



# Line Clearance, Opening and Cleaning for Tablet Packing line

(Ref. SOP MAN-055; MAN-075)

MAN-055 Procedures for Line Clearance, Line Opening and Line Cleaning  
MAN-075 Tablet Packing Machine construction, operation and cleaning



Product			Relevant process SOP: SOP MAN-075		
Date	BPN	Code No.	Pack Size	Type of Change	
				Change of Product	
Packing Line:				Change of BPN.	
				Change of Code.	

Tick operations which are ACCEPTABLE	√
Put a N/A against any operations NOT APPLICABLE	N/A

### Line Clearance

- If unacceptable standard is found, have it corrected BEFORE proceeding and note details of any **Non-Compliance** into **TABLE B** of this Form **and in the non-compliance logbook.**

**NOTE:** LINE CLEARANCE must be completed before LINE OPENING commences.

- The Operator completing the first check is to mark the boxes in **column A** and sign the signature line A. The Operator completing the second check is to mark the boxes in **column B** and sign the signature line B.
- Check that all product, components, batch documents, empty IBC's and Component boxes from the previous batch have been removed and the surrounding area is clean and clear.
- **EXCEPTIONS:** The following items may remain on the line, if identical to the requirements of the upcoming batch, but they must be removed if Planned maintenance is to follow
  - BASE FOIL (PVC/PVDC)
  - LID FOIL (Printed Foil)
  - SHIPPERS (Cartons)
  - TABLETS

A check must be made of these Material Code numbers during the Line Clearance.

- The **Wiper Brush** may stay in the machine when running the same Bulk batch.
- Use a Torch to check hard to see area's

**NOTE:** At any time a strip of "running in foil" can remain on line for the purpose of joining the new roll, due to a check for removal being carried out in the batch document.



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BPN:

**TABLE A – This check should be carried out in numerical order starting at the Compaker:**

	A	B
1. Check the Base Foil splicing station and surrounding area		
2. Check hopper and surrounding ledges including ladder		
3. Check broken tablet extraction area <b>(cover and vibrator grid should be removed and cleaned)</b>		
4. Check the forming area, surrounding ledges & cables including opening the door behind the forming station at the back of machine and checking the area		
5. Check "Machine" vacuum cleaner is clear and that the vacuum bag has been removed		
6. Raise the foil clamp and check underneath and surrounding area		
7. Check brush box is dismantled with brushes, (Paddles & Gearbox's) removed. <b>Except:</b> where the same bulk manufacture's batch number is to continue.		
8. Check product wiper brush and cover is removed and clean		
9. Remove/Open camera shroud and check area		
10. Check sealing station <b>(CAUTION - MAY BE HOT)</b> check the surrounding area including the ledge behind the bottom sealing plate.		
11. Check blister coding block has been removed & coding station is clear		
12. Check perforating station and surrounding area		
13. Lift index clamps and check surrounding area		
14. Check all ledges around and below the punching station area		
15. Check around & below the blister transfer conveyor		
16. Check the blister reject chute		
17. Check floor area and machine supports around the front of the machine		
18. Check the top of the machine		
19. Check the tablet reclaiming machine is clear, check all ledges are clear		
20. Check the bin containing the brush box parts		
21. All containers, bowls & trays are clean & product information sheet removed		

The Line is Clear and I have been **Trained** and **Assessed** to sign this Line Clearance:

A. Name: \_\_\_\_\_ Signature \_\_\_\_\_ Time \_\_\_\_\_ Date \_\_\_\_\_  
(Please print name clearly then sign and complete time and date)

The Line is Clear and I have been **Trained** and **Assessed** to sign this Line Clearance

B. Name: \_\_\_\_\_ Signature \_\_\_\_\_ Time \_\_\_\_\_ Date \_\_\_\_\_  
(Please print name clearly then sign and complete time and date)



# Line Clearance, Opening and Cleaning for Tablet Packing line

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BPN:

Begin the Line Clearance at the Pacliner Conveyor and work your way down the front of the machine:

**Table B - This check should be carried out in NUMERICAL ORDER**

**A B**

	A	B
1. Check the Blue Dye Station, ensuring that no blisters have been left in the vacuum bowl and that the area is clear		
2. Check around, below and inside blister eject chute		
3. Check the area around the blister stacker pay special attention to all ledges		
4. Check the whole length of the blister conveyor belt around and below		
5. Check the leaflet loading area and folding mechanism is clear		
6. Check around the carton transfer arms and ledges surrounding		
7. Check the carton coder has been removed and area is clear		
8. Check the length of the carton loading magazine		
9. Check inside and under the Pacliner including all ledges and hoses		
10. Check around outfeed conveyor & all ledges below & around check weigher		
11. Check the outfeed rollers and conveyor along its full length		
12. Ensure that the computer workstation and product information board is clear		
13. Check inside the chest of draws under Computer workstation table		
14. Check around & below including all ledges of the shipper taping machine		
15. Check around & under the turntable conveyor		
16. Check around & under the fixed table conveyor		
17. Check that the floor area around the rear and under the machine including the machine supports are clear		
18. Open door behind leaflet inserter and check area		
19. Check vacuum cleaner is clear and that the vacuum bag has been removed		
20. Check Foil lifter, and PVC mandrel including all ledges and surrounding area		
21. Check that no desiccant bags have been left on the line		

