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Standard Operating Procedure

Title: Operation of the Flexicon FMB200

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Table of Contents

- 1.0 Purpose
- 2.0 Scope
- 3.0 Authority and Responsibility
- 4.0 Startup of Flexicon FMB200 Filler
- 5.0 Changeover of Flexcon FMB200 Parts
- 6.0 Setup of the Flexicon FMB200 for Dispensing
- 7.0 Touch Screens
- 8.0 Malfunctions in Production
- 9.0 Troubleshooting

1.0 Purpose

This SOP describes the procedures for setup and operation of the Flexicon FMB200 for filling, stopper insertion and sealing of glass vials.

2.0 Scope

This SOP applies to the use of the Flexicon FMB200 for the Aseptic filling of biopharmaceutical product in glass vials.

3.0 Authority and Responsibility

3.1 The Director, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

- 3.2 The Manager, Formulation and Filling, is responsible for training personnel in this procedure and for documenting this training with Biopharmaceutical Quality Assurance.
- 3.3 Production personnel are responsible for the execution of this procedure.
- 3.4 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

4.0 Startup of Flexicon FMB200 Filler

4.1 Control Module Appearance (Figure 1)



Control Panel Description

1.	Starts production on machine
2.	Stops the machine
3.	Keypad for master control (MC12P) to the pumps. Filling parameters are set here.
4.	Control panel (touch screen), Setting different parameters for running machine are done here.
5.	MC12P display

- 4.2 Turn on the Main Power switch to the "ON" position.
- 4.3 The **STANDBY** menu (Figure 2) will appear on the touch screen.

Revision Number: 05



Figure 2

- 4.4 Turn on house Pharmaceutical Air supply. If the "AIR ON" has a green background, proceed. If the background is red, touch the "AIR ON" to obtain a green background.
- 4.5 Press **OPERATION**, the operational touch screen (Figure 3) will be displayed on the controller.

Operation Screen

VIAL	Controls vial feeding (on/off) to the machine. When VIAL is off, indexing and scroll will stop because no viola will be ready.
	Viais will be ready
FILL	Controls start signal (on/off) to monoblock. When FILL is on, the MC12P must be programmed and ready.
CAP	Controls the capping and vibrators (on/off).
INSERT	Controls the stopper feeding and the stopper vibrators (on/off).
STANDBY	Returns to the STANDBY -menu. See section 2.3.
ADJUST	Brings up a new screen, which will be described in section 5.3.
STATUS	Brings up a new screen, which will be described in section 2.7-2.9.
STEP	Press start and then step, this will index a vial to next position in the star wheel.

- 4.6 Determine the operations you wish the Flexicon FMB200 to perform. Touch the screen to highlight the operation in green. All green, highlighted activities will be performed.
- 4.7 Touch Status and then reset to set all values to zero. The **STATUS** menu (Figure 4) is used for determining the number of vials produced and the number of error events that occurred. The **STATUS** menu lists the error that causes the machine stop. If an error message occurs, touch the message on the screen and follow the instructions on the screen to correct the error, and then press the RESET button, then the start button.







STOPPER ERROR	Number of errors occurred in stopper insertion station
CAP ERROR	Number of errors occurred in cap placing station
VIALS OK	Number of vials through without error event
TOTAL	Number of indexing, cannot be reset

- 4.8 The **STATUS** screen menu list the alarms, which occur.
 - 4.8.1 For example (Figure 5), in order to reset the alarm for protection guards, the guard is closed and the start button is pushed.



Figure 5

- 4.9 The **STATUS** screen menu lists the Error which occurred.
 - 4.9.1 For example, Error MC12 not responding (Figure 6). An error is corrected by following the instruction on the screen and then pressing the RESET button, then the start button.

4.9.2 This message indicates an error was received that the MC12P (integrated filler controller) that was not activated before starting the FMB200. Follow the instructions on the screen and reset the error.





- 4.10 Before starting the filling process, the Master Controller "MC12P" should be programmed to the desired filling parameters.
 - 4.10.1 The display (Figure 7) will show the following.

STAND	BY			
		Figure	7	

4.10.2 Press the <GO> key (Figure 8), and the display will show the following.

* MC12 V1.0X (C) FMB 200 Flexicon 90-00 * PRESS GO TO CONTINUE.

