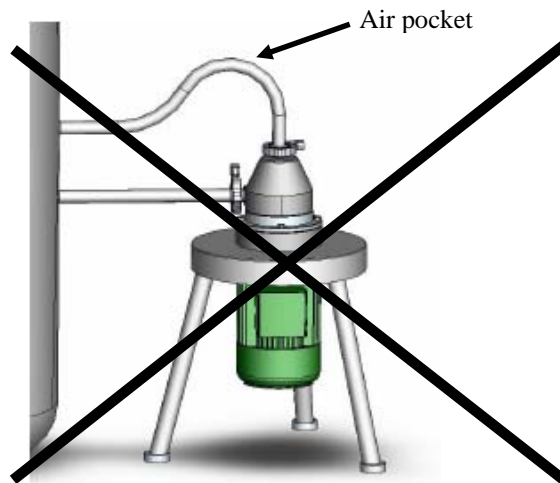


Fig.5.8.2

*Ignoring above prohibitions will definitely cause damage to the bearing*



Make sure that nobody is working inside the vessel.  
Never work close to the Drive Unit while it is connected to its driving source.

The following matters must be considered during the start-up of a mixing system:

Before start-up; it is necessary that the installation procedures according to chapters 5.4, 5.5, 5.6 and 5.7 are completely understood and fulfilled.



Keep away from movable parts.



To avoid magnetic decoupling during start-up and continuous production, it is important that the acceleration, retardation time and speed level are considered.

1. Connect the Drive Unit to its driving source.
2. Adjust the max. / min. speed and acceleration / retardation time to a value applicable to the actual product and system.
3. Start the High Shear In-Line Mixer for a few seconds, **ENSURE THAT THE MIXING HEAD IS ROTATING CLOCKWISE** (seen motor fan).
4. Start the mixer and slowly increase the speed to its working level of rotation.



If any signs of malfunction, abnormal noise, smells, etc. occur; **THE MIXER SHOULD IMMEDIATELY BE STOPPED, and the cause investigated.**

**Now your High Shear In-Line Mixer is ready to be put in use!**

## 6. Operation

### 6.1 Operating limits

Process medium: Newtonic liquids  
Medium temp: 5° - 135° C  
Pressure: See appropriate calculation for the actual pressure vessel



To avoid cavitation, resulting in a dry running “rumbling noise” (which might cause damage to the bearing unit), it is important to optimize (adjust) the mixing speed according to actual volume, temperature and viscosity.



Max speed, see product specification sheet for Drive Unit, HS T60 and HS T260



Do not overload the Drive Unit

### 6.2 Principles of operation



Always fill up enough liquid into the vessel and run the mixer before solid material or other substance is added.

#### Dry running:

In the manual, it is repeatedly emphasized that the mixer shall not be run dry. A physically dry bearing surface will shear, start screaming and finally break. The definition of a physically dry surface is that it is completely clean and free from any liquid film that can act as lubrication for the bearing. During certain processes this situation can develop and precautions must be taken to avoid it.

Typical application where such precaution must be taken is if the mixer is run at:

- High speed
- In hot WFI
- At atmospheric pressure
- During and after steam sterilization

It is important that these four factors are carefully considered during process validation work and controlled so that heavy damage does not occur.

Completely dry surfaces can rapidly be developed between the male and female bearing part due to sudden liquid boiling and cavitations. A typical scenario is:

*High frequency noise ⇒ Rumbling ⇒ Magnetic decoupling ⇒ Possible bearing damage*

Stop the High Shear In-Line Mixer immediately and inspect the male bearing ensuring that it is properly tightened and have full metal-to-metal contact to the Tank Plate. Make certain that the Rotor is not hitting any vessel surfaces. Check the bearings for cracks and damage.

#### **pH-limit:**

The bearing material, Silicone Carbide (male and female) will tolerate continuous contact with solution in the pH-range of 1-14.

#### **Temperature:**

Make sure that the motor does not operate with higher ambient temperature than 40°C.



**Do not exceed maximum operating temperature of 135°C inside the system.**

## 6.3 Cleaning procedure for the High Shear In-Line Mixer (CIP)

The High Shear In-Line Mixer is designed with an open design that enables the High Shear Rotor, Stator and Tank Plate and Housing to be easily cleaned while they are installed in the processing vessels. This procedure is generally called CIP (Cleaning In Place).



The operating personnel should, however, be aware of that the Rotor should be removed from the Tank Plate on a routine basis to check if magnetic particles from the raw materials have been collected on the internal surface of the Rotor.



Accumulation of magnetic particles on the inside of the Rotor can cause corrosion and damage the Rotor or the Tank Plate and Housing. A higher torque used by the motor can be an indication of accumulation of particles.

### CIP procedure

CIP- procedures can be performed in several different ways depending on various conditions prescribed by the actual application and specific processing conditions. These are recommendations to consider. The procedure must however be validated for every process and product.

