

**-- Technical Study --**  
**MTBF of**  
**Lighthouse Worldwide Solutions**  
**Particle Counters**

by Jason Kelly

## Technical Study – MTBF of Lighthouse Worldwide Solutions Particle Counters.

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Our Products are widely used in many industries throughout the world. You have come to rely on the data generated by our particle counters. With the importance of your data in making key operational decisions reliability of that data is of the highest importance.

Particle Counters sample air in controlled environments and Lighthouse particle counters are used in many of today's critical industrial cleanrooms, medical/pharmaceutical manufacturing, hospitals and R&D facilities. Over the 20 years that Lighthouse has been supplying particle counters we have built up thousands of Customers from many industrial sectors across the world.

We understand the importance of particle counters to our customers and the significance of the data generated from our products. In order to assure our customers on our product reliability and the reliability of our particle counters in between calibrations we have undertaken a major study looking at thousands of calibration service records going back many years. Our key performance indicator was the mean time between failures (MTBF) of our instruments between calibrations. In other words how reliable are our particle counters between calibration intervals. For consistency of the study we examined annual calibration intervals and looked back at the last 5 years of RMA's.



What is MTBF? The MTBF calculation can be defined as a measurement of how reliable a hardware product or component is. In this study we examined service RMA's returned to our service department looking at all models of Lighthouse particle counters. If the unit was returned to lighthouse in working order or without the need of a repair then it was considered in the study. Note repairs such as issues not covered under normal warranty were not considered. As the repair process itself could invalidate "as found" calibration data.

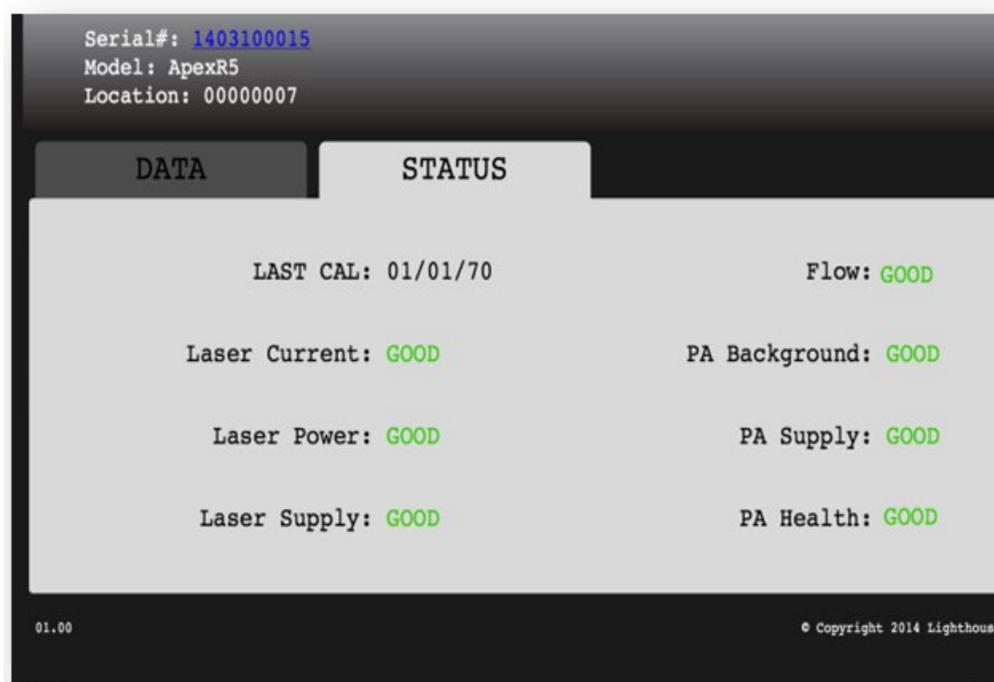
The study took a sample of 3000 RMA calibrations reports going back over 5 years. The 3000 sample records represent an adequate sample population in order to gather reliable and accurate statistical data. So why is the MTBF calibration data so important?

Our customer rely on us to provide reliable and accurate particle counting instruments and the data they produce holds valuable environmental information of the condition of their

processing environment during the manufacture or processing of their products. Lighthouse has been innovative in creating the world's first particle counter with a lot more self-diagnostics than any other particle counter available.

