

## High Shear Mixer User's guide

Technical Description

Installation

Operating Instructions

Maintenance



# Contents

<b>1. Introduction</b>	5
1.1 General	5
1.2 Warranty	6
1.3 Technical Service	6
<b>2. Safety</b>	7
2.1 Signs used in this manual	7
2.2 Warnings	7
2.3 Prohibitions	8
<b>3. Description</b>	9
3.1 Description of High Shear Mixer	9
3.1.1 HS T10	9
3.1.2 HS T60	10
3.1.3 HS T260	11
3.2 High Shear Rotor	12
3.3 High Shear Stator	13
3.4 High Shear Tank Plate	14
3.4.1 HS T10, Welded	14
3.4.2 HS T60, Welded	15
3.4.3 HS T60, Flanged	16
3.4.4 HS T260, Welded	17
3.4.5 HS T260, Flanged	18
3.5 Drive Unit	19
3.5.1 HS T10	19
3.5.2 HS T60	20
3.5.3 HS T260	21
3.6 Revolution Counter	22
3.7 Dimensions and Weights	23
3.7.1 HS T10	23
3.7.2 HS T60	24
3.7.3 HS T260	25

3.8 Noise level and Vibrations	25
3.8.1 Noise level	25
3.8.2 Vibrations and balancing	25
<b>4. Transport and Handling</b>	<b>26</b>
4.1 Transport	26
4.2 Handling	26
<b>5. Installation</b>	<b>27</b>
5.1 High Shear Tank Plate	27
5.1.1 HS Tankplate HS T10, T60 and T260, Welded	27
5.1.2 HS Tankplate HS T60 and T260, Flanged	28
5.2 Electrical Installation	30
5.3 Revolution Counter	32
5.4 Commissioning of Drive Unit	33
5.5 Installing of High Shear Stator	35
5.5.1 Installing of High Shear Stator HS T10, T60 and T260	35
5.6 Installing of High Shear Rotor	36
5.6.1 Installing of High Shear Rotor HS T10 and T60	36
5.6.2 Installing of High Shear Rotor HS T260	37
5.7 Installation of the Drive Unit	38
5.7.1 HS T10	38
5.7.2 HS T60	39
5.7.3 HS T260	40
5.8 Disassembly of Mixer system	41
5.9 Start-up	42
<b>6. Operation</b>	<b>44</b>
6.1 Operating limits	44
6.2 Principles of operation	44
6.3 Cleaning procedure for the High Shear Mixer (CIP)	48
6.3.1 Cleaning inside vessel	49
6.3.2 Separate cleaning of the High Shear Rotor	49
6.4 Sterilization procedure for the High Shear Mixer (SIP)	50
6.4.1 Sterilization by injection of pressurized steam	50
6.4.2 Sterilization by Superheated Water	50

6.4.3 Sterilization by steam autoclaving	51
<b>7. Service / Maintenance</b>	<b>52</b>
<b>8. Recommended spare parts and tools</b>	<b>53</b>
<b>9. Trouble Shooting</b>	<b>54</b>
<b>10. Putting out of action/ waste disposal</b>	<b>55</b>
<b>11. Start-Up checklist for High Shear Mixer</b>	<b>56</b>

# I. Introduction

## I.1 General

The High Shear Mixer is especially designed for the aseptic process in the pharmaceutical and biotech industry. The High Shear Mixer 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 the High Shear Mixer 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 Mixer. An added feature of this design is the ease of service when it is required.

The open design of the High Shear Mixer represents a major improvement.

- It totally eliminates the possibility for entrapment of air pockets inside the Rotor.
- 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.

## 1.2 Warranty

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

Repair under warranty 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 Millipore AB or their accredited representatives. All boxes, packing slips and correspondence should refer to the RGA number provided by Millipore.

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.

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

## 1.3 Technical Service

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

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

Phone: +46 (0)303-97520  
Fax: +46 (0)303-96079

nova\_info@millipore.com  
www.millipore.com

## 2. Safety

All High Shear Mixers are supplied as components and are intended to be mounted onto process vessels before use. The High Shear Mixers must not be modified in any way or run beyond their limits specified in this manual or addendums to this. The High Shear 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 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.**



**The Drive Unit has a noise level >70 dB**

## 2.3 Prohibitions



Before any kind of maintenance work with the High Shear Mixer, make sure that the vessel, (piping system), etc. where the mixer is installed, is at atmospheric pressure, cooled down to max 25 °C (77 °F), 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 Mixer each time it is used in a new application. It should be checked with regard to:

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



## 3. Description

### 3.1 Description of High Shear Mixer

The High Shear Mixer is available in one model and three sizes. They are 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.

