



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Cotton Inserter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1. To lay down a procedure for cleaning and Operation of cotton Inserter.

2.0 SCOPE:

2.1. This procedure is applicable for the cleaning and Operation of Cotton Inserter machine in production area.

3.0 RESPONSIBILITY:

3.1. Technical Associate : Cleaning and Operation

3.2. Production Officer / Executive : Supervision

3.3. Head Production : SOP Compliance

3.4. IPQA Person : Line Clearance

4.0 DEFINITION (S):

4.1. NA

5.0 PROCEDURE:

5.1. CLEANING:

5.1.1. Ensure that all the material of previous product are removed from packing cubicle.

5.1.2. Remove the "UNDER PROCESS" label and affix "UNDER CLEANING" label on machine with date and sign of production officer.

5.1.3. Switch "OFF" all the utility supply before cleaning.

5.1.4. Clean the control panel with dry lint free cloth.

5.1.5. Clean the top and outer S.S. surface of machine by 70% v/v IPA solution using lint free cloth.

5.1.6. Open guard and clean inside surface of the machine, hopper and its assembly by 70% v/v IPA solution using lint free cloth.

5.1.7. Replace the "UNDER CLEANING" status label by "CLEANED" status label on the machine with date and sign of production officer.

5.1.8. Record the cleaning activity in equipment usage log as per SOP.

5.1.9. Clean the surrounding area as per SOP.

