ProMixer™ 3DH Manual

3-Axis Hand Mixer

XM-3DHMS

Version 1.2

Table of Contents

Overview

Overview:

- The ProMixer™ 3DH mixer is a fast, low-cost manual tumble mixer that homogenizes powders of different particle size, shape, and density; liquids of different viscosities; solutions and suspensions.
- Helps ensure uniform mixing from batch to batch and operator to operator.
- Typical mixing time is 2-3 minutes.
- ProMixer™ 3DH is part of our ProMixer™ line of quality mixers. See ProFiller® Products on page 15 for more information on other products.

Features:

- Mixing based on 3-Dimensional inversion kinematics, also known as the Paul Schatz principle.
- 1.5 L and 2.0 L PET mixing jars included.
- Jars from 80-118 mm in diameter and up to 210 mm in height may be used. See page 7 for more information.
- Optional Brush insert enables mixing in small vials, jars, flasks, test tubes.
- Ergonomic handle to hold during mixing and an extra-wide Stainless Steel (Inox) base for stability.
- Can be bolted to a horizontal surface, or clamped to a table.
- Anodized Aluminum and Stainless Steel construction.
- Fully compatible with Inversina[a] jars and containers that fit in the Inversina[a] Manual 2L Mixer.

Mixer Specifications:

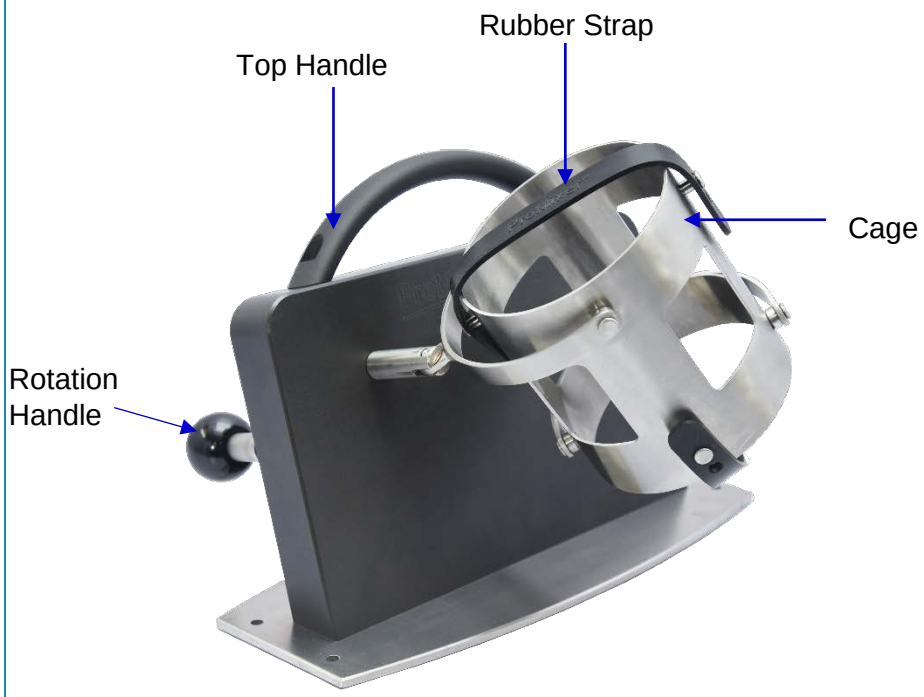
- Dimensions (L x W x H)

Base Plate	35 x 15 cm	14 x 6 in.
Overall	35 x 29 x 29 cm	14 x 12 x 12 in.
Approximate area for operation	45 x 40 x 50 cm	18 x 16 x 20 in.

- Recommended table height for standing operation: 70-90 cm / 27 -36 in.
- Weight without jar: 9 kg / 20 lb.
- Holds containers up to118 mm in diameter and 210 mm height.

[a] Inversina is manufactured by Bio-Components, Switzerland.

Parts Identification

Mixer	Mixing Jars (1.5 L & 2.0 L)
	

Mounting Mixer

Hold Handle

Stabilize the Mixer by holding the Top Handle with one hand while turning the Rotation Handle with the other hand.

Right and left hand position can be switched based on operator preference.

Bolt

Part Required: Optional XM-3DHBN M6 x 50 mm bolts with nyloc nuts (4). See Optional Accessories on page 14 to order. Drill required for installation.

Clamp

Part Required: Optional XM-3DHCC Clamps. See Optional Accessories on page 14 to order.

