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1.0 OBJECTIVE:

To lay down a Procedure for Operation & Cleaning of Automatic Capsule Filling Machine (A-120) & it's Accessories.

2.0 SCOPE:

This SOP is applicable for Operation & Cleaning of Automatic Capsule Filling Machine (A-120) used in Hard Gelatin Capsule Section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
IPA	Isopropyl Alcohol
PLC	Programme Logic Controller
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 OPERATION:

6.1.1 Trial Run:

6.1.1.1 Before running the machine in auto or manual mode, run the machine for at least one complete rotation of the Turret Assembly by turning the hand wheel provided on the motor shaft. The brakes on the motor are electrical type and are to be made ON manually and then one can turn the Hand wheel of the machine to inch the machine manually.

6.1.1.2 If the trial run is found 'OK' then, run the machine electrically by operating the 'Machine Inch' function key on the screen.

6.1.1.3 If this is found O.K., then the machine is ready for normal operation. You can now safely run the machine in auto mode by pressing the Start key. Before pressing the Start key ensure that vacuum pump and blower are in ON condition.

6.1.2   Machine Preparation:

6.1.2.1 The Machine preparation consists of two operations.

6.1.2.2 Loading the Capsules in the Capsule Hopper (only in the absence of empty capsule sorter and elevator).

6.1.2.3 Filling the Product in the Product Hopper.

6.1.2.4 Filling of pellets into the pellet hopper during pellet filling.

6.1.2.5 Filling of Tablets into the respective tablet hopper during tablet filling.

6.1.2.6 The operator performs these before the Capsule filling process begins.

6.1.3   Machine Operation:

6.1.3.1 The main supply to the Machine is switched 'ON' and 'OFF' using a switch on the Panel box.

6.1.3.2 The 'R', 'Y' & 'B' lights indicate that the three phases are connected properly and the machine receives the proper power supply.

The machine can be operated in two modes viz.

i)   Manual Mode.

ii)   Auto Mode.

Operating the relative function keys on the screen one can do this selection.

6.1.4   Manual Mode:

The inching function of the entire machine can be viewed on the trouble shoot screen. The following functions are available

- Machine Inch
- Vacuum Pump ON/OFF
- Auger inch
- Blower ON/OFF
- Loader Solenoid Valve ON / OFF
- Tablet station 1 Inch
- Tablet station 2 Inch
- Tablet station 3 Inch

6.1.5   Auto Mode:

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- The machine checks for following healthy conditions before actually starting the machine:

- Motor Trip   :   No

- Door Limit Switches :   Closed

- Drive Fault   :   No

- Emergency Off   :   Released

- Powder Level   :   OK

- Capsule Level   :   OK

- Feeder motor   :   OK

- Vacuum pump   :   OK

- Tablet Station magazine with tablet: OK

- Pallet level   :   OK

In this mode, the machine will run automatically on touching the **'Start'** function key. The vacuum pumps and blowers are to switch ON individually.

Touching the **'Stop'** function key can stop the machine.
There is a provision of automatic alarm display on the screen. The **'Alarm status'** function key will display the error screen indicating the respective error.

Note: The emergency stop push button will stop the entire operation of the machine at any given time.

6.1.6   CONTROL PANEL:

6.1.6.1 The System: The machine is operated & controlled through Mitsubishi make PLC FX3GE with 16 Digital Inputs and 14 Digital Outputs controls the Fully Automatic Capsule Filling Machine. The operator interface consists of Mitsubishi make touch panel (E1061) is used for Message display and Data Entry.

The PLC and variable frequency drive with all the power control are mounted inside the machine stand. The speed of the machine can be varied on the parameter screen in HMI. All the other operational systems are provided on the swing panel and HMI.

6.1.7   Operations and Controls:
The function keys of the HMI on the operating panel control all the machine operations

(1) Main Screen:

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On the main screen the following function keys are displayed:

(a) **Login**: On pressing this key, a keypad is displayed to enter the password for accessing the respective security level. The passwords are defined as follows:-

- Security level 1 – '1234.'

- Security level 2 – '2345'

- Security level 3 – '3456'

(b) **Logout**: On pressing this key the access to respective security level is logged out (denied).

(c) **Auto**: On pressing this key Auto mode is selected and auto function screen is displayed. On pressing the same key on the main screen, auto screen is deselected. This key is password protected with security level 2.

