

Operator: Validation Manager
Process: Validation
Session Start: 22-11-2013 09:16:26
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:

Vessel: Tunnel
Product: Pharma
Time Zone: UTC offset 01:00:00



Depyrogenation Validation

Depyrogenation Tunnel K1

Study made using TrackSense loggers and sensors

from Ellab A/S Denmark

Demo file from Ellab webpage

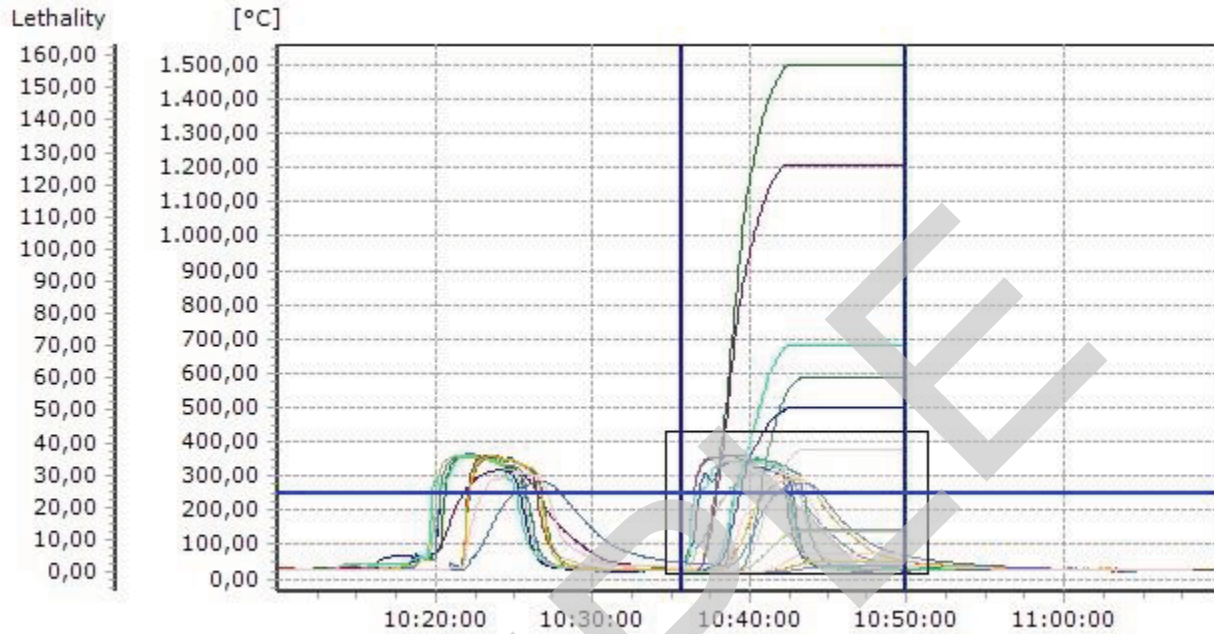


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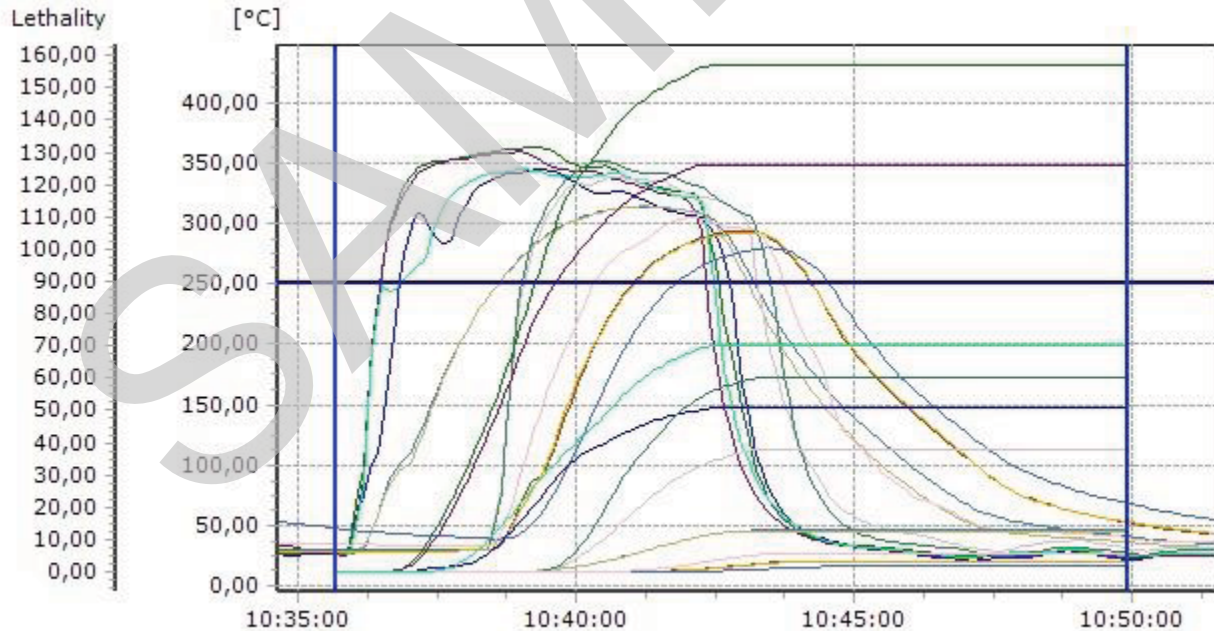
Vessel: Tunnel
Product: Pharma
Time Zone: UTC offset 01:00:00