*"Every data record includes a health check of all sensor components with 8 parameters monitored"*

The Apex range of particle counters host several key self-diagnostic parameters to alert end users if there are any issues with the data integrity. Every data record includes a health check of all sensor components including; last calibration, flow rate, laser supply voltage, laser current, laser power, photo detector power, photo detector background voltage, photo detector health.

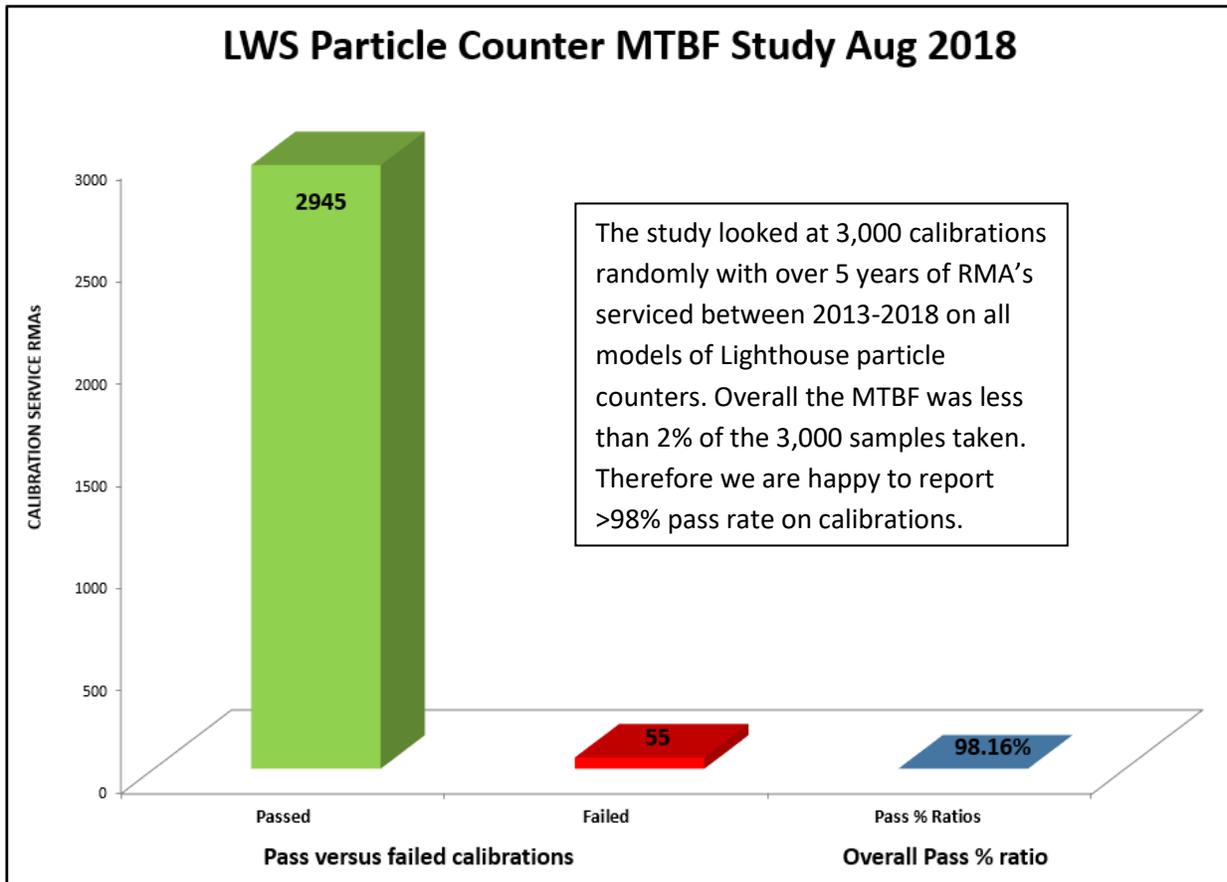


**APEX Remote particle counter web browser status information on sensor health**

Therefore with such innovation available with our Apex range and also with our older generation particle counters a major factor in the reliability of this data is the ability of the sensors to hold their calibrations and not drift. Our study included a mix of newer Apex generation particle counters and our older generation models so we did not cherry pick the results and presented a real analysis of all our product ranges.

