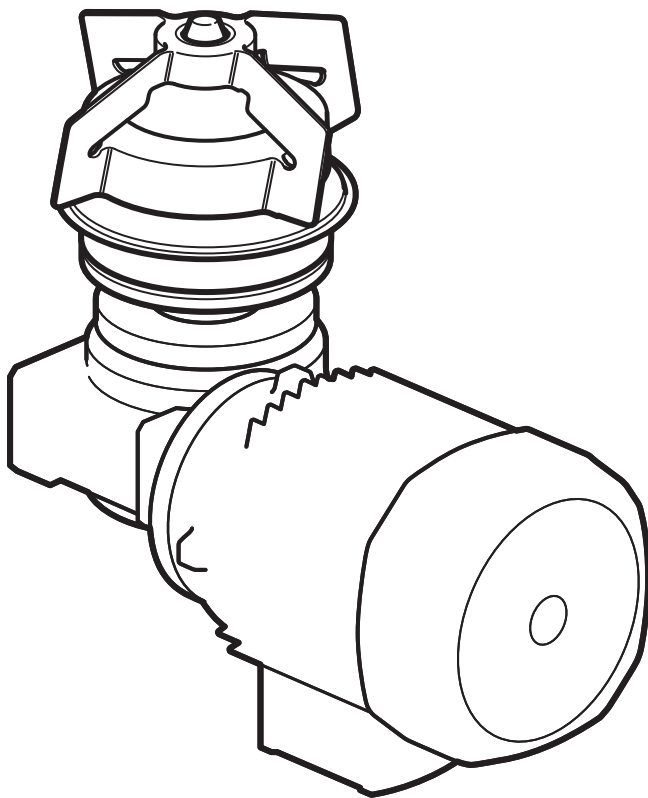




# NovAseptic<sup>®</sup> GMP Mixer

## Installation and User Guide



**Notice**

The information in this document is subject to change without notice and should not be construed as a commitment by Millipore Corporation. Millipore Corporation assumes no responsibility for any errors that may appear in this document. This manual is believed to be complete and accurate at the time of publication. In no event shall Millipore Corporation be liable for incidental or consequential damages in connection with or arising from the use of this manual.

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## EC Declaration of Incorporation

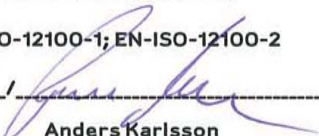
Within the Meaning of the EC-Machine Directive 98/37/EC, Annex II B

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 GMP Mixing application, magnetic coupled	
Product type:	NovAseptic <sup>®</sup> GMP Mixer	GM05/4... GM 1/4... GM 5/4... GM 10/4... GM 20/4... GM 50/4... GM 100/4... GM 200/4... GM 300/4...
Serial No:	See documentation for your NovAseptic <sup>®</sup> GMP Mixer	
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 June 2008 / 	
The undersigned:	Anders Karlsson	
Managing Director		

Millipore AB (Head quarters)  
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[www.millipore.com](http://www.millipore.com)



**INSPECTA**  
**EC DESIGN-EXAMINATION STATEMENT**

Application of the  
*Council Directive 97/23/EC of 29 May 1997 on Pressure Equipment, as amended, and Swedish ordinance AFS 1999:4*

STATEMENT NO.: **07-195220-02**  
This Statement consists of 2 pages

THIS IS TO STATE THAT THE COMPONENT  
WITH THE TYPE DESIGNATION  
**Tank Plate Mixer**  
MANUFACTURED BY  
**Millipore AB, Nödinge Sweden**

is found to comply with the relevant parts for design examination of the requirements in  
Annex I, Essential Safety Requirements and EN 13445

The equipment has been examined with respect to the relevant parts for design examination  
procedure of conformity assessment as described in Module B in the AFS 1999:4

APPLICATIONS  
Equipment Category: IV  
Design Pressure min/max: -1 / 10 bar(g)  
Design Temp. range: -80 / 200 °C  
Fluid: Group 1 and 2, see "limitations"  
Further details of the product and conditions for the statement are given overleaf.

MÖLNDAL, 2007-05-28  
**Inspecta Sweden AB**  
Notified Body No.: 0409




Pieter Jilderda  
Manager Design Review

Notice: The statement 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 statement invalid. The product liability rests with the manufacturer or his representative in accordance with the AFS 1999:4 (Directive 97/23/EC), as amended.



INSPECTA SWEDEN AB NEONGATAN 4 B 431 53 MÖLNDAL SWEDEN TEL (+46) 8 5011 3400 FAX (+46) 8 5011 3401 www.inspecta.com

Page 1 of 2  
PED, O, LHMPT, E-4874818, 001, 1/1/2007



## EC DESIGN-EXAMINATION STATEMENT

STATEMENT NO.: 07-195220-02

### DESIGN APPROVAL DOCUMENTS

AR-001010 REV. A DATED 2005-06-08  
AR-001011 REV. A DATED 2005-06-08  
AR-001012 REV. A DATED 2005-06-08  
AR-001013 REV. A DATED 2005-06-08  
AR-001014 REV. A DATED 2005-06-08  
AR-001015 REV. A DATED 2005-06-08  
AR-001016 REV. A DATED 2005-06-08  
AR-001017 REV. A DATED 2005-06-08  
AR-001291 REV. B DATED 2005-06-08  
AR-001078 REV. B DATED 2005-06-08

### LIMITATIONS

This document is based upon and replaces **EC Design-Examination Certificate number 05-584563-00 issued by Det Norske Veritas Inspection AB 2005-06-10**. The drawings stamped with DNV name and number are still valid.

The following has been changed:

- Name of manufacturer (has been changed from NovAseptic AB)
- Our document has been changed from a certificate to a statement.
- Fluid.

The resistance against corrosion has not been a part of this review. That has to be taken into consideration in each separate case.

Tank plate will be welded to the bottom of a vessel and pressure-tested with the vessel.  
External loads not allowed.

MÖLNDAL, 2007-05-28

**Inspecta Sweden AB**



Pieter Jilderda  
Manager Design Review



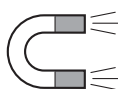
# Operator and Equipment Safety



- All installers and operators of the equipment must read and understand this installation and user manual before using this equipment. Failure to follow installation and operating instructions could result in operator injury or damage to the equipment.
- Any attempt to use the NovAseptic GMP Mixer equipment in a manner not specified by Millipore Corporation may result in damage to the equipment, voiding of product warranty, and possible operator injury.



- Any of the following can damage the mixer: external load; reaction forces and torque; corrosion, erosion, and fatigue; and decomposing of unstable liquids.
- Prior to operation, the equipment must be fully assembled according to the instructions in this manual.
- Use appropriate personal protective equipment and eye protection when operating the equipment.
- Protect drive unit against dust.
- Electric engine may cause sparks. Do not use near flammable liquids or gasses.
- The drive unit may be heavy. Use appropriate equipment to avoid injury.
- Do not install components close to rotating parts of the GMP Mixer.
- During mixing operations, mixer parts may become hot to the touch.
- Do not insert fingers into equipment; pinching may occur.
- The GMP Mixer is not classified for ATEX. Contact your Millipore representative for ATEX options
- Check the magnetic parts of the GMP Mixer regularly for foreign materials.
- Do not run with an empty vessel.
- Check that all components in the mixer are of correct size.
- Handle the mixing head and male bearing with care; bearing material is hard and brittle.



