



STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Procedure for Operation, Cleaning and Calibration of Check Weigher	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE :

To lay down a procedure for Operation, Cleaning and Calibration of Check Weigher. (Make-Sartorius and Model- ECONUS 600 g).

2.0 SCOPE :

This procedure is applicable for Operation, Cleaning and Calibration of Check Weigher (Make-Sartorius and Model- ECONUS 600g) in Production Area.

3.0 RESPONSIBILITY:

Production: Associate/Officer /Executive/Assistant Manager

Head Production: To ensure execution & compliance

Head QA: To ensure the compliance

4.0 PROCEDURE:

4.1 Machine set

- 4.1.1. Handling of the Check Weigher may be performed only by reliable, trained or instructed personnel such as technicians and engineers.
- 4.1.2. Wherever necessary, wear personal protective equipments.
- 4.1.3. The cabinet must be tightly closed during normal operation. Before opening the cabinet, Confirm power is switched off.

4.2 Setting:

- 4.2.1. Ensure that the Check Weigher is calibrated.
- 4.2.2. Open the compressed air valve.



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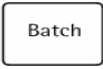
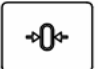









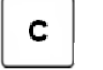


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


Keypad Information

Keys	Description
	Belt Start Key
	Belt Stop Key
	Batch Start/Stop Key
	Zero the weight on display, provided that weight is stable and weight is within zero set range
	Product Key
	Joker Key, Quick Opening of Configured menu
	Press key  to scroll down or key  to scroll up in a menu. Selection is possible with key  . The required setting for the selected menu item can be done with  or  .
	Soft keys – select the function
	Backspace/ delete
	Exit from current menu; continue operation at next higher level
	Enter / confirm



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 Fn	Function keys
 Info	Information on version number
 Setup	Setup Menu

4.3 Create New Product

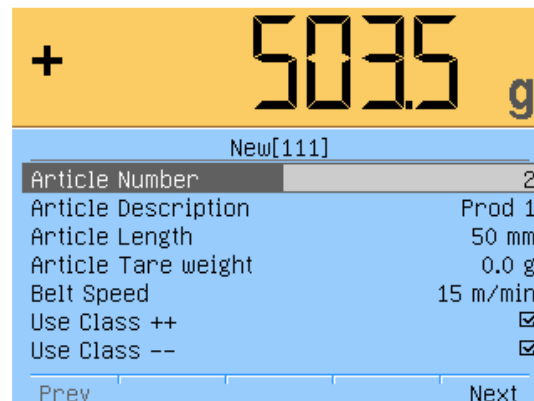
4.3.1 Remove the “CLEANED” status label and affix “UNDER PROCESS” label on the machine

4.3.1.1. Switch “On” the mains of the machine.


4.3.1.2. Display will show 0.0 weight display and press enter and then Press “F1” key.


4.3.1.3. Press Edit key and then press New.


4.3.1.4. Press enter “ENTER PASSWORD” appears on screen. Type the password and press enter key.




4.3.1.5. “PRODUCT/ARTICLE NUMBER” will automatically select.

4.3.1.6. Press key  to “PRODUCT DESCRIPTION” and press enter key. Feed the product description by using the Alphabet/numeric keys.

4.3.1.7. Press key  to “PRODUCT LENGTH” and press enter key. Feed the length of mono carton/outer carton by using the numeric keys.

4.3.1.8. Press key  to “PRODUCT TARE WEIGHT” and press enter key. If required feed the weight of mono carton/outer carton by using the numeric keys.

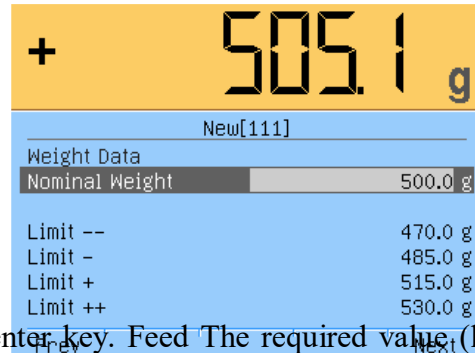
4.3.1.9. Press key  to “BELT SPEED” and press enter key. Feed the required speed by using the numeric keys.





