

Upstream Mixer

User's guide

Technical Description

Installation

Operating Instructions

Maintenance



Contents

1. Introduction	4
1.1 General	4
1.2 Warrantee	5
1.3 Technical Service	5
2. Safety	6
2.1 Signs used in this manual	6
2.2 Warnings	6
2.3 Prohibitions	7
3. Description	8
3.1 Upstream Mixing Head	9
3.2 USM Bearing unit	10
3.3 USM Tank Plate	11
3.4 Drive Unit	12
3.5 Revolution Counter	13
3.5.1 USM T60 and USM T260	13
3.6 Dimensions and Weights	14
3.7 Noise level and Vibrations	14
3.7.1 Noise level	14
3.7.2 Vibrations and balancing	14
4. Transport and Handling	15
4.1 Transport	15
4.2 Handling	15
5. Installation	16
5.1 USM Tank Plate	16
5.2 Electrical Installation	18

5.3 Revolution Counter	20
5.3.1 Revolution Counter USM T60 and USM T260	20
5.4 Commissioning of Drive Unit	21
5.5 Installing of USM Male Bearing	23
5.6 Installing of USM Mixing Head	24
5.7 Installation of the Drive Unit	26
5.7.1 USM T60	26
5.7.2 USM T260	27
5.8 Start-up	29
6. Operation	31
6.1 Operating limits	31
6.2 Principles of operation	31
6.3 Cleaning procedure for the USM Mixer (CIP)	35
6.3.1 Cleaning inside vessel	36
6.3.2 Separate cleaning of the USM Mixing Head	36
6.4 Sterilization procedure for the USM Mixer (SIP)	37
6.4.1 Sterilization by injection of pressurized steam	37
6.4.2 Sterilization by Superheated Water	37
6.4.3 Sterilization by steam autoclaving	38
7. Service / Maintenance	39
8. Recommended spare parts and tools	40
9. Trouble Shooting	41
10. Start-Up checklist for USM Mixer	42

I. Introduction

I.1 General

The Upstream Mixer is especially designed for the first aseptic process stage in the pharmaceutical and biotech industry. The Upstream 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 Upstream Mixer is based, will greatly improve the serviceability, cleanability and sterilizability of your mixing process.

Some of the reasons for that statement are:

The fact that the Mixing Head is driven by magnetic forces eliminates drive shafts through the vessel wall. Any possibility for seal leakage to occur is totally eliminated. An added feature of this design is the ease of service when it is required.

The open structure of the Mixing Head represents a major improvement in the design of magnetically driven mixers.

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

The complete range of Upstream Mixers will cover liquid mixing applications up to 20.000 litres - or more.

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 Warrantee

NovAseptic AB. offers comprehensive after-sales services. If any major defect develops, the Upstream 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.

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

1.3 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

www.novaseptic.com

2. Safety

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



The magnetic items (Upstream Mixing Head 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 Upstream 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 Upstream 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 USM Mixer is available in two models and sizes. It is designed to be used in liquid process vessels where powder incorporation is needed 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.

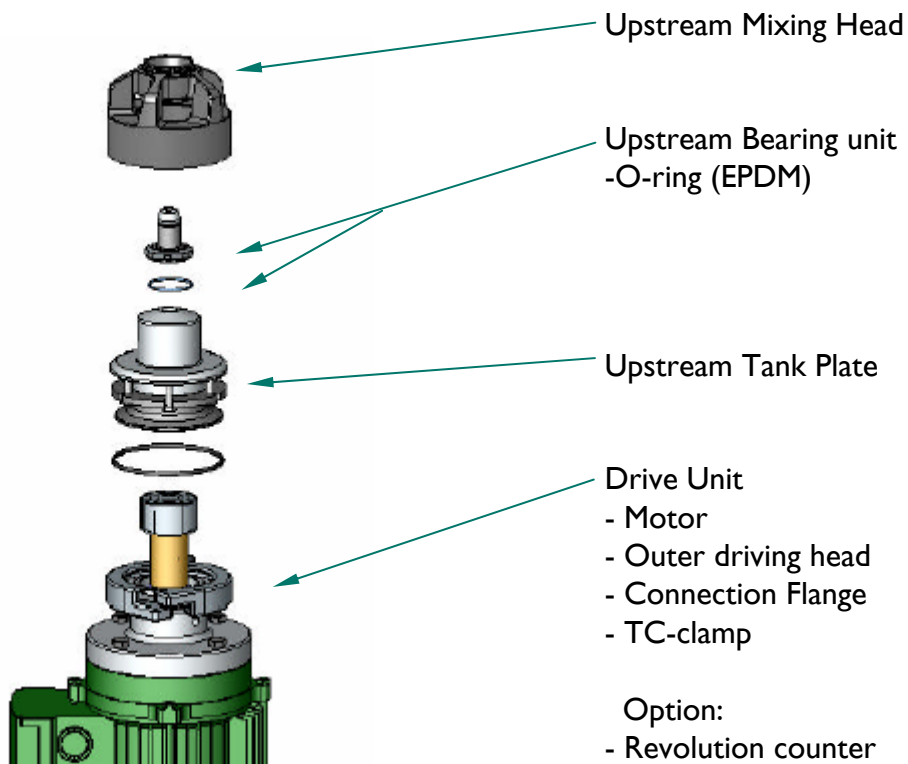
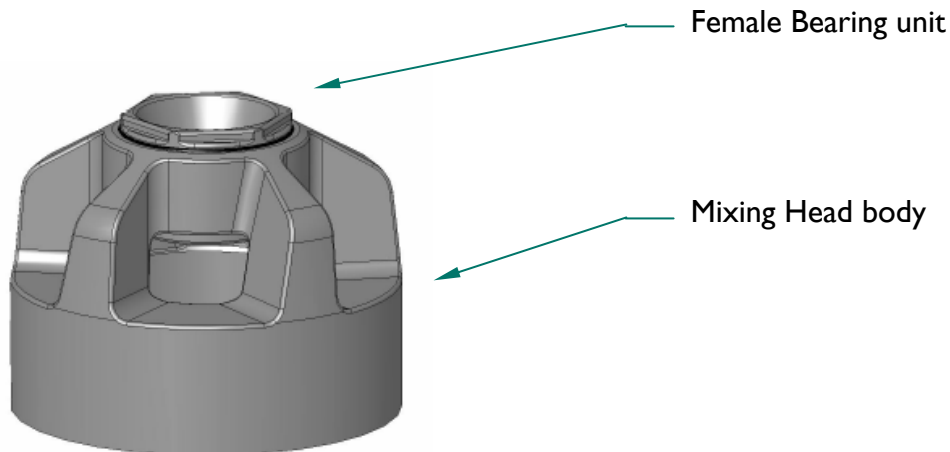


Fig.3.1 Exploded view Upstream Mixer

3.1 Upstream Mixing Head

All Upstream Mixing Head consist of the following parts:

- Mixing Head body, with a ring of permanent encapsulated magnets
- Removable female ceramic bearing



The USM Mixing Head is designed to operate in aseptic pharmaceutical processes. Therefore, they are designed free from pits, crevices, cavities, hidden areas, etc. is electro-polished to a high degree of smoothness.