DRIVE No.: 12

Figure 8

- 4.10.3 Verify that all connected filling stations (DRIVES) are displayed with their respective numbers in the bottom line.
- 4.10.4 Then press <GO> once more, and the display (Figure 9) will show the following.

F 5: 0 REV.	F 6: 1 fills	
F 3: 300 rpm	F 4: 75 ACC	
F 1: 10.00 mL	F 2: 4.8 TUBE	
ENTER FUNCTION No.:		11



4.10.5 The values displayed in the status lines will be the values of the last program used.

<u>NOTE</u>: If the programs on PLC (1-8) and in programs 1-8 in MC12P have already been established, it is not necessary to perform this step (4.11).

4.11 MC12P is now ready to be programmed. Select function 32, press enter. Press the desired program specified in BPR and press enter. Compare parameters to those listed in BPR. If the program does not match the desired parameters, proceed to section 6.8 to establish a new program.

5.0 Changeover of Flexcon FMB200 Parts

5.1 There is a unique set of change parts for each vial size. These parts are marked per following (refer to Figure 10).

See Fig 10	3 mL Vial	10 mL vial	5 mL vial
1. Vial guide	1	2	3
2. Star wheel	1	2	3
3. Height setting rods for vibrator	1V	2V	3V
4. Height setting rods for tool platform	1T	2T	3T
5. Scroll and scroll support	1	2	3
6. Ejector	1	2	1



Figure 10

- 5.2 Disassembling Vial Change Parts
 - 5.2.1 Changing format parts makes it possible to run the machine with the desired bottle. Always raise the tool platform and vibrators to a height where access to the format parts is possible before assembling or disassembling of vial change parts.

THE COMPRESSED AIR MUST BE TURNED ON FOR HEIGHT ADJUSTMENTS!

5.2.2 Before disassembling the change parts, it is necessary to release the trussing system (Figure 11). Loosen the thumbscrew (1) and the screw (3) while holding the rod (2). Push the rod slowly down.



Figure 11

- **NOTE:** Not necessary if only raising the tool platform (refer to 5.3 and 5.4). If in an Aseptic operation, do not touch stoppers or aluminum seals. Let them fall and do not clear them from the machine top until aseptic filling operations are complete.
- 5.3 Remove remaining caps in the cap bowl chute by pushing them back into the vibrator bowl in order to have a clear gap between the cap guide and the vibrator bowl.
- 5.4 Remove remaining stoppers in the stoppers bowl chute by pushing them back into the vibrator bowl in order to have a clear gap between stopper guide and the vibrator bowl.
- 5.5 Loosen the hand screws (1) (refer to Figure 12) and raise the vibrators by lifting them upward simultaneously to maximum height.
- 5.6 Loosen the hand screws (2) (refer to Figure 12) and raise the tool platform by lifting upward to maximum height.
- 5.7 When the tool platform and vibrators are raised, the format parts can then be dismantled and the parts can be taken for cleaning or replaced parts.



Figure 12

- 5.8 Take off the format parts (Figure 13).
 - 5.8.1 Lift the guides (1) from their lock pins.
 - 5.8.2 Loosen the screws (4).
 - 5.8.3 Loosen the thumb screw on the outlet pusher, turn the pusher (6) away from the star wheel.
 - 5.8.4 Lift the star wheel (2) from the boss (3).
 - 5.8.5 Remove the pusher.



Figure 13

5.9 Placing the format parts onto the Flexicon FMB200 Filler (refer to Figure 13).

5.9.1 As the parts are being placed on the Flexicon FMB200, wipe the parts with 70% IPA.

NOTE: VIAL CHANGE PARTS MADE OF POLYACETAL MAY NOT BE AUTOCLAVED OR DRY-HEAT STERILIZED.

- 5.9.2 Place the star wheel (2) on the boss (3) at the same time with the outlet pusher (6) onto the post (7).
- 5.9.3 Insert the bolts (4) into the star wheel and boss and tighten.
- 5.9.4 Check that the outlet pusher (6) is in the groove on the post (7) and tighten thumbscrew.
- 5.9.5 Place the guide (1).



Figure 15

5.10 HEIGHT SETTING (Figures 14 and 15)

THE COMPRESSED AIR MUST BE TURNED ON FOR HEIGHT ADJUSTMENTS!