#### 3.1.1 HS T10

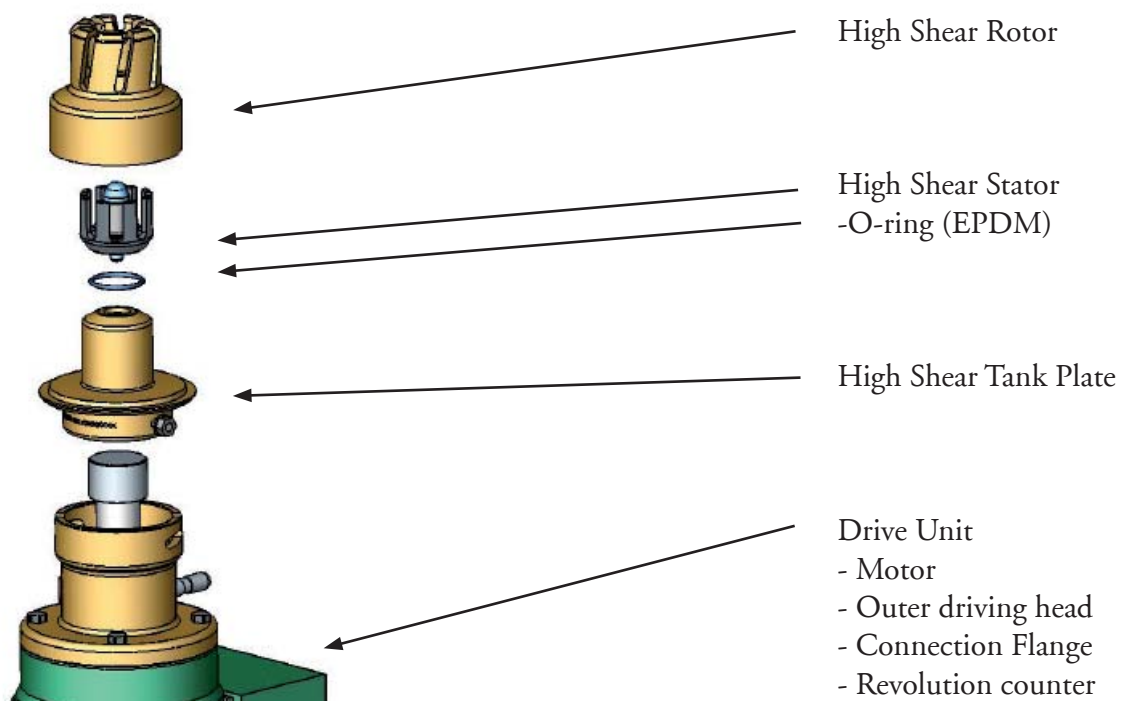


Fig.3.1.1.1 Exploded view High Shear T10

3.1.2 HS T60

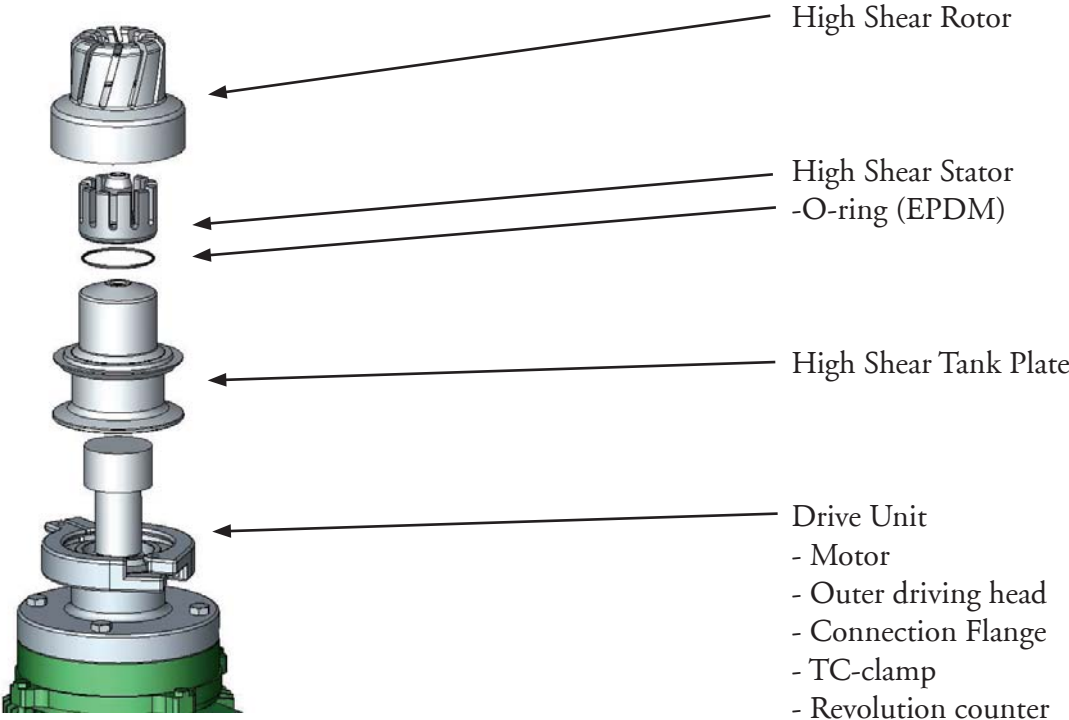


Fig.3.1.2.1 Exploded view High Shear T60

3.1.3 HS T260

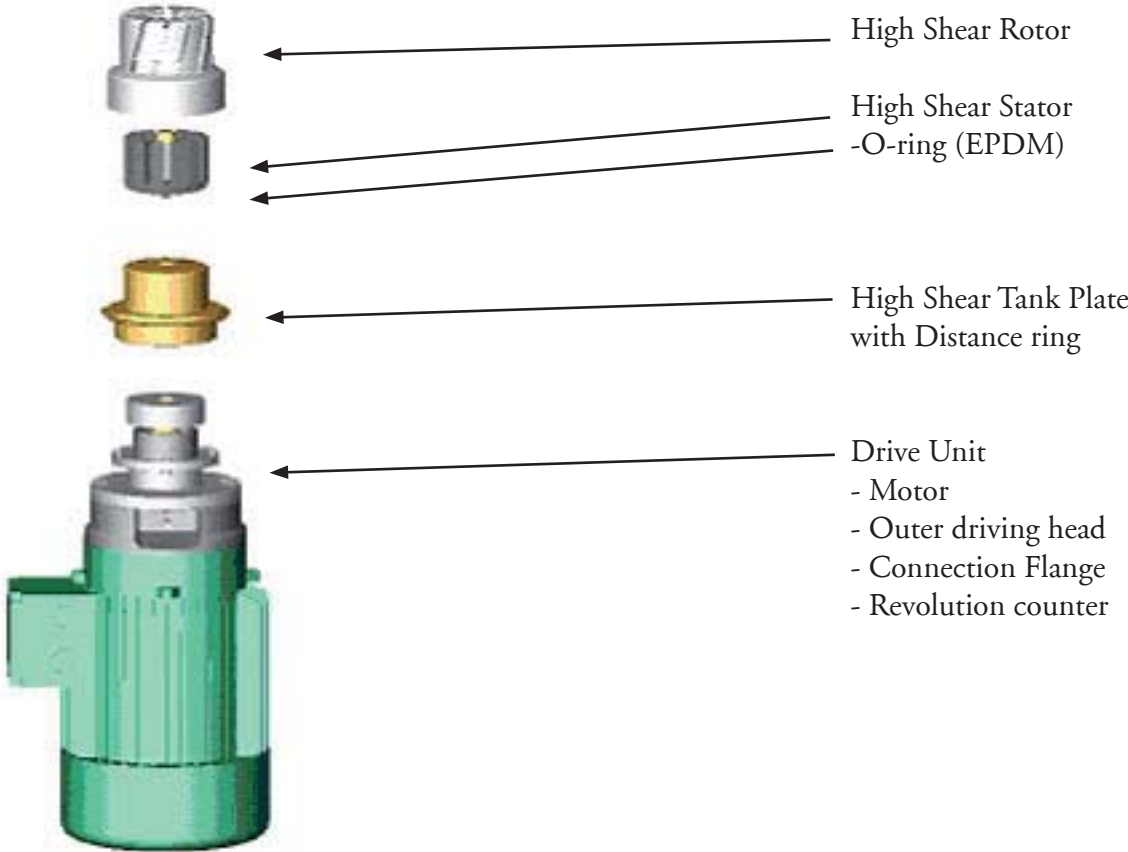


Fig.3.1.3.1 Exploded view High Shear Mixer T260

## 3.2 High Shear Rotor

All High Shear Rotor consist of the following parts:

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

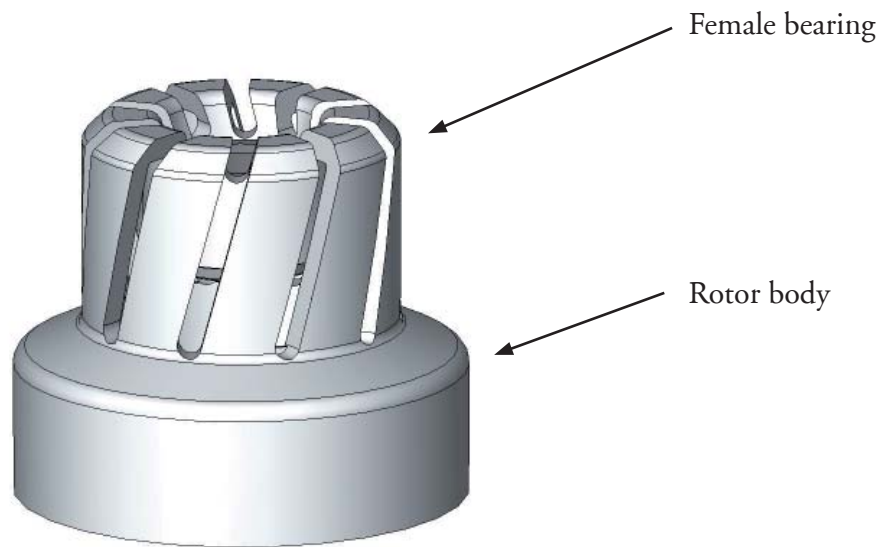


fig. 3.2.1 High Shear Rotor

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.

Each High Shear Rotor is marked with an individual ID No.



**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 (>275 °F).**



**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:

- o 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.
- o 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.

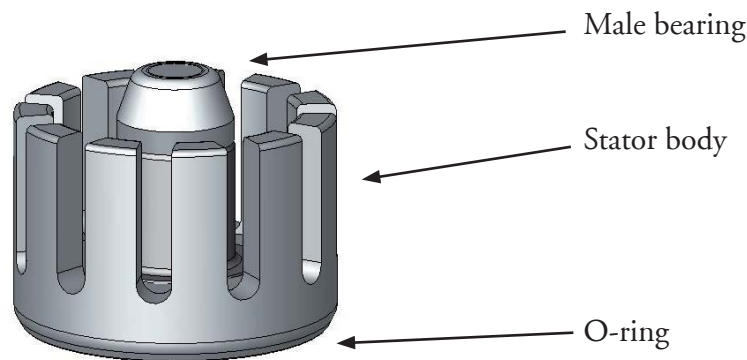


Fig.3.3.1 High Shear Stator

Each High Shear Stator is marked with an individual ID No.



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



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



**Avoid operating temperature >135 °C (>275 °F).**



**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

### 3.4.1 HS T10, Welded

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

- o Connection thread for High Shear Stator
- o Welding edge

The High Shear Tank Plate is to be seen as an integrated part of a pressure-device, e.g. the vessel on which it is mounted. So, it has to be approved according to the valid pressure vessel code.

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

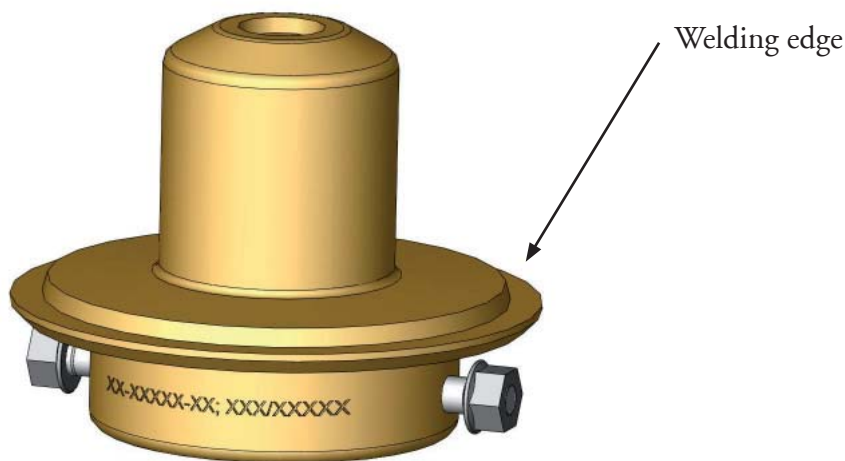


Fig.3.4.1.1 High Shear Tank Plate, HS T10, Welded



**Before the High Shear Tank Plate is welded into the vessel dish – make sure that the separate “Welding guideline For Tank Plate” is read and understood. Ignoring these guidelines might cause deformation of the plate and further malfunction of the entire mixing unit.**



**If the vessel and High Shear Tank Plate are to be electro polished, ensure that the inside of whole vessel is equally grounded and manually polished before electro polishing is performed.**

## 3.4.2 HS T60, Welded

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

- o Connection thread for High Shear Stator
- o Welding edge
- o TC-connection flange for Drive Unit

The High Shear Tank Plate is to be seen as an integrated part of a pressure-device, e.g. the vessel on which it is mounted. So, it has to be approved according to the valid pressure vessel code.

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

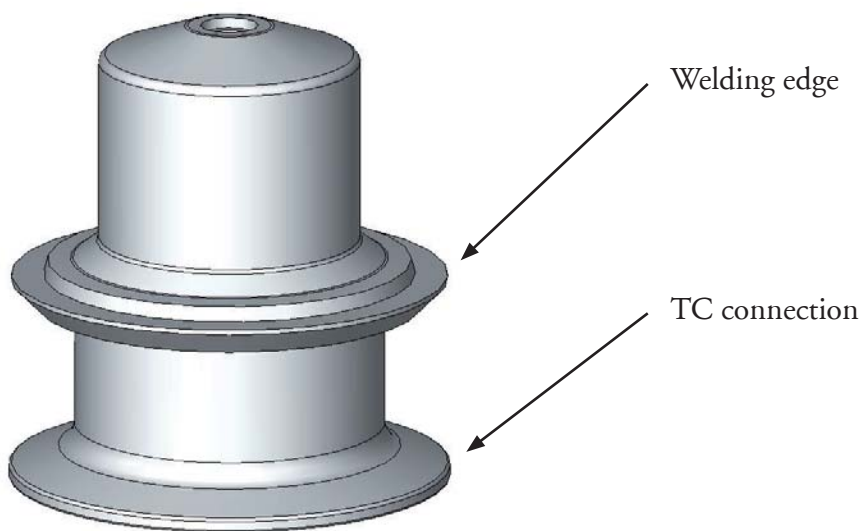


Fig.3.4.2.1 High Shear Tank Plate, HS T60, Welded



**Before the High Shear Tank Plate is welded into the vessel dish – make sure that the separate “Welding guideline For Tank Plate” is read and understood. Ignoring these guidelines might cause deformation of the plate and further malfunction of the entire mixing unit.**



**If the vessel and High Shear Tank Plate are to be electro polished, ensure that the inside of whole vessel is equally grounded and manually polished before electro polishing is performed.**

### 3.4.3 HS T60, Flanged

The HS Tank Plate is in its standard execution of a flanged type and includes:

- o Welding flange
- o Connection thread for HS Stator unit
- o O-ring
- o Flange adapter
- o TC-connection flange for Drive Unit

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

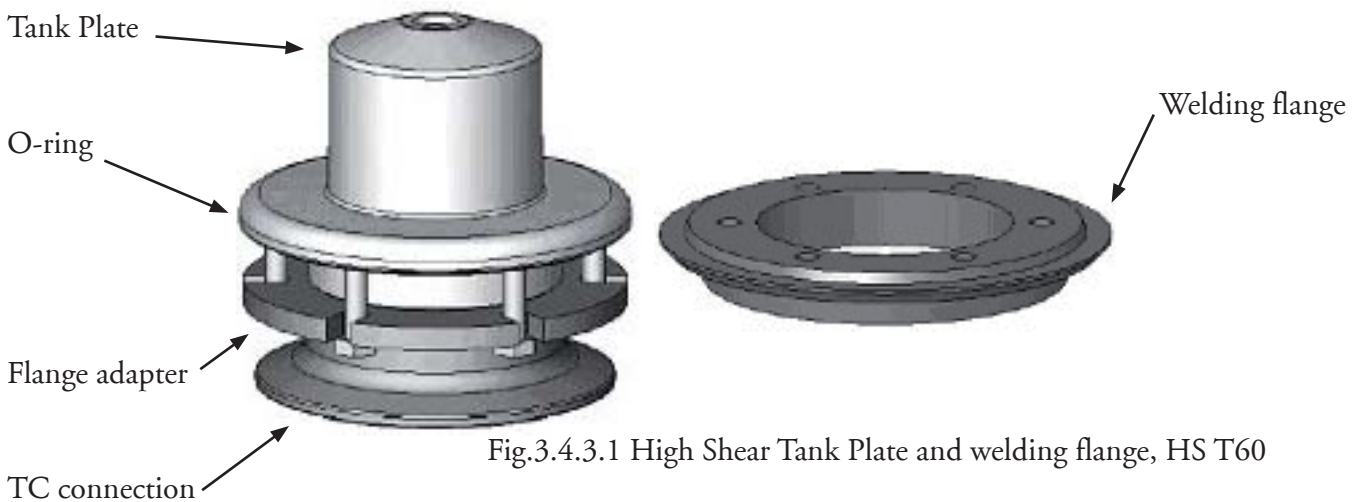


Fig.3.4.3.1 High Shear Tank Plate and welding flange, HS T60



**Before the Welding flange is welded into the vessel dish – make sure that the separate “Welding guideline For Tank Plate” is read and understood. Ignoring these guidelines might cause deformation of the plate and further malfunction of the entire mixing unit.**



**Installation/ welding of the tank plate adapter, please refer to the welding guideline and the use of the welding tool in order to prevent deformation.**



## 3.4.4 HS T260, Welded

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

- o Connection thread for High Shear Stator
- o Welding edge
- o Distance ring

The High Shear Tank Plate is to be seen as an integrated part of a pressure-device, e.g. the vessel on which it is mounted. So, it has to be approved according to the valid pressure vessel code.