Fig.3.1.1 Upstream Mixing Head



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 USM Mixing Head 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 USM Mixing Head may corrode if used with non compatible liquids or substances. This can lead to failure.



The Threaded bearing is left-hand threaded.

3.2 USM Bearing unit

All USM Bearing units consist of the following parts:

- A stainless steel support with a connection thread to the USM Tank Plate, and a groove for the o-ring.
- 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.3.2.1 USM Bearing unit



When connecting and disconnecting the bearing from the USM 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 USM Bearing unit 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 USM Bearing unit may corrode if used with non compatible liquids or substances. This can lead to failure.

3.3 USM Tank Plate

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

- Welding flange
- Connection thread for USM Bearing unit
- Flange adapter
- TC-connection flange for Drive Unit

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

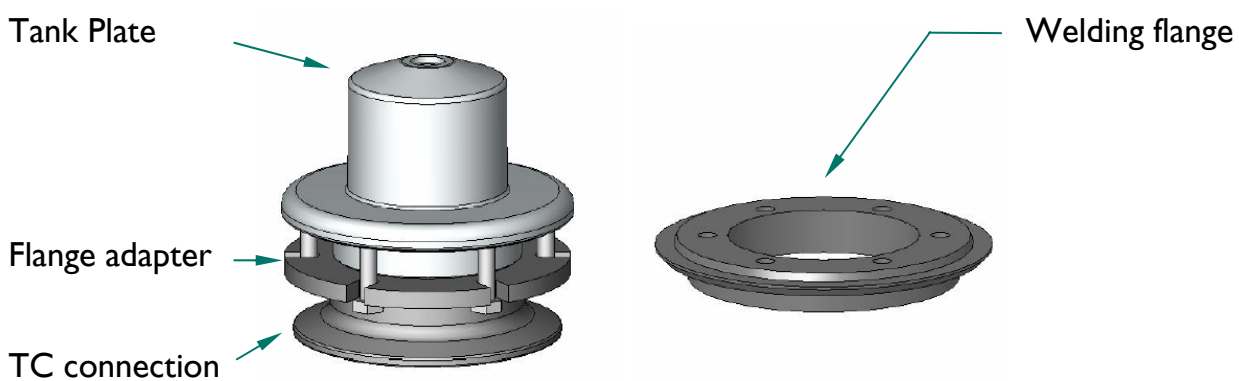


Fig.3.3.1 Tank Plate and welding flange



Before the USM 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 Drive Unit

The Drive Units consists of the following parts:

- TC-clamp (Only on USM T60)
- 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 Upstream Mixer documentation.

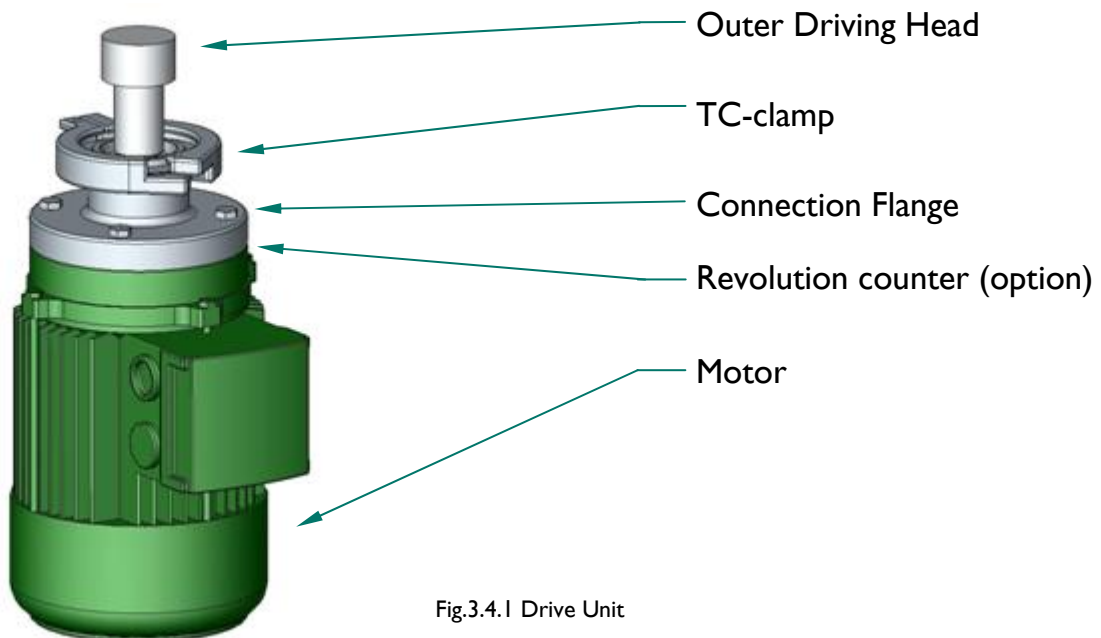


Fig.3.4.1 Drive Unit



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 Revolution Counter

3.5.1 USM T60 and USM T260

The USM 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.

