Minitab®

為確保製程始終如一地滿足客戶需求和期望，製程能力分析至關重要。透過量化製程能力實現預期結果，組織可以有效保證持續製造優質產品，最大程度度減少缺陷。無論製造業還是服務業，瞭解並利用製程能力分析對於推動持續改進、提高客戶滿意度，並在現今充滿活力的商業環境下持續邁向成功，至關重要。

那麼，為什麼太多的消費者無法正確使用或解讀這些指標？接下來，深入研究報告和解讀 Cpk 或 Ppk 值時，經常遺漏的一些重要考量因素。

Consideration 1: Is Your Process Stable?

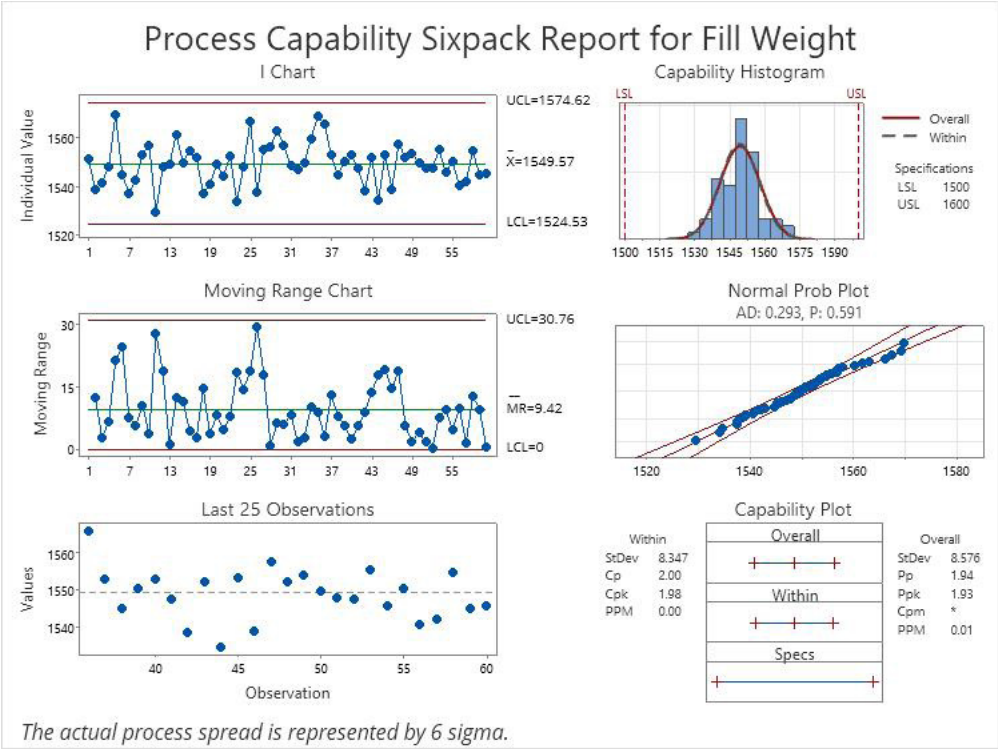
While we must get products out the door, the most successful companies take a step back and monitor their processes to make sure they are stable first. Making sure your process is stable is important to process capability for two reasons:

1. Focusing on process stability inherently reduces process variation which in turn increases process capability.
2. If the process isn't stable, then how can you even tell whether the process is capable. In other words, the question becomes: Capable when? If the process is shifting, we really don't know if it was capable of creating the required product when a particular customer received it.

For example, a beverage manufacturer is monitoring fill weights in a bottling process. The fill weights need to fall between 1500 and 1600 grams. Minitab Statistical Software's Capability Sixpack provides a quick overview of the process capability and stability. (Choose **Stat > Quality Tools > Capability Sixpack > Normal.**)

Pro Tip: Because your data was not collected in subgroups, use a subgroup size of 1 when filling out the dialog box.

In the resulting graphical display on the next page, we can conclude that this process is stable because no values fall outside the red control limits and no additional alerts for special cause variation appear on the I Chart or the Moving Range Chart.



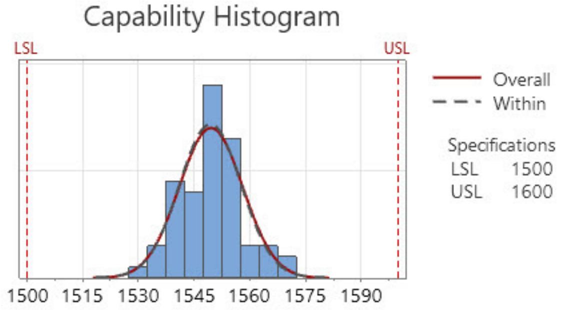
If on the other hand, alerts on the I Chart or Moving Range Chart indicated that the process mean or variation were shifting, your best course of action would be to stop and determine the root cause of these shifting patterns.

