

VALIDATION REPORT FOR STEAM STERILIZER

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Customer Name and Address:	EN VISION ENVIRO ENGINEERS PVT. LTD. Centralized Bio-Medical Waste Treatment Facility, Umarde Gaon, Next to Mutha Collage, Beside Umarde Dumping Ground, Adharwadi Jail Road, KALYAN WEST, Thane, Maharashtra-421301
Name of Equipment:	Steam Sterilizer
Identification No.:	1031

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MONITORED BY (RG TECHNOLOGIES)			REVIEWED BY (EN VISION ENVIRO ENGINEERS PVT. LTD.)	
Sign/Date				
Name	Sanjay Patel	Ganesh Patel		
Designation	Site Engineer	Technical Manager	User Department	Q.A.

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➤ **Details of Customer:**

Customer Name and Address:	EN VISION ENVIRO ENGINEERS PVT. LTD. Centralized Bio-Medical Waste Treatment Facility, Umarde Gaon, Next to Mutha Collage, Beside Umarde Dumping Ground, Adharwadi Jail Road, KALYAN WEST, Thane, Maharashtra-421301
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➤ **Validation Details:**

Name of Equipment	Steam Sterilizer	Acceptance Limit	+3°C
Identification No.	1031	Set Temperature	121.0°C
Make / Model	Modi Enterprise India MER-30	Validation Start Date	20/05/2022
Location / Department	-----	Validation Due Date	19/05/2023
Frequency of Reading	01 Min.	Sterilization Period	30 Minutes
Test Equipment Used	Data Logger	Nos of Probes Used	12 Channels
Cycle	Run -1 Heat Distribution in Empty Chamber Run - 2 Heat Penetration in Half Loaded Chamber Run - 3 Heat Penetration in Full Loaded Chamber		

➤ **Details of Master Instrument Used for Temperature Validation**

Name Of Standard Instrument	RGT Certi. No.	Inst. I.D. No / Sr. No.	Instrument Certi. No.	Valid Up to
Universal Input Data Logger - 16 Channel	001	RGT/UDL/01	RGT/E-751/21-22	20/08/2022
Thermocouple	014	RGT/TC/01	RGT/E-762/21-22	20/08/2022

NOTE: OUR REPORT TRACEABLE TO NATIONAL STANDARDS

➤ **Responsible Person:**

RG TECHNOLOGIES		EN VISION ENVIRO ENGINEERS PVT. LTD.	
Name	Designation	Name	Designation
Mr. Ganesh Patel	Technical Manager		

#Remark#

- The Results Reported in this Certificate is valid only at the time of and under the stated Conditions of the measurement.

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➤ **Purpose of Temperature Validation:**

The Temperature Validation Study is performed to check the following:

- To Determine the Temperature Variation of the Steam Sterilizer.
- To Check the Performance of Heating Source.

➤ **Pass Criteria:**

- The Result of Temperature Validation Study must objectively demonstrate that the Steam Sterilizer is able to control the Temperature within specified acceptance limit with high degree of accuracy.
- To ensure that the Temperature of the Chamber remains above 121.0°C and does not exceeds more than 124.0°C during sterilization period.

➤ **Procedure:**

- Locate 12 points as per taken measurements to place the sensor.
- Place the 12 sensors at different Specified Points.
- Connect the 12 sensors to Data Logger.
- Close the door of Steam Sterilizer Properly and start the Steam Sterilizer as per SOP.
- Ensure there is no leakage in the chamber.
- Collect the data and record the readings.
- Record the data for 01 minutes for Heat Distribution in Empty Cycle, Heat Penetration in Half & Full Loaded chamber respectively.

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Formula For F_0 Value Calculation

$$F_0 = \sum 10^{((t_a - t_b)/Z)} \times \Delta T$$

Whereas:

t_a = actual temperature measured.

t_b = base sterilization temperature i.e. 121.0°C

z = death value i.e. 10°C for steam sterilization

Δt = frequency of logged data time Interval

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➤ **Pre –Calibration of Thermocouple Sensor**

- Pre-calibration of Thermocouple sensor was carried out and results was satisfactory and temperature variation was under acceptance limit, brief observation given below

➤ **Observation Table:**

- **Date : 20/05/2022**
- **Calibration of Thermocouple Sensor at (100.0°C)**

Time	Std. Value	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
10:00:30	100.1	99.7	100.3	99.8	100.4	99.9	100.2	100.0	99.7	100.1	99.8	100.2	99.9
10:01:30	99.9	99.6	100.2	99.7	100.3	99.8	99.6	99.9	99.7	100.0	99.8	100.1	99.6
10:02:30	100.2	99.8	100.4	99.9	100.2	100.0	100.3	100.1	100.4	100.2	99.8	100.3	100.0
10:03:30	99.8	99.9	100.0	99.8	100.2	99.7	100.1	99.6	99.9	100.0	99.8	100.2	99.7
10:04:30	100.3	100.0	100.3	99.9	100.4	100.2	99.9	100.3	100.0	100.4	100.1	99.9	100.2

- **Calibration of Thermocouple Sensor at (121.0°C)**

Time	Std. Value	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
10:14:30	121.0	120.7	121.3	120.8	121.4	120.9	120.7	121.0	120.8	121.1	120.9	121.2	121.0
10:15:30	120.9	120.6	121.0	120.7	121.1	120.8	121.2	120.9	121.3	121.0	120.6	121.1	120.8
10:16:30	121.3	120.9	121.3	121.0	121.4	121.2	121.0	121.3	121.1	121.4	121.2	121.0	121.3
10:17:30	120.7	120.6	121.0	120.7	121.0	120.8	120.6	120.9	120.7	121.0	120.8	121.1	120.9
10:18:30	121.2	120.8	121.0	120.9	121.2	121.0	121.4	121.2	120.8	121.3	120.9	121.4	121.0

- **Calibration of Thermocouple Sensor at (130.0°C)**

Time	Std. Value	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
10:28:30	129.6	129.7	130.0	129.6	130.0	129.8	129.6	129.9	129.7	130.0	129.8	130.0	129.9
10:29:30	130.2	129.8	130.4	129.9	130.3	130.0	129.8	130.1	129.9	130.2	130.0	130.3	130.4
10:30:30	129.7	129.6	130.0	129.7	130.1	129.8	129.6	129.9	129.7	130.0	129.8	130.1	129.9
10:31:30	130.3	129.9	130.4	130.0	130.3	130.1	129.9	130.2	130.0	130.3	130.1	130.4	129.9
10:32:30	129.8	129.6	130.2	129.7	130.0	129.8	129.6	129.9	129.7	130.0	129.8	130.1	129.6

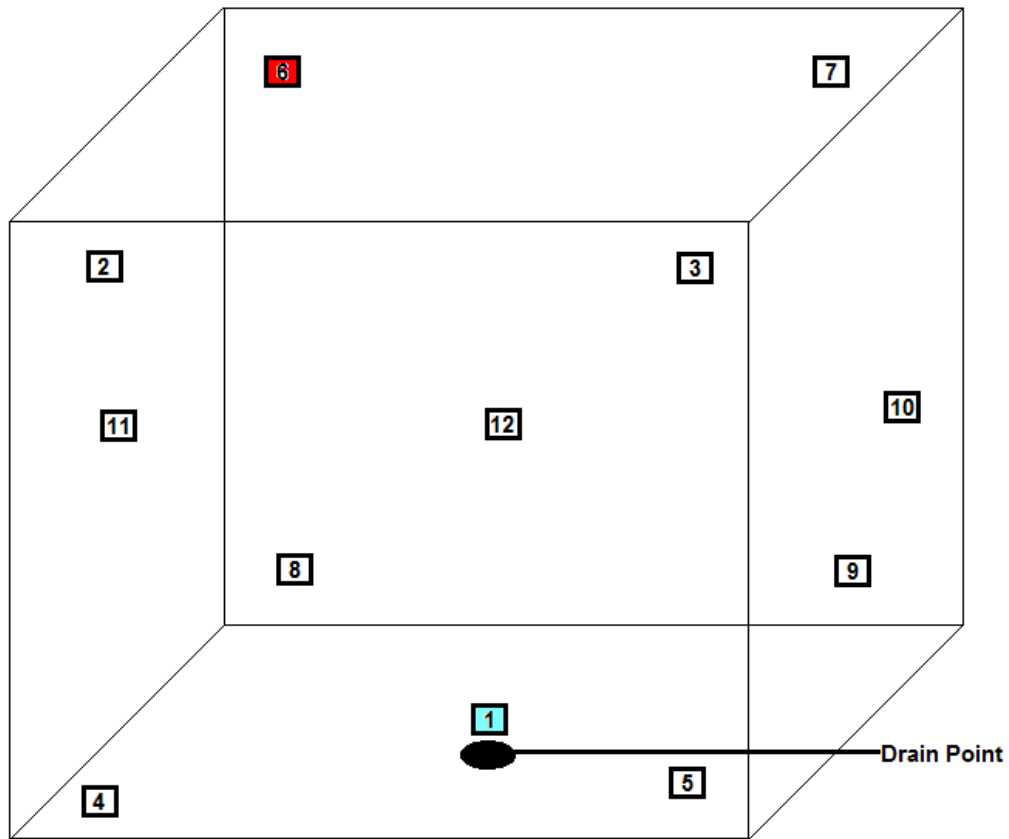
* Acceptance Limit: $\pm 0.5^{\circ}\text{C}$ against of Std. Value of Set Temperature

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Details of Cycle Parameters			
Cycle		Run - 1 Heat Distribution in Empty Chamber	
Sterilized Temperature Required		121.0°C - 124.0°C	
Sterilization Time Required		30 Minutes	
Set Temperature	121.0°C	Set Time	30 Minutes
Load Pattern.	Empty Chamber		
Diagram Indicating Position of Sensor Located Inside the Chamber			



Heat Distribution in Empty Chamber

■ Hot Point ■ Cold Point

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Run - 1 Heat Distribution in Empty Chamber (30 Minutes)

