



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation, Calibration and Cleaning of Tablet Tester

Effective Date:

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1.0 OBJECTIVE:

To lay down the procedure for the Operation, Cleaning and Calibration of Tablet Tester (Campbell, WWTDH-550).

2.0 SCOPE:

This procedure is applicable to the Operation, Calibration and Cleaning of Tablet Tester (Campbell, WWTDH-550) used in production department.

3.0 RESPONSIBILITY:

Production: Technical Associate/Officer /Executive/Assistant Manager

Head Production: To ensure execution & compliance

Head QA: To ensure the compliance

4.0 PROCEDURE :

4.1 Operation:

4.1.1 Check and ensure that all the systems of the machine are properly connected.

4.1.2 Check and ensure the cleanliness of the Tablet Tester.

4.1.3 Switch ON the instruments from the main switch on the rear panel of the instrument.

4.1.4 At power on initial screen appears as -

CAMPBELL ELECTRONICS

MODEL NO : WWTDH 550

SERIAL NO : 1505045



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S/W : H550 3.0

PRESS 'ENTER' KEY TO CONTINUE _

4.1.5 After pressing 'ENTER' operator login screen appears as-

CAMPBELL ELECTRONICS

USER NAME :

PASSWORD :

'P': CHANGE PASSWORD

'C': CONTINUE

'ESC': EXIT _

4.1.6 Selects continue by pressing 'C' and put user name and password to login.

4.1.7 Selects change password option by pressing 'P' and put user name, old password, new password, confirm password in order to change the old password.

4.1.8 Selects exit by pressing 'Esc' key then control goes back to Main menu.

4.1.9 There are 3-levels of login.

1. Administrator level
2. Supervisor level



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3. Operator /user level

4.1.10 After putting user name and password, depending on the level of login different menus appears in the next main menu screen.

4.1.11 Administrator level login appears as-

CAMPBELL ELECTRONICS	<Date>
	<Time>

'S' :- START TEST	LEVEL: ADMIN
'C' :- CALIBRATION / VERIFICATION	
'U' :- CREATE USER	
'R' :- CREATE RECIPE	'P' :- REPORT
'V' :- VIEW RECIPE	'T' :- SETTINGS
'E' :- EDIT RECIPE	'L' :- LOG OFF

Administrator main menu screen

4.1.12 In main menu screen date and time appears at right hand side top corner.

Here Administrator can use only 9 menu options.

4.1.13 Supervisor level login appears as-

CAMPBELL ELECTRONICS	<Date>
	<Time>



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'S' :- START TEST	LEVEL : S'VISOR
'C' :- CALIBRATION / VERIFICATION	
'R' :- CREATE RECIPE	'P' :- REPORT
'V' :- VIEW RECIPE	'T' :- SETTINGS
'E' :- EDIT RECIPE	'L' :- LOG OFF

Supervisor main menu screen

In main menu screen date and time appears at right hand side top corner.

Here Supervisor can use only 8 menu options.

4.1.14 User level login appears as-

CAMPBELL ELECTRONICS

<Date>

<Time>

'S' :- START TEST	LEVEL : USER
'C' :- CALIBRATION / VERIFICATION	
'V' :- VIEW RECIPE	
	'P' :- REPORT
	'L' :- LOG OFF

User main menu screen

In main menu screen date and time appears at right hand side top corner.

Here User can use only 5 menu options.



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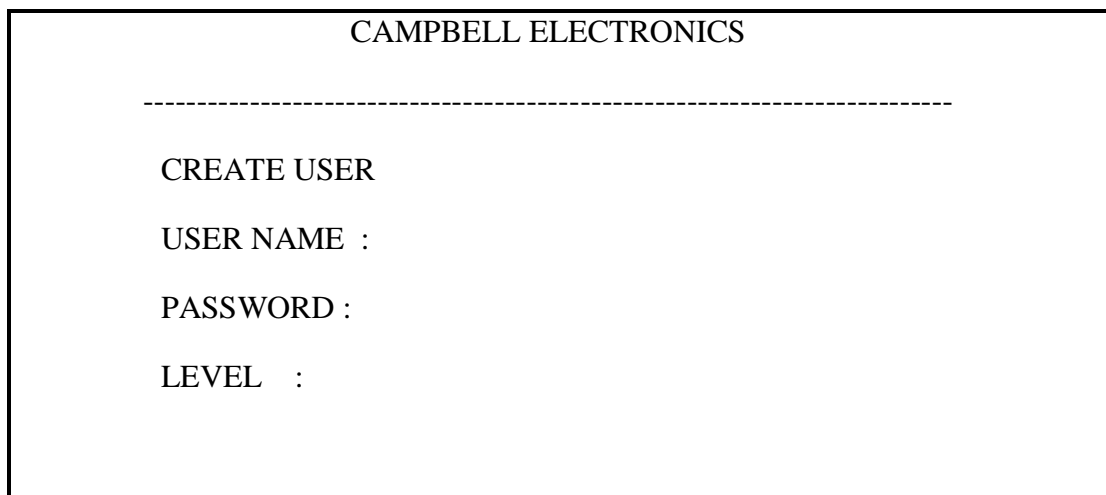
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4.1.15 To log off use 'L'-Log off menu followed by 'Y' key.