5.2. OPERATING PROCEDURE:

5.2.1. Switch "ON" the power supply, the following screen will be displayed:

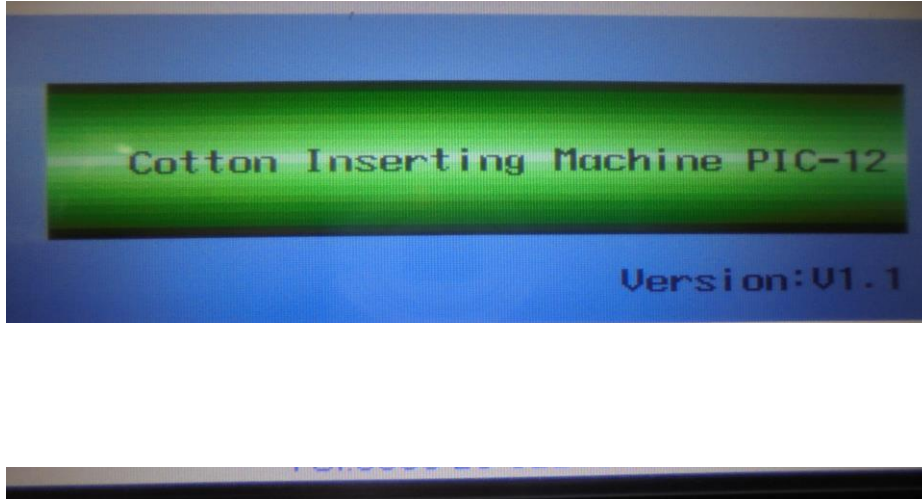


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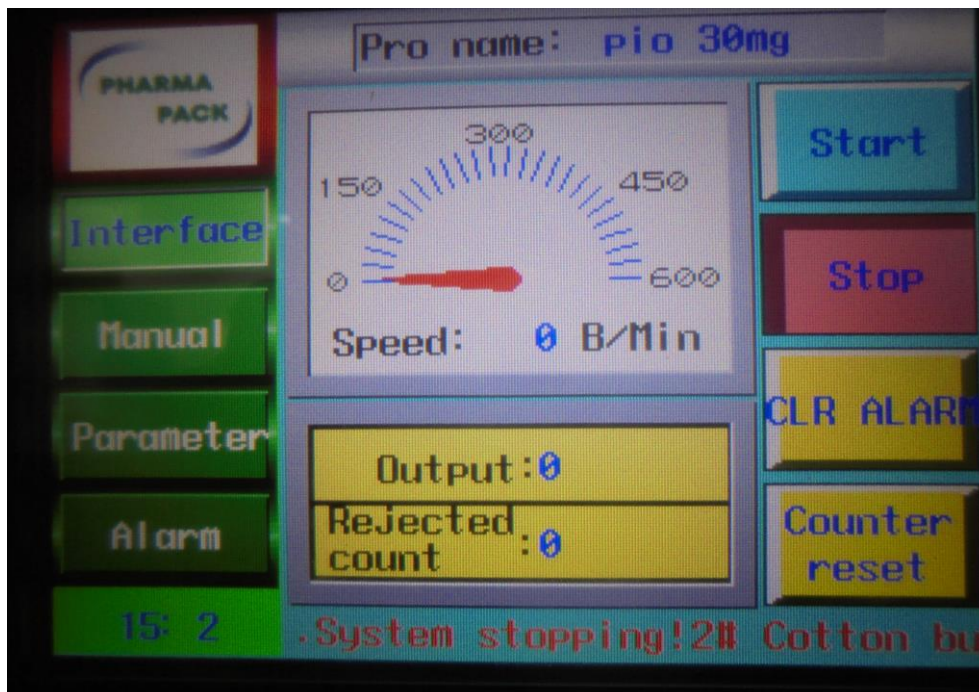
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5.2.2. Three different user has different rights assignment as mentioned below:

S.No.	Type of Functions	User Rights Assignment(Y/N)		
		Operator	Supervisor	Administrator (Production Head)
1.	RUN/STOP machine	Y	Y	Y
2.	Parameters Setting	N	Y	Y
3.	Change Password	N	N	Y

5.2.3. Click the first interface, input the password, then comes to main operation interface:





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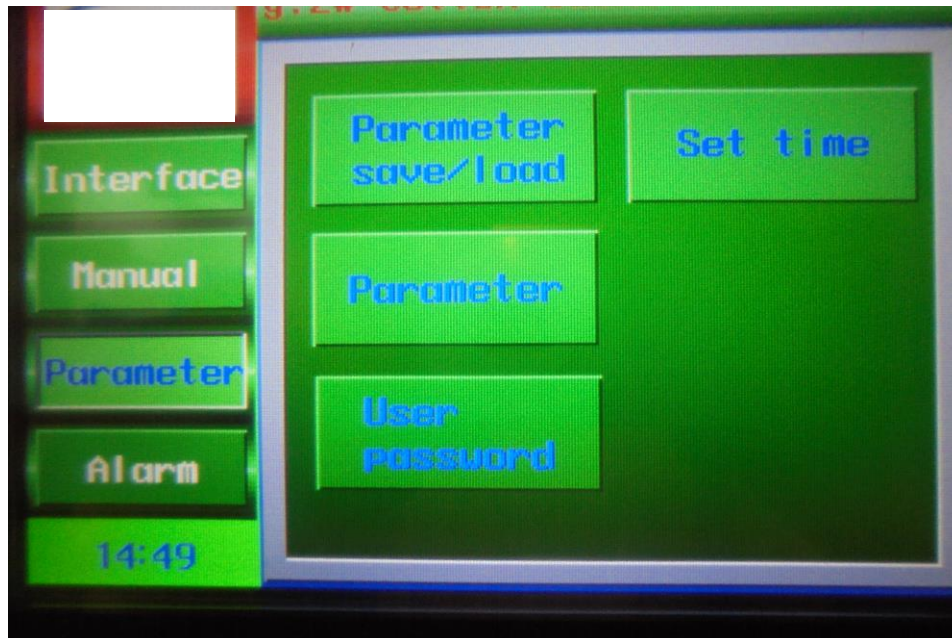
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- 5.2.3.1. Click button[Interface],[Manual],[Parameter],[Alarm] to switch to different interface:
- 5.2.3.2. Click button {Start}, or {Stop} and machine automatically start up or stop.
- 5.2.3.3. Output: Display the total output.
- 5.2.3.4. Speed: Display output per minute when machine automatically run.
- 5.2.3.5. Rejection count: Count the rejection count.
- 5.2.3.6. Clear alarm: Clear the alarm information.
- 5.2.3.7. Counter reset: Clear the output amount.
- 5.2.3.8. The bottom of the interface dynamically displays alarm information of the machine.