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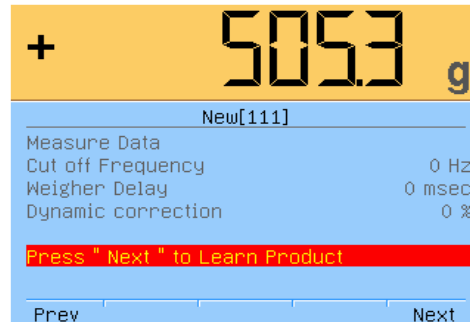
4.3.1.10 Press next to weight data. enter the nominal weight from BPR by using numeric keys.



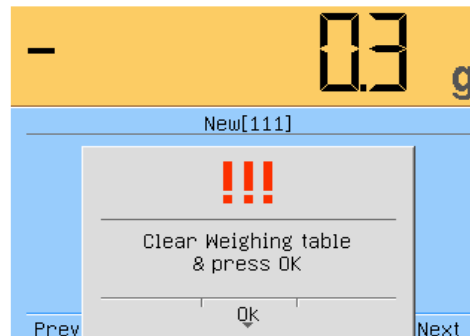
4.3.1.11 Press key  to “LIMIT (-)” and press enter key. Feed The required value (lower limit) from BPR by using the numeric keys.

4.3.1.12 Press key  to “LIMIT (+)” and press enter key. Feed The required value (higher limit) from BPR by using the numeric keys.

4.3.1.13 Press Next until display show to learn the product.



4.3.1.14 Press next and Clear weighing table and press OK.





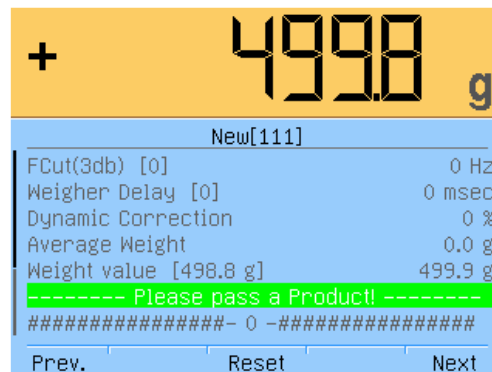
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4.3.1.15. Put the product on table of nominal value and press OK.

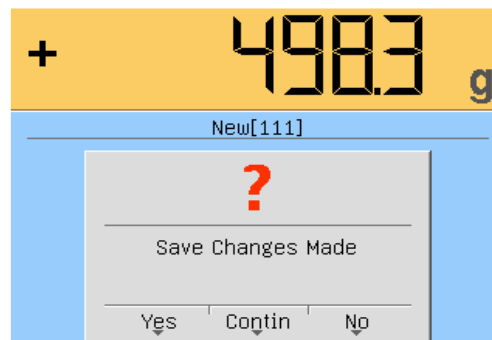


4.3.1.16. Please pass a product on running conveyor for atleast 25 times.



4.3.1.17. Dynamic correction should be less than 0.1%. If dynamic correction is more than 0.1 % repeat the step 4.3.1.17.

4.3.1.18. Once all the data is entered correctly, press EXIT key, it will display the message box asking for saving the product in to product data base. Press soft key [Yes] and Press Exit Key.




4.3.1.19. Before starting the operation ensure that the cartons taken for the setting are removed from the line.

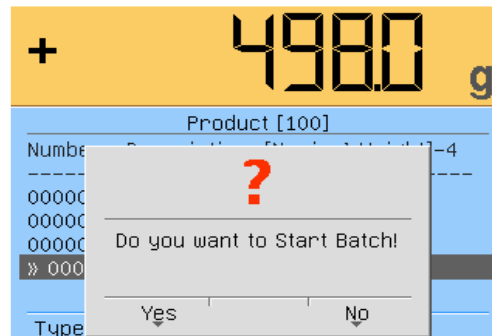


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4.3.1.20. Once the product is created and loaded for the batch we can start the batch.

To start a batch, go to Main menu window start belts & press Start Batch hard key , if belts are not started an error message is displayed otherwise a confirmation message is displayed, confirm by pressing [Yes].




As soon as batch starts the display shows the statistics menu automatically.

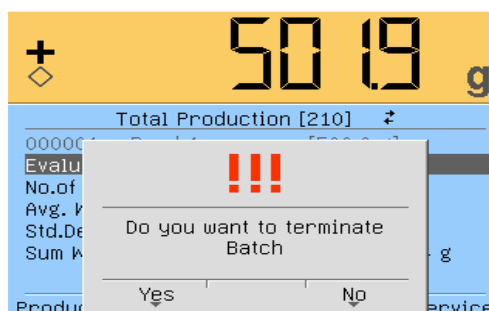
To start the belt press key  & to Stop press  key.