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

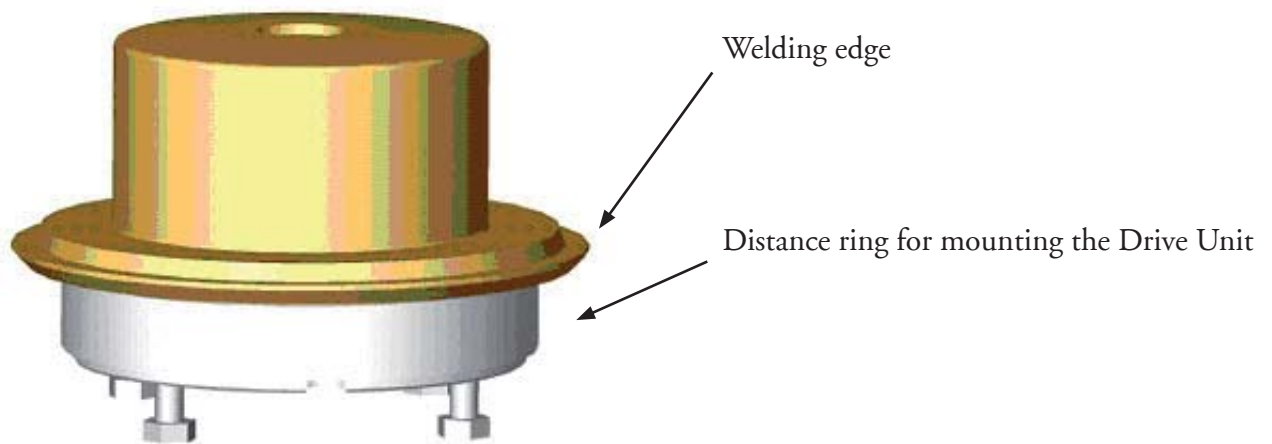


Fig.3.4.4.1 High Shear Tank Plate, HS T260, Welded



**Distance ring must be removed when welding the Tank Plate and installed again after welding.**



**Before the High Shear Tank Plate is welded into the vessel dish – make sure that the separate “Welding guideline For Tank Plate” is read and understood. Ignoring these guidelines might cause deformation of the plate and further malfunction of the entire mixing unit.**



**Installation/ welding of the tank plate, please refer to the welding guideline and the use of the welding tool in order to prevent deformation.**



**If the vessel and High Shear Tank Plate are to be electro polished, ensure that the inside of whole vessel is equally grounded and manually polished before electro polishing is performed.**

### 3.4.5 HS T260, Flanged

The High Shear Tank Plate is in its standard execution of a flanged type and includes:

- o Welding flange
- o Connection thread for HS Stator unit
- o Flange adapter
- o TC-connection flange for Drive Unit

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

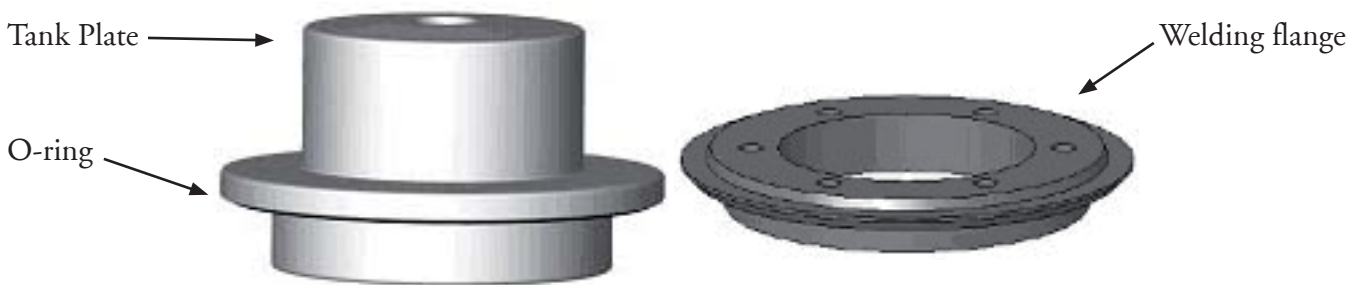


Fig.3.4.5.1 High Shear Tank Plate and welding flange, HS T260



**Before the Welding flange is welded into the vessel dish – make sure that the separate “Welding guideline For Tank Plate” is read and understood. Ignoring these guidelines might cause deformation of the plate and further malfunction of the entire mixing unit.**



**Installation/ welding of the tank plate adapter, please refer to the welding guideline and the use of the welding tool in order to prevent deformation.**

## 3.5 Drive Unit

### 3.5.1 HS T10

The Drive Units consists of the following parts:

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

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

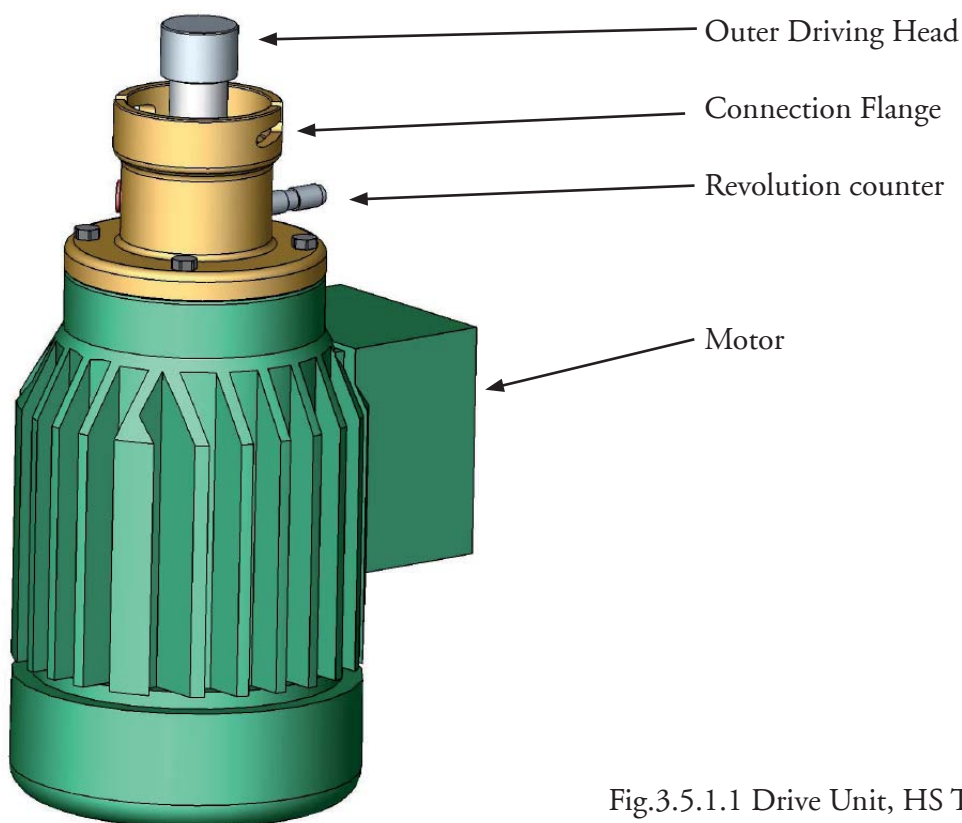


Fig.3.5.1.1 Drive Unit, HS T10



**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.**

## 3.5.2 HS T60

The Drive Units consists of the following parts:

- o TC-clamp
- o Motor
- o Connection Flange
- o Outer Driving Head
- o Adapter
- o Revolution counter

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

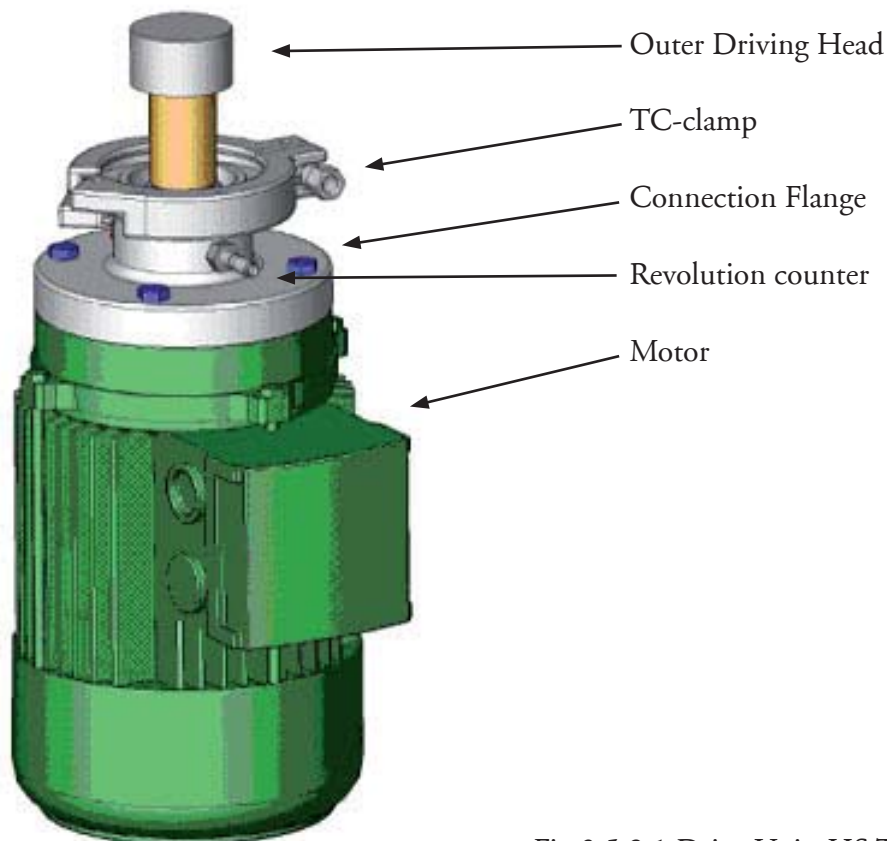


Fig.3.5.2.1 Drive Unit, HS T60



**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.**

## 3.5.3 HS T260

The Drive Units consists of the following parts:

- o Motor
- o Connection Flange, 2 Pcs
- o Outer Driving Head
- o Adapter
- o Revolution counter

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

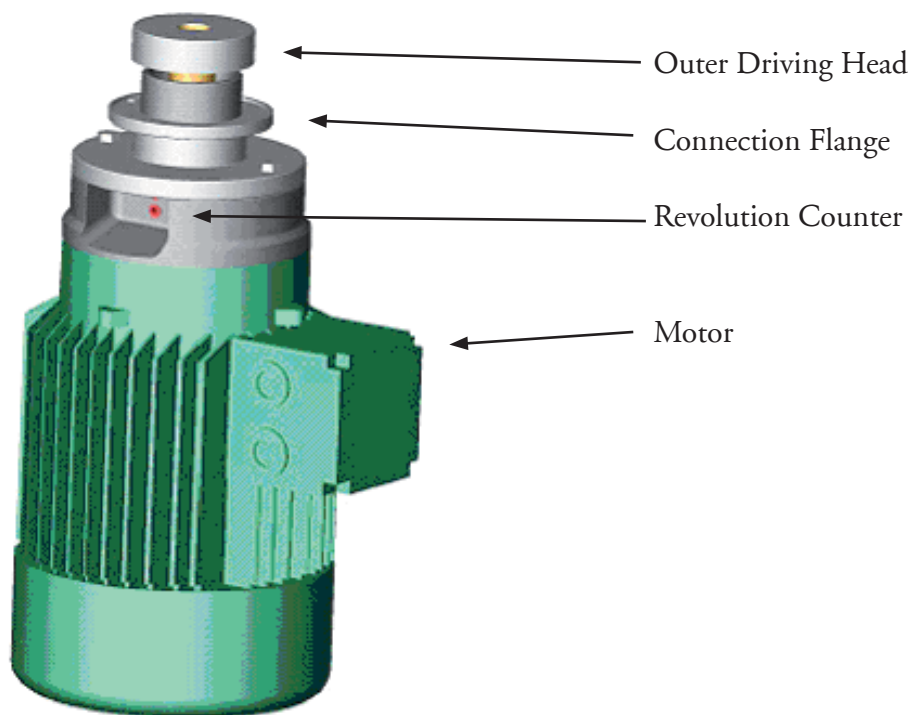


Fig.3.5.3.1 Drive Unit, HS T260



**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.**



**When continuous use of the motor at 60 Hz, the temperature can reach 100°C (212°F).**

### 3.6 Revolution Counter

The High Shear 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 (A) rotation speed and rotor (E) speed.

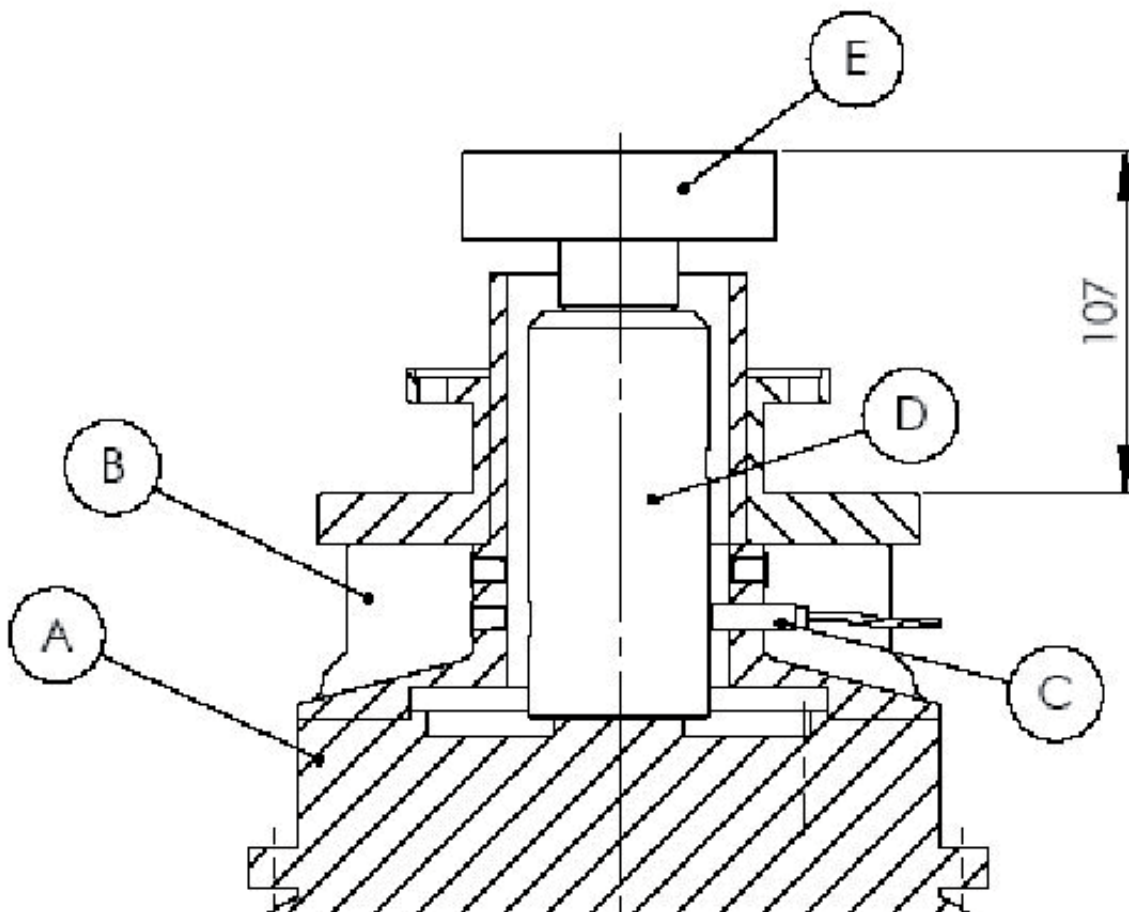


Fig.3.6.1 Revolution Counter on Drive Unit

## 3.7 Dimensions and Weights

### 3.7.1 HS T10

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

**Weight:** Shows the approx. weight of the High Shear Mixer and Drive Unit.

**Dimensions:** Shows the approx. dimensions of standard Drive Units

HS Size	HS Rotor	HS Stator	Tank Plate Welded	Drive Unit	Drive Unit		
	Weight (Kg)	Weight (Kg)	Weight (Kg)	Weight (Kg)	X (mm)	Y1* (mm)	Y2* (mm)
T10	0,5	0,1	0,5	6	130	229	271

\*Dimension Y is without extension.

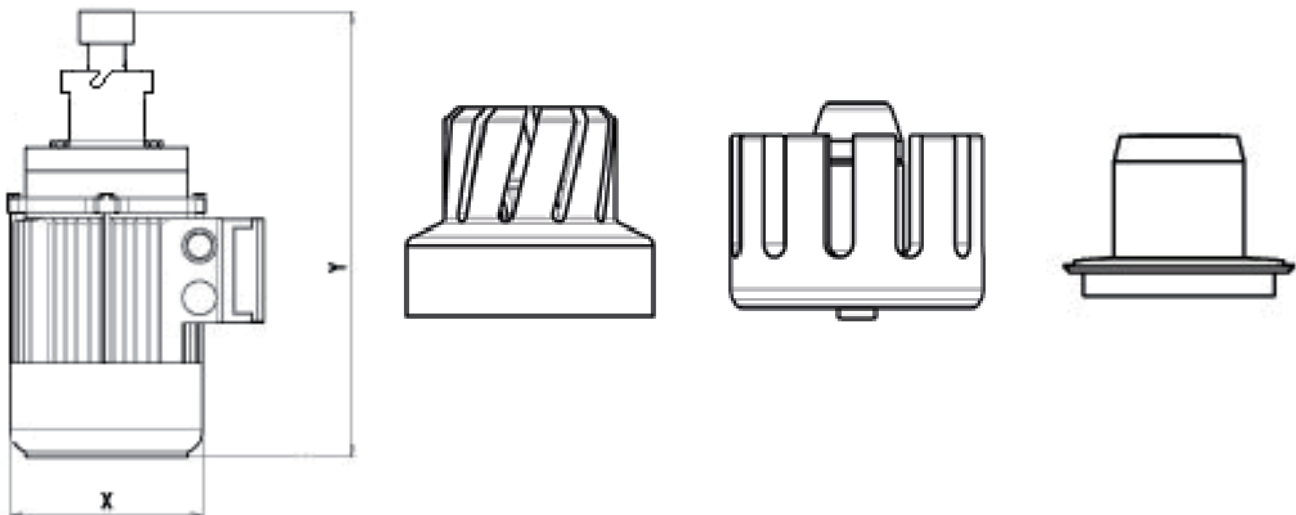


Fig.3.7.1.1

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

## 3.7.2 HS T60

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

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

Dimensions: Shows the approx. dimensions of standard Drive Units

HS Size	Rotor Weight (Kg)	Stator Weight (Kg)	Tank Plate		Drive Unit Weight (Kg)	Drive Unit		
			Welded Weight (Kg)	Flanged Weight (Kg)		X (mm)	Y1* (mm)	Y2* (mm)
T60	1,4	0,3	0,9	1,3	16	170	310	385

\*Dimension Y is without extension.

