TSI® AEROTRAK®
REMOTE 4-20 mA SENSORS
LIFE SCIENCE

APPLICATION NOTE CC-118 (A4)

Introduction

There is a need for end users to integrate AeroTrak Remote Particle Counters into third party building management systems and PLCs. To meet this requirement, TSI has enhanced the range of AeroTrak Remote Particle Counters to include Linear and Log 4-20 mA scaled analog outputs in this application note. TSI now offers, for the first time to the end user, the opportunity to select either a Log or Linear scaled output. In this application note, we discuss why a 4-20 mA Log scaled output is an advantage when monitoring critical processes in regulated life science applications.

As many of you already know, when a particle counter continuously monitors an aseptic manufacturing process, it is positioned to detect potential harm to the product. The purpose is to detect changes, transient events, particle excursions and deviations from processing norms that may pose an increased risk to the product or process. When an excursion occurs that exceeds predetermined action limits, a root cause investigation is performed. Section E of the FDA Aseptic Processing guidance 2004 clearly links the thoroughness of any root cause investigation to the severity of a particle excursion.

> **E. Particle Monitoring**
>
> Routine particle monitoring is useful in rapidly detecting significant deviations in air cleanliness from qualified processing norms (e.g., clean area classification). A result outside the established classification level at a given location should be investigated as to its cause. The extent of investigation should be consistent with the severity of the *excursion* and include an evaluation of trending data. Appropriate corrective action should be implemented, as necessary, to prevent future deviations.

Using the currently available particle counters with Linear scaled 4-20 mA outputs means measuring the size of a particle event can be challenging. If it is not possible to quantify the size of a particle excursion, then it becomes difficult to determine the extent to which a root cause investigation should be performed. This application note will explain why this is the case and detail how the new TSI 4-20 mA remotes solve this problem.

Remote Operation

In order to understand why it would be difficult to determine the size of a particle excursion, we must first examine how 4-20 mA sensors are integrated into building management systems or PLCs.

TSI remotes have four size bands. The end user will select which two size bands are configured for a 4-20 mA scaled output. The sample interval is typically configured for one minute. The 4-20 mA output signal will represent the actual number of particles counted at the chosen sizes during that one minute sample period, it is not normalised. It follows therefore, that when a 1 cubic ft/min flow rate instrument is used with a sample interval of 1 minute the 4-20 mA output signal will be in counts per ft^3.

It is important to note that EU GMP Annex is very clear in that it is not necessary to configure large sample intervals (volumes) on remote particle counters when monitoring. The purpose of monitoring particles in critical processes is to detect transient events and enable an immediate end user response to that event. This is the reason the sample interval is typically one minute in life science applications. Increasing the sample interval leads to an increased risk that a transient event will not be detected

When integrating a particle counter with 4-20 mA linear scaled outputs into a third party system, the end user needs to select a meaningful output range that will handle the level of particulate cleanliness in the area being monitored. This range must include the action and alert limits.

Figure 1 details the possible Linear output ranges that can be selected for the TSI remotes. In the next section we will work through whether selecting a linear output range will provide meaningful data for your application.

	4-20mA Analog Output with Logarithmic Characteristic *)	**4-20mA Analog Output with Linear Characteristic** *)							
	2 [log10(Counts+10)]+2	(Counts x 16 / FS) + 4							
	? Full Scale	Full Scale							
Counts	2	1.E+02	1.E+03	1.E+04	1.E+05	1.E+06	1.E+07	1.E+08	1.E+09
0	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00
1	4.08	4.16	4.02	4.00	4.00	4.00	4.00	4.00	4.00
2	4.16	4.32	4.03	4.00	4.00	4.00	4.00	4.00	4.00
3	4.23	4.48	4.05	4.00	4.00	4.00	4.00	4.00	4.00
5	4.35	4.80	4.08	4.01	4.00	4.00	4.00	4.00	4.00
6	4.41	4.96	4.10	4.01	4.00	4.00	4.00	4.00	4.00
7	4.46	5.12	4.11	4.01	4.00	4.00	4.00	4.00	4.00
8	4.51	5.28	4.13	4.01	4.00	4.00	4.00	4.00	4.00
9	4.56	5.44	4.14	4.01	4.00	4.00	4.00	4.00	4.00
1.0E+01	4.60	5.60	4.16	4.02	4.00	4.00	4.00	4.00	4.00
1.0E+02	6.08	20.00	5.60	4.16	4.02	4.00	4.00	4.00	4.00
1.0E+03	8.01		20.00	5.60	4.16	4.02	4.00	4.00	4.00
1.0E+04	10.00			20.00	5.60	4.16	4.02	4.00	4.00
1.0E+05	12.00				20.00	5.60	4.16	4.02	4.00
1.0E+06	14.00					20.00	5.60	4.16	4.02
1.0E+07	16.00						20.00	5.60	4.16
1.0E+08	18.00							20.00	5.60
1.0E+09	20.00								20.00