Jar Filling Volume and Dimensions

Filling Volumes of Jars Included with Shipment									
Jar Volume		Powder Volume[a]		Liquid Volume[b]		External Diameter		External Height	
1.5 L	51 fl oz	1.0 L	34 fl oz	1.35 L	46 fl oz	111 mm	4.4 in	188 mm	7.4 in
2.0 L	68 fl oz	1.5 L	51 fl oz	1.8 L	61 fl oz	117 mm	4.6 in	208 mm	8.2 in

[a] Usable volume up to 70% of jar volume.
[b] Usable volume up to 90% of jar volume.

Jar Dimensions for use with 3DH Mixer			
Outer Diameter (mm)	Height should be within range (mm)	Outer Diameter (in)	Height should be within range (in)
80	210	3.2	8.3
85	203 - 210	3.4	8.0 - 8.3
90	197 - 210	3.6	7.8 - 8.3
95	190 - 210	3.8	7.5 - 8.3
100	183 - 200	4.0	7.3 - 7.9
105	177 - 200	4.2	7.0 - 7.9
110	170 - 200	4.4	6.7 - 7.9
115	163 - 200	4.6	6.5 - 7.9
118	159 - 200	4.7	6.3 - 7.9

Unguator® Jars

Unguator® Jars can be mixed using the optional Flexible Brush inside its Jar (XM-3DHBJ). See Optional Accessories on page 14 to order.
Unguator® Jars in the following sizes fit:

- 20 g / 33 ml
- 30 g / 42 ml
- 50 g / 70 ml
- 100 g / 140 ml
- 200 g / 280 ml

Mixing Tips

Use this information as a guideline for mixing.

Factors that Affect Uniformity of Mixing

Mixing Technique

Jar Fill Level

The recommended jar fill level is from 10% - 70% based on air volume. Higher fill levels require exponentially longer mixing times. See page 7 to select the recommended jar size for the volume of powder.

Loading the Jar

- Make sure all powders are free of lumps. If required, pass powders through a 40 - 80 mesh screen.
- If **no** one or two ingredients make up more than 35% of the powder formula, add in all powders at the same time.
- If the largest one or two ingredients (referred to as major ingredients) make up 35% or more of the total weight of the formula, follow these loading instructions:
  - If total powder volume is less than 50% of jar volume: add in half the major ingredients, then add the other powder(s), then add the remaining major ingredients.
  - If total powder volume is more than 50% of jar volume: add in one quarter of the major ingredients, then add the other powder(s), then add another quarter of the major ingredients. Pre-mix for 1 minute. Add in remaining major ingredients.
- Blending volumes greater than 70% of jar fill capacity will exponentially increase mixing time.

Rotation Speed or RPM

A rotation speed of about 45 - 60 rpm (1 revolution per second or slower) is adequate for most powders. Higher speeds have not been shown to affect mixing rates for free-flowing materials in small blenders. If agglomeration (powder lumping) occurs, increase rotation speed, which will increase shear forces on the powder mixture and break up lumps.

Powder Properties

Particle Size - Powders of equal particle size will give the best results. When mixing powders of different particle sizes, smaller particles fall into the empty spaces between particles and sink to the bottom, pushing larger particles to the surface. For this type of powder, longer mixing times could potentially cause the powder to de-mix.

Particle Shape - Round particles mix more easily due to uniformity of shape. Other particle shapes do not move around each other as easily, resulting in longer mixing times.

Particle Density - Higher density particles move to the bottom of the powder.

Stickiness or powder repulsion - Powders that stick to or repel each other should first be mixed with an excipient such as Colloidal Silicon Dioxide (e.g. Aerosil 200) at 1-2% before mixing with other powders.

Environmental Conditions

Powders that retain static electricity can be difficult to blend. Increasing humidity in the room increases electrical conductivity in the air and decreases the effects of static electricity. Use a room humidifier to bring the humidity to 40-60%.

Mixer Size and Scaling Up or Down

If the % of air volume that the powder occupies is changed, the mixing time has to be increased or decreased. There is no direct proportionality between % of air volume and mixing time. We have observed that the mixing time increases exponentially as the % of air volume goes above 70%.

- The mixing time for a specific container size is not directly applicable for a different container size or shape even if the % of air volume the powder occupies is kept the same.
- A powder blend mixed successfully in a small container can be mixed in a larger container if the % of air volume is kept the same and the mixing time is increased. If the container size and powder volume increase 5-10X or more, it is difficult to determine mixing times to achieve a uniform blend.
- A powder blend mixed successfully in a large container can be mixed in a smaller container. If the % of air volume is kept the same, the mixing time can be reduced.
- Many studies have been done to establish mathematical correlations between container size and mixing time, but no universal correlation has been established. The guidelines found are specific to the powder blend.