- 5.10.1 It is imperative that the tool plate and vibrators have the adjusted height with regard to the specific vial. Therefore, a set of rods or spacers for each vial size is provided. These rods are to be placed under the tool plate and the vibrators in order to adjust the height of the operation units to the vial size.
- 5.10.2 Place the height setting rods in position and lower the tool platform until they are resting on the height setting rods. Tighten the hold-down screws (Figure 14).
- 5.10.3 Loosen the hand screws (1) and place the rod (2) for the vibrator on the column foot (Figure 15).
- 5.10.4 Vibrator (3) is pressed down so that the boss hits the rod.
- 5.10.5 While the rod is still in place, and the vibrator is held down, the two locking screws (1) are tightened.
- 5.11 Assembling/Disassembling In-Feed Scroll System (Figure 16)
 - 5.11.1 Turn off the machine in order to cut the power and air supply.
 - 5.11.2 Remove the sensor holder by unscrewing (1). Be careful not to damage the sensor.
 - 5.11.3 Remove the thumbscrews (5).
 - 5.11.4 Take the connector (3) off by loosening the nut and pulling the connector gently downward.
 - 5.11.5 The whole system is pulled out gently in the direction of the arrow shown.
 - 5.11.6 Disassemble the scroll by unscrewing bolt (2) and releasing the scroll from the clutch system (4). Pulling it out easily dismantles the support (6).
 - 5.11.7 Reverse these steps to reassemble the In-Feed Scroll.

Effective Date: MAY 24 2018



- 5.12 Assembling/Removing the Cap Placing System (Figure 17)
 - 5.12.1 Remove the vibratory unscrambling bowl.
 - 5.12.2 The cap chute (1) is then disassembled by removing the thumbscrew (2 and B). Care should be taken not to damage the optical fibers, which detect the caps in the chute.
 - 5.12.3 Dismantle the cap placer by removing the tall screw (A). To separate the chute from the cap placer, please hold seals above the joint to prevent them from sliding down. Remove the caps from the cap placer until the joint is free of caps. The chute and the cap placer can now be autoclaved.
 - 5.12.4 Releasing the clip and turning the bowl away from the machine dismantles the vibrator bowl for caps. The parts can now be cleaned or autoclaved.
 - 5.12.5 Reverse these steps to mount parts. The aseptic assembly of the cap placing system should occur before the stoppering system.



Figure 17

- 5.13 Assembling/Disassembling the Stopper System
 - 5.13.1 The aseptic assembly of the stopper system should occur after the cap placing system.
 - 5.13.2 TURN THE MAIN SWITCH OFF BEFORE DISASSEMBLING.
 - 5.13.3 Loosen the three thumb screws (1) (refer to Figure 18) and lift the stopper chute (2) off the linear vibrator (3). When assembling and tightening the stopper chute, place your hand on each fixation point and then fasten the screws (1).



Figure18

5.13.4 When placing the stopper chute, it is imperative that the chute is placed in a way that the pin (Figure 19) shown below rests against the chuck. It is also



imperative to fasten the thumbscrews in a way that the chute is held down completely.

Figure 19

5.13.5 Remove thumbscrew (1) after which the whole base plate (2) with jaws can be removed (Figure 20). The piston (3) can now be unscrewed from the piston rod, not performed routinely. Removing the two screws (4) and taking off the plate (5) makes it possible to release the jaws by turning them CCW, not performed routinely. This facilitates cleaning. The base plate with jaws is sterilized by autoclaving.



5.14 Assembling the Vibrator (Figure 21)

5.14.1 The vibratory unscrambling bowls (1) are mounted on the vibrators.

- 5.14.2 Press the skirt of the bowl onto the vibrator so that the skirt hits the lower edge of the vibrator. The bowl is now turned to the position where the outlet of the bowl fits the chute adequately (the marks must merge). It is very important to hit this point correctly.
- 5.14.3 The clip (1) is placed around the lower part of the skirt of the bowl and is tightly fastened. For the fastening, the supplied tee wrench is used, or the handle on the clip. The clip should be placed on the lower edge of the vibrator.



Figure 21

- 5.15 Adjusting Guides on the Outlay Tray (Figure 22)
 - 5.15.1 The guides on the outlay tray are adjusted according to the size of the vial to be processed on the machine. The black guides are moved sidewise by loosening all 4 screws (1).
 - 5.15.2 Place a vial in between and move the guides until the right gap is reached. The right distance between guides is when the vial can turn around without using much force.
 - 5.15.3 Fix the guides by fastening the screws (1).
 - 5.15.4 By removing the 4 screws (1), the guides can be lifted up facilitating cleaning.

