



PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering	SOP No.:
Title: Calibration of Kaye Digilink with Thermocouple of Blow Fill Seal Machine	Effective Date:
Supersedes: Nil	Review Date:
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1.0 **OBJECTIVE:**

To lay down the procedure for calibration of Kaye Digilink with Thermocouple of Blow Fill Seal Machine.

2.0 **SCOPE:**

This standard operating procedure (SOP) is applicable for calibration of Kaye Digilink with Thermocouple of Blow Fill Seal Machine.

3.0 **RESPONSIBILITY:**

Executive Engineering will perform the Calibration and prepare the data sheet.
Manger Engineering will check the data sheet and calibration certificate.
Manager QA will verify & approved the data and calibration certificate

4.0 **PROCEDURE:**

4.1 Instruments used

4.1.1 Low Temperature Reference (LTR).

Make: Kaye Instruments.

4.1.2 Universal Calibrator.

Make: Radix.

Model: Micro cal.

4.2 Procedure for calibration of Kaye Digilink

4.2.1 Note down the following parameter in calibration certificate.

Nomenclature.

Location.

Identification No.

Range.

Least Count.

Type.

Ambient Temperature (°C).

RH.

4.2.2 Refer SOP No:..... for calibration due date of field Instruments.

4.2.3 Switch 'ON' BFS machine main panel and put 'ON' the Kaye Digilink by opening front panel of Kaye Digilink.



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- 4.2.4 Select channel under calibration by pressing channel key and with UP/ DOWN arrow key of Kaye Digilink operating panel.
- 4.2.5 Connect mV / thermocouple terminals of universal calibrator to selected channel of Kaye Digilink.
- 4.2.6 Switch 'ON' universal calibrator and select thermocouple type on the calibrator display.
- 4.2.7 Keep universal calibrator in auto compensation mode.
- 4.2.8 Enter 0°C from keyboard of universal calibrator and simulate selected channel on Digilink read temperature on Digilink display.
- 4.2.9 Press INPUT 1 key once to read input 1 of selected channel from Kaye Digilink operating panel.
- 4.2.10 Press ALPHA SHIFT on Kaye Digilink operating panel till you get constant reading of current input value on Kaye Digilink display.
- 4.2.11 Press ENTER key on Kaye Digilink operating panel to enter this actual input1.
- 4.2.12 Press OUTPUT key on Kaye operating panel once to read set value of output 1 on Kaye Digilink display.
- 4.2.13 Enter simulator reading in output 1.
- 4.2.14 Press ENTER key to enter this value in output 1.
- 4.2.15 Note down three readings of full scale from keyboard of universal calibrator and simulate selected channel on Digilink.
- 4.2.16 Read temperature on Digilink of selected channel.
- 4.2.17 Press INPUT key twice on Kaye Digilink front panel to read input 2 of selected channel on Kaye Digilink display.
- 4.2.18 Press ALPHA SHIFT Key from Kaye operating panel till you get constant reading of current input 2 values.
- 4.2.19 Press ENTER key to enter this actual input 2 value in Kaye Digilink.
- 4.2.20 Press OUTPUT key twice from Kaye Digilink operating panel to read set value of output 2 on Kaye Digilink display.
- 4.2.21 Enter simulator output reading in output 2.
- 4.2.22 Press ENTER key from Kaye Digilink operating panel to enter this value in output 2 in Kaye Digilink.
- 4.2.23 Repeat the steps 4.2.5 – 4.2.22 for calibration of remaining channels.
- 4.2.24 Remove and destroy the calibration tag and note down in the destruction format as per SOP No : N/EN/028/01.
- 4.2.25 Fill up the calibrated tag and attached with the calibrated Kaye Digilink.
- 4.2.26 Note down the readings in the calibration certificate as per Annexure II



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- 4.3 Calibration of kaye Digilink with thermocouples
- 4.3.1 Required instruments (Universal calibrator, LTR).
- 4.3.2 Put 'ON' Kaye Digilink from Digilink toggle switch.
- 4.3.2 Switch 'ON' LTR.
- 4.3.3 Press the set switch on operating panel to set the required temperature of LTR.
- 4.3.4 Insert the thermocouple into well of LTR and set temperature 0°C from LTR operating panel and wait for stabilize the reading.
- 4.3.5 Connect under test thermocouple cable to Kaye Digilink selected channel.
- 4.3.6 Press INPUT key twice to read input 2 of selected channel.
- 4.3.7 Press ALPHA SHIFT repeatedly to read actual current input 2 values.
- 4.3.8 Press ENTER key to enter this actual value input 2 values.
- 4.3.9 Press OUTPUT key twice to read set value of output 2.
- 4.3.10 Press ENTER key to enter this value in output 2.
- 4.3.11 Repeat step 4.3.2 – 4.3.11 for calibration of remaining all thermocouples and all channels.
- 4.3.12 Note down the readings of universal calibrator and under calibration thermocouples sensors with Kay Digilink in the calibration certificate.
- 4.3.13 Destroy the due calibration tag and note down in the destruction format as per SOP No :.....
- 4.3.14 Fill up the calibrated tag and attached with the Sensors.
- 4.3.15 Note down the readings in the calibration certificate as per Annexure III.
- 4.3.16 Connect all thermocouple with Kaye Digilink at its specified locations.

