



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Sticker Labeling Machine (Make: CVC) with Domino Printer	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of Sticker Labeling Machine (Make: CVC) with Domino printer.

### 2.0 SCOPE:

This procedure is applicable to the Cleaning and Operation of Sticker Labeling Machine (Make: CVC) with Domino printer with in Production area.

### 3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation

Officer and Executive : Supervision of operation

Officer and Executive IPQA Person: Line Clearance and Supervision of operation

Head Production : SOP compliance

### 4.0 DEFINITION (S):

NA.

### 5.0 PROCEDURE:

#### 5.1 CLEANING:

5.1.1 Remove all material of previous product/batch from the machine.

5.1.2 Remove the "UNDER PROCESS" status label and affix "TO BE CLEANED" status label on machine with signature of production officer.

5.1.3 Remove all over printed Sticker labels and destroy them after reconciliation as per respective BPR.

5.1.4 Remove the release paper roll from the unwinding roller

5.1.5 Clean the unwinding rollers with 70% v/v IPA solution and with dry lint free cloth.

5.1.6 Clean all the sticky material from the label release plate with 70% v/v IPA solution.

5.1.7 Clean the sensor with dry cloth.

5.1.8 Clean the conveyor belt, bottle guide with wet cloth followed by lint free dry cloth.

5.1.9 Clean the wrapper round belt & bottle guide (rubber) with wet lint free cloth and remove all the sticky materials from there gently.

5.1.10 Wipe the SS machine covers with wet cloth followed by dry cloth.

#### 5.2 Cleaning for printing head

5.2.1 Remove the ink cartridge from the printing unit.

5.2.2 Clean the head of the ink cartridge with the help of lint free cloth.



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- 5.2.3 Store the ink cartridge in to the poly bag.
- 5.2.4 Frequency: At the end of process  
Status Labeling: - Affix "CLEANED" label on the machine as per SOP.
- 5.2.5 Record the details of cleaning of sticker labeling machine in equipment usage and cleaning log sheet as per SOP.

### 5.3 Machine set up and Operation:

- 5.3.1 Ensure that sticker labeling machine is cleaned.
- 5.3.2 Install the label roll on roll stand.
- 5.3.3 Bottle feed that feed one bottle from other and maintain the distance between two consecutive bottles.
- 5.3.4 Adjust bottle guide direct the bottle in a single direction.
- 5.3.5 Bottle label sensor sense the label and help in the dispensing.
- 5.3.6 Adjust the height of the label by adjusting the roller and guides with the help of rotating lever for up and down position of the label guide assembly.
- 5.3.7 Adjust the tightness of sticker roll ribbon from dancing roll spring and from stainless steel tension strip.
- 5.3.8 Switch on the machine and following screen will be displayed:



- 5.3.9 Login with the desired password as screen will display:-





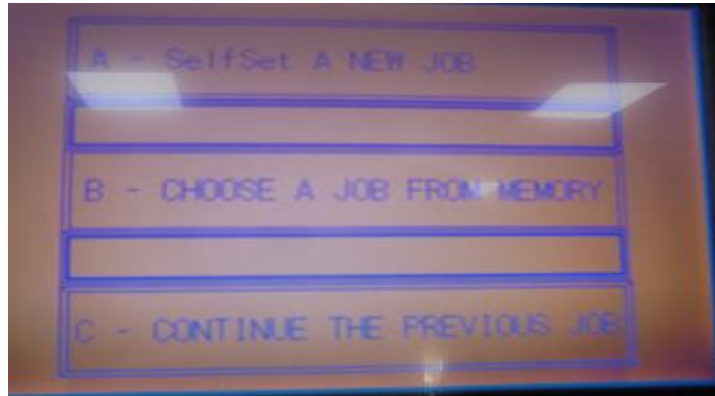
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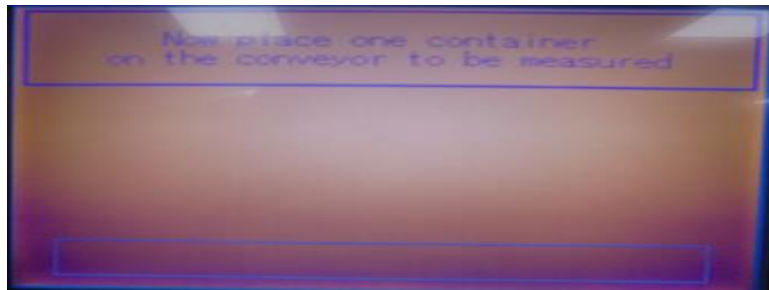
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5.3.10 Next screen will be shown as:-



5.3.11 Select the option A for setting of new product and screen will be displayed as follow:



5.3.12 Then place one container on the conveyor to be measured by the machine.

5.3.13 Then automatically machine will display as follow:



5.3.14 System will automatically sense the label and screen will be display as following:



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5.3.15 Then machine will display ready and screen will displayed as follow:



5.3.16 And home screen will be displayed as follow:



5.3.17 Press and hold  key to edit any parameters and screen will display as follow:





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5.3.18 Description of various parameters as listed below:-

S.No.	PARAMETER	DESCRIPTION
1.	OUTPUT/JOB	Total output of the machine
2.	LAB.REM.	Remaining label on the machine (not applicable).
3.	PROD.SP.D.	Current speed of the machine
4.	SEPRATE SPD.	Speed of the separator
5.	LAB.POS.	Label position on the machine
6.	PRINT TIME	Time of printing (not applicable)
7.	LAB. EXTENS	Extension of label if variance in label position observed
8.	LAB. HD-SPD.	Speed of the label output

5.3.19 After setting different parameters press SAVE MEM to save parameters.

5.3.20 Press OPTION B (refer point 5.3.10) and screen will display as follow:-



5.3.21 Select the desired recipe and press call memory to load the parameters and screen will display as follow:



5.3.22 Press OPTION C to run the previous loaded parameters of running batch (refer point 5.3.10) and screen will display as follow:-





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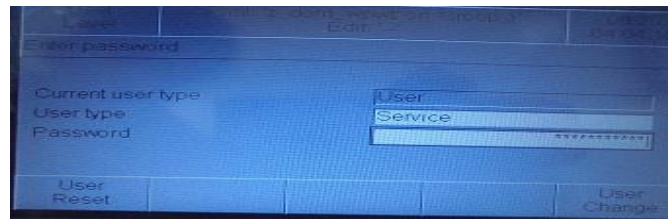


### 5.4 Procedure for creating the label in Domino Printer:


5.4.1 Switch "ON" the power supply of the printer controller unit screen will display as;



5.4.2 Press  key (lock) then screen will display as :



5.4.3 Select the field to select the user type 'SERVICE' and then enter password respectively then press 'user change'.

5.4.4 For creating a new message press  key and then press 'New Message' option. Press 'Definitions' option and set the value as per following table:




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S.No.	Parameter name	Description
1.	Message height	Height of each head is 12.7 mm
2.	Message width	Displays width of canvas (width can be changed as per requirement)
3.	Forward margin	Displays margin to be kept after starting of text.
4.	End margin	Displays margin to be kept after ending of text.
5.	Print start mode	Displays PRINT TYPE i.e. ENCODER base or sensor base(External)
6.	Print speed mode	Displays PRINT speed i.e. ENCODER base or sensor base (External)
7.	Production speed	It is the Velocity of the print (no need to set this value in case of encoder based system)
8.	Print direction	It displays in which direction we want to print i.e. left to right or right to left.
9.	# Of prints per object	Number of prints required on sensing of one object.
10.	Horizontal orientation	Its selection done as normal; and it depends on printing head mounting
11.	Vertical orientation	Its selection done as normal; and if head is operator side select it as mirrored.
12.	Horizontal resolution	300 dpi
13.	Vertical resolution	300 dpi




5.4.5 Enter the desired TEXT in the Data entry column by selecting the field with the help of arrow keys displayed on HMI as  and enter the words and numeric value with the help of Key pad on HMI.

5.4.6 After entering all parameters press ACCEPT NEW VALUES.

5.4.7 For starting second line again follows the point no. 5.5.4 and set the HORIZONTAL and VERTICAL value to set the position of the line (NOTE: If not done then both lines will superimpose on each other).

5.4.8 After entering all parameters press ACCEPT NEW VALUES.

5.4.9 Press on Save as option to save the label.

5.4.10 Then press on Load option to run the file. For starting and stopping the print we have to press  ,   
and .

### 5.5 Procedure for creating the message label required to print with Domino Printer.

5.5.1 Required message details to be overprint on sticker label as per instruction given in the respective batch packing record. Following details can be overprint on sticker label:

- Mfg. Lic. No.
- Batch No./Lot
- Mfg. Date
- Exp. Date.
- GTIN Number (If applicable).
- Serial Number (If applicable).
- 2D code (If applicable).



