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A Study about the Elimination of Component External Calibration in Intraoral Imaging Plate Scanner

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This thesis describes the process of how the external calibration of component in intraoral imaging plate scanner or photomultiplier tube (PMT) in specific could be eliminated using measurements and statistics. The result of this thesis will be applied to the new intraoral imaging plate scanner where the lean methodology should be fulfilled.

Three photomultipliers (PMT) with manufacturer’s measurement data were taken to perform the required tests. These tests were implemented in such a way that input X-ray dose level and supply voltage (HV) to the photomultiplier tubes were fluctuating in order to examine the behaviour of the system output signal.

Following that, the high voltage tolerance window was evaluated based on repeatability tests with three chosen tubes.

Finally, after analysing the output signal, the variation between manufacturer’s measurements and Kavo Kerr measurements was in the tolerance window. Therefore, elimination of the calibration process of photomultiplier tube in production line is feasible.

Keywords	Intraoral imaging plate scanner, photomultiplier tube, calibration, supply voltage, signal level, X-ray

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Abbreviations

ADC: Analog to digital converter

API: An application program interface

Cp: Process capability

Cpk: Process capability index

Eq: Equation

HV: High voltage

IP: Imaging plate

LED: Light emitting diode

LSL: Lower limit specification

MES: Manufacturing execution system

PMT: Photomultiplier tube

SNR: Signal to noise ratio

USL: Upper limit specification

σ: Standard deviation

µ: Process mean

µGy: MicroGray, X-ray dose unit

1 Introduction

Intraoral images are the most commonly used radiographic images in dentistry. An intraoral X-ray system is typically the first dental imaging device that is purchased by the clinic and used for diagnosis and treatment planning.

Kavo Kerr Group intraoral imaging plate scanner provides excellent intraoral images with efficient workflow because of its high-quality components and precision in design. The scanner consists of many components such as: photomultiplier tube, light collector, laser or mirror. Currently, some components need to be calibrated before being assembled into the scanner. Calibration is the process of determining the accuracy of components. This is an important step where the components are tested in variety of conditions to meet their specifications according to the manufacturer. Regularly, the calibration process requires external calibration device known as calibrator. As an illustration, in the intraoral imaging plate reader production line, photomultiplier tubes are calibrated using an in-house calibrator. The calibration process consumes time as well as human resources.

Following the new project objectives in terms of reducing manufacturing time, ease of service, and material flow, it would be beneficial for the program to eliminate unnecessary production steps for example: calibration of components. The scenario can be seen as type of “plug and play” system when the components after leaving from the manufacturing warehouse, are ready to function in the device. Therefore, the objective of this study was to find out whether some external calibrations could be eradicated.

2 Intraoral X-ray System

2.1 Intraoral Imaging

Intraoral imaging has been widely used over years in dentistry due to its versatility and high resolution images in visualizing teeth and bony structure. Nowadays, with the rapid change of technology, it’s one of the most common methods using X-ray for diagnostics in dental practice.

The main idea of intraoral imaging is to use X-ray beam to capture images of nearby objects. Intraoral radiographs are then stored in a flexible X-ray sensor called imaging plate. Imaging plate has a phosphor layer that can store X-ray energy and emits light when there is irradiation of visible light to it. Finally, the radiographs are processed and read by an intraoral imaging plate system.

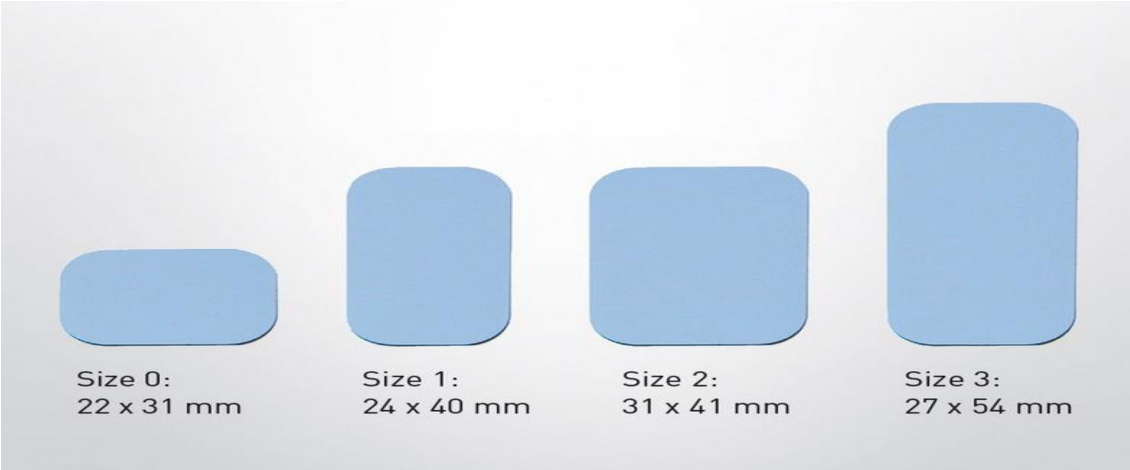


Figure 1: Different sizes of imaging plate (IP) [3]

Phosphor storage plates (PSP) have multiple sizes as can be seen in figure 1, allowing dentists to analyse bony structure of patients in different ages and mouth sizes.

The X-ray beam is taken from an X-ray generator. Being shown on figure 2, the generator has a flexible arm that could be positioned easily while providing stable and accurate results. The dentist will first position the generator's arm so that the X-ray beam is aligned with the imaging plate inside patient's mouth with the support of a plate holder. After that, X-ray beam is generated and radiographs of patient's teeth are exported. By placing multiple imaging plates in different positions in patient's mouth, the dentist could have accurate views on patient's teeth structure, hence giving correct examinations. Furthermore, to minimize the X-ray dose level used as a safety factor, X-ray beam is collimated with intention that the beam will only hit the area where the imaging plate is located.

Figure 2: X-ray images are captured and bony structures are examined. In the figure is Soredex MINRAY intraoral X-ray [5]

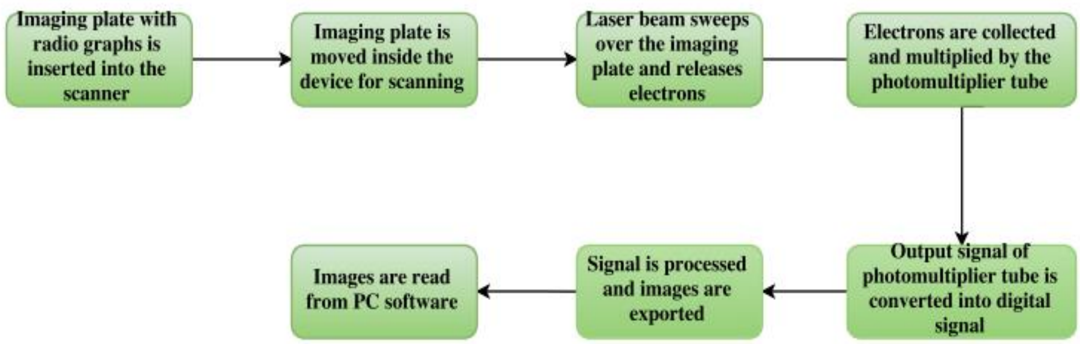
2.2 Intraoral Imaging Plate Scanner

Intraoral imaging plate scanner is one of the most commonly used products in dentistry. The scanner provides top resolution images with fast response time and great solutions for hygiene specialist. The scanner provides:

- Top quality images
- Instant images
- Low purchase and maintenance cost
- Low X-ray dose level usage

Figure 3: Soredex Diagora Optime [5]

Figure 3 shows one of the most popular intraoral imaging plate scanners on the market. The basic principles of an intraoral imaging plate scanner could be described as the flow chart shown below.



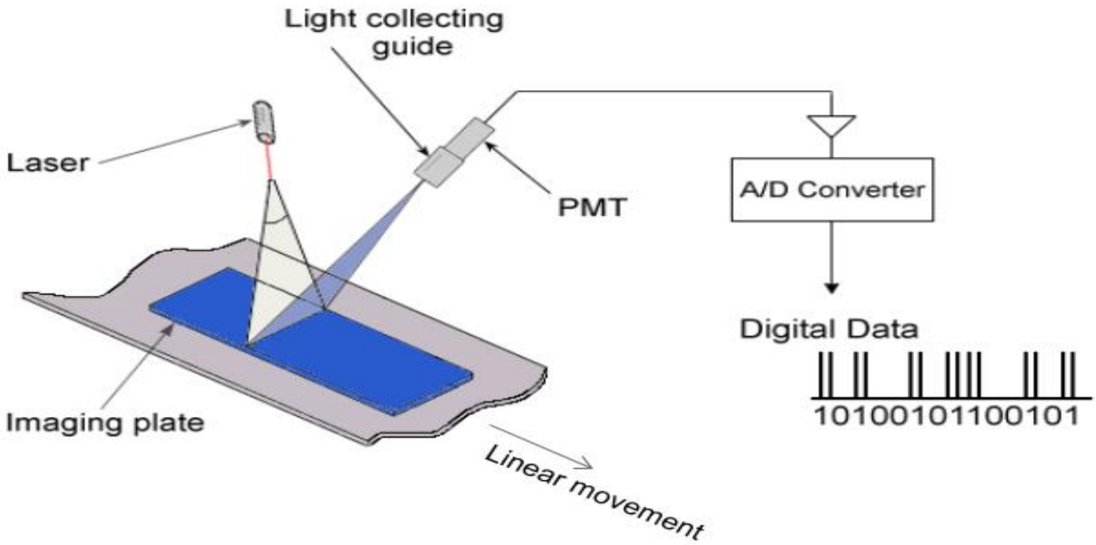


Figure 4: Basic operation of an intraoral imaging plate scanner

The basic operation of an intraoral imaging plate scanner is explained clearly in figure 4. After radiographs are captured and stored on an imaging plate, an intraoral device will read and process the image. The IP will be first inserted into the device, then moves along inside the scanner for scanning. The laser strikes a beam to the mirror and as a result, the laser beam will be reflected to an intended direction. When the mirror vibrates, the laser beam will move vertically, allowing the beam to hit the IP and therefore, emits electrons from the IP surface. Light collector will collect electrons and lead them to PMT. At this stage, PMT will receive electrons and multiply them through its dynodes. After that, PMT output signal will go to the main board of the scanner for processing. Finally, images will be read out using a computer software.

