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İSTANBUL KÜLTÜR UNIVERSITY
INSTITUTE OF GRADUATE STUDIES

ACCURACY ANALYSIS IN MEDICAL DEVICE QUALITY MEASUREMENT BY SOFTWARE AND NEW PERSPECTIVE OF MACHINE VISION SYSTEM

Masters of Quality And Production Management

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Members of Examining Committee:
Dr. Öğr. Üyesi Burçin Ataseven
Dr. Öğr. Üyesi Levent Polat

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Prefaces

First of all I would like to express my sinceret gratitude to my advisior Dr. Murat Taha Bilişik, who has provided invaluable guidance and support throughout this process and research. Also a big thanks to doctor Rostami who has provided me data from Eresk Yekta Tajhiz Factory in Iran.

The purpose of this dissertation is to introduce and demonstrate a new approach to quality control and inspection, this method combines mechanics, electronics and software, and checking new methods in visual inspection.

This study aims to explore the current state of the art in visual inspection system and to develop a appopriate visual inspection machine that can be used in various medical industries.

Chapter 1: introduction

Chapter 2: literature Review

Chapter 3: methodology

Chapter 4: conclusion and result

ABSTRACT

This dissertation investigates the impact of software and machinery on the accuracy of quality measurements for medical products, specifically focusing on key parameters of medical devices. The primary objective is to streamline quality control processes, reducing human errors. To achieve this, we leverage software and artificial intelligence in conjunction with visual inspection machinery.

Our study aims to assess the quality of medical products quantitatively by analyzing them as a percentage of the ideal quality. We seek to adapt the existing quality control framework to tailor it to the specific parameters that significantly influence equipment quality. In doing so, we adhere to ISO regulations and associated standards, which guide us in identifying these critical parameters and optimizing the quality control processes for various medical equipment.

It is important to note that our goal is not to replace established quality management standards but rather to introduce more efficient processes that can complement these standards. We also evaluate the accuracy of traditional quality control methods in comparison to the accuracy of quality control through visual inspection systems. In this dissertation, we present two case studies as empirical evidence, illustrating the impact of human error on quality control and the effectiveness of the visual inspection system.

Key Words: quality control software, quality control measurement, quality control of medical devices, visual inspection system for suture needles, visual inspection system for IVD kits. Visual inspection system for medical devices.

ÖZET

Bu tez, tıbbi ürünlerin kalitesinin ölçüm doğruluğuna kullanılan yazılım ve makine etkisini araştırmakta olup özellikle istenen tıbbi cihaz parametrelerine odaklanmaktadır. Temel amaç, kalite kontrol süreçlerini optimize ederek insan hatalarını azaltmaktır. Bu amacı gerçekleştirmek için yazılım ve yapay zeka ile birlikte görsel inceleme makinelerini kullanmaktayız.

Çalışmamız, tıbbi ürünlerin kalitesini ideal kalitenin yüzdesi olarak nicel olarak değerlendirmeyi hedeflemektedir. Bu kapsamda, ekipman kalitesini etkileyen belirgin parametreleri belirlemek ve bu parametreleri özelleştirmek için mevcut kalite kontrol çerçevesini uyarlamayı amaçlıyoruz. Bu süreçte ISO düzenlemelerine ve ilgili standartlara uymaktayız, bu düzenlemeler bize önemli parametreleri tanımlama konusunda rehberlik etmektedir ve çeşitli tıbbi ekipmanlar için kalite kontrol süreçlerini optimize etmemize yardımcı olmaktadır.

Önemli bir nokta, amacımız mevcut kalite yönetimi standartlarını değiştirmek değil, bu standartları tamamlamak için daha verimli süreçler tanıtmaktır. Ayrıca, geleneksel kalite kontrol yöntemlerinin doğruluğunu, görsel inceleme sistemleri ile karşılaştırarak değerlendirmekteyiz. Bu tezde, insan hatalarının kalite kontrol üzerindeki etkisini ve görsel inceleme sisteminin etkinliğini gösteren iki örnek çalışmayı sunmaktayız.

Anahtar Kelimeler: kalite kontrol yazılımı, kalite kontrol ölçümü, tıbbi cihazların kalite kontrolü, dikiş iğneleri için görsel inceleme sistemi, IVD kitleri için görsel inceleme sistemi, tıbbi cihazlar için görsel inceleme sistemi.