Be aware that the guides must not be sterilized by autoclaving or dry heat.



Figure 22

6.0 Setup of the Flexicon FMB200 for Dispensing

- 6.1 General
 - 6.1.1 Dispensing is performed using one or two of the peristaltic filler heads on the monoblock. The peristaltic filler heads are equipped with tube bridges and tube locks. The tube lock makes sure that the tubes do not slide through the filler head when dispensing. The tube bridge holds the outlet tubing in place during dispensing.
- 6.2 Volume, Capacity, and Choice of Tubes
 - 6.2.1 The Flexicon FMB200 is equipped with two (2) Quick Change dispenser heads QC12 and an optional micro-filler kit.
 - 6.2.2 The Quick Change head (QC12) operates within the volume ranges of 0.25mL to 250 mL.
 - 6.2.3 The Quick Change dispenser head equipped with the micro-filler kit operates within the range of 100 μ L to 1 mL.
- 6.3 Capacity of the Flexicon FMB200 depends if a single pump or both pumps are used, vial-indexing system, filling nozzle movement, and also on the size of tubing used.
 - 6.3.1 The silicone tubes provided by Flexicon are specially formulated for operating with the dispenser heads by Flexicon.
 - 6.3.2 The QC12 operates with the following tube dimensions: 0.8, 1.2, 1.6, 3.2, 4.8, 6.0, 8.0 mm ID.
 - 6.3.3 Select the tubing size based on the fill volume from the charts below. The tubing from the product supply to the "Y" or "T" should have nearly double the ID of the tubing in the dispensing head. This is because there are two peices of tubing in the dispensing head. Note: Volume limits are based on filling accuracy verification performed as part of the Operational Qualification Protocol (OQ-032).

Tube size (mm ID)	Wall Thickness (mm)	Filling volume (lower limit)	Filling volume (upper limit)
0.8	1.6	0.25mL	1.5mL
1.6	1.6	1.0mL	5.0 mL
3.2	1.6	5.0 mL	8.0 mL

Tubes and volumes for an individual QC12

6.3.4 The micro-filler kit operates with the following tube dimensions: 0.5 mm ID.

Tube size	Wall Thickness	Filling vo0lume	Filling volume
(mm ID)	(mm)	(lower limit)	(upper limit)
0.5	1.6	0.2 mL	1.0 mL

- 6.4 Assembling the Dispenser Head (Figure 23)
 - 6.4.1 Open the dispenser head by turning the two locking pins (1) over the tube bridge (2), after which the tube bridge can be lifted up. Remove the tube lock (3) from its dowel pin.

- 6.4.2 The tubes are always connected to one tube by a "Y" or "T"-piece. When mounting the "Y" or "T"-connector, it is important to have the connector as close to the head as possible.
- 6.4.3 The "Y" or "T"-connectors are always mounted on the right side of the pump head where there are two lanes for tubes to rest.



6.4.4 Place the assembled tubes in the dispenser head as shown in (Figure 24). Place the lock pin in order to hold the small tubes in place. Place the tube bridge in a way that the pads are on the same side as the Y-connector. **Revision Number: 05**

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- 6.5 The product vessel should be placed slightly above the pump heads to obtain a better priming of the dispensing tubing.
- 6.6 Setting Up the Filling Nozzle (Figure 25).
 - 6.6.1 The filling nozzles are mounted on a rod, which moves the filling nozzles into the vials during the filling.
 - 6.6.2 On the standby screen, press "AIR OFF" on the touch screen menu to turn the compressed air off.
 - 6.6.3 Place two empty vials in the star wheel at the filling position (positions 1 and 2 in the star wheel). The filling nozzle (1) is placed in its holder (2) and is fastened with two thumbscrews (4). When the thumbscrew (3) is loosened, the filling nozzles can be turned and moved up and down on the filling stand.
 - Push the filling stand to its bottom position and center the filling nozzle (1) in the 6.6.4 vial mouth. Adjust the height so that the lower end of the nozzle is just below the shoulder of the vial.
 - 6.6.5 Tighten the thumbscrew (4), and raise the filling stand to its upper position and check that the ends of the filling nozzles are above the vial.