Lucky for us, this isn't the case, and we can move on to our next consideration.

Consideration 2: Is Your Process Normal?

You might say, of course my process is normal. It's running the way it usually does. But when we talk about a normal process, we are actually referring to the shape of the measurements coming from your process.

Measurements like fill weights often follow a normal, or bell-shaped, pattern because bottles are filled automatically by a machine that tends to behave in a consistent manner. The resulting fill weights are centered around a specific value, the mean, then tail off in the same way on both the low side and the high side of the mean. From the previous Capability Sixpack, you can see from the histogram that the fill weights are reasonably bell-shaped.



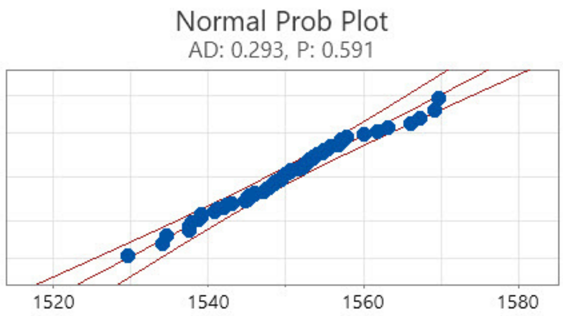
So far, so good. But as we improve our analytics expertise, we learn that it is often a good idea to pair a hypothesis test with any conclusions we might make from a visualization. That leads us to our third consideration.

Consideration 3: Does Evidence Against Normality Exist?

To move from the visual check of normality to a more sophisticated statistical approach, we can use the Anderson-Darling Test. The Anderson-Darling Test compares the data sample you have to a known distribution, such as the normal distribution. The hypotheses for the Anderson-Darling Test are:

H0: Data are from a normally-distributed population
H1: Data are not from a normally-distributed population

To understand the Anderson-Darling Test, we can move to the next graph in our Capability Sixpack – the Probability Plot shown below. The gridlines that form the background of the graph are not evenly spaced in the vertical direction. Instead, these gridlines are adjusted to reflect what a normal distribution looks like with space for more observations in the center and less space for observations on the high and low ends. The blue points on the graph do not assume any distribution, but if the distribution reflected in the grid is appropriate, the points will fall into a relatively straight line as they do here. Additionally, the p-value of P = 0.591 is larger than the standard benchmark of α = 0.05 for rejecting the null hypothesis. Therefore, there is no evidence against the data coming from a normally-distributed population.



For this data, we can proceed as though are data are from a normally-distributed population. Which brings us to the next thing to consider.

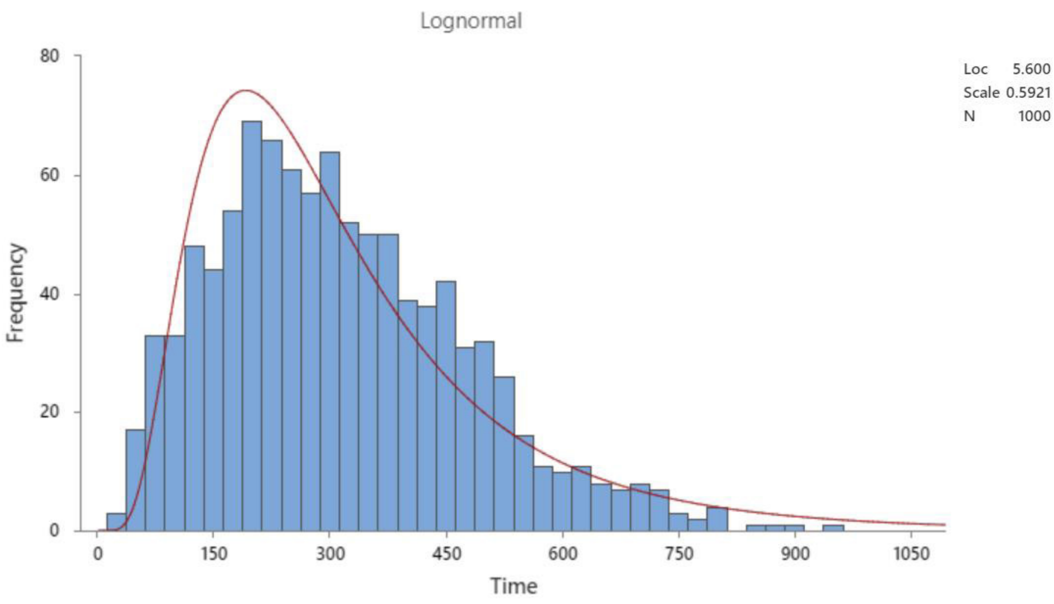
Consideration 4: Did You Prove the Data are Normal?