Graph



Graph Zoom



Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
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Time Marker Report

Name	Time Stamp	Description
Process start	16-09-2010 10:35:40	Tool 4
Process stop	16-09-2010 10:49:55	Tool 5

SAMPLE

Operator: Validation Manager Vessel: Tunnel
 Process: Validation Product: Pharma
 Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
 Session Stop: 22-11-2013 09:16:34
 Session Name: Depyrogenation Validation
 Session Text:



Channel Overview

Sensor ID	Logger ID	Name	E-Val Flex S/N	Description	Sample Rate 1 (hh:mm:ss)	Sample Rate 2 (hh:mm:ss)
26619-1	31513	LC 01	N/A	Temperature	00:00:05	N/A
26619-2	31513	LA 02	N/A	Temperature	00:00:05	N/A
29672-1	31768	Sensor in vial 1st run	N/A	Temperature	00:00:05	N/A
29672-2	31768	Sensor in vial 2nd run	N/A	Temperature	00:00:05	N/A
28761-1	31774	Sensor wo vial both run	N/A	Temperature	00:00:05	N/A
28761-2	31774	Sensor in vial 2nd run	N/A	Temperature	00:00:05	N/A
28775-1	31777	Defect	N/A	Temperature	00:00:05	N/A
28775-2	31777	Defect	N/A	Temperature	00:00:05	N/A
28773-1	31811	LC 09	N/A	Temperature	00:00:05	N/A
28773-2	31811	LA 10	N/A	Temperature	00:00:05	N/A
28751-1	31844	LC 11	N/A	Temperature	00:00:05	N/A
28751-2	31844	LA 12	N/A	Temperature	00:00:05	N/A
28768-1	31873	Sensor in vial	N/A	Temperature	00:00:05	N/A
28768-2	31873	Sensor in vial	N/A	Temperature	00:00:05	N/A

SAMPLE

Operator: Validation Manager Vessel: Tunnel
 Process: Validation Product: Pharma
 Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
 Session Stop: 22-11-2013 09:16:34
 Session Name: Depyrogenation Validation
 Session Text:



Unit Configuration

Name: High temperature tunnel
 Description: Depyrogenation @ 350°C
 Type: Tunnel

Sensor Setup

Position:	Sensor S/N:	Label:	Position Name:	Position Description:	Sensor Alias:	Sensor group:	Sample Rate:
1	None	1	Upper left				00:00:01
2	None	2	Lower left				00:00:01
3	None	3	Center				00:00:01
4	None	4	Center mid				00:00:01

Image Set 1



Operator: Validation Manager Vessel: Tunnel
 Process: Validation Product: Pharma
 Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
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Lethality Overview

Input parameter

Start Date :	16-09-2010
Ref. Temperature:	250,00 °C
Min. Temperature :	250,00 °C
Z-Value:	46,4 °C
D-Value:	5

