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The Integration and Use of Control Charts in Calibration

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Use of Control Charts in Calibration

INTRODUCTION

Manufacturing companies that adhere quality standards like TS16949, AS13003 and ISO 13485 are required to perform evidence of continuous improvement using statistical process control. For laboratories, we see the same in the ILAC-G24 standard. In addition, these same standards call out the requirement for calibration and traceability. Although these two topics might seem unrelated, there is evidence to suggest that the use of statistical techniques can be used to better predict calibration failures. With this knowledge comes a better understanding of when to set calibration intervals and when to replace instrumentation. The net result is reduced risk of incorrect measurements. This document will explain how to adopt statistical techniques to calibration studies using DataLyzer SPC software and gage management software.

CALIBRATION STUDY

Before we can even start to perform measurements, we need to have a calibrated measurement system. The calibration process has 2 purposes:

1. Make sure the measurement system is adequate to perform future measurements
2. Evaluate if the measurements performed in the past are correct (establish bias).

When we perform a calibration study, we check if the calibration results are within the required specification. In figure 1 you see how a typical calibration is performed

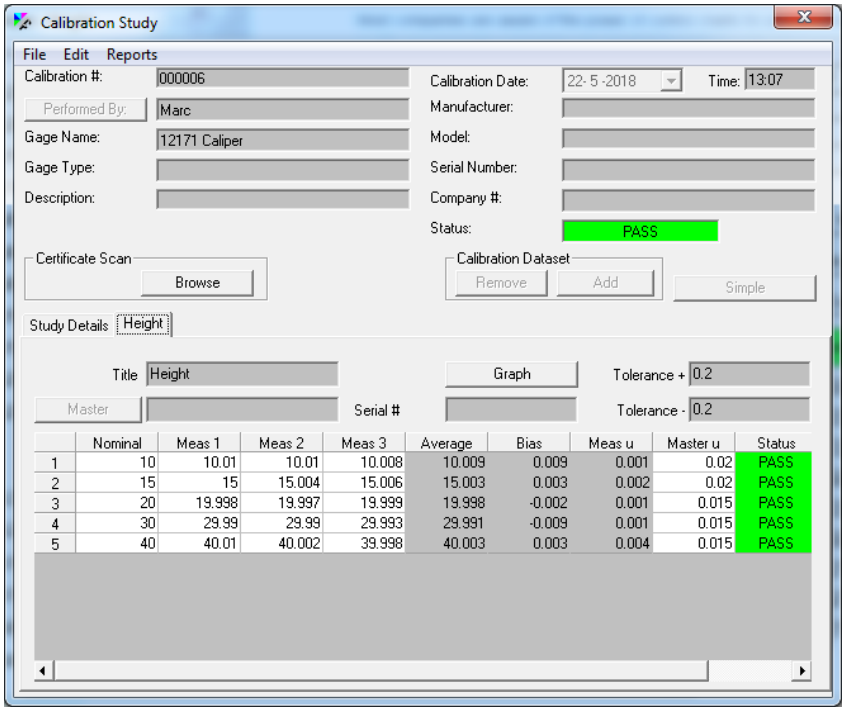

Figure 1: Example screen of a calibration study with 5 nominals

Based on the bias and uncertainty, the software establishes if the calibration was acceptable (Pass) or unacceptable (Fail).

Basically, it means if the bias + all uncertainty is within the specification limits then the calibration is acceptable.

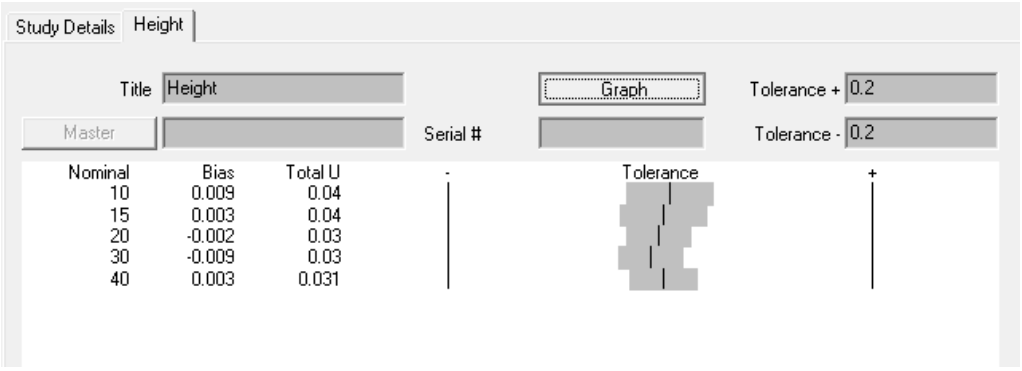

Figure 2: Graph bias and uncertainty of calibration study

If we look at the history of a number of calibration studies, we see the results of the studies in time.