While a hypothesis test and p-value can be very helpful for ruling out a distribution as being the correct one for the data at hand, they don't prove anything. Remember the saying "Innocent until proven guilty?" Well, in the case of Anderson-Darling tests, we assume that the distribution being tested is the correct one and look for evidence against that. So, if our Anderson-Darling Test results in a p-value greater than 0.05, we haven't proven anything; we simply haven't found enough evidence against that distribution representing the population that our sample came from.

The Anderson-Darling Test is available for several distributions in addition to the normal distribution. Because the null hypothesis for this test is always that the sample data come from a population that follows that particular distribution, we can often assume that several different distributions may be appropriate. In other words, we can use the p-value from the Anderson-Darling Test to rule out distributions, but we cannot use this p-value to prove a distribution is the correct one. This conundrum leads us to the next consideration.

Consideration 5: What if My Data are Nonnormal?

There are multiple reasons for why the Anderson-Darling normality test results in a p-value less than 0.05. The most logical (and common) reason is that your data come from a population that does not follow a bell-shaped pattern. For example, wait time data often contain a handful of extremely long times and might follow a pattern like you see in the histogram below.

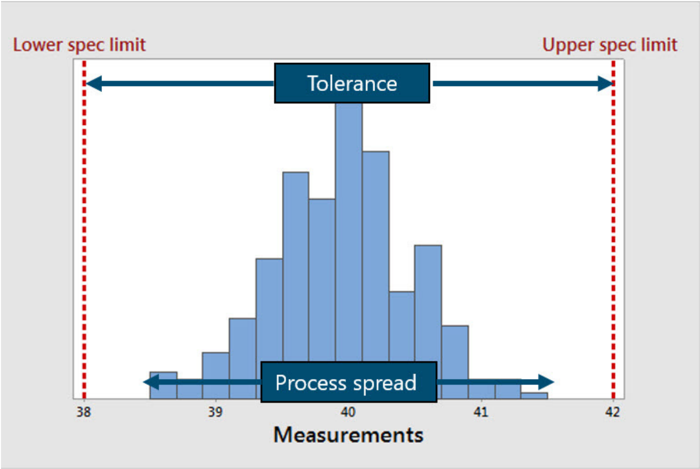


Nonnormality in the data is not a problem. Minitab Statistical Software has several other distributions, such as the lognormal distribution you see above, that you can use to estimate your process capability. Which brings us to the next consideration.

Consideration 6: Why Does Nonnormality Matter?

It turns out that for many situations in statistics, the assumption of normality is not really that important. Unfortunately, capability analysis is not one of those situations. Normality is not an important assumption for techniques involving differences in means, such as t-tests or ANOVA, because if you collect the means of individual data points coming from nonnormal populations, these means end up following a normal distribution.

On the other hand, if we want to determine the capability of a process falling within specification limits, the focus is on the individual observations falling at the tails of the distribution, not means. In simple terms, capability is the ratio of the tolerance to the process spread. To measure the spread of a process, we need to know the distribution, or shape, of the population from which the data were sampled.



When estimating process capability for situations such as patient wait time or the many other cases where you find that your data are nonnormal, we will need to consider looking beyond the traditional capability estimates established for data from a normal distribution. We also need to think about whether the data are indeed coming from a nonnormal population or if something else is causing a low Anderson-Darling p-value. This brings us to the next thing to consider.

Consideration 7: How Do Outliers Affect the Distribution?

Outliers, or data points that fall outside the expected range, can have a substantial impact on how well a distribution, normal or not, fits. When extreme outliers exist, it is likely that your Anderson-Darling p-value will be less than the 0.05 benchmark for every distribution you try, indicating that no distribution represents the right shape for your process. In this case, the first thing to consider is what caused the outliers to begin with.

Is your process not stable? (Refer back to Consideration 1.) Was the outlier caused by something explainable, but not typical, such as a measurement error? (Consider removing that data point.) Or, is the outlier just part of the data? In this case, a distribution-free (nonparametric) approach might be the way to go. Which leads us to the next consideration.