4.2 Create User:

4.2.1 'U': Create User -By pressing 'U' Key it will go into create user menu.

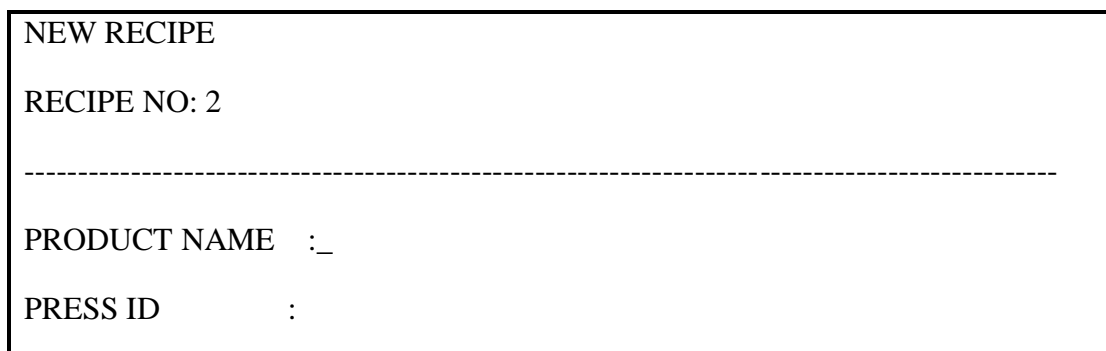
4.2.2 After putting User Name and Password when the user goes to the LEVEL option, the levels of users will be shown in numerical order.



Create User Menu Screen

4.3 Create recipe:

4.3.1 By pressing 'R' key the screen will show Create recipe menu. Here different recipes can be created. It starts from recipe no. 1.If we trying to create new recipe then recipe will auto increment to 2 and screen appears as-





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UNIT OF WIDTH: [m]m/[I]nch

NOMINAL WIDTH: 0.00

TOLERANCE: [A]BS/[P]CENT

+T1: 0.00

-T1: 0.00

+T2: 0.00

-T2: 0.00

- 4.3.5 Put the Nominal/Standard width here. To select unit of length as Millimeter press 'm' and as Inch press 'I'. For tolerance press 'A' for Absolute or press 'P' for Percent. Then press 'ENTER' and the screen appears as-

EDIT RECIPE

RECIPE NO: 2

UNIT OF THICKNESS: [m]m/[I]nch

NOMINAL THICKNESS: 0.00

TOLERANCE: [A]BS/[P]CENT

+T1: 0.00

-T1: 0.00

+T2: 0.00

-T2: 0.00

Create Recipe Menu Screen 4

- 4.3.6 Put the Nominal/Standard thickness. To select unit of length as Millimeter press 'm' and as Inch press 'I'. For tolerance press 'A' for Absolute or press 'P' for Percent. Then press 'ENTER' and the screen appears as-



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EDIT RECIPE

RECIPE NO: 2

UNIT OF DIAMETER: [m]m/[I]nch

NOMINAL DIAMETER: 0.00

TOLERANCE: [A]BS/[P]CENT

+T1: 0.00

-T1: 0.00

+T2: 0.00

-T2: 0.00

Create Recipe Menu Screen 5

- 4.3.7 Put the Nominal/Standard Diameter here. To select unit of length as Millimeter press 'm' and as Inch press 'I'. For tolerance press 'A' for Absolute or press 'P' for Percent. Then press "ENTER".

EDIT RECIPE

RECIPE NO: 2

UNIT OF HARDNESS: [K]p/[N]/[S]c/[U]d

NOMINAL HARDNESS: 0.00

TOLERANCE: [A]BS/[P]CENT

+T1: 0.00

-T1: 0.00

+T2: 0.00

-T2: 0.00

Create Recipe Menu Screen 1

- 4.3.8 Enter the Nominal/Standard Hardness here. To select unit of Hardness as Kilopond