- 6.6.6 The chosen tubing is pushed onto the filling nozzle and is clipped to the holder (5). Ensure the tubing is not kinked. The tube is mounted in the filler. Check that the tube can move freely up and down together with the filling nozzles.
- 6.7 Preparation for Dispensing
 - 6.7.1 When the tubing and "Y" or "T"-connectors have been assembled and mounted in the dispenser head, the tubing must be primed to fill the tubing with product.
 - 6.7.2 Place a collection container under the filling nozzle(s) and prime the tubes by going into the fill mode screen in the adjust menu of the FMB200. Hold down the touch screen buttons for PRIME PUMP 1 or PRIME PUMP 2.
 - 6.7.3 When the tubes are primed, they are mounted on the filling stand (holders). The next step is to calibrate the drives (dispensers).
- 6.8 Programming of MC12P
 - 6.8.1 The programming is established via functions. The function is entered in the MC12P by entering a function number followed by <ENT>. This will make the required function appear in the prompt line of the display and show the current value or information of the function. This value will automatically be overwritten when entering the new value followed by pressing <ENT>. Some values will not be accepted because they are not valid for this filling station.
 - 6.8.2 Furthermore, the F8 must be reset (zero). Nothing can be entered in this function as it only displays the number of fills completed since the latest reset of the function. (Reset by entering: <8>+<ENT>+<C>+<ENT>).
 - 6.8.3 The MC12P can operate in three different modes.
 - 6.8.3.1 Individual (I) Each drive has its operating parameters.
 - 6.8.3.2 Parallel (P) multi-head filling and multiple vials filled at same time.
 - 6.8.3.3 Serial (S) each drive is used to fill part of the total volume.
 - 6.8.3.4 The mode is in the top right-hand corner of the display, in front of the current drive number. "I1", for example, means that the mode is individual and the current drive address is 1.

- 6.8.3.5 To program, use function 40. Press <4> + <0> + <ENT> and then insert <1>, <2> or <3> followed by <ENT>.
- 6.9 Calibration of the Dispensers
 - 6.9.1 To achieve required accuracy and the capacity, it is necessary to calibrate the dispensers. The calibration helps to find the optimum for the filling process as to filling speed, acceleration, and subsequently the capacity.
 - 6.9.2 If the main parameters in the program are changed in the process of finding the optimum speed and acceleration, a recalibration is always necessary. Calibrations are performed initially and may be recalibrated at any time during the run.
 - 6.9.3 Mark and weigh an empty vial.
 - 6.9.4 Place the marked vial on the inlet conveyor.
 - 6.9.5 Clear the fill counter by entering <8> + <C>.
 - 6.9.6 Push <disp.> on MC12P.
 - 6.9.7 Activate FILL and VIAL on the touch screen menu.
 - 6.9.8 Select the way of filling in FILL MODE.
 - 6.9.9 Push START on the control panel.
 - 6.9.10 When the vial has been filled, pick the marked vial and weigh its contents to determine the weight of the liquid. Record the value.
 - 6.9.11 Using the MC12P, insert the weight in grams of the liquid by entering <Calib> + <ENT> and then enter the weight in grams of the liquid + <ENT>.
 - 6.9.12 Repeat steps 6.9.3 through 6.9.11 until the volume is within the accuracy required, preferably above the nominal value. If the calibrated volume is as desired, then production can start. Document the calibration in the Batch Production Record.
- 6.10 Operation
 - 6.10.1 Start up the Flexicon FMB200 by turning the main switch for the machine to the "ON" position. Press "OPERATION" on the "STANDBY" screen. Before starting any other functions on the machine, press the "START" button and press STEP on control panel a few times to reset the PLC registers.
 - 6.10.2 Fill the vibratory unscrambling bowls for stopper and aluminum seals with stoppers or aluminum seals. Do not exceed 75% of capacity.
 - 6.10.3 The vibratory speeds are preset in the program. Preset values may not be changed without Supervisory approval, but vibratory speeds can be adjusted in the screen, Figure 29. When the vibrators have filled the chutes with items, the vibrators will automatically stop, and the capping systems are now ready for production.
 - 6.10.4 Load vials onto the in-feed conveyor and activate the switches in the following order:

FILLING, CAPPING & STOPPER	
<cap></cap>	
<insert></insert>	
<fill></fill>	
<vial></vial>	

- 6.10.5 Press the Start button.
- 6.10.6 The machine now starts its automatic production with all functions activated. The speed of vial indexing is established in the program. Preset values may not be changed without Supervisory approval, but indexing speeds can be adjusted in the screen, Figure 29.
- 6.10.7 During the production the items are used continuously and items must, therefore, be refilled. When refeeding, supplies (vials, stoppers and seals) must be added using aseptic technique.