2.3 Signal Level and Signal to Noise Ratio (SNR)

Signal level is a 14-bit count parameter from Analog-to-digital converter (ADC) in the scanner's main circuit board indicating the light level collected from the imaging plate. Therefore, the value of signal level is in range between 0 and 16383. Normally, high signal level indicates more visual images while low signal level shows less clear images.

Signal to noise ratio (SNR) is a measure defined by the ratio between the signal level and background noise from the images. The larger the SNR, the higher contrast resolution the images have. Therefore, SNR is one fundamental parameter in evaluating the image quality. Both signal level and signal to noise ratio are calculated using ImageJ software.

2.4 Photomultiplier Tube

The external photoelectric effect is the emission of electrons when light strikes a metal surface. Photomultiplier tube is a non-thermionic vacuum tube, that is superior in applying this effect. Due to their great response when detecting very small signal with high gain and low noise, photomultiplier tubes have been widely used for decades in medical equipment.

A photomultiplier tube (seen in figure 5) consists of 6 main components including:

- Front window
- Photocathode layer
- Focusing electrodes
- Electron multiplier dynodes
- Anode
- Glass envelope

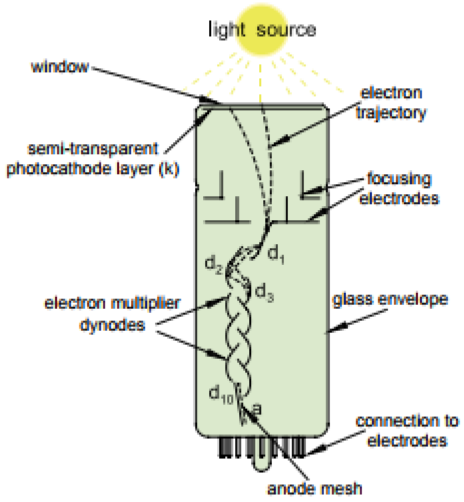


Figure 5: Structure of a photomultiplier tube [2]

When intended light beams enter the front window and hit the photocathode, the external photoelectric phenomenon occurs. Photoelectrons are produced then accelerated and focused by focusing electrodes into the dynodes. At this stage, dynodes will multiply the input photons through each of its vacuum tube with a very high gain. Finally, anode will collect the photoelectrons and provide an output current signal.

2.4.1 Spectral Response and Luminous Sensitivity

As mentioned above, photoelectrons are generated as conversion results from intended light beams energy. However, conversion efficiency might differ and vary depends on the incident input light wavelength. The spectral response indicates how well the input light wavelength and photocathode relate to each other. Spectral response characteristics are represented as radiant sensitivity and quantum efficiency.

Radiant sensitivity is calculated as how much photoelectric current transmitted by photocathode divided by input light radiant power at specific wavelength. Its unit is amperes per watts (A/W) and is calculated as formula:

$$Sk = \frac{Ik}{Lp} [A/W] \qquad \text{(Eq. 1)}$$

Sk: radiant sensitivity [A/W]

Ik: Measured photocurrent [A]

Lp: Incident radiant flux [W]

When incident light photons enter the photomultiplier tube, not all photons are converted into photoelectrons. Quantum efficiency is expressed as the ratio between the number photoelectrons collected from the photocathode and the number of input photons. Quantum efficiency is calculated as formula:

$$QE = \frac{h \cdot c}{\lambda \cdot e} \cdot Sk \cdot 100\% \ (\%) \qquad \text{(Eq. 2)}$$

QE: quantum efficiency [%]
h: Planck's constant, 6.63×10^{-34} [J·s]
c: light velocity and vacuum, 3×10^{8} [m/s]
λ: incident light wavelength [nm]
e: electron charge, 1.6×10^{-19} [C]

The process of measuring photomultiplier tube spectral response is expensive, time-consuming and complicated. Therefore, the evaluation of photomultiplier tube in terms of luminous sensitivity allows the measurement to be more practical. Luminous sensitivity is the output current obtained from the cathode divided by the incident luminous flux from a tungsten lamp at a distribution temperature of 2856K [1,38]. This parameter is useful and important when comparing sensitivity of different photomultiplier tubes of the same type.

2.4.2 Collection Efficiency

Collection efficiency (α) is the probability that photoelectrons will land on the effective area on the first dynode where they will be multiplied. This factor depends on the voltage between the photocathode and the first dynode. The figure 7 below shows the relationship between collection efficiency and the photocathode to first dynode voltage.

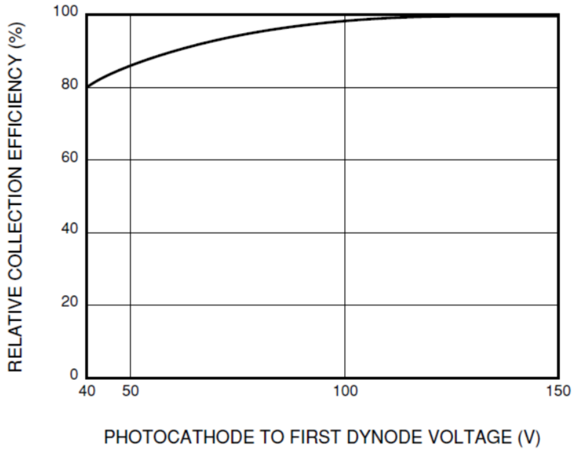


Figure 6: Collection efficiency and photocathode to first dynode voltage [1,46]

As can be seen from the figure 6, collection efficiency is at its maximum when the voltage between the photocathode and first dynode is over 125V.

2.4.3 Photomultiplier Tube Gain

Gain is a fundamental parameter of a photomultiplier tube. Due to its large value of gain, the parameter defines the reason why PMTs are widely used in low light detection applications. It’s the ratio of output current to the input cathode current and calculated with the following formula:

$$G = \frac{\alpha^{n} \cdot V^{k \cdot n}}{(n+1)^{k \cdot n}} \qquad (Eq. 3)$$

α: collection efficiency

n: number of dynodes

k: 0.7 to 0.8, depends on the structure and material of dynode.

V: supply voltage to the PMT [V]

Since, n and k are fixed for one photomultiplier tube, while α is normally equal to 1, the gain is an exponential function of supply voltage with power of kn. As a result, the gain or output signal will change dramatically if there is any small change of supply voltage.

This also means any small shift in temperature, humidity or magnetization is susceptible to the change in gain.

2.4.4 Anode Blue Sensitivity Index and Red-to-white Ratio

Anode blue sensitivity index is defined as the anode current obtained when a blue filter is placed in front of the photomultiplier tube. Each photomultiplier tube is provided with some parameters by manufacturer including: serial number, cathode luminous sensitivity, anode luminous sensitivity, dark current and cathode blue sensitivity index. The anode blue sensitivity index is then calculated as formula:

$$Anode\ blue\ sensitivity\ index\ = \frac{Anode\ luminous\ sensitivity\ [A/lm]}{Cathode\ luminous\ sensitivy\ [\mu A/lm]} \cdot Cathode\ blue\ sensitivity\ index$$

$$(Eq. 4)$$

Since the fraction results between anode luminous sensitivity and cathode luminous sensitivity are generally huge (some million), the anode blue sensitivity index value is normalized with the scale of one million for easier calculations and use. Because this parameter is expressed as an index, there isn't any unit for it.

Red-to-white ratio is used to evaluate the spectral response of a photomultiplier tube with incident light wavelength near infrared region. In the figure 6 below, blue filter is a Corning VS 5-58 polished to half stock thickness while red-to-white ratio is presented with two filters: Toshiba IR-D80A and Toshiba R-68.

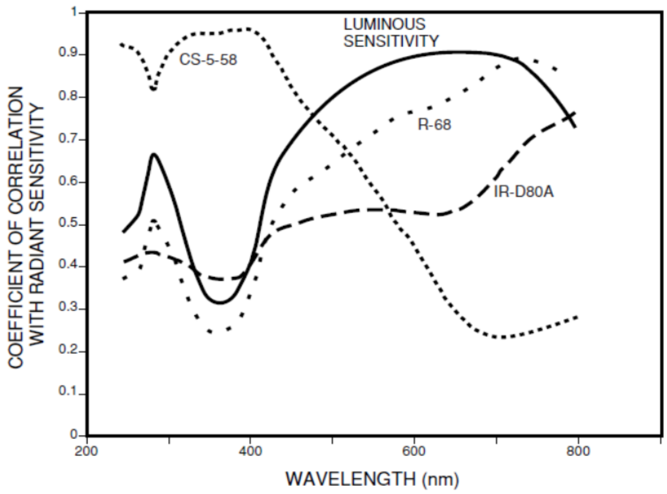


Figure 7: The correlation between luminous sensitivity and radiant sensitivity [1,42]

Figure 7 shows the correlation between luminous sensitivity and radiant sensitivity of different filters at certain wavelength. The blue sensitivity index (Cs 5-58) correlates well with radian sensitivity of PMT at wavelength about 450nm, at about 750 nm for R-68 and at 800 nm for two IR-D80A. This correlation simply means that instead of measuring spectral response of each filter, the photomultiplier tube with optimum sensitivity at a certain wavelength can be chosen by evaluating its sensitivity using a filter that has the best correlation value at that wavelength.