(d) **Manual**: On pressing this key Manual mode is selected and manual function screen is displayed. On pressing the same key on the main screen, manual mode is deselected. This key is password protected with the security level 1.

(e) **Alarm**: The alarm status screen is displayed when this key is pressed. The alarm present if any is displayed on this screen.

(f) **Troubleshoot**: On pressing this key, input and output status screen is displayed

(g) **Data Entry**: On pressing this key the data entry screen is displayed, this screen contains the settable parameters required for the operation of the machine. This key is password protected with the security level 3.

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(h)   **Auto setting**: On pressing this key the Auto function screen is displayed, this **screen** contains the settable parameters required for the operation of the machine. This key is password protected with the security level 3.

(2) Auto Function Screen:- The following screen is displayed on pressing the Auto key on the main screen after entering the password for security level 2.

In the auto mode the following function keys are displayed:

(a)   **Start**: On pressing this key machine starts in auto mode. The vacuum pump and blower are started with the machine

(b)   **Stop**: On pressing this key machine stops functioning.

(c)   **Take Sample**: The sampling action starts only after this key is pressed.

(d)   **Sample**: This key is used for selecting auto sampling or manual sampling. The status of the sampling procedure selected will be displayed besides the key. In manual sampling, sampling of the selected segment will take place after pressing TAKE SAMPLE key once. In auto sampling, sampling of all 10 segments will take place in 10 rotations of the turret. The process of auto sampling will take place after pressing TAKE SAMPLE key once.

(e)   **Loader SOV**: This key is used to ON / OFF the pneumatic cylinder for starting the loading of the capsule from the magazine to the raceway.

(f)   **Main**: Main screen will be displayed when HOME key is pressed on the auto mode screen.

(g)   **Time Reset**: This key is protected with password for security level 3. A separate reset keys are provided for resetting the machine run time. This key is functional when machine is in stop condition and this key is pressed for more than 3 sec.

(h)   **Day prod. Reset**: This key is protected with password for security level 3. A separate reset keys are provided for resetting the day production count. This key is functional when machine is in stop condition and this key is pressed for more than 3 sec.

(i)   **Total prod. Reset**: This key is protected with password for security level 3. A separate reset keys are provided for resetting the total production count. This key is functional when machine is in stop condition and this key is pressed for more than 3 sec.
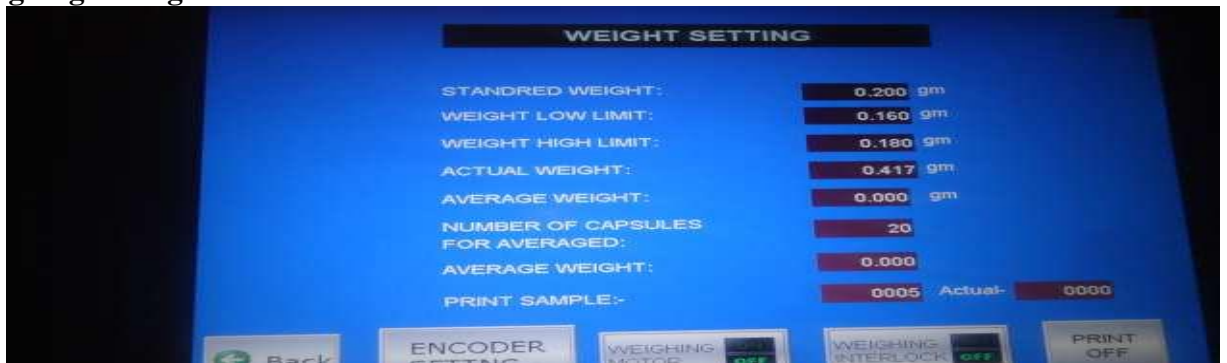
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3) Weighing setting screen:

(4) Manual Function Screen

This screen is displayed on pressing the manual key on the main screen after entering the password for security level 1

In the manual mode the following function keys are displayed:

a) **Vacuum Pump**: The Vacuum Pump is switched ON in manual mode when this function key is pressed and is made OFF when the same key is pressed again.

b) **Blower ON/OFF**: The blower can be switched ON in manual mode when this function key is pressed and is switched OFF when the same key is pressed again (Blowers are not supplied by anchor mark as per NO SCOPE OF SUPPLY).

c) **Loader 1 SOV:** This key is used to ON / OFF the pneumatic cylinder for starting the loading of capsules from the loader assembly.

d) **Machine Inch**: The machine can be operated in inch mode till the key is pressed.

e) **Auger motor Inch:** Powder Auger motor can be operated in inch mode till the key is pressed.

f) **TAB 1 Inch:** Tablet station 1 feeding vibrator can be operated in inch mode till the key is pressed.