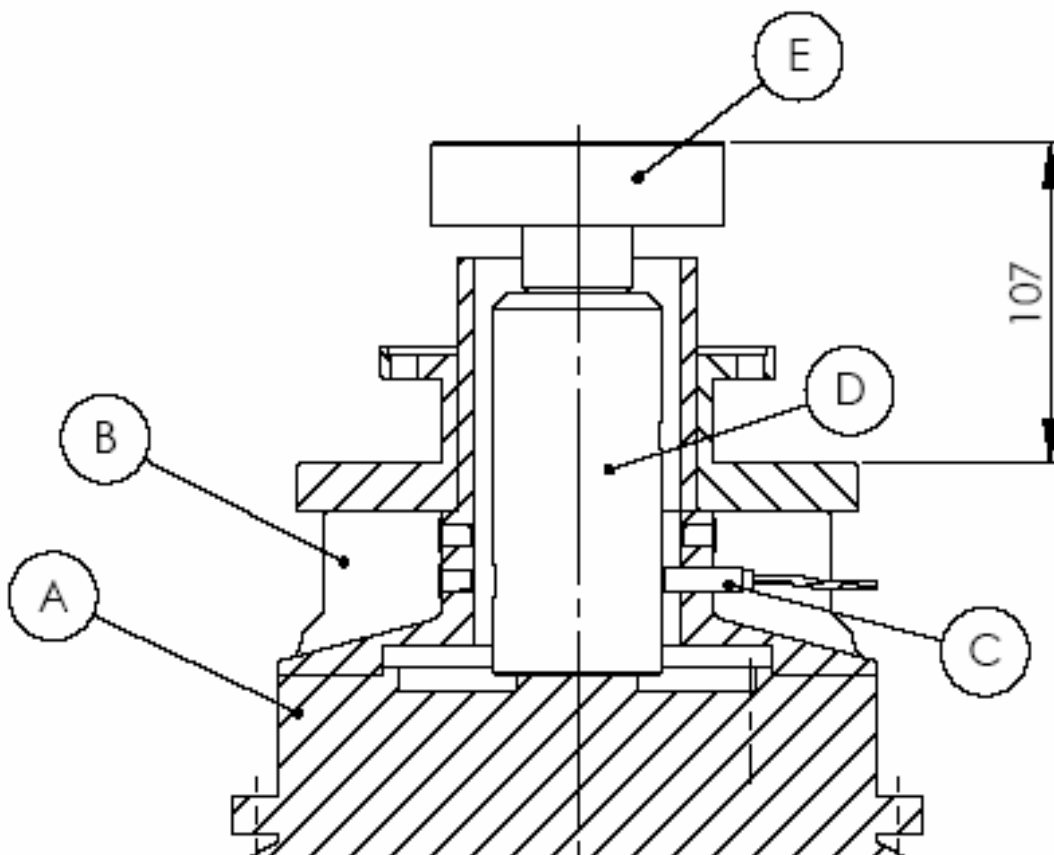


Fig.3.5.2.1 Drive Unit USM T260

3.6 Dimensions and Weights

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

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

Dimensions: Shows the approx. dimensions of standard Drive Units

USM Size	Mixing Head	Bearing unit	Tank Plate	Drive Unit	Drive Unit		
	Weight (Kg)	Weight (Kg)	Weight (Kg)	Weight (Kg)	X (mm)	Y1* (mm)	Y2* (mm)
T60	2,2	0,1	1,3	16	176	275	415
T260	3,4	0,3	3,3	58	219	325	505

*Dimension Y is without extension.

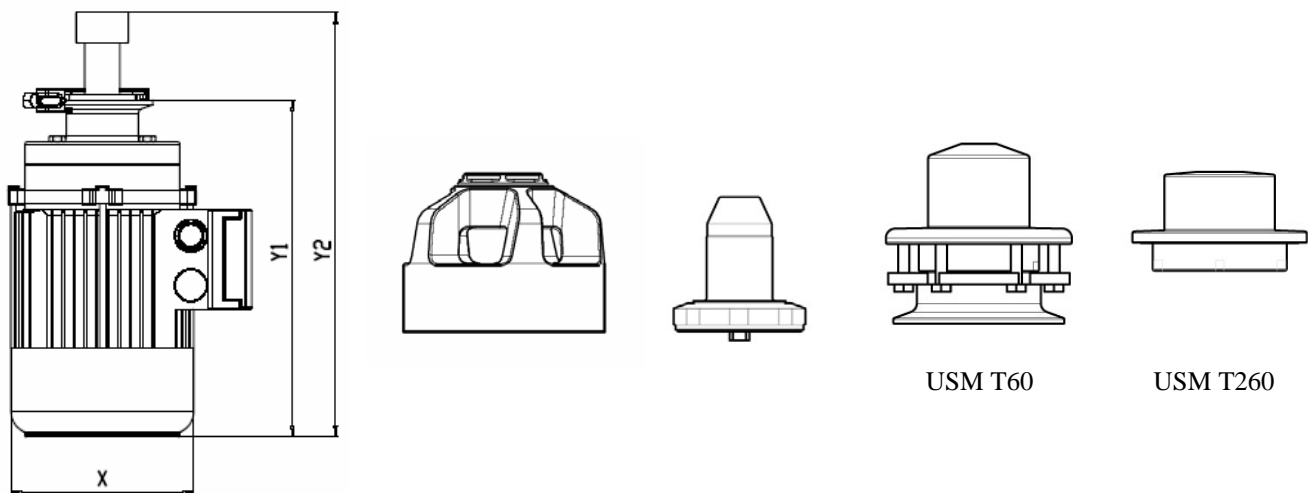


Fig.3.6.1

For more detailed information regarding dimensions and weights for the USM Mixing Head and Drive Unit, please refer to USM Mixer Product Specification Sheets.

3.7 Noise level and Vibrations

For detailed design data regarding noise level and vibrations, see motor data in the USM Mixer documentation and applied standards.

3.7.1 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 USM Mixer mounted in the vessel must be analyzed before the complete installation is declared in conformity with the machine directive

3.7.2 Vibrations and balancing

All motors 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 USM 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 USM Mixer **must not** be transported without being packed securely to avoid damage during transport or storage.

Keep the USM Mixing Head, Bearing unit, 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 USM 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 USM Mixing Head 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 USM Mixing Head 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 USM Mixing Head 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 USM Mixing Head onto its lower base magnetized ring.

To avoid damaging the rotating shaft and the outer driving head, the USM 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.

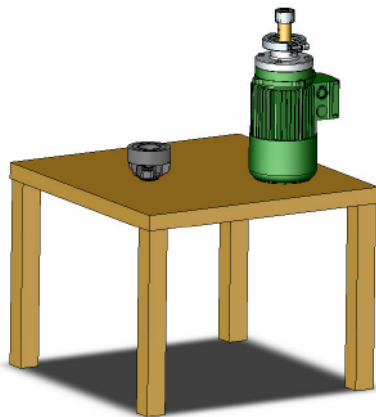


Fig. 4.2.1

5. Installation

Do not install the USM Mixing Head, Bearing unit 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 USM Mixing Head.

