TITLE: PROCEDURE FOR CALIBRATION

1.0 PURPOSE:

To describe the Procedure for Calibration

2.0 SCOPE:

This Procedure is applies to the instruments which are being used at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 **Electrician**

Is the responsibility of carrying out the calibration of Instruments by In house.

3.2 **Engineer:**

Is the responsible to monitor the activity

3.3 **Engineering Head:**

Is the overall responsibility for whole activity

3.4 **User Department:**

It is the user department responsibility to release the instruments for calibration, based on Annual calibration schedule.

4.0 DEFINITIONS:

4.1 **Calibration:** Calibration is the setting or correcting of a measuring device or base level, usually by adjusting it to match or confirm to a dependably known and unvarying measure.

5.0 PROCEDURE :

5.1 **Schedule :**

5.1.1 **In House Calibration:** Once in six months with ± 7 days of scheduled date or whenever necessary for Digital Temperature Indicator, Dial Pressure gauge and Dial Vacuum gauge

5.1.2 **External Calibration:**

5.1.2.1 Once in a year with ± 7 days of scheduled date or whenever necessary for PT-100 RTD Calibrator and Master gauges

5.1.2.2 Once in six months with ± 7 days of scheduled date or whenever necessary for RTD sensors.

5.2 **<u>In house Calibration of Digital temperature indicator</u>:**

5.2.1 Before starting of activity wear the safety Personal Protection Equipment (PPE) like Helmet, Goggles, Safety Shoe, Hand gloves, etc.,

5.2.2 Take a standard RTD Calibrator (PT-100), which is traceable & approved by National Testing Laboratory.

5.2.3 Open the covers of two chambers of the Digital Temperature Indicator (Main front Cover and terminal cover) and disconnect the RTD sensor terminals from DTI & connect standard RTD calibrator terminals to RTD sensor terminals of the Digital Temperature Indicator.

5.2.4 Step-1: Select and adjust the standard RTD calibrator knob at -50°C and check the display reading of the temperature indicator which should show -50°C. If any deviation is found adjust pot 1 which is located in the temperature Indicator until display reads -50°C and record the deviation if any.

5.2.5 Step-2: Select and adjust the standard RTD calibrator knob to 0°C and check the display reading of the temperature indicator which should show 0°C. If any deviation found adjust pot 1, which is located in the temperature indicator until, display reads 0°C and record the deviation if any.

5.2.6 Step-3: Select and adjust the standard RTD calibrator knob to 100°C and check the display reading of the temperature indicator which should show 100°C. If any deviation found adjust pot 2, which is located in the temperature indicator

As per the example given below:

5.2.6.1 If the temperature indicator shows positive error, decrease the display value by the same amount of error by adjusting Pot 2 of the temperature indicator.

Example # 1	Calibration Value Display reads Display error Display to be adjusted	100.0°C 101.0°C +1.0°C 100.0°C
Example # 2	Calibration Value Display reads Display error Display to be adjusted	-50.0°C -50.4°C +4.0°C -50.0°C

5.2.6.2 If the temperature indicator shows negative error, increase the display value by the same amount of error by adjusting Pot 2 of the temperature indicator.

Example # 1	Calibration Value Display reads Display error Display to be adjusted	100.0°C 99.0°C -1.0°C 100.0°C
Example # 2	Calibration Value Display reads Display error Display to be adjusted	-50.0°C -49.5°C -0.5°C -50.0°C

5.2.7 Step-4: Select and adjust the standard RTD calibrator knob at 199°C and check the display reading of the temperature indicator which should show 199°C if any deviation found adjust pot 2 which is located in the temperature indicator until, display reads 199°C and record the deviation if any.

5.2.8 Step-5: Select and adjust the standard RTD calibrator knob at 300°C and check the display reading of the temperature indicator which should show 300°C if any deviation found adjust pot 3 which is located in the temperature indicator until, display reads 300°C and record the deviation if any.

5.2.9 Step-6: Select and adjust the standard RTD calibrator knob at 350°C and check the display reading of the temperature indicator which should show 350°C if any deviation found adjust pot 3 which is located in the temperature indicator until, display reads 350°C and record the deviation if any.

5.2.10 Acceptance criteria of digital temperature indicator is ± 1 ^{0}C of reference temperature & display the calibration tag ED002-FM008 in the instrument.

5.2.11 Record the readings in In house calibration report of Digital Temperature Indicator ED002-FM002

5.2.12 During periodical calibration checks, if the Engineering Department found any error which is out of acceptance criteria same shall be informed to QA with report. If the readings are above the acceptance criteria, then send it for necessary repairs and Sticker should be displayed indicating “OUT OF ORDER”.

5.2.13 Then remove the meter from the position for necessary repairs (Disconnect supply before removing) and arrange calibrated standby DTI. Inform the same to concerned block in charge. After repairing and calibration of existing meter, standby

meter is to be replaced with the repaired one. If it is not repairable arrange new calibrated meter. Calibration activity should be performed as per ED002-FM002

5.2.14 In case of calibration facility not available at in-house, perform the calibration test of DTI by external calibration services.

5.3 **In-house calibration of Pressure gauge:**

5.3.1 Take the hand held test pump TP1-40.

5.3.2 Keep the Pump mode in pressure mode

5.3.3 Fix the master pressure gauge in one port and test gauge in other port.

5.3.4 Ensure both the gauges showing Zero pressure before applying the air pressure.

5.3.5 Step 1: Apply air pressure by pressing the pump bottom handles and adjust the pressure with the help of knob up to1 kg/cm² pressure showing in master gauge and check the reading in test gauge which should show 1 kg/cm² and record the deviation if any.