2.5 Calibration of Components

2.5.1 Definition of Calibration

“One accurate measurement is worth a thousand expert opinions” – Grace Murray Hopper (Dec 9 1906 to Jan 1 1992) [6].

Accurate measurement is one of the most important aspects in science and measuring. Implementing accurate measurements means we are able to understand, control and eventually aim to improvements.

Calibration is a set of operations when a device, instrument or component’s parameter is evaluated and configured to verify that its accuracy is within specifications provided by manufacturer or to a corresponding standard. Therefore, all the equipment and measuring devices must be calibrated to ensure the accuracy and reliability of the measurement results.

2.5.2 Purposes of Component Calibration in Intraoral System

The main purpose of calibration is to improve the measurement accuracy as there are always variations and errors in any measurement. By understanding the errors in measurement, corrections could be implemented to make sure that the deviations are within the acceptance level.

In an intraoral device, some components such as mirror or photomultiplier tube are calibrated before being assembled into the device. Having calibration process means minimizing any measurement uncertainty, as well as factors that cause the inaccurate measurements, for example, temperature or humidity. This process allows all the component parameters to meet required specifications, hence to function properly inside the system. Additionally, it enables users to gain their confidence in controlling and monitoring the measurement values, hence supporting in creating a high quality intraoral imaging plate scanner.

2.5.3 Calibration of Components in Intraoral Device

The calibration of components is implemented using in-house calibrators. Since the intraoral device consists of many components that could have influence on the measurement results, the calibrator is designed with intention that only one parameter is changed at a time. Therefore, a known parameter is required, normally called the nominal value. This allows users to adjust unit under test parameters and make any corrections if needed. By applying this method, the behaviour of component could be determined by examining its influence on system output. Additionally, in order to maintain the correctness and reliability of measurement values, the maintenance and calibration of the calibrator are required periodically.

3 Self-calibrated Intraoral Scanner

The main motivation behind this study is to take the first step toward a self-calibrated device to fulfill the company's lean manufacturing principles: minimizing human effort, space and resources. Lean simply means maximizing the productivity, creating more values while minimizing the waste. Applying the lean principles will not only optimize the product flow but also allow the project to adapt to the rapid changes in market demands and finally, to create a top-quality scanner. Further information about lean can be found in appendix 1.

A self-calibrated device means that it is able to calibrate all the components inside without the need of any external calibration process (figure 8).

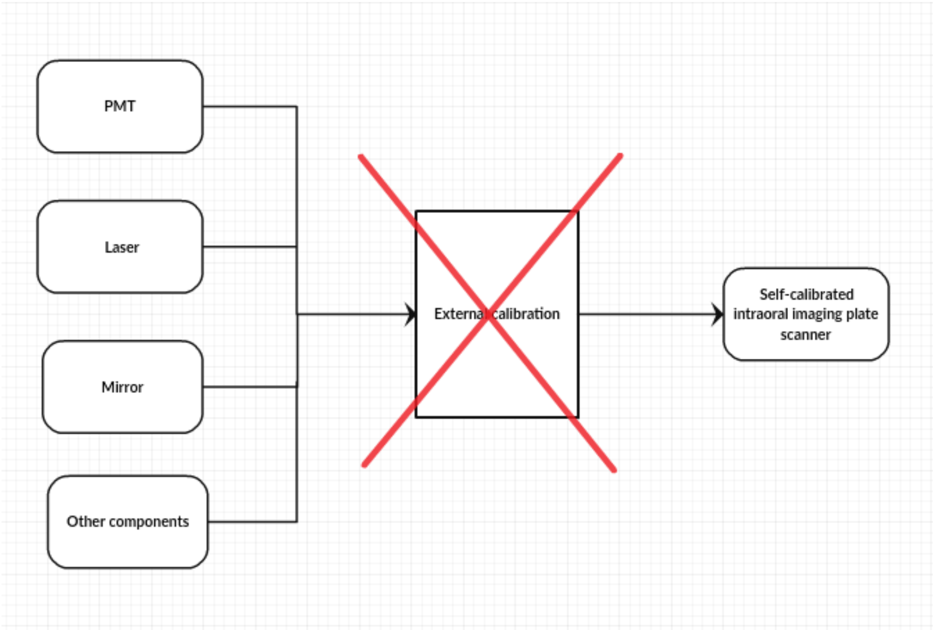


Figure 8: A self-calibrated intraoral imaging plate scanner

This concept brings plenty of advantages to the manufacturing chain, service line and creates an error free system where the variations and human errors are minimized.

3.1 Improve the Workflow and Productivity

In business practice, it’s crucial to find out new methods to improve the workflow while reducing the waste and more important, to maximize the profits. Product manufacturing is a time-consuming and complicated process. Therefore, eliminating any manufacture process while maintaining product quality will bring short and long term benefits to any business practise.

Firstly, the elimination of external calibration will reduce time in manufacturing. There is no longer need for building or maintaining the calibrator. The new intraoral device will have new components with different specifications and sizes. This leads to the fact that the old calibrators aren’t usable anymore for calibrating new components. Consequently, a new calibrator is needed and more time is required. In addition, the maintenance of the calibrator needs to be kept up periodically to ensure the measurement correctness. Furthermore, calibrating components and recording their values also require time. The concept of a self-calibrated device will simply overcome these issues. Saving time means saving money and resources for other investments.

Cutting down the process of calibration will not only reduce time but also optimize working space and storage. Reduction of unnecessary devices will save more space for new tests or other operations, therefore, increase the efficiency.

Finally, product quality improvement is an essential benefit when applying the concept. As the device complexity increases, the more quality issues it arises. For this reason, all the variations, mistakes and human errors must be minimized. Without the external calibration, errors in measurements and in recording data to the system database will be cancelled.

3.2 Ease of Service and Material Flow

Having a self-calibrated device allows the ease of service and material flow improvements. Manufacturing is the process of converting materials from one to another form and adding values to them. Therefore, material flow plays a vital impact on the whole supply and manufacturing chain. Eliminating external calibration will optimize the material flow by reducing flow time and unnecessary steps: from transportation of materials to manufacturing stage, from importing measurement values into database to maintenance work and repair service center.

4 Methodology

Due to the system complexity, this thesis will first work on the elimination of photomultiplier tubes calibration. However, if this hypothesis is proven, the result of this study can be applied to other components inside intraoral imaging plate scanner such as: laser or mirror.

In the production line, each PMT is calibrated, giving a high voltage (HV) value in the range of 100-230 if successful (100 is about 385 V and 230 is about 885V supply voltage to PMT). Each tube HV values is then correlated to a certain anode blue sensitivity index calculated from parameters provided by manufacturer.

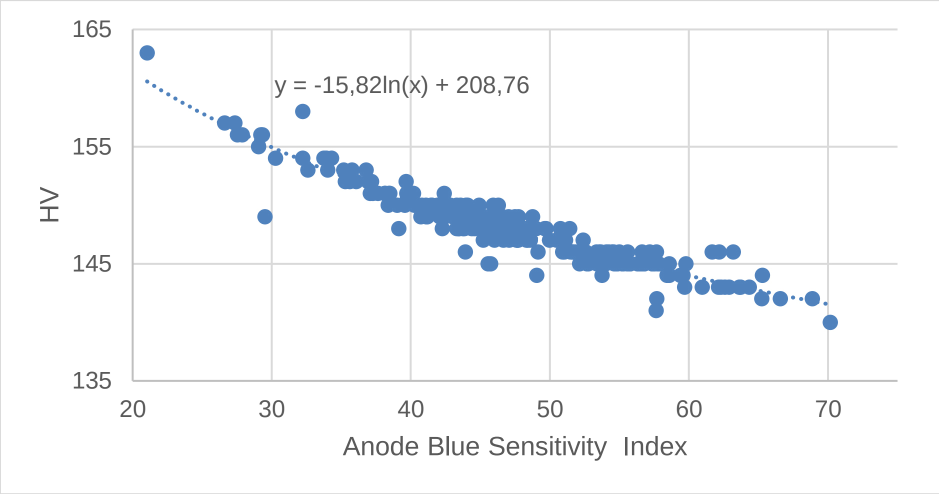


Figure 9: Manufacturer's and Intraoral scanner imaging plate reader production line measurements

In order to validate the repeatability of current calibration system, measurement values of 206 photomultiplier tubes were taken and they formed an equation where the correlation between calculated manufacturer's data and the data from production line is seen (Figure 9).

First, some representative PMTs were selected to calculate the HV values based on the defined equation. The calibration process with these PMTs was repeated to find out the correct values and examine whether there were variations in HV values in each of them. The comparison between the calculated HV values and the calibrated ones was made, resulting in some variations.

On the other hand, the overall variation tolerance was examined based on experiments with X-ray images received from a working intraoral imaging plate scanner. Finally, the hypothesis was proven right when this variation in calculations fits the variation tolerance based on X-ray images. The entire workflow and implementation are shown in figure 10.