Keep the USM Mixing Head and Bearing unit 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.

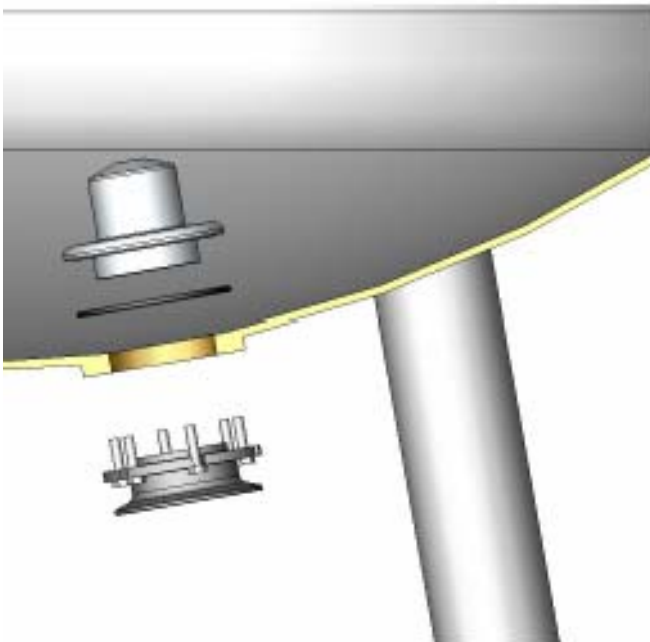


Before any kind of maintenance work, make sure the vessel has been cooled down, emptied, depressurized and ventilated from any possible gases or any traces of dangerous products. Disconnect all media during maintenance work.

5.1 USM Tank Plate

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 USM Tank Plate and all necessary certificates, approvals, etc. have been received and documented.

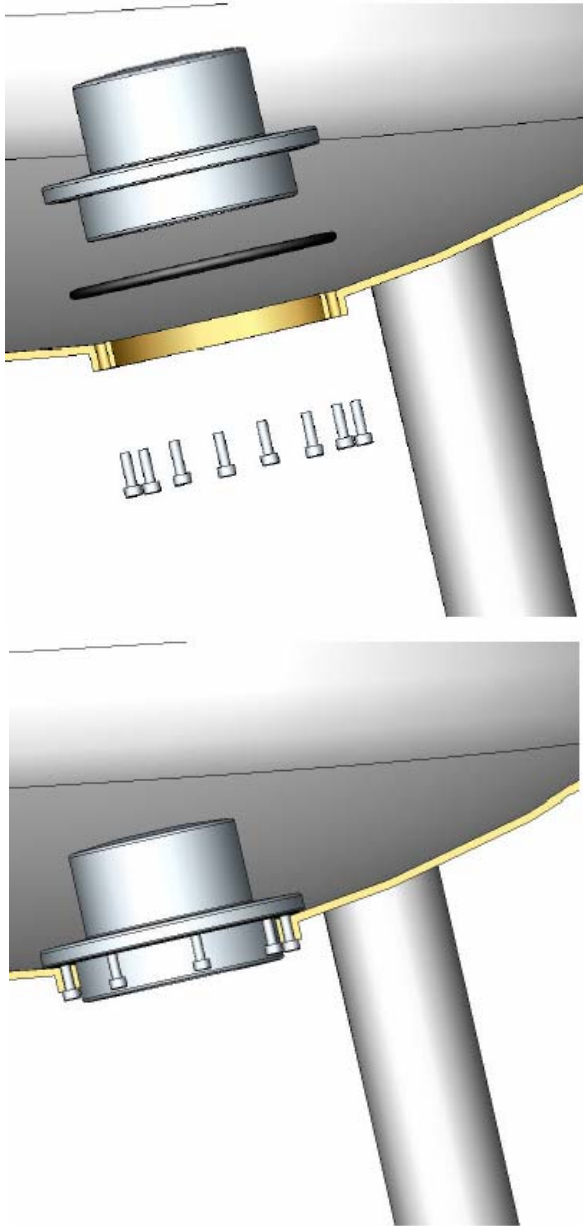
Flange Tank Plate
USM T60



Welded Tank Plate
USM T60 and T260

Follow the instructions in the manual,
Welding guideline for Tank Plate

USM T260



After the welding is performed on Tank Plate adapter, make sure that there is no distortion. NovAseptic's 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:

- 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.

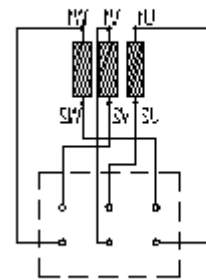


Fig. 5.2.1

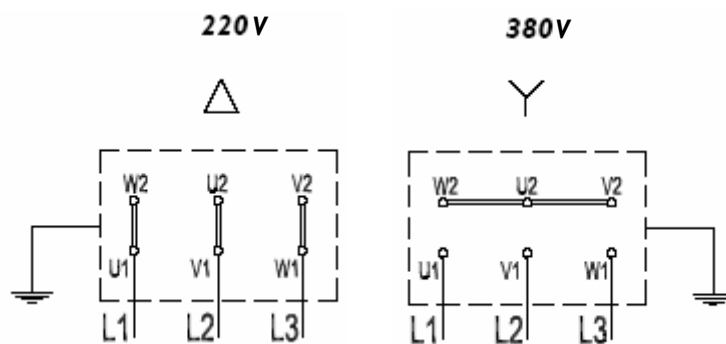


Fig. 5.2.2

USA

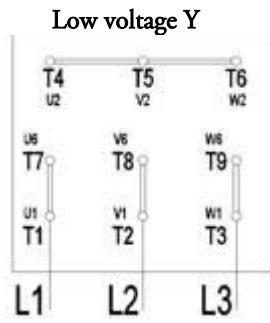


Fig. 5.2.3



Fig. 5.2.4

5.3 Revolution Counter

5.3.1 Revolution Counter USM T60 and USM T260

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

Technical information

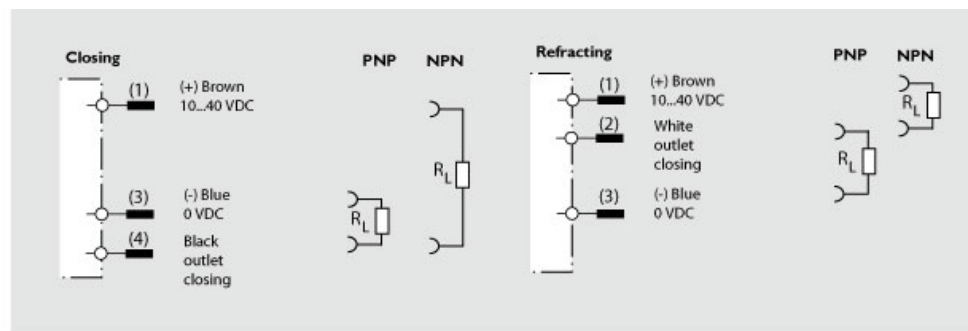
Supply voltage	10...40 VDC, $\pm 10\%$ reverse connection protection
Current consumption	Max 13 mA
Control output	200 mA, open collector, short-circuit protection
Sensing object	Metal
Indicator	Indication of operation LED yellow
Ambient Temperature	-40...70°C (with no icing)
Enclosure rating	IP67, IEC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