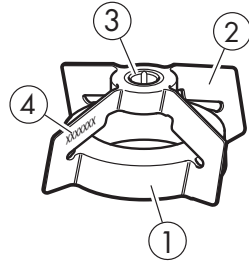
- Keep electrically controlled medical devices and magnetically stored media away from magnetic parts of the GMP mixer.
- The mixing head must be completely submerged during operation to ensure sufficient lubrication.
- The system must be properly grounded.

# NovAseptic GMP Mixer Components

Catalogue numbers and specifications for the components listed here can be found on the appropriate specification sheet.

## Mixing Head (GM#/12#)

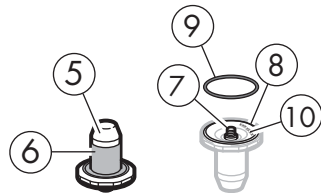
Handle the mixing head with care. The bearing material is hard and brittle. Keep the magnetic body away from any particles that may adhere to it.



Key Number	Description
1	Magnetic body
2	Wings
3	Silicone carbide female bearing
4	Serial number

## Male Bearing (GM#/2#)

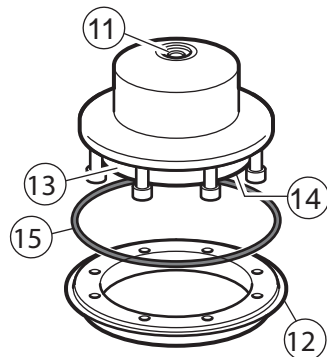
The male bearing keeps the mixing head in a correct position; it mounts on the tank plate inside vessel.



Key Number	Description
5	Stainless steel support
6	Silicone carbide bearing
7	Connection thread
8	Groove
9	O-ring
10	Serial number

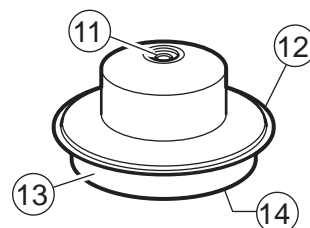
## Tank Plate (GM#/3#) or Flanged Tank Plate (GM#/312)

Each tank plate is marked with the serial number and a mill stamp that corresponds to its heat number. The tank plate is mounted, welded, or flanged onto the vessel and is considered an integrated part of the vessel. The tank plate must comply with your local pressure code.



*Flanged tank plate*

Key Number	Description
11	Male bearing connection thread
12	Welding edge
13	Drive unit connection flange
14	Serial number
15	O-ring (on flanged tank plate only)



Welded tank plate



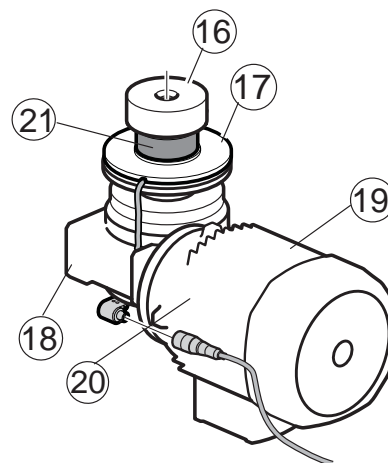
### Drive Unit (GM#/4#-#)

The drive unit delivers the rotating torque to the mixing head and is mounted on the outside of the vessel. The speed counter is an optional feature on standard GMP Mixer drive units.

Drive units with speed counter: catalogue no GM#/4B#-#

Drive units without speed counter: catalogue no GM#/4A#-#

Key Number	Description
16	Magnetic outer drive head
17	Tank plate connection flange
18	Gearbox unit
19	Motor
20	Serial number label
21	Speed Counter



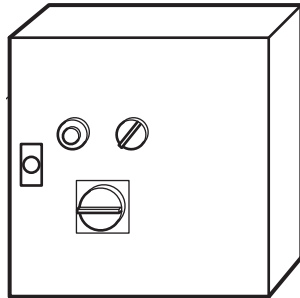
### Required Tools

The following tools are required for installation of the NovAseptic GMP Mixer. These tools are NOT included with the mixer, but are available from Millipore. Catalogue numbers and specifications for the components can be found at [www.millipore.com](http://www.millipore.com).

Description	Purpose
Multi tool (GT#/25)	Installation tool for mixing head and male bearing for use in small vessels
Tightening tool (GT#/26)	Installation tool for male bearing
Heatsink tank plate (G94-#)	Attached to the tank plate during welding to prevent deformation
NovAseptic gauge 1 (G91-#)	For verification of geometry after welding
NovAseptic gauge 2 (G92-#)	

## Additional Equipment

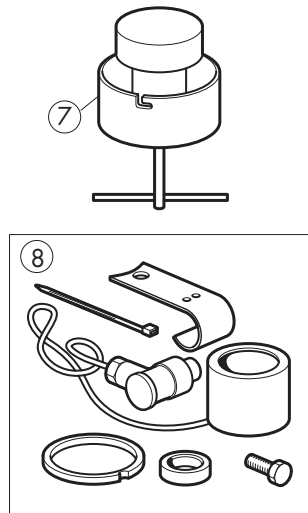
The following additional equipment is available from Millipore. Catalogue numbers and specifications for the component shown here can be found at [www.millipore.com](http://www.millipore.com).



Description	Purpose
Control cabinet (G50-#, G51-#)	Speed control device for mixer. Regulates rotation speed and ramp time for the motor. This equipment is required for all installations.

## Optional Equipment

The following options are available from Millipore. Catalogue numbers and specifications for the components shown here can be found at [www.millipore.com](http://www.millipore.com).



Key Number	Description	Purpose
7	Mixing head attractor (GT#/AW)	Keeps the mixing head in place when vessel is moved. Substitute for the drive unit during transport.
8	Speed counter kit (GM#/67)	Speed counter installation kit. The speed counter indicates the rotational speed of the mixing head and the outer drive head. Optional equipment available on AC drive unit.

# Installation and Operating Parameters

Please refer to the appropriate product specification sheet for more information.

<b>Tank Plate and Welding Flange</b>		
<b>Parameter</b>	<b>Minimum</b>	<b>Maximum</b>
Temperature	-80 °C (-112 °F)	200 °C (392 °F)
Pressure	-1 barg (-14.5 psig)	10 barg (145 psig)

<b>Mixing Head, Male Bearing, and Tank Plate</b>		
Define the operating parameters inside the vessel. GMP Mixers are designed for non explosive and non hazardous areas.		
<b>Parameter</b>	<b>Minimum</b>	<b>Maximum</b>
Temperature	5 °C (41 °F)	135 °C (275 °F)
pH	1	14
Viscosity	1 cP	800 cP
Media	Media may not contain magnetic particles	
Rotation speed	see Product Specification Sheet	
Minimum acceleration and deceleration time	Five seconds (Specific to each application; set accordingly.)	

<b>Drive Unit</b>		
Defines the operating parameters inside the vessel.		
<b>Parameter</b>	<b>Minimum</b>	<b>Maximum</b>
Ambient temperature	0 °C (32 °F)	40 °C (104 °F)

## Noise level and Vibrations

Noise levels are measured according to ISO<sup>®</sup>1680 standard, and are within maximum levels specified by standards CEI 2-24/IEC 34-9. Vibration falls under standard class N and is specified by standard CEI 2-23/IEC 34-14.