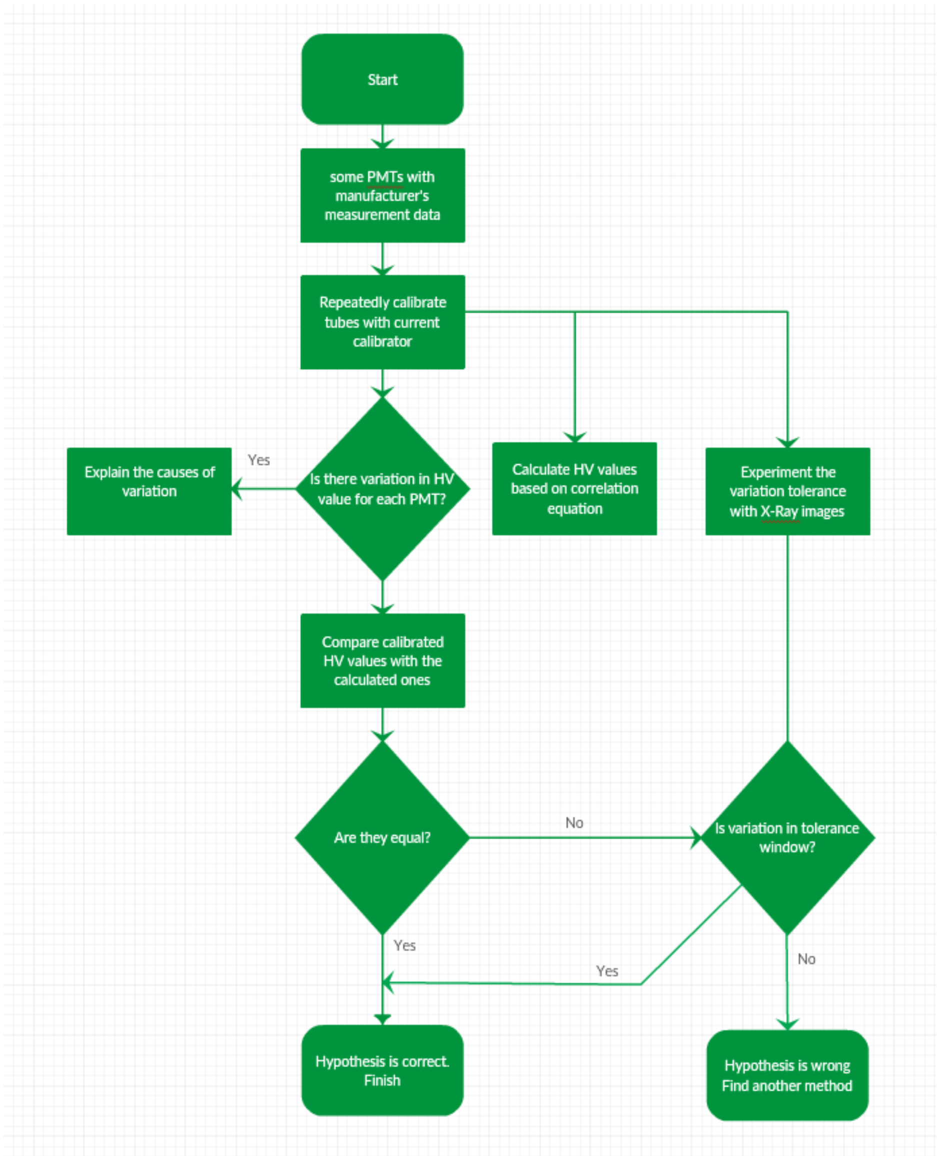


Figure 10: Flowchart of how the hypothesis was proven

5 Test Implementation

5.1 Representative Tube Selections and Repeatability Test

Three photomultiplier tubes were selected based on their anode blue sensitivity indices calculated from manufacturer's measurement data: low, medium and high and their values are shown in table 1 below.

Table 1: Selection of photomultiplier tubes

Photomultiplier tube	Anode blue sensitivity index
A	32.24
B	47.55
C	62.17

By choosing 3 photomultiplier tubes with different anode blue sensitivity indices, the overall behaviours of PMTs could be studied based on the change in supply voltages.

Three chosen PMTs above were calibrated using an in-house calibrator. Each tube was calibrated totally 16 times, twice per day and in different weather conditions. The main purpose of this test was to verify the measurement variation of the calibrator and later, to combine this test result with variation in calculation.

5.2 Determining Overall Tolerance Window Using X-ray Images

Three same selected PMTs were taken into the test using X-ray images to examine the output signal, hence determining the tolerance window.

Firstly, the X-ray images were captured in 2 dose levels: 100 µGy and 600 µGy by an X-ray generator. At each dosage, the HV values of 3 tubes were fluctuated resulting different images. In addition, at every dose level and supply voltage, a working intraoral imaging plate scanner was used to scan the X-ray images and export them to a connected computer. Finally, a computer software calculated the output signal and signal to noise ratio (SNR) of each image. This implementation (table 2) allows the determination of HV allowance lower and upper to pass the image quality test.

Table 2: HV tolerance window test

Dose level	Test Description	Evaluation
600 µGy	Change HV values in every captured image. At each image, calculate signal level.	Define the HV region where signal level is smaller than 16383 (upper limit).
100 µGy	Change HV values in every captured image. At each image, calculate SNR.	Define the HV region where SNR is at least 30 (lower limit).

5.3 Verification of Tolerance Limits

After determining HV tolerance window, some required measurements were executed for each tube to prevent underestimating or overestimating error margin.

Since the output signal level of the entire system depends on many components such as photomultiplier tube, mirror, laser, circuit board, it is difficult to examine the measurement uncertainties of all the components. However, in this specific case, the system variation in signal level could be verified by repeating the same measurement with all the components at the same parameters. In this case, the signal level and SNR of each tube at their measured HV upper and lower limit was calculated 10 times and some evaluations were made according to table 3.

Table 3: Tolerance limits verifications

Dose level	Test Description	Evaluation
600 µGy	Scan the images 10 times at the pre-defined HV upper limit.	Calculate the signal level. Verify that in all the cases, signal level is below 16383.
100 µGy	Scan the images 10 times at the pre-defined HV lower limit.	Calculate the SNR. Verify that in all the cases, SNR is above 30.
20 µGy	Scan the image at the pre-defined HV lower limit.	Verify that images are not fully white (verify the lower limit)

Images were scanned using X-ray generator and dose level was measured with a dose meter.

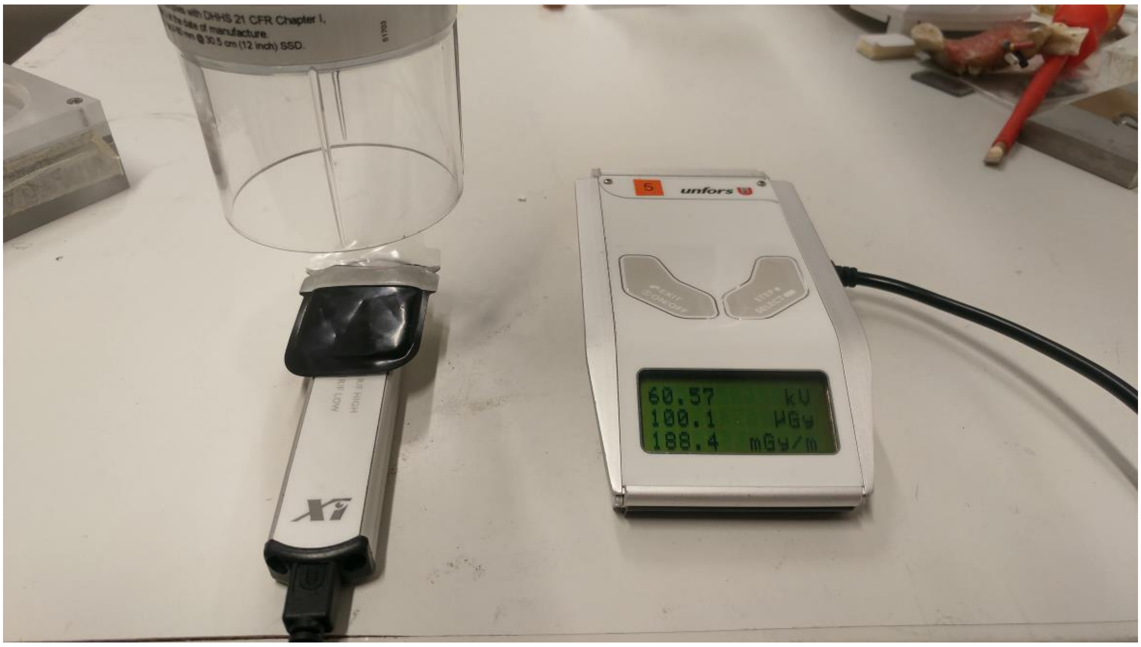


Figure 11: X-ray image is captured to an imaging plate at 100 µGy

In figure 11, the X-ray generator has about 1% variation in output X-ray exposal. This didn’t create much impact on overall test result

6 Test Results

6.1 Calibration Repeatability

The calibrated values of 3 photomultiplier tubes are shown as table 4 below.