4.3.1.21. Start passing the cartons on the Check Weigher.

4.3.1.22. Ensure the tower lamp indications and its rejection mechanism is functioning by passing the carton with less weight and higher weight as per frequency given in the BPR.

4.3.1.23. Tower lamp in case correct fill value glows green lamp, for low fill value glows yellow lamp and higher fill value glows red lamp.

4.3.1.24. After completion of batch press the Hard key  a message box is displayed confirming the stopping/terminate of the batch.





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4.3.1.25. At the end of activity, press “CONVEYOR STOP” to stop the conveyor belt. Switch “OFF” the mains of the Check Weigher and close the compressed air valve.

4.3.1.26. Wait till the black line on the screen disappears to restart the Check Weigher.

4.3.1.27. When there is change in product or pack size create new product in product list by repeating the step from 4.3.1.1 to 4.3.1.20.

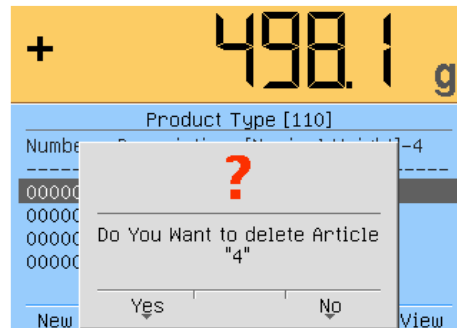
4.3.1.28. Check the rejection box of the Check Weigher and check the cartons for correct fill value. Reject the low and high fill weight tubes/ Blister/ Strip.

4.3.1.29. **Frequency:** – Every Two hours.

4.3.2 Delete Product/Article

4.3.2.1 Press F1, Soft key – [Delete] will display.

To delete a particular product/article provided no batch is running with the Selected product/article. To select a product/article to delete use arrow keys and press [Delete].



This dialogue is customer password protected.



4.3.3 Edit /Modify the Exist Product/Article

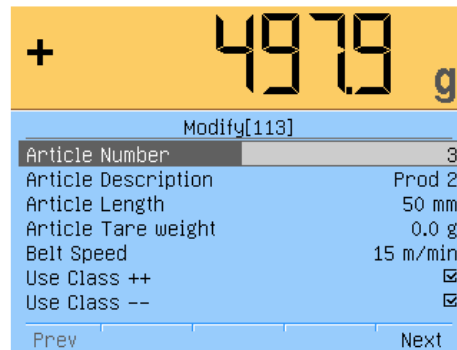


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4.3.3.1 Press F1, Soft key – [Modify] will display.

Here it is possible to modify all the entries related to a particular product/article provided no batch is running with the selected product/article. To select a product/article to modify use   keys and press [Modify].



This dialogue is customer password protected.

4.3.3.2 When there is change in batch of same product with similar pack size modify the limit and nominal value from BPR.

4.4 CLEANING PROCEDURE

- 4.4.1 Ensure that all the cartons/ tubes/ strips/ blisters of previous batch are removed.
- 4.4.2 Remove “TO BE CLEANED” label and update “Area Status Board” duly filled and signed.
- 4.4.3 Ensure that main power supply should ‘OFF’.
- 4.4.4 Enter the cleaning starting time in equipment usage log sheet as per SOP.
- 4.4.5 Clean the conveyor belts, rejection box, control panel and entire surface of Check Weigher by using dry lint free cloth.
- 4.4.6 Open the guards of the machine and clean with clean and dry lint free cloth.
- 4.4.7 Wipe the machine surface and panel with 70% w/w IPA solution.
- 4.4.8 Attach duly filled “CLEANED” status label on the machine with date and signed of the production officer.



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4.4.9 Enter the cleaning end time in equipment usage log sheet as per SOP.

4.5 CALIBRATION PROCEDURE

4.5.1 Caution:

4.5.1.1 Ensure that the Check Weigher is not touching from any surface.

4.5.1.2 Do not keep the Check Weigher in loaded in "OFF" condition.

4.5.1.3 Check the proper earthing of Check Weigher wherever applicable.

4.5.1.4 Avoid impact / mechanical shocks to the Check Weigher.

4.5.2 Daily verification

4.5.2.1 Check the cleanliness of the Check Weigher.

4.5.2.2 Take the fractional weight box or trolley of standard weights (which ever is required) and ensure that standard weights are duly calibrated.