M8
2 = refracting
4 = closing



M12
2 = refracting
4 = closing



5.4 Commissioning of Drive Unit

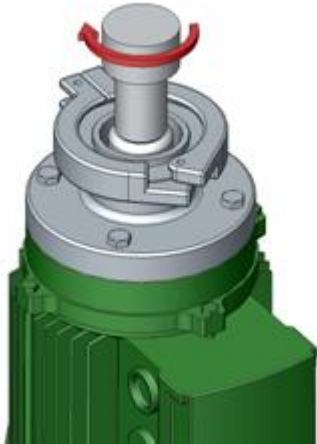


Fig. 5.4.1

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 USM Mixing Head may come off the bearing unit and Tank Plate, and cause damage to the vessel or the Bearing unit 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 the USM Mixer.



Incorrect rotation direction may unscrew the USM Bearing unit during operation causing malfunction and damage.

3. Assembly Drive Unit / Tank Plate

To check that the USM Tank Plate is correctly placed 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 placed into the vessel.



Before installing the Drive Unit, check that the USM Mixing Head has been removed.

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 of USM Male Bearing

1. Check O-ring

Check that the sealing o-ring is properly in place according to fig 5.5.1.

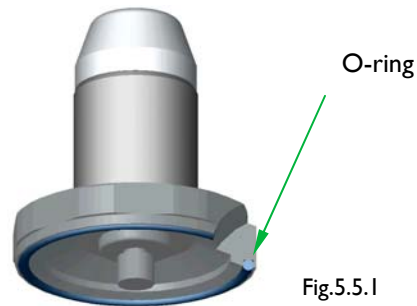


Fig.5.5.1

2. Mount the Male Bearing with a mounting tool for the bearing.

Screw the Bearing unit clockwise into the thread in the USM Tank Plate. Tighten the Bearing unit to steel/steel contact.

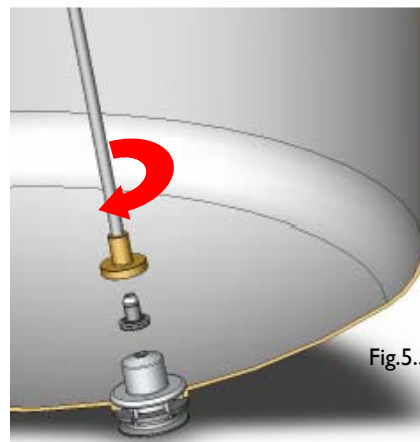


Fig.5.5.2

G20-008	G20-006
6 Nm [4.4 Lbft]	30 Nm [22.1 Lbft]



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

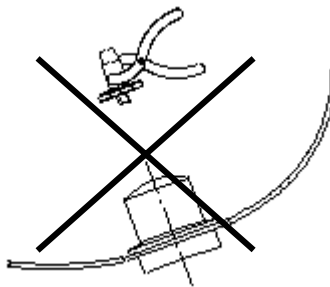


Fig.5.5.3

Never use any grip tools or other tools to mount the Bearing unit, then the USM Bearing unit 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 USM Bearing unit. Make sure that the Bearing unit also is completely dry. Ignoring this warning can result in material damage.



The USM Tank Plate thread must be cleaned before installation of the USM Bearing unit. If the thread is not cleanable please contact NovAseptic AB.

5.6 Installing of USM Mixing Head



Never install the USM Mixing Head while the Drive Unit is connected. The powerful magnetic forces can cause severe damage to the bearing.

USM T60

1. Add water into the vessel for smooth mounting. The water level should be above the Bearing unit.
2. Inspect the Mixing Head so that it does not contain any foreign particles, especially on the magnetic part.
3. Mount the USM Mixing Head with recommended mounting tool.

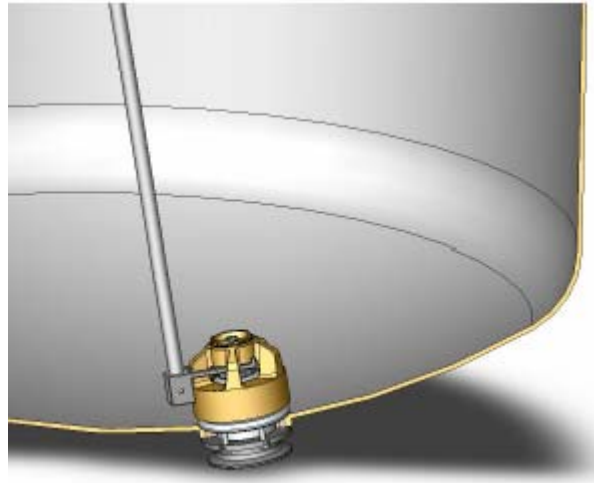


Fig.5.6.1

4. Position the USM Mixing Head very carefully and place it proper aligned onto the USM Tank Plate. Do not drop the Mixing Head onto the Bearing unit. 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 Mixing Head with the USM Mixing Head mounting tool.

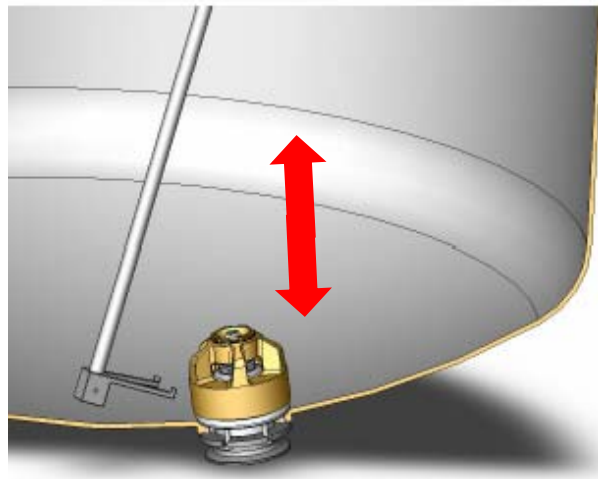


Fig.5.6.2

USM T260

Install after Drive Unit is attached. See chapter 5.7.