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g) **TAB2 Inch:** Tablet station 2 feeding vibrator can be operated in inch mode till the key is pressed.

h) **TAB3 Inch:** Tablet station 3 feeding vibrator can be operated in inch mode till the key is pressed.

i) **Alarm Status**: The alarm status screen is displayed when this key is pressed. The alarm present if any is displayed on this screen.

j) **Main**: When this key is pressed, main screen is displayed.

k) **Logout**: When this key is pressed, operator will be log out & HMI screen will be locked.

(5) Alarm Status Screen

The following screen is displayed when alarm key is pressed on the main screen.

- If any of the alarms have occurred then it will be displayed on the screen.

- The alarm will be displayed along with the '*' sign. Acknowledging of the alarm by pressing '√'.key on the screen.

- After acknowledging the alarm, if the alarm is active then '-'sign will be present in place of '*' and if the alarm is inactive no sign will be present.

- On pressing the 'OFF' key, the hooter is made OFF.

- On pressing the zoom symbol key, the font size of the alarm text is zoomed in or zoomed out.
- On pressing the watch symbol key, the time of alarm occurrence is displayed on the screen.

- Data Entry Screen.

6.1.8   Alarm Info Screen (Corrective Action Plans)

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- The following Alarm Info screen will be displayed in case of Emergency Push button pressed & Alarm Info key is pressed on Alarm screen.

- The following Alarm Info screen will be displayed incase of Air pressure is Low/High & Alarm Info key is pressed on Alarm screen.

