

🕒 Target 22 min

Special Reminders

GMP guidelines apply

surgical gloves or very clean hands

Hearing protection

Eye protection

lock & tag

If this is not done correctly, severe problems will occur

Use table on reverse of this form to determine correct position

Additional person(s) required

\square_1 Picture on front side

\oplus_1 Enlarged picture on reverse side

Obtain all tools & materials listed on reverse side

Related SOPs, documents, etc.

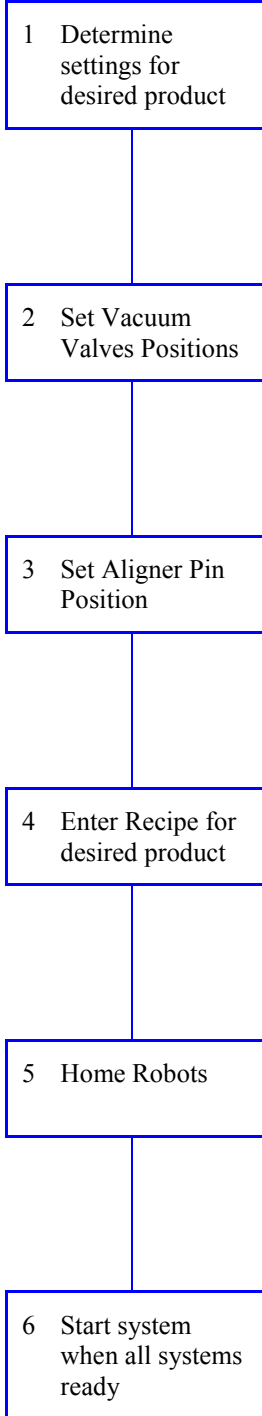
PPM-FLS001

PPM-FLS002

PPM-FLS010

PPM-FLS012

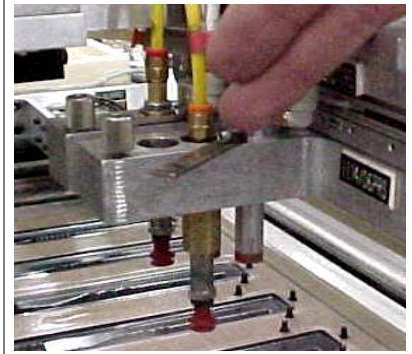
Procedure Overview



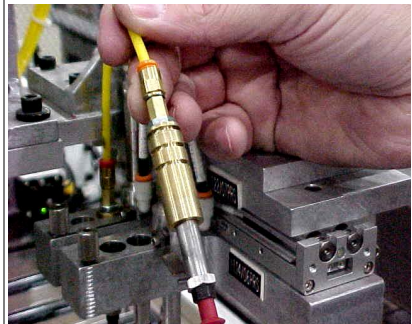
Instructions & Explanations

- 1.1 Complete pre-checks opposite
 - 1.2 Determine vertical & horizontal positions of Vacuum Valves for the product to be run i_1
 - 1.3 Lock & Tag before proceeding
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- 2.1 Do the following for each side of each Robot:
 - 2.2 Start with “handle” side of Robot. Loosen nut, move the locking bar out of position \square_1
 - 2.3 Place Vacuum Valve in correct vertical position $\oplus_1 \oplus_2$. Move locking bar back & tighten lock nut.
 - 2.4 Repeat for both Vacuum Valves on “handle side” of this bay.
 - 2.5 On “brush side” of Robot arm, Loosen nut & move locking bar out of position \square_1
 - 2.6 Place Vacuum Valve into correct vertical & horizontal position. $\square_2 \oplus_1 \oplus_2$
 - 2.7 Move locking bar back into position & tighten lock nut.
 - 2.8 Repeat for both Vacuum Valves on “brush side” of this bay
 - 2.9 Repeat for each bay of each Line
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- 3.1 For each Robot do the following:
 - 3.2 Confirm required Aligner Pin i_1
 - 3.3 Pull Pin out \square_3
 - 3.4 Loosen both knobs
 - 3.5 Place Pin in correct position & move plate until knob moves all the way down i_1
 - 3.6 Tighten the knobs
-
- 4.1 Identify correct recipe for product to be run i_1
 - 4.2 Go to a Control Screen \square_4 .
 - 4.3 From *Operation* Screen, touch *Tool* screen, On *Tool* screen touch *Recipe* area & scroll until required recipe is shown
 - 4.4 Touch *Select Table Entry* & enter your password
 - 4.5 Enter value for Recipe & confirm
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- 5.1 On Control Screen *Operation* screen, touch *Home Robots*
 - 5.2 Watch the Robots to ensure they “Home” correctly
 - 5.3 Clear any faults
-
- 6.1 Notify operators of other systems. Press green Start button \square_4

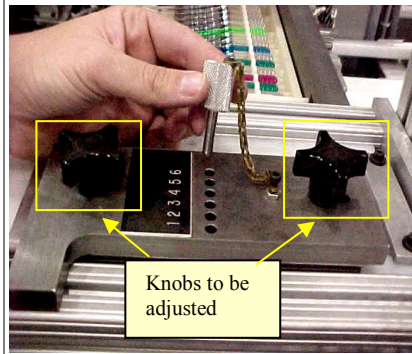
\square_1 ↓ 2.1. Loosen nut, move locking bar