Required Temperature	121.0°C + 3°C
Set Temperature	121.0°C
Date	20/05/2022

OBSERVATION TABLE

Time	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
11:00:15	33.5	34.1	33.7	34.2	33.9	34.3	33.6	34.4	33.5	34.6	33.3	34.9
11:01:15	35.6	36.3	35.2	36.5	35.8	36.7	35.2	36.8	35.1	36.1	35.7	36.2
11:02:15	39.1	40.6	39.6	40.5	39.2	40.1	39.5	40.2	39.8	40.8	39.9	40.7
11:03:15	41.6	42.5	41.2	42.6	41.5	42.3	41.6	42.1	41.7	42.0	41.5	42.8
11:04:15	45.3	46.5	45.2	46.9	45.8	46.8	45.9	46.2	45.1	46.8	45.2	46.9
11:05:15	49.2	50.2	49.5	50.7	49.3	50.1	49.8	50.3	49.7	50.4	49.3	50.6
11:06:15	52.7	53.8	52.4	53.9	52.3	53.2	52.2	53.1	52.3	53.2	52.3	53.0
11:07:15	55.9	56.6	55.2	56.2	55.1	56.1	55.8	56.8	55.9	56.9	55.0	56.1
11:08:15	58.1	59.1	58.4	59.0	58.3	59.5	58.2	59.6	58.3	59.7	58.4	59.9
11:09:15	61.3	62.7	61.5	62.2	61.6	62.1	61.9	62.3	61.8	62.4	61.3	62.5
11:10:15	64.2	65.3	64.1	65.8	64.8	65.9	64.7	65.2	64.6	65.1	64.2	65.3
11:11:15	68.5	69.1	68.0	69.6	68.4	69.8	68.3	69.7	68.2	69.2	68.4	69.0
11:12:15	70.3	71.5	70.4	71.3	70.3	71.2	70.8	71.1	70.9	71.6	70.2	71.8
11:13:15	72.4	73.6	72.8	73.2	72.5	73.1	72.4	73.5	72.3	73.7	72.4	73.1
11:14:15	75.9	76.5	75.1	76.1	75.0	76.9	75.6	76.2	75.8	76.3	75.1	76.8
11:15:15	78.3	79.6	78.4	79.3	78.3	79.0	78.6	79.5	78.2	79.6	78.4	79.0
11:16:15	80.1	81.5	80.4	81.6	80.3	81.8	80.2	81.9	80.1	81.4	80.3	81.3
11:17:15	85.6	86.6	85.3	86.3	85.2	86.2	85.1	86.1	85.8	86.8	85.7	86.9
11:18:15	88.2	89.4	88.5	89.1	88.3	89.0	88.2	89.5	88.1	89.6	88.6	89.7
11:19:15	92.8	93.3	92.7	93.2	92.8	93.8	92.6	93.9	92.4	93.5	92.3	93.4
11:20:15	94.1	95.8	94.6	95.6	94.2	95.4	94.1	95.5	94.8	95.2	94.0	95.6
11:21:15	98.2	99.2	98.5	99.1	98.2	99.0	98.3	99.7	98.4	99.9	98.3	99.5
11:22:15	100.6	101.6	100.5	101.3	100.3	101.4	100.8	101.0	100.7	101.5	100.6	101.9
11:23:15	107.3	108.3	107.6	108.2	107.2	108.1	107.1	108.6	107.3	108.6	107.3	108.7
11:24:15	109.6	110.1	109.4	110.5	109.1	110.6	109.8	110.2	109.9	110.4	109.5	110.8
11:25:15	113.6	114.3	113.2	114.8	113.0	114.9	113.4	114.1	113.6	114.6	113.1	114.2
11:26:15	115.2	116.4	115.3	116.7	115.2	116.6	115.1	116.4	115.3	116.6	115.5	116.1
11:27:15	117.2	118.7	117.4	118.3	117.1	118.2	117.3	118.1	117.2	118.6	117.1	118.9
11:28:15	118.3	119.3	118.6	119.2	118.2	119.0	118.1	119.8	118.3	119.9	118.2	119.7
11:29:15	120.4	120.3	120.5	120.7	120.6	120.8	120.2	120.0	120.1	120.6	120.5	120.4
11:30:15	121.6	121.9	122.0	121.9	122.0	122.7	122.4	122.1	121.9	122.6	121.7	121.7
11:31:15	121.6	122.1	122.1	122.0	121.5	122.7	121.9	121.8	121.9	121.7	121.7	121.7
11:32:15	122.0	122.1	121.8	122.2	122.0	121.8	122.4	122.1	122.1	122.2	122.0	122.1
11:33:15	121.6	121.8	121.7	121.8	121.5	122.7	122.4	121.8	121.9	121.7	121.9	121.7
11:34:15	122.3	122.0	122.1	122.0	122.2	122.7	121.9	121.8	121.9	122.6	121.7	122.3
11:35:15	121.6	121.8	122.1	122.1	121.5	122.1	122.4	121.8	121.9	121.7	121.8	122.3
11:36:15	122.3	122.2	121.9	122.2	122.4	121.8	122.1	121.8	121.9	121.7	121.9	122.3
11:37:15	121.6	122.3	122.1	122.2	121.5	121.9	122.4	121.8	122.0	122.6	122.0	122.3
11:38:15	121.6	121.8	122.1	121.9	122.3	121.8	121.8	121.8	122.2	122.3	122.0	122.1
11:39:15	122.3	122.5	121.8	122.2	121.5	122.2	122.0	121.8	122.1	121.7	122.0	122.2
11:40:15	121.6	121.8	122.0	121.9	122.1	121.8	122.4	121.6	121.9	122.4	121.8	121.7
11:41:15	122.3	122.5	122.1	121.8	121.5	121.9	121.8	122.1	122.2	121.7	122.0	121.9
11:42:15	122.0	121.8	122.1	121.9	122.1	122.7	121.8	121.8	122.1	121.7	122.0	122.3
11:43:15	121.6	122.1	122.1	122.2	121.5	122.1	121.8	121.8	121.9	122.3	122.0	122.3
11:44:15	121.6	122.0	122.1	121.8	122.1	122.7	122.4	121.8	122.2	122.6	122.0	122.1
11:45:15	122.3	121.8	122.1	122.0	121.5	121.8	122.1	121.8	121.9	121.7	121.6	121.7
11:46:15	121.6	122.2	121.7	122.0	122.0	122.7	122.1	121.9	121.9	121.7	122.0	122.3

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11:47:15	121.6	121.8	122.1	121.8	122.4	122.7	122.0	121.8	122.1	122.3	121.9	122.3
11:48:15	122.0	122.0	122.0	122.0	121.9	122.1	121.8	121.8	122.1	121.7	121.5	121.7
11:49:15	121.6	122.1	122.1	121.8	121.7	122.1	122.0	121.8	121.9	121.7	122.0	122.1
11:50:15	122.3	121.8	122.1	121.9	122.4	122.1	122.1	122.1	122.1	122.3	122.0	122.3
11:51:15	121.6	121.8	122.1	121.8	121.8	122.2	121.9	121.8	122.2	121.7	121.6	121.7
11:52:15	122.0	122.5	122.1	121.8	122.4	122.1	121.9	121.8	121.9	121.7	122.0	121.7
11:53:15	121.6	121.8	122.1	122.2	121.9	122.1	122.1	121.8	122.0	122.3	121.7	122.3
11:54:15	121.6	122.0	122.1	121.8	121.9	122.7	121.8	121.9	121.9	121.7	122.0	122.3
11:55:15	122.0	121.9	122.0	121.8	121.5	122.2	121.8	121.8	122.2	122.4	121.9	122.1
11:56:15	121.6	121.8	122.1	122.1	122.0	122.7	121.9	121.8	121.9	121.7	121.8	122.3
11:57:15	122.3	121.8	121.9	121.8	122.1	122.1	122.1	121.8	122.1	122.6	122.0	122.1
11:58:15	121.6	121.8	121.8	122.0	121.5	122.7	121.8	122.1	122.2	121.7	121.5	121.7
11:59:15	121.6	122.5	122.1	121.8	122.0	122.7	122.1	121.8	121.9	122.3	122.0	122.3
12:00:15	121.6	122.1	122.1	122.0	122.2	122.7	122.1	121.8	122.2	122.6	122.0	121.9
12:01:15	120.7	120.3	120.5	120.0	120.8	120.9	120.7	120.5	120.4	120.2	120.1	120.3
12:02:15	118.5	117.6	118.4	117.2	118.2	117.1	118.2	117.8	118.1	117.9	118.0	117.7
12:03:15	116.6	115.1	116.2	115.2	116.6	115.3	116.7	115.5	116.8	115.7	116.5	115.3
12:04:15	114.2	113.3	114.8	113.7	114.2	113.2	114.0	113.1	114.7	113.4	114.7	113.6
12:05:15	111.1	110.8	111.5	110.1	111.3	110.0	111.1	110.8	111.8	110.9	111.9	110.1
12:06:15	108.6	107.3	108.2	107.6	108.1	107.1	108.7	107.9	108.2	107.2	108.4	107.6
12:07:15	106.2	105.3	106.6	105.8	106.8	105.9	106.3	105.1	106.3	105.4	106.3	105.3
12:08:15	104.3	103.6	104.7	103.3	104.5	103.9	104.6	103.0	104.4	103.2	104.3	103.5
12:09:15	101.5	100.0	101.6	100.4	101.3	100.7	101.4	100.2	101.3	100.5	101.6	100.7
12:10:15	99.1	98.4	99.5	98.2	99.7	98.3	99.6	98.1	99.4	98.2	99.7	98.1

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Parameters Computed During Sterilization Period			
Time	Minimum Temp. (°C)	Maximum Temp. (°C)	Average (°C)
11:30:15	121.6	122.7	122.1
11:31:15	121.5	122.7	122.0
11:32:15	121.8	122.4	122.1
11:33:15	121.5	122.7	121.9
11:34:15	121.8	122.7	122.1
11:35:15	121.5	122.4	121.9
11:36:15	121.8	122.4	122.1
11:37:15	121.5	122.4	122.0
11:38:15	121.6	122.3	121.9
11:39:15	121.5	122.5	122.0
11:40:15	121.6	122.4	121.9
11:41:15	121.5	122.5	122.0
11:42:15	121.8	122.7	122.0
11:43:15	121.5	122.2	121.9
11:44:15	121.6	122.7	122.1
11:45:15	121.5	122.3	121.9
11:46:15	121.6	122.7	122.0
11:47:15	121.6	122.7	122.0
11:48:15	121.8	122.1	122.0
11:49:15	121.6	122.1	121.9
11:50:15	121.8	122.4	122.1
11:51:15	121.6	122.2	121.9
11:52:15	121.8	122.5	122.1
11:53:15	121.6	122.2	122.0
11:54:15	121.6	122.7	122.0
11:55:15	121.5	122.2	121.9
11:56:15	121.6	122.7	122.0
11:57:15	121.8	122.3	122.0
11:58:15	121.5	122.7	121.9
11:59:15	121.6	122.7	122.1
12:00:15	121.6	122.7	122.1

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Sign/Date				
Name	Sanjay Patel	Ganesh Patel		
Designation	Site Engineer	Technical Manager	User Department	Q.A.