The Line is Clear and I have been **Trained** and **Assessed** to sign this Line Clearance:

**A.** Name: \_\_\_\_\_ Signature \_\_\_\_\_ Time \_\_\_\_\_ Date \_\_\_\_\_  
(Please print name clearly then sign and complete time and date)

The Line is Clear and I have been **Trained** and **Assessed** to sign this Line Clearance

**B.** Name: \_\_\_\_\_ Signature \_\_\_\_\_ Time \_\_\_\_\_ Date \_\_\_\_\_  
(Please print name clearly then sign and complete time and date)



## Line Clearance, Opening and Cleaning for Tablet Packing line

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BPN:
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**EXCEPTIONS: Circle 'YES' or 'NO' in the box and confirm by ticking the box, A or B.**

**Write the Material Number. If no Material Number is applicable write N/A, & confirm by ticking the box A or B.**

**A    B**

Check if the <b>bulk tablets</b> have been removed from the line	Yes/No		
If <b>No</b> , check against batch documentation that the <b>bulk tablets</b> are the correct material number to be used for this BPN.	Material No.		
Check the <b>brushes</b> and wiper brush has been removed from the machine	Yes/No		
If <b>NO</b> , check the brushes are correct for this BPN	Yes/Na		
Check if the <b>LID FOIL ROLL</b> has been removed from the machine. (A "running in strip of foil" may be left on machine; a check is made in Line Opening that it has been removed before production starts.)	Yes/No		
If <b>NO</b> , check against batch documentation that the <b>LID FOIL</b> is the correct Material Number to be used for this BPN	Material No.		
Check if the <b>BASE FOIL</b> has been removed from the machine.	Yes/No		
If <b>NO</b> , check against batch documentation that <b>BASE FOIL</b> is the correct Material Number to be used for this BPN	Material No.		
Check if the <b>SHIPPERS</b> have been removed from the line.	Yes/No		
If <b>NO</b> , check against batch documentation that <b>SHIPPERS</b> are the correct Material Number to be used for this BPN	Material No.		

**All NON-COMPLIANCE found during this Line Clearance is to be recorded below (and in the Non-Compliance logbook). If nothing found, place a line across table, sign and record "NONE"**

Record Position found e.g. 11 And table A or B	Description of what was found e.g. A blister	BPN	Comments/Action	Sign

The Line is Clear and I have been **Trained** and **Assessed** to sign this Line Clearance:

A. Name: \_\_\_\_\_ Signature \_\_\_\_\_ Time \_\_\_\_\_ Date \_\_\_\_\_  
(Please print name clearly then sign and complete time and date)

The Line is Clear and I have been **Trained** and **Assessed** to sign this Line Clearance

B. Name \_\_\_\_\_ Signature \_\_\_\_\_ Time \_\_\_\_\_ Date \_\_\_\_\_  
(Please print name clearly then sign and complete time and date)



# Line Clearance, Opening and Cleaning for Tablet Packing line

(Ref. SOP MAN-055; MAN-075)

BPN:

LINE OPENING	A	B
Product information board is correct against the batch documentation.		
Verify that the correct vibrator gird has been installed		
Check each brush to verify that they are the correct brushes to be installed, and check that each brush has a grub screw fitted <b>(required only when changing bulk manufactures batch numbers)</b>		
All IPA bottles labelled and within expiry date		
Check that new Vacuum bags have been installed		
Check that the correct forming tools have been placed in the machine		
Components checked against transfer order		
Transfer Order checked ( <b>TO</b> signed checked)		
IBC bins are checked for details against the batch document		
Components for this <b>BPN</b> entered into the batch documentation		
Check that the correct recipe has been installed in the Compaker		
Check that the Correct program has been installed on the Checkweigher		

### Product details are correct against the batch document

Bulk Code Number:		
Manufacturer's Batch Number:		
Description:		
Lab Batch Number:		

### Lid Foil

Foil material code & description correct against batch document, & sample taken.		
Correct <b>PRINT</b> on both sides of blister and correct <b>BPN</b> and <b>EXPIRY DATE</b>		
Sample of coded blisters attached to the batch document		

### Cartons

Carton code correct against the batch documentation		
Correct <b>BPN</b> and <b>EXPIRY DATE</b> on the sample carton		
Date of Manufacture (If Applicable)		
Sample of coded carton attached to the batch document		