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CHAPTER: INTRODUCTION

We measure the accuracy of each product quality according to quality control parameters every medical equipment has special parameters should be recognized. The result of quality control are representative of quality of products, and two types of medical products have been examined in this paper first in vitro diagnostic (IVD) and the second Suture needle for heart surgery. After output of the final product, the final product has parameters that are inspected in order to be used by the customer, for all equipment parameters are different, we use software and new technology related to parameters and we will see what is difference between quality control results with new method inspection and old method inspection. in new way to quality control we use softwares and in the old way most we inspect without software and machine to do procedure.

This has been mentioned common tools by this paper utilized in intelligent manufacturing systems like process monitoring, diagnostics and control, made large progress in order to handle quality problem, actually quality problems are decreasing by developing intelligent manufacturing. The model for quality control about each product could be different depends on parameters, data and relevant information of the products.[1]

Automated Visual Inspection Systems (AVIS) is a way to quality control and inspection automatically instead of through manual inspections. This possible to inspection by machine via image processing and Artificial Intelligence techniques. Intelligent visual inspection systems (IVIS) are related to different subjects such as pattern recognition, image processing, machine learning, image analysis, signal processing and software and hardware behind artificial vision systems as well as Artificial Intelligent (AI) techniques.[2]

[1] (Wuest, Liu, C. Y. Lu, & Thoben, 2014)

[2] (Yazdi, Satria, & Golkar, 2011)

1. CHAPTER: LITERATURE

2.1. what is visual inspection and challenges

Visual inspection is an essential aspect of many industrial processes, as it helps to ensure the quality and reliability of products. Despite its importance, visual inspection has faced several technical challenges and problems that have hindered its effectiveness and efficiency. This chapter reviews the literature on these challenges and problems in the field of visual inspection technology.

One of the main challenges in visual inspection is the detection of small things, such as cracks on bottle or needle, defects on small needls, and particls in liquids, that are often difficult to detect using traditional inspection methods. This is particularly important in pharmaceutical and medical equipment industries such as needle production line and lequid medicines, where the detection of small defects can have significant consequences in terms of safety and performance.

In order to overcome this challenge, researchers have developed various image processing techniques, such as image enhancement and pattern recognition, that can be used to improve the detection of small things. Also challenges when performing inspection by using microscope.

Another challenge in visual inspection is changing of product appearance due to changes in lighting, camera position, and other environmental factors such as moving particles in liquid in bottle pharmaceutical during moving on conveyor[3]. This changing can result in inconsistent

[3] (Zhang, Zhong, Yang, & Li, 2018)

inspection results and make it difficult to detect defects in some cases. To address this issue, researchers have developed techniques for image normalization, which help to reduce the impact of variability in product appearance on inspection results.

A third challenge in visual inspection is the difficulty in identifying defects in complex shapes and patterns, such as this found in suture needle shape and all sides the needle. This challenge is often due to the limited field of view of the inspection system and the difficulty in detecting defects in complex shapes and patterns. To overcome this challenge, researchers have developed techniques for multiview inspection, which involve taking images from multiple angles to increase the field of view and improve the accuracy of defect detection.

another challenge in visual inspection is the cost and complexity of the inspection system, which can be a barrier to widespread adoption. To overcome this challenge, researchers have developed cost-effective inspection systems that use simple and low-cost hardware and software components. Additionally, researchers have also developed techniques for automating the inspection process, which can help to reduce the cost and complexity of the inspection system.

also there is two type of visual inspection manual visual inspection and Automatic visual inspection , for manual visual inspection of medical devices is so challenging, the difficulty to ensure that standard procedures are followed by multiple operators doing inspection, too many manual steps, such as data transfer, and paper-based documentation , tracking process, several time inspection and comparison of results with defined specifications.

the field of visual inspection technology faces several technical challenges and problems that must be overcome in order to improve inspection processes. The importance is developing techniques for detecting small defects, reducing variability in product appearance, improving the detection of defects in complex shapes and patterns, and reducing the cost and complexity of the inspection system.

2.2. Manual quality control and inspaction

Manual Inspection Quality

Manual inspection quality is a method of assessing the quality of products through visual inspection by a trained inspector. This method has been used for many years and is still widely used today, despite the advent of automated inspection technologies. The main advantage of manual inspection quality is that it allows for a highly detailed assessment of the product, which can uncover even minor defects that may be missed by automated systems. However, this method is also highly dependent on the skill and experience of the inspector, and it can be time-consuming and costly to carry out.

2.3.Visual inspection machines for the quality assessment of surgical needles (figure1)

A crucial aspect of the study is that it provides a comprehensive understanding of the existing research, current state-of-the-art technologies, and gaps in the field.

The quality of surgical needles is critical for ensuring patient safety and successful surgical outcomes.

Visual Inspection for Quality Assessment of Surgical Needles Visual inspection involves examining the surface of the needle for defects such as burrs, cracks, pits, and bends. This technique is commonly used in the manufacturing process of surgical needles to ensure that the needles are free of defects that could compromise their integrity and cause harm to the patient. The effectiveness of visual inspection depends on the operator's skill, the lighting conditions, and the size and type of defects being inspected.

In recent years, the demand for high-quality medical needles has increased, and their quality has become a critical issue in the healthcare industry. Surgical needles are used for various surgical procedures, and their quality affects the safety and success of the operation. Conventional manual inspection methods for needle quality assessment are time-consuming and prone to human error.

To overcome these limitations, several studies have proposed the use of visual inspection machines for the assessment of surgical needle quality. These machines use computer vision and machine learning algorithms to detect and categorize defects in surgical needles.

It is unavailable to find studies exactly about the quality of surgical needles; in this case, we check every parameter according to an article.

In the article by Xiaoying Wang, Casey Jowers, Maciej Mazur, Alexander Buddery, Damon Kent, Alireza Bab-Hadiashar, Mark Easton. (2022), by Focusing on ivf needles, they have checked the quality of the medical needle tips. The invention of the study is to develop procedures to automatically prepare a virtual dataset of synthetic images, generate a large-scale synthetic image dataset by the automated photo-realistic rendering of a three-dimensional (3D) parametric model to simulate manufacturing variation, and use a novel approach to accurately estimate quantitative quality standards of IVF needles with an explicit relationship between needle quality and its geometry information tips with minimum resources.

In the case of the detection of defects on surface surgical needles in a study by Xin Wen, Jvran Shan ,Yu He and Kechen Song (2022) about steel surface defect recognition, steel products include bar/wire, which are defect categories related to wire defects. They are classified into texture feature-based methods and shape feature-based methods, and this machine learning algorithm is a deep learning method to detect defects; it is the newest way to achieve high detection speed and accuracy. This method can be used in order to detect defects on the surface of needles to find cracks, grooves, and shapes in the needles.

Studies on Visual Inspection for Quality Assessment of Surgical Needles Several studies have examined the effectiveness of visual inspection for the quality assessment of surgical needles. In a study by Jiancheng Jia (2009), trained inspectors visually inspected syringes for defects. This study can be used to determine shape, angle, sizes and diameters. The study found that machine vision inspection had high sensitivity and specificity, which operated at a higher production rate while providing 100% inspection to ensure the product quality of every unit, was developed and presented. However, the study also highlighted the limitations of visual inspection, such as the potential for human error and the inability to detect certain types of defects.

Visual inspection machines have shown promising results for the assessment of surgical needle quality. These machines use computer vision and machine learning techniques to accurately detect various types of defects in surgical needles, such as surface defects, geometric defects, and sharpness. Further research is needed to develop and optimize these systems for practical use in the healthcare industry.

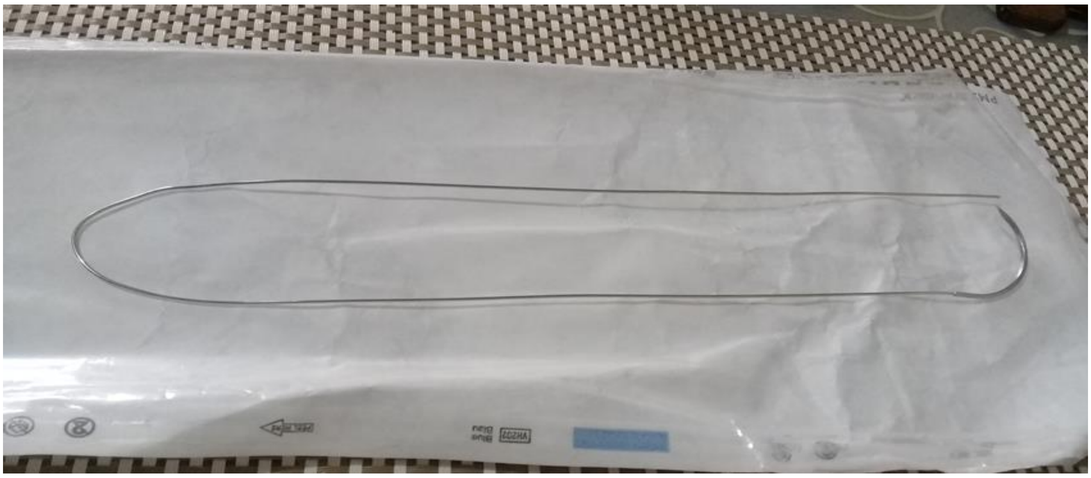

Figure 1 Needle

Visual inspection machines for the quality assessment of laboratory bottles with liquid kits

The accuracy and efficiency of these machines are essential for ensuring the safety and reliability of laboratory samples.

In recent years, the demand for high-quality laboratory bottles with liquid kits has increased, and their quality has become a critical issue in the healthcare industry. Conventional manual inspection methods for laboratory bottle quality assessment are time-consuming and prone to human error. The method used to check the quality of these is the same as for pharmaceutical liquid bottles. Access to studies about pharmaceutical bottles is almost always available, but for laboratory kits, it can be a new perspective to use the automatic visual inspection method.

To overcome these limitations, several studies have proposed the use of visual inspection machines for the assessment of laboratory bottle quality. These machines use computer vision and machine learning algorithms to detect and categorize defects in laboratory bottles, such as cracks, scratches, and leaks. Also, demonstrate some particles in liquid. Several studies are there, and every article mentions just checking the quality of special parameters in that case, and we take information from them, this is the challenge in my study.

In a study by Hui Zhang et al. (2018), a deep learning-based visual inspection system was proposed for the automatic detection of Liquid Particle Inspection of Pharmaceutical Injection. The system was a new design of machine that consists of three parts; mechanical system, image acquisition system, and a distributed industrial electrical computer control system with a specific algorithm on a dataset of pharmaceutical injections with various types of parameters and was able to accurately classify the defects with high accuracy. This method is supposed to investigate particles by tracking particles in liquid and the types of particles in laboratory containers.

Another study by Leila Yazdi, Anton Satria Prabuwono, Ehsan Golkar (2011) proposed an automated Visual Inspection Systems (AVIS) based on computer vision and image processing techniques with software and hardware behind artificial vision systems for the detection of fill level and cap bottles. The system was able to accurately detect the level of substance and cap closure in bottles with a new Feature Extraction (FE) technique.

A study by Muhamad Haziq Hasnul Hadi et al. (2021) proposed a color inspection system that combines machine learning algorithms and computer vision techniques for the assessment of color scales. The system was able to accurately measure the color of liquids in containers as a portable device. In this article, define color according to the standards via visual inspection. As well as a new method that utilizes AI artificial intelligence for color determination.

Visual inspection machines have shown promising results for the assessment of liquid and bottle quality. These machines use computer vision and machine learning techniques to accurately detect various types of defects in bottles and liquid in bottles, such as cracks, scratches and closure caps in containers, in addition to detects particles in liquid and color variations. Further research is needed to develop and optimize these systems for practical use in the healthcare industry.

