Validation of Final Test Equipment Specific to Medical Device

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Abstract. This paper presents the process of evaluating the capability of the testing process using the CMK and Cpk indices. This analysis starts by defining critical parameters and designating a golden sample unit. Data are collected and statistically analyzed in order to determine the variability and the degree of process centeredness with respect to the specified limits. CMK and Cpk indices are calculated and the results are interpreted according to the quality standards. The evaluation of the performance of the equipment consist of ambient pressure measurements and capability indices analyses. Thus, if the Cpk index doesn't meet the imposed requirements, root causes are identified and corrective actions are implemented in order to monitoring the process in real time, to maintain stability and improve the performance of the test equipment.

1 Introduction

In modern manufacturing processes, final product testing is essential to ensure compliance with technical specifications and quality standards. To guarantee accurate and reliable measurements, test equipment must be capable of detecting product variations with high accuracy and repeatability. The evaluation of the process capability is realized through inferential statistically analysis of the measurement variation determined by the capability indicators. These parameters help to determine the stability of the process and the positioning of the data distribution according to the specified limits.

The process performance can be measured by using process capability indices [1-3]. This way could be considered an efficient tool for keeping the analyzed processes under control [4]. Measurement system errors are the main source that can affect the data recorded for the purpose of evaluating the capability of a process [5, 6].

In accordance to its specifications, the machine capability is the measure of the actual quality. Capability indices analysis plays an important role in develop and use of effective monitoring and control systems for process performance, product quality, and continued suitability and capability of processes.

The evaluation of the capability of the test process is performed by statistically analysing the measurement variation using the indicators Cp and Cpk. These parameters

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help to determine the stability of the process and the positioning of the data distribution in relation to specified limits.

The purpose of this paper is to detail the main steps necessary to evaluate the capability of the testing process, from data collection to interpretation of results and application of corrective actions. Through this evaluation, the performance of the final tests can be optimized and the number of non-conforming products can be reduced.

The validation of a final test equipment of a medical device using the two Measurement System Analysis (MSA) methods, Capability Machine Index (CMK) and Process Capability Index (Cpk) involves several steps in order to ensure that the testing is accurate, capable and repeatable so that any product nonconformities can be detected.

Two main analyses are involved for their determination:

• Capability of the test equipment (CMK) which checks the performance of the equipment independent of the process.

• The capability of the test process (Cpk) which analyses the performance of the test under normal production conditions.

For a clearer detailing of this process we detail each step structurally.

2 Evaluation of test equipment capability (CMK)

Through this evaluation the performance of the equipment can be verified without taking into account variations in the manufacturing process. To accomplish this step, a number of steps have to be accomplished.

A first step is the preparation of the CMK test which is based on the selection of golden samples having well defined characteristics and previously measured with reference equipment. In the case of the presented process, the standard piece is validated with the functional test.

A second step is the configuration of the test equipment which checks the integrity of the test equipment (sensors, fixtures, and auxiliary connections), the test conditions (supply voltages, ambient temperature and humidity) and the conditions for mounting the part in the fixture in order to avoid positioning errors.

A third step is the elimination of human influence whereby the process is automated as much as possible so that human influence is minimized to avoid possible human errors.

A fourth step is data collection for the realization of the CMK indicator. For this step it is necessary to test the golden sample unit at least 30 times consecutively, resulting in a total of 450 measurements for the 15 measurable parameters of the unit.

Thus, after the unit testing, the data resulting from the final test are extracted in the form of test logs (test parameterization documents) whose values are entered in Minitab software and in the statistical analysis table in Excel.

A fifth step is the CMK calculation by which the values measured by the final test are analyzed resulting in the reports extracted in the previous step.

The considered relation refers to:

$$CMK = \frac{\min\,(USL-\overline{X}\,,\overline{X}\,-LSL)}{3\sigma}, \tag{1}$$

where: USL = Upper Specification Limit;
LSL = Lower Specification Limit;
$\overline{X}$ = mean of the measurements;
σ = standard deviation of the measurements.