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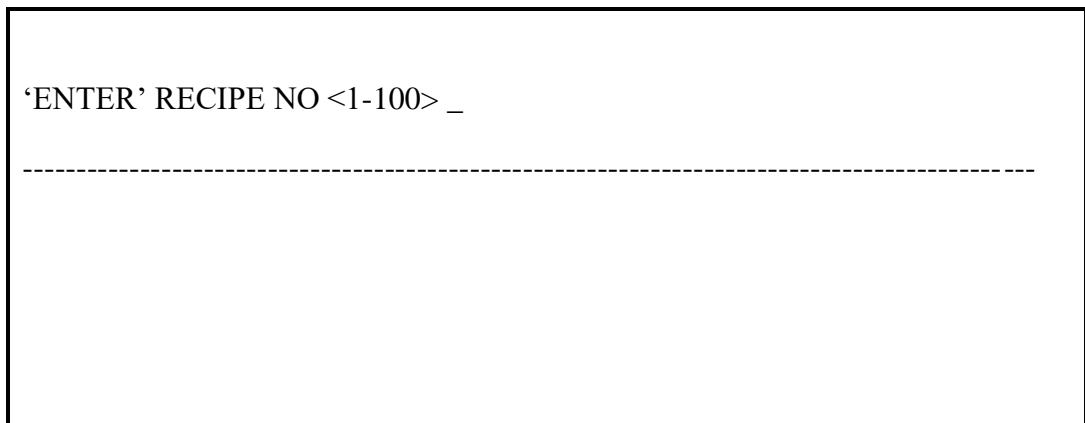
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press 'K', as Newton press 'N' as Strong Cubb press 'S' and for User Defined press 'U'. For tolerance press 'A' for Absolute press 'P'.

4.4 View recipe:

By pressing 'V' key it will go into the View recipe menu. It shows different recipes which have created. The screen appears as-



View Recipe Menu Screen

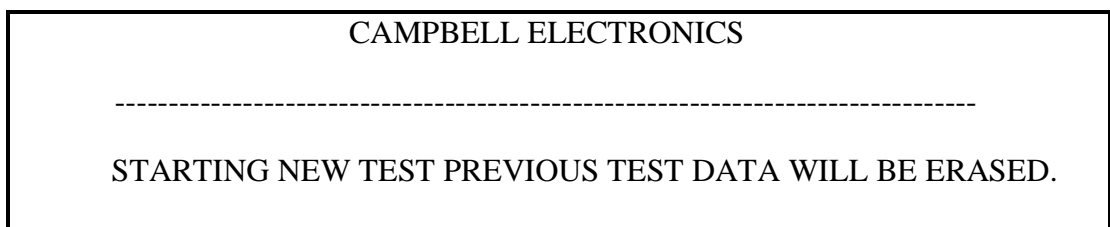
4.4.1 Put the recipe no. then it will show the View recipe screen.

4.5 Edit Recipe:

4.5.1 By pressing 'E' key it will go into edit recipe menu. Here different recipes can be edited which have been already created.

4.6 Initial Setting :

4.6.1 By pressing 'S' key in the Main Menu Screen it will go into Start test menu.





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DO YOU WANT TO PRINT OUT?

‘P’ : CONTINUE WITH PRINT OUT

‘C’ : CONTINUE WITHOUT PRINT OUT _

Start Test Menu Screen 1

4.6.2 It is necessary for the end user to have print report of the last data conducted by pressing “P” key.

4.6.3 If continue without printing, and then go for “C”. It appears as-

TEST NO :

RECIPE NO : _

Start Test Menu Screen 2

4.6.4 Put the recipe no. regarding the test tablet and press ‘ENTER’ key. Then next Start test menu appears as –

TEST NO :

RECIPE NO :

BATCH NO : _

Start Test Menu Screen 3

4.6.5 Press ‘ENTER’ Key after putting the Batch no. to view the next screen. It appears



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as-

TEST NO:

RECIPE NO:

VALID SAMPLES : 170

FOR WEIGHT : 50

FOR WIDTH : 50

FOR THICKNESS : 10

FOR DIAMETER : 50

FOR HARDNESS : 10

Start Test Menu Screen 4

If 50 samples for weight, 50 samples for width, 10 samples for thickness, 50 samples for diameter and 10 samples for hardness check to be performed.

4.6.6 Add the above value above the screen and press “ENTER” key to view the next screen of Auto and Manual mode screen.

4.6.7 **Test in manual mode:**

4.6.7.1 After press “ENTER” key to Start test menu screen 4. Then next Start test menu appears, where unit ask about test mode whether Auto mode or Manual mode. It appears as-



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TEST NO:

[A]UTO / [M]ANNUAL_

Start Test Menu Screen 5

For auto mode press 'A' key. For manual mode press 'M' key.

4.6.7.2 If manual mode selects ,the display appears as-

TEST NO:

[A]UTO / [M]ANNUAL_

'ENTER' BACK OFF DISTANCE (2mm-15mm) : _

Start Test Menu Screen 6

4.6.7.3 After putting the back off distance screen displays as-



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NO.	WEIGHT	WIDTH	THICK	DIAM	HARDNESS
	50	50	10	50	10 N

-----SAMPLE NO 1-----

1

ESC: ABORT TEST_

'ENTER': CONTINUE

Start Test Menu Screen 7

4.6.7.4 Place the tablet towards the load cell and press 'ENTER' key two times.

4.6.7.5 Place the tablet Horizontally to measure 'Width'. Jaw will start moving forward until tablet touches load cell without breaking tablet and goes back to home position.