### 6.3.1 Cleaning in place

Following must be considered and fulfilled:

1. The High Shear Rotor must rotate easily before CIP.



**Inhibited rotation can lead to severe damage.**



**Time between end of the production and start of CIP must be minimized to avoid that the product dries and get stuck between Rotor and Stator which will inhibit rotation.**

2. During CIP, the Rotor must be submerged.



**Dry operation will immediately cause damage to the bearing.**

3. In order to achieve a proper cleaning effect the High Shear In-Line Mixer must be operated. Acceleration and rotation speed must be validated. Rotation speed must not exceed 3600 rpm
4. During draining the High Shear In-Line Mixer should not be operated.

### 6.3.2 Separate cleaning of the High Shear Rotor

The above-described cleaning methods will clean the High Shear Rotor, Stator and Tank Plate on a day-to-day basis. However, if any of the raw materials that are used in the formulation contain magnetic particles these will be caught in the magnetic field on the inside surfaces of the High Shear Rotor and will not be removed by the normal CIP procedure.

To remove these particles the High Shear Rotor has to be taken out from the vessel and cleaned manually as follows:

1. -Disconnect and remove the Housing unit from the vessel according to the procedure described in this User's guide.
2. -Remove the Rotor from the Tank Plate and check for particles stuck to the inside of the Rotor. If necessary clean the Rotor as follows:
  - Spray the Rotor with a high velocity jet cleaner.
  - Clean with a soft brush or a sponge and a standard detergent (soap).
  - Magnetic particles should be cleaned with ultrasonic sound

After cleaning assemble the High Shear Rotor into the Housing, see chapter 6.3, connect the Drive Unit and run a standard CIP procedure as described in your SOP (Standard Operating Procedure).

## 6.4 Sterilization procedure for the High Shear In-Line Mixer (SIP)

The High Shear In-Line Mixer is designed with an open design that enables the Rotor, Stator, Tank Plate and Housing to be sterilized while they are situated in the processing vessels. This procedure is generally called SIP (Sterilization In Place).

The three most commonly used methods for SIP are:

1. Injection of pressurized steam into the processing vessels to achieve a steam temperature of minimum 121°C.
2. Re-circulation of Superheated Water that has been heated up to minimum 121°C and kept under pressure.
3. The equipment that is to be sterilized is placed in a steam autoclave into which pressurized steam is injected. Normally a temperature of minimum 121°C is used.

### 6.4.1 Sterilization by injection of pressurized steam

The High Shear In-Line Mixer can be Sterilized In Place with the Drive Unit connected.



**Do not run the High Shear In-Line Mixer during any step of the SIP.**



**Dry operation will immediately cause damage to the bearing.**

### 6.4.2 Sterilization by Superheated Water

As the Rotor will be fully soaked in Superheated Water during the whole sterilization period - **No action needs to be taken with the High Shear In-Line Mixer.**



**Do not run the High Shear In-Line Mixer during any step of the SIP.**



**Dry operation will immediately cause damage to the bearing.**


## 7. Service / Maintenance

The inspections below should be performed on a routine basis, (every 6 months) to ensure trouble free operation of the mixing system. Abrasive or high solid contents can wear out the bearings more rapidly. Rumbling, de-coupling, high pitch noise or other unfamiliar noises can indicate that the bearings are worn out.



During actions, make sure that warnings and prohibitions are considered, and that the instruction mentioned earlier in this manual are followed.



Component	Object	Checked against	Test Method	Action if:	Action	Done by: USER	Done by: 
<b>High Shear Rotor</b>	<i>Surface:</i>	Foreign particles	Visual	- The magnet shows adhering of foreign material	⇒ Cleaning (acc. to 6.3.3)	X	-
	<i>Female bearing:</i>	Scratches	Visual	- The surfaces shows any damages	⇒ Re-polishing	X*	X
		Surface damage	Visual	- The surfaces shows any damages	⇒ Exchange of Bearing	-	X
<b>High Shear Stator</b>	<i>Bearing part:</i>	Surface damage	Visual	- The surfaces show any damage	⇒ New bearing	-	X
	<i>O-ring:</i>	Damage	Visual	- The o-ring indicates cracks, discoloring, etc.	⇒ New o-ring	X	-
	<i>Stainless steel part:</i>	Surface damage	Visual	- The surface shows signs of damage	⇒ Replace or polish	-	X
		Damage to the thread	Nut gauge	- The nut does not enter the thread	⇒ Re-threading	-	X
	Damage to the teeth	Visual	- The teeth shows signs of damage	⇒ Replace	-	X	
<b>High Shear Tank Plate</b>	<i>Upper thread:</i>	Damage to the thread	Screw gauge	- The screw does not enter the thread.	⇒ Re-threading	X*	X
<b>Drive Unit:</b>	<i>Outer Driving Head:</i>	Foreign particles	Visual	- The magnet shows adhering of foreign material	⇒ Cleaning	X	-
	<i>Motor</i>	Cable failure	Visual	- The cable is damage	⇒ Exchanged of Cable	X	-

\* Can be done by user after approval from NovAseptic.



## 8. Recommended spare parts and tools

It is recommended that the following spare parts be kept in stock to provide for any replacement that may become necessary due to wear or damage. It is also recommended that spare parts be kept in stock in order to avoid major stops in production.