Another step is CMK index interpretation (Figure 1 and Figure 2).

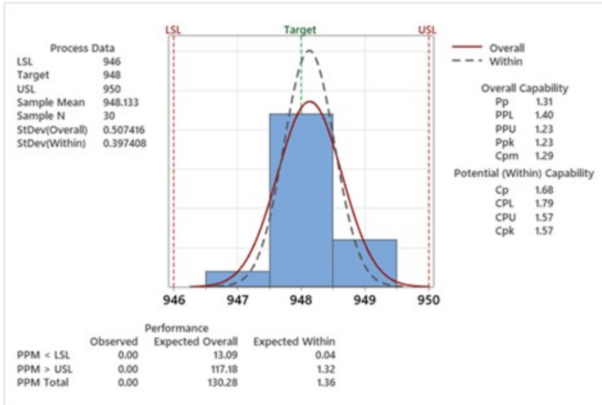

Fig. 1. Cpk values for ambient pressure measurements.

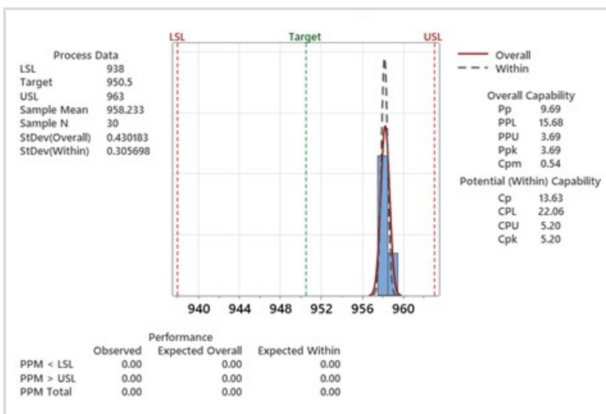

Fig. 2. Report of analyzed capability indices.

In this step the obtained results are discussed in accordance with established values of the capability indices (Table 1).

Table 1. Interpretation of CMK results.

CMK	Interpretation
CMK ≥ 1.67	The equipment is capable and it can be used in production
CMK between 1.33 and 1.67	Acceptable, but may need improvement
CMK < 1.33	The equipment is not capable; it needs to be adjusted

In order to achieve this step, the last evaluation consists in determination of CMK indicator. If the CMK is insufficient, the corrective actions are identified. In the case of the presented process, there were two values measured outside to the limits for which corrective actions were determined to modify the external factors influencing these values (Table 2).

Table 2. Capability indices results.

Characteristics	CMK_1	Status	CMK_2	Status	CMK_3	Status
Ambient pressure after setup*	1.57	OK	1.57	OK	1.31	Not OK
Ambient pressure after setup** (%)	1.48	OK	1.70	OK	1.25	Not OK
* The test limits are variable, and the value returned by the sensor depends on the ambient pressure, it measures in the hall. For this reason, we observe variation between measurements. ** The test limits are variable, and the value returned by the sensor depends on the ambient pressure, it measures in the hall. For this reason, we observe variation between measurements.						

3 Capacity process capability check (CPK)

This evaluation determines whether the test equipment and test method are stable and it can correctly detect for conforming and non-conforming parts. This indicator measures both the variability of the process and the position of the distribution in accordance with the specifications.

To determine this assessment, the following steps are defined:

- Definition of the test parameters by which the critical product parameters such as voltage, frequency and physical dimensions, specification limits (USL and LSL), measuring equipment and methods used as well as the units of measurement and instrument accuracy are chosen.
- Selection of the test batch: as in the determination of the CMK indicator, a golden sample unit will be chosen and tested consecutively 30 times to generate a total of 450 measurements.
- Determination of the test mode: for the determination of this step a validated test equipment having CMK value ≥ 1.67 will be used; stabilization of external disturbing factors (e.g. temperature, humidity, vibration) will be ensured and human influences will be eliminated to eliminate errors.
- Data collection for CPK evaluation; after the tests are performed, data will be automatically extracted from the software system of the validated equipment to be processed by SPC software.
- Creation of histograms and control charts analyzing the distribution of measured values, verifying if the data indicate a normal distribution and identifying possible anomalies (e.g. extreme values).
- Computation of Cp and CPK.

