Cleaning and Operation of Breaking Force Tetser (Electrolab)

1.0   OBJECTIVE:

To lay down a procedure for cleaning, operation and calibration of Breaking force tester (Electrolab).

2.0   SCOPE:

This procedure is applicable to the cleaning, operation and calibration of Breaking force tester (Electrolab) in production area.

3.0   RESPONSIBILITY:

Technical Associate   : Cleaning and Operation

Officer and Executive : Calibration, Supervision

Head Production   : SOP compliance

4.0   DEFINITION (S):

NA

5.0   PROCEDURE:

5.1   CLEANING:

5.1.1   Dedust the tablet platform of apparatus with the help of brush and collect all the powder and crushed tablet in tablet collecting bowl. And finally dispose the tablets in disposal bin in respective area.

5.1.2   Clean the apparatus with dry lint free cloth followed by moist lint free cloth.

5.1.3   Cleaning should be done in each type A and Type B cleaning.

5.2   MACHINE SETTING FOR MODEL (EHT5PR):

5.2.1   **LOGIN:**

5.2.1.1   Switch ON the apparatus, the screen displays

5.2.1.2

USER LOGIN
USER NAME :   ENTER USER NAME
PASSWORD :   ENTER PASSWORD
LOGIN

5.2.1.3   Enter the user name and password in three different levels.

5.2.2   Product setup

5.2.2.1   The instrument initializing screen displays, after initializing dashboard screen displays with following icon.

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- Product setup
- Method setup
- Setting
- Report
- Run

5.2.2.2 Press product setup keys present on dashboard screen , product setup screen displays with following icon.

- Product setup	- New Product
- Product info	- Copy Product
- Parameter	- Load Product
- Units	- Delete Product
- Limits	

5.2.2.3 Press on existing product recipe to load the save recipe for the respective product by using up"▲" and down "▼" arrow keys as per BMR.

5.2.2.4 Press on new product key to add new product.

5.2.2.5 Product info. screen will display with following icon.

- Product name
- Product description
- Tablet shape

5.2.2.6 Press on product name tab and enter the product name using keypad as per BMR.

5.2.2.7 Press on product description tab and enter the product description using keypad as per BMR.

5.2.2.8 Press on tablet shape icon to select the shape of tablet Round / Square / Ablong / other as per BMR.

5.2.2.9 Press on Save icon to save the product info.

5.2.2.10 Press parameter key present on dashboard screen , product parameter screen displays.

5.2.2.11 Press on mode icon to select : AUTO / MANUAL mode.

5.2.2.12 Hardness method is fix method as a constant speed.

5.2.2.13 Press on Delay key to enter desired value (Range:01 sec to 99 sec)

5.2.2.14 Press on Hardness speed (mm/sec) key and enter the desire value.
(Range:0.500 mm/sec to 3.000 mm/sec).

5.2.2.15 Press on Save icon to save the parameter.

5.2.2.16   Press on units key product units screen will display with following icon.

-Hardness unit

5.2.2.17   Press on Hardness unit to select the N (Newton).

5.2.2.18   Press on Save icon to save the Product Hardness unit.

5.2.2.19   Press Limits key product limits screen will display with following icon.

-Hardness

5.2.2.20   Press hardness key following icon will display.

-       Nominal

-       "T1+"

-       "T1-"

-       "T2+"

-       "T2-"

5.2.2.21   Press Nominal tab to enter the desire value i.e standard value as per BMR and select the

hardness unit and limits.

For N : (Range:0.000 to 800.000).

5.2.2.22   "T1+", this is the upper limit of hardness.

"T1-" , this is the lower limit of hardness.

"T2+ , this is the deviated upper limit of hardness.

"T2-", this is the deviated lower limit of hardness.

Enter the value to press the respective keys.

5.2.2.23   Press on Save icon to save the product hardness parameter.

5.2.2.24   Press back key to exit.

5.2.2.25   Press dashboard key to back on dashboard screen.

5.2.3   Method setup

5.2.3.1   Press method setup key present on dashboard screen , method setup screen displays with

following icon.

-       Method select   - New   -   copy

-       Method information   -   Load   -   Delete

5.2.3.2   Press on existing product method to load the save method for the respective product using

up"▲" and down "▼" arrow keys.