*)Based on 16-Bit D/A converter design

Figure 1

Example

In this example, we are monitoring Grade B/ ISO 7 in operation, using a TSI Remote 7510-A2F. For simplicity we will consider counts @ ≥0.5 µm only.

The flow rate of the particle counter is 1 ft^3/min (cubic foot per minute). A sample interval of 1 minute is configured. This means, as discussed in the previous section, that the 4-20 mA signal will be equivalent to counts/ft^3. See the tables in Figure 2 below for the particle limits for ≥0.5 µm at ISO 7 and Grade B in operation.

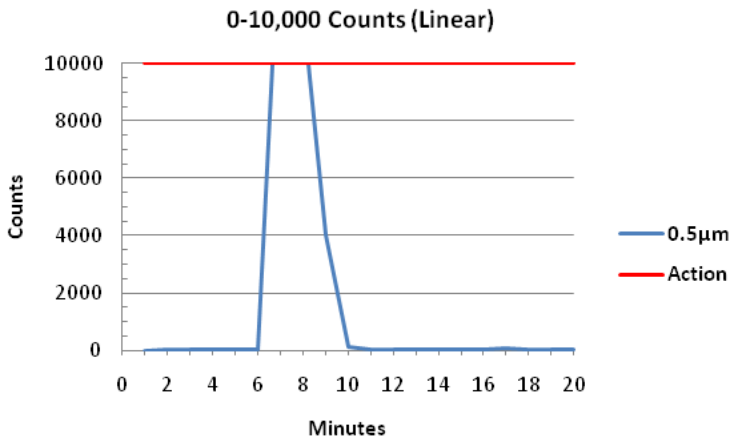
Clean Area Classification (0.5 µm particles/ft^3.	ISO Designation[b]	≥0.5 µm particles/m^3	Microbiological Active Air Action Levelsc (cfu/m^3)	Microbiological Settling Plates Action Levels [c,d] (diam. 90 mm; cfu/4 hours)
100	5	3,520	1[e]	1[e]
1000	6	35,200	7	3
10,000	7	352,000	10	5
100,000	8	3,520,000	100	50

	Maximum permitted number of particles per m^3 equal to or greater than the tabulated size			
	At Rest		In Operation	
Grade	**0.5 µm**	**5.0 µm**	**0.5 µm**	**5.0 µm**
A	3 520	20	3 520	20
B	3 520	29	352 000	2 900
C	352 000	2 900	3 520 000	29 000
D	3 520 000	29 000	Not defined	Not defined

Figure 2: US FDA 2004 (top) and EU GMP Annex 1 (bottom) Classification Tables

Clearly, 0-100 (1E+02) and the 0-1,000 (1E+03) ranges, as detailed in Figure 1, are not large enough to output particle counts up to the limit of 10,000(1E+04) Counts/ft^3 which is ISO 7.