Please refer to Product Specification Sheets and accompanying parts listed in the final documentation file delivered with your High Shear In-Line Mixer.

NovAseptic mounting tools for the High Shear Rotor and Stator are to be used during mounting.

<b>Spare parts and tools</b>
High Shear Stator
O-rings
<i>EPDM</i>
High Shear Rotor
High Shear Housing
High Shear Stator mounting tool



**Never use parts other than those supplied or recommended by NovAseptic. Use of parts not supplied or recommended by NovAseptic will nullify any Warrantees and may cause premature wear, or more seriously, may cause component failure and possible injury of personnel.**

# 9. Trouble Shooting


When actions are taken, follow the instructions mentioned earlier in this manual.  
A correct installation is also essential.

A = During start-up.  
B = In routine use.

<i>Problem</i>		<i>Possible causes</i>	<i>Actions</i>
<b>Motor / High Shear Rotor does not rotate:</b>	A A,B  A,B	- No power. - Overload protection switched off.  - Heavy load of particles stuck onto the magnets.	- Inspect power supply. - Check the setting amp. Value or the ambient temperature.  - Cleaning, acc. to pt. 6.3.
<b>High amp. value:</b>	A,B A,B	- Ambient temperature too high. - Motor mechanically overloaded.	- Environment chilling. - Check all transmissions.
<b>High Shear Rotor scratches onto High Shear Tank Plate:</b>	A A,B  A,B A	- Bearing worn out. - Loose High Shear Stator  - Particles stuck onto the magnets. (- Deformation after welding).	- Exchange Bearing. - Tighten Bearing and check rotation direction. - Cleaning, acc. to pt. 6.3 - *
<b>Outer Driving Head scratches the High Shear Tank Plate:</b>	A B A	- Warped shaft. - Drive Unit not properly in place. - Particles stuck onto magnets. (- Deformation after welding). - Lose Outer Driving Head	- Exchange of motor and adapter. - See procedure 5.6 - Cleaning - * - Tighten Outer Driving Head against shaft.
<b>Magnetic disconnection of High Shear Rotor:</b>	A,B  B  A A,B	- Charging failure, "dry running".  - Unexpected viscosity changes.  - Wrong rotation direction.  - Short acceleration/ retardation time. - Heavy load of particles stuck onto the magnets	- See guideline pt. 6.2  - An investigation together with NovAseptic has to be performed. Tighten Bearing and adjust rotation direction. - Increase the time. - Cleaning, acc. to pt. 6.3.
<b>High Shear Rotor is running eccentrically:</b>	A  B	- High Shear Stator not properly in Place.  - Bearings worn out.	- Tighten the High Shear Stator acc. to pt.5.4 - Exchange Bearing.
<b>Abnormal / "Rumbling" noise:</b>	A,B	- Dry running.	- See guideline pt.6.2
<b>Loss of running speed:</b>	A A,B	- Incorrect, incoming power. - Missing phase/s (AC)	- Check AC. - Check the fuses.
<b>Revolution counter, Incorrect amount of signals:</b>		- Revolution counter unit is incorrect mounted on the Drive Unit flange.	- Make sure that the Revolution counter unit is mounted correctly.
<b>No signal from Revolution counter detected:</b>		- Corroded socket pins. - Cable worn of.	- Revolution counter to be replaced. - Revolution counter to be replaced.

\* = Tolerances should be verified after welding (see separate instruction "Welding Guideline For Tank Plate").

# 10. Start-Up checklist for High Shear In-Line Mixer

- |  | Tick off   |
|--|--|
| 1. The High Shear In-Line Mixer manual has been carefully read and understood, especially section #2. regarding safety.                    |  <input type="checkbox"/> |
| 2. Check that the inlet pipe air has been ventilated.  | <input type="checkbox"/>   |
| 3. Check that Electric current is connected to the control unit.   | <input type="checkbox"/>   |
| 4. If a Revolution counter is delivered with the High Shear In-Line Mixer, check that the counter is connected.                            | <input type="checkbox"/>   |
| 5. Perform commissioning on Drive Unit according to instructions given in chapter 5.4 in the High Shear In-Line Mixer User's guide.        | <input type="checkbox"/>   |
| 6. Install the High Shear Stator according to installation instructions given in chapter 5.5 in the High Shear In-Line Mixer User's guide. | <input type="checkbox"/>   |
| 7. Install the High Shear Rotor according to installation instructions given in chapter 5.6 in the High Shear In-Line Mixer User's guide.  | <input type="checkbox"/>   |
| 8. Install the Drive Unit according to installation instructions given in chapter 5.7 in the High Shear Mixer In-Line User's guide.        | <input type="checkbox"/>   |
| 9. Start up the High Shear In-Line Mixer according to chapter 5.8, the High Shear In-Line Mixer User's guide.                              | <input type="checkbox"/>   |
| 10. Do not exceed operating limits for the High Shear In-Line Mixer, see chapter 6.1 in the High Shear In-Line Mixer User's guide.         | <input type="checkbox"/>   |

**Now your High Shear In-Line Mixer is ready to be put in use!**