<u>Caution</u>: When feeding additional vials to the conveyor, make sure that no vials tip over. Do not overfill the unscrambling bowls with stoppers or seals.

- 6.10.8 If it is necessary to stop the machine while vials are being refed, using the button <STOP> or opening the door. When the vials are ready, activate the switch <VIAL> and press <START>.
- 6.10.9 If the machine runs out of vials and caps, it will stop automatically. The Flexicon FMB200 restarts automatically when these items are replaced.

7.0 Touch Screens

7.1 Service Menu (Figure 26)



Figure 26

	Time consumption for each function on the machine can be seen here,
TIME	e.g., fill time, capping time etc.
INPUT	Input signals on the system plc are envisaged here.
OUTPUT	Output signals on the system plc are envisaged here.
ALARM LIST.	A list of alarms occurred appears here.
	By pressing the service key, the next menu appears provided that the
SERVICE KEY	override key inside the control desk is turned on.
VIAL POSITION.	Indicates the vial position graphically.

7.2 Service Key (Figure 27)

- 7.2.1 In this menu the parameters for cap, stoppers, and frequency inverters are set. The options available in this menu are not used in every day operation, only if an adjustment is needed after a period of time.
- 7.2.2 The available parameters can be saved as a program and loaded.





7.3 Adjust Menu (Figure 28)



Speed	Speed of vibrators and indexing is adjusted here.
Fill Mode	Way of filling is determined here.
Operation	Shifts back to operation menu.
Load	Loads a program related to formats saved by operator.
Factory Setting	Factory settings for each format can be loaded here.
Save	A set of parameters, also called programs can be saved here.

- 7.4 Speed Adjustment (Figure 29)
 - 7.4.1 A parameter is adjusted by first selecting the bar to be adjusted (↑), then pressing arrow down or up (blue boxes) switch on the screen. The adjustment scale is a percentage relative to full speed (100%). Do not set the speed higher than required for the item to pace with the production carried out by the machine.

Revision Number: 05

Effective Date: MAY 24 2018



Figure 29

INDEX SPEED	The index speed, i.e., speed of the star wheel
STOPPER/CIR	The rotating speed of the vibrator for the stopper
STOPPER/LIN	The vibration on the stopper feeding chute
CAPS/CIR	The rotating speed of the vibrator for the aluminum seals
Arrow Up	Increases value
Arrow Down	Decreases value

7.5 Fill Mode (Figure 30)

7.5.1 The Filling mode menu provides different options as to the ways the filling station can operate.



NO DIVE	This option holds the filling stand still and there is no up and	
	down movement.	
DESCEND	Activating this switch provides up and down movement for the	
	filling stand. The drive dispenses as the filling stand goes down.	
	The Filling stand returns when dispensing is finished.	
DESCEND/BOTTOM	The drive dispenses as the filling stand goes down, the filling	
	stand returns when dispensing is finished and the filling nozzle	
	has been at bottom.	
BOTTOM FILLING	The drive dispenses when the filling stand is at bottom and	
	returns when dispensing is finished. This method is suitable for	
	micro filling where droplet can add inaccuracy to filling process.	
PRIME 1	When pushed, activates the drive no. 1 and runs continuously as	
	long as it is held. This function primes tubing and evacuates air	
	bubbles from tubing.	
PRIME 2	When pushed, activates the drive no. 2 and runs continuously as	
	long as it is held. This function primes tubing and evacuates air	
	bubbles from tubing.	

7.6 Save Program (Figure 31)

- 7.6.1 In this screen programs can be saved. Programs consist of a set of parameters, which include: Speed, Fill mode, Frequencies and Delays for cap and stoppers (the delays and frequencies are preset by factory and should not be changed). The programs are designated a number and the number is inserted when a specific program is to be saved. There can only be 8 saved programs.
 - **NOTE:** The Program number should, for practical reasons, follow the format number.



Figure 31

- 7.7 Load Program (Figure 32)
 - 7.7.1 In this screen the programs can be loaded. The programs are designated a number and the number is inserted when a specific program is to be loaded.
 - 7.7.2 If a program is to be loaded from PLC and there is no program saved in the MC12P, then a beep is generated.