5.2.3.3   Press new key to add new method.

5.2.3.4   Press Method info key following icon will display.

- Method name

- Hardness sample size

5.2.3.5   Enter the necessary information as BMR by enter value in the respective icon.

5.2.3.6   Press on Save icon to save the product method.

5.3   MACHINE OPERATION MODEL (EHT5PR)

5.3.1   Press the product setup key to load the recipe for respective product.

5.3.2   Press the run key present on dashboard screen following icon will display.   -

- Product run   -   Calibration

- Easy run   -   Verification

- Single run

5.3.3   Press the Product run key ,product info. Setup screen displays with following auto loaded product information. .

- Product name   -Batch Identity

- Press identity   - Container number

- Operator   - comment

- Next

5.3.4   Press next key to start the product run test.

5.3.5   Now put the tablet sample horizontally for measure the product hardness one by one.

5.3.6   Result screen displays during sample test run with following icon.

- Statistics   -   Table

- Abort   -   Play

- Next

5.3.7   Press respective icon showing the different sample reading during test.

5.4   CALIBRATION OF HARDNESS MODEL (EHT5PR)

5.4.1   Press the run key following icon displays.

- Product run   -   Calibration

- Easy run   -   Verification

- Single run

5.4.2   Press the calibration key following icon displays.

- Hardness

- Thickness

5.4.3   Press next key to proceed the calibration procedure.

5.4.4   Follow the instruction written on screen.

5.4.5   After initializing, Place the machine in vertical position.

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5.4.6   Press RUN key present on screen and remove tongue, place the platform between the jaw and zero it when the message displays.

5.4.7   Press run key present on screen,When the message displays on "PLACE THE WEIGHT ON PLATFORM" then place 5 kg (Range 1-20 kg)certified weight on the platform genteelly. then press RUN key.

5.4.8   H.calibration result screen displays after getting 5 readings with mean press save to save the harness calibration result.

5.4.9   Display screen shows calibration done, Remove the platform then press OK.
Screen shows the instruction remeasure offset then place the platform,remeasured platform weight and press OK.

5.4.10   After pressing OK, H verification Screen displays.

5.4.11   Place 5 kg certified weight on the platform genteelly and press next icon.

5.4.12   H.Verification result screen displays after getting 5 readings with mean press save to save the harness verification result.

5.4.13   For saving hardness calibration data press OK.

5.4.14   After pressing OK, remove platform and keep machine horizontally.

5.5   VERIFICATION OF HARDNESS MODEL (EHT5PR)

5.5.1   Press the run key following icon displays.

5.5.2   Press the Verification key following icon displays.

- Hardness
- Thickness

5.5.3   Press next key to proceed the Verification procedure.

5.5.4   Follow the instruction written on screen.

5.5.5   After initializing, Place the machine in vertical position.

5.5.6   Press RUN key present on screen and remove tongue, place the platform between the jaw and zero it when the message displays.

5.5.7   Press run key present on screen,When the message displays on "PLACE THE WEIGHT ON PLATFORM" then place 5 kg (Range 1-20 kg) certified weight on the platform genteelly. then press RUN key.

5.5.8   H.verification result screen displays.

5.5.9   After getting 5 reading with mean, press SAVE icon to save the hardness verification result.

5.5.10   For saving hardness verification data press OK. After pressing OK, remove platform and keep machine horizontally.

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5.6   CALIBRATION OF THICKNESS MODEL (EHT5PR)