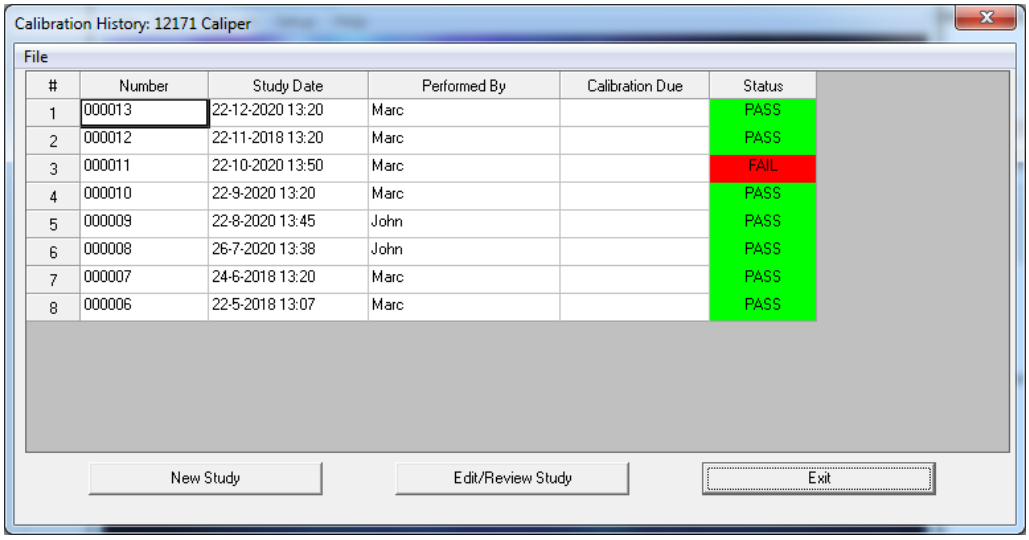

Figure 3: Calibration history

Although we see in the history that all studies passed, except the study in October, we do not see any trend in the data and we also don't see if all calibrations were in control.
To get better more useful information, we need to look at the control charts for that study.

ADDING A CONTROL CHART

What we can do is show the calibration results in a control chart. To apply SPC in a useful manner we need to normalize the results.

For example, the results of the nominal 10 from figure 1 are automatically stored in the control chart in the following way:

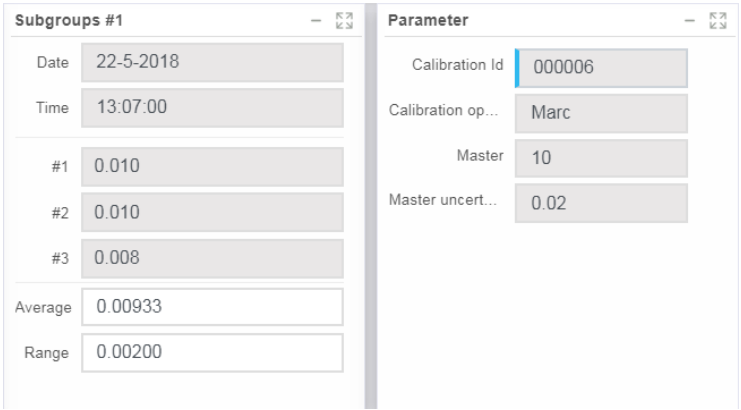

Figure 4: DataLyzer SPC Qualis 4.0 data entry screen calibration results

As you can see the deviation from the nominal is stored. This way it is possible to store all results from a calibration study in 1 chart.
We can now show all calibration results in the control chart:

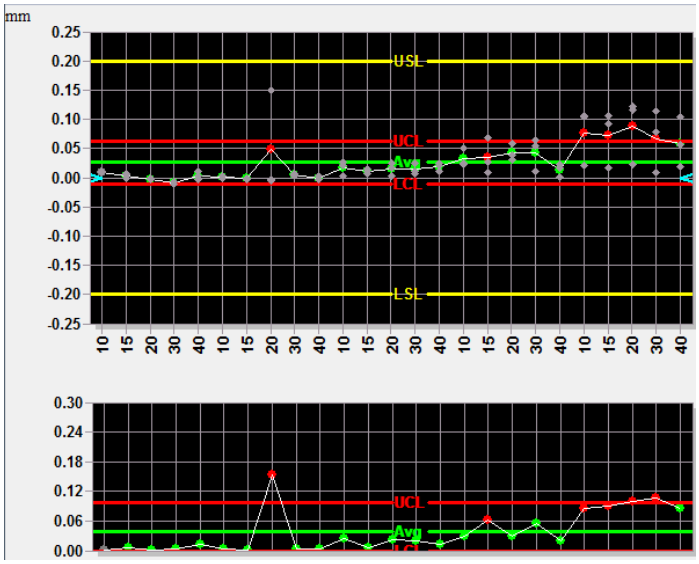

Figure 5: Calibration results 12171 caliper

The X axis between the charts shows the nominals for each subgroup. Each 5 subgroups belong together and have the same calibration id. In the second calibration you can see a clear out of control for nominal 20. During the calibration measurement, a special cause of variation has occurred. If we look to the results without applying SPC, the results would look like figure 6.

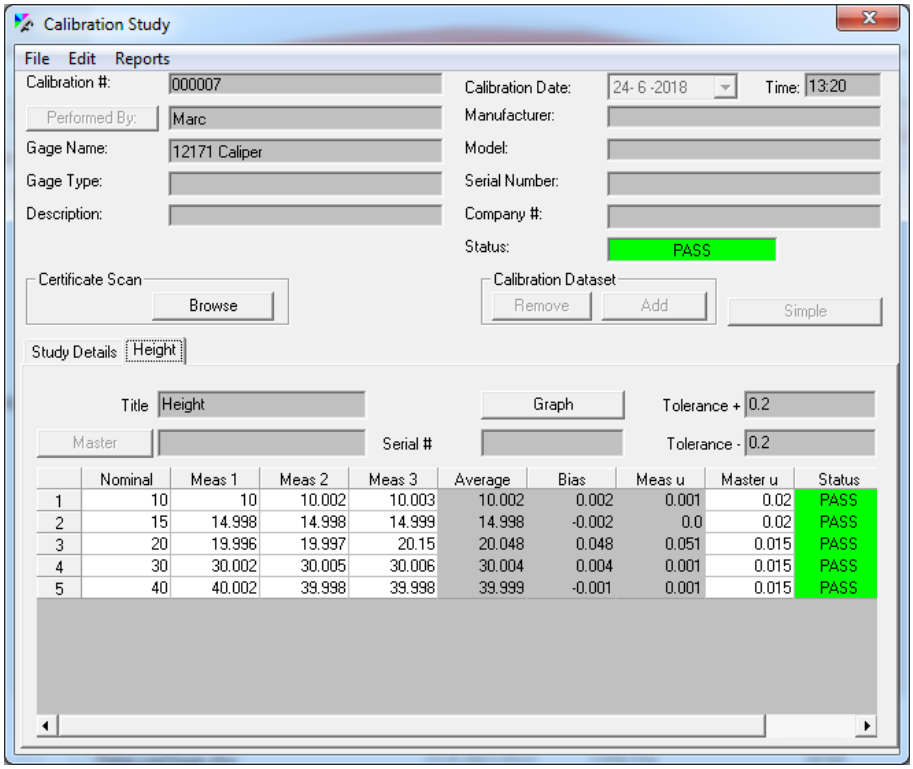

Figure 6: Calibration results in June without applying SPC

If we look at the results, we can see that measurement 3 of nominal 20 is deviating a lot from measurement 1 and 2 but during calibration this will not raise an alarm.

If we apply SPC during the calibration study, it will then show as figure 7 and the operator can perform the measurement again and avoid disturbances during calibration.

The range out indicates you are still within specification, but the 3 measurements are suspect because a special cause of variation appeared.