Table 4: Calibration values of 3 chosen PMTs

Test number	Tube A HV value	Tube B HV value	Tube C HV value
1	156	147	144
2	157	147	144
3	158	148	145
4	158	149	145
5	158	148	145
6	158	148	145
7	158	149	145
8	158	148	145

9	158	148	146
10	158	148	146
11	158	149	146
12	158	148	145
13	158	148	146
14	158	149	145
15	158	148	146
16	157	148	145
Minimum	156	147	144
Maximum	158	149	146
Average	157,75	148,125	145,1875
Biggest variation	2	2	2

According to the calibrator specifications, the variation should be ± 1. However, based on the test result, the tolerance variation of 3 tubes was at ± 2. When the tubes were first calibrated in the first day, the HV values were about 1 lower than the average value. After the first 2 tests, all 3 tubes gave stable results with the variation at ± 1. This phenomenon was due to the characteristic of a photomultiplier tube provided by manufacturer: for stable operation, warm-up of the photomultiplier tube for about 30 to 60 minutes is recommended (Hamamatsu Photonics, August 2007)[1,64]. However, at current process of calibration and recording the values, all the tubes are calibrated once in a very short time only after being unboxed from the batch. Therefore, the calibrator variation can be considered to be retained at ± 1.

Moreover, different weather factors were measured including: room's temperature and humidity as well as calibrator's temperature. The device temperature was ranging from 25°C to 38°C while the humidity level was between 25% and 65%. However, as the calibrator was adequately stable, the temperature and humidity in this case had minor impact on calibrated output. Therefore, environmental impacts could be neglected in this case.

6.2 Tolerance Window Test

6.2.1 HV Upper Limit

The upper HV limit was determined by defining the HV value point where the signal level is below 16383 at 600 µGy X-ray dosage.

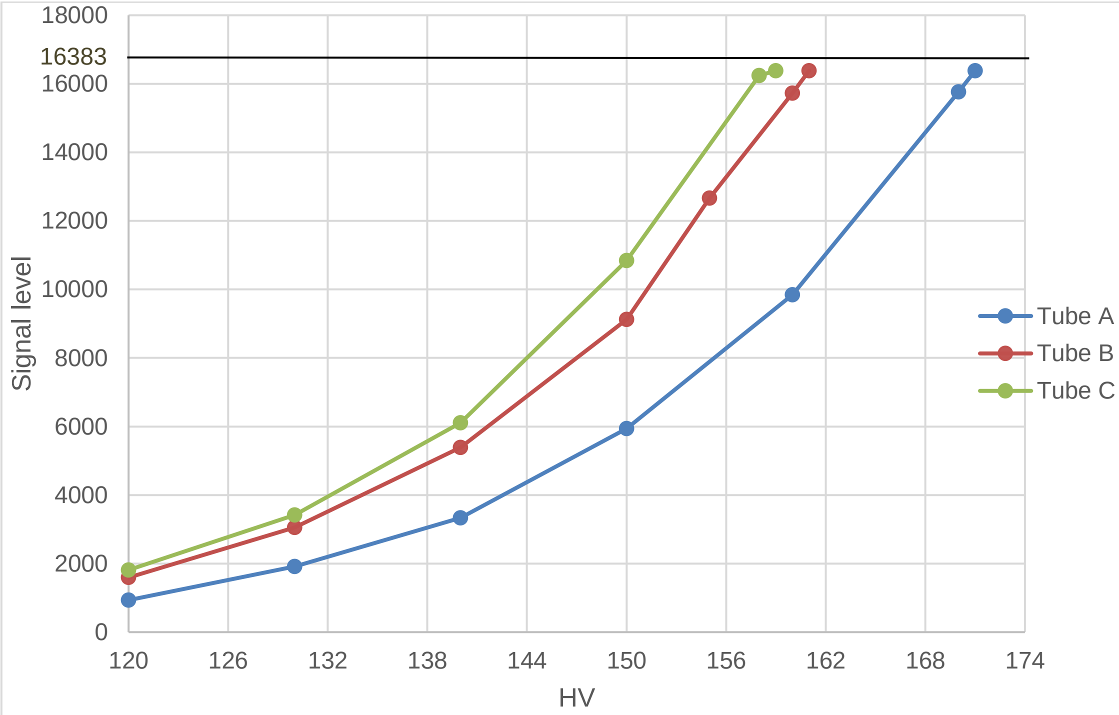


Figure 12: Signal level vs HV at 600 µGy

As can be seen from figure 12, the maximum values for tube A, B and C so that signal level is below 16383 were: 170,160 and 158 accordingly (table 5).

Table 5: HV upper limits

Photomultiplier tube	Reference HV	Maximum HV
A	158	170
B	148	160
C	145	158

Following the previous measurement, the next step was to verify and make the final decision in determining the HV upper limit.

After scanning images from 3 tubes 10 times each at their pre-defined HV upper limit, it's clear to see that the signal levels in all the test cases were below the limit (figure 13). Therefore, these maximum HV fulfilled the requirement.

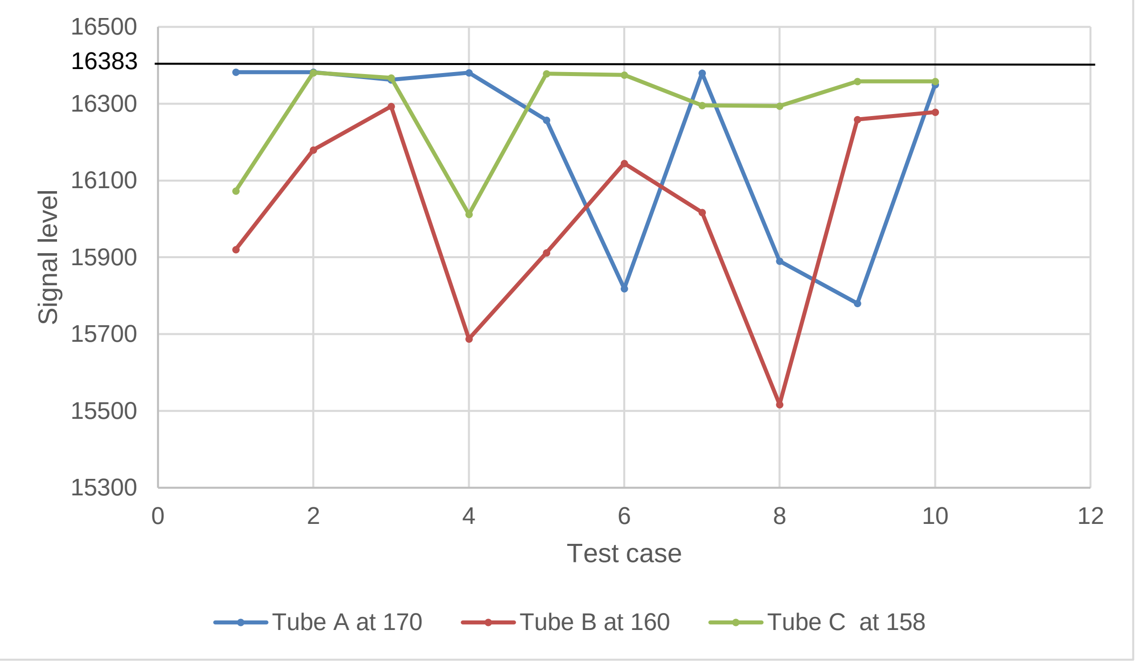


Figure 13: HV upper limit repeat test

6.2.2 HV Lower Limit

The lower HV limit was determined by defining the HV value point where the SNR ≥ 30 at 100 µGy X-ray dosage.

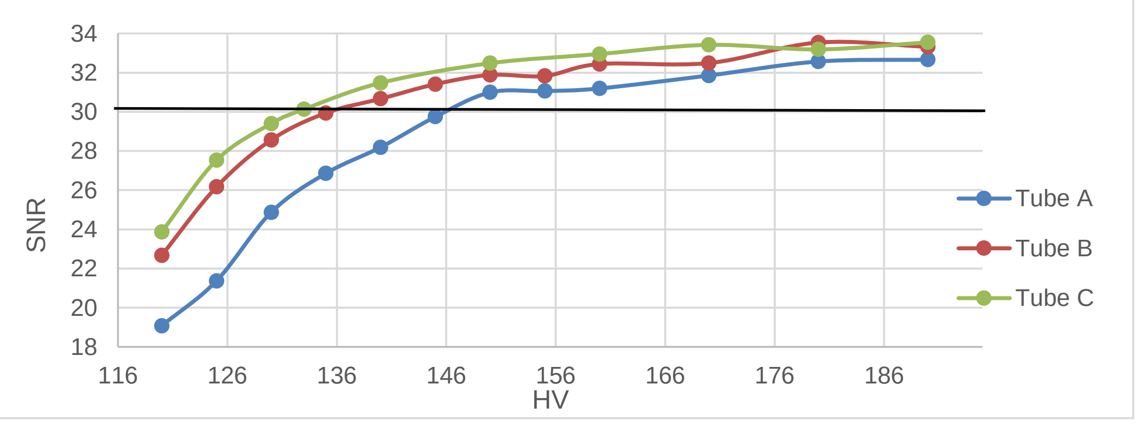


Figure 14: SNR vs HV at 100 µGy

According to the figure 14, the minimum HV values for tube A, B, C so that SNR is at least 30 were: 146, 136 and 132 accordingly (table 6).

Table 6: HV lower limits

Photomultiplier tube	Reference HV	Minimum HV
A	158	146
B	148	136
C	145	132

Same tests were repeated as in verifying the HV upper limit, the HV lower limits could be validated in similar way. However, after implementing the tests with each tube at pre-defined minimum HV above, the results didn’t show as expected.

