

VALIDATION SUMMARY REPORT

Walk-in Refrigeration Storage / Cold Room

Title: Validation Summary Report for Walk-in Refrigeration / Cold Room Model DT820

Manufacturer:	Polar King International, Inc.
Model Number:	L820
Equipment ID / Serial No:	A19119314

Revision Number: 1

Issue Date: 1/09/2020



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1.0 INTRODUCTION

The Validation Summary Report summarizes the qualification activities measured on the Walk-In Cold Room, Polar King Unit A19119314. The unit is manufactured by Polar King International, Inc. and has a model number of L820. It is controlled by a KE2 Therm Solutions model 20460. This summary also covers any discrepancies encountered throughout the validation study.

2.0 REFERENCES

Temperature mapping of storage area, technical supplement to WHO Technical Report Series, No. 961, 2011.

3.0 SUMMARY

3.1 INSTALLATION & QULAIFICATION

The validation study for A19119314 was completed on January 6th, 2020. Verifications for the study were documented and saved using Vaisala Veriteg vLog.

3.1.1 System Components Identification

Identification information for the Cold Room was verified. This included model and serial numbers for the condensing unit, compressor, and structure. Refrigerant type and expansion valve were confirmed, as was insulation thickness.

3.1.2 Documentation Verification

Documentation for installation and maintenance of A19119314 was obtained. These documents were reviewed, and include manuals, quality control reports and production worksheets.

3.1.3 Refrigeration System Components Visual Inspection

A visual inspection of refrigeration system components was conducted to verify the equipment was installed in accordance with the manufacturer's recommendation. Critical components were confirmed to be in new working order. No damage was noted.

3.1.4 Electrical Supply Verification

A Fluke Multimeter was used to confirm the provided voltage supply was in accordance with requirements specified on the serial plate of the Cold Room.



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3.1.5 Thermostatic Controller Identification

The installation location of the thermostatic control was noted and documented as required. Vaisala temperature data logger #8 was used to mirror the thermocouple location. All set points used for testing were documented as necessary.

3.1.6 Refrigeration System Spare Parts

No spare parts are required for the Validation Summary.

3.2 OPERATION QUALIFICATIONS

3.2.1 Vaisala Validation Equipment Calibration Verification

Calibration documentation for (18) Vaisala DL1000-1400 was reviewed and all temperature data loggers were found to be in calibration as required.

3.2.2 Temperature Data Logger Placement

The set-up of all temperature monitoring loggers was done in accordance with acceptable usage practices, obtaining measurements at multiple low, medium and high points within the Cold Room. A total of 18 data points were logged in each study, as shown in Figure 1.

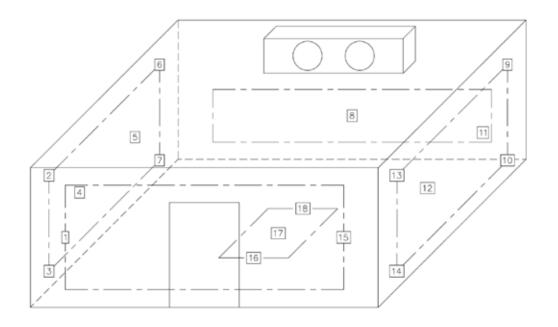


Figure 1



Manufacturer:	Polar King International, Inc.
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Table 1: Temperature Data Logger Locations and Labels

Data Logger Location	Data Logger Label	Alternate Data Logger Label
1	VA Logger #1	17341013
2	VA Logger #2	17341014
3	VA Logger #3	17381125
4	VA Logger #4	17381130
5	VA Logger #5	17381127
6	VA Logger #6	17381085
7	VA Logger #7	17381084
8	VA Logger #8	17381124
9	VA Logger #9	17381128
10	VA Logger #10	17381126
11	VA Logger #11	17381086
12	VA Logger #12	17381082
13	VA Logger #13	17371094
14	VA Logger #14	17381121
15	VA Logger #15	17381122
16	VA Logger #16	16451060
17	VA Logger #17	17381123
18	VA Logger #18	17371120

3.2.3 24-HR Empty Unit Thermal Mapping (-30°C Set Point)

At a set point of -30.0°C the Cold Room was tested empty, with the door closed. The average ambient temperature during the test period was 20.96°C, (69.73°F). Temperature data loggers were positioned as shown in figure 1. Temperature data was recorded for a 24 hr period, from 09:00pm EST on 01/03/20 to 09:00pm EST on 01/04/20. The data was logged at 30 second intervals. The summarized data for all 18 temperature data loggers can be found in Table 2. No deviations were noted.



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Table 2: Temperature Data Logger Locations and Labels

Data Logger Location	Data Logger Label	Data Logger Label (Alternate)	Max Temp (°C)	Avg. Temp (°C)	Min Temp (°C)
1	VA Logger #1	17341013	-24.04	-29.50	-29.96
2	VA Logger #2	17341014	-22.12	-29.46	-30.18
3	VA Logger #3	17381125	-23.72	-29.53	-30.11
4	VA Logger #4	17381130	-23.96	-29.34	-29.82
5	VA Logger #5	17381127	-24.82	-28.99	-29.24
6	VA Logger #6	17381085	-22.56	-28.68	-29.00
7	VA Logger #7	17381084	-24.90	-29.02	-29.25
8	VA Logger #8	17381124	-23.54	-29.43	-29.91
9	VA Logger #9	17381128	-22.29	-29.19	-29.85
10	VA Logger #10	17381126	-23.73	-29.28	-29.85
11	VA Logger #11	17381086	-23.90	-29.11	-29.75
12	VA Logger #12	17381082	-24.53	-29.17	-29.48
13	VA Logger #13	17371094	-22.71	-29.42	-29.81
14	VA Logger #14	17381121	-24.75	-29.54	-29.76
15	VA Logger #15	17381122	-24.55	-29.50	-29.87
16	VA Logger #16	16451060	-25.06	-29.64	-29.90
17	VA Logger #17	17381123	-25.22	-29.67	-29.91
18	VA Logger #18	17371120	-24.22	-29.70	-29.98

3.2.4 Empty Unit Open Door Temperature Recovery (5°C Set Point)

At an average ambient temperature of 20°C (68.00°F) testing was conducted between 12:30pm EST and 01:30pm EST on 01/05/20. After 21 minutes, 7 data loggers showed temperatures more than ½ degree outside of the acceptable zone, a per test parameters the door was closed.

Graphical reports were saved and filed.



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3.2.5 Empty Unit Power Failure Test (-30°C Set Point)

The test was conducted between 08:58am EST and 12:15pm EST on 01/06/20. Temperature was logged at 30 second intervals. The logged data showed the empty Cold Room, with the power supply disconnected; held temperature within (+/- 10°) for 2 hours and 10 minutes; when exposed to an average ambient temperature of 21.37°C (70.46°F). With restored power, the unit stabilized within the acceptable range in approximately 2 minutes. The graphical report is appended. No deviations were noted.



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3.3 Qualification Deviations

No deviations were found during testing.

4.0 CONCLUSION

Temperature validation of A19119314 was deemed successful. It should be noted that (2) defrost cycles were manually initiated to illustrate temperature movement during such cycles. Under normal operation, the KE2 control will initiate defrost cycles on demand; unless otherwise initiated by customer.



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5.0 Approvals

In review of the collected data for this Validation Summary Report, this study has been deemed successfully completed with satisfactory results. All deviations are listed within the Validation Summary report and are available by request as appendices. The Polar Leasing unit #916-8396 has been successfully validated.

Name: Todd Ellinger Title: VP Business Admin	Signature:
Name: David C. Schenkel	Signature: Dolc 5 chl
Title: President	Date: 1/8/20

Polar Leasing Company Approvals:

The signatures below indicate a full review and understanding of the validation data, thus fully completing the requirements of the report.

Name: Bart Tippman	Signature: Jang 1
Title: President	Date: 1-8-20
Name:	Signature:
Title:	Date:

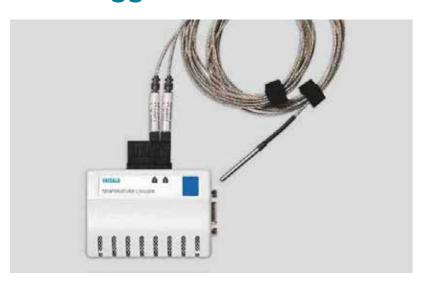


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VAISALA

www.vaisala.com

Vaisala DL1000-1400 Temperature Data Logger



The 1000/1400 temperature data loggers include the VL-series for regulated environments and the SP-series for non FDA/GxP regulated industries. The VL-series of data loggers, together with vLog VL software, provide a superior, high accuracy solution for use in FDA/GxP regulated environments by ensuring tamperproof files and electronic records that meet 21 CFR Part 11 requirements. The SP-series provides a compact, easily deployable, highly

accurate measurement and recording device. Coupled with vLog SP software for downloading, displaying, analyzing and reporting of recorded environmental data, the SP-series was designed for use in non FDA/GxP regulated environments. Optional browser-based viewLinc software provides 24/7 multi-stage alarm notification and remote monitoring for both the VL and SP series of data loggers.

Features/Benefits

- Industry-leading precision and accuracy
- Printed reports for any time period
- 10-year battery
- Validation and continuous monitoring with the same model
- Two year limited warranty
- Superior alternative to chart recorders and hard-wired systems
- Traceable to SI units through national metrology institutes.*
- Timebase calibrated over the operating temperature range
- Adjustable time based recording
- Snap-in logger cradle for easy network connectivity
- Two probe options give high accuracy - from -90 °C to +70 °C
- * Measurement results are traceable to the international system of units (SI) through national metrology institutes (NIST USA, MIKES Finland, or equivalent) or ISO/IEC 17025 accredited calibration laboratories.

Applications

Ideal for Monitoring & Validation of:

- Refrigerators & Freezers (to -90 °C)
- Incubators
- Stability Chambers
- Warehouses
- Ambient conditions



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Technical Data

General	
Size	85 x 59 x 26 mm (3.4 x 2.3 x 1") 76 g (2.7oz)
Interfaces	RS-232 serial, USB, Ethernet,
	WiFi, PoE network interface available
Mounting	3M Dual Lock™ Fasteners
	Snap-in connector locks provide secure probe
	connections
PC Software	Graphing & Reporting Software
	vLog SP for SP-series
	vLog VL for VL-series
	viewLinc for continuous monitoring & alarming
	OPC Server to add on to existing OPC compatible
	monitoring systems
Internal Clock	Accuracy ±1 min./month-25 °C to +70 °C
	$(-13 ^{\circ}\text{F to} + 158 ^{\circ}\text{F})$
Electromagnetic C	Compatibility FCC Part 15 and CE
Power Source	Internal 10-year lithium battery
	(Battery life specified with sample interval
	of 1 min. or longer)
Logger Operating/	-40 °C to +85 °C (-40 °F to +185 °F)

Intornal	Tomporaturo	Sancar

Storage Range

Series	Sensor Type
1000-21x	Precision-tolerance epoxy-
	encapsulated NTC thermistor

0 %RH to 100 %RH non-condensing

Memory	
Data Sample Capacity	
1000-2XX	48,100 12-bit samples
1400-44X	85,300 12-bit samples
Memory Type	Non-volatile EEPROM
Memory Modes	User selectable: wrap (FIFO) or stop when
	memory is full. User selectable start time.
	User selectable stop time (VL series only).
Sampling Rates	User-selectable (in 10 second intervals)
	from once every 10 seconds to once a day.

Recording Span: 1000-2xx

	NUMBER OF CHANNEI	LS ENABLED
SAMPLE INTERVAL	1	2
10 Seconds	5.5 Days	2.7 Days
1 Minute	1.1 Months	16.7 Days
5 Minutes	5.5 Months	2.7 Months
15 Minutes	1.3 Years	8.3 Months
1 Hour	5.4 Years	2.7 Years





Recording Span: 1400-44x

	<u> </u>			
	NUMI	BER OF CHAI	NNELS ENAB	LED
SAMPLE				
INTERVAL	1	2	3	4
10 Seconds	9.8 Days	4.9 Days	3.2 Days	2.4 Days
1 Minute	1.9 Months	29.6 Days	19.7 Days	14.8 Days
5 Minutes	9.8 Months	4.9 Months	3.2 Months	2.4 Months
15 Minutes	2.4 Years	1.2 Years	9.8 Months	7.4 Months
1 Hour	9.7 Years	4.8 Years	3.2 Years	2.4 Years





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EPT Series Temperature Probes

Sensor Models

"N" Range External Probes	EPT-23N-XXN and EPT-22W-XXN
Operating/Storage Range	-40 °C to +95 °C (-40 °F to +203 °F)
Connector Color Code	Black
"V" Range External Probes	EPT-23N-XXV and EPT-22W-XXV
Operating/Storage Range	-95 °C to +95 °C (-139 °F to +203 °F)
Connector Color Code	Blue

EPT - XXX - XXX External Probe - Temperature 23N or 22W Probe Length – 10 or 25' Probe Range – V or N

Sensor Tips

EPT-23N-XXX	Stainless Steel
	Diameter 3.2 mm (1/8")°F)
	Length 38 mm (1.5")
EPT-22W-XXX (liquid submersible)	Sealed Teflon Tip
	Diameter 3 mm (0.12")
	Length 28 mm (1.1")
Probe Lengths	3 m (10') and 7.6 m (25')
Cable Construction	2mm (0.07") Diameter
	Teflon coated cable

Temperature Probe Accessories

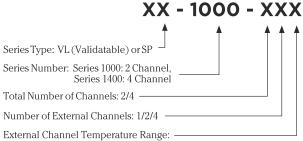
Thermal Dampening Block, for use in refrigerators and freezers, simulates a glycol bottle to reduce viewLinc alarms generated by opening and closing a door.





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Product Part Number Legend: Guide for reading the product tables and selecting the most appropriate model for your application.



Please refer to the Temperature Range and Accuracy table below for external probe options.

Temperature Range and Accuracy

Internal Sensor

Calibrated	
Measurement Range	-25 °C to +70 °C (-13 °F to +158 °F)
Operating/Storage Range	-40 °C to +85 °C (-40 °F to +185 °F)
	0 %RH to 100 %RH non-condensing
Initial Accuracy	+/-0.10 °C over +20 °C to +30 °C
	(+/-0.18 °F over +68 °F to +86 °F)
	+/- 0.2 °C over - 25 °C to + 70 °C
	(+/- 0.36 °F over -13 °F to +158 °F)
One Year Accuracy	+/-0.15 °C over +20 °C to +30 °C
	(+/-0.27 °F over +68 °F to +86 °F)
	+/-0.25 °C over -25 °C to +70 °C
	(+/-0.45 °F over -13 °F to +158 °F)
Resolution	0.02 °C at +25 °C (0.04 °F at +77 °F)

External Probes - All Models

"N" RANGE EXTERNAL PRO	DBE
Calibrated	
Measurement Range	-25 °C to +70 °C (-13 °F to +158 °F)
Operating/Storage Range	-40 °C to +95 °C (-40 °F to +203 °F)
Initial Accuracy*	+/-0.10 °C over +20 °C to +30 °C
	(+/-0.18 °F over +68 °F to +86 °F)
	+/-0.15 °C over -25 °C to +70 °C
	(+/-0.27 °F over -13 °F to +158 °F)
One Year Accuracy*	+/-0.2 °C over +20 °C to +30 °C
	(+/-0.36 °F over +68 °F to +86 °F)
	+/-0.25 °C over -25 °C to +70 °C
	(+/-0.45 °F over -13 °F to +158 °F)
Resolution	0.02 °C at +25 °C (0.04 °F at +77 °F)
"\/" DANGE EVTEDNIAL DDC	NDE

V" RANGE EXTERNAL PROBE

-25 °C to +70 °C (-13 °F to +158 °F)

Calibrated

Resolution

-90 °C to -40 °C (-130 °F to -40 °F) Measurement Range Operating/Storage Range -95 °C to +95 °C (-139 °F to +203 °F) Initial Accuracy* +/- 0.2 °C over -90 °C to -40 °C (+/- 0.36 °F over -130 °F to -40 °F) One Year Accuracy* +/-0.25 °C over -90 °C to -40 °C (+/-0.45 °F over -130 °F to -40 °F) 0.02 °C at -80 °C (0.04 °F at -112 °F)

*Specification for external channels is for a probe calibrated to the specific channel of the data logger and with the data logger at



Please contact us at www.vaisala.com/requestinfo



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