5.6.1   Press the run key following icon displays.

-        Product run   -   Calibration

-        Easy run   -   Verification

-        Single run

5.6.2   Press the Calibration key following icon displays.

-       Hardness

-       Thickness

5.6.3   Press next key to proceed the Thickness procedure.

5.6.4   Follow the instruction written on screen.

5.6.5   After initializing, Place the reference gauge between the jaw.

5.6.6   After putting the gauge,press run key and wait for thickness calibration process.

5.6.7   Thickness calibration result screen displays and shows the result.

5.6.8   After getting 5 reading with mean, press SAVE icon to save the T calibration result.

5.6.9   After Press the save key , Th verification screen displays.

5.6.10   Enter reference (5.000-35.000 mm) and tolerance (0.000 mm-1.000 mm) limit with in range.

5.6.11   Verification screen displays and press next icon to proceed

5.6.12   After initializing, Place the reference gauge between the jaw.

5.6.13   After putting the gauge,press run key and wait for thickness calibration process.

5.6.14   Thickness calibration result screen displays and shows the result.

5.6.15   After getting 5 reading with mean, press SAVE icon to save the Th calibration result.

5.7   VERIFICATION OF THICKNESS MODEL (EHT5PR):

5.7.1   Press the run key following icon displays.

-        Product run   -   Calibration

-        Easy run   -   Verification

-        Single run

5.7.2   Press the verification key following icon displays.

-       Hardness

-       Thickness

5.7.3   Press next key to proceed the Thickness procedure.

5.7.4   Follow the instruction written on screen.

5.7.5   After initializing, Place the reference gauge between the jaw.

5.7.6   After putting the gauge,press run key and wait for thickness verification process.

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5.7.7 Thickness verification result screen displays and shows the result.

5.7.8 After getting 5 reading with mean, press SAVE icon to save the Th verification result.

Note: User login and password applicable for the only model EHT5PR Version 1.2.

5.8 MACHINE SETTING FOR MODEL (EBT-2PRL)

5.8.1 Switch on the apparatus.

5.8.2 The instrument initializing screen displays, after initializing home screen displays with following icon.

- Product set up   - Verification   - Easy run   -
Setting   - Report   - Product run

5.8.3 Press product set up key the product select screen displays.

5.8.4 Press "→" to view/edit product detail, Product info. Screen displays.

5.8.5 Press "+" key to add new product parameter on product info. screen.

5.8.6 Enter the details of product name, comment and shape of tablets.

5.8.7 Press "→" key for next step, Product measure screen displays.
- Mode   - Backoff dis.   - Constant speed   - T
Sample   - H Sample   - Delay
Press mode to select the mode of operation i.e. Auto/ manual.

5.8.8 Press H sample to enter the number of hardness sample as per BMR.

5.8.9 Press "→" key for next step, Units & methods screen displays.

5.8.10 Enter the hardness unit N (Newton) by pressing unit force icon as per BMR.

5.8.11 Click on PL on to on the icon.

5.8.12 Press "→" key for next step, "T" screen displays, select the "H" screen by pressing H icon.

5.8.13 Enter the nominal value (Range:0.000 to 800.000).
"PL+", this is the upper limit of hardness.
"PL-", this is the lower limit of hardness.
Enter the both value as per BMR.

5.8.14 Press save icon to save the product set up.

5.8.15 Using "←" key to back on home screen.

5.9 MACHINE OPERATION MODEL (EBT-2PRL)

5.9.1 Press product run key, product select screen displays.

5.9.2 Press on existing product to load the save product info. for the respective product using up"▲" and down "▼" arrow keys.