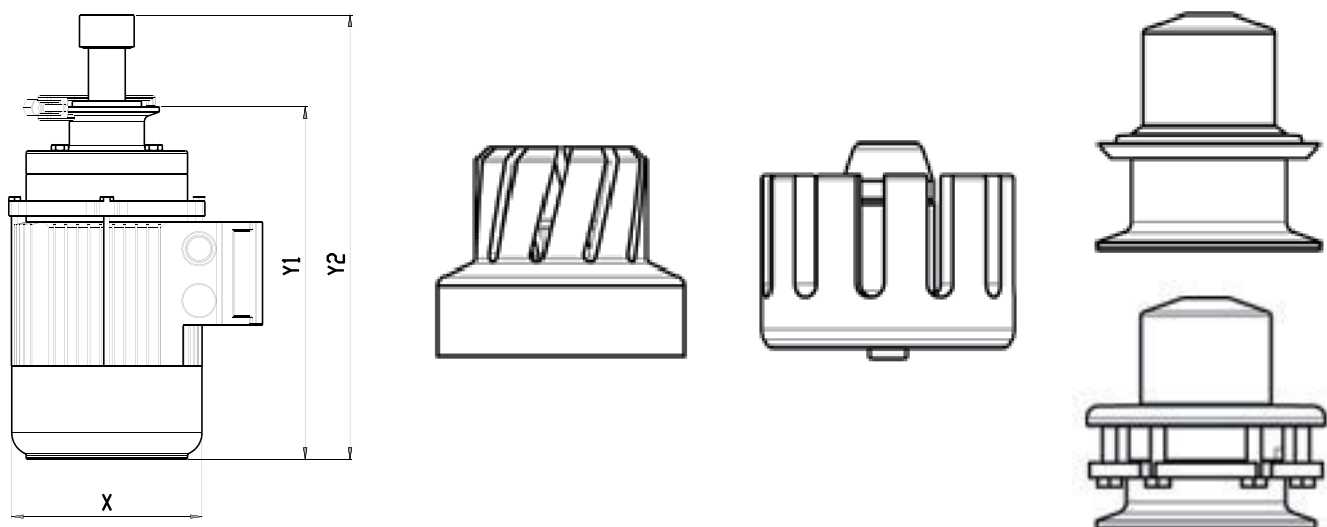


Fig.3.7.2.1

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



## 3.7.3 HS T260

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

**Weight:** Shows the approx. weight of the High Shear Mixer and Drive Unit.

**Dimensions:** Shows the approx. dimensions of standard Drive Units

HS Size	Rotor Weight (Kg)	Stator Weight (Kg)	Tank Plate		Drive Unit Weight (Kg)	Drive Unit	
			Welded Weight (Kg)	Flanged Weight (Kg)		X (mm)	Y* (mm)
T260	3,4	2,0	2,5	3,3	70	170	555

\*Dimension Y is without extension.

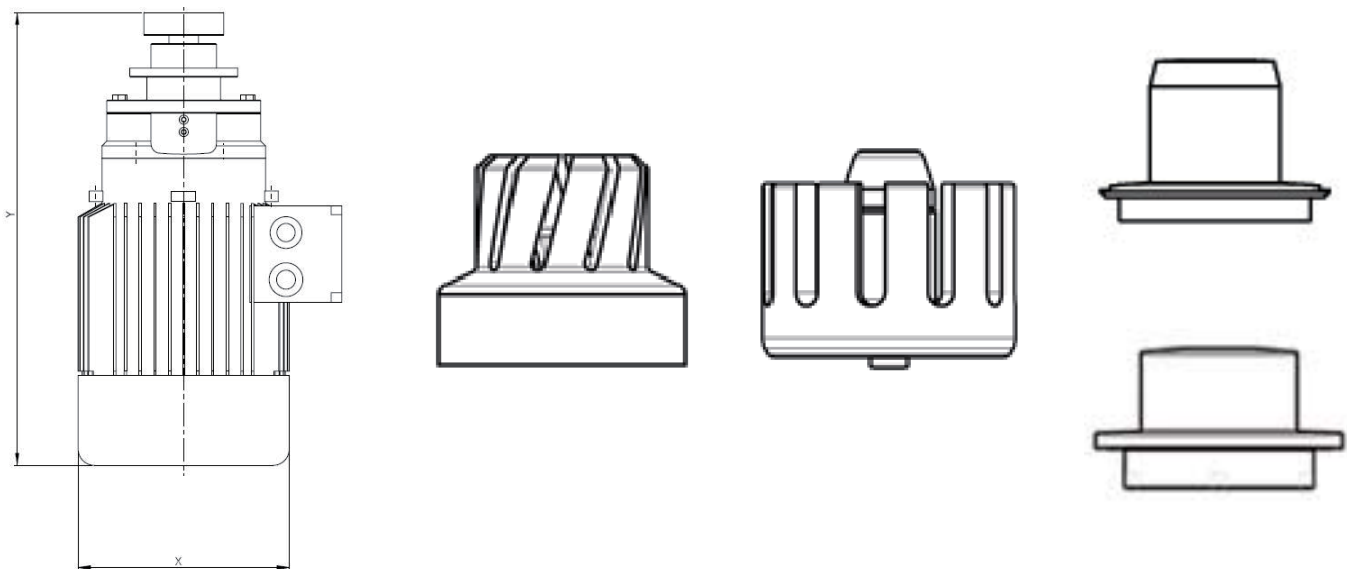


Fig.3.7.3.1

For more detailed information regarding dimensions and weights for the High Shear Rotor and Drive Unit, please refer to High Shear 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 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 Mixer mounted in the vessel 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 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 Mixer **must not** be transported without being packed securely to avoid damage during transport or storage.

Keep the High Shear 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 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 Rotor is 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 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 for HS T10 and HS T60 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. Put the Drive Unit for HS T260 on a clean place to avoid magnetic particles on the Outer Driving head.



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 Rotor and Stator 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 High Shear Tank Plate

#### 5.1.1 HS T10, T60 and T260 Tank Plate, welded

Before first use, ensure that the "Welding Guideline For Tank Plate" have been carefully followed for the installation of the High Shear Tank Plate and all necessary certificates, approvals, etc. have been received and documented.



**After the welding is performed, make sure that there is no distortion. NovAseptic® Mixer Gauge, see the Welding Guideline For Tank Plate, section 4. Final Control.**

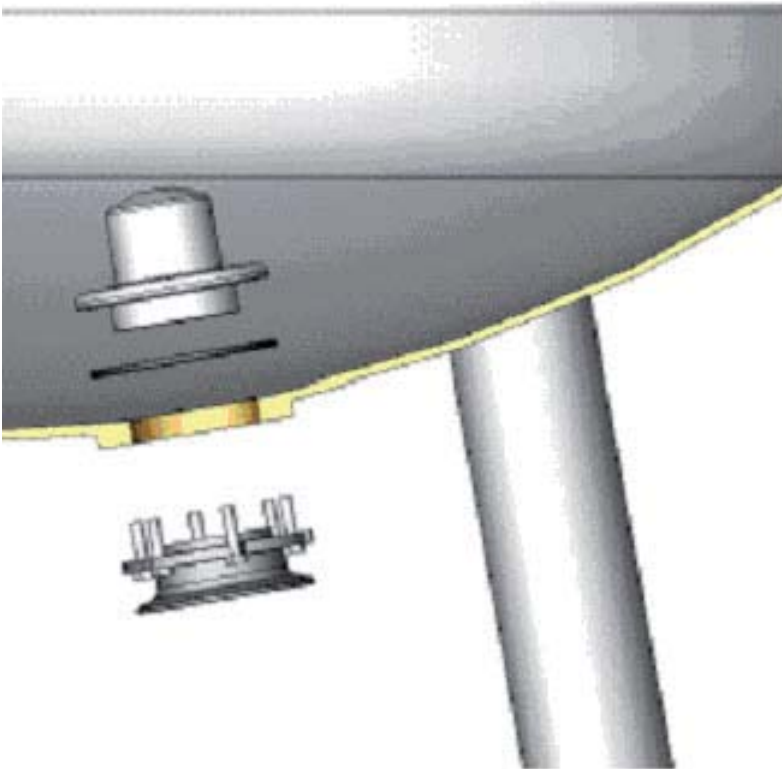


An authorized welder must perform all welding work.

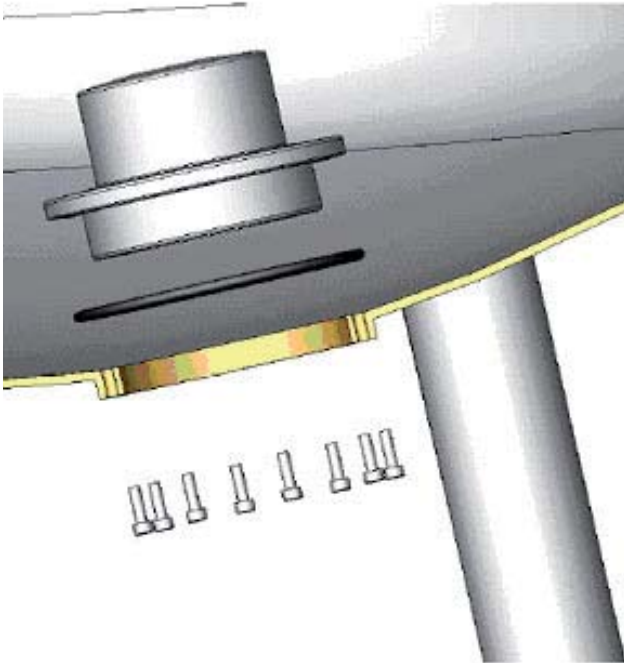
## 5.1.2 HS T60 and T260 Tank Plate, Flanged

Before first use, follow the instructions for flanged Tank Plate or ensure that the "Welding Guideline For Tank Plate" instruction for flanged Tank Plate have been carefully followed for the installation of the HS Tank Plate and all necessary certificates, approvals, etc. have been received and documented.

### Flange Tank Plate HS T60



HS T260



**After the welding is performed on Tank Plate adapter, make sure that there is no distortion. NovAseptic® Mixer Gauge, see the Welding Guideline For Tank Plate, section 4. Final Control.**



An authorized welder must perform all welding work.