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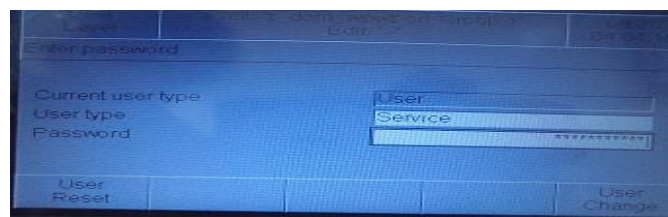
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5.5.2 Switch “ON” the power supply of the printer controller unit screen will display as;

S.No.	Parameter name	Description
1.	Message height	12.7 For single printing Head
2.	Message width	50 (width can be changed as per requirement)
3.	Forward margin	20 (margin can be changed as per requirement)
4.	End margin	0 (margin can be changed as per requirement)
5.	Delay after input intell, micropurge	0 (value can be changed as per requirement)
6.	Print start mode	External i.e. ENCODER base or sensor base (External or Internal)
7.	Print speed mode	External i.e. ENCODER base or sensor base (External or Internal)
8.	Production speed	10 (Value can be changes as per requirement)
9.	Speed Modification	0 (Value can be changes as per requirement)
10.	Space between the elements of message	0 (Value can be changes as per requirement)
11.	Distance between print	0 (Value can be changes as per requirement)
12.	# of prints per object	1 (Number of prints required on sensing of one object).
13.	Print Direction	Normal (Depends upon the printing head mounting).
14.	Horizontal orientation	Normal; it depends on printing head mounting
15.	Vertical orientation	Normal; if head is operator side then select it as mirrored.
16.	Horizontal resolution	300 dpi (Value may be changed as per requirement)
17.	Vertical resolution	300 dpi (Value may be changed as per requirement)



5.5.3 Press key (lock) then screen will display as:



5.5.4 Select the field to select the user type ‘SERVICE’ and then enter password respectively then press ‘user change’.

5.5.5 For creating a new message press key and then press ‘New Message’ option. Press ‘Definitions’ option and set the value as per table:






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5.5.6 Enter the desired TEXT in the Data entry column by selecting the field with the help of arrow keys displayed on HMI as  and enter the words and numeric value with the help of Key pad on HMI.

5.5.7 After entering all parameters press 'ACCEPT NEW VALUES'.

5.5.8 For starting second line again follows the point no. 5.6.4 and set the 'HORIZONTAL' and 'VERTICAL' value to set the position of the line. (NOTE: If not done then both lines will superimpose on each other).

5.5.9 After entering all parameters press 'ACCEPT NEW VALUES' for saving the new changes done in label.

### 5.5.10 Steps to create the identifier Batch field in label for Reetrak:

5.5.10.1 Press the 'Create new' filed option and then press the 'Variable Text' Option and set the values as per following:

S.No.	Field name	Parameter
1.	Field Name	Batch No.
2.	Horizontal Position	0
3.	Vertical Position	0
4.	Font	Ocrb/ocr-b-10bt
5.	Font Size	7 (Font size may change as per requirement)
6.	Font Style	Complete
7.	Rotation	No Rotation
8.	Negative Printing	No
9.	Chimney Tower Print	No
10.	Visible Print	Yes
11.	Default Size	20
12.	Mandatory data for vtext	No

5.5.10.2 Press 'Accept new value' option for adding the field in label.

5.5.10.3 Press 'Move' option to move the field, press Left, Right, Up and Down to move the field in label area.

5.5.10.4 Press 'Escape' option to fix the filed position in label area.

### 5.5.11 Steps to create the identifier Expiry field in label for Reetrak:

5.5.11.1 Press the 'Create new' filed option and then press the 'Variable Text' Option and set the values as per following:

S.No.	Field name	Parameter
1.	Field Name	EXP
2.	Horizontal Position	0
3.	Vertical Position	0
4.	Font	Ocrb/ocr-b-10bt
5.	Font Size	7 (can be change as per requirement)
6.	Font Style	Complete
7.	Rotation	No Rotation
8.	Negative Printing	No



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9.	Chimney Tower Print	No
10.	Visible Print	Yes
11.	Default Size	20
12.	Mandatory data for vtext	No

5.5.11.2 Press 'Accept new value' option for adding the field in label.

5.5.11.3 Press 'Move' option to move the field, press Left, Right, Up and Down to move the field in label area.

5.5.11.4 Press 'Escape' option to fix the filed position in label area.

### 5.5.12 Steps to create the identifier Expiry 2D field in label for Reetrak:

5.5.12.1 This field added if EXP field is needed to add in 2D Datamatrix barcode.

5.5.12.2 Press the 'Create new' filed option and then press the 'Variable Text' Option and set the values as per following:

S.No.	Field name	Parameter
1.	Field Name	EXP2D
2.	Horizontal Position	0
3.	Vertical Position	0
4.	Font	Ocrb/ocr-b-10bt
5.	Font Size	7 (can be change as per requirement)
6.	Font Style	Complete
7.	Rotation	No Rotation
8.	Negative Printing	No
9.	Chimney Tower Print	No
10.	Visible Print	No
11.	Default Size	20
12.	Mandatory data for vtext	No

5.5.12.3 Press 'Accept new value' option for adding the field in label.

5.5.12.4 Press 'Move' option to move the field, press Left, Right, Up and Down to move the field in label area.

5.5.12.5 Press 'Escape' option to fix the filed position in label area.

### 5.5.13 Steps to create the identifier GTIN field in label for Reetrak:

5.5.13.1 Press the 'Create new' filed option and then press the 'Variable Text' Option and set the values as per following:

S.No.	Field name	Parameter
1	Field Name	GTIN
2	Horizontal Position	0
3	Vertical Position	0
4	Font	Ocrb/ocr-b-10bt
5	Font Size	7 (Font size may change as per requirement)
6	Font Style	Complete



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7	Rotation	No Rotation
8	Negative Printing	No
9	Chimney Tower Print	No
10	Visible Print	Yes
11	Default Size	20
12	Mandatory data for vtext	No

5.5.13.2 Press 'Accept new value' option for adding the field in label.

5.5.13.3 Press 'Move' option to move the field, press Left, Right, Up and Down to move the field in label area.

5.5.13.4 Press 'Escape' option to fix the filed position in label area.

### 5.5.14 Steps to create the identifier Serial No. field in label for Reetrak:

5.5.14.1 Press the 'Create new' filed option and then press the 'Variable Text' Option and set the values as per following:

S.No.	Field name	Parameter
1.	Field Name	SERIAL
2.	Horizontal Position	0
3.	Vertical Position	0
4.	Font	Ocrb/ocr-b-10bt
5.	Font Size	7 (Font size may change as per requirement)
6.	Font Style	Complete
7.	Rotation	No Rotation
8.	Negative Printing	No
9.	Chimney Tower Print	No
10.	Visible Print	Yes
11.	Default Size	20
12.	Mandatory data for vtext	No

5.5.14.2 Press 'Accept new value' option for adding the field in label.

5.5.14.3 Press 'Move' option to move the field, press Left, Right, Up and Down to move the field in label area.

5.5.14.4 Press 'Escape' option to fix the filed position in label area.

### 5.5.15 Steps to create the 2D Datamatrix Barcode field in label for Reetrak:

5.5.15.1 Press the 'Create new' filed option and then press the 'Barcode' Option and then press '2D Barcode option' set the values as per following:

S.No.	Field name	Parameter
1.	Field Name	BARCODE
2.	Barcode Type	Datamatrix GS1-128
3.	Data Entry	<< Data to be entered in Barcode >> eg: 01#GTIN#17#EXP2D#10#LOT#<GS>21SERIAL#
4.	Horizontal Position	0



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5.	Vertical Position	0
6.	Coding Mode	Auto
7.	Symbol Size	26x26 (value may be changed as per requirement)
8.	Modify bar Height	2 (value may be changed as per requirement)
9.	Module Width	0.40 (value may be changed as per requirement)
10.	Font	Ocrb/ocr-b-10bt
11.	Rotation	No Rotation
12.	Negative Printing	No

5.5.15.2 Press 'Accept new value' option for adding the field in label.

5.5.15.3 Press 'Move' option to move the field, press Left, Right, Up and Down to move the field in label area.

5.5.15.4 Press 'Escape' option to fix the filed position in label area.

5.5.16 Press on 'Save as' option to save the label. Then press on Load option to run the file.

5.5.17 For starting and stopping the print we have to press  ,  and .

### 5.6 Precautions:

5.6.1 Do not take out Cartridge while machine is in ON conditions.

5.6.2 If machine displays cartridge ink level low change the cartridge if required.

5.6.3 For cleaning of cartridge always switch OFF the machine and use dry lint free cloth.

### 6.0 ABBREVIATION (S):

SOP: Standard Operating Procedure

HMI: Human Machine Interface

### 7.0 REFERENCE (S):

SOP: Status Labeling.

### 8.0 ANNEXURE (S):

NA

### 9.0 DISTRIBUTION:

**Master Copy** : Quality Assurance

**Controlled Copy (S)** : Production department, Quality Assurance

**Reference Copy (S)** : Production department