5.9.3 Press "→" key Product info setup screen displays.

5.9.4   Enter the necessary information as per batch record.

5.9.5   Press "→" key to run the test.

5.10   CALIBRATION OF HARDNESS MODEL (EBT-2PRL)

5.10.1   Press verification key present on home screen.

5.10.2   T verification screen displays, press on "H" icon present on screen.

5.10.3   H calibration screen displays, click on calibration icon.

5.10.4   Press the reference icon and enter the 5.000 kg . (Range:1.000-20.000kg)

5.10.5   Press the tolerance icon and enter the +/-100 g. (Range +/-50 g to 200g)

5.10.6   Check the nothing is placed on jaw. Click √ to proceed.

5.10.7   Jaw is adjusting for calibration.

5.10.8   Place the machine in vertical position.

5.10.9   Place the platform between the jaws,once stabilise press √ to set zero.

5.10.10   Place the 5 kg certified weight on the platform genteelly.

5.10.11   Press √ to run the calibration test.

5.10.12   After getting 5 reading with mean, press SAVE icon to save the hardness calibration result.

5.10.13   After calibration over remove the platform & weight and keep machine horizontally.

5.11   VERIFICATION HARDNESS MODEL (EBT-2PRL)

5.11.1   Press verification key present on home screen.

5.11.2   T verification screen displays, press on "H" icon present on screen.

5.11.3   H Verification screen displays, click on verification icon.

5.11.4   Press the reference icon and enter the 5.000 kg . (Range:1.000-20.000kg)

5.11.5   Press the tolerance icon and enter the +/-100 g. (Range +/-50 g to 200g)

5.11.6   Check the nothing is placed on jaw. Click √ to proceed.

5.11.7   Jaw is adjusting for verification.

5.11.8   Place the machine in vertical position.

5.11.9   Place the platform between the jaws,once stabilise press √ to set zero.

5.11.10   Place the 5 kg certified weight on the platform genteelly.

5.11.11   Press √ to run the verification test.

5.11.12   After getting 5 reading with mean, press SAVE icon to save the hardness calibration result.

5.11.13   After verification over remove the platform & weight and keep machine horizontally.

5.12   CALIBRATION OF THICKNESS MODEL (EBT-2PRL)

5.12.1   Press verification key present on home screen.

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5.12.2	T verification screen displays click on calibration icon.
5.12.3	Press the reference icon and enter the 10.000mm.(Range:0.000-35.000mm)
5.12.4	Press the tolerance icon and enter the +/-0.20 mm. (Range +/-0.000 to 1.000mm)
5.12.5	Check the nothing is placed on jaw. Click √ to proceed.
5.12.6	After initializing, Place the reference gauge between the jaw.
5.12.7	After putting the gauge,press run key and wait for thickness calibration process.
5.12.8	Thickness calibration result screen displays and shows the result.
5.12.9	After getting 5 reading with mean, press SAVE icon to save the T calibration result.

5.13   **VERIFICATION OF THICKNESS MODEL (EBT-2PRL):**

5.13.1	Press verification key present on home screen.
5.13.2	T verification screen displays click on verification icon.
5.13.3	Press the reference icon and enter the 10.000mm.(Range:0.000-35.000mm)
5.13.4	Press the tolerance icon and enter the +/-0.20 mm. (Range +/-0.000 to 1.000mm)
5.13.5	Check the nothing is placed on jaw. Click √ to proceed.
5.13.6	After initializing, Place the reference gauge between the jaw.
5.13.7	After putting the gauge,press run key and wait for thickness verification process.
5.13.8	Thickness verification result screen displays and shows the result.
5.13.9	After getting 5 reading with mean, press SAVE icon to save the T verification result.

5.9   **CALIBRATION AND VARIFICATION FREQUENCY:**

    * The Calibration for Hardness and Distance should be done half yearly (i.e. once
      In six month).

    * The Verification for Hardness and Distance should be done once in Month.

6.0   **ABBREVIATION (S)**

BMR	:	Batch manufacturing record
mm	:	Millimeter
kN	:	Kilo Newton
MMI	:	Men machine interface
Mg	:	Miligram
Gm	:	Gram

7.0   **RERERENCE (S):**

    Nil

Cleaning and Operation of Breaking Force Tetser (Electrolab)

8.0 **ANNEXURE (S):**

Annexure –I : Hardness/Thickness Calibration & Verification Record

9.0 **DISTRIBUTION:**

Master Copy **:** Quality Assurance

Controlled copy (S) : Production department, Quality Assurance

Reference copy (S) : Production department

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ANNEXURE-I

BREAKING FORCE TESTER (ELECTROLAB)

HARDNESS/THICKNESS CALIBRATION & VERIFICATION RECORD

Department   :   Production

Year :   _____

Equipment ID   : _____ Standard Weight Box ID : _____(Standard Weight To Be Used For Verification: 1 to 20 Kg)

Calibration Done On :_____   Calibration Due On:_____ Frequency : Calibration :- Half year / Verification :- Monthly

Date	Standard Weight (5 Kg) Used for Hardness Calibration	Calibration Status	Standard Weight Used for Hardness Verification	Verification Result	Deviation In Kg	Done By	Checked By	Remarks
			1.2	1.3	1.4	1.5		1.6
			1.7	1.8	1.9	1.10		1.11
			1.12	1.13	1.14	1.15		1.16
			1.17	1.18	1.19	1.20		1.21
			1.22	1.23	1.24	1.25		1.26
			1.27	1.28	1.29	1.30		1.31

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Date	Standard Block Gauge used for Thickness Calibration	Calibration Status	Standard Block Gauge used for Thickness Verification	Verification Result	Deviation in mm	Done By	Checked By	Remarks
			1.32	1.33	1.34	1.35		1.36
			1.37	1.38	1.39	1.40		1.41
			1.42	1.43	1.44	1.45		1.46
			1.47	1.48	1.49	1.50		1.51
			1.52	1.53	1.54	1.55		1.56
			1.57	1.58	1.59	1.60		1.61