## 5.2 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.

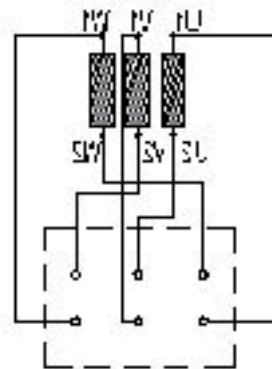


fig 5.2.1

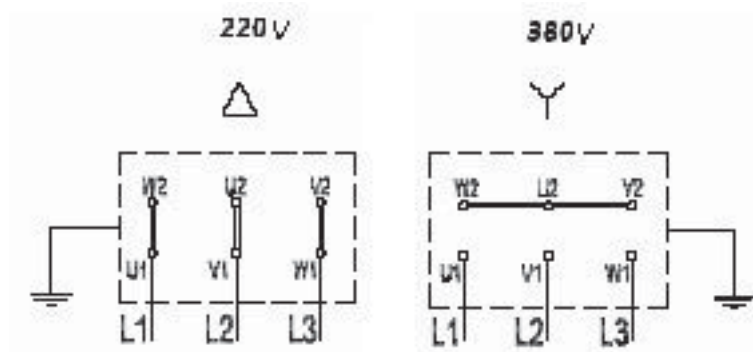


fig 5.2.2

## USA

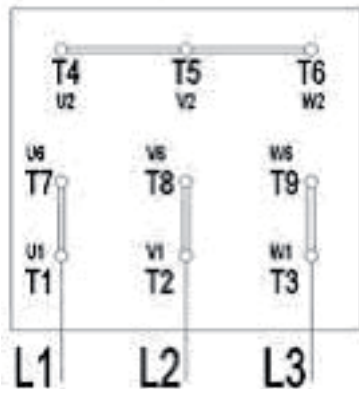


fig 5.2.3

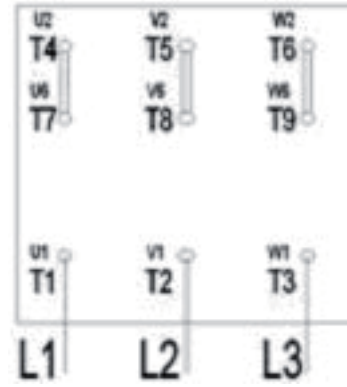


fig 5.2.4

## 5.3 Revolution Counter

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

### Technical information

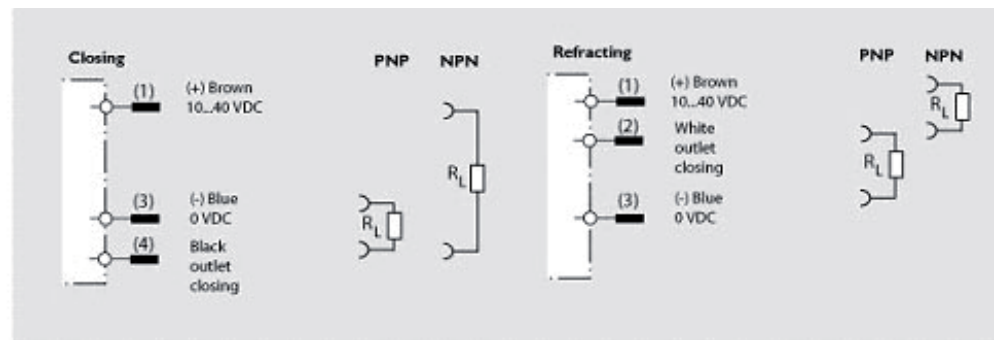
Supply voltage	10...40 VDC, ±10% reverse connection protection
Current consumption	Max 13 mA
Control output	200 mA, open collector, short-circuit protection
Sensing object	Metal
Indicator	Indication of operation LED yellow
Ambient Temperature	-40...70°C (with no icing), -40.....158°F (with no icing)
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





## 5.4 Commissioning of Drive Unit

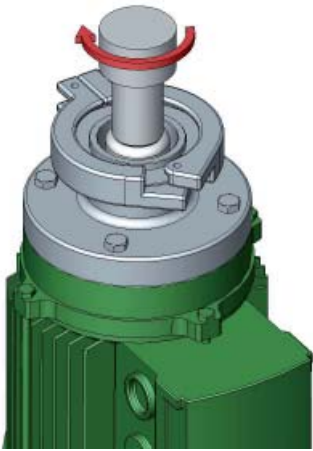


fig 5.4.1

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 vessel or the Stator may unscrew. 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.

1. Install the Drive Unit to a frequency converter, see chapter 5.2, electrical installation
2. Rotation direction. The proper rotation direction is clockwise see fig 5.4.1.



**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 Mixer.**



**Incorrect rotation direction may unscrew the High Shear Stator during operation causing mal function and damage.**

3. Assembly Drive Unit / Tank Plate

To check that the High Shear Tank Plate is correctly welded into the vessel, the Drive Unit should be connected to the Tank Plate.

- 3.a Mount the Drive Unit to the Tank Plate to check that they fit together correctly after the Tank Plate has been welded into the vessel.



Before installing the Drive Unit, check that the High Shear Rotor has been removed.



**The HS T260 Drive Unit weighs approximately 70 kg.**

3.b Run the mounted Drive Unit at low speed and listen for scratching noises.



**Scratching noises indicate contact between Outer Driving Head and Tank Plate. This will lead to malfunction and damage. Immediately perform troubleshooting if noises appear.**

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

## 5.5 Installing the High Shear Stator

### 5.5.1 Installation of the High Shear Stator, HS T10, T60 and T260

1. Check O-ring

Check that the sealing O-ring is properly in place according to fig 5.5.1.1.



fig 5.5.1.1



**For High Shear T260, make sure that the Drive Unit is mounted before the installing the stator, see chapter 5.7.**

2. Use proper lubrication (H<sub>2</sub>O) on O-ring before installing the stator. See installation guide for Stator.
3. Mount Stator with High Shear mounting tool for stator.



fig 5.5.1.2

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

T10 G20-010	T60 G20-005	T260 G20-007
6 Nm [4.4 Lbft]	20 Nm [14.8 Lbft]	30 Nm [22.1 Lbft]



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

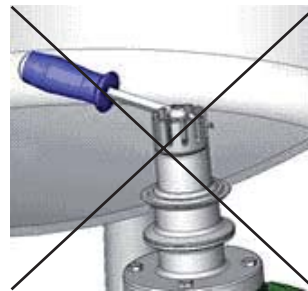
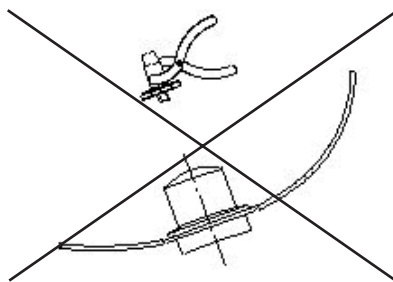


fig 5.5.1.3

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 vessel must be clean and completely dry inside, 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 Millipore AB.**

## 5.6 Installation of the High Shear Rotor

### 5.6.1 Installation of the High Shear Rotor, HS T10 and T60



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

1. Add water into the vessel for smooth mounting. The water level should be above the Stator.
2. Inspect the Rotor so that it does not contain any foreign particles, especially on the magnetic part.
3. Mount the High Shear Rotor with recommended mounting tool.
4. Position the High Shear Rotor very carefully and place it proper 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
5. Rotate it by hand or with the mounting tool to ensure that it will rotate without any scratching.
6. Release and retract the Rotor with the High Shear Rotor mounting tool.

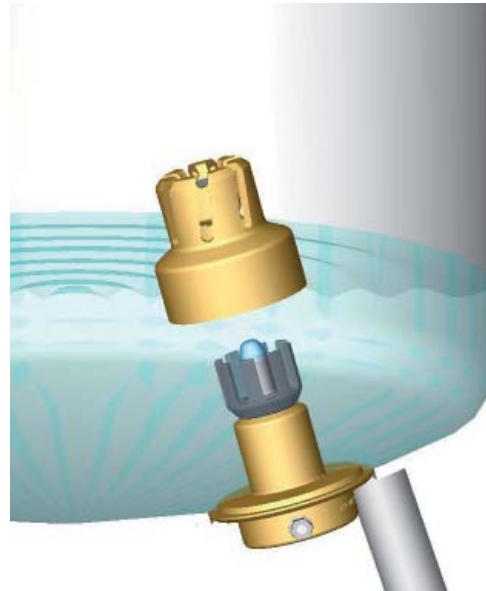


fig 5.6.1.1 HS T10

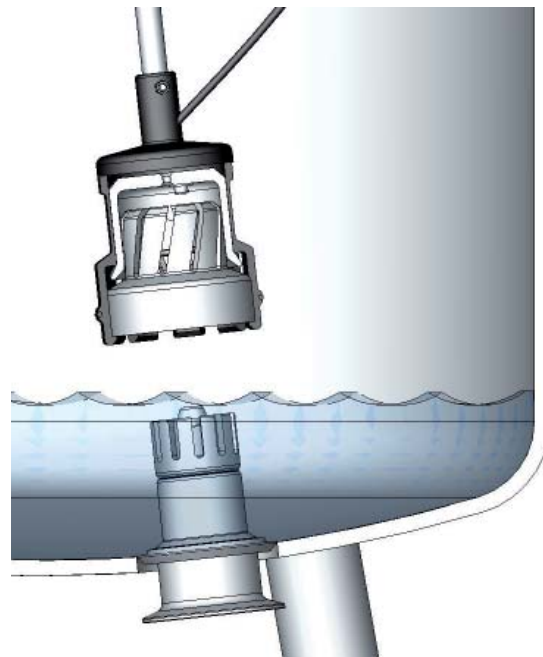


fig 5.6.1.2 HS T60



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

## 5.6.2 Installation of the High Shear Rotor, HS T260



Never install the High Shear Rotor while the Drive Unit is in drive position. The powerful magnetic forces can cause severe damage to the bearing.

1. Install the Drive unit according to chapter 5.7.3 before installing the High Shear Rotor T260.
2. Inspect the Rotor so that it does not contain any foreign particles, especially on the magnetic part.
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 Stator. The Stator surfaces are very brittle and can be easily destroyed, fig 5.6.2.1
4. Lubricate the bearing with a few water drops. Rotate it by hand to ensure that it will rotate without any scratching.
5. Raise the Drive Unit by tightening the screws (A) according to fig. 5.7.3.2. Gap (B) is reduced to 0 mm.

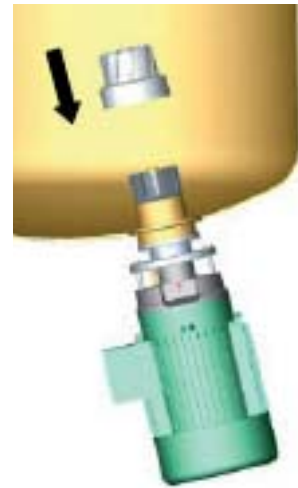


fig 5.6.2.1



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

## 5.7 Installation of the High Shear Drive Unit

### 5.7.1 Installation of the Drive Unit, HS T10

Follow enclosed installation instructions for the Drive Unit:

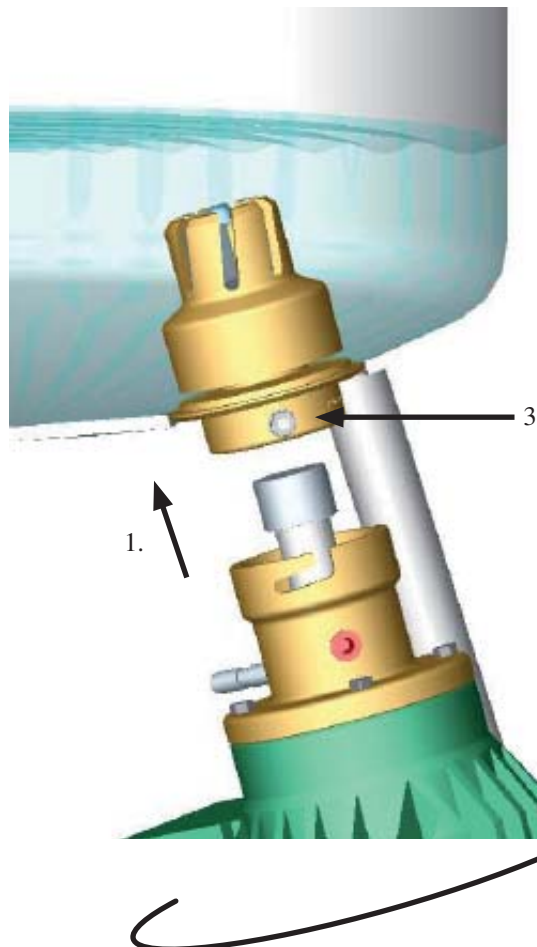


#### Mounting HS T10

The High Shear Rotor and Stator are to be mounted before the Drive Unit 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 T10, with Welded Tank Plate

1. Insert the Outer Driving Head unit into the Tank Plate, and put the slots onto the two screws on the Tank Plate
2. Turn the Drive Unit 15° to the right, or to its stop position.
3. Tighten the two nuts properly with a wrench.