Operating Instructions

Operating Tips

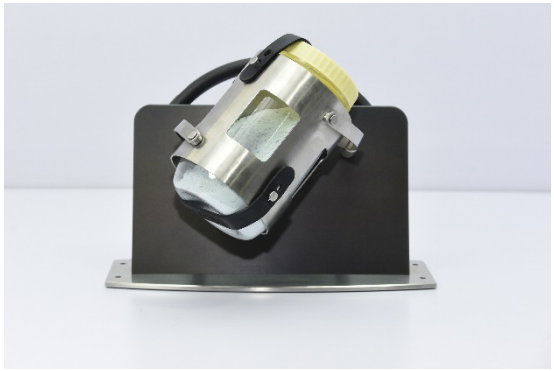
- Mix at same speed as you hand-mix a cake batter (approximately 45-60 rpm or less than 1 rotation/sec). If no one or two ingredients make up more than 35% of the powder formula, add in all powders at the same time.
- High speed mixing not required or recommended for mixing powders.
- For powder mixing, allow 2-3 minutes for mixing time. Mix at less than 1 rotation per second to avoid reducing particle size. Rotate about 90-120 times.
- For soluble powder and liquids mixing, mix at a higher rpm.
- If lumps are present in the powder, order the optional Stainless Steel (Inox) Balls to break them up (XM-SB20). See Optional Accessories on page 14 to order.
- For more details about powder mixing, see Mixing Tips on pages 8-9.

Operating Instructions

1. Add product to jar and cover tightly. See Mixing Tips on page 8 for general powder mixing tips.

2. With bottom strap in place, insert jar into Cage and secure in place with top strap.

3. Hold Top Handle and turn Rotation Handle 90-120 revolutions, or about 2-3 minutes for most powders. See above for Operating / Mixing Tips.



4. Open top strap to remove jar.

Mix using smaller vials, Unguator® jars or containers of other shapes

- Requires optional Flexible Brush and Jar accessory (XM-3DHBJ). See Optional Accessories on page 14 to order.
- Flexible Brush can be inserted directly into Cage to accommodate containers of 60-75 mm diameter that may not fit into Flexible Brush placed inside the Jar.
- A gap of up to 5 cm between the ends of the Flexible Brush is normal and does not affect its performance.

1. Insert Flexible Brush into straight mouth jar. The flexible plastic need not form a closed circle.

2. Add product to mixing container(s) and close.

3. Insert mixing container(s) into brush. If container does not fit inside Jar, remove Flexible Brush from Jar and insert Brush directly into the Cage. Place container inside Flexible Brush.

4. Close jar. With bottom strap in place, insert jar into Cage.

5. Secure jar in place with top strap.

6. Hold Top Handle and turn Rotation Handle 90-120 revolutions, or about 2-3 minutes for most powders. See Operating Tips on previous page. Open top strap to remove jar.

Cleaning and Lubrication

Cleaning

Mixing Jars and Straps

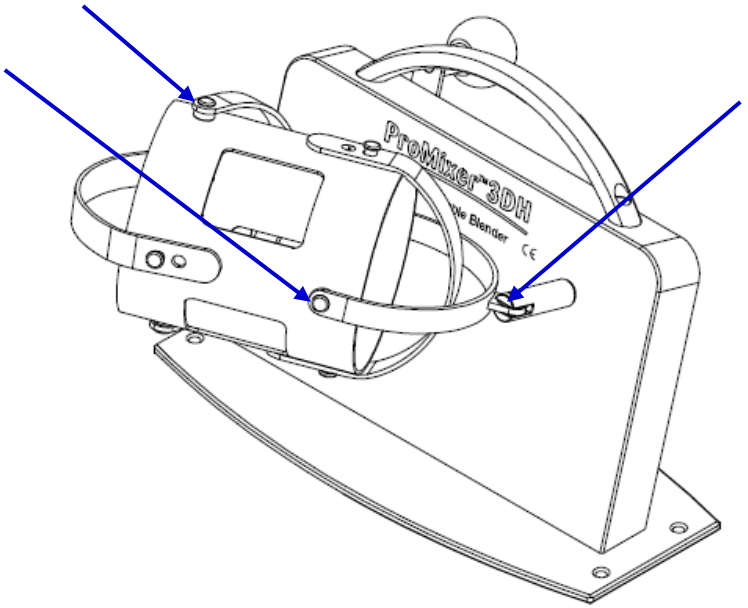
- Wash with warm, soapy water. Rinse. Dry thoroughly.
- DO NOT place in dishwasher.