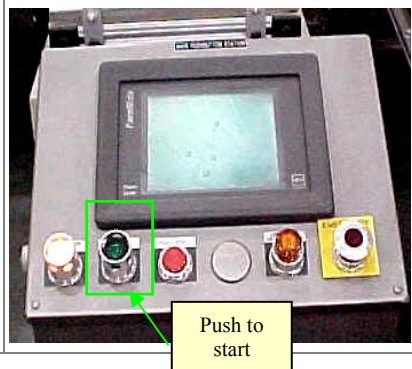
\square_2 ↓ 2.5 Place in correct vertical & horizontal position



\square_3 ↓ 3.2 Pull Pin out



\square_4 ↓ 4.2 Control Screen & 6.1



- ✓ Pre-Checks** (Things to check before starting this process)
- Ensure that all product from previous run has been removed from the area & documentation for line clearances completed
 - Ensure that the Former & Sealer areas of the machine are ready & have sufficient raw materials available
 - Ensure that new product in filled trays is available & ready to load
 - Stack each bay of each line with filled trays of the new product to be run
 - Ensure your hands are very clean or wear gloves when performing this procedure as you will be touching parts that will come in direct contact with tooth brushes.

🔧 Tools & Materials Required

Item Description & Quantity required	Step
<input type="checkbox"/> No special tools are required for this procedure	

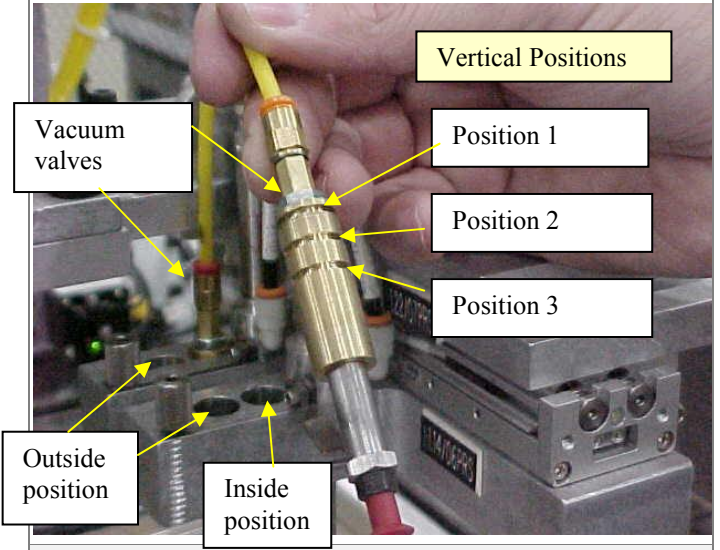
👤 People (Who is required or needs to be notified)

- Notify the people who will be operating the other parts of the machine & coordinate your activities with theirs.
- Notify any other personnel who may need to be aware of this changeover

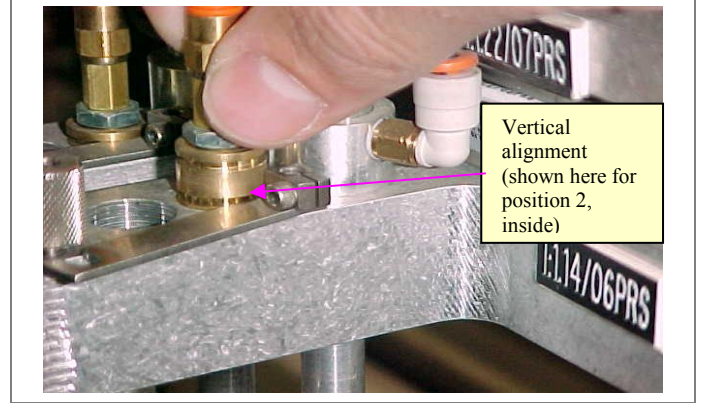
🔑 Key Learning/Performance Points

ITEM	C	Step
1. Using the table below, specify the Vacuum Valve and Aligner pin position for any given product.		1.2
2. Demonstrate how to lock and tag the machine	C	1.3
3. For any given product, demonstrate how to find and select the appropriate <i>Recipe</i>		4.5
4. Perform a Loader System Changeover as per this PPM		all

5. **#1 Step 2.2 Vacuum valves positions**



#2 Position vertically & horizontally



Recipe No.	Toothbrush Type	Blister Type	Vacuum Valve Position Horizontal (Brush Side)	Vacuum Valve Position Vertical (Brush Side/Handle Side)	Aligner Pin Position
1	Brush-type1 Jets	Brush-type1	Inside	Position 1 / Position 2	4
2	Brush-type1 Trees	Brush-type1	Outside	Position 1 / Position 2	4
5	Brush-type2 Single Compact	Brush-type2	Outside	Position 1 / Position 1	5
6	Brush-type2 Single Full	Brush-type2	Outside	Position 1 / Position 1	4
7	Brush-type2 Dual Compact	Brush-type2	Outside	Position 1 / Position 1	5
8	Brush-type2 Dual Full	Brush-type2	Outside	Position 1 / Position 1	4
9	Brush-type2 Pro Compact	Brush-type2	Outside	Position 1 / Position 1	5
10	Brush-type2 Pro Full	Brush-type2	Outside	Position 1 / Position 1	4
11	Brush-type2 Youth	Brush-type2	Inside	Position 1 / Position 1	6
12	Brush-type3 Full	Brush-type3	Inside	Position 1 / Position 2	1
13	Brush-type3 Compact	Brush-type3	Inside	Position 1 / Position 1	3
14	Brush-type4 Full	Brush-type4	Inside	Position 1 / Position 1	2
15	Plus Full	Brush-type4	Inside	Position 1 / Position 1	2
16	Brush-type5 Compact	Brush-type5	Inside	Position 1 / Position 1	4
17	Brush-type5 Full	Brush-type5	Inside	Position 1 / Position 1	3