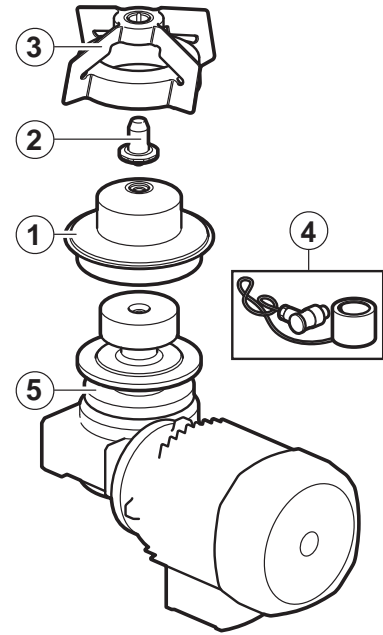
# Installation



Use the Installation Checklist and the Installation Qualification Checklist (in this manual) as guides for installing the mixer and initiating use. Use the Maintenance Checklist as a guide for followup care of the mixer.

Install the GMP Mixer components in the following order:

1. Tank plate (refer to the NovAseptic Tank Plate Welding Guide for installation instructions.)
2. Male bearing
3. Mixing head
4. Speed counter (optional, installed on the drive unit)
5. Drive unit



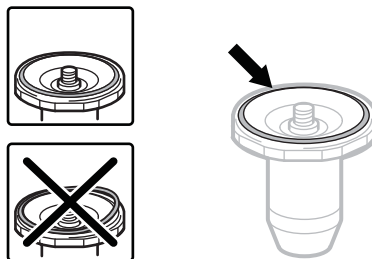
## Male Bearing Installation

See NovAseptic Mixer GMP Male Bearing Installation Guide 00101868PU for additional information.

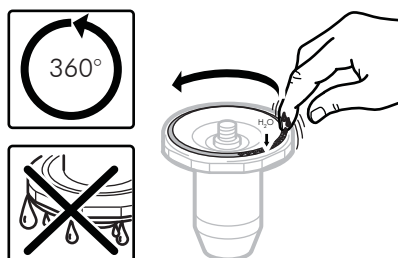
- The vessel must be clean and completely dry inside.
- Do not use grip tools on bearing surfaces.
- Follow all local safety codes before entering the vessel.
- Handle the male bearing with care.

### Mounting the Male Bearing

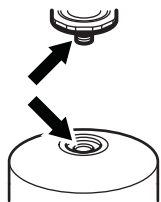
1. Ensure proper position of the O-ring on the male bearing.



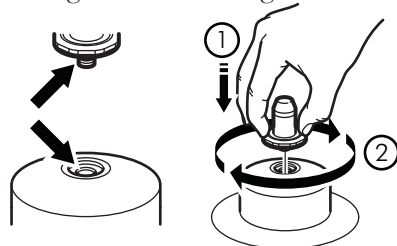
2. For minimal friction, lubricate the visible part of the O-ring with a small amount of purified water.



- Remove the protective cap. Ensure that the thread connection in the tank plate and male bearing are clean, dry, and free from foreign material.

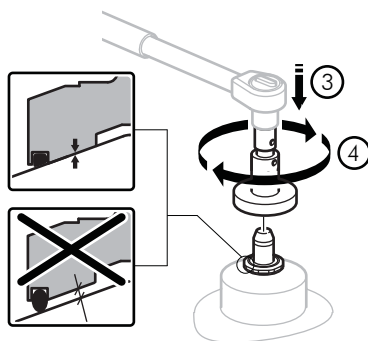


- Tighten the male bearing clockwise by hand into the thread of the tank plate, making sure that it is aligned with the center line of the tank plate.



- Position the male bearing in the appropriate tightening tool or multi-tool with a torque wrench. Ensure that the tool fits the nut. Tighten the bearing to metal-to-metal contact, applying torque according to table below.

Important: Ensure metal-to-metal contact by applying recommended torque in table below. If bearing is not installed properly it may come off.



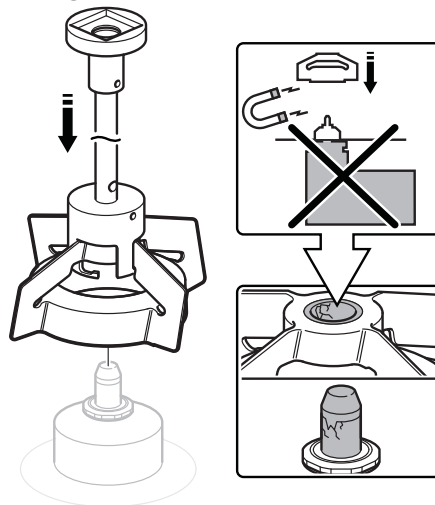
Catalogue Number	Torque
GM05/23	6Nm/4.4Lbft
GM05/24	
GM1/23	
GM1/24	
GM510/23	
GM510/24	
GM20/23	13Nm/9.6Lbft
GM20/24	
GM50300/23	30Nm/22.1Lbft
GM50300/24	

## Mixing Head Installation

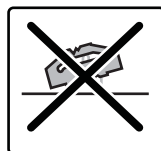
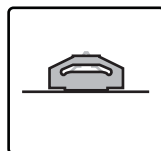
See NovAseptic GMP Mixing Head Installation Guide 00101787PU for additional information.



- Handle the mixing head with care.
  - Use extreme care when mounting the mixing head on to the male bearing; mixer bearings are brittle.
  - Do not mount the drive unit before installing the mixing head. The powerful magnetic force between the mixing head and the outer drive head may cause severe damage to bearings or personal injury.
  - Follow all local safety codes before entering the vessel.
1. Remove any foreign magnetic particles from the mixing head.  
If the mixing head must be placed on a table, place the female bearing downward to prevent magnetic particles from adhering to the magnetic surface of the mixing head.
  2. Remove the drive unit.
  3. Install the mixing head using the multi-tool. Mixing head sizes GMP 5 000–30 000 must be installed by hand.
  4. Carefully position the mixing head by turning it while lowering it onto the male bearing.



5. Align the mixing head with the tank plate. Ensure that the mixing head rotates smoothly.



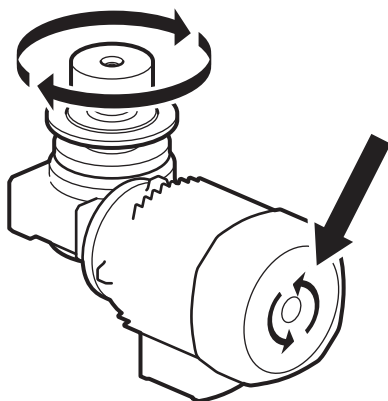
## Drive Unit Installation



- The drive unit may be heavy. Use appropriate equipment to avoid injury.
- Never use the drive unit without a frequency converter. See Control Cabinet in this guide.
- See the Electrical Installation section of this manual for electrical information.

### Check direction of rotation

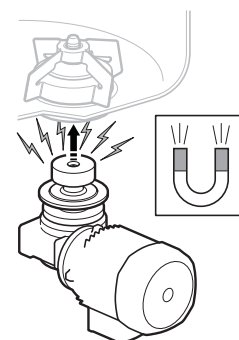
Turn on the motor. Verify that the drive head rotates clockwise and that the fan rotates counter clockwise. A sticker on the motor indicates the correct rotation direction of the fan.