Mount the USM Mixing Head with recommended mounting tool. See instruction on USM T60.

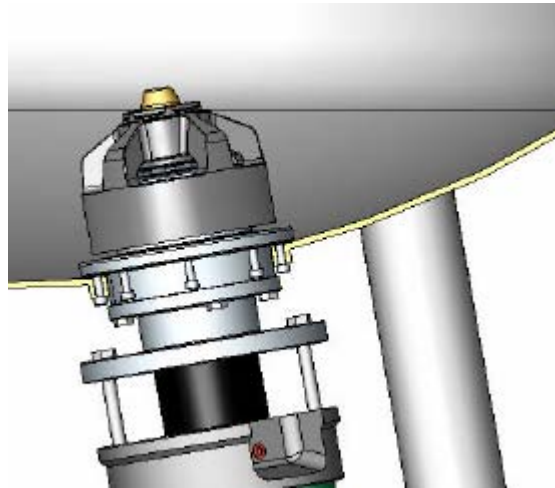


Fig.5.6.1



A special tool should be used to mount the USM Mixing Head.
Without the correct mounting tool, the material may damage.

5.7 Installation of the Drive Unit

Follow enclosed installation instructions for the Drive Unit:



Mounting

The USM Mixing Head and Bearing unit 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 Mixing Head to the magnets of the Drive Unit.

5.7.1 USM T60

USM T60

1. Insert the USM Drive Unit into the USM 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.

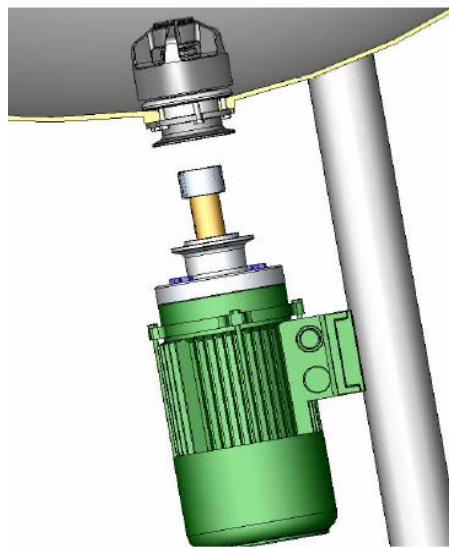


Fig.5.7.1

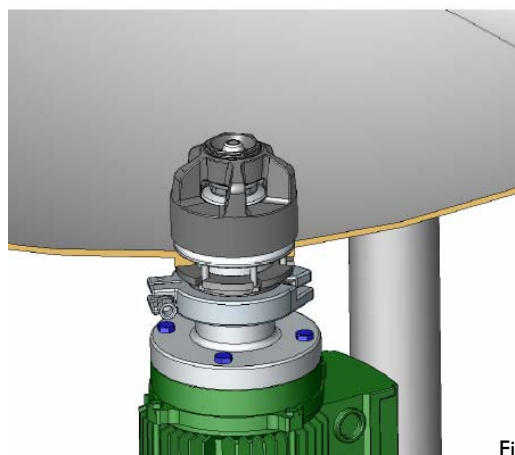


Fig.5.7.2

5.7.2 USM T260



Never install the USM Mixing Head while the Drive Unit is in drive position. The powerful magnetic forces can cause severe damage to the bearing.

1. Mount the Drive Unit to the Tank Plate, fig 5.7.2.1

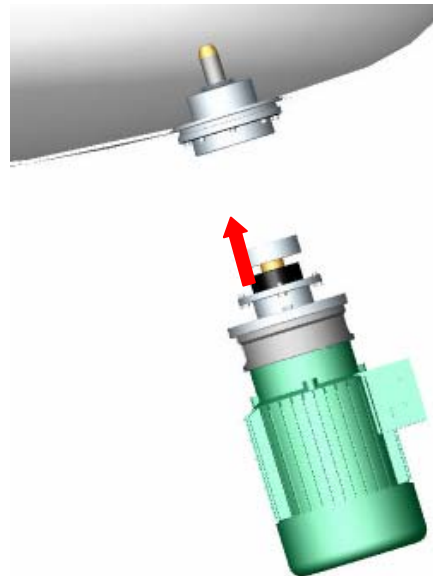


Fig.5.7.2.1

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 5.7.2.2

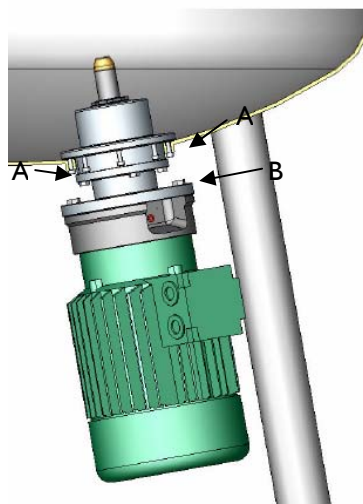


Fig.5.7.2.2

3. Inspect the Mixing Head so that it does not contain any foreign particles, especially on the magnetic part.
4. Position the USM Mixing Head very carefully and place it proper aligned onto the USM Tank Plate. Do not drop the Mixing Head onto the Male bearing. The Male bearing surfaces are very brittle and can be easily destroyed, fig 5.7.2.3.
5. Rotate it by hand to ensure that it will rotate without any scratching.