5.2.4. Parameter interface:



- 5.2.4.1. Machine function interface:
- 5.2.4.2. Press [Parameter save/load], switch to parameter save/load interface.
- 5.2.4.3. Press [Set parameter], switch to parameter setting interface.
- 5.2.4.4. Press [User password], switch to set time interface.
- 5.2.4.5. Press [Set time], switch to set time interface.
- 5.2.4.6. Press [view parameter], switch to parameter display interface.

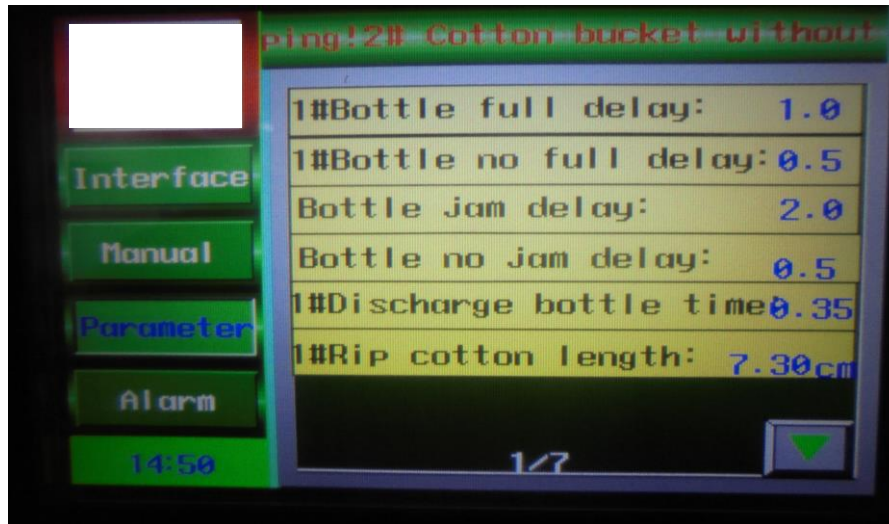


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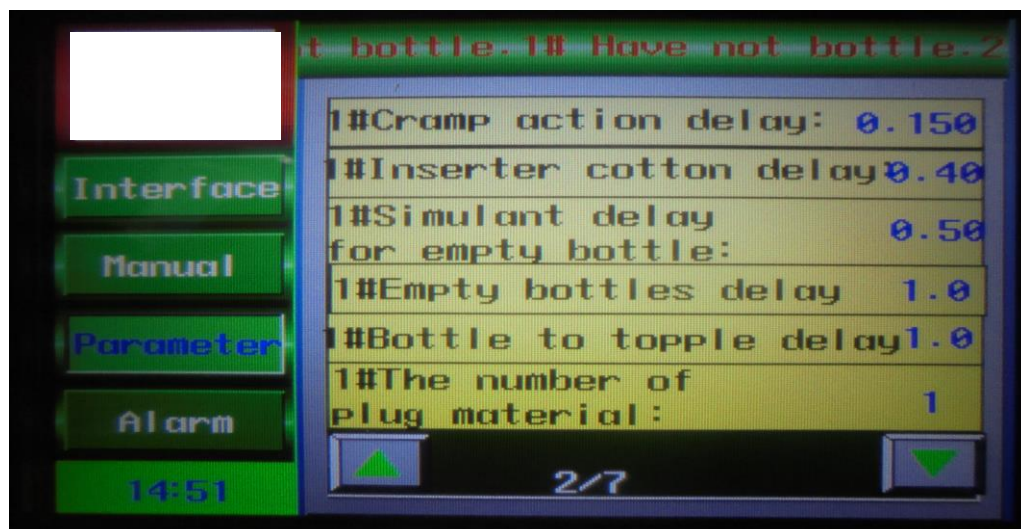
Parameter setting:

5.2.5. **Set parameter 1:**



- 5.2.5.1. Bottle full delay: time for detecting the bottle at entrance.
- 5.2.5.2. Bottle no full delay: time for not detecting the bottle at entrance.
- 5.2.5.3. Bottle jam delay: time for detecting bottle jam at exit.
- 5.2.5.4. Bottle no jam delay: time for detecting bottle no jam at exit.
- 5.2.5.5. Discharge bottle delay: time for location cylinder locating bottle.
- 5.2.5.6. Rip cotton length: The length of ripped cotton.

5.2.6. **Set parameter 2:**



- 5.2.6.1. The number of plug material: set bags amount of desiccant in each bottle.



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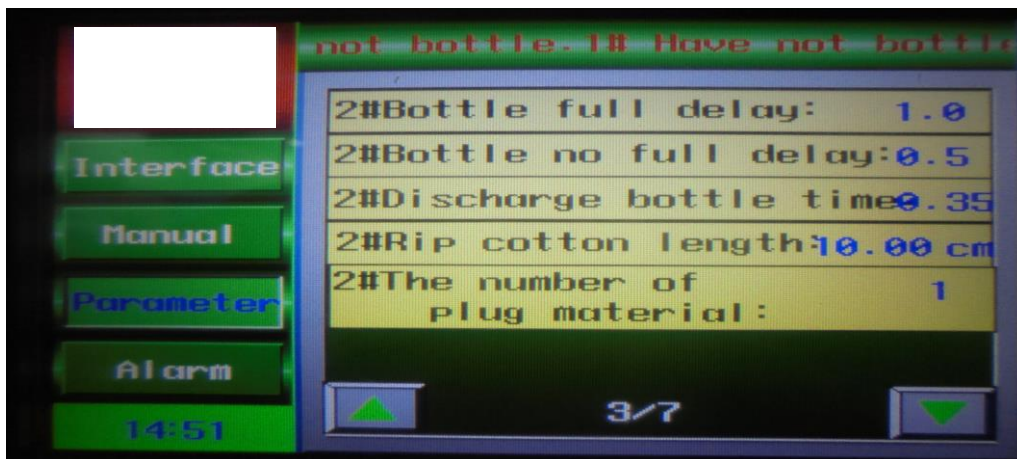
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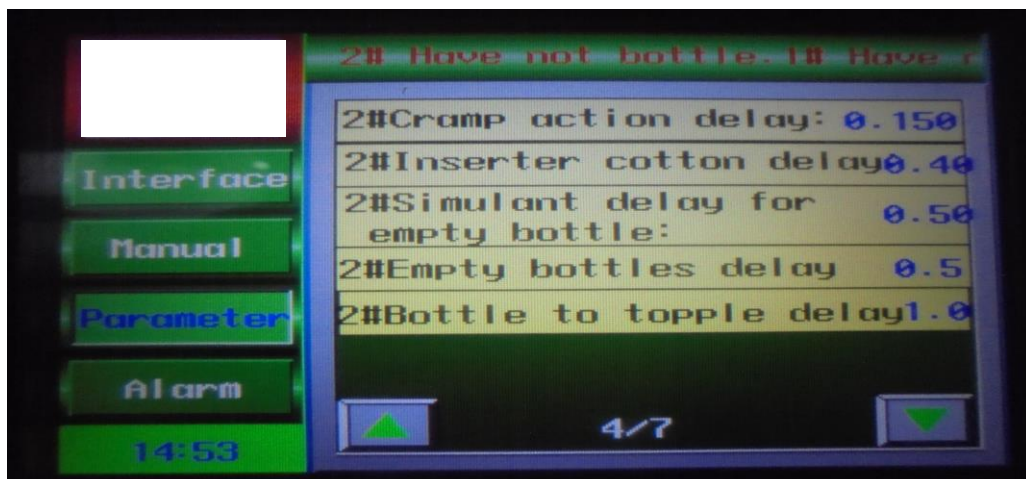
- 5.2.6.2. Continuous no cotton quantity: the quantity of no cotton.
- 5.2.6.3. Inserting machine cotton delay: delay time for cotton insertion.
- 5.2.6.4. Stimulant delay for empty bottle: stimulant time for in feeding empty bottle.
- 5.2.6.5. Reject delay: time for delay reject bottle.
- 5.2.6.6. Reject action delay: time for reject cylinder.

5.2.7. Set parameter 3:



- 5.2.7.1. 1#Turnable motor speed;1#Cotton inserter machine turntable motor speed.
- 5.2.7.2. 2#Turnable motor speed;2#Cotton inserter machine turntable motor speed.
- 5.2.7.3. 1#Discharge bottle ahead of time;1#cotton inserter infeed bottle ahead of time.
- 5.2.7.4. 2#Discharge bottle ahead of time;2#cotton inserter infeed bottle ahead of time.:
- 5.2.7.5. Set value: set the product quantity.

5.2.7.6. Set parameter 4:



- 5.2.7.7. Left bottle jam delay: left side full bottle detect time.

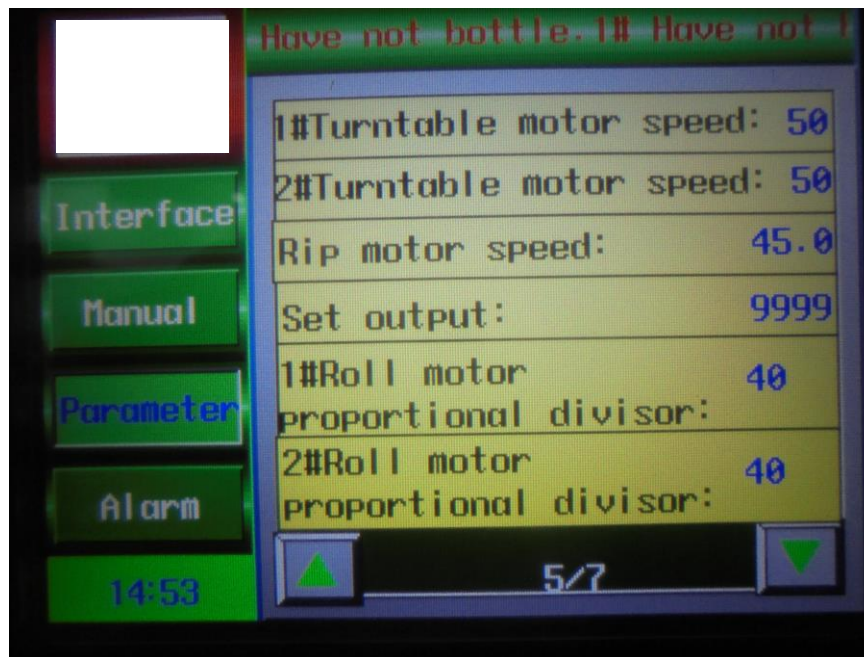


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- 5.2.7.8. Left bottle no jam delay: left side bottle no jam detect time.
- 5.2.7.9. Right bottle jam delay: right side full bottle detect time.
- 5.2.7.10. Right bottle no jam delay: right side bottle no jam detect time.
- 5.2.7.11. 1#bottle to topple delay:1#cotton inserter bottle down delay time.
- 5.2.7.12. 2#bottle to topple delay:2#cotton inserter bottle down delay time.

5.2.8. Set parameter 5



- 5.2.8.1. 1#Reject delay pulse count:1#cotton inserter reject movement delay pulse number, encoder synchronous switch on is valid.
- 5.2.8.2. 2#Reject delay pulse count:2#cotton inserter reject movement delay pulse pulse number, encoder synchronous switch on is valid.
- 5.2.8.3. 1#Reject action pulse count:1#cotton inserter reject movement delay pulse pulse number, encoder synchronous switch on is valid.
- 5.2.8.4. 2#Reject action pulse count:2#cotton inserter reject movement delay pulse pulse number, encoder synchronous switch on is valid.
- 5.2.8.5. 1#Discharge bottle pulse count:1#cotton inserter reject movement delay pulse pulse number, encoder synchronous switch on is valid.
- 5.2.8.6. 2#Discharge bottle pulse count:2#cotton inserter reject movement delay pulse pulse number, encoder synchronous switch on is valid.

5.2.9. Option set for selector switch:

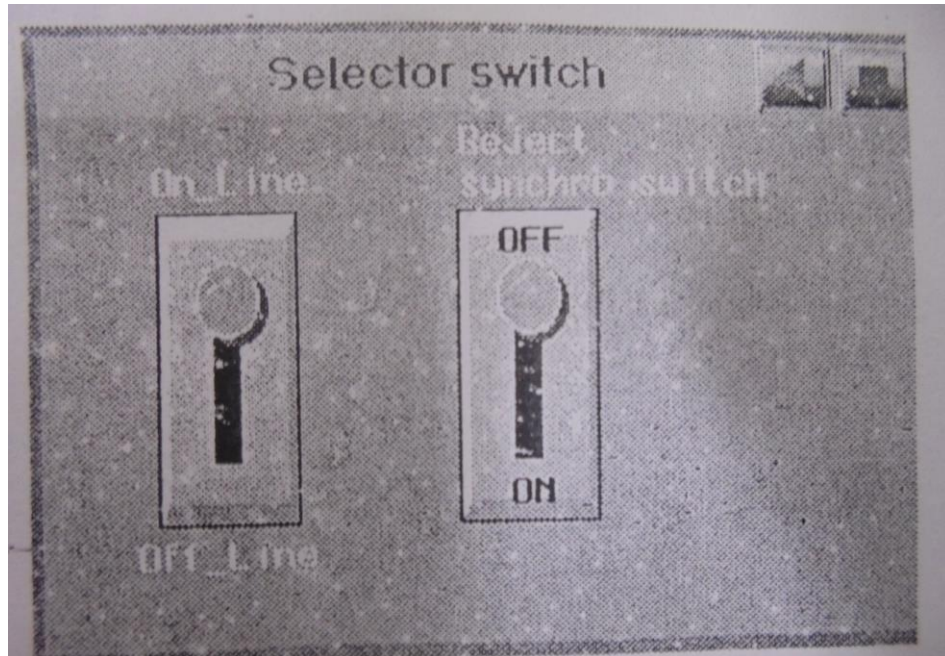


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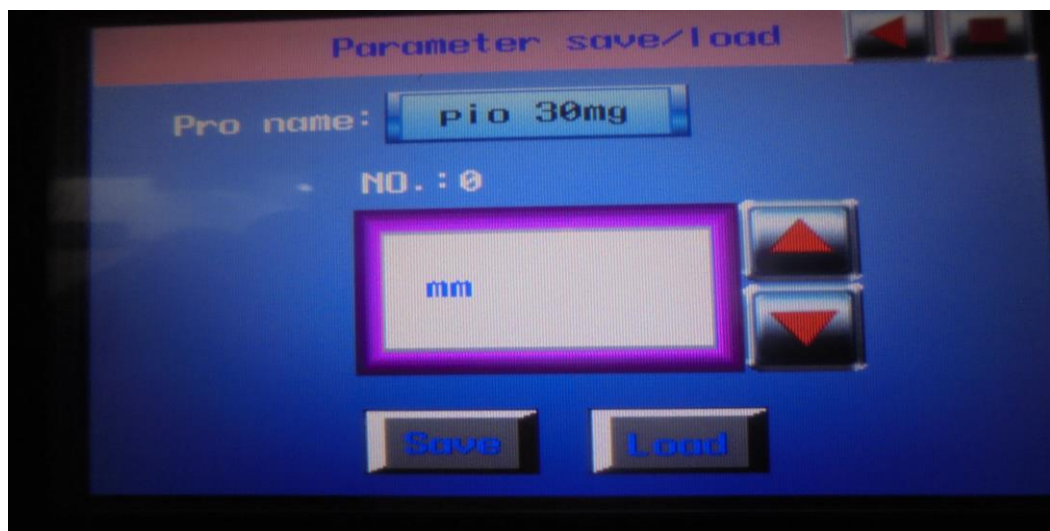
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5.2.9.1. When selector switch is 'Off-line', the machine can automatically run without conveyor working and when it is ON- line, the machine can work only if conveyor starts.