### Mounting the Drive Unit



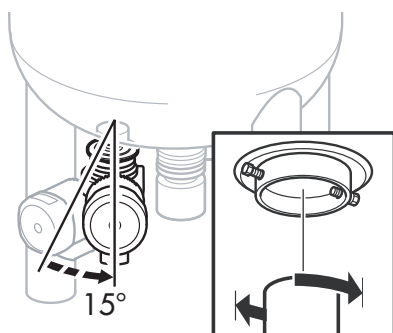
- Handle the drive unit with caution to avoid personal injury and damage to the equipment.
- Do not make any adjustments to screws and bolts.
- There is a powerful magnetic force between the mixing head and the outer drive head.



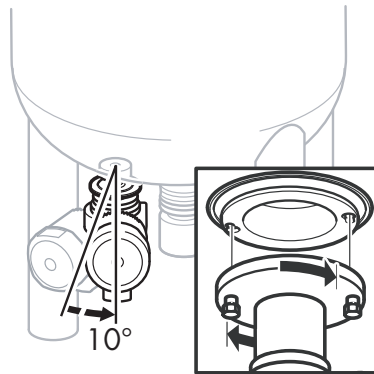
Mount the drive unit onto the vessel following the instructions for the appropriate mixer size:

#### GMP 50, GMP 100, GMP 500, and GMP 50 DC

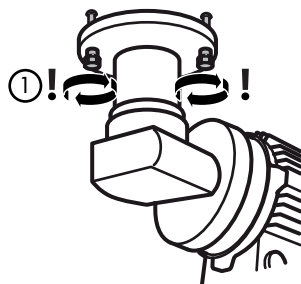
1. Install the drive unit into the tank plate. Put the two studs on the tank plate into the slots on the drive unit.
2. Turn the drive unit clockwise (view from below) to the stop position, approximately 15°.
3. Tighten the two nuts with a wrench.



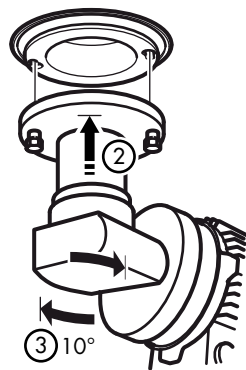
## GMP 1000 and GMP 2000



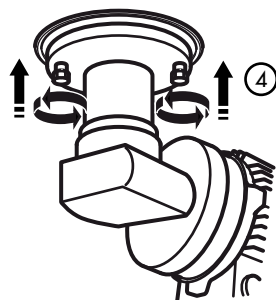
1. Tighten the screws (1) in a clockwise direction (view from below).



2. Install the drive unit into the tank plate. Insert the locking screws into the two oval holes in the tank plate (2).

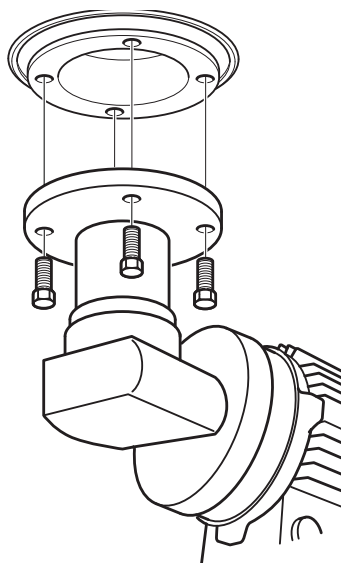


3. Turn the drive unit (3) clockwise (view from below) to the stop position, approximately 10°.
4. Tighten the two screws (4) counter clockwise (view from below) with a wrench.





## GMP 5000, GMP 10 000, GMP 20 000 and GMP 30 000



1. Install the drive unit into the tank plate. Align the four holes in the drive unit to the threaded holes in the tank plate.
2. Screw the four bolts into the tank plate and tighten them with a wrench.

### Electrical Installation



- When working on live drive controllers, prevent accidents by observing applicable national regulations.
- All electric installations, including the variable frequency drive, must be performed by an authorized electrician.
- The mixer must be operated with a variable frequency drive to function properly.
- Drive units require the following speed control device:
  - 3-phase AC motor    Frequency converter
  - 1-phase DC motor    Thyristor controller

### Before installation

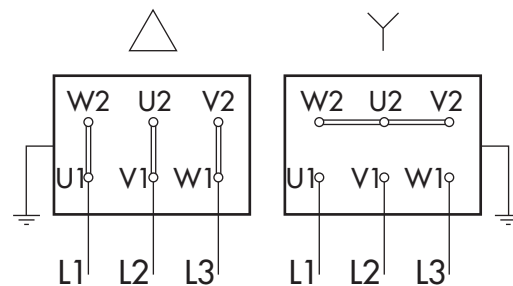


- Ensure that all incoming power is equipped with an emergency stop and an on/off switch that can be locked in both positions.
- Ensure that the motor cables are shielded (to avoid electrical disturbance).
- Ensure that the drive unit is properly grounded.
- Ensure that the electric cables are long enough so that the drive unit can be disassembled and removed from the vessel.

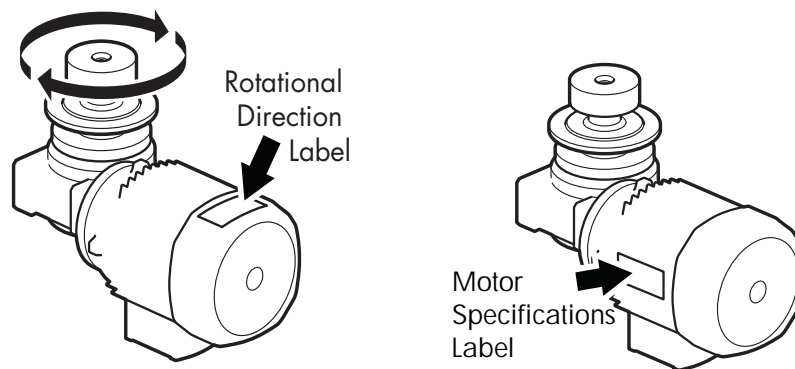
## AC Motor Installation

The AC motor in the standard NovAseptic GMP Mixer is three phase.

1. Connect the drive unit according to the control cabinet specifications. The drive unit can be Y- or  $\Delta$ -connected, depending on the supply voltage from the speed control device.



2. Ensure that the supply voltage and overload protection are set according to the motor specification data. Ensure that the electrical cover and the conduit entries are properly in place. Check that the outer drive head rotates clockwise.



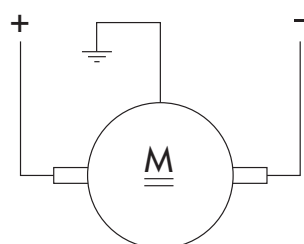
## Drive Unit Thermistor

All standard NovAseptic GMP drive units are equipped with a positive temperature coefficient (PTC) thermistor probe. Millipore recommends installation of the probe. Thermistor protection units continuously monitor the temperature of the motor through a probe embedded in the motor windings. If the nominal operating temperature of the probe is reached, a rapid increase in resistance is converted into a switching function. This can be used to switch off the motor or to signal a fault. Accidental breaks in the supply circuits of the thermistors are also detected.