Sensor lethality overview

Name	Description	Start Time	End Time	Max. Value
LC 01 (F0) Lethality 1		10:35:40	10:49:55	51,11
LA 02 (F0) Lethality 1		10:35:40	10:49:55	157,02
Sensor in vial 1st run (F0) Lethality 1		10:35:40	10:49:55	126,26
Sensor in vial 2nd run (F0) Lethality 1		10:35:40	10:49:55	12,75
Sensor in vial 2nd run (F0) Lethality 1		10:35:40	10:49:55	12,47
LC 09 (F0) Lethality 1		10:35:40	10:49:55	37,72
LA 10 (F0) Lethality 1		10:35:40	10:49:55	3,40
LC 11 (F0) Lethality 1		10:35:40	10:49:55	60,29
LA 12 (F0) Lethality 1		10:35:40	10:49:55	3,25
Sensor in vial (F0) Lethality 1		10:35:40	10:49:55	1,61
Sensor in vial (F0) Lethality 1		10:35:40	10:49:55	5,66
Lethality - Sensor wo vial both run		10:35:40	10:49:55	70,01

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:



Limit Report

Name: Depyrogenation Tunnel
Description: Depyrogenation of 20 ml ampules @ minimum temperature of 250°C

Input parameters

Criteria: Passed when 250,00 °C < Value
Triggering : Individually, Temperature
Data Series: LC 01

Range

Time: 16-09-2010 10:35:40 to 10:49:55

Triggering Interval

from	to
16-09-2010 10:36:50	16-09-2010 10:42:45

Summary Time: **00:05:55**

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:



Limit Report

Name: Depyrogenation Tunnel
Description: Depyrogenation of 20 ml ampules @ minimum temperature of 250°C

Input parameters

Criteria: Passed when 250,00 °C < Value
Triggering : Individually, Temperature
Data Series: LA 02

Range

Time: 16-09-2010 10:35:40 to 10:49:55

Triggering Interval

from	to
16-09-2010 10:36:30	16-09-2010 10:42:30

Summary Time: 00:06:00

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:



Limit Report

Name: Depyrogenation Tunnel
Description: Depyrogenation of 20 ml ampules @ minimum temperature of 250°C

Input parameters

Criteria: Passed when 250,00 °C < Value
Triggering : Individually, Temperature
Data Series: Sensor in vial 1st run

Range

Time: 16-09-2010 10:35:40 to 10:49:55

Triggering Interval

from	to
16-09-2010 10:36:30	16-09-2010 10:42:20

Summary Time: **00:05:50**

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:



Limit Report

Name: Depyrogenation Tunnel
Description: Depyrogenation of 20 ml ampules @ minimum temperature of 250°C

Input parameters

Criteria: Passed when 250,00 °C < Value
Triggering : Individually, Temperature
Data Series: Sensor in vial 2nd run

Range

Time: 16-09-2010 10:35:40 to 10:49:55

Triggering Interval

from	to
16-09-2010 10:38:40	16-09-2010 10:43:10

Summary Time: **00:04:30**

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:



Limit Report

Name: Depyrogenation Tunnel
Description: Depyrogenation of 20 ml ampules @ minimum temperature of 250°C

Input parameters

Criteria: Passed when 250,00 °C < Value
Triggering : Individually, Temperature
Data Series: Sensor wo vial both run

Range

Time: 16-09-2010 10:35:40 to 10:49:55

Triggering Interval

from	to
16-09-2010 10:36:55	16-09-2010 10:42:25

Summary Time: **00:05:30**

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:



Limit Report

Name: Depyrogenation Tunnel
Description: Depyrogenation of 20 ml ampules @ minimum temperature of 250°C

Input parameters

Criteria: Passed when 250,00 °C < Value
Triggering : Individually, Temperature
Data Series: Sensor in vial 2nd run

Range

Time: 16-09-2010 10:35:40 to 10:49:55

Triggering Interval

from	to
16-09-2010 10:38:40	16-09-2010 10:43:05

Summary Time: 00:04:25

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:



Limit Report

Name: Depyrogenation Tunnel
Description: Depyrogenation of 20 ml ampules @ minimum temperature of 250°C

Input parameters

Criteria: Passed when 250,00 °C < Value
Triggering : Individually, Temperature
Data Series: LC 09

Range

Time: 16-09-2010 10:35:40 to 10:49:55

Triggering Interval

from	to
16-09-2010 10:39:05	16-09-2010 10:43:15

Summary Time: **00:04:10**

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:



Limit Report

Name: Depyrogenation Tunnel
Description: Depyrogenation of 20 ml ampules @ minimum temperature of 250°C