- The following Alarm Info screen will be displayed incase of Vacuum pump motor / blower motor / auger motor trip & Alarm Info key is pressed on Alarm screen
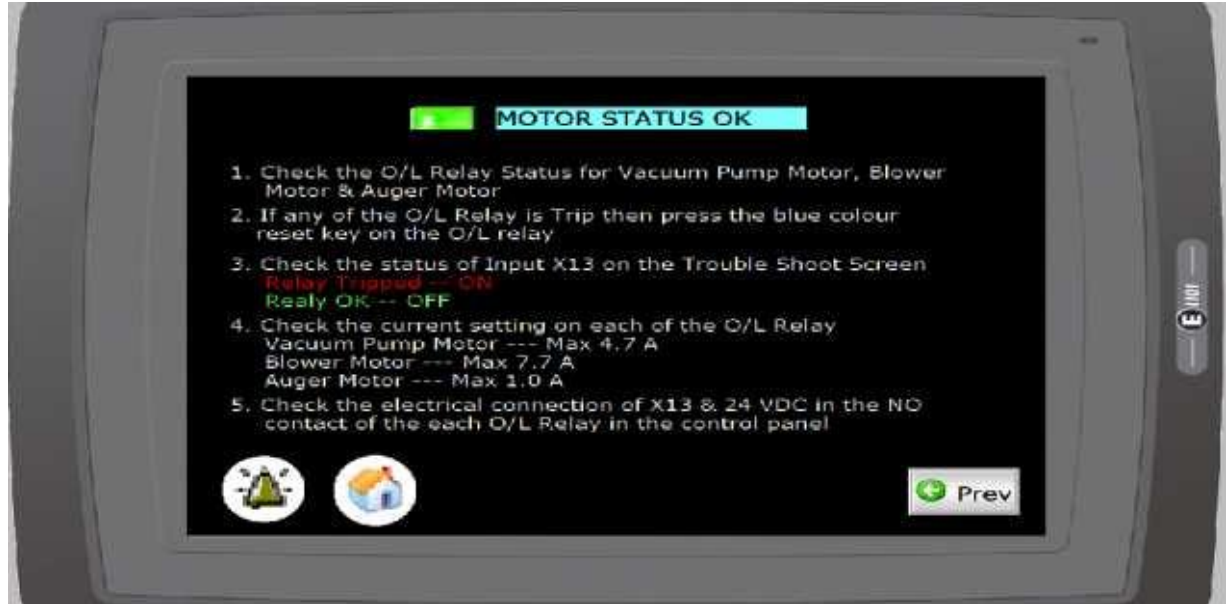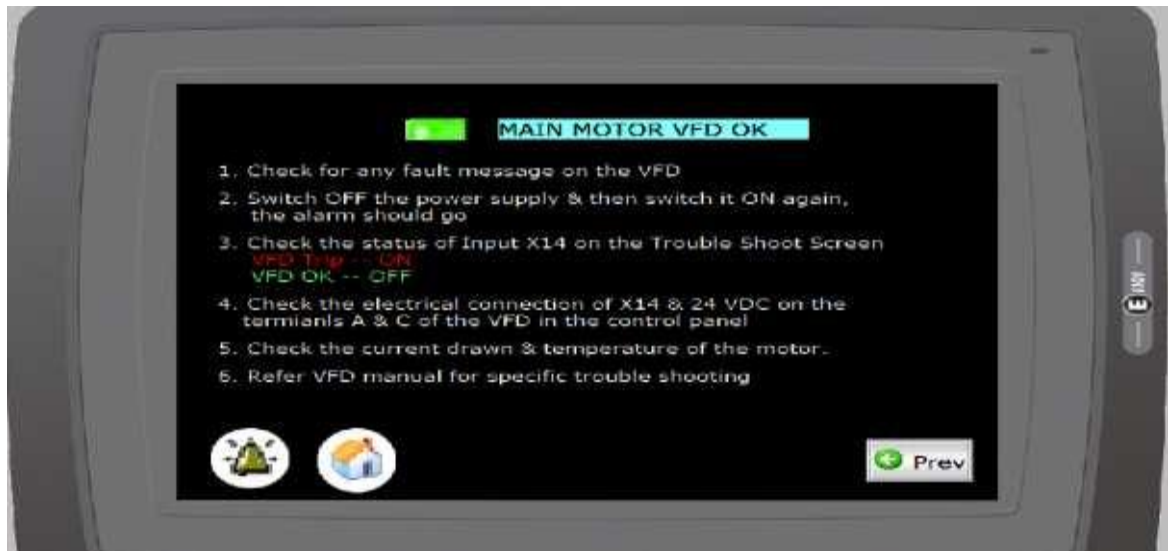
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- The following Alarm Info screen will be displayed incase of Main motor VFD fault & Alarm Info key is pressed on Alarm screen