Mixer Base

- Wipe with a damp cloth.
- Optionally, blow compressed air to remove dust.
- DO NOT place in dishwasher. The Anodized Aluminum portion of the Mixer will discolor.

Lubrication

Lubricate areas indicated below if you hear a noise while turning Rotation Handle. Use any food-grade lubricant oil.



Frequently Asked Questions / Troubleshooting

Frequently Asked Questions

1. What is typical mixing time?

Mixing powders takes about 90-120 rotations of the handle, typically taking 2-3 minutes.

2. How much powder can I mix in ProMixer 3DH?

Recommended jar fill level is from 10% - 70%. The 1.5 L and 2 L jars shipped with your ProMixer 3DH can mix from 0.15 – 1.05 L, and 0.2 – 1.4 L, respectively. For other jar sizes compatible with the ProMixer 3DH, see page 7. For tips on mixing technique and jar fill volumes, see Mixing Tips on pages 8-9.

3. Can I mix small vials, jars, flasks, or test-tubes?

Yes. Order the optional Flexible Brush with Jar and Lid to mix these items. See page 14.

4. Can I mix liquids?

Yes. Liquids of different viscosities, solutions, and suspensions can be mixed using the ProMixer 3DH.

5. Can I mix powder and liquid?

Yes. For mixing soluble powders and liquids a higher rpm is recommended.

6. Is there a larger mixer available?

Yes. ProMixer 750 accommodates up to a 750 ml shell. ProMixer 10L accommodates up to a 10 liter shell.

7. Is ProMixer 3DH compatible with Inversina® Jars?

Yes. Inversina® jars for the Inversina® Manual 2L Mixer and any containers that fit in it are compatible with ProMixer 3DH.

8. What are the Materials of Construction?

Product contact parts (Jar and Lid) are of food-grade PET and Polypropylene. Metal parts are Anodized Aluminum or Stainless Steel.

Troubleshooting

Issue	Remedy
1. ProMixer is making noise	Lubricate. See page 12.
2. Jar too loose in Cage	Tighten Straps. Use optional Flexible Brush. See Optional Accessories on page 14 to order.
3. Jar too small for Cage	Use optional Flexible Brush. See Optional Accessories on page 14 to order.

Optional Accessories

Optional Accessories

Item Description			Item Code
Flexible Brush, Jar & Straps Flexible Brush with jar, lid, and straps to accommodate the jar size. Flexible Brush fits inside the jar and allows for safe mixing of small vials, jars, flasks, tubes, etc. Included 1.0 liter jar is food grade and can be used alone for mixing product. For Unguator® jars, use flexible brush directly in mixer cage.			XM-3DHBJ
Stainless Steel Inox Balls Three 20 mm diameter balls to break up lumps in fine or hygroscopic powders. May not break up all lumps and may require up to 500 revolutions.			XM-SB20
Table Bolts & Nuts Use to permanently mount 3DH Mixer to a table. Size M6 x 50mm hex head bolt and nyloc nuts (4) made of SS304. For tables up to 32mm (1.3 in.) thickness. For thicker tables, a longer bolt is required.			XM-3DHBN
C-Clamps (2) Use to mount 3DH Mixer to a table. Mixer can be removed in minutes for portability. Made from Stainless Steel (Inox).			XM-3DHCC

Spare Parts

Item Description			Item Code
Jars		1.5 Liter	XM-3D1500
		2.0 Liter	XM-3D2000
Cage Rubber Straps Rubber straps holding 1.5 or 2 liter jar in cage. 250mm L x 20mm W x 3mm thick.			XM-3DHRS

ProFiller Products

ProMixer™

Mixers from 130ml to 10L. Traditional motor driven mixers in two sizes and a selection of drum and V-shells. A 3-Axis 2L manual shaker-mixer that uses rotation, translation and inversion.