CAMPBELL ELECTRONICS

NO.	WEIGHT	WIDTH	THICK	DIAM	HARDNESS
	50	50	10	50	10 N

-----SAMPLE NO 1-----

1

9.49

Start Test Menu Screen 8



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4.6.7.6 Place the tablet Vertically to measure 'Thickness'. Jaw will start moving forward until tablet touches load cell without breaking tablet and goes back to home position.

CAMPBELL ELECTRONICS					
NO.	WEIGHT	WIDTH	THICK	DIAM	HARDNESS
	50	50	10	50	10 N
-----SAMPLE NO 1-----					
1		9.49	6.70		

Start Test Menu Screen 9

4.6.7.7 Place the tablet Horizontally to measure 'Diameter'. Jaw will start moving forward until tablet touches load cell without breaking tablet and goes back to home position.

CAMPBELL ELECTRONICS					
NO.	WEIGHT	WIDTH	THICK	DIAM	HARDNESS
	50	50	10	50	10 N
-----SAMPLE NO 1-----					
1		9.49	6.70	18.55	

Start Test Menu Screen 10

4.6.7.8 Place the tablet Horizontally to measure 'Hardness'. Jaw will start moving forward until tablet breaks and goes back to home position.



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CAMPBELL ELECTRONICS					
NO.	WEIGHT	WIDTH	THICK	DIAM	HARDNESS
	50	50	10	50	10 N
-----SAMPLE NO 1-----					
1		9.49	6.70	18.55	130.42

Start Test Menu Screen 11

4.6.8 Operation in Auto Mode:

4.6.8.1 All the screens and functions in the manual mode remains same till the below screen

TEST NO:
[A]UTO / [M]ANNUAL_

Start Test Menu Screen 12

4.6.8.2 Here press 'A' for auto mode and the display appears as-

TEST NO:
[A]UTO / [M]ANNUAL

'ENTER' DELAY (1 SEC – 15 SEC) : _

Start Test Menu Screen 13



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4.6.8.3 Put the delay seconds and press 'ENTER' key to view the next screen.

TEST NO: [A]UTO / [M]ANNUAL ----- 'ENTER' back of distance (2mm – 15mm) : _
--

Start Test Menu Screen 14

4.6.8.4 Put the backup distance and press 'ENTER' to start the test.

4.6.8.5 As the 'ENTER' key is pressed the function starts automatically

4.7 View Statistics:

4.7.1 While set tests are going on, then press 'ESC' key to go to Statistic Menu .it appears as-

CAMPBELL ELECTRONICS ----- 'V' :- VIEW STATISTICS 'R' :- RESUME TEST 'X' :- EXIT FROM TEST
--



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'P' :- PRINT SLIP AND EXIT _

View Statistics Menu Screen 1

4.8 Settings:

- 4.8.1 By pressing 'T' key on the main menu screen at the Administrator level and Supervisor level, Setting Menu screen appears as-

CAMPBELL ELECTRONICS

'C' : REAL TIME CLOCK SETTING

'R' : RESET TEST NO.

'N' : COMPANY NAME.

'P' : PRINTER SET

'ESC' : EXIT _

Setting Menu Screen

- 4.8.2 By pressing 'C' key 'Real Time and clock setting as shown below

REAL TIME CLOCK SETTING

DATE :



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MON :
YEAR :
HOURS :
MIN :

Real Time Clock Setting Menu Screen

4.8.3 By pressing 'R' key the 'Reset Test No. Menu appears as -

CAMPBELL ELECTRONICS	

RESET SERIAL NUMBER CONFIRMATION	
'R' :	RESET TEST SR. NO.
'ESC' :	EXIT

Reset Test No. Menu Screen

4.8.4 By pressing 'R' key the Test Numbers will be Reset and the unit returns to Main Menu.

4.8.5 By pressing 'N' key the Company Name Menu Screen appears as -

CAMPBELL ELECTRONICS	

COMPANY NAME : _	



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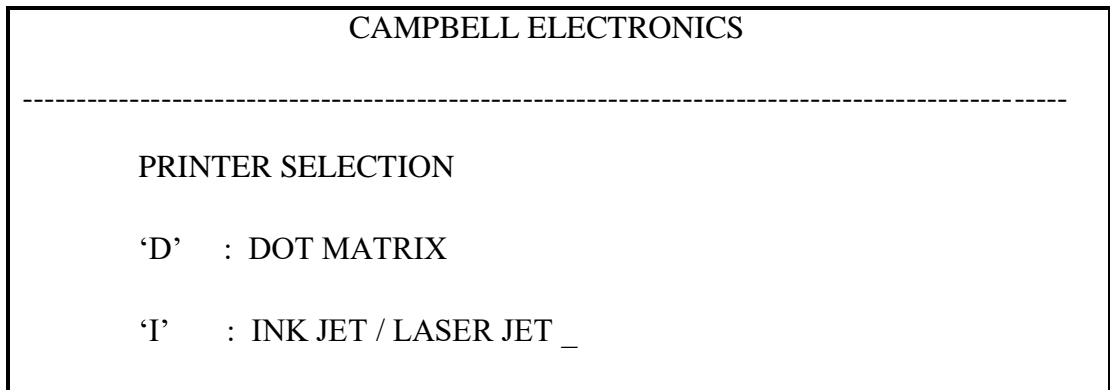
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Company Name Menu Screen

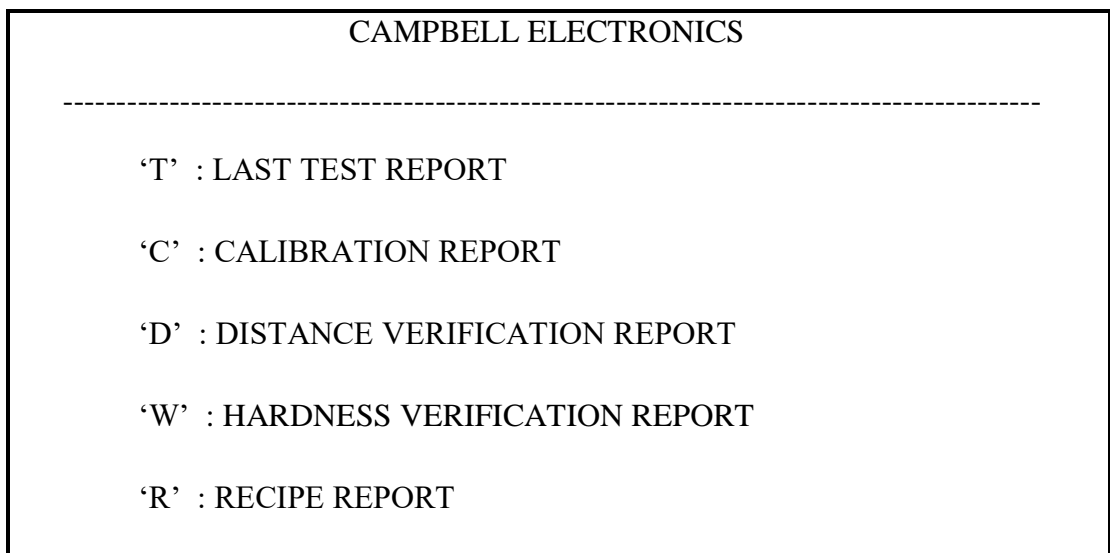
4.8.6 By pressing 'P' key' the Printer setting Menu Screen appears as-



Printer setting Menu Screen

4.9 REPORT:

4.9.1 In main menu by pressing the 'P' key ,then 'Report Menu' appears as -





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'U' : USER REPORT

Report Menu Screen

4.10 Calibration/Verification

- 4.10.1 Press the 'C' key in the Main Menu to open the Calibration/Verification Menu
Screen appears as-

CAMPBELL ELECTRONICS

'V' :- DISTANCE VERIFICATION

'L' :- HARDNESS VERIFICATION

'C' :- DISTANCE CALIBRATION

'Q' :- HARDNESS CALIBRATION

'ESC' :- EXIT

Calibration/Verification Menu Screen

- 4.10.2 Distance Calibration:

- 4.10.2.1 In the Calibration Menu, press 'C' key to enter into the Distance Calibration Menu Screen.
- 4.10.2.2 The unit will show Coarse Calibration first followed by Fine Calibration as shown below.
- 4.10.2.3 Here, tongue starts moving forward from home position, then tongue jaw touches the load cell and comes back to ensure the Zero position.



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CALIBRATING SYSTEM . . .

CALIBRATING COARSE CYCLE . . .

ESC :- TO ABORT _

Distance calibration Menu Screen 1

CALIBRATING SYSTEM . . .

CALIBRATING FINE

ESC :- TO ABORT _

Distance calibration Menu Screen 2

4.10.2.4 After ensuring the zero position the display appears as-



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CALIBRATING SYSTEM . . .

PUT 10mm GAUGE ON TONGUE AND PRESS 'ENTER' KEY_

ESC :- TO ABORT

Distance calibration Menu Screen 3

4.10.2.5 To continue the calibration, put 10 mm gauge on tongue and press 'ENTER' key.

If the result is in acceptable limits the unit will complete the calibration and display will return to main menu otherwise the display will prompt the following screen.

CALIBRATING SYSTEM . . .

GAUGE DIMENSION NOT IN ACCEPTANCE LIMIT

CALIBRATION ABORTED.

'ENTER' :- TO ABORT

Distance calibration Menu Screen 4



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4.10.3 Distance Verification:

4.10.3.1 In the Calibration/Verification Menu Screen press 'V' key to 'ENTER' into the 'Distance Verification Menu Screen' appears as -

DISTANCE VERIFICATION ----- PUT ANY KNOWN VALUE GAUGE ON JAW 'ENTER' VALUE OF GAUGE : _
--

Distance Verification Menu Screen 1

4.10.3.2 After putting value of gauge press 'ENTER'. Then the screen appears as-

DISTANCE VERIFICATION ----- PUT ANY KNOWN VALUE GAUGE ON JAW 'ENTER' VALUE OF GAUGE : 10 'ENTER' : START
--

Distance Verification Menu Screen 2

4.10.3.3 Place 10 mm Gauge block on jaw and press 'ENTER' key to start the verification test. The jaw moves forward and measures the dimension of Gauge block and come back to home position.



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DISTANCE VERIFICATION

BLOCK SIZE(mm) : 10.00

VERIFICATION RESULT (mm) : 9.99

DEVIATION (mm) : 0.01

‘ENTER’ : VERIFY AGAIN

ESC : EXIT

Distance Verification Menu Screen 3

4.10.4 Hardness Calibration:

4.10.4.1 In the Calibration/Verification Menu Screen press the ‘Q’ key to ‘ENTER’ in to the ‘Hardness Calibration Menu Screen’ appears as-

CAMPBELL ELECTRONICS

HARDNESS CALIBRATION

DO YOU WANT TO CALIBRATE FOR HARDNESS?

‘ENTER’ : CONTINUE

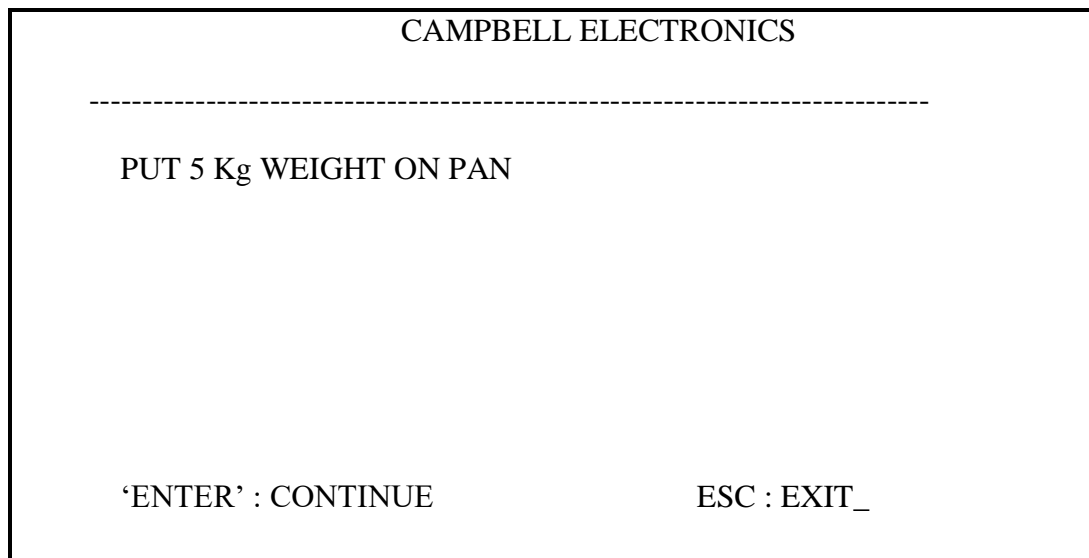
ESC : EXIT_



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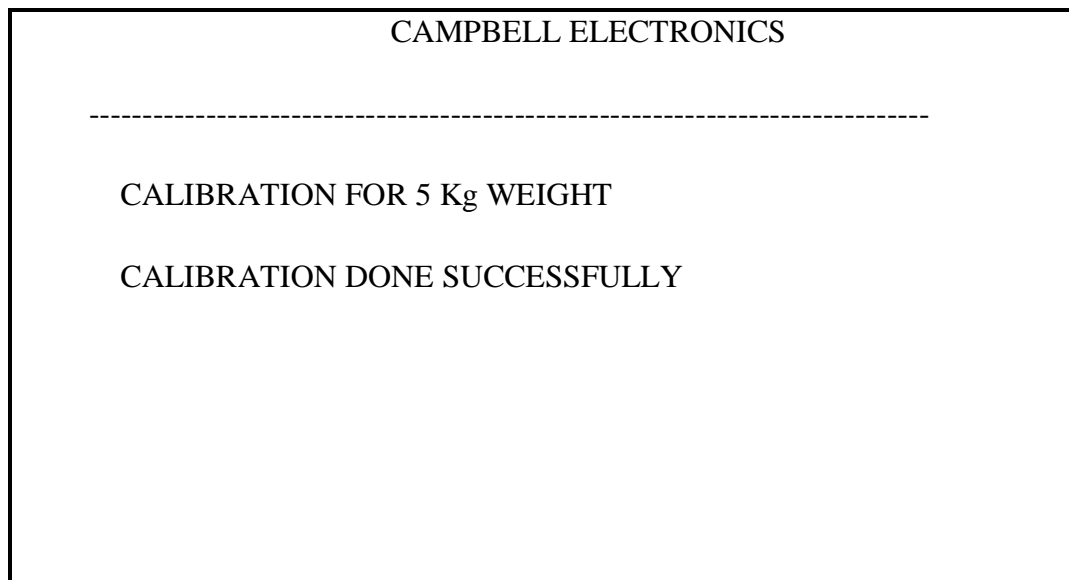
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4.10.4.5 After completing Calibration for Zero Reference, the display will appears as