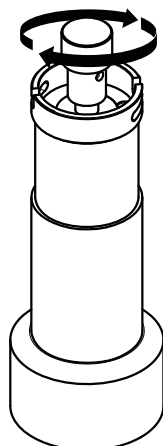
Motor current higher than recommended could cause damage to the bearings through decoupling of the mixing head.

## DC motor Installation

1. Make connections according to the following illustration. Ensure that the electrical cover and the cable gland entries are properly in place.



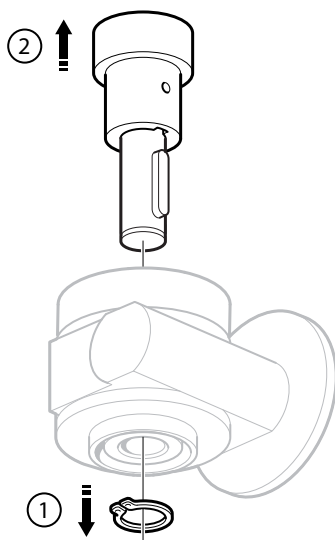
2. Turn on the motor and check that the rotor rotates clockwise. A label on the motor indicates the correct rotational direction.



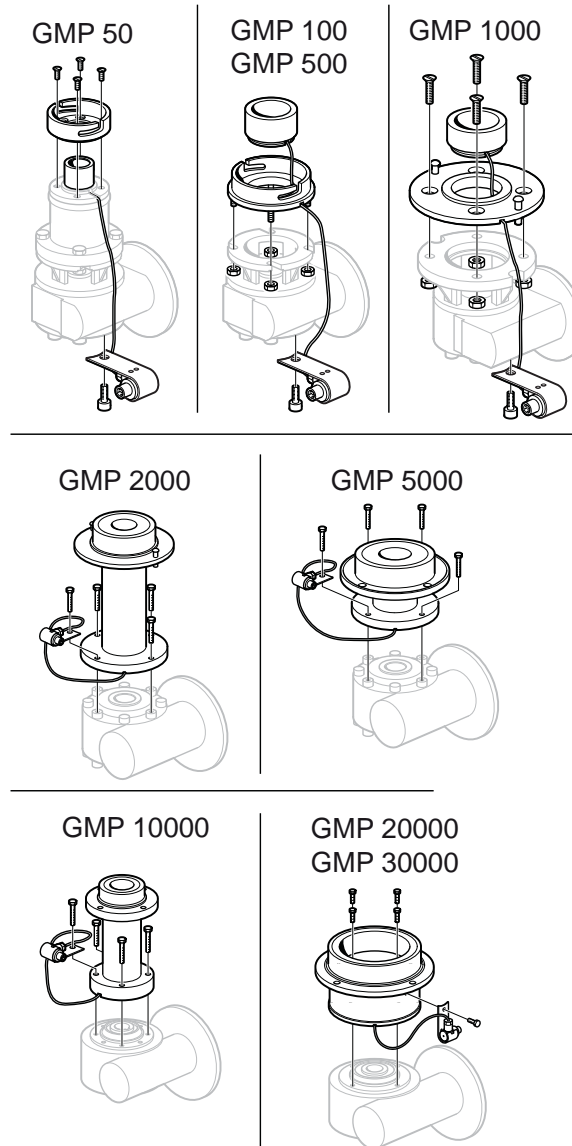
### Speed Counter Installation

The speed counter may be ordered separately. Use the instructions below to install the speed counter. Speed counter kit catalogue number GM#/67

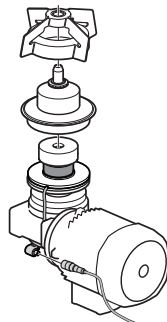
1. Remove the outer drive head from the drive unit.



- Mount the speed counter on the drive unit according to the following illustration (different procedures for different GMP sizes). Note in which order to assemble the components, and how the cable should run.



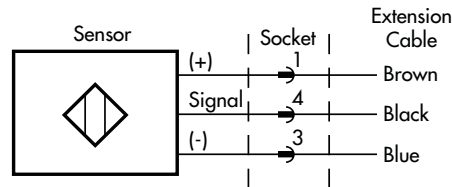
- For GMP 2000, 5000, and 10000, the cable runs inside the drive unit flange. Run the cable tight against the wall to prevent it from becoming entangled. If the cable is long and tends to buckle, place the ring inside the drive unit flange with the cable clamped between the ring and the wall.
- Use a strap to mount the contact in the contact holder. Tighten the contact holder on the drive unit according to the following illustration. Collect leftover cable with a strap.



5. For GMP 50, insert an extension plate between the shaft and the outer drive head.
6. Insert the outer drive head on top of the speed counter unit.
7. Socket type is series 713 M12x1. Connect the socket cable according to the following:

#### Socket Connection:

Socket type: Series 713 M12x1



8. Check that the number of pulses per rotation is correct:

GMP 50	3	GMP 1000	5	GMP 10000	6
GMP 100	3	GMP 2000	6	GMP 20000	12
GMP 500	4	GMP 5000	8	GMP 30000	12

### Control Cabinet Installation

The installation must be performed by an authorized electrician.

The control cabinet must be installed with correct fuse.

### Control Cabinet Installation Specifications

1. Select the appropriate control cabinet according to Product Specification Sheet SP1175EN00.  
Maximum allowed current during startup is controlled and programmed. See the data specification label for maximum allowed current and, attached to the motor.
2. Set torque. For AC motors, see product specification sheet SP1004EN00. For DC motors, see specification sheet SP1008EN00.
3. Verify that the correct EPM-prom is installed according to product specification sheet.
4. If the control cabinet is not supplied by Millipore, ensure that a variable frequency drive is installed. Millipore supplies general information and standard parameters. Perform validation for each individual process.

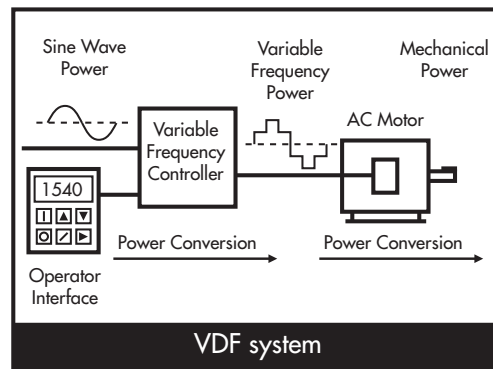


- Instantaneous start may lead to a breakdown.
- Minimum frequency feed to motor: 6 Hz
- Maximum frequency feed to motor: 50 Hz (60 Hz optional)
- Ramp up/down: minimum 5 seconds (Specific to each application; set accordingly.)
- Motor current higher than recommended could cause damage to the bearings through decoupling of the mixing head.

## Variable-Frequency Drive

A variable frequency, adjustable-speed drive (VFD) controls the rotational speed of an alternating current (AC) electric motor by controlling the frequency of the electrical power supplied to the motor. VFDs are also known as adjustable-frequency drives (AFD), variable speed drives (VSD), AC drives, and inverter drives.

When starting a motor, a VFD initially applies a low frequency and voltage to the motor. A VFD increases the applied frequency and voltage at a controlled rate and accelerates the load without drawing excessive current.