VALIDATION REPORT FOR STEAM STERILIZER

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Run - 1 Heat Distribution in Empty Chamber (30 Minutes) Lethal Rate & F₀ Value Calculation of all position

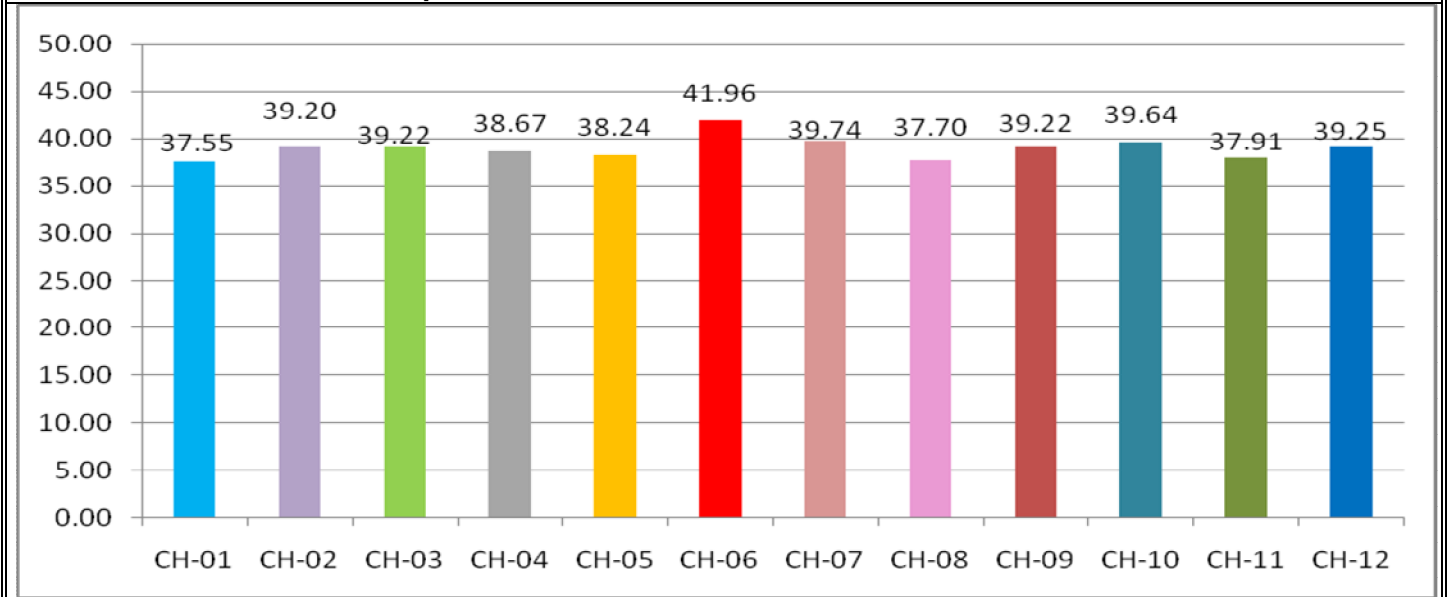
Time	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
11:30:15	1.15	1.23	1.26	1.23	1.26	1.48	1.38	1.29	1.23	1.45	1.17	1.17
11:31:15	1.15	1.29	1.29	1.26	1.12	1.48	1.23	1.20	1.23	1.17	1.17	1.17
11:32:15	1.26	1.29	1.20	1.32	1.26	1.20	1.38	1.29	1.29	1.32	1.26	1.29
11:33:15	1.15	1.20	1.17	1.20	1.12	1.48	1.38	1.20	1.23	1.17	1.23	1.17
11:34:15	1.35	1.26	1.29	1.26	1.32	1.48	1.23	1.20	1.23	1.45	1.17	1.35
11:35:15	1.15	1.20	1.29	1.29	1.12	1.29	1.38	1.20	1.23	1.17	1.20	1.35
11:36:15	1.35	1.32	1.23	1.32	1.38	1.20	1.29	1.20	1.23	1.17	1.23	1.35
11:37:15	1.15	1.35	1.29	1.32	1.12	1.23	1.38	1.20	1.26	1.45	1.26	1.35
11:38:15	1.15	1.20	1.29	1.23	1.35	1.20	1.23	1.20	1.32	1.35	1.26	1.29
11:39:15	1.35	1.41	1.20	1.32	1.12	1.32	1.26	1.20	1.29	1.17	1.26	1.32
11:40:15	1.15	1.20	1.26	1.23	1.29	1.20	1.38	1.15	1.23	1.38	1.20	1.17
11:41:15	1.35	1.41	1.29	1.20	1.12	1.23	1.23	1.29	1.32	1.17	1.26	1.23
11:42:15	1.26	1.20	1.29	1.23	1.29	1.48	1.23	1.20	1.29	1.17	1.26	1.35
11:43:15	1.15	1.29	1.29	1.32	1.12	1.29	1.23	1.20	1.23	1.35	1.26	1.35
11:44:15	1.15	1.26	1.29	1.20	1.29	1.48	1.38	1.20	1.32	1.45	1.26	1.29
11:45:15	1.35	1.20	1.29	1.26	1.12	1.20	1.29	1.20	1.23	1.17	1.15	1.17
11:46:15	1.15	1.32	1.17	1.26	1.26	1.48	1.29	1.23	1.23	1.17	1.26	1.35
11:47:15	1.15	1.20	1.29	1.20	1.38	1.48	1.26	1.20	1.29	1.35	1.23	1.35
11:48:15	1.26	1.26	1.26	1.26	1.23	1.29	1.23	1.20	1.29	1.17	1.12	1.15
11:49:15	1.15	1.29	1.29	1.20	1.17	1.29	1.26	1.20	1.23	1.17	1.26	1.15
11:50:15	1.35	1.20	1.29	1.23	1.38	1.29	1.29	1.29	1.29	1.35	1.26	1.15
11:51:15	1.15	1.20	1.29	1.20	1.20	1.32	1.23	1.20	1.32	1.17	1.15	1.17
11:52:15	1.26	1.41	1.29	1.20	1.38	1.29	1.23	1.20	1.23	1.17	1.26	1.17
11:53:15	1.15	1.20	1.29	1.32	1.23	1.29	1.29	1.20	1.26	1.35	1.17	1.35
11:54:15	1.15	1.26	1.29	1.20	1.23	1.48	1.23	1.23	1.23	1.17	1.26	1.35
11:55:15	1.26	1.23	1.26	1.20	1.12	1.32	1.23	1.20	1.32	1.38	1.23	1.29
11:56:15	1.15	1.20	1.29	1.29	1.26	1.48	1.23	1.20	1.23	1.17	1.20	1.35
11:57:15	1.35	1.20	1.23	1.20	1.29	1.29	1.29	1.20	1.29	1.45	1.26	1.29
11:58:15	1.15	1.20	1.20	1.26	1.12	1.48	1.23	1.29	1.32	1.17	1.12	1.17
11:59:15	1.15	1.41	1.29	1.20	1.26	1.48	1.29	1.20	1.23	1.35	1.26	1.35
12:00:15	1.15	1.29	1.29	1.26	1.32	1.48	1.29	1.20	1.32	1.45	1.26	1.23
F₀ Value	37.55	39.20	39.22	38.67	38.24	41.96	39.74	37.70	39.22	39.64	37.91	39.25

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Sign/Date				
Name	Sanjay Patel	Ganesh Patel		
Designation	Site Engineer	Technical Manager	User Department	Q.A.

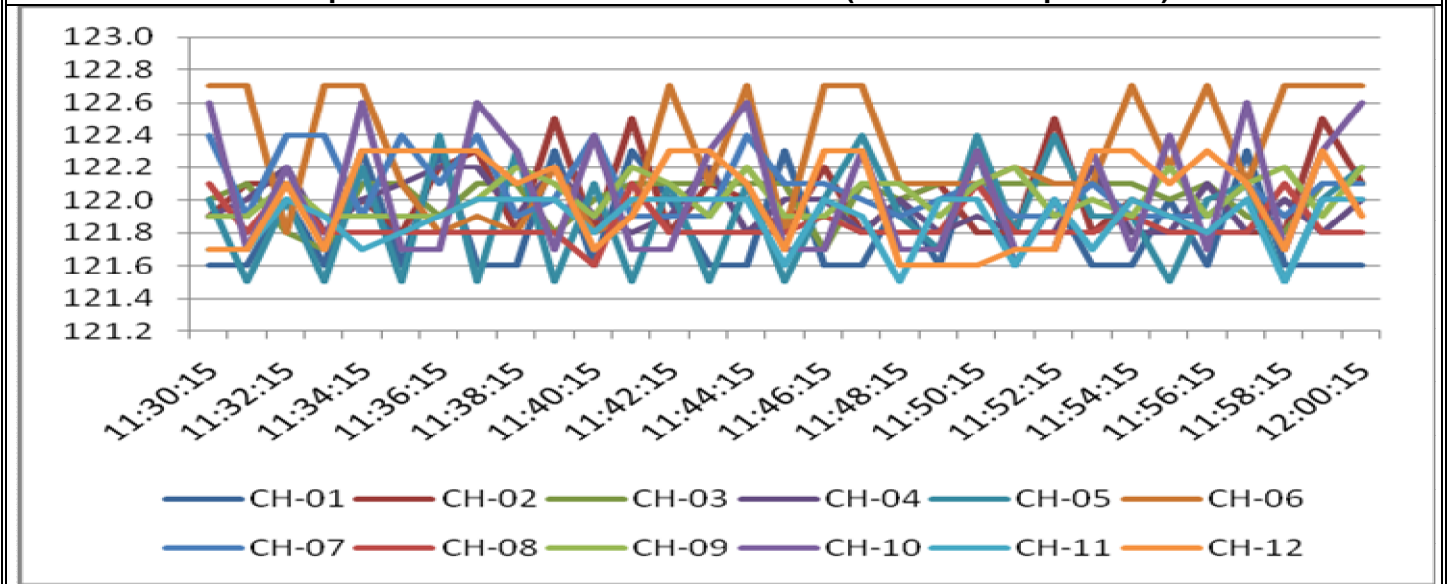
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Graphical Presentation of F₀ Value Of all Locations



Graphical Presentation: Steam Sterilizer (Time V/s Temperature)



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VALIDATION REPORT FOR STEAM STERILIZER

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Summary Report: Heat Distribution in Empty Chamber (30 Minutes)

Hot and Cold Spot during Sterilization Period As Per F₀ Value

Hot Spot: Position CH-06 **Cold Spot: Position CH-01**

F₀ Values for all Locations

Position	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
F₀ Values	37.55	39.20	39.22	38.67	38.24	41.96	39.74	37.70	39.22	39.64	37.91	39.25

Minimum and Maximum Temperature Observed During Sterilization Phase for all Probes

Minimum Temperature	Maximum Temperature	Difference
121.5	122.7	1.2

Minimum, Maximum and Average Temperature of Each Probe

Position	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
Minimum	121.6	121.8	121.7	121.8	121.5	121.8	121.9	121.6	121.9	121.7	121.5	121.6
Maximum	122.3	122.5	122.1	122.2	122.4	122.7	122.4	122.1	122.2	122.6	122.0	122.3
Average	121.8	122.0	122.0	122.0	121.9	122.3	122.1	121.8	122.0	122.1	121.9	122.0
Diff.	0.7	0.7	0.4	0.4	0.9	0.9	0.5	0.5	0.3	0.9	0.5	0.7

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Designation	Site Engineer	Technical Manager	User Department	Q.A.