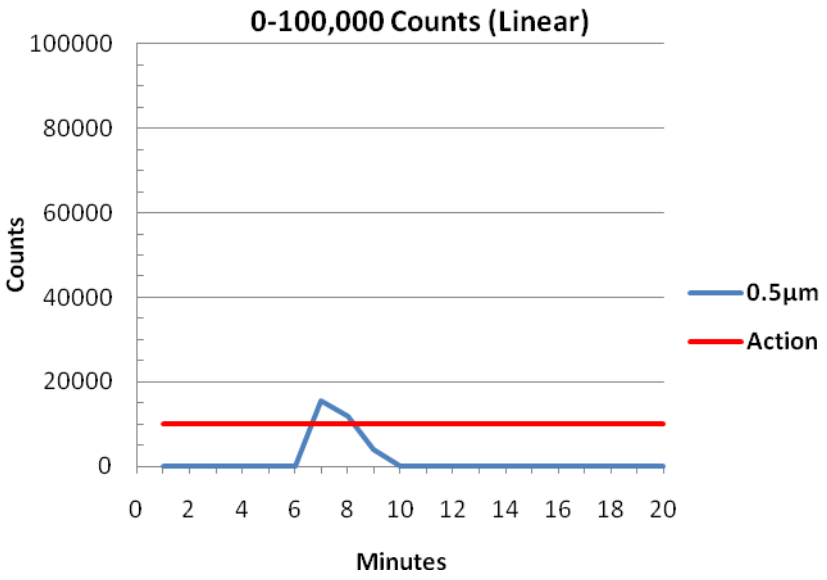
Would 0-10,000 (1E+04) work? It is tempting to think 0-10,000 counts/ft^3 linear scale would be suitable. See the graph below for an example of a particle excursion over a 20 minute period when the 4-20 mA scale is set to 0-10,000 counts to see why it may not be appropriate.



You can see that the graph reaches full scale (10,000 counts/ft^3 or 20mA) during the event. The operator or manager when investigating this event has no idea if the counts were just over the

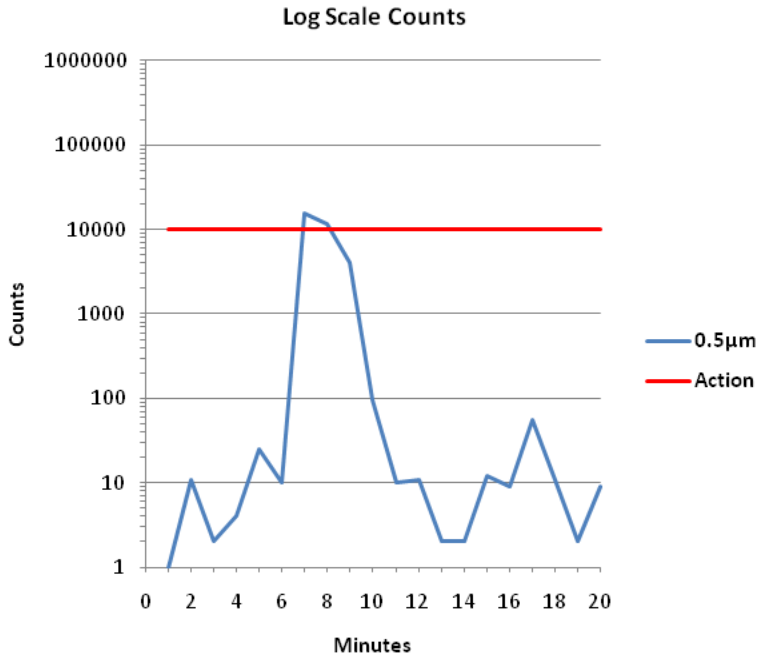
action limit or significantly over the limit. In other words it is impossible to determine the severity of the excursion from this graph when using this scale. Clearly the 0-10,000 scale is not suitable. Let us now examine the same data but using the next linear scale available to us.

The graph below shows the same data but with a 0-100,000 linear scale selected on the TSI remote.



It is now possible to asses the size of the particle excursion and perform an appropriate root cause investigation. It would be possible to measure a very large excursion on this scale. The broad range has now introduced a new problem, it has now become difficult to clearly distinguish low particle counts. Let us now examine the same data but this time using the 4-20 mA Log scaled output.

The graph below shows the same data but this time with log scale selected on the TSI Remote.



It is now possible to asses the size of the particle excursion and perform an appropriate root cause investigation. It is now possible to distinguish small numbers of particles and very large numbers on the same graph.

Discussion

Presentation of data on a logarithmic scale is always helpful when data covers a large range of values which is very common in cleanroom environments. The TSI FMS software presents particle count information in a Log scaled format as it is recognised as the most effective way to present particle count data

In this application note we have shown how TSI remotes deliver meaningful particle count data via the Log scaled 4-20mA analog outputs to building management systems and PLCs. This enables end users to manage potentially large variations of particle count information, meaning that critically important process data will not be missed, greatly assisting in root cause analysis.

UNDERSTANDING, ACCELERATED

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