5.3.6 Step 2: Repeat the above step 5.4.5 and apply pressure of 2,4,6 and 7 kg/cm² for the gauges of range 0 to 7 kg/cm² and record the deviation if any.

5.3.7 Step 3: Repeat the above step 5.4.5 and apply pressure of 5, 10, 15, 20 and 21kg/cm² for the gauges of range 0 to 21 kg/cm² and record the deviation if any.

5.3.8 If the Pressure gauge shows more or less than the reference value

5.3.9 Example: Master gauge reading : 2.0 Kg/cm^2

Test gauge reading : 2.1 Kg/cm^2

Display error : + 0.1 Kg/cm^2

The display error is within the limit of acceptance criteria

Example: Master gauge reading : 2.0 Kg/cm^2

Test gauge reading : 1.8 Kg/cm^2

Display error : - 0.2 Kg/cm^2

The display error is within the limit of acceptance criteria

5.3.10 The accuracy of the testing gauge shall be checked by comparing with the master gauge in suitable increments within the working range.

5.3.11 Acceptance criteria for pressure gauge under calibration shall be ±0.2 Kg/cm^2

5.4 **In-house calibration of Vacuum gauge:**

5.4.1 Take the hand held test pump TP1-40.

5.4.2 Keep the Pump mode in Vacuum mode

5.4.3 Fix the master Vacuum gauge in one port and test gauge in other port.

5.4.4 Ensure both the gauges showing Zero vacuum before applying the vacuum.

5.4.5 Apply vacuum to the test setup with the help of Pressing handles and valve control and vacuum 200, 400, 600 and 720mmHg showing in master gauge and check the reading in test gauge which should show same value as master vacuum gauge and record the deviation if any.

5.4.6 If the Vacuum gauge shows more or less than the reference value

Example: Master gauge reading : 680 mmHG

Test gauge reading : 690 mmHG

Display error : + 10 mmHG

The display error is within the limit of acceptance criteria

Example: Master gauge reading : 680 mmHG

Test gauge reading : 670 mmHG

Display error : - 10 mmHG

The display error is within the limit of acceptance criteria

5.4.7 The accuracy of the testing gauge shall be checked by comparing with the master gauge in suitable increments within the working range.

5.4.8 Acceptance criteria for vacuum gauge under calibration shall be ± 20 mmHG.

5.5 Whenever some deviations are observed within due date of the calibration, concerned department in charge shall intimate to Engineering Head about the deviation.

5.6 After recalibration, the observed deviations and corrections shall be intimated to QA department along with details of the instrument by Engineering Head.

5.7 During periodical calibration checks if the Engineering Department found any error which is out of acceptance criteria same shall be informed to QA with report. If the readings are above the acceptance criteria, then send it for necessary repairs and sticker should be displayed indicating "OUT OF ORDER".

5.8 Then remove the Gauge from the position for necessary repairs and arrange calibrated standby Vacuum gauge & pressure gauge. Inform the same to concerned block in charge. After repairing and calibration of existing gauge, stand by gauge is to be replaced with the repaired one. If it is not repairable arrange new calibrated gauge. Calibration activity should be performed as per ED002-FM004.

5.9 The QA department shall investigate the history of instrument usage up to previous calibration date with the help of production and Engineering department and also prepare a report with final conclusion.

5.10 If the error of the gauge is not complies with the acceptance criteria replace with new gauge after informing to QA department with report.

5.11 Record the DPG and DVG observations in Gauge Calibration Observation Record, ED002-FM004.

6.0 FORMATS / ANNEXURE(S):

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Ch. Shankar	M. Ramesh	Ch. Mahendar Reddy
Department	Engineering	Engineering	Quality Assurance

6.1 In house calibration report of Digital Temperature Indicator : ED002-FM002

6.2 Gauge calibration observation record : ED002-FM004

6.3 Calibration Tag : ED002-FM008

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.	Remarks
00	01.08.2009	New SOP	---	---
01	17.07.2014	1) Removed the process of external calibration procedure for RTD sensors. 2) Included the Internal Calibration schedule for DTI and RTD Sensors	---	---
02	10.09.2014	1) Included the Calibration Log for digital temperature indicators, current version of MT-F-012 and Calibration Log for RTD sensors, current version of MT-F-013 2) Records are included in records column	---	---
03	01.01.2016	1) MT-F-003, MT-F-012, MT-F-013 removed from forms. 2) In house calibration schedule for DTI extended from three months to six months and relaxation period also extended ±3 days to ±7 days 3) Calibration of RTD sensors procedure	---	---

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Ch. Shankar	M. Ramesh	Ch. Mahendar Reddy
Department	Engineering	Engineering	Quality Assurance

Revision No.	Effective Date	Details of Revision	Ref. CCF No.	Remarks
		removed from SOP. 4) Included Calibration schedule of RTD sensors by external agency every six months with ±7 days relaxation period. 5) In records, MT-F-003, MT-F-012, MT-F-013 removed and MT-F-039, MT-F-040 introduced.		
04	01.01.2017	1. SOP format changed in line with SOP-QA-001-04 2. Calibration definition included 3. SOP MT-003-03 Merged with this SOP 4. Title name changed to Procedure for calibration 5. Gauge calibration observation record ED002-FM004 included	ED-CRF- 006/16	----
05	10.08.2017	1. SOP format changed in line with SOP-QA-001-05. 2. External calibration for DTI incorporated whenever required.	CCF/GEN/17007	--