Figure 15: SNR at pre-defined minimum HV at 100 μGy

Clearly, there were cases when tube B and C gave SNR below 30 (figure 15). These values didn’t match the requirements. Therefore, the minimum HV for these two tubes must be increased. In this case, minimum HV for tube B and C were increased by 1 and the tests for these tubes were repeated. It is clear to see that, in figure 16, at new HV, all the tubes gave SNR above 30.

Figure 16: SNR at new minimum HV at 100 µGy

Additionally, tubes A, B and C were tested at their minimum HV defined in section above at 20 µGy, giving images as shown below (figure 17).

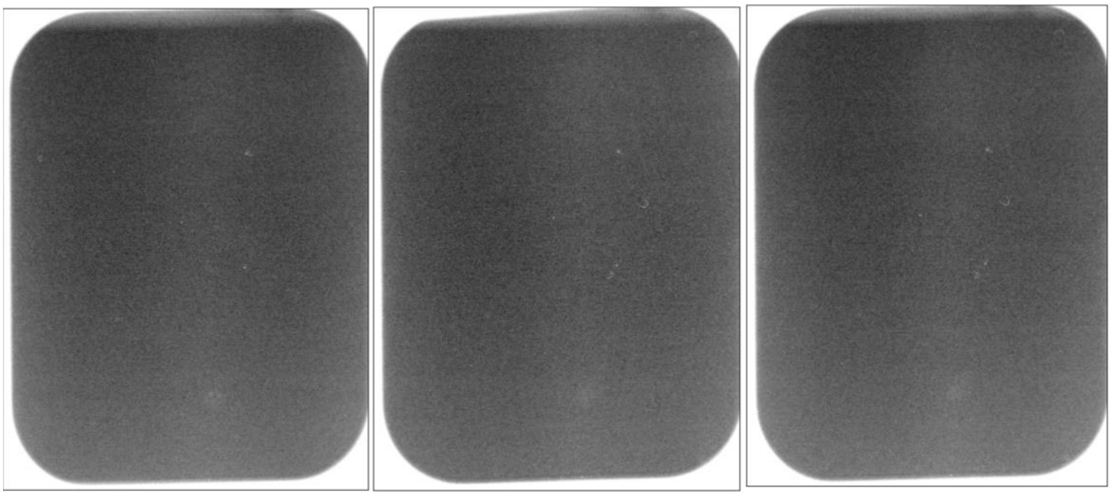


Figure 17: Scanned images of tube A, B and C (from left to right) at 20 µGy

Apparently, all the images were not fully white. Therefore, pre-defined minimum HV values were acceptable. Finally, the tolerance window of each tube was recorded in table 7.

Table 7: Tolerance window summary

Tube	HV Tolerance window [upper/lower]
A	+12/-12
B	+12/-11
C	+12/-12

As all the tubes gave similar results and tube B gives the smallest tolerance interval, the overall HV tolerance window must be based on tube B: +12/-11. This simply means, if a PMT has HV reference at 160, the usable range of HV value could fluctuate between 149 and 172.

7 Analysis

7.1 Variation between Calculated and Production Line Values

A data collection of 206 photomultiplier tubes calibrated HV values was taken, resulting in a correlation equation between calculated manufacturer's measurement data and Kavo Kerr one:

$$y = -15.8229\ln(x) + 208.763 \qquad \text{(Eq. 5)}$$

where: y is HV (from Kavo Kerr)

x is anode blue sensitivity index (calculated from manufacturer's data)

The equation 5 illustrates that the higher anode blue sensitivity index the PMT has, the less supply voltage required. As in this case, the PMT is designed with intention that it only allows blue light to travel through its front window. Because of that, the blue filter plays an important role in defining the spectral response of photomultiplier tube with blue light.

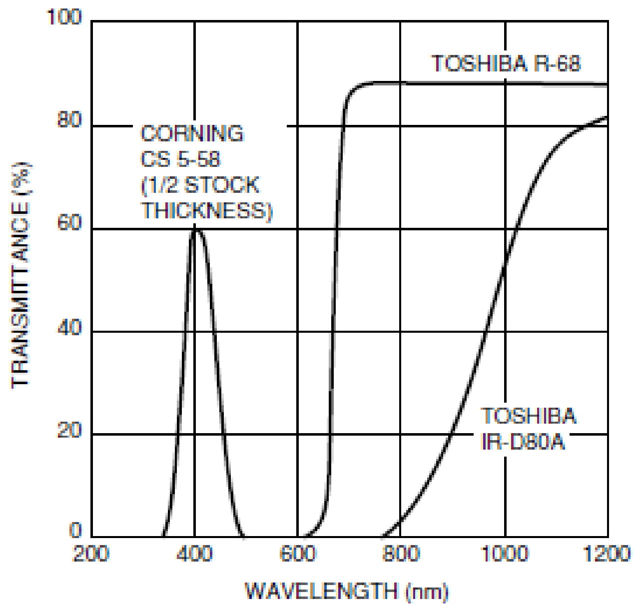


Figure 18: Spectral transmittance of optical filters (blue filter: CS 5-58) [1,41]

Figure 18 shows that any small change in the incoming blue light wavelength or small variation in filters between different PMTs could cause dramatical fluctuation in light transmittance. Since the input light wavelength and filters are difficult to adjust and measure separately, the supply voltage can be used to compensate these factors. In other words, some PMTs might require higher supply voltage than the others to achieve the same output signal.

Due to the differences in measuring method, calibrating, test set ups and system characteristics, there were variations between the HV calculated based on anode blue sensitivity index and HV obtained from production line calibrator.

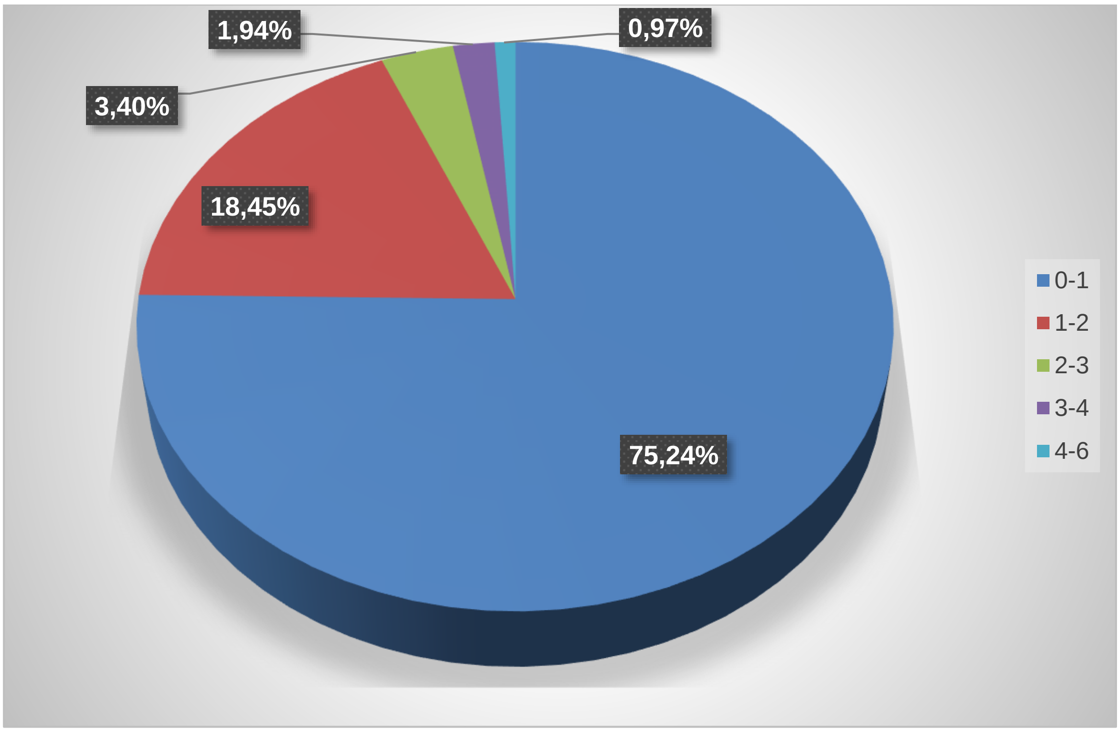


Figure 19: Differences in HV from calculation and from production line

The evidence from the figure 19 shows that in most of the measured tubes, the variation is insignificant as more than 93%, the variation is less than 2. Additionally, less than 3% has the variations from 3 to 6.

In order to maintain the device as one of the best intraoral imaging plate scanners in the market, the measurement of every single component inside needs to be drastically accurate or in other words, the worst-case estimation must be taken into account. Accordingly, for the photomultiplier tube, even though there was only one out of 206 tubes has the variation at 6, this difference must be considered when fitting it into the overall tolerance window.

7.2 Process Measurement Potential Capacity

Process capability is a technique to find out the measurable property of a process to a specification assuming that process output is approximately normally distributed. Generally, the final solution of the process capability is specified either in the form of calculations or histograms (figure 20).