- The following Alarm Info screen will be displayed incase of Capsule level is low in the capsule hopper & Alarm Info key is pressed on Alarm screen
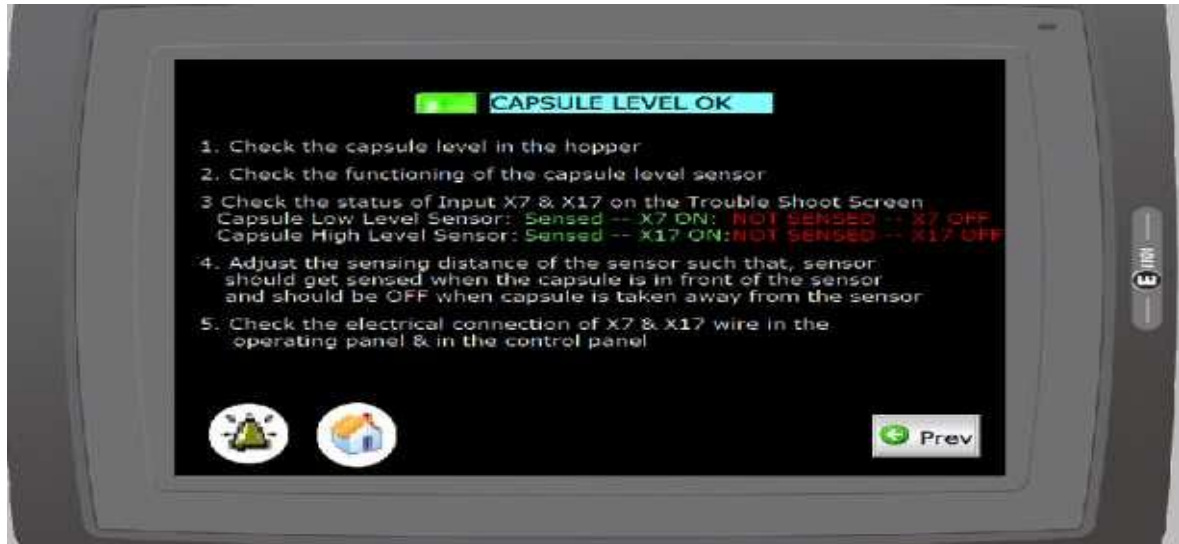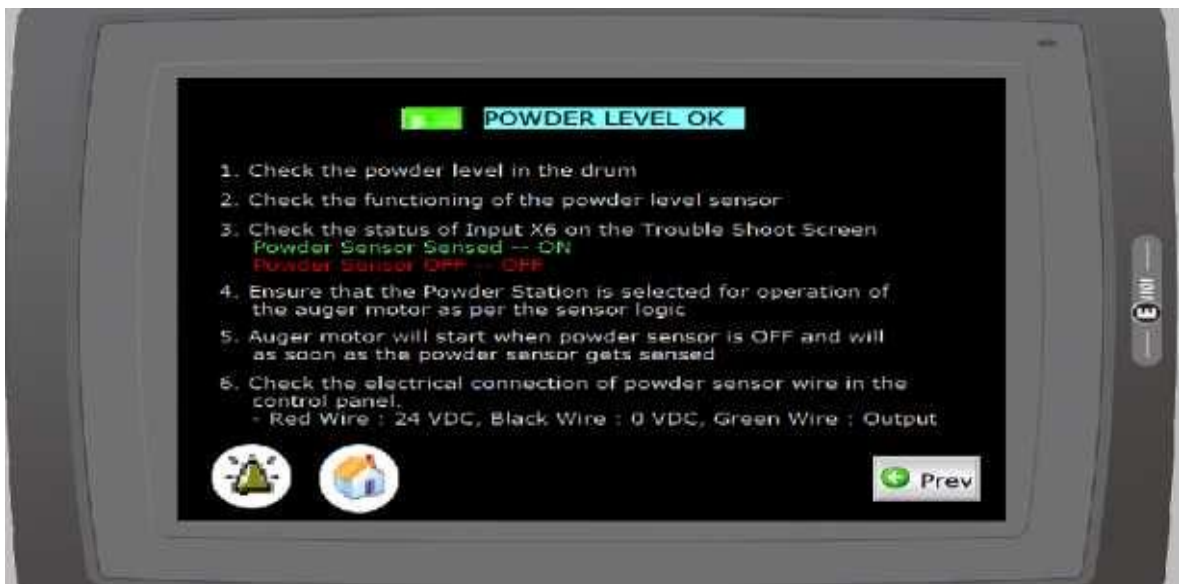
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- The following Alarm Info screen will be displayed incase of Powder level is low in the powder hopper & Alarm Info key is pressed on Alarm screen.

- The following Alarm Info screen will be displayed incase of safety door is open & Alarm Info key is pressed on Alarm screen
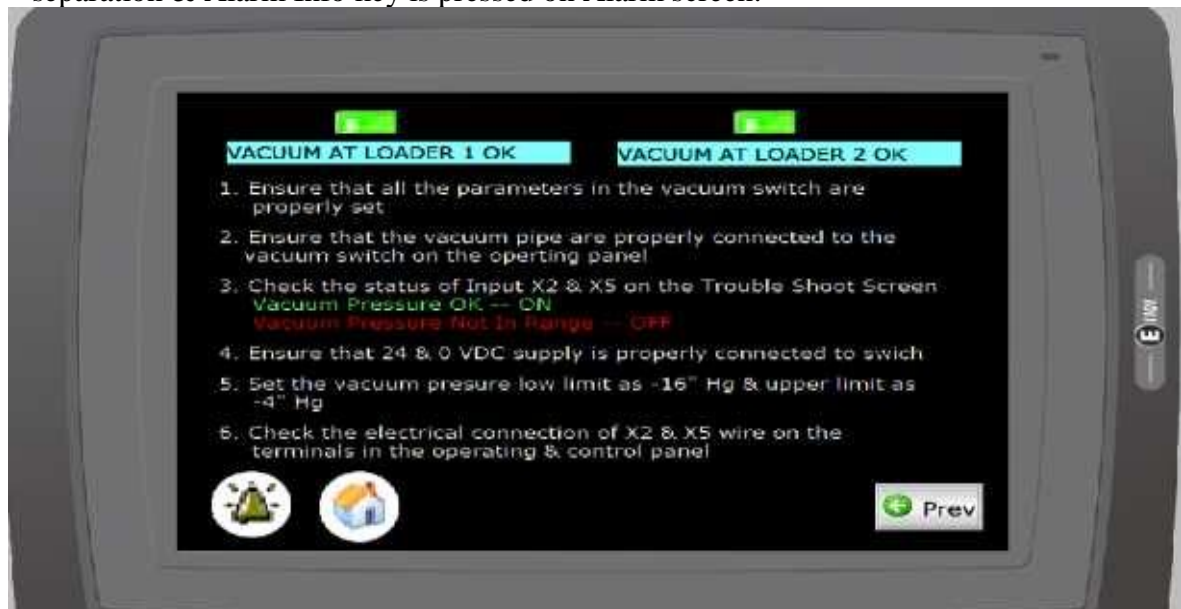
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- The following Alarm Info screen will be displayed incase of Vacuum level is low for separation & Alarm Info key is pressed on Alarm screen.
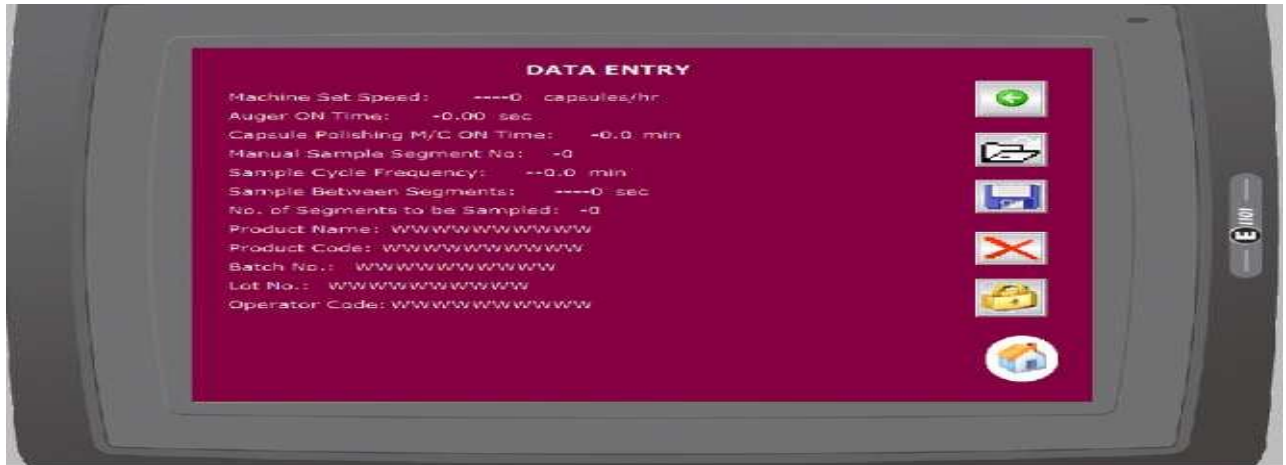

Interlock

(6) Data Entry Screen

- The following screen is displayed when Data Entry key is pressed on the main screen after entering the password for security level 3.

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- The following settable parameters are provided on the Data Entry Screen of HMI.

a) **Machine Speed**: It is the speed at which the machine runs in auto mode.

b) **Auger ON Time**: Is the time delay for the auger motor to stop after the powder sensor has sensed the powder.

c) **Cap. Polishing ON Time**: It is the time for which capsule polishing machine remains ON in auto mode after the capsule filling machine is stopped in auto mode.

d) **Man. Sample Segment No.** : It is the segment number which is to be sampled in manual mode.

e) **Sample Cycle Frequency**: It is the time interval between the two sampling cycles in auto mode.

f) **Sample between Segments**: It is time interval between the two consecutive segments to be sampled.

- No. of segments to be sampled is the number of segments that will be sampled in succession once the sampling bit is ON and will remain ON till the set number of segments are sampled.

- Additional information regarding the Product Code, Product Name, Batch No., Lot No., and Operator Code can be entered for the given recipe.

The following function keys are provided on the Data Entry Screen

(a) Load   : This key is used to load the required recipe for operating the machine in auto mode.