Hardness Calibration Menu Screen 4

4.10.4.6 Then load the 5.0 Kg weight on the Weight Holder and press 'ENTER' key to continue the Calibration. Then the display will show the below screen





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'ENTER' : CONTINUE _

Hardness Calibration Menu Screen 5

- 4.10.4.7 Press 'ENTER' key to continue the Calibration process and the display will show the below screen.

CAMPBELL ELECTRONICS

CALIBRATION DUE DATE

1. AFTER 1 MONTH
2. AFTER 3 MONTHS
3. AFTER 6 MONTHS

Hardness Calibration Menu Screen 6

- 4.10.4.8 Select any of duration by pressing the appropriate Numerical key. Then the display will show the below screen.



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CAMPBELL ELECTRONICS

CALIBRATION DATE : <Date>

CALIBRATION DUE DATE : <Date>

'ENTER' : CONTINUE

Hardness Calibration Menu Screen 7

- 4.10.4.9 Then press the 'ENTER' key to print the calibration data and after printing is over the displays shows the Main Menu Screen. Remove the weight from the Weight Holder.

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PRINTING.....

PRINTER ERROR

'ENTER' : RETRY

ESC : EXIT

Hardness Calibration Menu Screen 8



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4.10.5 Hardness Verification:

4.10.5.1 In the Calibration/Verification Menu Screen press 'L' key to 'ENTER' into the Hardness Verification Screen.

CAMPBELL ELECTRONICS

HARDNESS VERIFICATION

DO YOU WANT TO VERIFICATION FOR HARDNESS?

'ENTER' : CONTINUE

ESC : EXIT

Hardness Verification Menu Screen 1

4.10.5.2 Press 'ENTER' to continue and the display will shows

CAMPBELL ELECTRONICS

SLIDE OUT LOADCELL COVER AND ARRANGE

SET UP FOR CALIBRATION / VERIFICATION.

REFER OPERATING MANUAL.