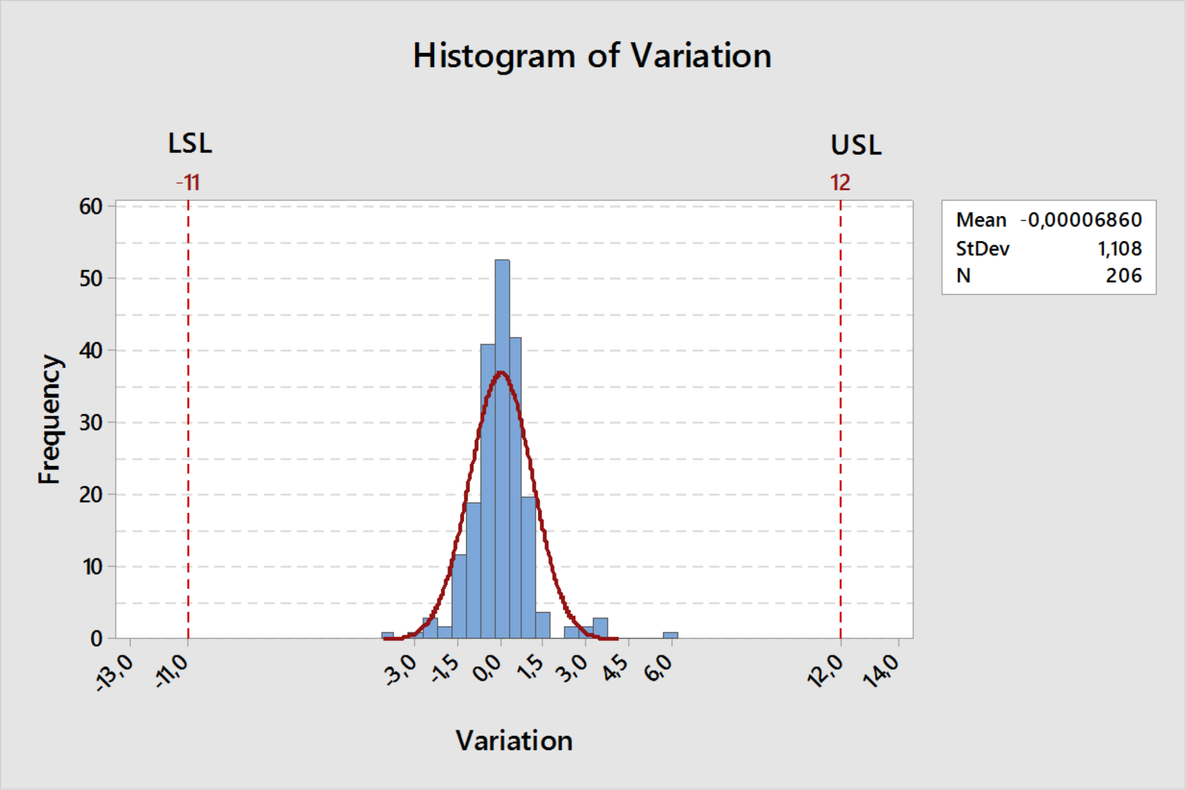


Figure 20: Histogram of HV variation

Data collection of 206 measured PMTs was used to calculate process capacity to examine process performance to specifications: to check whether HV variation meets HV tolerance window. The histogram was built with Minitab software.

7.2.1 Process Capability

Process capability (*Cp*) estimates whether the process is capable of producing if the mean value were at centered between two limits.

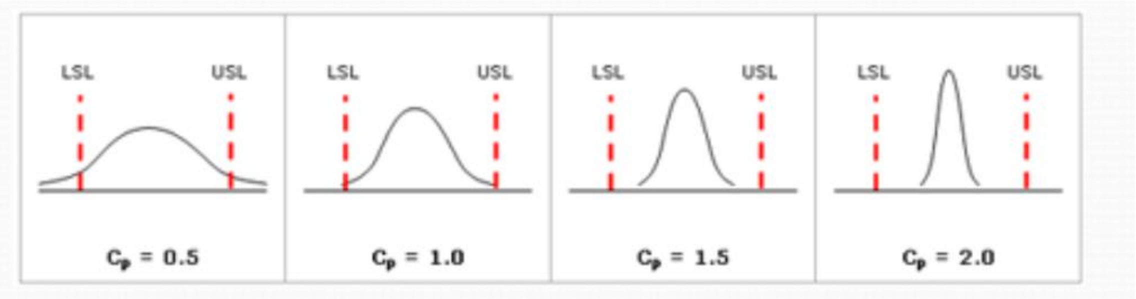


Figure 21: Process population in different *Cp* [13]

Figure 21 demonstrates how the data is spread relative to specification limits with different values of *Cp*. Low *Cp* value means high process variation while high *Cp* value indicates the process is well-capable of producing within the specification limits.

Process capability is calculated using formula:

$$Cp = \frac{USL-LSL}{6\sigma} \qquad \text{(Eq. 6)}$$

USL: upper limit specification

LSL: lower limit specification

σ: standard deviation

In this case, as result obtained from chapter 5, USL = 12 and LSL = -11. From sample data collection, σ = 1,105.

$$Cp = \frac{USL-LSL}{6\sigma} = \frac{12-(-11)}{6 \cdot 1.105} = 3{,}47 \qquad \text{(Eq. 7)}$$

7.2.2 Process Capability Index

Process capability index (*Cpk*) is an index used to measure how close a process is running to its specification limits, relative to the natural variability of the process. The larger the index, the less likely it is that any item will be outside the specs. [Neil Polhemus]

Process capacity index is calculated using formula:

$$Cpk = \min[\frac{USL-\mu}{3\sigma}, \frac{\mu-LSL}{3\sigma}] \qquad \text{(Eq. 8)}$$

USL: upper limit specification

LSL: lower limit specification

σ: standard deviation

μ: process mean

In this case, USL = 12, LSL = -11, σ = 1.10501108 and $\mu = -0.0116$. Therefore,

$$Cpk = \min\left[\frac{USL - \mu}{3\sigma}, \frac{\mu - LSL}{3\sigma}\right] = \min\left[\frac{12 - (-0.0116)}{3 \cdot 1.105}, \frac{(-0.0116) - (-11)}{3 \cdot 1.105}\right]$$

$$= \min[3.623; 3.315] = 3.315 \qquad \text{(Eq. 9)}$$

There are many standards, measurement techniques defining the required *Cpk* value for reliable measurement and Six Sigma quality process is one of the most common one. Six Sigma is a set of techniques and tools for process measurement. It's an important and popular factor used to detect, remove and minimize any variability in manufacturing and business. Further information about Six Sigma process can be found in appendix 2.

Table 8: Recommended minimum process capability [8]

Situation	Recommended minimum process capability for two-sided specifications
Existing process	1.33
New process	1.50
Safety or critical parameter for existing process	1.50
Safety or critical parameter for new process	1.67
Six Sigma quality process	2.00

Table 8 shows recommended minimum process capability in different situations. Since *Cpk* was calculated as 3.315, the process comforted Six Sigma quality process or in other words, HV variation in calculation fits well within the tolerance window.

7.3 Final Result Analysis

After implementing all the required tests and analysis, it is sufficient and reasonable to conclude that the external calibration of PMTs could be eliminated. Instead, HV value will be calculated using formula:

$$y = -15.8229\ln(x) + 208.763 \qquad \text{(Eq. 10)}$$

with x being the anode blue sensitivity index.

This means, without the need of calibrator, the optimal HV value for each PMT can be determined based on the anode blue sensitivity index calculated from measurement data provided by manufacturer.

8 Reference Implementation

8.1 A Memory in PMT

Currently, PMT serial number and calibrated HV value are read, stored separately and manually into system database. This method is not suitable and efficient for making an automatic system. The appearance of memory in PMT will solve this issue. Instead of reading and importing manufacture's measurement data manually from the papers, all the desired data could be stored into a memory inside PMT, for example an EEPROM (figure 21).

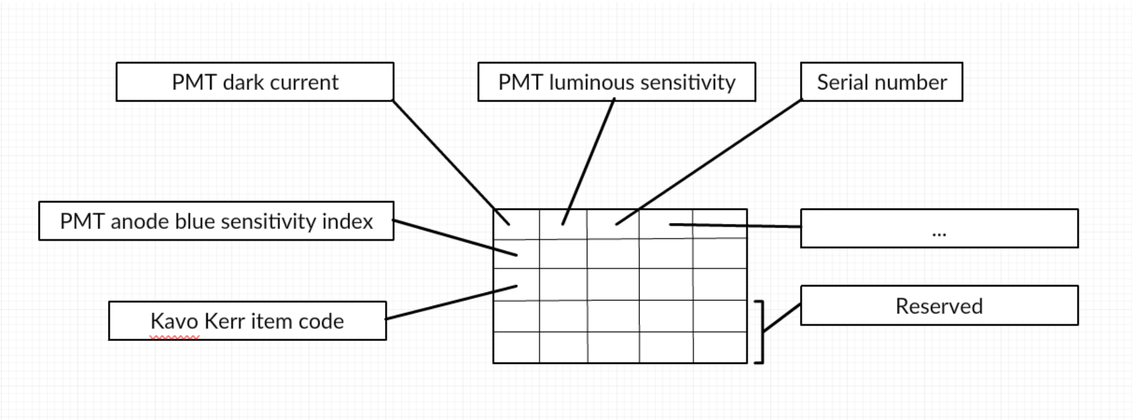


Figure 22: Desired data could be stored in memory

Furthermore, in the case of exporting spare part for maintenance or service field, the process of validating the right component, serial number or HV value becomes much easier since all the required data is stored in the memory along side with PMT. In addition, besides being used for storing manufacturer data, there are possibilities that spaces could be reserved in memory for writing other parameters such as: assembling date, last error code or signal level at reference HV. Combining all the data will greatly ease the services and processes. The communication protocol, for example: I2C could be used for reading and writing to the memory.

8.2 Data Process in Firmware

After inserting PMT into the scanner, the firmware will read and calculate HV value based on anode blue sensitivity index. A corresponding voltage will be generated from the main circuit board and supplied back to the PMT.

MES stands for Manufacturing Execution Systems and are computerized systems used to optimize production activities by giving instructions, guides and decisions. In the level of intraoral scanner, MES API (application program interface) will give assembling instructions to scanner firmware by sending commands at intended period of time. During assembling process, scanner firmware will calibrate other components while setting up desired parameters to the system. Finally, when the assembly is finished, a request from MES API will be sent and it asks for all the scanner parameter values such as: scanner serial number, PMT serial number, PMT anode blue sensitivity index, mirror frequency and so on. The manufacturing workflow with MES API guides and instruction is described in figure 23.

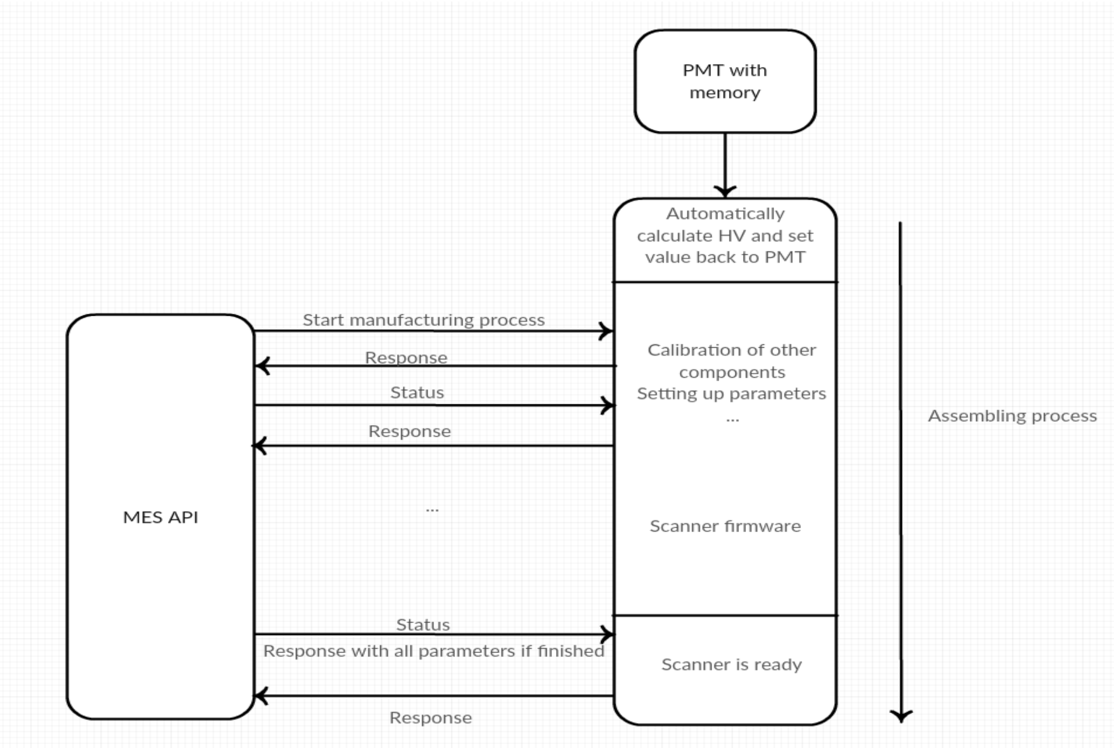


Figure 23: MES API in managing assembly workflow

8.3 PMT Self-diagnostics

The main idea of PMT self-diagnostics is to verify that PMT is operating normally when scanner first boots up. A blue LED with constant current will be used as supply input signal to the PMT. The PMT is considered to function normally when there is certain output signal from it. After this self-test, the LED will be turned off and input signal will be generated from electrons released from Imaging Plate (IP) instead. Note that this test is not intended to obtain PMT HV value but simply check whether PMT is defective or not.

8.4 Evaluating Equation for Calculating HV of New PMT

As mentioned in section 7.3, the optimal HV could be calculated based on pre-defined equation. However, even though the PMT characteristics remain, this equation will change when the new PMTs with different specs are used in the new product. Therefore, a method to define new equation is necessary.

In order to evaluate a new equation, the correlation between supply voltage and anode blue sensitivity index need to be acquired with a certain number of samples. Combining all the factors such as: simplicity, feasibility and accuracy, a new calibrator is needed to examine reference HV for each new PMT. This calibration stage must be implemented before the final version of firmware is released and could be eliminated after that.

9 Conclusion

By implementing different measurements and using statistics, the following result was obtained and initial goal was achieved: It is possible to eliminate the external calibration of components in intraoral imaging plate scanner, starting with the photomultiplier tube.

While doing this study, there have been several limitations. First of all, the definition of a good quality image is not so clear as it depends on the user purposes and perspectives. Additionally, there are several other factors that create impacts on image quality beside SNR and signal level for example: image resolution, pixel sizes or operating modes.

However, the image quality performance was analysed at a reasonable and sufficient level.

Secondly, there are also limitations in making reference implementation. The operations of reading and calculating HV value are implemented within scanner firmware as well as creating new MES API. This is out of the author's competence. Nevertheless, a brief explanation of data process in firmware was shown, this could help in making the firmware later for new product.

Finally, since the hypothesis was proven, the result of this study could be applied to other components in the intraoral imaging plate scanner, hence enhance the process of applying lean principles into manufacturing and service to make a self-calibrated device.

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Appendices

Lean

WHAT IS LEAN?

The core idea is to maximize **customer value** while minimizing waste. Simply, lean means creating more value for customers with fewer resources.

A lean organization understands customer value and focuses its key processes to continuously increase it. The ultimate goal is to provide perfect value to the customer through a perfect value creation process that has zero waste.

To accomplish this, lean thinking changes the focus of management from optimizing separate technologies, assets, and vertical departments to optimizing the flow of products and services through entire value streams that flow horizontally across technologies, assets, and departments to customers.

Eliminating waste along entire value streams, instead of at isolated points, creates processes that need less human effort, less space, less capital, and less time to make products and services at far less costs and with much fewer defects, compared with traditional business systems. Companies are able to respond to changing customer desires with high variety, high quality, low cost, and with very fast throughput times. Also, information management becomes much simpler and more accurate.

Lean for Production *and* Services

A popular misconception is that lean is suited only for manufacturing. Not true. Lean applies in every business and every process. It is not a tactic or a cost reduction program, but a way of thinking and acting for an entire organization.

Businesses in all industries and services, including healthcare and governments, are using lean principles as the way they think and do. Many organizations choose not to use the word lean, but to label what they do as their own system, such as the Toyota Production System or the Danaher Business System. Why? To drive home the point that lean is not a program or short term cost reduction program, but the way the company operates. The word **transformation or lean transformation** is often used to characterize a company moving from an old way of thinking to lean thinking. It requires a complete transformation on how a company conducts business. This takes a long-term perspective and perseverance.

The term "lean" was coined to describe Toyota's business during the late 1980s by a research team headed by Jim Womack, Ph.D., at MIT's International Motor Vehicle Program.

The characteristics of a lean organization and supply chain are described in *Lean Thinking*, by Womack and Dan Jones, founders of the Lean Enterprise Institute and the Lean Enterprise Academy (UK), respectively. While there are many very good books about lean techniques, *Lean Thinking* remains one of the best resources for understanding "what is lean" because it describes the *thought process*, the overarching key principles that must guide your actions when applying lean techniques and tools.

"Just as a carpenter needs a vision of what to build in order to get the full benefit of a hammer, Lean Thinkers need a vision before picking up our lean tools," said Womack. "Thinking deeply about purpose, process, people is the key to doing this."

Purpose, Process, People
Womack and Jones recommend that managers and executives embarked on lean transformations think about three fundamental business issues that should guide the transformation of the *entire organization:*

- **Purpose**: What customer problems will the enterprise solve to achieve its own purpose of prospering?
- **Process**: How will the organization assess each major value stream to make sure each step is valuable, capable, available, adequate, flexible, and that all the steps are linked by flow, pull, and leveling?
- **People**: How can the organization ensure that every important process has someone responsible for continually evaluating that value stream in terms of business purpose and lean process? How can everyone touching the value stream be actively engaged in operating it correctly and continually improving it?

[Lean Enterprise Institute, 12**]**

Six Sigma quality process

Six Sigma (6σ) is a set of techniques and tools for process improvement. It was introduced by engineers Bill Smith & Mikel J Harry while working at Motorola in 1986. [1][2] Jack Welch made it central to his business strategy at General Electric in 1995.

It seeks to improve the quality of the output of a process by identifying and removing the causes of defects and minimizing variability in manufacturing and business processes. It uses a set of quality management methods, mainly empirical, statistical methods, and creates a special infrastructure of people within the organization who are experts in these methods. Each Six Sigma project carried out within an organization follows a defined sequence of steps and has specific value targets, for example: reduce process cycle time, reduce pollution, reduce costs, increase customer satisfaction, and increase profits.

The term Six Sigma (capitalized because it was written that way when registered as a Motorola trademark on December 28, 1993) originated from terminology associated with statistical modelling of manufacturing processes. The maturity of a manufacturing process can be described by a sigma rating indicating its yield or the percentage of defect-free products it creates. A six sigma process is one in which 99.99966% of all opportunities to produce some feature of a part are statistically expected to be free of defects (3.4 defective features per million opportunities). Motorola set a goal of "six sigma" for all of its manufacturing operations, and this goal became a by-word for the management and engineering practices used to achieve it. [10]