**NOTE!** Screws on the Tank Plate must be screwed out before connecting the Drive Unit

fig 5.7.1.1

## 5.7.2 Installation of the Drive Unit, HS T60

Follow enclosed installation instructions for the Drive Unit:



### Mounting HS T60

The High Shear Rotor and Stator are to be mounted before the Drive Unit 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 T60, with Welded and Flanged Tank Plate

1. Insert the High Shear Drive Unit into the High Shear Tank Plate.



Grip the Drive Unit on the motor, to avoid fingers getting caught between the two flanges causing injury, that can occur when the strong magnetic force are pulling the TC-flange together.

2. Connect the Drive Unit to the Tank Plate flange and secure with a TC-clamp.
3. Tighten the TC-clamp nut properly with a wrench.

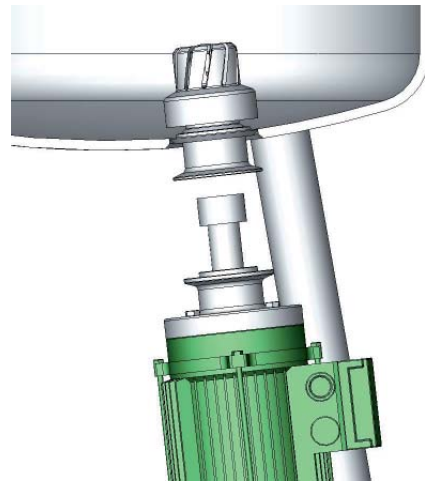


fig 5.7.2.1

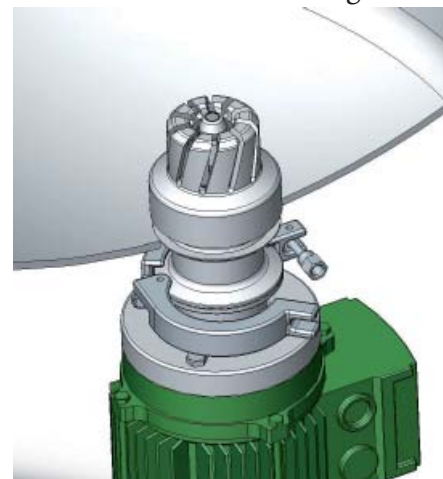


fig 5.7.2.2

## 5.7.3 Installation of the Drive Unit, HS T260



### Mounting HS T260

The High Shear Rotor and Stator are to be mounted after the Drive Unit has been lowered from the Tank Plate 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.

1. Mount the Drive Unit to the Tank Plate, fig 5.7.3.1



fig 5.7.3.1

2. Lower the Drive Unit, attached by two screws (A). When the Drive Unit is completely lowered the gap (B) is approx 40mm between flange and Drive Unit, fig 5.7.3.2

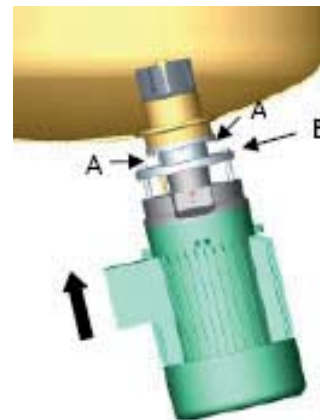


fig 5.7.3.2



## 5.8 Disassembly of Mixer system

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



### **Dismounting**

The Drive Unit must be dismounted before the High Shear Rotor can be lifted from the Stator to avoid the risk of personal injury and damage to the bearing.

## 5.9 Start-up

Before and during Start-up



The vessel must be filled up with enough liquid to cover the High Shear Rotor.



Dry operation will immediately cause damage to the bearing!

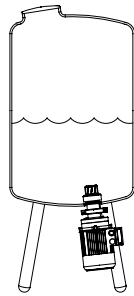


Fig.5.9.1

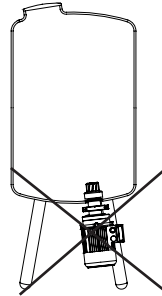


Fig.5.9.2

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 volume.
3. Start the High Shear Mixer for a few seconds, ENSURE THAT THE MIXING HEAD IS ROTATING CLOCKWISE (seen from above).
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 Mixer is ready to be put in use!**

## 6. Operation

### 6.1 Operating limits

Process medium:	Newtonic liquids, max 800 cP
Medium temp:	5° - 135° C (41° - 275° F)
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 T10, T60 and T260

### 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. See fig 6.3.1.1.



HS T260 may produce dangerous noise when running, use ear protectors if necessary.

Three main methods of adding insoluble substance, liquids or solids

## Method 1. Full vortex

- Applicable when the substance involved have a high separation factor
- Applicable when the substances being mixed are not easily pulled down towards the High Shear Mixer (it floats on the surface).
- Applicable when the substance being mixed clumps together
- Applicable when generation of foam is not permissible.

### How to achieve vortex

- Keep fluid volume between 1:1-1:2 (D:H)
- Keep  $\alpha$ -angel as small as possible.  
To achieve a small  $\alpha$ -angel  
-Install the High Shear Mixer as close to the centerline of the dished end as possible. For dimensions please consult corresponding Product Specification Sheets.  
-Use a shallow dished end e.g. Klöpper shape

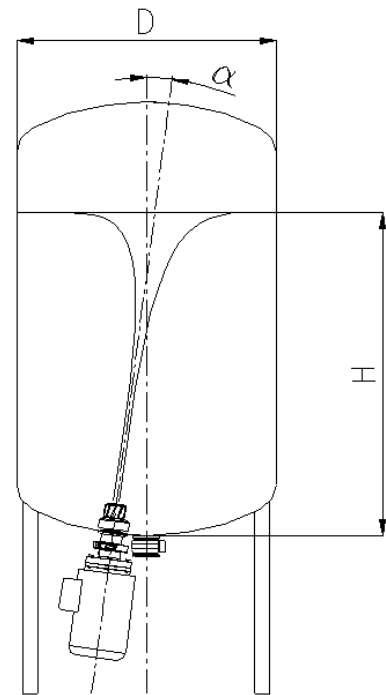


fig 6.2.1

## Method 2. No vortex

- Applicable when generation of foam is not desired.
- Applicable when the substance being mixed does not float to the surface.

### How to avoid vortex

- Keep fluid volume  $<1:1$ . (D:H)
- Keep  $\alpha$ -angel as large as possible.

### To achieve a large $\alpha$ -angel.

- -Install the High Shear Mixer as far from the centerline of the dished end as possible.  
-Use a deep dished end e.g. SMS shape.

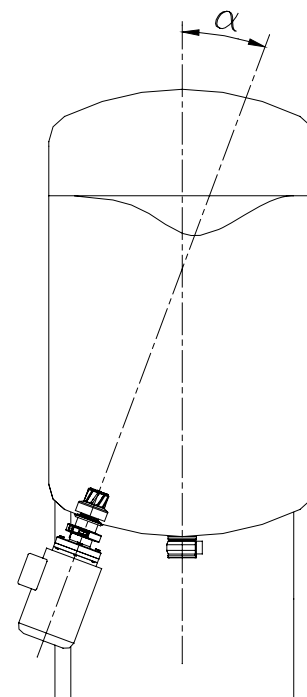


fig.6.2.2



Due to different viscosity and properties of the fluid and vessel, the exact limit for the vortex formation can change.

## Principles of controlling vortex

### Method 3. Combo mixing

- Applicable when the substance being mixed has the characteristics described in the first method and must be sucked down through the vortex and when generation of foam is not desired.

This is a common situation and can easily be managed by a combination of a High Shear Mixer and a standard NovAseptic® Mixer. This is called Combo mixing.

### How to control vortex

- Install the High Shear Mixer to achieve vortex, see above.
- Install the NovAseptic® Mixer opposite to the High Shear Mixer,  $A = 0.5 \times L$ .
- Keep Working volume between 1:1-1:2
- Create the vortex by starting the High Shear Mixer.
- Collapse the vortex by starting the NovAseptic® Mixer while the High Shear Mixer is still running.
- The High Shear Mixer can be turned off if the desired effect is accomplished.

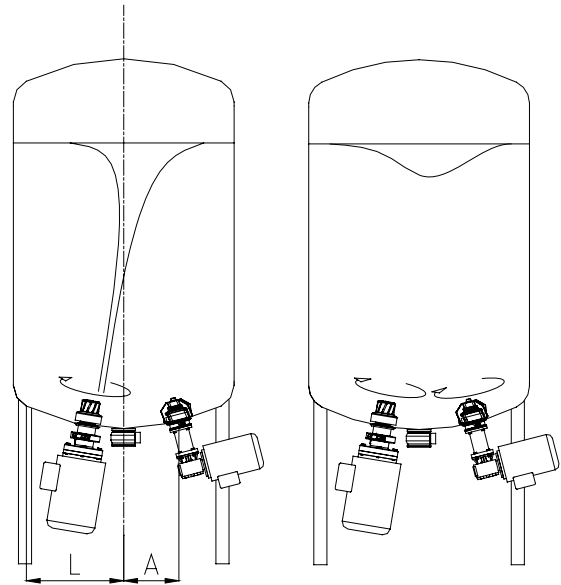


Fig.6.2.3



Due to different viscosity and properties of the fluid and vessel, the exact limit for the vortex formation can change.

## 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:

- o High speed
- o In hot WFI
- o At atmospheric pressure
- o 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:



Stop the High Shear 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 (104°F).



**Do not exceed maximum operating temperature of 135°C (275°F) inside the vessel.**

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

The High Shear Mixer is designed with an open design that enables the High Shear Rotor, Stator and Tank Plate 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 vessel 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 vessel. 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 inside vessel

Following must be considered and fulfilled:

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



**Inhabited 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 min 100 mm se Fig.6.3.1.1.



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

3. In order to achieve a proper cleaning effect the High Shear Mixer must be operated. Acceleration and rotation speed must be validated. Rotation speed must not exceed 1000 rpm
4. During draining the High Shear Mixer should not be operated.