3DH 3-Axis Mixer

750ml

10L

V-Shells 220ml-5L

Drum Shell 130ml-10L

ProFiller®

Capsule Filling Machines with output of 2000-14000 capsules/hour in sizes 000-5, 00el-2el and AAA -D

1100 or 1120
Handheld 100 or 120-hole

3600
Handheld 300-hole

Bench-top Filler
with choice of Orienter
300 Holes

\+

3700
Hand-Held Orienter

or

3800
European Style
Orienter

or

X900
Automatic Orienter

ProMolds™

Anodized Aluminum Molds

TTM
Tablet & Triturate

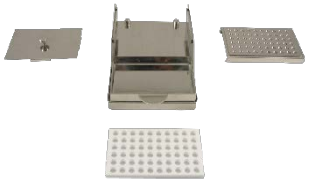
TLM
Troche & Lozenge

RDTM
Rapid Dissolve Tablet

RSM
Rocket Shaped Rectal Suppository

Other Equipment

ProTRM™
Three Roll Ointment Mill



ProCoater™
For enteric film & coating of
capsules & caplets

ProFunnel™
Funnel for precision capsule
filling on a balance

ProCounters™
Divide 300 capsules into batches
of 30, 60 or 100

Materials Used

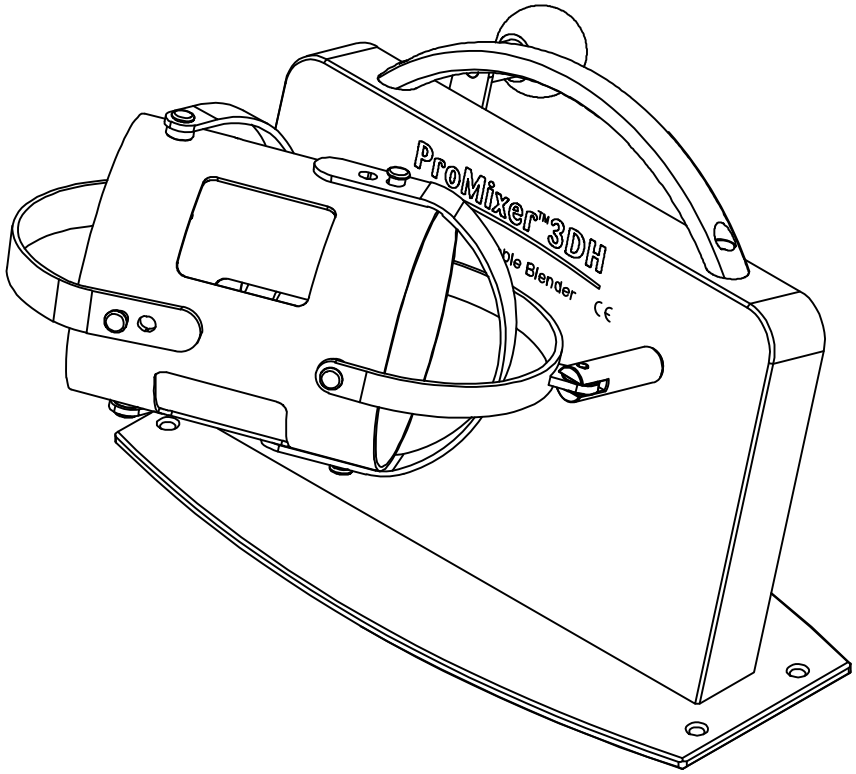
The Materials tables below cross-reference to the Customer Drawing to show the Material of Construction for product contact parts. Food Grade Status refers to 21CFR177 or EU10/2011 compliance.

Product Contact Materials

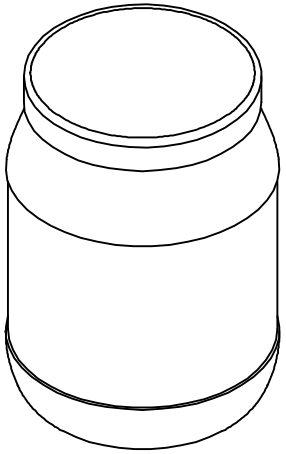
Material Code	Description	Product Contact	Food Grade Status
I	PET	✓	Food Grade
K1	Polypropylene (food grade)	✓	Food Grade

No materials of animal origin were used during the manufacture of this machine.
This product is considered TSE (Transmissible Spongiform Encephalopathy) free.