4.4 Acceptance criteria:

- 4.4.1 BFS Thermocouples = $\pm 1^\circ$

5.0 SAFETY AND PRECAUTIONS:

Not Applicable

6.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date
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7.0 REFERENCES:

- IS 2848 – 1986 for Temperature Sensor.
- Operating manual of LTR (-25)/140.
- Operating manual of universal calibrator.
- Operating manual of Kaye Digilink.

8.0 ABBREVIATIONS:

- SOP: Standard Operating Procedure.
- LTR: Low Temperature Reference.
- BFS: Blow Fill Seal.
- RH: Relative Humidity
- QA: Quality Assurance

9.0 ANNEXURE:

- Annexure – I: List of Thermocouple.
- Annexure – II: Calibration certificate
- Annexure – III: Calibration certificate



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Annexure – I List of Thermocouple

Channel No.	Name	Location
101	TC1 thermocouple	Steam inlet
103	TC3 thermocouple	Prod. Filter 1 vertical
105	TC5 thermocouple	Prod. Filter 2 vertical
107	TC7 thermocouple	Prod. Supply Drain inlet
108	TC8 thermocouple	Prod. Drain filter 1 inlet
109	TC9 thermocouple	Prod. Filter 1 drain
110	TC10 thermocouple	Valve V3 Drain
111	TC11 thermocouple	Test Air filter drain
112	TC12 thermocouple	Buffer tank vessel
113	TC13 thermocouple	Prod. Filter 2 drain
114	TC14 thermocouple	Buffer tank filter drain
115	TC15 thermocouple	Buffer tank filter outlet drain
116	TC16 thermocouple	Buffer tank drain
117	TC17 thermocouple	Balloon Filter outlet
118	TC18 thermocouple	Fill nozzle steam cup Drain
119	TC19 thermocouple	Fill nozzle Steam cup drain
120	TC20 thermocouple	Blow filter down
203	TC21 thermocouple	Full nozzle Blowing line outlet.
204	TC22 thermocouple	Blow filter outlet
205	TC23 thermocouple	Balloon filter Drain
206	TC24 thermocouple	Blow Fill Vent
207	TC25 thermocouple	Top and Bottom tank
208	TC26 thermocouple	Bottom or holding tank
209	TC27 thermocouple	Nozzle vertical 1
210	TC28 thermocouple	Nozzle vertical 2
211	TC29 thermocouple	Nozzle vertical 3
212	TC30 thermocouple	Nozzle vertical4
213	TC31 thermocouple	Top of suspension tank
214	TC32 thermocouple	Top of suspension tank
312	Mx Temp	Max temp.
313	Mx CHNL	Max Temp channel Location
314	MIN TMP	Min Temp.
315	MIN CHNL	Min temp. Channel location



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Annexure – II Calibration certificate

Certificate No:	Calibration On:
Tested at:	Next due On:

ITEM DETAILS

Nomenclature: BFS Kaye Digilink.	Location:
I.D No.:	Type:
Range:	Ambient Temperature:
Least Count.	RH:

STANDARD USED FOR CALIBRATION

S.No.	Nomenclature	Cert. No.	Tractability to	Validity
1	Universal Calibrator.			
2	LTR (-25)/140.			

OBSERVED READINGS

S.No.	Standard Temperature (°C)	Sensor under Calibration (°C)	Deviation in °C
1			
2			
3			
4			
5			

Reference used: IS 2848 – 1986 for Temperature Sensor

REMARKS: 1 . Maximum accuracy of this temperature sensor is within / outside specified.
2. All measurement standards used for calibration are traceable to National Standards with unbroken chain.

Calibrated By:

Certified By:



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Annexure – III Calibration certificate

Certificate No:	Calibration On:
Tested at:	Next due On:

ITEM DETAILS

Nomenclature: BFS Kaye Digilink.	Location:
I.D No.:	Type:
Range:	Ambient Temperature:
Least Count.	RH:

STANDARD USED FOR CALIBRATION

Sr. No.	Nomenclature	Cert. No.	Tractability to	Validity
1				
2				



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OBSERVED READINGS

S. No.	T/C ID	SET TEMP	READING OF LTR	READING ON KAYE DIGILINK	DEVIATION	SIGN
1						
2						
3						
4						
5						
6						
7						
8						

Reference used: IS 2848 – 1986 for Temperature Sensor

REMARKS: 1. Maximum accuracy of this temperature sensor is within / outside specified.
2. All measurement standards used for calibration are traceable to National Standards with unbroken chain.

Calibrated By:

Certified By: