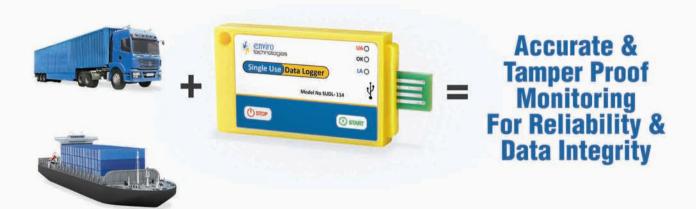


# enviroSUDL

# A Single Use Ultra Sub Zero to Low **Temperature Monitoring System**

to assist in GDP



The Single Use enviroSUDL has been designed specifically to continuously and accurately monitor and log, in a tamper proof manner, the temperature of the export consignments in transit, providing rich MIS in 21 CFR compliant PDF format to ensure accuracy and Data Integrity.

- It accurately monitors ultra sub zero to low temperatures.
- Logs at set intervals, after the Start Delay as set by you, and also when a deviation event takes place.
- Can log as many as 6000 readings in transit.
- Excellent Battery life depending on the frequency of temperature logging ie the interval.
- Auto Email. Logged data is automatically sent by email, directly to the registered id of the exporter.
- The same data can also be uploaded to the Enviro website, with a unique device ID, to be accessed by the exporter.
- Various important MIS reports and graphs are available, such as the MKT Calculation in 21 CFR part 11 compliant PDF Format and the TTI report as per USP chapter 1118 on monitoring devices.

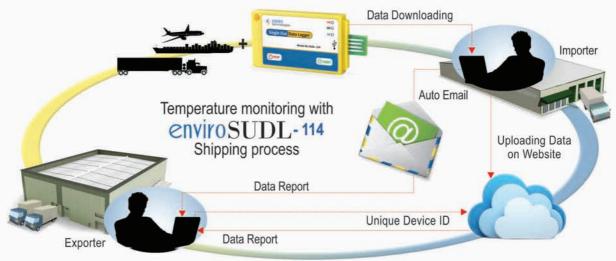
Solutions of Enviro Technologies for Accurate, Tamper Proof & therefore Authentic and Reliable monitoring of environmental parameters - to ensure GMP, GDP & Data Integrity.



Enviro also offers effective solutions for the monitoring of environmental parameters, suitable for Pharma Clean Rooms and Warehouses.



# Flow Diagram of the Enviro Single Use Data Logger



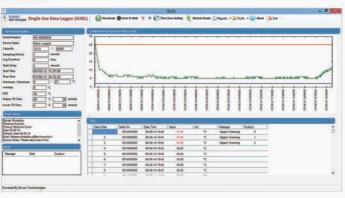
# **Technical Specifications:**

Temperature Measurement Range	-30 °C to +70 °C (-22 °F to +158 °F)	
Accuracy	±0.5°C	
Temperature Resolution	0.25°C	
Data Storage Capacity	6000 Points	
Log Cycle	120 Days or 6000 transactions whichever happens first	
Log Interval	As per Logging Interval Table	
Battery	CR2032 Lithium battery	
Shelf Life	1 Year	
Dimensions	36mm x 76mm x 9mm	
Weight	24 gm	
Usage type	Single use	

# Transaction Days set by the user & corresponding logging intervals

No of days	Logging Interval Minuts	
1	1	
3	1	
5	1	
7	2	
15	4	
30	8	
45	10	
60	15	
90	22	
120	29	
120	60	

#### Software



# **Device Configuration** (Factory Setting)

Device/ Version: SUDL/1 Serial Number: xxxxxxxxxxxx

#### An Example of Device Information (To be set by the user)

Start Delay:	1 Munute	Mini. Alarm Limit :	2°C
No. of Days:	5 Days	Lower TTI Limit :	30 Minutes
Description:	XYZ Company	Max. Alarm Limit:	25 °C
		Higher TTI Limit :	30 Minutes

Other options can be set by the User

#### **Data Report**

#### Mean Kinetic Temperature Report

Transaction Count :	1313	Mini. Average Temp. :	5°C	
Start Time:	06/06/14 18:39:00	Max. Average Temp.:	27 °C	
Stop Time :	07/06/14 16:33:23	Average Week Temp. :	16 °C	
No. of Weeks :	1			
Mean Kinetic Temp.:	16 °C			

#### **Time Temperature Integration Report**

Data Order	Alert Type	Start Time	Duration
1	Upper Alert	06/06/14 18:50:00	00:36:00
2	Upper Alert	07/06/14 01:41:00	03:08:00
3	Upper Alert	07/06/14 14:42:00	04:22:00

# Readings Summary

Transaction Count :	1313	Mini. Temp. :	5°C
Start Time:	06/06/14 18:39:00	Max. Temp.:	27 °C
Stop Time :	07/06/14 16:33:23	Average Temp. :	6°C
Sampling Period :	1 Minute	MKT:	16°C
Alert Count :	0		

#### **Readings Data**

Data Order	Date and Time	Reading	Message
1	06/06/14 18:40:00	27 °C	Upper Warning
2	06/06/14 18:41:00	27 °C	Upper Warning
3	06/06/14 18:42:00	26 °C	Upper Warning
4	06/06/14 18:43:00	25 °C	
5	06/06/14 18:44:00	25 °C	



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