ProMixer 3DH	OVERVIEW	DWG. NO.1



BASE ASSY.
REFER DWG.NO. 2 & 3



JAR 1500ml. & 2000ml.
REFER DWG.NO. 4

ACCESSORIES

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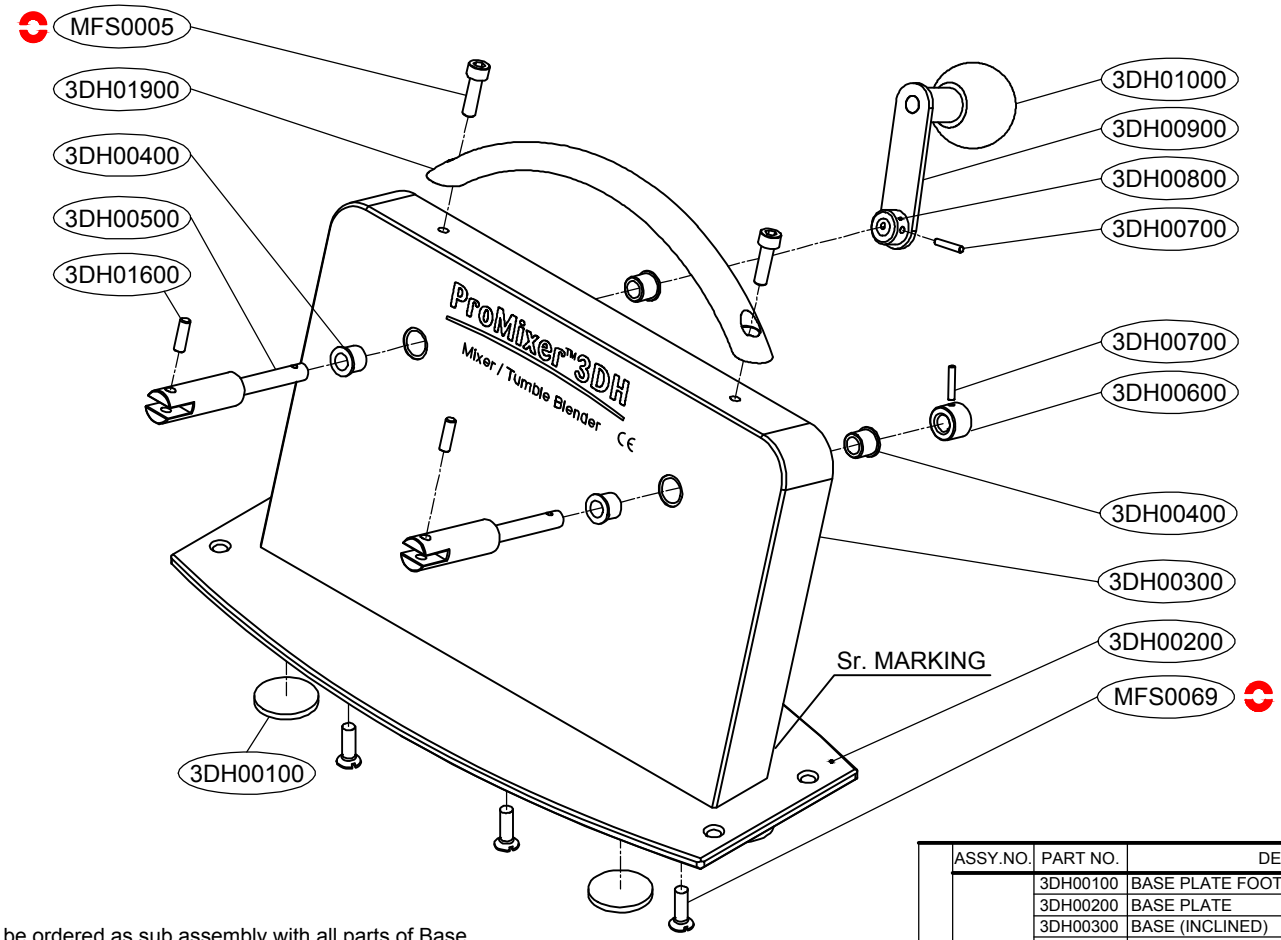
ProMixer 3DH	BASE ASSY.	DWG. NO.2



Base should be ordered as sub assembly with all parts of Base assembly as shown in this drawing.

* Material of construction (MOC) is given for product contact parts only.

Permanent loctite 270 threadlocker applied.

Removable loctite 222 threadlocker applied.