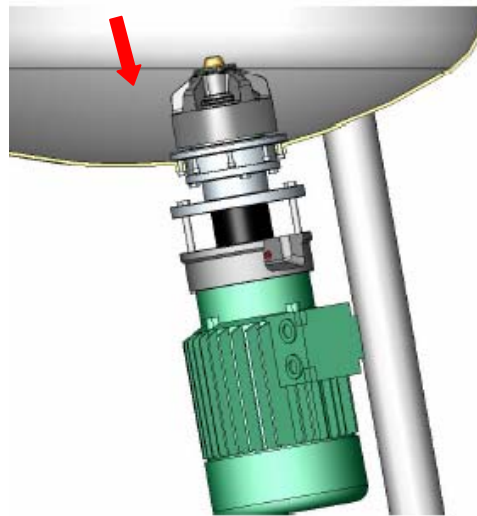


Fig.5.7.2.3

6. Attach the Drive Unit, tighten the screws (A) between flange and Drive Unit until there is no gap (B). , fig 5.7.2.4.

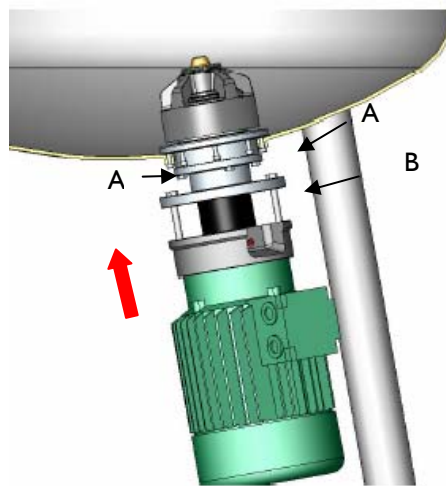


Fig.5.7.2.3

7. The USM Mixer is now ready to use

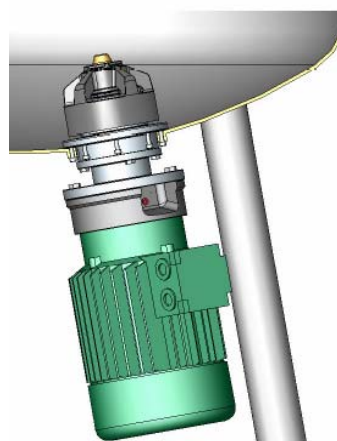


Fig.5.7.2.4

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 USM Mixer.



Dismounting

The Drive Unit must be dismantled before the USM Mixing Head can be lifted from the Bearing unit to avoid the risk of personal injury and damage to the bearing.

5.8 Start-up

Before and during Start-up



The vessel must be filled up with enough liquid to cover the USM Mixing Head.

Dry operation will immediately cause damage to the bearing!

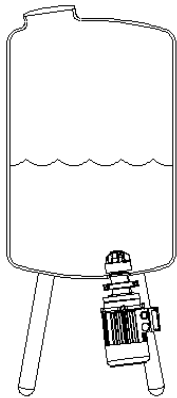


Fig.5.8.1

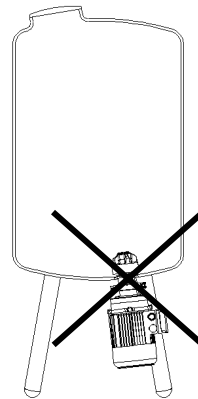


Fig.5.8.2

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 volume.
3. Start the USM 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 USM 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.



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 6.3.1.2.

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 USM 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 Working volume between 1:1-1:2 (D:H)
- Keep α -angel as small as possible.
To achieve a small α -angel
-Install the USM 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

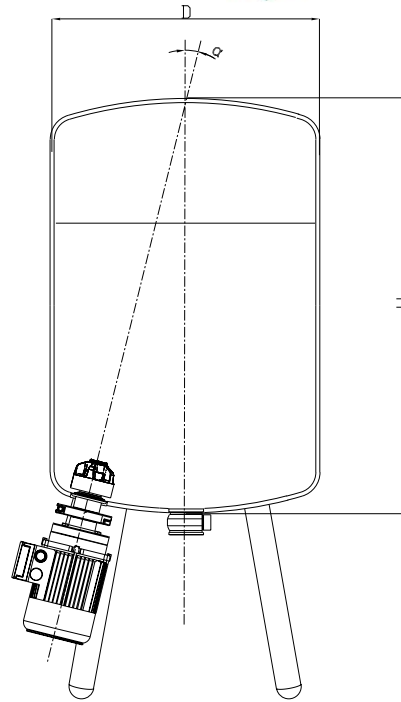


Fig.6.2.1

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 Working volume $< 1:1$. (D:H)
 - Keep α -angel as large as possible.
 - Reduce speed.
- To achieve a large α -angel.
- -Install the USM Mixer as far from the centerline of the dished end as possible.
-Use a deep dished end e.g. SMS shape.

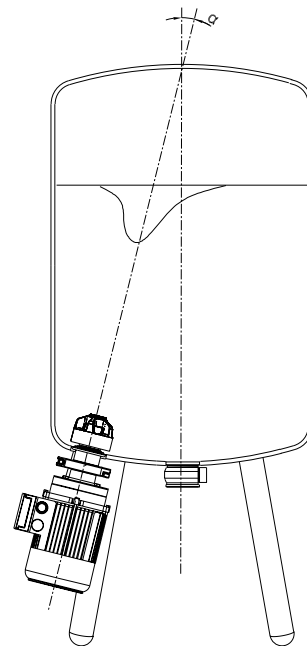


Fig.6.2.2

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 USM Mixer and a standard NA-Mixer. This is called Combo mixing.

How to control vortex

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

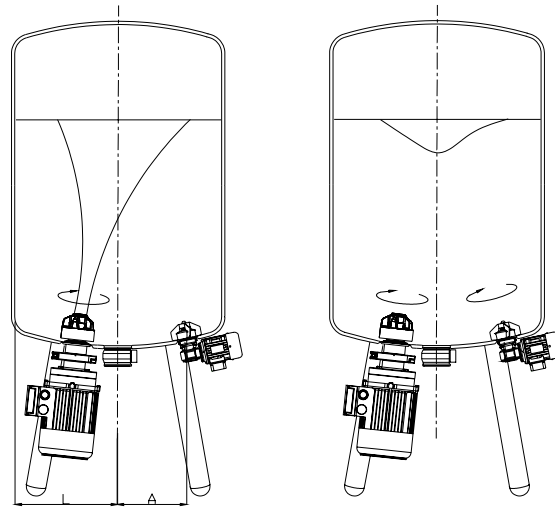


Fig.6.2.3

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 unit part due to sudden liquid boiling and cavitations. A typical scenario is:

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

Stop the USM Mixer immediately and inspect the Bearing unit ensuring that it is properly tightened and have full metal-to-metal contact to the Tank Plate. Make certain that the Mixing Head 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 vessel.

6.3 Cleaning procedure for the USM Mixer (CIP)

The USM Mixer is designed with an open design that enables the USM Mixing Head, Bearing unit 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 Mixing Head 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 Mixing Head.