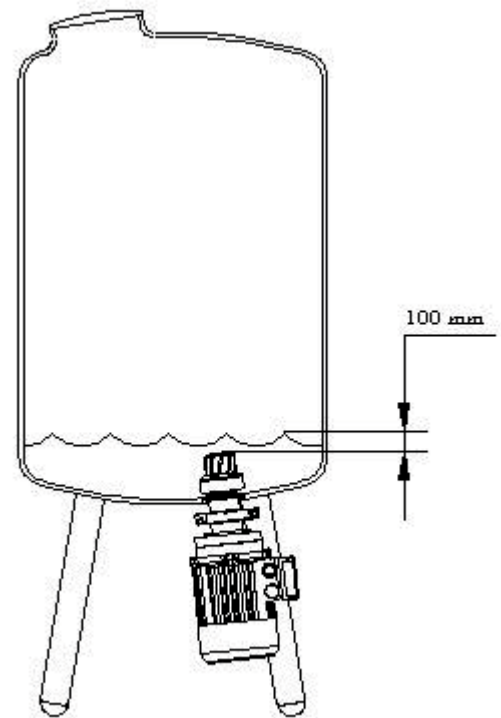


Fig.6.3.1.1

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

After cleaning assemble the High Shear Rotor into the vessel, 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 Mixer (SIP)

The High Shear Mixer is designed with an open design that enables the Rotor, Stator and Tank Plate 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 (250°F).
2. Re-circulation of Superheated Water that has been heated up to minimum 121°C (250°F) 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 (250°F) is used.

### 6.4.1 Sterilization by injection of pressurized steam

The High Shear Mixer can be Sterilized In Place with the Drive Unit connected to the vessel.



**Do not run the High Shear 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 Mixer.



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



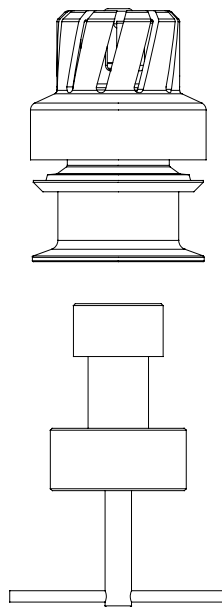
**Dry operation will immediately cause damage to the bearing.**

## 6.4.3 Sterilization by steam autoclaving

This sterilization method means that the entire process vessel including the High Shear Rotor is placed inside a steam autoclave where the temperature is raised to the actual sterilization temperature, normally 121°C (250°F). This process includes a pre-vacuum period, to remove most of the air inside the equipment that shall be sterilized.



Note! The Drive Unit must be removed from the vessel and the vessel should be kept in an upright position during sterilization in autoclave/oven.



High Shear Rotor Attractor HS T10 and T60

fig 6.4.3.1



**If the Drive Unit is unattached during transportation and sterilization in autoclave/oven, a High Shear Rotor attractor must be mounted to ensure safe handling of the male and female bearing.**



**After an autoclaving process the High Shear Rotor and its Female Bearing as well as the connecting Male Bearing will be completely dry and can in such condition damage if the mixer is run. Therefore, avoid running the mixer before any liquid has wetted the High Shear Rotor.**

## 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: Millipore
High Shear Rotor	<i>Surface:</i>	Foreign particles	Visual	- The magnet shows adhering of foreign material	⇒ Cleaning (acc. to 6.3.3)	X	-
		Scratches	Visual	- The surfaces shows any damages	⇒ Re-polishing	X*	X
	<i>Female bearing:</i>	Surface damage	Visual	- The surfaces shows any damages	⇒ Exchange of Bearing	-	X
High Shear Sator	<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>	Damage to the outer nut	Visual	- The nut shows signs of damage	⇒ Grind/polishing	X*	X
		Damage to the thread	Nut gauge	- The nut does not enter the thread	⇒ Replace	-	X
		Damage to the teeth	Visual	- The teeth shows signs of damage	⇒ Replace	-	X
High Shear Tank Plate	<i>Upper thread:</i>	Damage to the thread	Screw gauge	- The screw does not enter the thread.	⇒ Re-threading	X*	-
Drive Unit:	<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 Millipore AB.

## 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 Mixer.

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

Spare parts and tools		
HS T10	HS T60	HS T260
High Shear Stator	High Shear Stator	High Shear Stator
O-rings	O-rings	O-rings
EPDM	EPDM	EPDM
Silicone	Silicone	-
PTFE coated silicone	PTFE coated silicone	-
High Shear Rotor	High Shear Rotor	High Shear Rotor
-	Tank Plate Flanged	Tank Plate Flanged
-	O-rings	O-rings
-	EPDM	EPDM
Complete stator mounting tool	Complete stator mounting tool	Complete stator mounting tool
-	Complete rotor mounting tool	-
Rotor Attractor	Rotor Attractor	-



Never use parts other than those supplied or recommended by Millipore AB. Use of parts not supplied or recommended by Millipore AB will nullify any Warranty 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.

Problem		Possible causes	Actions
Motor / High Shear Rotor does not rotate:	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.
High amp. value:	A,B A,B	- Ambient temperature too high. - Motor mechanically overloaded.	- Environment chilling. - Check all transmissions.
High Shear Rotor scratches onto High Shear Tank Plate:	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 - *
Outer Driving Head scratches the High Shear Tank Plate:	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.
Magnetic disconnection of High Shear Rotor:	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.
High Shear Rotor is running eccentrically:	A B	- High Shear Stator not properly in Place. - Bearings worn out.	- Tighten the High Shear Stator acc. to pt.5.4 - Exchange Bearing.
Abnormal / "Rumbling" noise:	A,B	- Dry running.	- See guideline pt.6.2
Loss of running speed:	A A,B	- Incorrect, incoming power. - Missing phase/s (AC)	- Check AC. - Check the fuses.
Revolution counter, Incorrect amount of signals:		- Revolution counter unit is incorrect mounted on the Drive Unit flange.	- Make sure that the Revolution counter unit is completely aligned, and completely in contact with the Drive Unit flange without any gap in between.
No signal from Revolution counter detected:		- 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. Putting out of action/ waste disposal



The NovAseptic<sup>®</sup> Mixer parts must be disposed according to the domestic environmental standards.

## I I. Start-Up checklist for High Shear Mixer

✓ Tick off

1. The High Shear Mixer manual has been carefully read and understood, especially section #2. regarding safety.
2. Check that there is a NovAseptic High Shear Tank Plate installed properly into the actual vessel.
3. Check that Electric current is connected to the control unit.
4. If a Revolution counter is delivered with the High Shear Mixer, check that the counter is connected.
5. Perform commissioning on Drive Unit according to instructions given in chapter 5.4 in the High Shear Mixer User's guide.
6. Install the High Shear Stator according to installation instructions given in chapter 5.5 in the High Shear Mixer User's guide.
7. Install the High Shear Rotor according to installation instructions given in chapter 5.6 in the High Shear Mixer User's guide.
8. Install the Drive Unit according to installation instructions given in chapter 5.7 in the High Shear Mixer User's guide.
9. Start up the High Shear Mixer according to chapter 5.8, the High Shear Mixer User's guide.
10. Do not exceed operating limits for the High Shear Mixer, see chapter 6.1 in the High Shear Mixer User's guide.

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





MILLIPORE

## EC Declaration of Incorporation

Within the Meaning of the EC-Machine Directive 98/37/EC, Annex II B

Herewith we:

**Millipore**  
**Rödjans väg 7**  
**SE-449 34 Nödinge, Sweden**

declare under our sole responsibility, that the mixer mentioned hereafter corresponds to the relevant safety and health requirements taken as a basis of the EC-directive.

The mixer must not be put into service until the machinery into which it has been incorporated has been declared in conformity with the Machinery Directive.

In case of a change or modification to the mixer, which is not agreed with Millipore, this declaration becomes invalid.

Product description:

**Mixer for aseptic High Shear application,  
magnetic coupled**

Product type:

**Novaseptic® High Shear Mixer HS-T10;  
HS-T60; HS-T260**

Serial No:

**See documentation for your  
High Shear Mixer HS-T10; HS-T60; HS-T260**

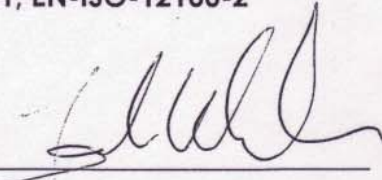
EC-directive taken as a basis:

**98/37/EC (Machinery Directive)**  
**73/23/EEC (Low voltage Directive)**  
**89/336/EEC (EMC Directive)**

Applied harmonized standards:

**EN-ISO-12100-1; EN-ISO-12100-2**

Date/Manufacturer's signature:

19/12-06,   
Johan Westman

The undersigned:

Managing Director



# DET NORSKE VERITAS DESIGN-EXAMINATION STATEMENT

*Application of the AFS 1999:4  
(Council Directive 97/23/EC of 29 May 1997 on Pressure Equipment),  
as amended.*

STATEMENT No. 02-756390-02  
This Statement consists of 2 pages

*This is to certify that the component*

*with the type designation(s)*

**Tank plate Mixer**

*Manufactured by*

**NovAseptic AB, Sweden**

*is found to comply with*

the relevant parts for design examination of the requirements in Annex I, Essential Safety Requirements and SS-EN 13445 (Unfired pressure vessels).

*The equipment has been examined with respect to the relevant parts for Materials, Design for adequate strength and Hydrostatic pressure test as described in the AFS 1999:4 (Directive 97/23/EC)*

#### *Applications*

*Equipment Category : IV*

*Design Pressure min/max. : -1 / +7*

*Design Temp. range : -80 / +200 °C*

*Medium : Medicine*

*Further details of the product and conditions for the certification are given overleaf.*

*Place and date*

*Notified Body No.:*

0409

Mölnådal, 2004-02-03

DET NORSKE VERITAS INSPECTION AB

  
Jan Pihlquist

Notice: The certificate is subject to terms and conditions, if any, overleaf. Any significant changes in design or construction of the product, the quality system or amendments to the AFS 1999:4 (Directive 97/23/EC) or Standards referenced above may render this certificate invalid. The product liability rests with the manufacturer or his representative in accordance with the AFS 1999:4 (Directive 97/23/EC), as amended.



**Statement No. 02-756390-02**

### **Limitations**

The Tank plate is welded into a tank-bottom and will be pressure tested together with the tank.

Applicable for materials 1.4404 and 1.4435 per EN 10272 and DIN 17 440

DNV PMA rev 1, covering A479 Gr316L

DNV PMA rev 1, covering 1.4404 according to DIN 17.440

DNV PMA rev 1, covering 1.4435 according to DIN 17.440

### **Design Approval documentation**

NovAseptic: Produkt-specifikation PS-002 utgåva A.

NovAseptic: Artikel-specifikation AS-006 utgåva 0.

Stress Analyses no HV421-01 to HV421-08 (FEM-Analyses)

Drawing No. AR-05\_32

Drawing No. AR-1\_32

Drawing No. AR-5\_32

Drawing No. AR-10\_32

Drawing No. AR-20\_32

Drawing No. AR-50\_32

Drawing No. AR-100\_32

Drawing No. AR-200\_32

Drawing No. AR-001078 rev 00

### **End of Statement**