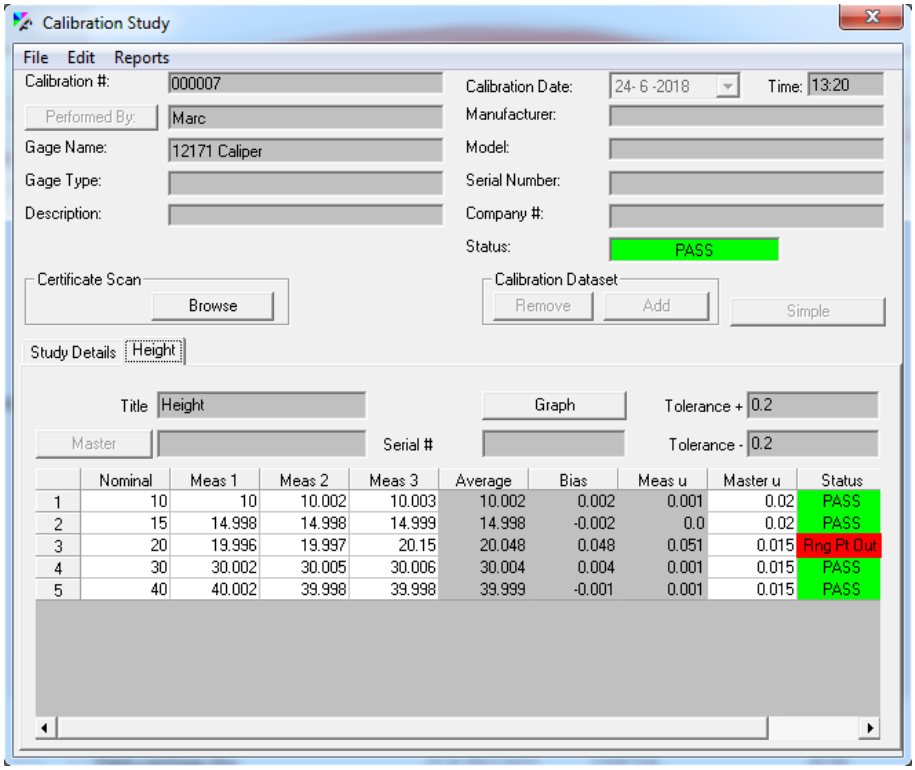

Figure 7: Calibration study with SPC analysis

The control charts help us to find causes of variation during the calibration, but it also shows us if the gage is drifting in time. In figure 8, you see the complete history of the gage calibration.

From the chart, you can clearly see that the gage is drifting in time and that the variation is increasing. Although none of the calibration measurements is out of specification, the application of measurement uncertainty and master uncertainty caused the calibration of nominal 15 in the month of October to result in a Fail.

We always try to avoid a fail during calibration because a fail means all measurements since the last successful calibration are suspect and basically should be remeasured!

But the control chart is giving us all kind of signals that the gage is not performing as it should:

- We have various out of controls on the average and range chart (see figure 5)
- The Ppk value clearly indicates the gage is about to fail.

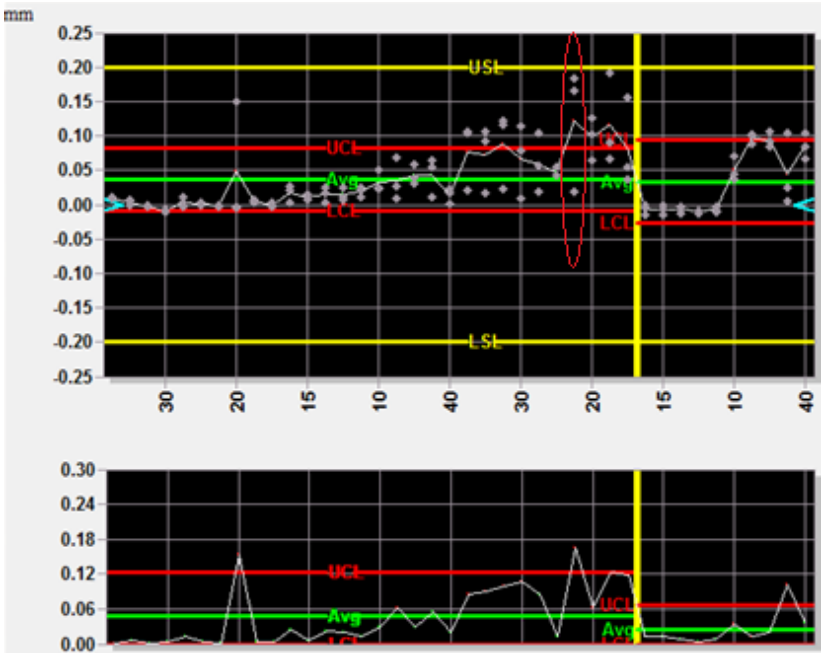

Figure 8: Calibration results 12171 caliper

In figure 9 you see the calibration results of the last 3 calibrations. The graph and Ppk value (0.9) clearly indicate that the gage is not performing as it should perform, and it is just chance if a calibration study will fail.