### Notes

- Consult the parameters settings and circuit and terminal diagrams before installing the control cabinet.
- Validate the current media and process conditions. If the production conditions are in any way altered after commissioning of the mixer, a new validation must be performed.
- Validate the possible maximum and minimum operating speed for each process.
- Set VFD unit to 100% nominal power (kW) and current (A) of the motor rating.

# Operation



- Ensure that the installation has been performed correctly and that the parameters are correctly programmed.
- Ensure that no one is working inside the vessel.
- Ensure that a sufficient level of liquid covers the mixing head and the male bearing to ensure sufficient lubrication of the bearing.
- Never work close to the drive unit while it is connected to its driving source.
- Keep away from moving parts.
- Regulate speed, acceleration, and deceleration carefully to avoid magnetic decoupling.
- Stop the mixer immediately if any signs of malfunction, abnormal noise, or smell occurs.
- Do not exceed operation temperature of 135 °C (275 °F) inside vessel.
- Vessel diameter to liquid height ratio should be 1:1–1:2 when vortex for the process is required.
- Use extra precaution because of pressure buildup when the mixer is running at high speed:
  - When it is running with hot WFI
  - When it is running at atmospheric pressure
  - During or after steam sterilization

## Starting the Mixer

1. Fill the vessel to a minimum level that completely covers the mixing head and the male bearing to provide sufficient lubrication of the bearing.
2. Start the mixer and increase the speed slowly to a minimum speed (50 rpm).  
(Note: the first time the mixer is started, run it for a few seconds at this speed and check that the motor fan is turning in the correct direction.)
3. Increase the speed slowly to working speed. If the mixer makes a rumbling noise, stop the mixer immediately and consult the troubleshooting section in this guide.

## Operating Notes

- The mixing head must be completely covered with liquid during operation.
- Fill the vessel and the mixer with liquid before adding solid material.
- Always ensure that the mixing head is always completely covered with liquid during all operation.
- For operation during draining, stop the mixer before the liquid level reaches below the top of the mixer. This will ensure the mixer is not run dry. If the mixer has been run dry, turn off the mixer and inspect the bearings. Consult the troubleshooting section.
- Avoid buildup of large quantities of solids on the bottom of the vessel

## Disassembly



Before dismounting the drive unit:

- Ensure that the power supply is turned off.
- Ensure that the vessel is empty and ventilated.
- Ensure that the vessel is at atmospheric pressure.
- Ensure that the vessel is cooled to below 25 °C (77 °F).
- Ensure that all connected media is shut off.
- Before entering the vessel, follow the local safety precautions.
- The drive unit may be heavy. Use appropriate equipment to avoid injury.

Dismount the mixer in the following order to prevent personal injuries and damage to the equipment:

1. Drive Unit
2. Mixing Head
3. Male Bearing

## Storage

- Do not store in areas exposed to weather or humidity.
- Always place wood or other non-magnetic material between floor and product, to avoid direct contact with the floor.
- For storage periods exceeding 60 days, protect all coupling surfaces (such as flanges and shafts on the drive unit) with a suitable anti-oxidation product (Mobilarma® 248 or equivalent).
- For storage periods exceeding 6 months, turn the rotor outer driving head on the drive unit every 1–2 months.

## Recycle and Disposal

Recycle and dispose of equipment according to local laws and regulations.



# Cleaning and Sterilizing Procedures

## Cleaning in Place (CIP)

GMP mixers are designed for CIP using any of the following processes: sprayball, rotary jethead, or submerged.

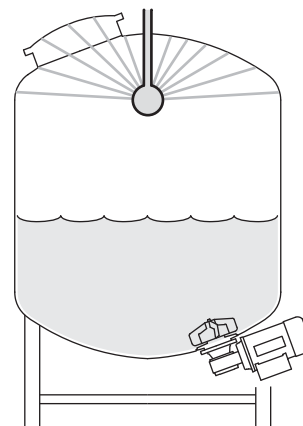
### Sprayball and Rotary Jethead Cleaning

Start the liquid circulation through the sprayball or jethead before starting the mixer to ensure lubrication of the bearing.



#### NOTE:

- Recommended maximum speed of the mixing head is 100 rpm.
- Ensure that the bearings are continuously lubricated.
- Stop the mixer before turning off the sprayball/jethead function.
- Add liquid before running the mixer after cleaning to ensure lubrication of the bearings.



### Submerged Cleaning

Introduce enough cleaning or rinsing liquid into the vessel to cover the mixing head and the male bearing.

#### NOTE:

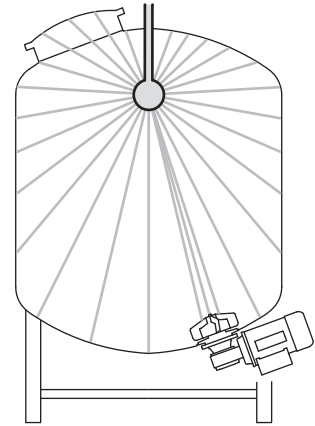
- Avoid vortex.
- Add liquid before running the mixer after cleaning to ensure lubrication of the bearings.
- Magnetic Particles
  - a. If presence of magnetic particles is suspected, remove the mixing head. Remove the particles and reinstall the mixing head. (Refer to Male Bearing Installation, Mixing Head Installation, and Drive Unit Installation in this manual.)
  - b. Magnetic particles are not removed from the mixing head during CIP; they must be removed manually or by alternative cleaning. Magnetic particles can cause corrosion and damage. They can also cause a higher torque, which may cause the mixing head to decouple and severely damage the vessel.

## Sterilizing in Place (SIP)

GMP mixers are designed for SIP.

### Sterilization by Pressurized Steam

The mixer can be intermittently operated during the initial condensate phase of the sterilization sequence up to 100 °C (212 °F). Recommended maximum speed of the mixing head is 50 rpm for no longer than 30 seconds.



### NOTES

- Make sure that condensate lubricates the bearing surfaces.
- Recommended maximum speed of the mixing head during sterilization is 50 rpm.
- Turn the mixer off when the temperature reaches 100 °C (212 °F).
- Add liquid before restarting the mixer after sterilization to secure lubrication of the bearings.
- Magnetic Particles
  - a If presence of magnetic particles is suspected, remove the mixing head. Remove the particles and reinstall the mixing head. (Refer to Male Bearing Installation, Mixing Head Installation, and Drive Head Installation in this manual.)
  - b Magnetic particles are not removed from the mixing head during CIP; they must be removed manually or by alternative cleaning. Magnetic particles can cause corrosion and damage. They can also cause a higher torque, which may cause the mixing head to decouple and severely damage the vessel.

### Other sterilization methods

For information on using other sterilization methods, please contact your Millipore representative for NovAseptic GMP Mixer product information. Commissioning

# Installation Checklist

To ensure correct installation, before using the mixer make sure to complete each step in this checklist, and check the applicable box.

Note: Follow all cautions and warnings in the installation section of this manual.