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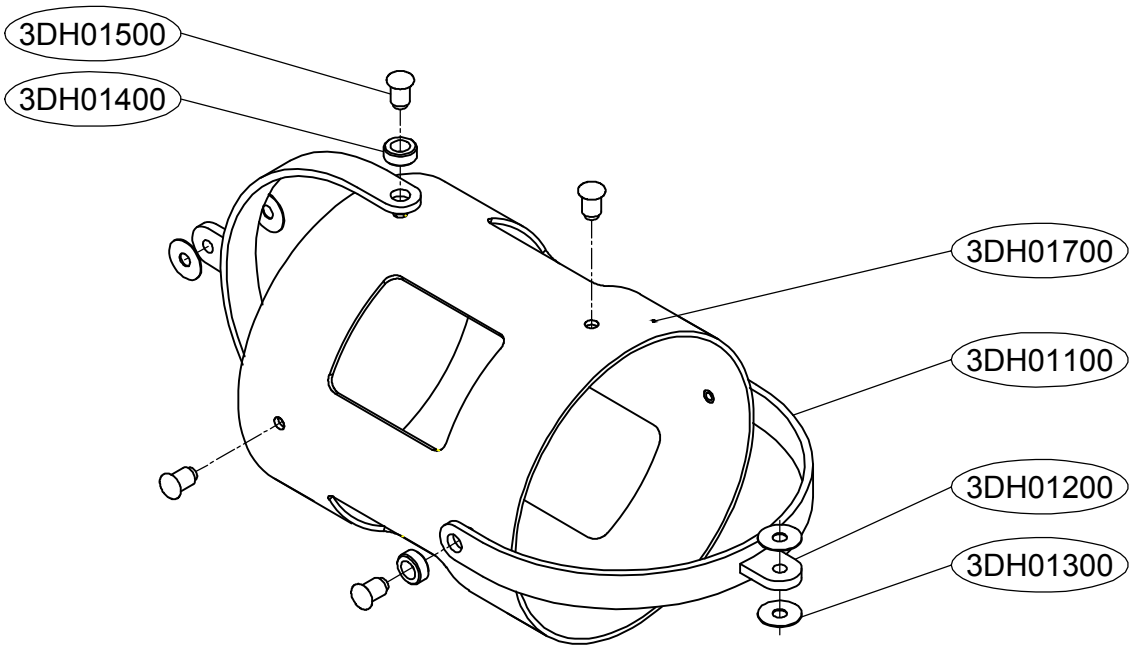
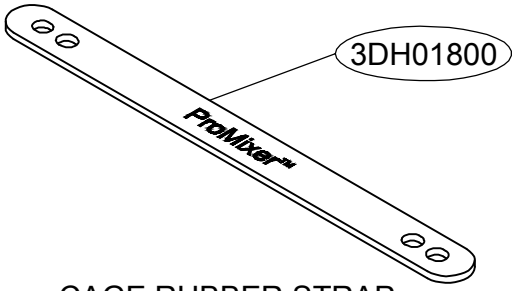
BASE ASSY. 1/2

ASSY.NO.	PART NO.	DESCRIPTION	QTY.	MATERIAL
BASE ASSY. A3DH00100	3DH00100	BASE PLATE FOOT	4	*
	3DH00200	BASE PLATE	1	*
	3DH00300	BASE (INCLINED)	1	*
	3DH00400	BASE BUSH	4	*
	3DH00500	LINK SHAFT	2	*
	3DH00600	LINK SHAFT COLLAR	1	*
	3DH00700	DOWEL PIN (L. SHAFT COLL. & HAN. BUSH)	2	*
	3DH00800	HANDLE BUSH	1	*
	3DH00900	HANDLE STRIP	1	*
	3DH01000	REVOLVING HANDLE	1	*
	3DH01600	DOWEL PIN (LINK)	2	*
	3DH01900	TOP HANDLE	1	*
	MFS0069	CSK. SCREW (BASE PLATE)	3	*
	MFS0005	ALLEN HD. SCREW (TOP HANDLE)	2	*

ProMixer 3DH	CAGE ASSY. (PART OF BASE ASSY.)	DWG. NO.3





CAGE RUBBER STRAP

Cage should be ordered as sub assembly with all parts of Cage assembly as shown in this drawing.

* Material of construction (MOC) is given for product contact parts only.

Permanent loctite 270 threadlocker applied.

Removable loctite 222 threadlocker applied.