Input parameters

Criteria: Passed when 250,00 °C < Value
Triggering : Individually, Temperature
Data Series: LA 10

Range

Time: 16-09-2010 10:35:40 to 10:49:55

Triggering Interval

from	to
16-09-2010 10:41:05	16-09-2010 10:44:10

Summary Time: **00:03:05**

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:



Limit Report

Name: Depyrogenation Tunnel
Description: Depyrogenation of 20 ml ampules @ minimum temperature of 250°C

Input parameters

Criteria: Passed when 250,00 °C < Value
Triggering : Individually, Temperature
Data Series: LC 11

Range

Time: 16-09-2010 10:35:40 to 10:49:55

Triggering Interval

from	to
16-09-2010 10:39:05	16-09-2010 10:43:30

Summary Time: 00:04:25

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:



Limit Report

Name: Depyrogenation Tunnel
Description: Depyrogenation of 20 ml ampules @ minimum temperature of 250°C

Input parameters

Criteria: Passed when 250,00 °C < Value
Triggering : Individually, Temperature
Data Series: LA 12

Range

Time: 16-09-2010 10:35:40 to 10:49:55

Triggering Interval

from	to
16-09-2010 10:41:05	16-09-2010 10:44:15

Summary Time: **00:03:10**

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:



Limit Report

Name: Depyrogenation Tunnel
Description: Depyrogenation of 20 ml ampules @ minimum temperature of 250°C

Input parameters

Criteria: Passed when 250,00 °C < Value
Triggering : Individually, Temperature
Data Series: Sensor in vial

Range

Time: 16-09-2010 10:35:40 to 10:49:55

Triggering Interval

from	to
16-09-2010 10:41:50	16-09-2010 10:44:30

Summary Time: **00:02:40**

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
Session Stop: 22-11-2013 09:16:34
Session Name: Depyrogenation Validation
Session Text:



Limit Report

Name: Depyrogenation Tunnel
Description: Depyrogenation of 20 ml ampules @ minimum temperature of 250°C

Input parameters

Criteria: Passed when 250,00 °C < Value
Triggering : Individually, Temperature
Data Series: Sensor in vial

Range

Time: 16-09-2010 10:35:40 to 10:49:55

Triggering Interval

from	to
16-09-2010 10:40:20	16-09-2010 10:43:45

Summary Time: 00:03:25

Operator: Validation Manager Vessel: Tunnel
 Process: Validation Product: Pharma
 Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
 Session Stop: 22-11-2013 09:16:34
 Session Name: Depyrogenation Validation
 Session Text:



Advanced Validation Report

Name: Advanced Validation Report
 Description:
 Cycle:
Total Test Result: Passed

Input parameters

Process Temperature: 250,00 °C
 Process Band (K): 90,00
 Process Upper Band (K): 90,00
 Process Lower Band (K): 0,00
 Maximum Process Time: 01:00:00
 Mode: Heat Distribution with Ambient and Core
 Heat Penetration with Core
 Define Periods by: Temperature
 Maximum Temperature Fluctuation (K): 90,00
 Maximum Temperature Difference (K): 90,00
 Maximum Come Up Time: 00:10:00
 Maximum Equilibration Time: 00:10:00
 Minimum Holding Time (Total): 00:00:25
 Maximum Holding Time (Total): 00:15:00

Process Time

Process Start Time: 16-09-2010 10:35:40
 Process End Time: 16-09-2010 10:49:55
 Process Duration: 00:14:15
 Max. Allowed Process Duration: 01:00:00
 Process Test Result: Passed

Heat Distribution

Cold Zone:	252,06 °C	16-09-2010 10:41:50	Sensor in vial
Hot Zone:	336,26 °C	16-09-2010 10:41:50	LC 11
Delta:	84,20 °C		

Come Up Time

Come Up Start Time: 16-09-2010 10:35:40
 Come Up End Time: 16-09-2010 10:41:50
 Come Up Duration: 00:06:10
 Max. Allowed Come Up Duration: 00:10:00
 Come Up Test Result: Passed

Operator: Validation Manager Vessel: Tunnel
 Process: Validation Product: Pharma
 Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
 Session Stop: 22-11-2013 09:16:34
 Session Name: Depyrogenation Validation
 Session Text:



Equilibration Time

Equilibration Start Time:	16-09-2010 10:36:30
Equilibration End Time:	16-09-2010 10:41:50
Equilibration Duration:	00:05:20
Max. Allowed Equilibration Duration:	00:10:00
Equilibration Test Result:	Passed