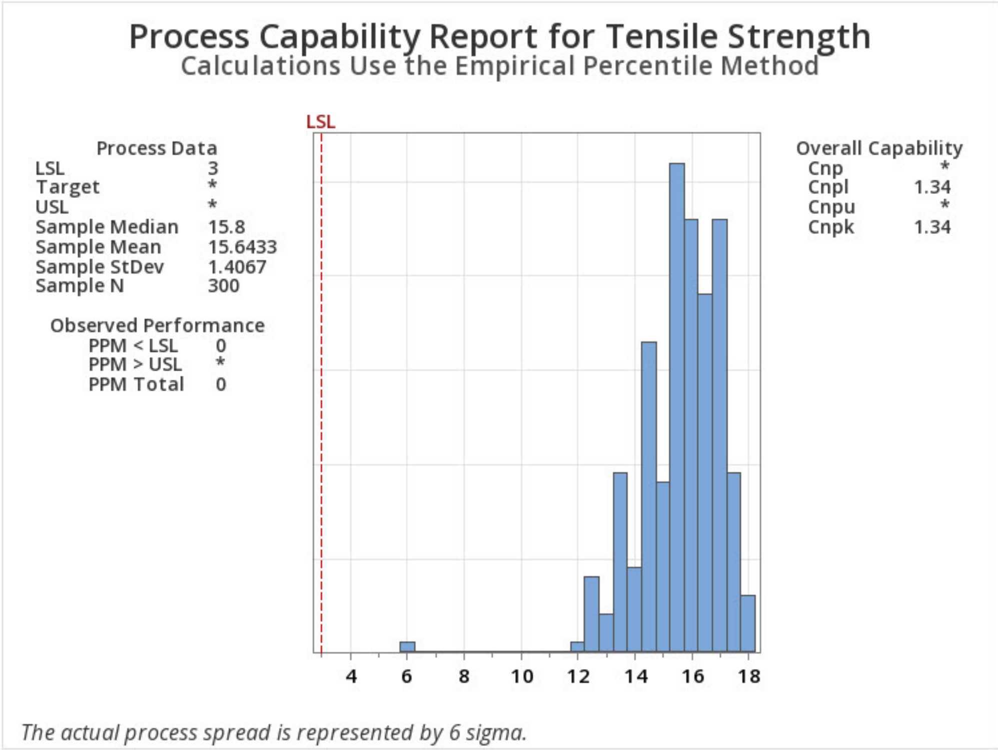
Consideration 8: Must I Assume a Distribution?

Assuming a distribution is common in statistical analyses. It allows us to fill in gaps and make assumptions about what is going on in places where limited or no data exists. However, there are times, especially when extreme outliers exist, that a distribution-free approach may be the best option. One caveat with this though – a distribution-free approach will require more data because you will need enough data, ideally a few hundred data points, to get a good reflection of what the population looks like.

For example, a medical device company needs to make sure that the tubing used in an oxygen device is capable of meeting a specific strength specification. But when testing was done on samples of this tubing, one sample broke unexpectedly with less force. Here, the outlier is still above the lower specification limit, but creates a problem when looking for an appropriate distribution.

Fortunately, Minitab Statistical Software now offers a Nonparametric Capability Analysis (Choose **Stat >**

Quality Tools > Capability Analysis > Nonparametric.) In the results on the next page, the nonparametric capability statistic, Cnpk, is 1.34, which is above the common capability benchmark of 1.33. Without the need to assume a distribution, we can conclude our process is capable, even with the outlier.



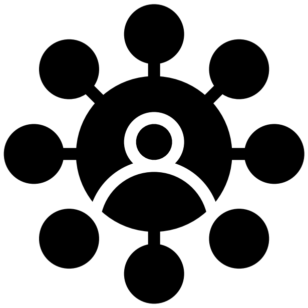
As you can see, having a distribution-free approach in your bag of tricks is quite useful. But with all the options now available, how do we choose between them? This leads to our next consideration.

Consideration 9: Which Approach Should I Choose?

Three general approaches exist for handling nonnormal data when estimating capability. We can:

- Use a nonnormal distribution, such as the lognormal or Weibull distribution.
- Use a function of the data, such as the log of the data, to make the data in the long tails of the histogram less extreme and hence, the data more bell-shaped or normal.
- Use an approach that does not require an assumed distribution.