  To determine the two indices, it is necessary to determine the standard deviation:

$$\sigma = \sqrt{\frac{\Sigma\left(X_i - \bar{X}\right)^2}{n-1}}, \tag{2}$$

where: *Xi* represents each measured value; $\overline{X}$ represents the average of the measured values; *n* is the total number of measurements;

To determine the Cp index (potential capability of the process) which indicates how well the process fits within the specification limits, the calculation formula is used:

$$Cp = \frac{USL-LSL}{6\sigma}, \tag{3}$$

where:

USL is the upper specified limit;

LSL is the lower specified limit;

6σ is the range of natural variability.

Therefore, to determine the CPK index, which indicates whether the analyzed process is centered in accordance to the specifications, the relation was used:

$$CPK = \min\left(\frac{USL - \bar{X}}{3\sigma}, \frac{\bar{X} - LSL}{3\sigma}\right), \quad (4)$$

where:

$\bar{X}$ = is average of measurements;

$USL - \bar{X}$ = how far is the average from the upper limit;

$\bar{X} - LSL$ = how far is the mean from the lower limit.

The identified causes are synthetically presented in Table 3.

Table 3. Detected causes.

Problem identified	**Possible causes**	**Corrective actions**
High dispersion (high σ)	- Large process variations - Equipment instability	- Statistical process control (SPC) - Control fixture verification - Equipment calibration
Lagged process ($\bar{X}$ is close to USL or LSL)	- Systematic errors - Calibration problems	- Equipment recalibration - Process adjustment
Abnormal fluctuations	- External factors (temperature, noise, etc.)	- Environmental control
Frequent rebounds occur	- Too tight tolerances, test errors	- Specification review - Test fixture adjustment

4 Conclusions

The ongoing transformation of production requirements—shaped by customer demand for high-quality and safe products, increasing product diversification, regulatory frameworks and specific standards, as well as heightened market competitiveness—exerts a considerable influence on manufacturing industries. In this context, the reduction of defect rates assumes particular importance during periods of economic downturn, when firms emphasize cost-efficient production and the minimization of losses arising from quality deficiencies [7, 8].

Process capability indices are valuable tools for assessing manufacturing performance and product quality across various production processes. Traditionally, capability indices of the process are computed based on the relationship between the process mean and standard deviation, assuming a normally distributed process. However, for non-normal processes, many researchers have proposed robust versions of process capability indices by modifying the classical formulations. Most studies on robust process capability indices have focused on first and second generation indices, while limited research has been conducted on third-generation process capability indices [9].

The evaluation of the capability of the test process using the CMK and Cpk indices method is essential to ensure rigorous quality control in production. Through this statistical analysis of the measurement variation, the stability of the analyzed process is determined, so that it complies with the required specifications.

The implementation of a continuous monitoring system and the application of corrective actions allow us to optimize the process, reduce the number of rejects and increase the reliability of measurements. By applying the correct methodology, final testing becomes an efficient tool in guaranteeing product quality and maintaining a robust manufacturing process.

At the same time, this paper presents a clear methodology regarding the steps necessary for validating testing equipment, making this methodology extremely useful for the field of quality. By presenting the two indices, namely equipment capability (CMK) and process capability (Cpk), in this paper and illustrating them with real environmental pressure measurement data and capability reports presented in Figures 1 and Figure 2. The role and interpretation criteria of these indices in accordance with industry standards have been clarified, while also increasing the practical relevance of the study according to the examples presented in Figures 1 and Figure 2.

This paper does not include a detailed description of medical devices, focusing instead on the general study of the application of this methodology in the medical industry.

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