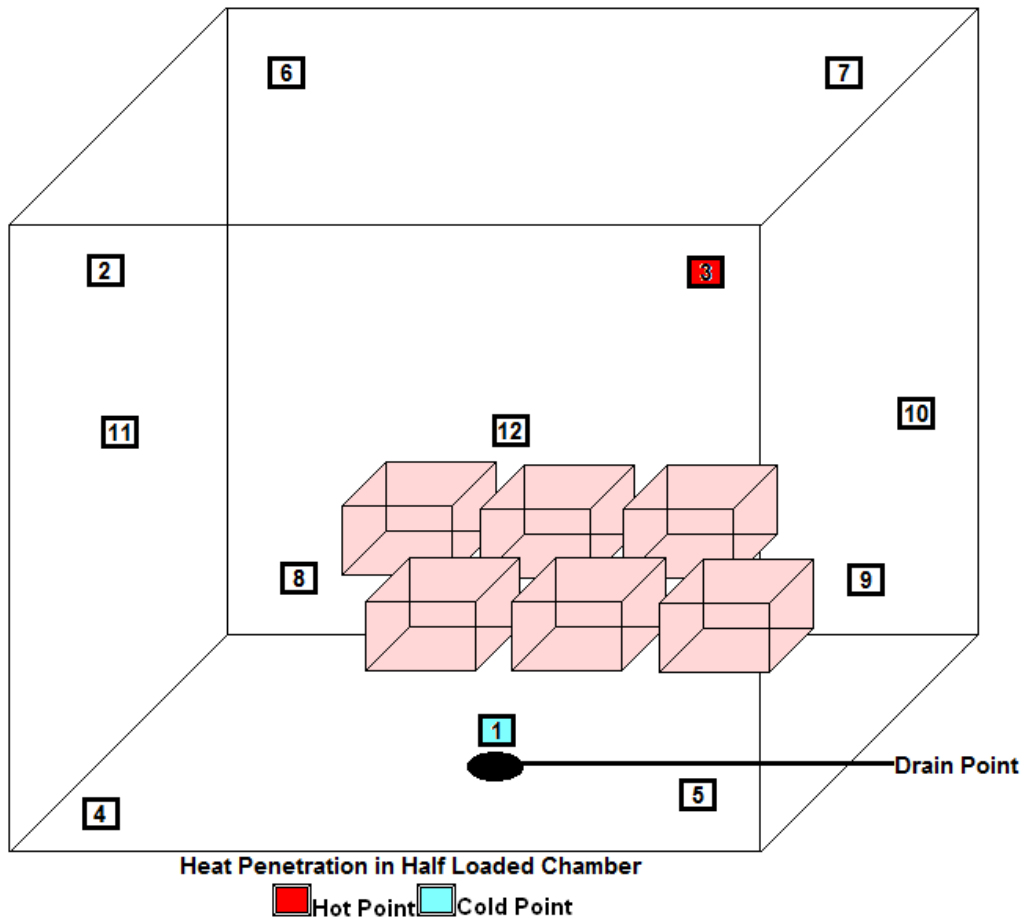
VALIDATION REPORT FOR STEAM STERILIZER

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Details of Cycle Parameters

Cycle		Run - 2 Heat Penetration in Half Loaded Chamber	
Sterilized Temperature Required		121.0°C - 124.0°C	
Sterilization Time Required		30 Minutes	
Set Temperature	121.0°C	Set Time	30 Minutes
Load Pattern.		Half Loaded Chamber	

Diagram Indicating Position of Sensor Located Inside the Chamber



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VALIDATION REPORT FOR STEAM STERILIZER

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Run -2 Heat Penetration in Half Loaded Chamber (30 Min.)

Required Temperature	121.0°C +3°C
Set Temperature	121.0°C
Date	20/05/2022

OBSERVATION TABLE

Time	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
12:30:38	51.4	50.5	51.6	50.3	51.4	50.3	51.7	50.2	51.5	50.5	51.4	50.2
12:31:38	53.6	52.4	53.7	52.2	53.1	52.5	53.6	52.4	53.2	52.7	53.4	52.5
12:32:38	55.1	54.3	55.8	54.1	55.9	54.2	55.1	54.9	55.4	54.5	55.5	54.4
12:33:38	57.3	56.5	57.8	56.8	57.6	56.9	57.3	56.2	57.2	56.3	57.1	56.2
12:34:38	59.2	58.6	59.3	58.7	59.2	58.2	59.5	58.1	59.6	58.0	59.7	58.9
12:35:38	61.4	60.3	61.7	60.8	61.6	60.9	61.8	60.4	61.9	60.2	61.5	60.1
12:36:38	68.9	67.2	68.3	67.1	68.2	67.0	68.7	67.3	68.2	67.7	68.3	67.4
12:37:38	70.6	69.1	70.8	69.2	70.4	69.1	70.8	69.2	70.5	69.4	70.8	69.2
12:38:38	72.0	71.4	72.7	71.3	72.5	71.2	72.7	71.5	72.6	71.3	72.8	71.3
12:39:38	74.2	73.6	74.6	73.2	74.8	73.1	74.9	73.0	74.1	73.8	74.2	73.9
12:40:38	76.0	75.5	76.4	75.1	76.7	75.2	76.8	75.5	76.2	75.3	76.7	75.5
12:41:38	79.6	78.3	79.3	78.6	79.8	78.7	79.9	78.3	79.5	78.2	79.6	78.1
12:42:38	80.3	79.6	80.4	79.2	80.2	79.8	80.3	79.8	80.5	79.1	80.6	79.5
12:43:38	82.2	81.4	82.6	81.3	82.5	81.2	82.8	81.4	82.6	81.3	82.7	81.2
12:44:38	84.6	83.0	87.7	83.2	87.2	83.1	87.1	83.8	87.9	83.9	87.2	83.1
12:45:38	87.3	86.3	87.8	86.3	87.7	86.0	87.2	86.1	87.1	86.5	87.5	86.9
12:46:38	90.4	89.6	90.5	89.8	90.6	89.2	90.8	89.1	90.9	89.3	90.7	89.4
12:47:38	92.7	91.4	92.8	91.3	92.5	91.2	92.7	91.3	92.4	91.5	92.6	91.3
12:48:38	95.3	94.6	95.9	94.0	95.1	94.8	95.2	94.9	95.8	94.7	95.5	94.5
12:49:38	97.6	96.7	97.3	96.1	97.2	96.2	97.1	96.3	97.8	96.6	97.7	96.4
12:50:38	99.4	98.3	99.4	98.5	99.2	98.6	99.5	98.6	99.9	98.2	99.8	98.1
12:51:38	101.8	100.6	101.4	100.6	101.5	100.9	101.3	100.8	101.5	100.7	101.3	100.3
12:52:38	103.5	102.3	103.1	102.8	103.2	102.9	103.0	102.1	103.5	102.4	103.5	102.7
12:53:38	105.4	104.6	105.2	104.9	105.7	104.4	105.1	104.6	105.3	104.2	105.6	104.8
12:54:38	107.6	106.5	107.5	106.3	107.4	106.1	107.3	106.8	107.2	106.9	107.1	106.3
12:55:38	109.3	108.6	109.6	108.0	109.1	108.2	109.2	108.1	109.3	108.3	109.8	108.4
12:56:38	111.2	110.5	111.4	110.8	111.8	110.0	111.9	110.2	111.6	110.1	111.2	110.7
12:57:38	113.7	112.6	113.5	112.4	113.9	112.2	113.7	112.5	113.1	112.6	113.4	112.8
12:58:38	115.1	114.3	115.2	114.5	115.7	114.6	115.3	114.8	115.4	114.2	115.5	114.9
12:59:38	117.6	116.3	117.6	116.8	117.2	116.8	117.1	116.9	117.0	116.4	117.8	116.3
13:00:38	119.5	118.6	119.3	118.3	119.4	118.6	119.5	118.9	119.0	118.7	119.6	118.1
13:01:38	120.2	119.6	120.4	119.2	120.3	119.1	120.2	119.0	120.1	119.7	120.5	119.9
13:02:38	121.9	121.8	122.2	121.8	121.8	121.7	121.7	121.8	121.8	121.9	121.9	121.6
13:03:38	121.6	121.8	122.2	121.8	122.1	121.8	122.0	122.2	121.8	121.9	121.7	121.8
13:04:38	121.6	122.4	121.8	122.3	122.2	122.2	122.1	122.2	121.9	121.9	122.1	122.4
13:05:38	121.6	122.3	122.1	122.2	122.1	122.0	122.1	122.0	121.9	122.0	121.7	122.4
13:06:38	122.5	122.2	121.9	121.8	121.6	122.0	121.9	121.9	122.0	121.8	122.2	122.1
13:07:38	121.6	122.3	122.3	122.4	122.1	122.1	121.9	121.4	121.8	122.1	122.1	122.1
13:08:38	122.1	121.8	121.8	121.8	121.6	122.3	121.6	121.9	122.4	121.9	121.9	121.8
13:09:38	122.1	121.9	121.9	122.4	121.6	122.4	122.3	121.8	121.9	122.0	121.8	122.1
13:10:38	122.3	122.4	121.8	122.4	121.6	122.0	122.3	121.4	121.8	122.3	122.0	122.1
13:11:38	122.0	122.0	121.9	122.1	122.3	121.8	121.6	121.4	121.8	122.0	122.0	121.9
13:12:38	121.6	122.1	122.6	122.1	122.0	122.0	121.5	122.1	121.8	122.2	122.1	122.1
13:13:38	121.8	122.1	122.5	121.8	122.0	121.8	121.5	121.5	122.3	122.0	121.7	122.1
13:14:38	121.6	121.8	122.1	122.1	121.6	121.8	122.3	121.8	122.4	121.8	121.9	122.2
13:15:38	122.0	122.0	122.6	122.1	122.3	121.8	122.4	121.6	122.3	121.6	122.1	122.3
13:16:38	121.6	121.8	121.8	121.9	121.6	121.8	121.6	121.7	121.8	121.6	122.0	122.2

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Sign/Date				
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VALIDATION REPORT FOR STEAM STERILIZER

Report No:	Validation Start Date:	Validation Due Date:	Page No.
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13:17:38	122.0	121.8	121.9	122.1	121.6	122.2	122.1	121.7	122.4	121.6	121.8	122.1
13:18:38	122.0	122.1	122.6	122.1	121.6	122.5	122.4	121.6	122.1	122.1	121.8	121.9
13:19:38	121.8	121.8	121.9	122.2	122.3	122.5	122.0	122.3	122.5	121.9	121.8	121.8
13:20:38	121.6	121.8	122.4	122.3	122.2	122.2	121.9	122.2	121.8	122.1	122.1	122.0
13:21:38	121.6	121.9	122.5	121.8	121.6	122.0	121.6	122.1	122.2	122.1	121.9	122.0
13:22:38	122.4	121.8	122.3	121.8	122.3	122.1	121.5	122.3	122.3	121.6	122.1	122.1
13:23:38	122.0	122.1	121.9	121.8	121.6	122.2	121.5	121.8	121.8	121.9	122.1	121.7
13:24:38	121.6	121.8	121.9	122.3	121.6	121.8	121.9	121.6	121.9	122.3	121.8	121.9
13:25:38	122.0	121.8	122.0	121.8	121.6	122.4	121.9	121.8	121.8	121.6	121.8	122.1
13:26:38	122.0	122.0	121.8	121.8	122.1	122.3	121.9	122.3	122.5	122.3	121.8	122.0
13:27:38	121.6	122.1	122.4	122.2	122.2	122.0	121.9	122.1	121.9	121.8	121.8	121.8
13:28:38	121.6	122.0	122.3	122.4	122.3	122.6	121.6	122.3	121.8	121.6	122.1	121.8
13:29:38	122.0	121.8	122.4	122.1	122.2	121.8	121.9	121.6	122.4	121.9	121.8	121.9
13:30:38	122.2	122.0	121.9	121.8	121.6	122.2	122.0	121.7	122.2	122.2	122.0	122.1
13:31:38	121.8	121.8	122.2	121.8	122.3	122.3	121.6	121.9	122.0	122.0	122.2	121.9
13:32:38	122.0	122.2	121.9	122.2	121.6	122.2	122.2	122.3	121.8	122.2	121.9	121.8
13:33:38	120.3	119.5	120.1	119.3	120.0	119.0	120.2	119.2	120.8	119.3	120.9	119.4
13:34:38	119.3	118.3	119.3	118.2	119.5	118.1	119.4	118.6	119.2	118.7	119.3	118.3
13:35:38	117.3	116.6	117.2	116.8	117.1	116.9	117.3	116.9	117.8	116.8	117.2	116.2
13:36:38	115.3	114.8	115.2	114.5	115.8	114.8	115.7	114.1	115.9	114.0	115.4	114.5
13:37:38	113.5	112.3	113.6	112.2	113.2	112.4	113.1	112.8	113.5	112.6	113.6	112.1
13:38:38	111.6	110.1	111.5	110.6	111.1	110.9	111.9	110.2	111.4	110.1	111.3	110.4
13:39:38	109.6	108.3	109.7	108.8	109.2	108.9	109.1	108.3	109.5	108.5	109.6	108.4
13:40:38	107.5	106.4	107.3	106.1	107.7	106.2	107.5	106.4	107.8	106.3	107.9	106.2
13:41:38	105.3	104.6	105.4	104.3	105.6	104.1	105.8	104.2	105.2	104.7	105.4	104.9
13:42:38	103.4	102.9	103.5	102.6	103.2	102.2	103.1	102.1	103.0	102.8	103.8	102.7
13:43:38	101.5	100.5	101.7	100.8	101.3	100.5	101.8	100.4	101.6	100.2	101.9	100.3
13:44:38	100.6	99.2	100.1	99.0	100.5	99.7	100.7	99.6	100.9	99.3	100.3	99.1
13:45:38	99.6	98.6	99.5	98.3	99.2	98.8	99.1	98.7	99.6	98.2	99.8	98.0

MONITORED BY (RG TECHNOLOGIES)			REVIEWED BY (EN VISION ENVIRO ENGINEERS PVT. LTD.)	
Sign/Date				
Name	Sanjay Patel	Ganesh Patel		
Designation	Site Engineer	Technical Manager	User Department	Q.A.