'ENTER' : CONTINUE

ESC : EXIT_

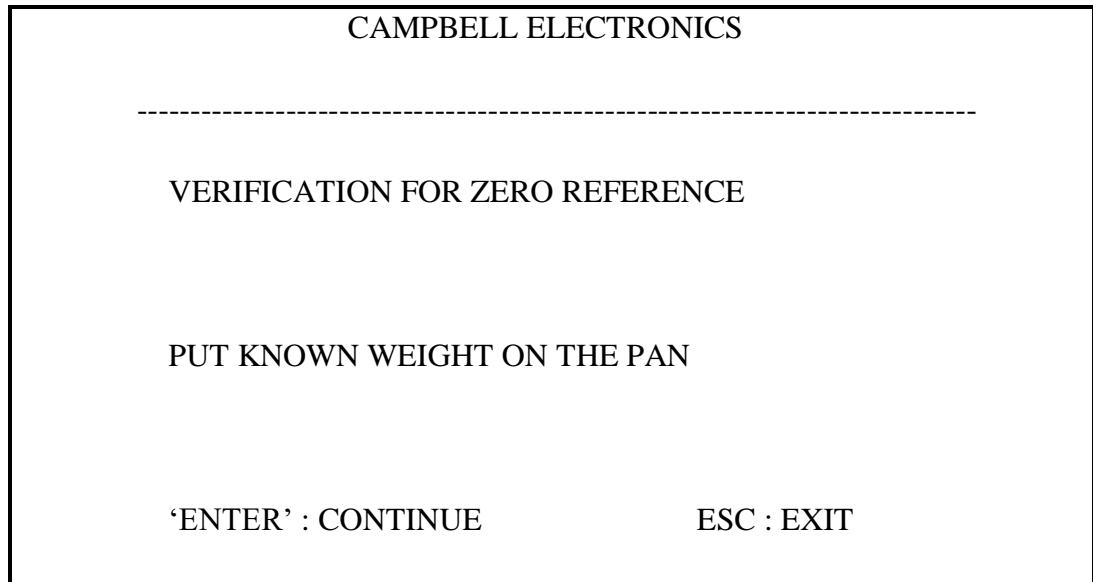
Hardness Verification Menu Screen 2



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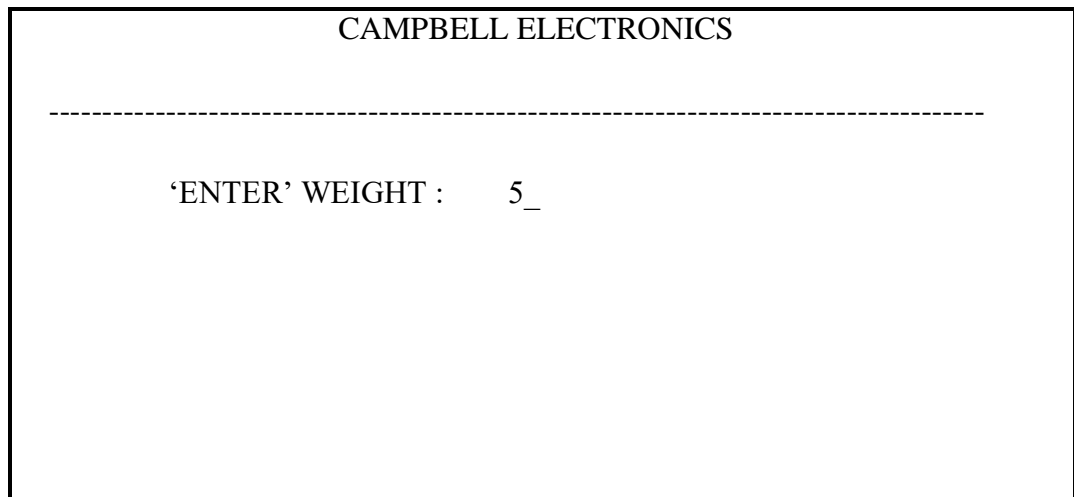
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4.10.5.3 Perform the above indicated steps as point no. 4.10.4.3 to 4.10.4.4 to set up for Hardness Verification and press 'ENTER' to continue.



Hardness Verification Menu Screen 3

4.10.5.4 After verification for zero reference the unit will indicate to load known weight on the weight holder. Then press 'ENTER' to 'ENTER' into next screen.



Hardness Verification Menu Screen 4



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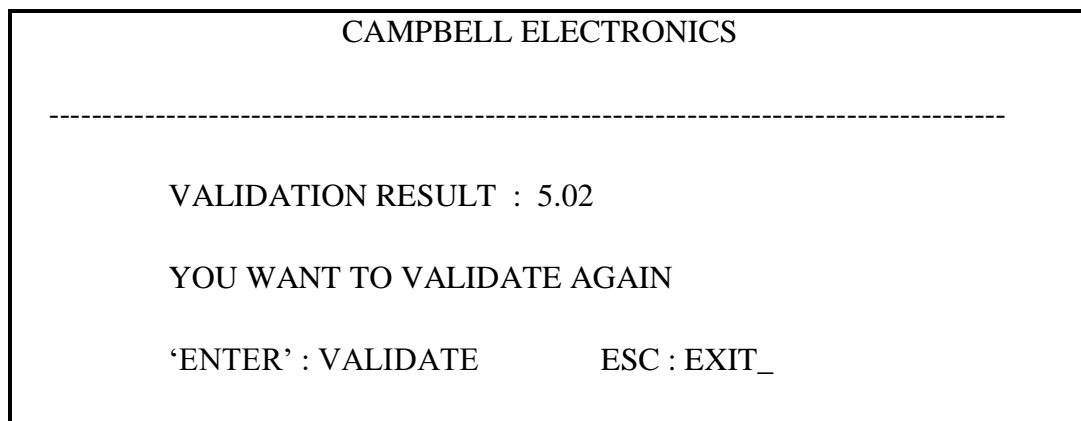
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4.10.5.5 Here 'ENTER' the value of Weight in the screen and press 'ENTER'.



Hardness Verification Menu Screen 5

4.10.5.6 Press 'ESC' to exit from the Verification Screen and 'ENTER' into the Main Menu Screen.

4.10.5.7 **Frequency:**

Verification should be performed once daily.

Calibration should be performed monthly ± 3 days and after any breakdown.

4.11 Cleaning:

4.11.1 Clean the Platform, area between jaws, load cell, moving Jaws, Tablet Debris Collection Box and Outer Side of the Tablet Tester with the help of dry Lint free cloth followed by lint free cloth dipped in 70% V/V IPA once daily before starting of activity and no powder is adhered to the jaws before further testing.

4.11.2 Clean the platform, area between jaws and load cell & moving jaws with help of dry lint free cloth and nylon brush after every test.

4.12 Precaution:

4.12.1 Never keep the hardness tester jaws under tension, when not in use.



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4.12.2 Do not perform operation without putting Tablet between the moving Jaws.

5.0 ANNEXURE (S):

Annexure-I:TABLET TESTER CALIBRATION RECORD(CAMPBELL WWTDH 550)

Annexure-II:TABLET TESTER DAILY VERIFICATION RECORD(CAMPBELL WWTDH 550)

6.0 REFERENCE (S) :

SOP: Preparation, approval, Distribution control, Revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) /DEFINITION (S) :

V/V : Volume / Volume

kg : Kilogram

IPA : Isopropyl Alcohol



PHARMA DEVILS

PRODUCTION DEPARTMENT

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REVISION CARD

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