4.5.2.3 Calibrate the Check Weigher with 1%, 50% and 95% of its capacity and record the observation in Annexure-I.

4.5.2.4 Place the weight in the center of platform of Check Weigher one by one in ascending order. Check the observations for the variation (if any) and record the observation in Annexure-I.

4.5.2.5 **Tolerance:** The Variation should not be more than $\pm 0.1\%$ of the standard weight.

4.5.2.6 If the daily verification is does not within limit then then put "OUT OF CALIBRATION" label.

4.5.2.7 **Frequency:** Daily before start of operation.

4.5.3 Monthly Calibration:



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4.5.3.1. Check the cleanliness of the Check Weigher.

4.5.3.2. Take the fractional weight box or trolley of standard weights and ensure that standard weights are duly calibrated.

4.5.3.3. Calibrate the Check Weigher with 1% , 20%, 50% and 95% of its maximum capacity and record the observation in Annexure-II.

4.5.3.4. Place the weight in the center of platform of Check Weigher one by one in ascending order. Check the observations for the variation (if any) and record the observation in Annexure-II.

4.5.3.5. **Tolerance:** The Variation should not be more than $\pm 0.1\%$ of the standard weight.

4.5.3.6. If the monthly calibration is does not found within limit then put "OUT OF CALIBRATION" label.

4.5.4 Maintenance:

4.5.4.1. If the Check Weigher is out of calibration inform to concerned service agency for rectification.

4.5.4.2. After rectification recalibrate the Check Weigher.

4.5.4.3. All the record relating to service and calibration to be maintained.

4.5.5 Challenge test of Check Weigher:

4.5.5.1. Collect the challenging packed carton from the designated place.

4.5.5.2. Operate the Check Weigher by pressing the start button.

4.5.5.3. Load the challenging packed carton in the conveyor belt of the Check Weigher machine.



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4.5.5.4. Ensure that challenging packed carton must be rejected in rejection box.

If any packed carton passed through the conveyor that means challenge test is failed.

4.5.5.5. Check the below points if challenge test is failed:

4.5.5.6. Sensors need to be cleaned.

4.5.5.7. Repeat the challenging test up to satisfactory.

4.5.5.8. Record the observation of challenge test in BPR as per Annexure III.

4.5.5.9. Frequency: Before start of operation, any stoppage of machine and at any major break down.

5.0 ANNEXURE (S)

Annexure I- Daily Verification of Check Weigher.

Annexure II- Monthly Calibration of Check Weigher.

Annexure III-Challenge Test of Check weigher

6.0 REFERENCE (S)

SOP- Preparation, approval, distribution control, revision and Destruction of Standard Operating Procedure

SOP- Procedure of filling of Equipment Log Book.

7.0 ABBREVIATION (S) / DEFINITION (S)



PHARMA DEVILS

PRODUCTION DEPARTMENT

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BPR : Batch Packing Record

SOP : Standard Operating Procedure

IPA : Iso Propyl Alcohol

W/W : Weight/ Weight

Q.A. : Quality Assurance

SOP : Standard operating Procedure

Gm : Gram

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S)FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---



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ANNEXURE III

CHALLENGE TEST FOR CHECK WEIGHER

Good Filled Cartons: Pass the target filled wt. carton on the check weigher

Low weight rejection: By putting one empty tube in empty carton or putting one blister/strip less in filled carton

High weight rejection: By putting one extra empty tube or additional blister/strip into the filled carton and put the filled carton on check weigher

Date/Time:	Parameter	Weight of cartons									Checked By Prod.	Verified By Q.A.
		Good Filled Cartons			Low Wt. Filled Cartons			High Wt. Filled Cartons				
		Pass	Pass	Pass	Rejected	Rejected	Rejected	Rejected	Rejected	Rejected		
		1 st wt.	2 nd wt.	3 rd wt.	4 th wt.	5 th wt.	6 th wt.	7 th wt.	8 th wt.	9 th wt.		
Speed (80-130 Piece/min.)												
	Obs.											
	Result											
	Obs.											
	Result											
	Obs.											
	Result											
	Obs.											
	Result											

Remarks: Obs. Stands for Observation. Observation row write "A" for accepted and "R" for Rejected and in result row write **ok** for satisfactory and **not ok** for not satisfactory.