VALIDATION REPORT FOR STEAM STERILIZER

Report No:	Validation Start Date:	Validation Due Date:	Page No.
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Parameters Computed During Sterilization Period			
Time	Minimum Temp. (°C)	Maximum Temp. (°C)	Average (°C)
13:02:38	121.7	122.2	121.8
13:03:38	121.6	122.2	121.9
13:04:38	121.6	122.4	122.1
13:05:38	121.6	122.3	122.1
13:06:38	121.6	122.5	122.0
13:07:38	121.4	122.4	122.0
13:08:38	121.6	122.3	121.9
13:09:38	121.6	122.4	122.1
13:10:38	121.4	122.4	122.0
13:11:38	121.4	122.3	121.9
13:12:38	121.5	122.6	122.0
13:13:38	121.5	122.5	121.9
13:14:38	121.6	122.3	121.9
13:15:38	121.6	122.6	122.1
13:16:38	121.6	121.9	121.7
13:17:38	121.6	122.2	121.9
13:18:38	121.6	122.6	122.1
13:19:38	121.8	122.5	122.1
13:20:38	121.6	122.4	122.1
13:21:38	121.6	122.5	121.9
13:22:38	121.5	122.4	122.1
13:23:38	121.5	122.2	121.9
13:24:38	121.6	122.3	121.8
13:25:38	121.6	122.4	121.9
13:26:38	121.8	122.3	122.0
13:27:38	121.6	122.4	122.1
13:28:38	121.6	122.6	122.1
13:29:38	121.6	122.4	122.0
13:30:38	121.6	122.2	121.9
13:31:38	121.6	122.3	122.0
13:32:38	121.6	122.3	122.1

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VALIDATION REPORT FOR STEAM STERILIZER

Report No:	Validation Start Date:	Validation Due Date:	Page No.
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Run -2 Heat Penetration in Half Loaded Chamber (30 Min.) Lethal Rate & F₀ Value Calculation of all position

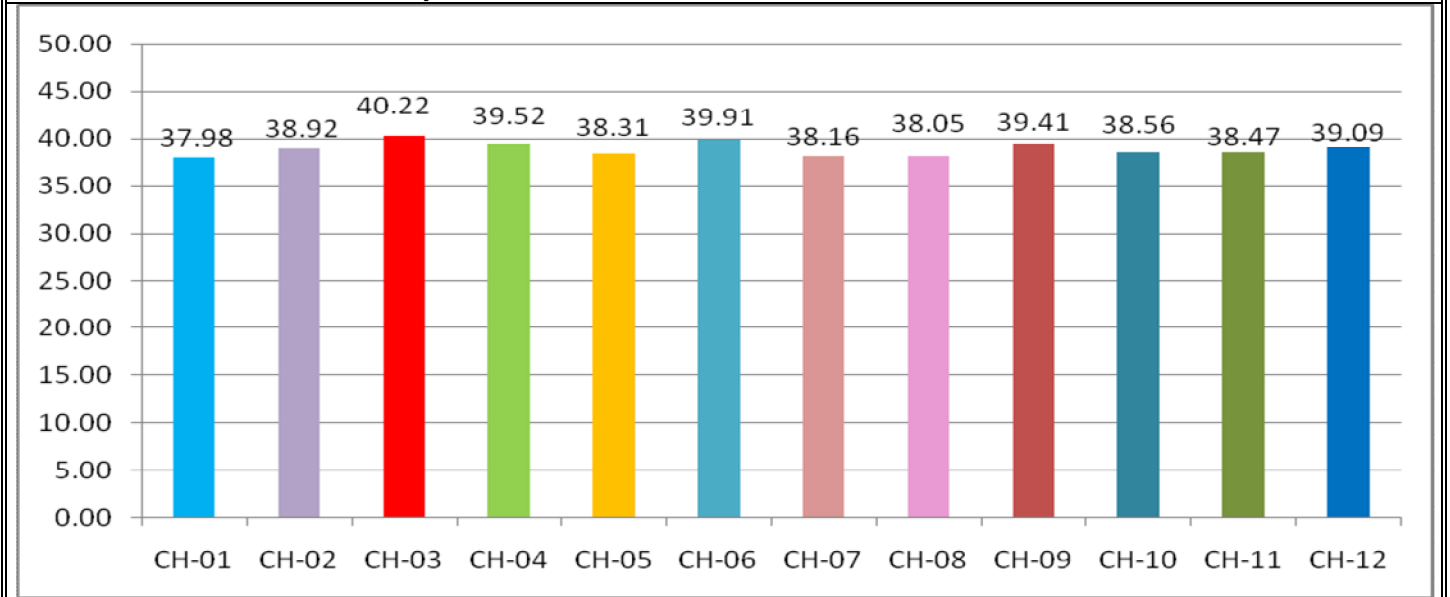
Time	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
13:02:38	1.23	1.20	1.32	1.20	1.20	1.17	1.17	1.20	1.20	1.23	1.23	1.15
13:03:38	1.15	1.20	1.32	1.20	1.29	1.20	1.26	1.32	1.20	1.23	1.17	1.20
13:04:38	1.15	1.38	1.20	1.35	1.32	1.32	1.29	1.32	1.23	1.23	1.29	1.38
13:05:38	1.15	1.35	1.29	1.32	1.29	1.26	1.29	1.26	1.23	1.26	1.17	1.38
13:06:38	1.41	1.32	1.23	1.20	1.15	1.26	1.23	1.23	1.26	1.20	1.32	1.29
13:07:38	1.15	1.35	1.35	1.38	1.29	1.29	1.23	1.10	1.20	1.29	1.29	1.29
13:08:38	1.29	1.20	1.20	1.20	1.15	1.35	1.15	1.23	1.38	1.23	1.23	1.20
13:09:38	1.29	1.23	1.23	1.38	1.15	1.38	1.35	1.20	1.23	1.26	1.20	1.29
13:10:38	1.35	1.38	1.20	1.38	1.15	1.26	1.35	1.10	1.20	1.35	1.26	1.29
13:11:38	1.26	1.26	1.23	1.29	1.35	1.20	1.15	1.10	1.20	1.26	1.26	1.23
13:12:38	1.15	1.29	1.45	1.29	1.26	1.26	1.12	1.29	1.20	1.32	1.29	1.29
13:13:38	1.20	1.29	1.41	1.20	1.26	1.20	1.12	1.12	1.35	1.26	1.17	1.29
13:14:38	1.15	1.20	1.29	1.29	1.15	1.20	1.35	1.20	1.38	1.20	1.23	1.32
13:15:38	1.26	1.26	1.45	1.29	1.35	1.20	1.38	1.15	1.35	1.15	1.29	1.35
13:16:38	1.15	1.20	1.20	1.23	1.15	1.20	1.15	1.17	1.20	1.15	1.26	1.32
13:17:38	1.26	1.20	1.23	1.29	1.15	1.32	1.29	1.17	1.38	1.15	1.20	1.29
13:18:38	1.26	1.29	1.45	1.29	1.15	1.41	1.38	1.15	1.29	1.29	1.20	1.23
13:19:38	1.20	1.20	1.23	1.32	1.35	1.41	1.26	1.35	1.41	1.23	1.20	1.20
13:20:38	1.15	1.20	1.38	1.35	1.32	1.32	1.23	1.32	1.20	1.29	1.29	1.26
13:21:38	1.15	1.23	1.41	1.20	1.15	1.26	1.15	1.29	1.32	1.29	1.23	1.26
13:22:38	1.38	1.20	1.35	1.20	1.35	1.29	1.12	1.35	1.35	1.15	1.29	1.29
13:23:38	1.26	1.29	1.23	1.20	1.15	1.32	1.12	1.20	1.20	1.23	1.29	1.17
13:24:38	1.15	1.20	1.23	1.35	1.15	1.20	1.23	1.15	1.23	1.35	1.20	1.23
13:25:38	1.26	1.20	1.26	1.20	1.15	1.38	1.23	1.20	1.20	1.15	1.20	1.29
13:26:38	1.26	1.26	1.20	1.20	1.29	1.35	1.23	1.35	1.41	1.35	1.20	1.26
13:27:38	1.15	1.29	1.38	1.32	1.32	1.26	1.23	1.29	1.23	1.20	1.20	1.20
13:28:38	1.15	1.26	1.35	1.38	1.35	1.45	1.15	1.35	1.20	1.15	1.29	1.20
13:29:38	1.26	1.20	1.38	1.29	1.32	1.20	1.23	1.15	1.38	1.23	1.20	1.23
13:30:38	1.32	1.26	1.23	1.20	1.15	1.32	1.26	1.17	1.32	1.32	1.26	1.29
13:31:38	1.20	1.20	1.32	1.20	1.35	1.35	1.15	1.23	1.26	1.26	1.32	1.23
13:32:38	1.26	1.32	1.23	1.32	1.15	1.32	1.32	1.35	1.20	1.32	1.23	1.20
F₀ Value	37.98	38.92	40.22	39.52	38.31	39.91	38.16	38.05	39.41	38.56	38.47	39.09