*"The study took a sample of 3000 RMA calibration reports going back over 5 years looking at all Lighthouse models of particle counters"*

The results of the study were no surprises to our management team here at Lighthouse as we have and continue to build quality into our product development and manufacturing processes. We wanted to let our customers know that they can be assured that Lighthouse award winning products are the No.1 choice when it comes to reducing risk of MTBF's on calibrations and are the most user friendly products on the market with more special features and diagnostic parameters to mitigate against failures in calibration that may affect product quality.

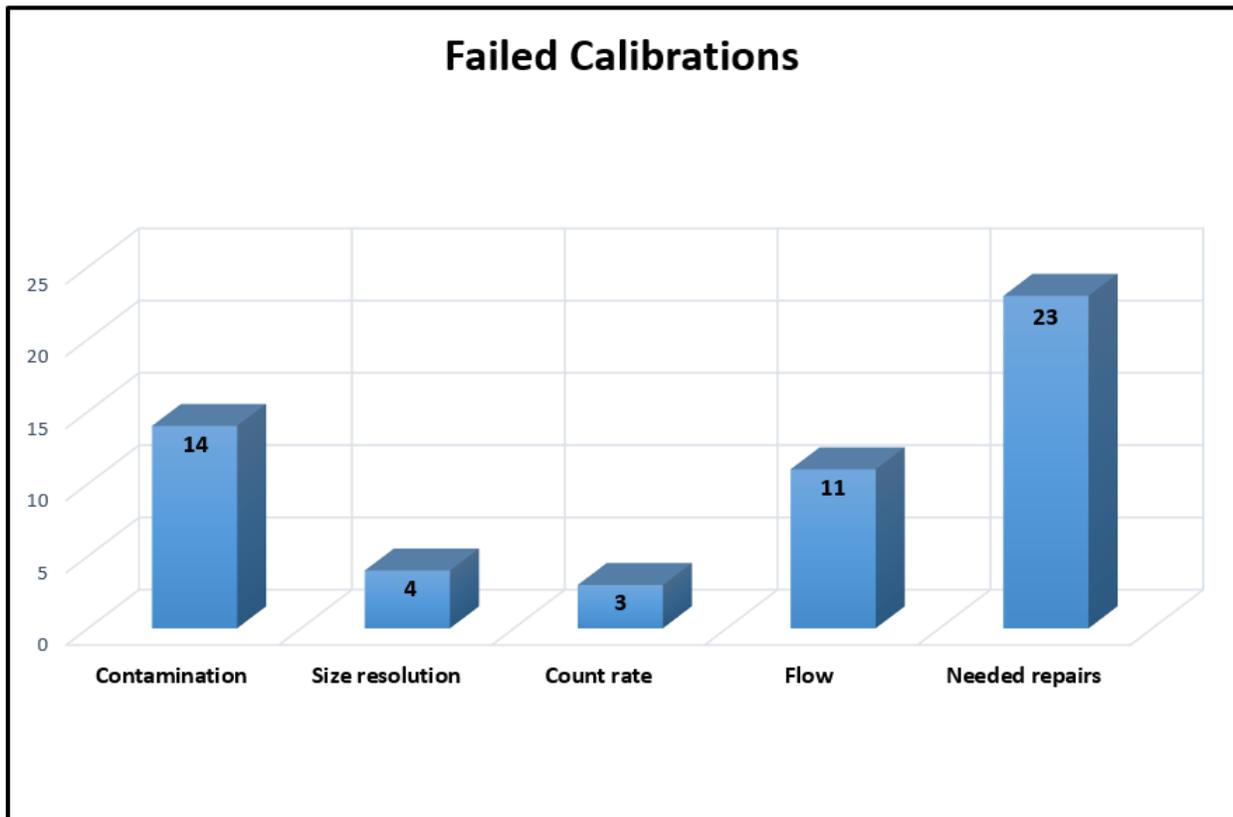


LWS Technical study of over 3,000 particle counter calibrations MTBF rates

*“The results of the study were no surprises to our management team here at Lighthouse as we have and continue to build quality into our product development and manufacturing processes”.*