5.2.9.2. When reject synchro switch is "ON", encoder synchronous switch "ON" is valid.

5.2.10. Parameter save/load:



5.2.10.1. On manual operation interface, unlock bottle, plug, plug cotton, rip cotton reject and jog turntable, reset turntable and circulating single step can be conducting separately. For doing machine setting followed as:



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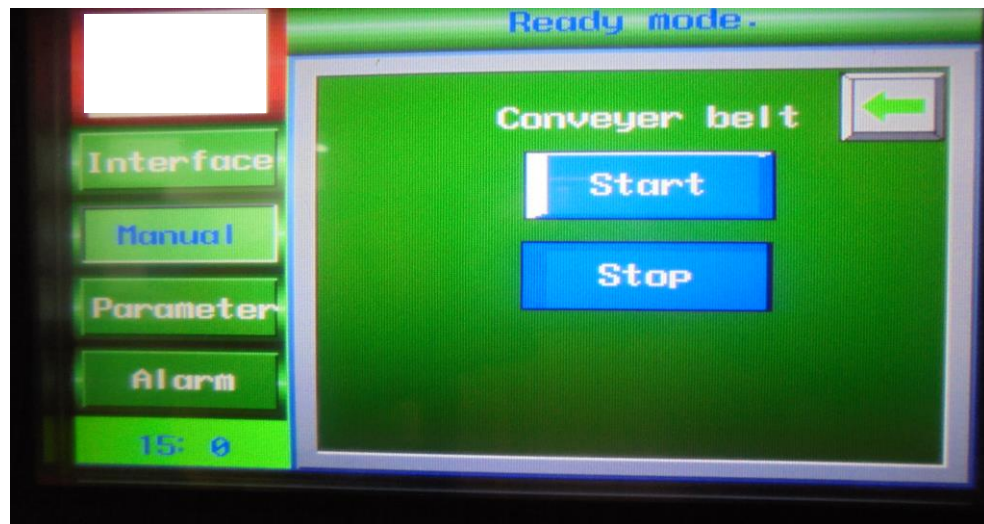
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5.2.11. Conveyor operation:



5.2.11.1. [Start]/[Stop] the conveyor.

5.2.12. Alarm information displaying.

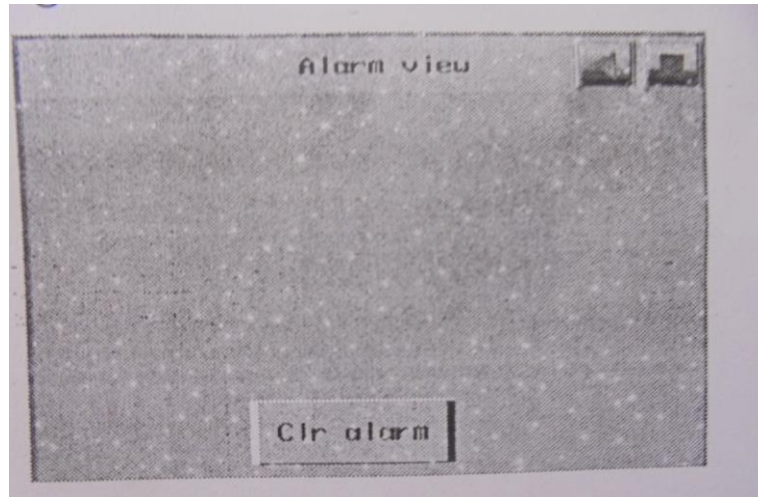


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5.2.12.1. Press [Clr alarm] button to clear alarm information.