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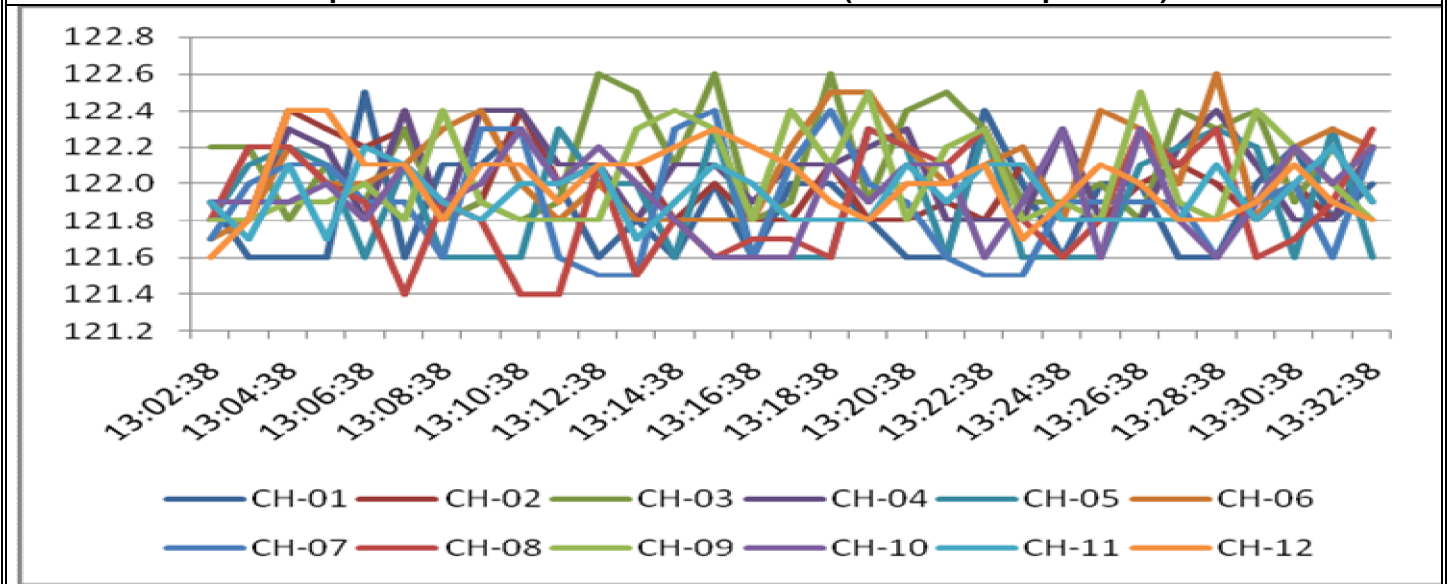
VALIDATION REPORT FOR STEAM STERILIZER

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Graphical Presentation of F₀ Value Of all Locations



Graphical Presentation: Steam Sterilizer (Time V/s Temperature)



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Summary Report: Heat Penetration in Half Loaded Chamber (30 Min.)

Hot and Cold Spot during Sterilization Period As Per F₀ Value

Hot Spot: Position CH-03	Cold Spot: Position CH-01
---------------------------------	----------------------------------

F₀ Values for all Locations

Position	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
F₀ Values	37.98	38.92	40.22	39.52	38.31	39.91	38.16	38.05	39.41	38.56	38.47	39.09

Minimum and Maximum Temperature Observed During Sterilization Phase for all Probes

Minimum Temperature	Maximum Temperature	Difference
121.4	122.6	1.2

Minimum, Maximum and Average Temperature of Each Probe

Position	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
Minimum	121.6	121.8	121.8	121.8	121.6	121.7	121.5	121.4	121.8	121.6	121.7	121.6
Maximum	122.5	122.4	122.6	122.4	122.3	122.6	122.4	122.3	122.5	122.3	122.2	122.4
Average	121.9	122.0	122.1	122.0	121.9	122.1	121.9	121.9	122.0	121.9	121.9	122.0
Diff.	0.9	0.6	0.8	0.6	0.7	0.9	0.9	0.9	0.7	0.7	0.5	0.8

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Designation	Site Engineer	Technical Manager	User Department	Q.A.

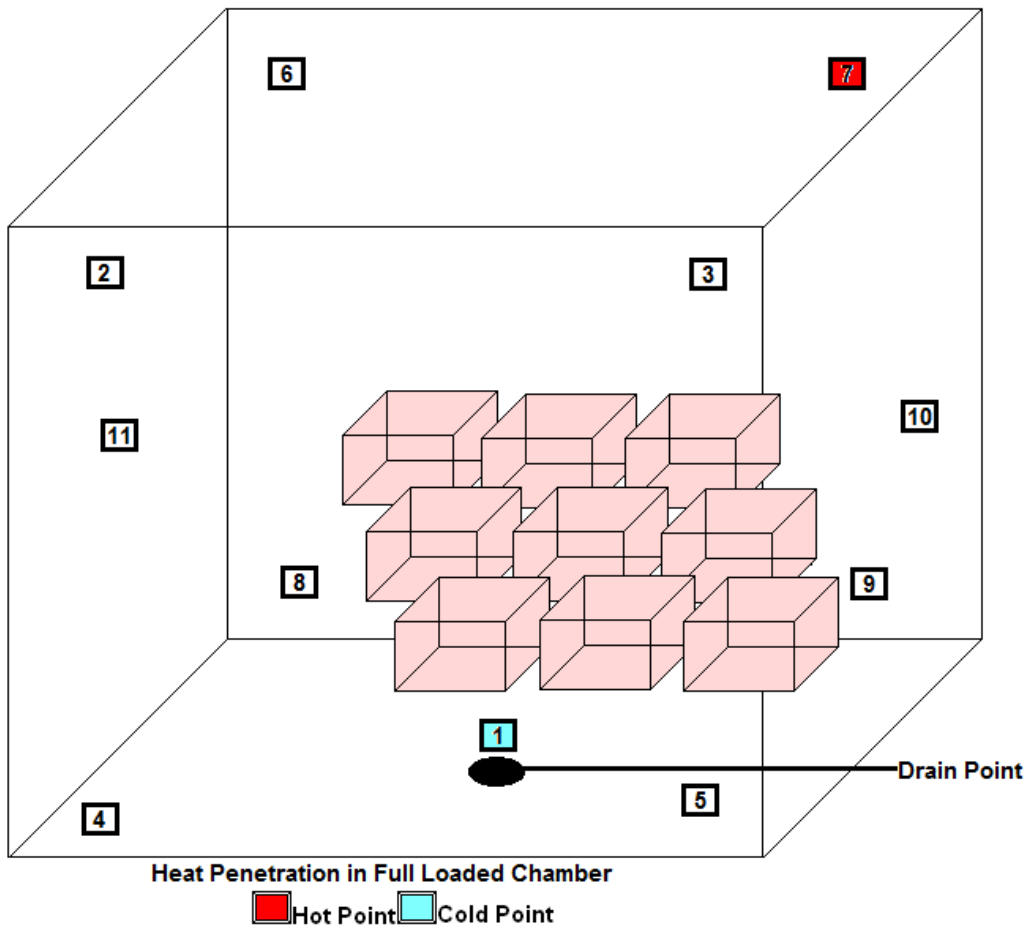
VALIDATION REPORT FOR STEAM STERILIZER

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Details of Cycle Parameters

Cycle		Run - 3 Heat Penetration in Full Loaded Chamber	
Sterilized Temperature Required		121.0°C - 124.0°C	
Sterilization Time Required		30 Minutes	
Set Temperature	121.0°C	Set Time	30 Minutes
Load Pattern.		Full Loaded Chamber	

Diagram Indicating Position of Sensor Located Inside the Chamber



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VALIDATION REPORT FOR STEAM STERILIZER

Report No:	Validation Start Date:	Validation Due Date:	Page No.
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Run - 3 Heat Penetration in Full Loaded Chamber (30 Min.)

Required Temperature	121.0°C +3°C
Set Temperature	121.0°C
Date	20/05/2022

OBSERVATION TABLE

Time	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
14:05:21	75.4	74.1	75.4	74.0	75.9	74.3	75.7	74.6	75.8	74.1	75.4	74.0
14:06:21	76.5	75.3	76.7	75.9	76.2	75.1	76.5	75.0	76.2	75.3	76.7	75.9
14:07:21	77.5	76.9	77.3	76.4	77.1	76.8	77.6	76.4	77.7	76.9	77.3	76.4
14:08:21	78.4	77.1	78.6	77.0	78.5	77.7	78.9	77.2	78.4	77.1	78.6	77.0
14:09:21	79.5	78.9	79.0	78.2	79.7	78.3	79.2	78.5	79.5	78.9	79.0	78.2
14:10:21	80.4	79.0	80.1	79.5	80.3	79.3	80.4	79.6	80.3	79.0	80.1	79.5
14:11:21	82.5	81.5	82.5	81.4	82.4	81.6	82.5	81.2	82.1	81.5	82.5	81.4
14:12:21	84.0	84.8	85.3	84.0	85.5	84.8	85.6	84.0	85.5	84.8	85.3	84.0
14:13:21	85.4	85.1	86.3	85.0	86.7	85.5	86.3	85.4	86.0	85.1	86.3	85.0
14:14:21	86.4	86.0	87.4	86.2	87.6	86.3	87.5	87.0	87.4	86.0	87.4	86.2
14:15:21	87.4	87.7	88.6	87.1	88.5	87.4	88.2	87.5	88.6	87.7	88.6	87.1
14:16:21	88.5	88.2	89.3	88.4	89.7	88.2	89.8	88.2	89.9	88.2	89.3	88.4
14:17:21	90.5	90.1	91.3	90.5	91.8	90.4	91.7	90.3	91.8	90.1	91.3	90.5
14:18:21	92.2	92.1	93.3	92.5	93.0	92.4	93.0	92.2	93.5	92.1	93.3	92.5
14:19:21	95.3	95.4	96.2	95.3	96.5	95.7	96.4	95.1	96.3	95.4	96.2	95.3
14:20:21	97.5	97.0	98.4	97.1	98.4	97.6	98.3	97.7	98.4	97.0	98.4	97.1
14:21:21	99.5	98.1	99.0	98.5	99.2	98.0	99.2	98.2	99.1	98.1	99.0	98.5
14:22:21	101.2	101.2	102.3	101.5	102.8	101.3	102.4	101.7	102.8	101.2	102.3	101.5
14:23:21	105.2	105.3	106.7	105.0	106.2	105.6	106.0	105.1	106.3	105.3	106.7	105.0
14:24:21	106.3	105.8	106.8	105.0	106.3	105.7	106.1	105.2	106.4	105.8	106.8	105.0
14:25:21	107.5	106.7	107.2	106.4	107.0	106.1	107.3	106.8	107.2	106.7	107.2	106.4
14:26:21	108.5	107.6	108.4	107.3	108.2	107.7	108.9	107.1	108.4	107.6	108.4	107.3
14:27:21	110.3	109.1	110.7	109.9	110.8	109.4	110.6	109.8	110.3	109.1	110.7	109.9
14:28:21	111.2	110.1	111.0	110.3	111.4	110.0	111.6	110.3	111.8	110.1	111.0	110.3
14:29:21	112.3	111.7	112.5	111.1	112.4	111.7	112.2	111.6	112.6	111.7	112.5	111.1
14:30:21	113.2	112.3	113.4	112.2	113.6	112.3	113.4	112.4	113.2	112.3	113.4	112.2
14:31:21	114.3	113.6	113.8	113.5	113.7	113.0	113.9	113.6	113.5	113.6	113.8	113.5
14:32:21	114.2	113.8	113.9	113.7	113.9	113.1	113.9	113.8	113.7	113.8	113.9	113.7
14:33:21	115.4	114.2	115.3	114.2	115.3	114.2	115.3	114.2	115.3	114.2	115.3	114.2
14:34:21	116.2	115.3	116.3	115.2	116.6	115.8	116.2	115.7	116.7	115.3	116.6	115.1
14:35:21	116.3	115.6	116.5	115.2	116.8	115.9	116.9	115.9	114.9	115.6	116.7	115.2
14:36:21	116.2	115.3	116.6	115.2	116.3	115.1	116.3	115.2	116.6	115.2	116.9	115.2
14:37:21	117.5	116.5	115.7	116.9	115.2	116.3	115.2	116.4	115.0	116.5	115.7	116.9
14:38:21	118.5	117.8	116.3	117.0	116.2	117.5	116.1	117.5	116.2	117.8	116.3	117.0
14:39:21	120.3	119.0	120.1	119.2	120.6	119.0	120.4	119.7	120.5	119.0	120.8	119.2
14:40:21	121.8	121.7	121.9	121.8	121.7	121.6	121.8	122.4	122.3	122.1	122.1	121.6
14:41:21	121.7	121.8	122.1	122.3	121.9	121.6	122.5	121.7	121.8	121.9	122.2	122.2
14:42:21	122.1	121.8	121.7	122.3	121.7	121.8	121.9	121.7	122.1	122.3	122.1	121.9
14:43:21	121.7	121.7	121.8	122.0	122.0	122.3	121.9	122.3	122.1	121.8	122.0	121.8
14:44:21	122.1	121.9	121.8	122.0	121.8	122.0	121.8	122.4	121.9	122.0	121.9	121.9
14:45:21	121.9	121.9	122.3	122.0	122.3	122.5	122.1	121.7	121.8	122.2	122.2	121.9
14:46:21	122.1	121.8	122.1	121.8	122.6	121.6	122.5	121.6	121.8	121.8	122.3	121.9
14:47:21	121.7	121.7	121.8	122.3	122.1	121.8	122.4	121.9	121.8	121.9	122.2	122.0
14:48:21	121.6	121.8	122.2	122.1	122.0	121.8	122.4	122.4	122.0	121.9	121.8	121.6
14:49:21	121.9	121.7	121.7	121.9	122.6	121.8	122.6	121.8	121.8	121.8	122.2	122.5
14:50:21	121.6	122.1	121.7	122.5	122.4	122.3	122.0	121.9	122.0	122.2	122.2	121.9
14:51:21	121.8	122.3	122.3	121.9	121.9	122.2	122.2	121.8	122.0	121.9	122.6	122.5