Minitab Statistical Software offers all of these approaches, including a distribution identification tool to help you select an appropriate distribution or transformation. (Choose **Stat > Quality Tools > Individual Distribution Identification**.) These proven approaches are great for cases where you know exactly how you want to handle the nonnormality in your data. However, if you aren't sure where you want to start or find all of this information a little overwhelming, let me point you to one final consideration.



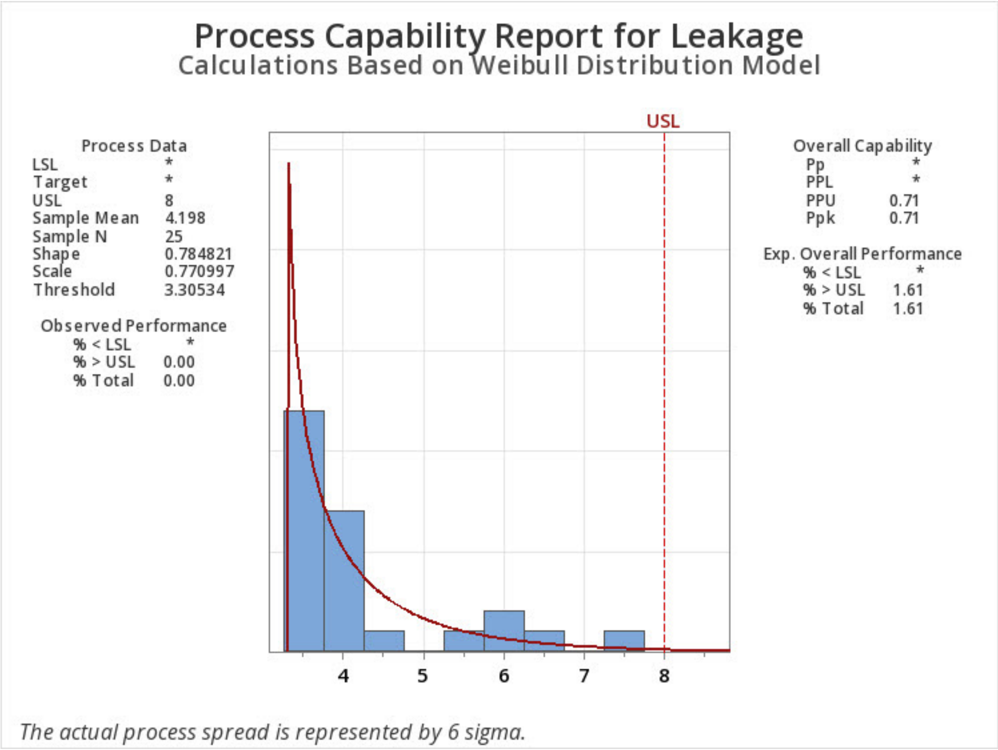
Consideration 10: Let Context-Specific AI Decide

Minitab Statistical Software's new Automated Capability Analysis uses the information gathered from many years of experience in the quality market to provide an automated approach to providing the most accurate capability statistic through rules-based artificial intelligence based on your data.

For example, a pharmaceutical company needs to estimate the capability of their process to seal pill bottles with minimal air leakage. Using a leak testing machine, they measure the leakage coming from a sample of these bottles. Using Automated Capability Analysis, Minitab Statistical Software will find a reasonable capability estimate for these data taking into account everything we've discussed here and more. (Choose **Stat > Quality Tools > Capability Analysis > Automated**.)

And the results are in! The routine will begin with the normal distribution and if that fits, we're done. (Why go looking for trouble if we don't have to?) In the leakage data case, the routine proceeded through various distributions, from more common to less common, and landed on one that is a good fit.

From the graph below, we see that this process isn't capable. For a process to be considered capable, Ppk needs to be well above 1.0, typically 1.33 or 1.5. The Ppk of 0.71 indicates that the expected process spread is quite a bit wider than the tolerance and we can expect to see a defect rate of around 1.61%.



Minitab Statistical Software's Automated Capability Analysis followed a set of rules that a statistician would likely follow to analyze this data. But if your domain expertise tells you that another approach, such as a transformation, might work better for your situation, simply click the **Select an Alternative Method** button directly from the results and select the method of your choice.

Final Thoughts

From the food we eat to the medical devices we use to the healthcare we are provided, we all are touched by the decisions made around whether a product is capable of meeting our requirements. A well thought out approach to capability analysis is critical to providing high quality products. Whether you want to remain in the driver's seat yourself, allow AI to make choices for you, or use a combination of both, Minitab Statistical Software has got you covered!