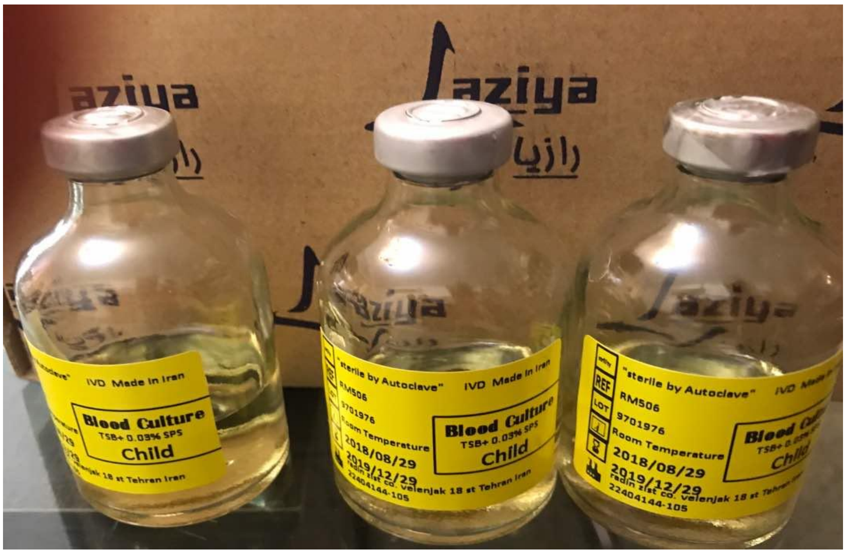

Figure 2 Bottle Laboratory

2.4. History of visual inspection and its development

Visual inspection systems have played an important role in the medical device industry for many years. The earliest forms of visual inspection systems involved manual inspection by human operators, which was time-consuming and prone to errors. However, with advancements in technology, automated visual inspection systems have been developed to ensure the quality and consistency of medical devices.

Visual inspection systems have been integral to the medical device industry for an extended period. In the initial stages, these systems relied on manual inspection conducted by human operators. Unfortunately, this manual approach had its drawbacks. It was time-consuming, subject to human error, and often led to inconsistencies in the inspection process. The human eye's limitations in terms of sustained attention and potential fatigue further exacerbated these challenges.

Nonetheless, with the rapid advancements in technology, the landscape of visual inspection systems has evolved significantly. The transition from manual inspection to automated visual inspection systems marked a pivotal moment. These automated systems leverage cutting-edge technologies such as computer vision, image processing, and machine learning to revolutionize the inspection process.

In essence, the transition from manual visual inspection to automated systems showcases the transformative power of technology in improving accuracy, efficiency, and reliability in the medical device industry. It's a testament to the industry's adaptability and commitment to embracing innovations that enhance overall quality and performance.

In the 1950s and 1960s, inspection began with product quality control , the field of inspection and quality control was quite different from today, and several myths and misconceptions existed due to the limited technological advancements and understanding of quality management. One common myth was the belief that inspecting every single product or item would guarantee high quality or there was a misconception that human inspectors were infallible and could identify all defects accurately.

And during time actually by starting Industrial Revolution with the rise of industrialization, mass production led to the need for more standardized and consistent products and inspection methods became more formalized, and tools like gauges and templates were introduced to measure dimensions and tolerances.

And in the current time Advancements in digital imaging and machine vision enabled automated visual inspection with high precision. Lean Six Sigma methodologies integrated statistical analysis and process improvement into quality management. Data analytics and AI-driven tools have enhanced predictive maintenance and quality forecasting. Also there is some standards just belong to Medical equipment quality management and Emphasis on risk management and compliance with international quality standards (ISO 9001, ISO 13485, etc.)

Throughout history, the focus has shifted from simply identifying defects to preventing them and optimizing processes for quality. Inspection and quality control have evolved from manual, visual methods to highly automated, data-driven approaches. The integration of technology, statistical methods, and a culture of continuous improvement has shaped the development of quality management practices as we know them today.

Today, visual inspection systems are an essential part of the medical device production process. They are used to inspect products such as catheters, stents, and pacemakers to ensure they meet industry standards for safety and quality. These systems have become increasingly sophisticated, utilizing high-resolution cameras, advanced image processing software, and machine learning algorithms to detect even the tiniest defects in medical devices.

2.5. International standards in quality control medical devices

There are several international standards that are relevant to medical devices and laboratory industries. Here are some of the key ones:

ISO 13485 - Quality management systems for medical devices

ISO 14971 - Risk management for medical devices

IEC 60601 - Medical electrical equipment

ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories

ISO 15189 - Medical laboratories - Requirements for quality and competence

Good Manufacturing Practice (GMP) - Guidelines for pharmaceutical products

ISO 13485 is the most important standard for medical device manufacturers, as it outlines the requirements for a quality management system that meets regulatory requirements for medical devices. ISO 14971 provides guidance on managing risks associated with medical devices, while IEC 60601 outlines safety requirements for medical electrical equipment.

ISO/IEC 17025 and ISO 15189 provide requirements for testing and calibration laboratories and medical laboratories, respectively. These standards outline the requirements for technical competence and quality management for laboratories.

Good Manufacturing Practice (GMP) is a set of guidelines for ensuring that pharmaceutical products are consistently produced and controlled according to quality standards. These guidelines apply to all aspects of the manufacturing process, including production, quality control, and testing.