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Sign/Date				
Name	Sanjay Patel	Ganesh Patel		
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VALIDATION REPORT FOR STEAM STERILIZER

Report No:	Validation Start Date:	Validation Due Date:	Page No.
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14:52:21	121.5	122.0	121.9	122.5	122.6	122.5	122.6	121.6	121.9	121.7	122.4	121.9
14:53:21	121.8	121.8	122.2	121.9	122.1	121.7	121.9	122.4	122.3	121.8	122.3	122.4
14:54:21	122.1	121.7	121.7	122.4	121.8	122.0	122.5	121.9	122.1	121.8	121.8	121.9
14:55:21	121.5	122.0	121.7	121.9	122.2	121.6	121.9	122.0	122.3	121.7	122.6	122.4
14:56:21	122.1	122.1	121.8	122.0	122.5	122.3	122.6	122.4	122.5	121.8	122.2	121.8
14:57:21	121.9	122.3	121.7	122.0	121.7	121.7	122.1	121.9	122.4	122.0	122.2	121.9
14:58:21	121.6	122.2	121.8	122.4	122.3	122.5	122.6	121.9	121.9	121.8	122.5	122.4
14:59:21	121.7	122.0	121.7	122.1	121.8	121.6	122.3	121.7	122.1	121.9	122.3	121.6
15:00:21	122.1	122.2	121.7	122.2	122.4	122.1	121.8	121.6	122.3	121.8	122.3	122.4
15:01:21	121.8	122.3	121.8	121.8	122.4	122.0	122.4	122.2	122.0	121.8	122.6	121.9
15:02:21	122.1	121.7	121.7	121.9	122.3	122.4	122.1	121.6	122.1	122.0	122.6	122.0
15:03:21	121.7	121.8	122.1	121.8	122.4	122.4	122.3	122.4	121.9	122.0	121.8	122.3
15:04:21	122.1	122.4	121.7	122.0	122.3	121.7	121.8	121.8	122.2	121.9	121.9	121.6
15:05:21	121.6	122.3	122.2	121.8	121.8	122.0	121.9	121.9	122.1	121.9	122.0	121.6
15:06:21	122.1	122.4	121.7	122.2	122.1	122.2	122.0	122.3	121.8	121.8	122.3	122.0
15:07:21	121.9	122.3	122.1	122.3	122.3	121.6	122.2	121.9	122.3	121.8	122.3	122.1
15:08:21	122.1	122.4	122.1	121.8	121.7	122.3	121.8	122.0	121.9	122.3	121.8	121.9
15:09:21	121.8	122.2	121.9	121.8	121.9	122.1	122.1	121.7	121.8	121.8	121.8	122.3
15:10:21	121.7	122.0	121.8	122.0	122.2	122.5	122.4	121.7	122.1	121.9	121.9	121.8
15:11:21	120.1	119.6	120.5	119.4	120.8	119.7	120.5	119.3	120.5	119.4	120.5	119.6
15:12:21	119.5	118.1	119.6	118.3	119.4	118.2	119.6	118.1	119.6	118.2	119.7	118.6
15:13:21	118.1	117.6	118.2	117.6	118.1	117.3	118.5	117.6	118.4	117.3	118.1	117.5
15:14:21	117.6	116.2	117.6	116.2	117.6	116.2	117.3	116.2	117.3	116.2	117.7	116.6
15:15:21	116.2	115.3	116.8	115.1	116.4	115.6	116.7	115.1	116.5	115.1	116.6	115.2
15:16:21	115.5	114.8	115.4	114.3	115.4	114.2	115.4	114.6	115.4	114.3	115.1	114.6
15:17:21	113.2	112.1	113.6	112.6	113.5	112.1	113.5	112.2	113.5	112.2	113.6	112.2
15:18:21	112.5	111.6	112.4	111.5	112.4	111.6	112.1	111.6	112.1	111.6	112.2	111.4
15:19:21	111.9	110.4	111.2	110.1	111.6	110.2	111.2	110.3	111.6	110.1	111.3	110.5
15:20:21	109.4	108.3	109.5	108.6	109.1	108.7	109.6	108.4	109.7	108.2	109.6	108.4
15:21:21	106.4	107.2	106.8	107.6	106.2	107.8	106.1	107.4	106.2	107.3	106.5	107.8
15:22:21	105.9	104.3	105.1	104.5	105.1	104.7	105.2	104.3	105.1	104.6	105.2	104.7
15:23:21	104.6	103.2	104.6	103.2	104.4	103.1	104.6	103.2	104.8	103.6	104.3	103.1
15:24:21	100.1	99.1	100.2	99.6	100.2	99.4	100.3	99.5	100.7	99.3	100.2	99.2
15:25:21	98.3	97.6	98.1	97.3	98.5	97.6	98.4	97.2	98.8	97.9	98.7	97.6

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Sign/Date				
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Designation	Site Engineer	Technical Manager	User Department	Q.A.

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Parameters Computed During Sterilization Period			
Time	Minimum Temp. (°C)	Maximum Temp. (°C)	Average (°C)
14:40:21	121.6	122.4	121.8
14:41:21	121.6	122.5	122.0
14:42:21	121.7	122.3	121.9
14:43:21	121.7	122.3	122.0
14:44:21	121.8	122.4	122.0
14:45:21	121.7	122.5	122.1
14:46:21	121.6	122.6	122.0
14:47:21	121.7	122.4	122.0
14:48:21	121.6	122.4	122.0
14:49:21	121.7	122.6	122.0
14:50:21	121.6	122.5	122.1
14:51:21	121.8	122.3	122.1
14:52:21	121.5	122.6	122.2
14:53:21	121.7	122.4	122.0
14:54:21	121.7	122.5	122.0
14:55:21	121.5	122.2	121.9
14:56:21	121.8	122.6	122.2
14:57:21	121.7	122.3	121.9
14:58:21	121.6	122.6	122.2
14:59:21	121.6	122.3	121.9
15:00:21	121.6	122.4	122.0
15:01:21	121.8	122.4	122.1
15:02:21	121.6	122.4	122.0
15:03:21	121.7	122.4	122.1
15:04:21	121.7	122.4	122.0
15:05:21	121.6	122.3	121.9
15:06:21	121.7	122.4	122.1
15:07:21	121.6	122.3	122.1
15:08:21	121.7	122.4	122.0
15:09:21	121.7	122.2	121.9
15:10:21	121.7	122.5	122.0

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Run - 3 Heat Penetration in Full Loaded Chamber (30 Min.) Lethal Rate & F₀ Value Calculation of all position