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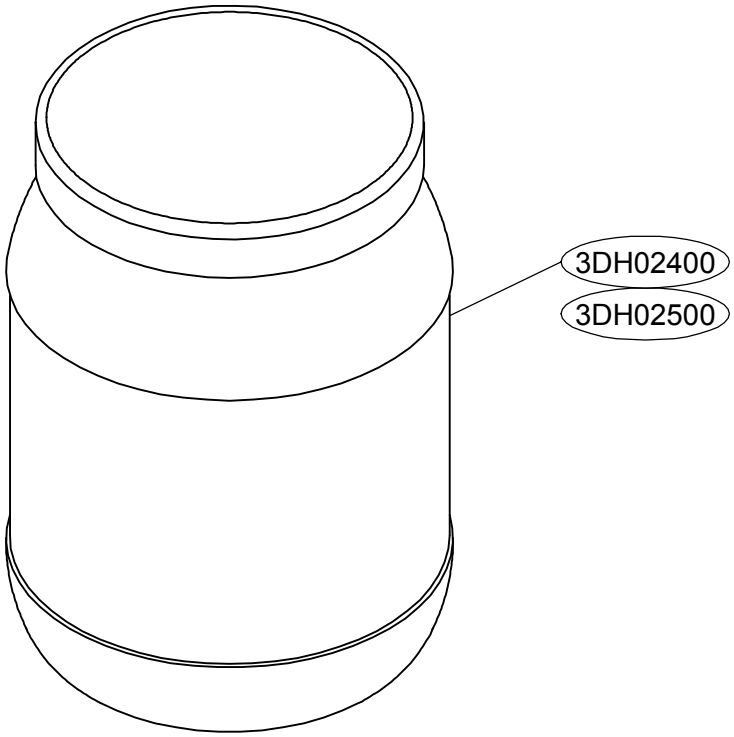
BASE ASSY. 2/2

ASSY.NO.	PART NO.	DESCRIPTION	QTY.	MATERIAL
CAGE ASSY. A3DH00200	3DH01100	LINK	2	*
	3DH01200	LINK CONNECTOR	2	*
	3DH01300	LINK SHAFT WASHER	4	*
	3DH01400	LINK PIN SPACER	4	*
	3DH01500	LINK PIN	8	*
	3DH01700	CAGE	1	*
	3DH01800	CAGE RUBBER STRAP	2	*

ProMixer 3DH	ACCESSORIES	DWG. NO.4



JAR 1500ml. & 2000ml.

Permanent loctite 270 threadlocker applied.
Removable loctite 222 threadlocker applied.

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PART NO.	DESCRIPTION	QTY.	MATERIAL
3DH02400	JAR BASE 1500 ML	1	I
	JAR LID 1500 ML	1	K1
3DH02500	JAR BASE 2000 ML	1	I
	JAR LID 2000 ML	1	K1

Custom Capsules Pvt. Ltd.

Works : B-8/1, MIDC, Tarapur, Camlin Naka, Dist. Palghar, Maharashtra, Pin-401 506. India
Phone : 02525 - 272538 Fax No. : 02525 - 272357

DECLARATION OF CONFORMITY

Product Name	:	Powder mixer
Model	:	Promixer™ 3DH
Serial Number	:	
Manufacturer	:	Custom Capsules Pvt. Ltd. B 8/1 Camlin naka, Tarapur MIDC, Boisar, Dist: Thane, Maharashtra, India, 401506
Contact Person	:	A.H. Varma Email : ahv@customcapsules.com Phone : + 91-2525-272538 Fax : + 91-2525-272537

It is hereby confirmed that the above product complies with the applicable requirements set out in the following directives.

2006/42/EC : Machinery directive

The harmonized standards applied are as follows.

EN ISO 12100:2010 : Safety of machinery. General principles for design. Risk assessment and risk reduction

EN 349:1993 + A1:2008 : Safety of machinery. Minimum gaps to avoid crushing of parts of the human body.

The above declaration is made with the following assumptions.

1. The machine is properly installed.
2. Proper care has been taken of all safety considerations.

We confirm the correctness of all the information mentioned above.

CE

Signed

Name: A.H. Varma
Position: Asst. Manager Q.A.

Place: MIDC Tarapur, India
Date:

Warranty and Contact Information

Warranty:

This product has a one year warranty on parts against manufacturing defects. On-site service is not included. Problems due to accidental damage or use other than as described in this manual are not covered.

Please include Serial Number with all correspondence.

Technical support or order Change Parts, Spare Parts, Accessories:
Please contact your distributor or Torpac using information below. Emails are typically received and responded to within 24-48 hours.

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Custom Capsules Pvt. Ltd.
For Torpac, Inc.
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Torpac specializes in custom size/shape capsules, including veterinary capsules, and laboratory scale pharmaceutical processing equipment.