(b) Save   : This key is used to save the recipe. On pressing this key, it prompts either "Replace Existing" or "Save as New'. On selecting the required function, the recipe is saved.

(c) Delete : This key is used to delete the selected recipe.

(d) Logout: This key is used to logout from the existing security level.

(e) Main   : This key is used to view the main screen.

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(f) Previous Screen: This key is used to view the previous screen.

(7) TROUBLE SHOOT SCREEN

- The INPUT / OUTPUT & the Interlock status is displayed when the trouble shoot key is pressed on the main screen.

- The INPUT SCREEN shows the details of the input status. When any input is ON, it displays ON before the input text and if it is OFF then it displays OFF.

- The OUTPUT SCREEN shows the status of the outputs. When any output is ON, it displays ON before the output text and if it is OFF then it displays OFF.

- The Interlock SCREEN shows the status of the Interlocks. When any interlock is not working proper, it displays RED indication before the Interlock text and if it is OK then it displays GREEN.

- On pressing the PREV key the previous screen is displayed.

- On pressing the HOME key Main screen is displayed.

- INPUT Screen 2-

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INPUT Screen 3-
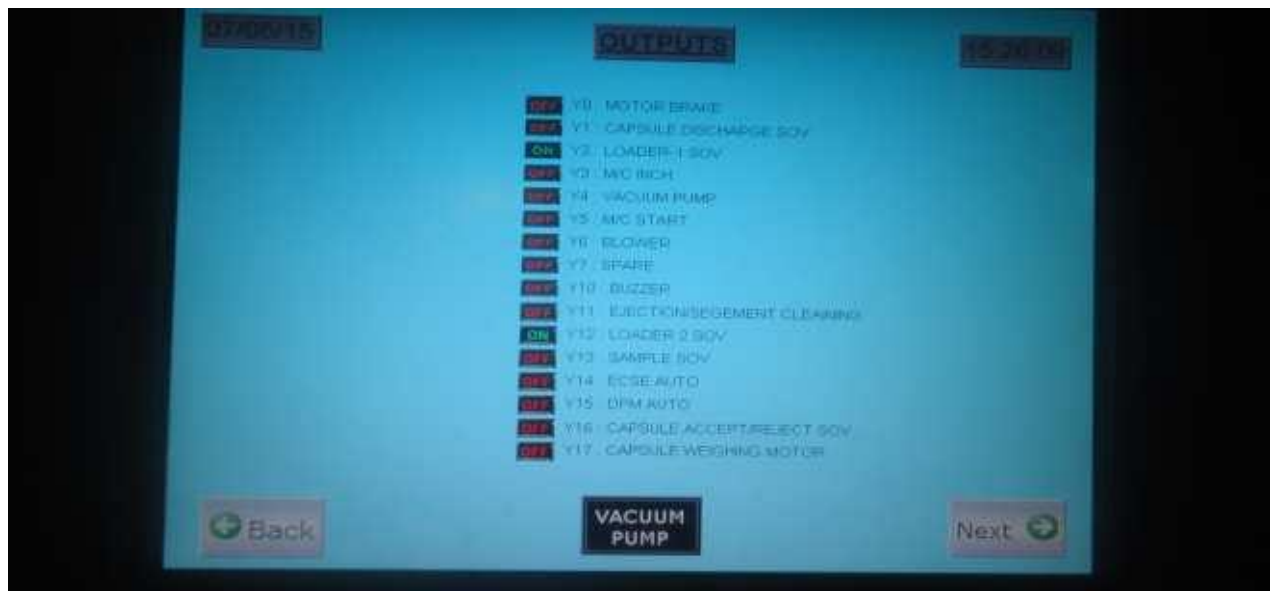
Input Screen 3

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Input Screen 4

6.2   CLEANING:

6.2.1   CLEANING OF SORTER ELEVATOR:

6.2.1.1 Switch "OFF" the machine by turning the isolator switch to "OFF" position.

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6.2.1.2 Open the lid of the hopper and remove the empty capsule shells & collect in double polythene bag.