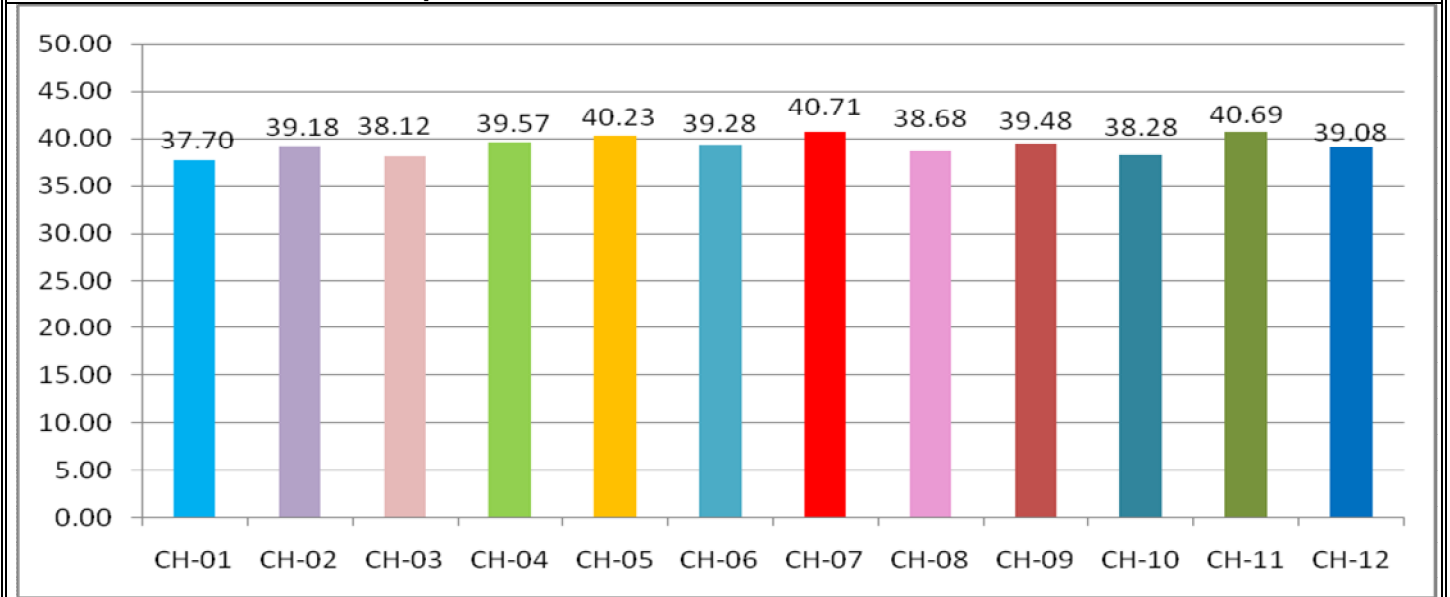
Time	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
14:40:21	1.20	1.17	1.23	1.20	1.17	1.15	1.20	1.38	1.35	1.29	1.29	1.15
14:41:21	1.17	1.20	1.29	1.35	1.23	1.15	1.41	1.17	1.20	1.23	1.32	1.32
14:42:21	1.29	1.20	1.17	1.35	1.17	1.20	1.23	1.17	1.29	1.35	1.29	1.23
14:43:21	1.17	1.17	1.20	1.26	1.26	1.35	1.23	1.35	1.29	1.20	1.26	1.20
14:44:21	1.29	1.23	1.20	1.26	1.20	1.26	1.20	1.38	1.23	1.26	1.23	1.23
14:45:21	1.23	1.23	1.35	1.26	1.35	1.41	1.29	1.17	1.20	1.32	1.32	1.23
14:46:21	1.29	1.20	1.29	1.20	1.45	1.15	1.41	1.15	1.20	1.20	1.35	1.23
14:47:21	1.17	1.17	1.20	1.35	1.29	1.20	1.38	1.23	1.20	1.23	1.32	1.26
14:48:21	1.15	1.20	1.32	1.29	1.26	1.20	1.38	1.38	1.26	1.23	1.20	1.15
14:49:21	1.23	1.17	1.17	1.23	1.45	1.20	1.45	1.20	1.20	1.20	1.32	1.41
14:50:21	1.15	1.29	1.17	1.41	1.38	1.35	1.26	1.23	1.26	1.32	1.32	1.23
14:51:21	1.20	1.35	1.35	1.23	1.23	1.32	1.32	1.20	1.26	1.23	1.45	1.41
14:52:21	1.12	1.26	1.23	1.41	1.45	1.41	1.45	1.15	1.23	1.17	1.38	1.23
14:53:21	1.20	1.20	1.32	1.23	1.29	1.17	1.23	1.38	1.35	1.20	1.35	1.38
14:54:21	1.29	1.17	1.17	1.38	1.20	1.26	1.41	1.23	1.29	1.20	1.20	1.23
14:55:21	1.12	1.26	1.17	1.23	1.32	1.15	1.23	1.26	1.35	1.17	1.45	1.38
14:56:21	1.29	1.29	1.20	1.26	1.41	1.35	1.45	1.38	1.41	1.20	1.32	1.20
14:57:21	1.23	1.35	1.17	1.26	1.17	1.17	1.29	1.23	1.38	1.26	1.32	1.23
14:58:21	1.15	1.32	1.20	1.38	1.35	1.41	1.45	1.23	1.23	1.20	1.41	1.38
14:59:21	1.17	1.26	1.17	1.29	1.20	1.15	1.35	1.17	1.29	1.23	1.35	1.15
15:00:21	1.29	1.32	1.17	1.32	1.38	1.29	1.20	1.15	1.35	1.20	1.35	1.38
15:01:21	1.20	1.35	1.20	1.20	1.38	1.26	1.38	1.32	1.26	1.20	1.45	1.23
15:02:21	1.29	1.17	1.17	1.23	1.35	1.38	1.29	1.15	1.29	1.26	1.45	1.26
15:03:21	1.17	1.20	1.29	1.20	1.38	1.38	1.35	1.38	1.23	1.26	1.20	1.35
15:04:21	1.29	1.38	1.17	1.26	1.35	1.17	1.20	1.20	1.32	1.23	1.23	1.15
15:05:21	1.15	1.35	1.32	1.20	1.20	1.26	1.23	1.23	1.29	1.23	1.26	1.15
15:06:21	1.29	1.38	1.17	1.32	1.29	1.32	1.26	1.35	1.20	1.20	1.35	1.26
15:07:21	1.23	1.35	1.29	1.35	1.35	1.15	1.32	1.23	1.35	1.20	1.35	1.29
15:08:21	1.29	1.38	1.29	1.20	1.17	1.35	1.20	1.26	1.23	1.35	1.20	1.23
15:09:21	1.20	1.32	1.23	1.20	1.23	1.29	1.29	1.17	1.20	1.20	1.20	1.35
15:10:21	1.17	1.26	1.20	1.26	1.32	1.41	1.38	1.17	1.29	1.23	1.23	1.20
F₀ Value	37.70	39.18	38.12	39.57	40.23	39.28	40.71	38.68	39.48	38.28	40.69	39.08

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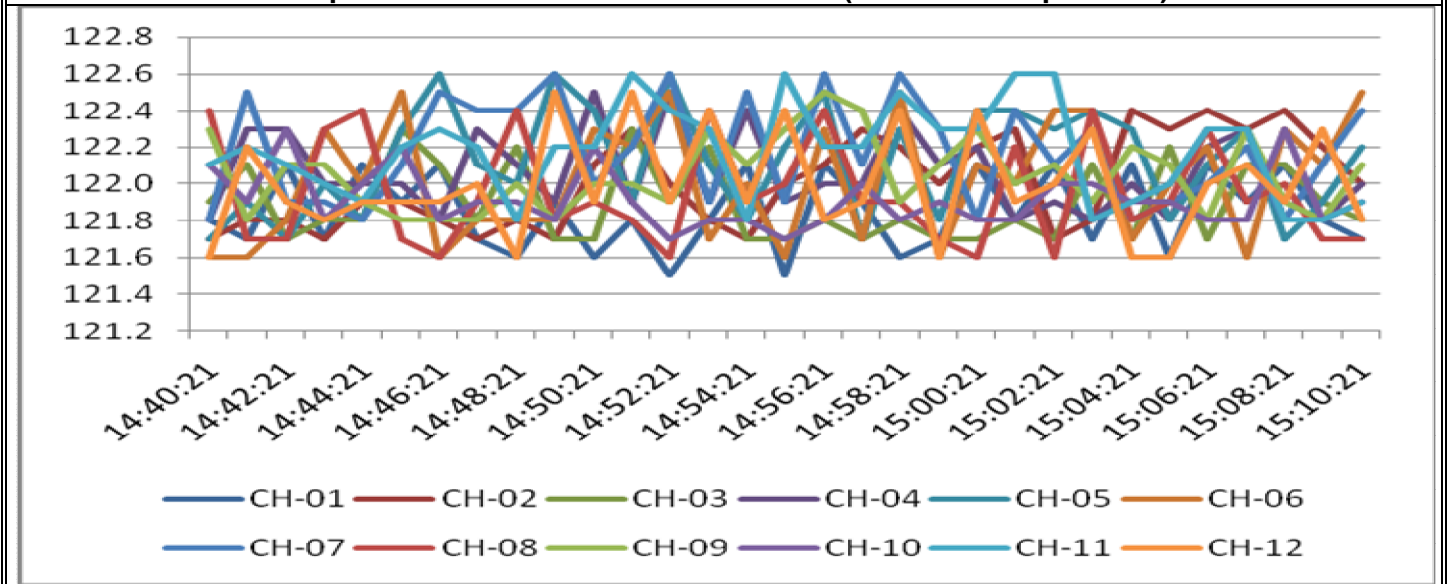
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Graphical Presentation of F₀ Value Of all Locations



Graphical Presentation: Steam Sterilizer (Time V/s Temperature)



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Summary Report: Heat Penetration in Full Loaded Chamber (30 Min.)

Hot and Cold Spot during Sterilization Period As Per F₀ Value

Hot Spot: Position CH-07	Cold Spot: Position CH-01
---------------------------------	----------------------------------

F₀ Values for all Locations

Position	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
F₀ Values	37.70	39.18	38.12	39.57	40.23	39.28	40.71	38.68	39.48	38.28	40.69	39.08

Minimum and Maximum Temperature Observed During Sterilization Phase for all Probes

Minimum Temperature	Maximum Temperature	Difference
121.5	122.6	1.1

Minimum, Maximum and Average Temperature of Each Probe

Position	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
Minimum	121.5	121.7	121.7	121.8	121.7	121.6	121.8	121.6	121.8	121.7	121.8	121.6
Maximum	122.1	122.4	122.3	122.5	122.6	122.5	122.6	122.4	122.5	122.3	122.6	122.5
Average	121.8	122.0	121.9	122.1	122.1	122.0	122.2	122.0	122.0	121.9	122.2	122.0
Diff.	0.6	0.7	0.6	0.7	0.9	0.9	0.8	0.8	0.7	0.6	0.8	0.9

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➤ **Post –Verification of Thermocouple Sensor**

- Post-Verification of Thermocouple sensor was carried out and results was satisfactory and temperature variation was under acceptance limit, brief observation given below

- **Observation Table:**

- **Date: 20/05/2022**

- **Verification of Thermocouple Sensor at (100.0°C)**

Time	Std. Value	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
16:00:15	99.9	99.6	99.9	99.7	100.0	99.8	99.6	99.9	99.7	100.3	99.8	100.1	99.9
16:01:15	100.0	99.8	100.2	99.9	100.3	99.7	100.4	99.6	99.9	100.1	99.8	100.0	100.3
16:02:15	99.7	99.7	100.0	99.6	100.0	99.8	100.1	99.9	99.6	100.0	99.9	100.1	99.7
16:03:15	100.1	99.8	100.3	99.7	100.4	99.9	100.2	100.0	99.8	100.1	99.7	100.2	99.9
16:04:15	99.8	99.9	100.2	99.6	100.1	99.9	99.6	100.1	99.7	100.2	99.8	99.6	100.0

- **Verification of Thermocouple Sensor at (121.0°C)**

Time	Std. Value	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
16:14:15	120.6	120.7	121.0	120.6	121.0	120.9	121.0	120.8	120.6	121.0	120.7	121.0	120.6
16:15:15	121.1	120.8	121.4	120.9	121.3	121.0	120.8	121.1	120.9	121.2	121.0	121.3	121.1
16:16:15	120.7	120.9	121.1	120.6	121.0	120.8	121.1	120.6	120.9	121.1	120.7	121.0	120.8
16:17:15	121.2	120.8	121.1	120.9	121.4	121.0	120.8	121.2	120.9	121.3	121.0	121.4	121.1
16:18:15	120.8	120.6	121.2	120.7	121.0	120.8	120.6	120.9	120.7	121.0	120.8	121.1	120.9

- **Verification of Thermocouple Sensor at (130.0°C)**

Time	Std. Value	CH-01	CH-02	CH-03	CH-04	CH-05	CH-06	CH-07	CH-08	CH-09	CH-10	CH-11	CH-12
16:28:15	129.9	129.6	130.2	129.7	130.3	129.8	129.6	129.9	129.7	130.0	129.8	130.1	129.9
16:29:15	130.2	129.8	130.4	130.0	129.8	130.1	130.4	130.2	129.9	130.3	129.8	130.4	129.8
16:30:15	130.0	129.7	130.3	129.8	130.4	129.6	130.2	130.0	129.7	130.2	129.8	130.3	129.9
16:31:15	129.8	129.6	130.2	129.8	130.3	129.9	130.0	129.7	129.9	130.0	129.8	130.1	129.6
16:32:15	130.1	129.7	130.3	129.9	130.4	129.8	129.7	130.0	129.8	130.1	129.9	130.2	130.0

* Acceptance Limit: $\pm 0.5^{\circ}\text{C}$ against of Std. Value of Set Temperature

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VALIDATION REPORT FOR STEAM STERILIZER

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➤ **Observations:**

- The data collected during Monitoring are regenerated and attached for brief study of the Autoclave.
- Temperature is maintained between 121.0°C to 124.0°C during Sterilization Process.

➤ **Conclusion:**

- The Temperature uniformity of the Chamber is found Satisfactory.
- The Validation of the **Steam Sterilizer (1031)** is carried out and result is satisfactory and meets the acceptance criteria.

➤ **Certification:**

- **Based on the above observations and summary reports, It is concluded that STEAM STERILIZER (1031) is operating within the acceptance limit of 121.0°C to 124.0°C, hence it is qualified for its Further use.**

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