With the >98% pass rate on the calibrations meaning that 2945 out of 3000 were within tolerance between calibrations. We also collected the details on the failures so we can better understand what failures were causing the calibrations to fail as found tests during the calibration. From the table below although we tried to eliminate instruments that required a

repair separate to the calibration some were included. These failures were physical failures such as PCB components, damaged sensor optics and sensors with alignment issues due to improper care. Putting the instruments in need of repair the two major faults observed were contamination and flow issues. These are common issues seen and can be avoided with better care of the instrument when used in the field. For example sensors should be capped when not in use and when cleaning processes are in progress. In fact sensor contamination is one of the biggest issues that will see particle counters fail in between calibrations. This study highlights the need for end users to develop robust SOP's in order to take good care of their particle monitoring instruments.



**Overview of failures seen in the technical study with 45% of these failures down to contamination issues that can be avoidable**

Given the significance and importance of particle counter data and the integrity of that data it is important that end users are aware of the proper way to protect particle counters from sensor contamination and flow issues. In reality these instruments are used in Cleanrooms so the air being sampled should be clean. Exposure to high concentrations of cleaning aerosol or fluid causes early failures that may go undetected until your particle counter fails calibration. This is a Quality Managers worst-case scenario particularly if the calibration is annual. Imagine going

back over a year's data to quantify if the failure has an impact on product quality. How much would such an investigation cost in man hours? Where such incident would require multi-department involvement with top managers part of the investigation. Particle Counter users need to be further educated in the handling of these sensitive instruments. Most contamination issues can be easily avoided by following well documented SOP's and users receiving or making the time to be trained on the usage of this equipment. Data Integrity is a big factor in product releases and our customers rely on our products. The more we can assist our customers to understand the issues we can help them mitigate potential costly issues with practical SOP's. However a simple procedure is required and to avoid most contamination issues simply cap the sample inlet during cleaning processes. This easy process will eliminate contamination issues that can cause early calibration failures.

We at lighthouse continue to make more innovative design processes in our calibration services. This year we have released a new particle delivery system (PDS) which has further enhanced our particle counter calibrations. The PDS was thoroughly validated and tested for 18 months before release and our engineering team has provided a more accurate and reliable calibration tool to enable repeatability and constancy on Lighthouse calibrations worldwide. The PDS before its final release was tested in-house on 20 calibration benches for 18 months and the lowest standard deviation from the data obtained saw a <1.5% difference in all calibrations. The PDS roll out worldwide will be completed by October 2018 and all of our distributors will be fully trained on the new PDS and we will be following up with intra laboratory testing to validate each facility worldwide. The PDS has also been designed for onsite calibrations so our customers can experience minimum downtimes.



Part of the Particle Delivery System which enables Lighthouse to reach more consistency in calibrations. Lighthouse will complete a worldwide delivery of the PDS to all lighthouse and Lighthouse partners service centers.

*"This easy process will eliminate contamination issues that can cause early calibration failures".*

In summary of this technical study we at Lighthouse can assure our customers that our technology and our calibration MTBF is efficient, reliable and you can be assured of the highest quality when using Lighthouse products. By looking after the particle counters and avoiding contamination issues by capping the sensor inlet our customers can be assured of a 98% MTBF on calibrations and that save a lot of wasted energy and paperwork post calibration if avoidable failures are observed.

If you need further information email the author on [jasonk@golighthouse.com](mailto:jasonk@golighthouse.com)

### **About the author**

Jason Kelly is Vice President of Services at Lighthouse Worldwide Solutions. He has been involved in particle counter service and calibrations for over 20 years where he has successfully managed and implemented several ISO 17025 particle counter service facilities worldwide. With over 20 years in management, Jason Kelly now manages the Lighthouse Systems Group, located in Oregon. A specialist on Environmental Monitoring Systems Service, design, installation, validation, and ongoing support, his experience includes working for top life-science, semi-conductor companies assisting in procurement, delivery, and compliance to ensure regulatory acceptance of monitoring systems in cGMP processes. Jason's international work includes projects in the USA, UK, Ireland, Europe, Asia and Australia.