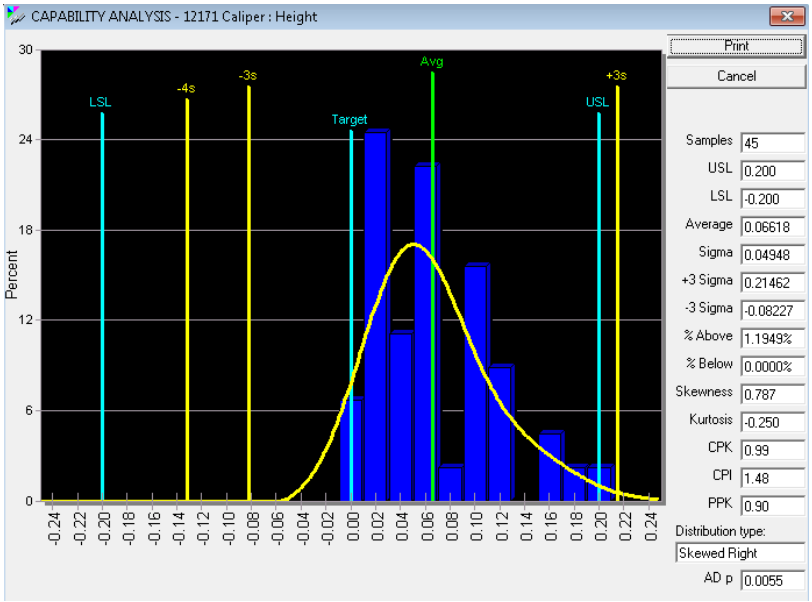

Figure 9: Capability results of calibration

After the calibration in October, the gage is repaired so in the control chart we start with a “new” calibration process indicated by the yellow line in figure 8 and the control limits are recalculated.

If we show the variation of the calibrations in a box and whisker graph, (figure 10), we even get a clearer picture what is happening.

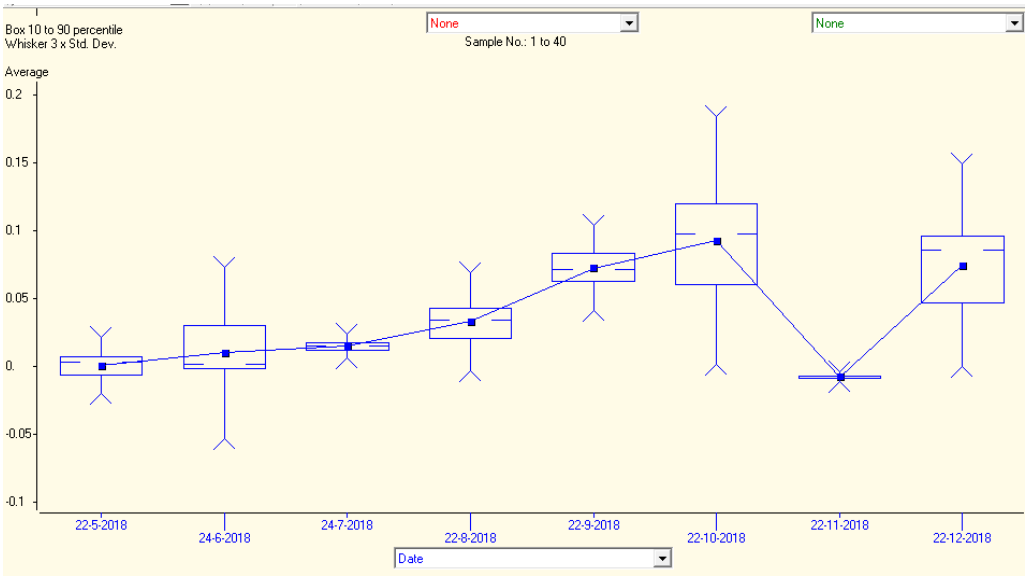

Figure 10: Box and whisker of Calibration results 12171 caliper

Conclusion

In this document we have showed the added value of applying SPC during the calibration process.

Applying SPC during calibration provides better and more useful information and makes it easier to predict if the next study will fail. Based on control charts, you can take actions quicker to prevent failures during calibration.

In real life, it is important that these results are automatically available, and no repeated data entry is required.

So, in the DataLyzer suite of software solutions, if you enter the results during a calibration studies, the charts can be automatically created with all graphs being instantly available. During the calibration study, SPC alarm messages can be generated.

ABOUT DATALYZER

Partners in continuous improvement for 40 years, DataLyzer provides a turnkey solution of training and software systems which includes:

- World-class Quality Management Systems consultancy
- Certificated, eLearning training - APQP, FMEA, Gage Management/MSA, Lean, OEE, Six Sigma and SPC etc.
- An integrated, modular suite of world-class software solutions
- Global installation and training services with continuing support and advice.

Software solutions include, Process Flow, FMEA, Control Plan; Ballooning, real-time SPC and OEE, with Gage Management/MSA, Mould Management, Certificate of Analysis (for reports like FAIR, ISIR and PPAP) and now developing CAPA.

We also provide integrated dashboards, providing advanced real-time/in-process, enterprise and supplier performance monitoring, analytics and reporting capability.

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