6.2.1.3 Remove the capsules from sorting plate with the help of forceps.

6.2.1.4 Remove the capsules from ventury pipe, discharge tube & delivery chute if any.

6.2.1.5 Remove the capsules from collection box.

6.2.1.6 Clean the machine using Vacuum Cleaner.

6.2.1.7 Wipe the machine with clean lint free cloth and affix the label as "Cleaned"

6.2.2   Cleaning of filling, De-dusting & Polishing machine, Mini filled capsule sorter & Empty capsule sorter:

6.2.2.1 For Product Changeover (Type B Cleaning):

6.2.2.1.1 Switch 'OFF' the electric supply to the machine & accessories.

6.2.2.1.2 Dismantle all Accessories, clean with Vacuum Cleaner & take to washing area by placing in a caret.

6.2.2.1.3 Clean the machine platform, doors and other non removable parts with Vacuum Cleaner. Mop with 70 % isopropyl alcohol (prepare by adding 70 ml isopropyl alcohol in 30 ml purified water).

6.2.2.1.4 Clean the Accessories with 2% solution of Extran MA-02 using nylon brush.

6.2.2.1.5 Wash thoroughly with potable water followed by rinse with purified water.

6.2.2.1.6 Wipe the all Accessories with clean lint free cloth.

6.2.2.1.7 Finally mop with 70 % isopropyl alcohol.

6.2.2.1.8 QA shall collect the swab sample with intimation slip/ analysis report & send to QC for analysis.

6.2.2.1.9 Use the machine after receiving swab test intimation slip cum analysis report from QC showing negative identification.

6.2.2.1.10 If report shows positive identification then follow points **(6.2.2.4)** to **(6.2.2.9).**

6.2.2.1.11 Enter the cleaning details in "Machine Utilization Record".

6.2.2.1.12 Affix a label as "Cleaned" on the machine.

6.2.2.2 For Batch Changeover (Type A Cleaning):

6.2.2.2.1 Clean the holder plates & top surface of the table with a brush to remove the powder use vacuum to suck off the powder.

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6.2.2.2.2 Clean all cap holders & body holders with nylon brush.

6.2.2.2.3 Clean the tamping pins with wet cloth & dosing disc by nylon brush.

6.2.2.2.4 Remove all the powder form the drug hopper by vacuum.

6.2.2.2.5 Clean all the accessories by using Vacuum Cleaner.

6.2.2.2.6 Finally clean all the parts with clean dry lint free cloth.

6.2.2.2.7 Cleaning of vacuum pump & filter:

6.2.2.2.7.1 Loose the screw & open the housing cover.

6.2.2.2.7.2 Remove the powder from the housing and collect in a polythene bag.

6.2.2.2.7.3 Clean the filter with compressed air.

6.2.2.2.8 Cleaning of air displacement unit:

6.2.2.2.8.1 Agitate the filter bag by pressing the knob at the top of the assembly.

6.2.2.2.8.2 Remove the powder from the bag collect in polythene bag and destroy as per SOP "Destruction Procedure of Rejected In-process Materials and In-process Samples".

6.2.2.2.8.3 Wash the filter bag with purified water and dry with compressed air.

6.2.2.2.9 Cleaning of filter ring of empty capsule sorter:

6.2.2.2.9.1 Remove the sorting device & open the filter ring by loosing the screw.

6.2.2.2.9.2 Clean the filter ring using Vacuum Cleaner and reinstall.

6.2.2.2.9.3 Enter the cleaning details in "Machine Utilization Record".

6.2.2.2.9.4 Affix a label as "Cleaned" on the machine.

6.2.2.2.10 Frequency of Cleaning:

6.2.2.2.10.1 Frequency of cleaning as per step-**6.2.2.1**

(a) Product to Product Changeover.

(b) If cleaned equipment is kept idle for more than the hold time.

(c) After 5 batch of the same product.

(d) After any Maintenance of Contact Parts.

(e) Changeover of one Batch to Next Batch of the same Product with descending potency.

(f) In case of colour change (any strength).

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6.2.2.2.11 Frequency of cleaning as per step-**6.2.2.2**

(a) Changeover from one Batch to Next Batch of the same Product with same potency.

(b) Changeover from one batch to next Batch of the same Product with Higher Potency.

7.0   ANNEXURES:

Not Applicable

ENCLOSURES: SOP Training Record

8.0   DISTRIBUTION:

- Controlled Copy No. 01   Quality Assurance
- Controlled Copy No. 02   Production
- Master Copy   Quality Assurance

9.0   REFERENCES:

Operating Manual

10.0   REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By