2.6. Accuracy analysis in quality control

Accuracy analysis is done by comparing the measured values to a related standard or reference value. This can be done using statistical methods such as regression analysis, correlation analysis, or analysis of variance. The results of the analysis can be used to evaluate the accuracy of the measurement or test and identify any sources of error. It is important in quality control because it helps ensure that the products or processes being tested meet the required standards and specifications. This is particularly important in the medical device industry, where accuracy and precision are critical for ensuring patient safety and product efficacy.

The accuracy of quality control for medical products can be significantly improved by using visual inspection systems. Traditional quality control methods that rely on human inspectors can be prone to errors, particularly when inspecting large quantities of products or products with complex geometries.

Visual inspection systems, on the other hand, use advanced imaging and sensing technologies to detect defects and inconsistencies in products with high accuracy and precision. These systems can also operate at high speeds, which is particularly important for industries that require high-volume production. By combining visual inspection systems with statistical methods, it is possible to increase accuracy in quality control.

Using visual inspection systems in quality control for medical products can significantly improve accuracy and efficiency, reducing the risk of product defects and non-compliance with regulatory requirements. The accuracy of quality control using visual inspection systems can vary depending on a variety of factors, including the type of inspection system and parameters of the products, the type of product being inspected, and the specific requirements of the regulatory environment in which the product is being produced and marketed. In this study, we focus on products not the environment.

However, studies have shown that visual inspection systems can significantly improve the accuracy of quality control in various industries, including the medical device industry. For example, a study in 2022 by Xiaodong Wang, Xianwei Xu et al. robust scale defects[4] detection found that a machine vision system used for defect detection method for syringe scale had an accuracy rate of 99.7% in detecting surface defects. Another study automated quality control inspection of geometric tip defects in medical needle manufacturing by Xiaoying Wang et al, (2022) of deep machine algorithm used for detecting defects on needles tips and had an accuracy rate 11.02% than the machine learning models and showed an overall accuracy of 92%.[5]

The journals are peer-reviewed scientific journals that publish research related to various aspects of the industry, not just useful for healthcare; actually about medical devices, it is very rare to find articles about types of medical devices automated quality inspection articles just take information from other available articles, including different manufacturing, quality control methods, and statistical methods.

Suppose a manufacturer produces a certain type of IVD kit and wants to ensure that the results of the test are accurate and reliable. Regression analysis is a useful tool in evaluating the accuracy and reliability of IVD kits and ensuring that they meet the required standards and specifications. The manufacturer can perform regression analysis on the test results to evaluate the accuracy of the test and identify any sources of error. The manufacturer can compare the results of the IVD kit to known reference standards. They can then use regression analysis to determine how closely the test results align with the reference value. This can involve calculating the regression coefficient, which is a measure of the strength of the relationship between the test results and the reference value.

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[4] (Xiaodong Wang, 2022)

[5] (Wang, et al., 2022)

2.7. Chellenging during in the visual inspection system implementation

Skilled people involved in the implementation of visual inspection systems may experience several problems. Implementing a visual inspection system requires a deep understanding of the inspection process and the ability to design an inspection system that is effective and efficient. Also they may face challenges in determining the appropriate lighting, camera placement, and image processing algorithms required for accurate inspection. Another problem, is in selecting the appropriate hardware and software required for the inspection system. The selection process may be complicated due to the wide variety of cameras, lenses, lighting, and image processing software available on the market. Integration with existing production systems such as conveyors, robots, and controllers. Some errors are there to compromise accuracy, which makes system implementation complex. Managing system maintenance and updates: Skilled people must also ensure that the inspection system is regularly maintained and updated to ensure optimal performance. This includes regularly cleaning the camera lens, calibrating the system, and updating the software to incorporate new features and functionalities. The system needs to adapt and be trained; for this reason should be train to spme body to work with the machine and software.

For some organisations implementing machines by trial and error could be quite expensive. This is because trial and error can be a time-consuming and inefficient way to develop and optimize an inspection system. The system includes some parts by trial and error increase cost consists: this may need to purchase multiple cameras, lighting setups, and image processing software to test different configurations, maybe the result is inaccurate or unreliable results, which can be costly to correct. Skilled personnel involved in the trial and error process may need to spend significant time designing and testing different configurations.