Holding Time

Holding Start Time:	16-09-2010 10:41:50
Holding End Time:	16-09-2010 10:42:20
All Holding Times (Start, End, Duration):	16-09-2010 10:41:50 16-09-2010 10:42:20 00:00:30
Holding Duration (Total):	00:00:30
Min. Allowed Holding Duration (Total):	00:00:25
Max. Allowed Holding Duration (Total):	00:15:00
Holding Test Result:	Passed

Homogeneous Band

Homogeneous Temperature (K):	84,20
Max. Allowed Homogeneous Temperature (K):	90,00
Homogeneous Temperature Test Result:	Passed

Fluctuation Band

Temperature Fluctuation (K):	68,66
Max. Allowed Temperature Fluctuation (K):	90,00
Temperature Fluctuation Test Result:	Passed

Summary Report in Holding Time

Sensor ID	Name	Fluctuation (°C)
26619-1	LC 01	7,84
26619-2	LA 02	26,73
29672-1	Sensor in vial 1st run	68,66
29672-2	Sensor in vial 2nd run	4,44
28761-1	Sensor wo vial both run	19,31
28761-2	Sensor in vial 2nd run	5,45
28773-1	LC 09	6,46
28773-2	LA 10	8,95
28751-1	LC 11	8,60
28751-2	LA 12	8,58
28768-1	Sensor in vial	14,47
28768-2	Sensor in vial	3,08

Lethality Calculation

Min. Allowed Lethality Value in Process Time:	30,00
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Operator: Validation Manager Vessel: Tunnel
 Process: Validation Product: Pharma
 Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
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Lethality - Reference Temperature:	250,00 °C
Min. Temperature for Lethality-Calculation:	250,00 °C
Lethality - Z-Value:	46,4 °C
Lethality - D-Value:	5,00

Individual Analysis

Name	Lethality value in Process Time	Lethality Status
Lethality - Sensor wo vial both run	70,01	Passed

Process Time

Lethality Min.:	Lethality - Sensor wo vial both run	70,01
Lethality Max.:	Lethality - Sensor wo vial both run	70,01
Lethality Delta:		0,00

Lethality overview

Sensor ID	Name	Lethality value in Come Up Time	Lethality value in Holding Time	Lethality value in Cooling Time
28761-1	Sensor wo vial both run	66,27	3,44	0,30

Come Up Time

Lethality Min.:	Sensor wo vial both run	66,27
Lethality Max.:	Sensor wo vial both run	66,27
Lethality Delta:		0,00

Holding Time

Lethality Min.:	Sensor wo vial both run	3,44
Lethality Max.:	Sensor wo vial both run	3,44
Lethality Delta:		0,00

Cooling Time

Lethality Min.:	Sensor wo vial both run	0,30
Lethality Max.:	Sensor wo vial both run	0,30
Lethality Delta:		0,00

Operator: Validation Manager Vessel: Tunnel
Process: Validation Product: Pharma
Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
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Sensor Adjustment Report

ID	Sensor Value	Standard Value	Deviation	Calibration Timestamp
26619-1	N/A	N/A	N/A	N/A
26619-2	N/A	N/A	N/A	N/A
29672-1	N/A	N/A	N/A	N/A
29672-2	N/A	N/A	N/A	N/A
28761-1	N/A	N/A	N/A	N/A
28761-2	N/A	N/A	N/A	N/A
28775-1	N/A	N/A	N/A	N/A
28775-2	N/A	N/A	N/A	N/A
28773-1	N/A	N/A	N/A	N/A
28773-2	N/A	N/A	N/A	N/A
28751-1	N/A	N/A	N/A	N/A
28751-2	N/A	N/A	N/A	N/A
28768-1	N/A	N/A	N/A	N/A
28768-2	N/A	N/A	N/A	N/A

SAMPLE

Operator: Validation Manager Vessel: Tunnel
 Process: Validation Product: Pharma
 Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
 Session Stop: 22-11-2013 09:16:34
 Session Name: Depyrogenation Validation
 Session Text:



Statistics Report

Name: K1 Tunnel

Description:

Input parameters

Data Series Type: Temperature
 Data series: LC 01, LA 02, LC 11, LA 12, Sensor wo vial both run, Sensor in vial 2nd run, Sensor in vial, Sensor in vial, LC 09, LA 10, Sensor in vial 1st run, Sensor in vial 2nd run
 Start Time: 16-09-2010 10:35:40
 Stop Time: 16-09-2010 10:49:55
 Output: Data Series analysis
 Functions: Min., Max., Average, Standard Deviation

Data Series analysis

Min average 130,55 °C Sensor in vial
 Max average 173,84 °C LA 02

ID	Name	Min.	Max.	Average	Standard Deviation
26619-1	LC 01	20,82 °C	344,34 °C	160,77 °C	137,86 °C
26619-2	LA 02	23,45 °C	362,40 °C	173,84 °C	149,17 °C
28751-1	LC 11	25,09 °C	351,88 °C	135,02 °C	134,93 °C
28751-2	LA 12	28,82 °C	292,25 °C	140,37 °C	96,29 °C
28761-1	Sensor wo vial both run	23,80 °C	344,68 °C	163,15 °C	139,96 °C
28761-2	Sensor in vial 2nd run	29,10 °C	314,29 °C	163,05 °C	106,84 °C
28768-1	Sensor in vial	39,04 °C	279,62 °C	140,65 °C	86,67 °C
28768-2	Sensor in vial	32,60 °C	305,54 °C	130,55 °C	103,75 °C
28773-1	LC 09	28,54 °C	338,63 °C	133,59 °C	128,08 °C
28773-2	LA 10	28,97 °C	294,30 °C	140,17 °C	96,42 °C
29672-1	Sensor in vial 1st run	23,41 °C	359,18 °C	166,88 °C	147,70 °C
29672-2	Sensor in vial 2nd run	27,13 °C	313,68 °C	169,96 °C	103,76 °C

Operator: Validation Manager Vessel: Tunnel
 Process: Validation Product: Pharma
 Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
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TrackSense Logger Settings Report

TrackSense Logger Settings

Logger S/N: 31513

Sensor ID:	26619	Factory Calibration Date:	09-09-2010
Logger S/N:	31513	Start/Stop Trigger Source:	N/A
Adjust Start Time:	Yes	Start Process Value:	N/A
Start Time:	16-09-2010 10:10:00	Stop Process Value:	N/A
Adjust Stop Time:	No	Stop Process Enable Value:	N/A
Stop Time:	18-09-2010 03:50:00	Sampling Control Trigger Source:	N/A
Sample Rate 1:	00:00:05	Sampling Control Minimum Value:	N/A
Sample Rate 2:	N/A	Sampling Control Maximum Value:	N/A
Firmware Version:	23.6.0.0		

TrackSense Logger Settings

Logger S/N: 31768

Sensor ID:	29672	Factory Calibration Date:	20-01-2010
Logger S/N:	31768	Start/Stop Trigger Source:	N/A
Adjust Start Time:	Yes	Start Process Value:	N/A
Start Time:	16-09-2010 10:10:00	Stop Process Value:	N/A
Adjust Stop Time:	No	Stop Process Enable Value:	N/A
Stop Time:	18-09-2010 03:50:00	Sampling Control Trigger Source:	N/A
Sample Rate 1:	00:00:05	Sampling Control Minimum Value:	N/A
Sample Rate 2:	N/A	Sampling Control Maximum Value:	N/A
Firmware Version:	23.7.0.0		

TrackSense Logger Settings

Logger S/N: 31774

Sensor ID:	28761	Factory Calibration Date:	17-12-2009
Logger S/N:	31774	Start/Stop Trigger Source:	N/A
Adjust Start Time:	Yes	Start Process Value:	N/A
Start Time:	16-09-2010 10:10:00	Stop Process Value:	N/A
Adjust Stop Time:	No	Stop Process Enable Value:	N/A
Stop Time:	18-09-2010 03:50:00	Sampling Control Trigger Source:	N/A
Sample Rate 1:	00:00:05	Sampling Control Minimum Value:	N/A
Sample Rate 2:	N/A	Sampling Control Maximum Value:	N/A
Firmware Version:	23.7.0.0		

TrackSense Logger Settings

Logger S/N: 31777

Sensor ID:	28775	Factory Calibration Date:	17-12-2009
Logger S/N:	31777	Start/Stop Trigger Source:	N/A
Adjust Start Time:	Yes	Start Process Value:	N/A
Start Time:	16-09-2010 10:10:00	Stop Process Value:	N/A
Adjust Stop Time:	No	Stop Process Enable Value:	N/A
Stop Time:	18-09-2010 03:50:00	Sampling Control Trigger Source:	N/A
Sample Rate 1:	00:00:05	Sampling Control Minimum Value:	N/A
Sample Rate 2:	N/A	Sampling Control Maximum Value:	N/A
Firmware Version:	23.7.0.0		

Operator: Validation Manager Vessel: Tunnel
 Process: Validation Product: Pharma
 Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
 Session Stop: 22-11-2013 09:16:34
 Session Name: Depyrogenation Validation
 Session Text:



TrackSense Logger Settings		Logger S/N: 31811	
Sensor ID:	28773	Factory Calibration Date:	17-12-2009
Logger S/N:	31811	Start/Stop Trigger Source:	N/A
Adjust Start Time:	Yes	Start Process Value:	N/A
Start Time:	16-09-2010 10:10:00	Stop Process Value:	N/A
Adjust Stop Time:	No	Stop Process Enable Value:	N/A
Stop Time:	18-09-2010 03:50:00	Sampling Control Trigger Source:	N/A
Sample Rate 1:	00:00:05	Sampling Control Minimum Value:	N/A
Sample Rate 2:	N/A	Sampling Control Maximum Value:	N/A
Firmware Version:	23.7.0.0		

TrackSense Logger Settings		Logger S/N: 31844	
Sensor ID:	28751	Factory Calibration Date:	17-12-2009
Logger S/N:	31844	Start/Stop Trigger Source:	N/A
Adjust Start Time:	Yes	Start Process Value:	N/A
Start Time:	16-09-2010 10:10:00	Stop Process Value:	N/A
Adjust Stop Time:	No	Stop Process Enable Value:	N/A
Stop Time:	18-09-2010 03:50:00	Sampling Control Trigger Source:	N/A
Sample Rate 1:	00:00:05	Sampling Control Minimum Value:	N/A
Sample Rate 2:	N/A	Sampling Control Maximum Value:	N/A
Firmware Version:	23.7.0.0		

TrackSense Logger Settings		Logger S/N: 31873	
Sensor ID:	28768	Factory Calibration Date:	17-12-2009
Logger S/N:	31873	Start/Stop Trigger Source:	N/A
Adjust Start Time:	Yes	Start Process Value:	N/A
Start Time:	16-09-2010 10:10:00	Stop Process Value:	N/A
Adjust Stop Time:	No	Stop Process Enable Value:	N/A
Stop Time:	18-09-2010 03:50:00	Sampling Control Trigger Source:	N/A
Sample Rate 1:	00:00:05	Sampling Control Minimum Value:	N/A
Sample Rate 2:	N/A	Sampling Control Maximum Value:	N/A
Firmware Version:	23.7.0.0		

Operator: Validation Manager Vessel: Tunnel
 Process: Validation Product: Pharma
 Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
 Session Stop: 22-11-2013 09:16:34
 Session Name: Depyrogenation Validation
 Session Text:



Audit Trail Report

ID	Text	TimeStamp	User	Import Date Time	Import User
	Create Session:ZZKL VALIDATION TEST 01(HIGH TEMPRETURE) (ID:1961)(ZGBG011\ELLAB->ID:3) Access Point Serial Number:5 Sample Rate:5 Transmission Rate:5-Process:'340°C7min'-Operator:'cb'			2010-9-16 10:05:24 (China Standard Time)	
	Start Logger(s) in Session(ID:1961)(ZGBG011\ELLAB->ID:3) [Logger SN:31513 Sensor SN:26619]			2010-9-16 10:06:00 (China Standard Time)	
	Start Logger(s) in Session(ID:1961)(ZGBG011\ELLAB->ID:3) [Logger SN:31768 Sensor SN:29672] [Logger SN:31774 Sensor SN:28761] [Logger SN:31777 Sensor SN:28775] [Logger SN:31811 Sensor SN:28773]			2010-9-16 10:07:27 (China Standard Time)	
	Start Logger(s) in Session(ID:1961)(ZGBG011\ELLAB->ID:3) [Logger SN:31844 Sensor SN:28751]			2010-9-16 10:08:23 (China Standard Time)	
	Start Logger(s) in Session(ID:1961)(ZGBG011\ELLAB->ID:3) [Logger SN:31873 Sensor SN:28768]			2010-9-16 10:08:50 (China Standard Time)	
	SKY Session Started for Session ID: 3 Settings: Template Name: USB1 Com Type: USB Access Point Serial: 5 Channel: 18 Radio Module Address: 4660 Stop Mode: Off			2010-9-16 10:12:04 (China Standard Time)	
	SKY Session Stop Online Started for Session ID: 3 Settings: Template Name: USB1 Com Type: USB Access Point Serial: 5 Channel: 18 Radio Module Address: 4660 Stop Mode: Off			2010-9-16 10:47:17 (China Standard Time)	
	Session Validation for Session ID: 3 - Sky Session ClosedTransmission State Succeeded for All SKY Loggers Sensor SN: 26619 Some data points have not been transmitted. Read logger in reader station - [Contains data gab]			2010-9-16 10:56:00 (China Standard Time)	

Operator: Validation Manager Vessel: Tunnel
 Process: Validation Product: Pharma
 Session Start: 22-11-2013 09:16:26 Time Zone: UTC offset 01:00:00
 Session Stop: 22-11-2013 09:16:34
 Session Name: Depyrogeneration Validation
 Session Text:



ID	Text	TimeStamp	User	Import Date Time	Import User
	Read Logger(s) in Session(ID:1961)(ZGBG011\ELLAB->ID:3) [Logger SN:31768 Sensor SN:29672]			2010-9-16 11:07:26 (China Standard Time)	
	Read Logger(s) in Session(ID:1961)(ZGBG011\ELLAB->ID:3) [Logger SN:31873 Sensor SN:28768] [Logger SN:31777 Sensor SN:28775] [Logger SN:31844 Sensor SN:28751] [Logger SN:31774 Sensor SN:28761]			2010-9-16 11:09:37 (China Standard Time)	
	Read Logger(s) in Session(ID:1961)(ZGBG011\ELLAB->ID:3) [Logger SN:31811 Sensor SN:28773] [Logger SN:31513 Sensor SN:26619]			2010-9-16 11:10:25 (China Standard Time)	
	Import Session from 'HUNAN KELUN DEP(100916).d7x' (Session ID:1961)	2010-09-16 05:31:42	Jan Eriksen		
	Edit Data Series-'LC 03' Name to:'Sensor in vial'- Session ID:1961	2010-09-16 07:50:15	Jan Eriksen		
	Edit Data Series-'LC 07' Name to:'Defect'- Session ID:1961	2010-09-16 07:50:48	Jan Eriksen		
	Edit Data Series-'LA 08' Name to:'Defect'- Session ID:1961	2010-09-16 07:50:57	Jan Eriksen		
	Edit Data Series-'LC 13' Name to:'Sensor in vial'- Session ID:1961	2010-09-16 07:51:21	Jan Eriksen		
	Edit Data Series-'LA 14' Name to:'Sensor in vial'- Session ID:1961	2010-09-16 07:51:34	Jan Eriksen		
	Edit Data Series-'Sensor in vial' Name to:'Sensor in vial 1st run'- Session ID:1961	2010-09-16 09:00:25	Jan Eriksen		
	Edit Data Series-'LA 04' Name to:'Sensor in vial 2nd run'- Session ID:1961	2010-09-16 09:00:46	Jan Eriksen		
	Edit Data Series-'LC 05' Name to:'Sensor wo vial both run'- Session ID:1961	2010-09-16 09:01:09	Jan Eriksen		
	Edit Data Series-'LA 06' Name to:'Sensor in vial 2nd run'- Session ID:1961	2010-09-16 09:01:37	Jan Eriksen		
	Edit Data Series-'Sensor in vial' Name to:'Sensor in vial both runs'- Session ID:1961	2010-09-21 13:09:10	Jan Eriksen		
	Edit Data Series-'Sensor in vial' Name to:'Sensor in vial both runs'- Session ID:1961	2010-09-21 13:09:30	Jan Eriksen		
	Export Session(ID:1961) to:C:\Datafiler\ValSuite data\Customers \Kelun YueYang China\HUNAN KELUN DEP(100916).d7x	2010-09-21 13:10:10	Jan Eriksen		
	Export Session(ID:1961) to:G:\Depyrogeneration test 2.d7x	2010-11-18 11:29:00	Jan Eriksen		
	Add to Session(ID:1961)-Unit(Name:High temperature tunnel)	2010-11-18 11:46:04	Jan Eriksen		