Revision Number: 05





- 7.8 Factory Settings (Figure 33)
 - 7.8.1 The machine is provided with settings inserted from the factory. These settings relate to the formats available for the machine.
 - 7.8.2 Each format has its own specific set of parameters. In case of malfunction, the factory settings can be loaded and production can be initiated with these parameters. Then adjustments to different parameters can be made.
 - 7.8.3 Loading program number 1 loads the factory settings for format number 1, etc.





- 7.9 Parameters set on the screen menus such as speed and fill mode can be saved together with parameters set in the master controller MC12P. Saving programs on plc as well as on MC12P must be done as follows.
 - 7.9.1 Set and save the parameters on MC12P by applying function 31. Designate a number to the program starting with number 1.
 - 7.9.2 Set the parameters for FMB200 on the touch screen display. Save the parameters in a program with the same number as on program in MC12P.
 - 7.9.3 Since there are 8 programs on the screen of the FMB200, only 8 MC12P programs can be saved together with the FMB200 programs. Numbers for the programs must correspond to one another, e.g., a program with number 1 cannot be saved together with program number 2 on MC12P.

8.0 Malfunctions in Production

- 8.1 The machine is equipped with a number of control functions, which will stop the machine in the event of malfunctioning. When a malfunction is detected, the button <STATUS> begins to flash and the machine stops. By pushing on the STATUS, the occurred error is shown in another screen.
- 8.2 Safety switches are placed on the guard before opening the guard, press stop. The guards should not be used to stop the monoblock.
- 8.3 In certain cases of malfunctioning, the machine may lose its synchronization. In such cases, the following procedure is performed to resynchronize the Flexicon FMB200.
 - 8.3.1 Check that the filling nozzles and all tools are in the correct position so vials can enter and move with the star wheel.
 - 8.3.2 Check that the vial pusher points toward the center of the star wheel.
 - 8.3.3 With all functions turned OFF, press <START> then the <STEP> button. The star wheel proceeds to the next station after which it is synchronized.
 - 8.3.4 Press the desired functions and restart the machine by pressing the button <START>.

9.0 Troubleshooting

- 9.1 When intervention is necessary to remove a vial or stopper/cap:
 - 9.1.1 Set all functions to off on the control panel.
 - 9.1.2 Then press START followed by STEP.
 - 9.1.3 Repeat press STEP until the star wheel is on an empty vial.
 - 9.1.4 Correct the problem.
 - 9.1.5 Then press START to proceed with filling the vials.
- 9.2 Machine does not react even when power is on.
 - 9.2.1 Check if the emergency stop is released.
- 9.3 When START is activated, nothing happens.
 - 9.3.1 Check if the "VIAL" has been activated.
- 9.4 When the machine is started, the vial goes through and nothing happens.
 - 9.4.1 Height setting rod placed under tool plate is not the correct one.
 - 9.4.2 Vial inlet sensor does not see the vial, Vial inlet sensor is not set correctly.
- 9.5 No stoppers or caps in the chutes.
 - 9.5.1 Check the vibrator bowls.
 - 9.5.2 Check the chutes for jammed item.
- 9.6 Too much noise generated by vibrators.
 - 9.6.1 Check if the vibrator bowls are fixed and the clamp is tight.
 - 9.6.2 Reduce the speed of vibrators in the Adjust menu.

	9.7	Stoppers	fall off.
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- 9.7.1 Check the main air pressure for adequacy.
- 9.7.2 Stoppers may have excess silicone.
- 9.7.3 Stopper insertion piston may have accumulated silicone and needs to be wiped clean.
- 9.8 When running with lyophilized stoppers, nothing happens.
 - 9.8.1 Inlet sensor is set high. Move the inlet sensor down.
- 9.9 A grating sound is generated at the outlet.
 - 9.9.1 Star wheel has not been placed correctly, the pusher hits the wheel.
 - 9.9.2 Place the wheel so it rests completely on the boss.
- 9.10 When restarting, a cap or stopper error happens.
 - 9.10.1 Push VIAL off.
 - 9.10.2 Empty the star wheel by using STEP.
 - 9.10.3 Push START and fill the chutes with item.
- 9.11 When filling, a large overshoot/undershoot is observed.
 - 9.11.1 The MC12P is out of calibration. Use function 80 and program MC12P again.
- 9.12 One of the filling stations fills when no vial is present in the wheel slot.
 - 9.12.1 A vial has manually been removed from the wheel.
 - 9.12.2 Use STEP to empty the wheel and run again.