### Line Clearance, Opening and Cleaning for Tablet Packing line

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BPN:

#### Shipper Labels

Product description correct		
Finished goods code correct		
<b>PON</b> and <b>EXPIRY</b> correct		

#### Leaflets

Leaflet code correct against batch documents		
Leaflet sample attached to sample sheet		

#### Log Book

Batch details recorded in Log Book.		
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I have been **Trained** and **Assessed** to sign this Line Opening

A. Name: \_\_\_\_\_ Signature \_\_\_\_\_ Time \_\_\_\_\_ Date \_\_\_\_\_  
(Please print name clearly then sign and complete time and date)

I have been **Trained** and **Assessed** to sign this Line Opening

B. Name: \_\_\_\_\_ Signature \_\_\_\_\_ Time \_\_\_\_\_ Date \_\_\_\_\_  
(Please print name clearly then sign and complete time and date)

**NOTE:** The machine may now be started for the purpose of carrying out all challenges/tests.(refer PI sheet for a list of challenges.)

**NO** Finished packs are to be placed in shippers until **ALL** tests are complete and **PASS**.

#### MATERIAL STAGING BAY CLEARANCE:

- If unacceptable standard is found, have it corrected **BEFORE** proceeding and note details of any non-compliance into **TABLE B** of this Form and in the Non-compliance logbook.

A B

Check that all product, components, batch documents, empty tablet containers, and component boxes from the previous batch have been removed and the surrounding area is clean and clear.		
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The Staging area is Clear and I have been **Trained** and **Assessed** to sign this Clearance:

A. Name: \_\_\_\_\_ Signature \_\_\_\_\_ Time \_\_\_\_\_ Date \_\_\_\_\_  
(Please print name clearly then sign and complete time and date)

The Staging area is Clear and I have been **Trained** and **Assessed** to sign this Clearance

B. Name \_\_\_\_\_ Signature \_\_\_\_\_ Time \_\_\_\_\_ Date \_\_\_\_\_  
(Please print name clearly then sign and complete time and date)



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BPN:

## LINE CLEANING

1. The Line Cleaning is to be carried out in accordance with the area specific **SOP MAN-075**.
2. All product components and batch documents removed from line.
3. **EXCEPTIONS:** The following items may remain on the line:  
**WIPER BRUSH, LID FOIL, BASE FOIL, SHIPPERS and TABLETS.**  
A check must be made of these Material Code numbers during the Line Clearance.
4. Cleaning is to be done using the vacuum, and 70% IPA. (**Safety Glasses and Gloves must be worn when using IPA.**) Ensure the IPA expiry has not elapsed.
5. **ENSURE THAT THERE IS NO PRODUCT RESIDUE LEFT ON THE MACHINE PARTS.**
6. Before maintenance is to be performed all components are to be removed from the line.

**NOTE:** This Checklist must be completed before performing a Line Clearance for next BPN

## COMPAKER MACHINE

Check the vibrator grid has been removed and cleaned	
Vacuum hoses behind the machine have been removed and shaken. Leave off for Line Clearance ( <b>Not required if running the same manufactures batch number</b> )	
Check brush box has been dismantled with brushes, gearbox's, and guards removed. Inspect each brush for tablets and for missing grub screws. ( <b>These items do not have to be removed if running the same manufactures batch number</b> ).	
Coding plate has been removed	
Check all ledges and surrounding areas of Compaker	
The <b>BLANK</b> recipe has been loaded into the Scan Ware	
The <b>BLANK</b> recipe has been loaded into the Compaker	

## PACLINER MACHINE

Coding block removed.	
Check Blister stacker assembly around and below	
Check inside and under Pacliner paying special attention to all ledges.	
The <b>BLANK</b> recipe has been loaded into the Pacliner	

## CHECKWEIGHER

Setting set to <b>BLANK</b>	
Check in feed and out feed conveyor	

## GENERAL WORK AREA

Ensure that the computer workstation is clear.	
Ensure that the area, ledges and floor behind the machine are clean and clear	
Check tablet reclaiming machine has been dismantled and clear	
Vacuum cleaner's and hoses clean and clear	



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BPN:

All containers, trays & tubs are clean and stored upside down with forms removed	
Floor area around the front and under the machine is clean and clear including the fixed and rotating turntable.	
Product information Board is clear.	
If monthly preventative maintenance is to follow, all materials on line must be removed.	

**LINE CLEANING** is completed, sign below and also record the details & sign off in the logbook.

The line has been cleaned and I have been **trained and assessed** to sign this line cleaning:

Name \_\_\_\_\_ Signature \_\_\_\_\_ Time \_\_\_\_\_ Date \_\_\_\_\_  
(Print name clearly then sign and complete time & date)