Accumulation of magnetic particles on the inside of the Mixing Head can cause corrosion and damage the Mixing Head 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 USM Mixing Head 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 Mixing Head and Bearing unit which will inhibit rotation.

2. During CIP, the Mixing Head must be submerged min 100 mm se Fig.6.3.1.2.



Dry operation will immediately cause damage to the bearing.

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

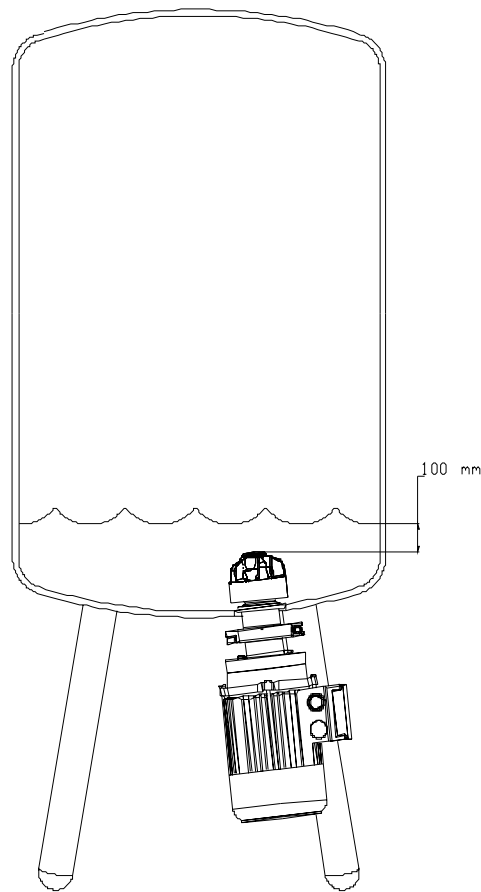


Fig.6.3.1.2

6.3.2 Separate cleaning of the USM Mixing Head

The above-described cleaning methods will clean the USM Mixing Head, Bearing unit 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 USM Mixing Head and will not be removed by the normal CIP procedure.

To remove these particles the USM Mixing Head 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 Mixing Head from the vessel and check for particles stuck to the inside of the Mixing Head. If necessary clean the Mixing Head as follows:
 - o Spray the Mixing Head 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 USM Mixing Head into the vessel, se 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 USM Mixer (SIP)

The USM Mixer is designed with an open design that enables the Mixing Head, Bearing unit 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.
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 USM Mixer can be Sterilized In Place with the Drive Unit connected to the vessel.



Do not run the USM 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 Mixing Head will be fully soaked in Superheated Water during the whole sterilization period - **No action needs to be taken with the USM Mixer.**



Do not run the USM Mixer during any step of the SIP.



Dry operation will immediately cause damage to the bearing.

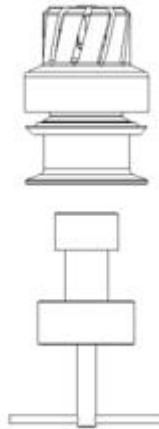
6.4.3 Sterilization by steam autoclaving

This sterilization method means that the entire process vessel including the USM Mixing Head is placed inside a steam autoclave where the temperature is raised to the actual sterilization temperature, normally 121°C.

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.



USM Mixing Head Attractor

Fig.6.4.3.1



If the Drive Unit is unattached during transportation and sterilization in autoclave/oven, a USM Mixing Head attractor must be mounted to ensure safe handling of the male and feBearing unit.



After an autoclaving process the USM Mixing Head and its FeBearing unit as well as the connecting Bearing unit 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 USM Mixing Head.


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: 
USM Mixing Head	<i>Surface:</i>	Foreign particles	Visual	- The magnet shows adhering of foreign material	⇒ Cleaning (acc. to 6.3.3)	X	-
	<i>FeBearing unit:</i>	Scratches	Visual	- The surfaces shows any damages	⇒ Re-polishing	X*	X
		Surface damage	Visual	- The surfaces shows any damages	⇒ Exchange of Bearing	-	X
USM Bearing unit	<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	
USM Tank Plate	<i>Upper thread:</i>	Damage to the thread	Screw gauge	- The screw does not enter the thread.	⇒ Re-threading	X*	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 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 USM Mixer.

NovAseptic mounting tools for the USM Mixing Head and Bearing unit are to be used during mounting.

Spare parts and tools	
USM T60	USM T260
USM Bearing unit	USM Bearing unit
O-rings	O-rings
<i>EPDM</i>	<i>EPDM</i>
USM Mixing Head	USM Mixing Head
USM Bearing unit mounting tool	USM Bearing unit mounting tool
USM Mixing Head mounting tool	USM Mixing Head mounting tool
USM Mixing Head attractor	USM Mixing Head attractor



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>
Motor / USM Mixing Head 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.
USM Mixing Head scratches onto USM Tank Plate:	A A,B A,B A	- Bearing worn out. - Loose USM Bearing unit - 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 USM 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 USM Mixing Head:	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.
USM Mixing Head is running eccentrically:	A B	- USM Bearing unit not properly in Place. - Bearings worn out.	- Tighten the USM Bearing unit 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. Start-Up checklist for USM Mixer

Tick off

- | | | | |
|-----|-------------------------------------------------------------------------------------------------------------------------|---|--------------------------|
| 1. | The USM Mixer manual has been carefully read and understood, especially section #2. regarding safety. | ✓ | <input type="checkbox"/> |
| 2. | Check that there is a NovAseptic USM Tank Plate installed properly into the actual vessel. | | <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 USM 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 USM Mixer User's guide. | | <input type="checkbox"/> |
| 6. | Install the USM Bearing unit according to installation instructions given in chapter 5.5 in the USM Mixer User's guide. | | <input type="checkbox"/> |
| 7. | Install the USM Mixing Head according to installation instructions given in chapter 5.6 in the USM Mixer User's guide. | | <input type="checkbox"/> |
| 8. | Install the Drive Unit according to installation instructions given in chapter 5.7 in the USM Mixer User's guide. | | <input type="checkbox"/> |
| 9. | Start up the USM Mixer according to chapter 5.8, the USM Mixer User's guide. | | <input type="checkbox"/> |
| 10. | Do not exceed operating limits for the USM Mixer, see chapter 6.1 in the USM Mixer User's guide. | | <input type="checkbox"/> |

Now your USM Mixer is ready to be put in use!