## Install the Male Bearing

		<b>Complete</b>
<b>1</b>	Ensure the proper position of the O-ring on the male bearing.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>2</b>	Lubricate the O-ring with purified water.	
<b>3</b>	Ensure that the thread connection in the tank plate is clean, dry, and free from foreign material.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>4</b>	Position the male bearing in the appropriate tightening tool or multi-tool.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>5</b>	Tighten the male bearing clockwise.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>6</b>	Tighten the bearing to metal-to-metal contact; use table to determine correct torque.	<input type="checkbox"/> yes <input type="checkbox"/> no

## Install the Mixing Head

		<b>Complete</b>
<b>1</b>	Inspect and remove any foreign magnetic particles from the mixing head.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>2</b>	Remove the drive unit. Install the mixing head.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>3</b>	Position the mixing head and align it with the tank plate.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>4</b>	Ensure that the mixing head rotates smoothly.	<input type="checkbox"/> yes <input type="checkbox"/> no

## Before Installing the Drive Unit

		<b>Complete</b>
<b>1</b>	Turn on the motor. Verify that the drive head rotates clockwise and that the fan rotates counterclockwise.	<input type="checkbox"/> yes <input type="checkbox"/> no

## Install the Drive Unit – GMP 50, GMP 100, GMP 500

		<b>Complete</b>
<b>1</b>	Install the drive unit into the tank plate; put the two studs on the tank plate into the slots on the drive unit.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>2</b>	Turn the drive unit clockwise (view from below) to the stop position.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>3</b>	Tighten the two nuts with a wrench.	<input type="checkbox"/> yes <input type="checkbox"/> no

## Install the Drive Unit – GMP 1000 and GMP 2000

		<b>Complete</b>
<b>1</b>	Fit screws and tighten clockwise (view from below).	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>2</b>	Install the drive unit into the tank plate. Install locking screws into the two oval holes in the tank plate	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>3</b>	Turn the drive unit clockwise (view from below) to the stop position.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>4</b>	Tighten the two screws clockwise (view from below).	<input type="checkbox"/> yes <input type="checkbox"/> no

## Install the Drive Unit – GMP 5000, GMP 10000, GMP 20000, GMP 30000

		<b>Complete</b>
<b>1</b>	Install the drive unit into the tank plate. Align the four holes in the drive unit to the threaded holes in the tank plate.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>2</b>	Screw the four bolts into the tank plate and tighten.	<input type="checkbox"/> yes <input type="checkbox"/> no

## Before Installing the Electrical Components

		<b>Complete</b>
<b>1</b>	Ensure all incoming power is equipped with an emergency stop and an on/off switch.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>2</b>	Shield motor cables.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>3</b>	Ensure the drive unit is grounded.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>4</b>	Ensure electrical cables are long enough to enable the drive unit to be disassembled and removed from the vessel.	<input type="checkbox"/> yes <input type="checkbox"/> no

## Install the AC Motor

		<b>Complete</b>
<b>1</b>	Connect the drive unit.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>2</b>	Ensure that the supply voltage and overload protection are set. Ensure that the electrical cover and conduit entries are in place. Ensure that the outer drive head rotates clockwise (view from above).	<input type="checkbox"/> yes <input type="checkbox"/> no

## Install the DC Motor

		<b>Complete</b>
<b>1</b>	Make electrical connections. Make sure the electrical cover and the cable gland entries are properly in place.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>2</b>	Ensure that the motor rotates clockwise (view from above)	<input type="checkbox"/> yes <input type="checkbox"/> no

## Install the Speed Counter (Optional)

		<b>Complete</b>
<b>1</b>	Remove the outer drive head from the drive unit.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>2</b>	Mount the speed counter on the drive unit according to the illustrations in this manual for each GMP size.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>3</b>	For GMP 2000, 5000, and 10000, ensure the cable is installed correctly.	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n/a
<b>4</b>	Mount the contact in the contact holder; tighten the contact holder on the drive unit. Collect leftover cable.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>5</b>	For GMP 50, insert an extension plate between the shaft and the outer drive head.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>6</b>	Insert the outer drive head on top of the speed counter unit.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>7</b>	Connect the socket cable.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>8</b>	Check that the number of pulses per rotation is correct.	<input type="checkbox"/> yes <input type="checkbox"/> no

## Install the Control Cabinet

		<b>Complete</b>
<b>1</b>	Select the appropriate control cabinet.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>2</b>	Set torque according to AC motor and DC motor.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>3</b>	Verify that the correct EPM-prom is installed.	<input type="checkbox"/> yes <input type="checkbox"/> no
<b>4</b>	If the control cabinet is not supplied by Millipore, install a frequency converter.	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> n/a

# Commissioning

## Valid Regulations

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

Complete this checklist to ensure regulations are met.

Commissioning Checkpoint	Date	Signature
Tank plates are cylindrical inside the vessel. Use NovAseptic Gauge 1.		
Mixing Head freewheel. Use NovAseptic Gauge 2.		
Male Bearing tightened, Male Bearing installed metal-to-metal.		
Outer Drive Head turns clockwise.		
Before each startup:		
The bearings are intact.		
The mixing head is properly positioned.		
The mixing head is not running dry.		
The mixing head is always covered by liquid during operation.		
The process medium shall be Newtonic liquids with viscosity from 1 to 800 cp.		
Free from magnetic particles.		

# Installation Qualification Checklist

Use this installation qualification for each vessel and mixer to ensure that the correct mixer has been installed and all important information has been gathered for future use.

## Installation Qualification

Different applications require different operating parameters on the frequency converter depending on:

- Density of liquid
- Viscosity of liquid
- Temperature of liquid
- Geometry of vessel
- Type of mixing required

### General Information

Vessel number	
Vessel type	
GMP type	
Vessel Manufacturer	
Country	
Site Location	
Millipore Representative	

### GMP Mixer Information

	Serial Number	Catalogue Number	Notes
Drive unit			
Tank plate			
Welded flange (if applicable)			
Mixing head			
Male bearing			

## Check Points

### Frequency Converter Settings

	Original Value	New Value	Comments
<b>Standard Control Unit</b>			
CE2 Configuration E2			
C10 Min Frequency (Hz)			
C11 Max Frequency (Hz)			
C12 Acceleration Time (sec)			
C13 Deacceleration Time (sec)			
C14 Operation Type			
C16 Umin			
C22 I <sub>max</sub> (%)			
c20 I <sub>2T</sub> -limit			
c42 Start after low-high level			
<b>Control Units G50-005 and G51-003</b>			
P10 Configuration TB-13A			
P23 Min Frequency (Hz)			
P24 Max Frequency (Hz)			
P19 Acceleration Time (sec)			
P20 Deacceleration Time (sec)			
P03 Operation Type			
P27 Umin			
P25 I <sub>max</sub> (%)			
P26 I <sub>2T</sub> -limit			

Additional comments



# Maintenance Checklist

To ensure safety and proper performance, perform quarterly inspection of the GMP Mixer according to the following table. Make copies of this table to use at each inspection. Refer to applicable instructions within this guide.

Note: Follow all installation recommendations, cautions and warnings in this manual.