Alarm information list

S.No.	Alarm information	Cause and remedy
1.	EMERGENCY	[EMERGENCY STOP] button is press down. Loose[Emergency stop] button
2.	Servo Alarm	Servo motor fault, specific reasons refer to information on digital display of servo motor.
3.	Caution, safe door is open	Close all safety door
4.	Bottle jam	Bottle jam at exit
5.	Have not bottle	Lacks of bottle
6.	Bottle to topple alarm	Fallen bottle at entrance
7.	Desiccant falling time	Desiccant jams at falling inlet so clear the inlet.
8.	Conveyor belt stop	Conveyor not start up
9.	Alarm for 1#2# cylinder	Plug cotton cylinder error
10.	Continuous on cotton	When no cotton comes continuous
11.	Starting position error	Sensor is not in its original position. Press [Reset] position.
12.	Work bin overfilling	Rejection collection bin is full
13.	Alarm for continuous rejection	When there is continuous rejection



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S.No.	Alarm information	Cause and remedy
14.	Low pressure	Compress air pressure is low
15.	Production reached	Output reached the preset value
16.	Power "OFF"	Power is not "ON"
17.	Lacking Desiccant	Replace the desiccant plate

5.2.13. Setting of cotton inserter cylinder

5.2.13.1. Adjust the height of cotton inserter cylinder with the help of side wheel.

5.2.13.2. The height of cotton inserter cylinder should be such that the plug of cylinder should not touch the tablet. There should be sufficient gap between tablet bed and the plug of cylinder to avoid any damage of tablet.

5.2.13.3. The container after cotton insertion should be checked for any damage of tablet by production officer and IPQA person.

5.2.13.4. The tablet shall be verified for any damage after cotton insertion at the start up test for bulk packing and after any maintenance activity of machine.

6.0 ABBREVIATION (S):

6.1. SOP : Standard Operating Procedure.

6.2. MMI : Man Machine Interface.

7.0 REFERENCE (S):

7.1. SOP: Making entries in equipment usage and cleaning log sheet.

7.2. SOP: Cleaning of Production Area.

8.0 ANNEXURE (S):

8.1. Annexure-I: Cleaning Checklist of cotton inserter machine.

9.0 DISTRIBUTION:

9.1. Master Copy : Quality Assurance

9.2. Controlled copy (S): Production department/Quality Assurance

9.3. Reference copy (S): Production department

10.0 REVISION CARD:



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S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of Revision	Effective Date
01	00	NA	New SOP	NA	



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ANNEXURE I

CLEANING CHECKLIST OF COTTON INSERTER

Name of the Equipment		COTTON INSERTER
Equipment I.D. No.		Date
Previous Product:		
Batch No.		
S.No.	Activity	Activity Performed
1.	Ensure that all the material of previous product are removed from packing cubicle.	
2.	Remove the "UNDER PROCESS" label and affix "TO BE CLEANED" label on the machine with sign and date of production officer.	
3.	Switch "OFF" all utility supply before cleaning.	
4.	Clean the control panel with dry lint free cloth.	
5.	Clean the top surface of machine and its parts by dry lint free cloth.	
6.	Open guard and clean inside surface of machine, hopper and its area with dry lint free cloth.	
7.	Wipe all the S.S. parts of machine with 70% v/v IPA solution followed by mopping with dry lint free cloth.	
8.	Wipe the inner and outer surface of Conveyor belt and rejection box with 70% v/v IPA solution.	
9.	Wipe the machine guards with dry lint free cloth.	
10.	Remove the "TO BE CLEANED" status label with "CLEANED" status label on the machine with sign and date of production officer.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

Note: Put '√' mark if activity performed and put 'X' if activity not performed.