Vessel ID \_\_\_\_\_

Inspection date \_\_\_\_\_

Volume \_\_\_\_\_

Manufacturer \_\_\_\_\_

Date of manufacture \_\_\_\_\_

Design pressure \_\_\_\_\_

Design temperature \_\_\_\_\_

Product description \_\_\_\_\_

Viscosity \_\_\_\_\_

Component / Maintenance Check	Notes	Complete
1	Drive Unit	
	Check cables for damage	<input type="checkbox"/> yes <input type="checkbox"/> no
	Check the gearbox for leakage	<input type="checkbox"/> yes <input type="checkbox"/> no
	Check the gearbox for noise	<input type="checkbox"/> yes <input type="checkbox"/> no
	Check for any contact mark on Tank Plate	<input type="checkbox"/> yes <input type="checkbox"/> no
	Check shaft and outer drive head rotation and wobbling movement	<input type="checkbox"/> yes <input type="checkbox"/> no
	Check outer drive head for damage caused by contact with Tank Plate	<input type="checkbox"/> yes <input type="checkbox"/> no
	Ensure bolt, screws, nuts and flange are in good condition and free of damage	<input type="checkbox"/> yes <input type="checkbox"/> no
2	Mixing Head	
	Inspect the silicone carbide on the female bearing for damage.	<input type="checkbox"/> yes <input type="checkbox"/> no
	Inspect the inside of the mixing head and bottom surface for damage. Check that mixing head rotates easily. Listen for noise.	<input type="checkbox"/> yes <input type="checkbox"/> no
	Inspect bottom surface of wings for marks and scratches.	<input type="checkbox"/> yes <input type="checkbox"/> no
	Inspect the magnetic body for particles.	<input type="checkbox"/> yes <input type="checkbox"/> no
3	Male Bearing	
	Remove and inspect ceramic bearing for cracks and abnormal wear.	<input type="checkbox"/> yes <input type="checkbox"/> no
	Inspect the stainless steel foot.	<input type="checkbox"/> yes <input type="checkbox"/> no
	Make sure the O-ring is not damaged.	<input type="checkbox"/> yes <input type="checkbox"/> no
	Check for loose ceramic parts.	<input type="checkbox"/> yes <input type="checkbox"/> no
	Check for thread deformation.	<input type="checkbox"/> yes <input type="checkbox"/> no
	Install and ensure male bearing is tightened to proper torque (metal-to-metal).	<input type="checkbox"/> yes <input type="checkbox"/> no
4	Tank Plate	
	Inspect tank plate for scratches, marks, and/or damage.	<input type="checkbox"/> yes <input type="checkbox"/> no

Inspected by:

Print name \_\_\_\_\_

Signature \_\_\_\_\_

Date inspection completed \_\_\_\_\_

# Spare Parts

The number of spare parts to keep on hand depends on the number of mixers in production and their application. For further information, please contact Millipore.

Millipore recommends the following equipment be kept in stock:

- Mixing head (GM#/12#)
- Male bearings (GM#/2#)
- Male bearing o-ring

See page 9 for required tools and accessories.

# Troubleshooting

During troubleshooting, follow the instructions in this manual. A correct installation is crucial to proper operation.

Before repair or service of the GMP Mixer, personnel must study and understand the user guide.

Before performing maintenance on the GMP Mixer, make sure that the vessel is:

- cooled down to below 25 °C (77 °F)
- emptied of liquid and hazardous gas
- free from traces of harmful products

It is the customer's responsibility to check the safety of the GMP Mixer used in a new application according to:

- External load
- Reaction forces and torque
- Corrosion, erosion, and fatigue
- Decomposing of unstable liquids

<b>Problem</b>	<b>Possible Causes</b>	<b>Solutions</b>
Motor/mixing head does not rotate	No power	Inspect power supply
	Overload protection tripped	Check the setting amp value and the ambient temperature
	Heavy load of particles stuck to the magnets	Clean the unit
High amp value	Ambient temperature too high	Chill the environment
	Motor mechanically overloaded	Check all transmissions
Mixing head scratches against tank plate	Male bearing worn out	Replace male bearing
	Female bearing holder is damaged	Repair mixing head
	Loose male bearing	Remove male bearing. Inspect male bearing and tank plate for damage. If it is undamaged, reinstall the bearing and check rotation direction of the mixing head.
	Particles stuck to the magnets	Remove particles.
	Deformation after welding	Review instructions for welding the tank plate and verify tolerances using appropriate gauges.

<b>Problem</b>	<b>Possible Causes</b>	<b>Solutions</b>
Outer drive head scratches the tank plate	Bent shaft	Contact Millipore service
	Bent hole-shaft in gearbox	Contact Millipore service
	Drive unit not properly in place	Install drive unit correctly
	Particles stuck to the magnets	Remove particles.
	Deformation of tank plate during welding	Review instructions for welding the tank plate and verify tolerances using appropriate gauges.
	Loose outer drive head	Position the outer drive head onto its lower end position against the shaft and tighten.
Magnetic disconnection of mixing head (decoupling)	Incorrect order of addition of substances, dry running	Review the guidelines under “Operation/Starting the Mixer.”
	Unexpected viscosity/density changes	Call your Millipore representative for consultation.
	Incorrect rotational direction of mixing head	Remove male bearing. Inspect male bearing and tank plate for damage. If it is undamaged, reinstall the bearing and check rotation direction of the mixing head.
	Short acceleration/retardation time	Increase the ramp time.
	Particles stuck to the magnets	Remove particles.
Mixing head running eccentrically	Male bearing is not properly in place	Remove male bearing. Inspect male bearing and tank plate for damage. If it is undamaged, reinstall the bearing and check rotation direction of the mixing head.
	Bearings worn out	Replace the male bearing and/or repair mixing head
Abnormal or “rumbling” noise	Deep vortex	Reduce speed. Ensure mixing head is fully covered with liquid at all times.
	Cavitation	Investigate: pressure, temperature, speed
	Dry running	Review the guidelines under “Operation /Starting the Mixer”
Loss of running speed	Incorrect incoming power	Check the power supply.
	Missing phase(s) (AC)	Check the fuses.

<b>Problem</b>	<b>Possible Causes</b>	<b>Solutions</b>
Speed counter: incorrect number of signals	Speed counter unit is incor- rectly mounted on the drive unit flange	Ensure that the speed sensor unit is completely aligned and completely in contact with the drive unit flange without any gap in between (Refer to speed counter user guide 00101788PU)
Speed counter: no signal	Corroded socket pins	Replace speed counter
	Cable worn	Replace speed counter

## Standard Warranty

Millipore Corporation (“Millipore”) warrants its products will meet their applicable published specifications when used in accordance with their applicable instructions for a period of one year from shipment of the products. MILLIPORE MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. The warranty provided herein and the data, specifications and descriptions of Millipore products appearing in Millipore’s published catalogues and product literature may not be altered except by express written agreement signed by an officer of Millipore. Representations, oral or written, which are inconsistent with this warranty or such publications are not authorized and if given, should not be relied upon. In the event of a breach of the foregoing warranty, Millipore’s sole obligation shall be to repair or replace, at its option, the applicable product or part thereof, provided the customer notifies Millipore promptly of any such breach. If after exercising reasonable efforts, Millipore is unable to repair or replace the product or part, then Millipore shall refund to the customer all monies paid for such applicable product or part. MILLIPORE SHALL NOT BE LIABLE FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL OR ANY OTHER INDIRECT DAMAGES RESULTING FROM ECONOMIC LOSS OR PROPERTY DAMAGE SUSTAINED BY ANY CUSTOMER FROM THE USE OF ITS PRODUCTS.



## To Place an Order or Receive Technical Assistance

For additional information call your nearest Millipore office. In the U.S. and Canada, call toll-free 1-800-MILLIPORE (1-800-645-5476) In the U.S., Canada and Puerto Rico, fax orders to 1-800-MILLIFX (1-800-645-5439). On the Internet [www.millipore.com](http://www.millipore.com).