Implementing a visual inspection system by trial and error can be a costly and inefficient process. It may be more effective to work with experienced professionals who can design and optimize the system based on their expertise and knowledge of the industry. This can help to minimize development time, reduce costs, and ensure accurate and reliable inspection results.

In recent years, most factories prefer to increase the quality of their medical devices and adoption of automation and machine vision technology in industries such as manufacturing, automotive, electronics, pharmaceuticals, and food processing. This is driven by the need to improve product quality, reduce production costs, and increase productivity and efficiency. With the continued advancement of technology and the increasing need for quality control and efficiency in manufacturing and other industries, it is expected that the adoption of visual inspection machines will continue to grow in the future.

There has been an increasing interest in automation and machine vision technology in Turkey, especially in the automotive, textile, and electronics industries. The Turkish government has also been supportive of initiatives to increase productivity and efficiency in manufacturing through the adoption of advanced technologies such as machine vision systems.

2. Chapter: methodology

3.1. In vitro diagnostic (IVD)

Medical device intended by the manufacturer for the examination of specimens derived from the human body, to provide information for diagnostic, monitoring or compatibility purposes. IVDs include reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus, or other articles. They are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction and determination of physiological status. The parameters of quality in these products include the table below (table 1). During this process of quality control of in vitro diagnostic kits, I have 4 chain procedures to develop and improve quality management of products: first, the continuous process of monitoring the quality control of raw materials and suppliers; second, the continuous production process and control during production; and third, the final quality control and customer feedback and satisfaction. In part of tracking procedure, in every procedure we have gates that have acceptance limits to jump to another process. This way, we way help to improve quality control through a visual inspection to govern all processes without confusing and ignoring some details in the inspection process and quality management.

According to sampling standard AQL ISO 2859 can be 13 pieces from one box has 40 units, through manual checking all of the accepted by the inspector.

We check again these 13 bottles manually and reached to these results as shown in figure 3 as below,

Quality control for every product is different. For example, for the IVD kit, we investigate parameters, but only some parameters can be measured automatically which is too effective on the quality of the final product. For most IVD kits, we also need to control microorganisms using microbial culture media (Microbiological Culture Media), sterilization and storage conditions in the warehouse and freezer. Due to this, only the parameters listed in the below table can be controlled automatically with the interference of the software.

Figure 3 Bottles Box In Vitro Diagnosis

Laboratory Bottle Box (IVD)

3.2. The relevant feature for glass containers bottle

The relevant features for detecting glass containers in a pharmaceutical production line include:

The shape and size of the bottles are important features. The size of the bottle is important, as it can be used to determine the scale of the object in the image. The color of the bottles should be clear. The surface of the bottles should be smooth. The label information can be used to identify specific types of bottles and to reject bottles that do not match the desired criteria. Also, the closure cap and ring should be controlled to meet the requirements of the standard.[6]

[6] (Eshkevari, Jahangoshai Rezaee, Zarinbal, & Izadbakhsh, 2021)

These features can be used by image processing algorithms, such as training of artificial neural networks, to detect and locate glass containers in the image. The specific features that are used may depend on the design of the bottles, the lighting conditions, and the desired accuracy and efficiency of the detection system.

3.3. Evaluation of manual quality control In Vitro Diagnostic (IVD)

Percent error = (TV - OV) / TV * 100%, OV is manually checking average and TV is three times checking average as table 1.

Manually checking average	Three times checking average			Percent error
3.2	8.5	5.3	0.623529	62.35294118
1.4	2.5	1.1	0.44	44
0	2.64	2.64	1	100
0	7.5	7.5	1	100
0	2	2	1	100
4.6	23.14	18.54	0.80121	80.12100259

Table 1 Average Error

In report of the factory overall percentage error is 0.9 so accuracy is 99.1%

In order to check the accuracy of this report, we checked completely one carton, not random, and three times overall percentage error is 4.62; so the accuracy is 95.3%

In total, manual inspection with random investigation quality control percentage accuracy is 95.3% and percentage of error is 3.79.

Actually, checking quality control manually has errors, and without integrating software and machines, errors increase during inspection. Table2

index	parameters	Standards/target	Manually checking average	Three times checking average
1	Weighing the kit	MDR/Directive 98/79/EC WHO organization The National Committee for Clinical Laboratory Standards (NCCLS) İSO 13485 should be 30	31	32.8
	Product color and particle	MDR/Directive 98/79/EC WHO organization The National Committee for Clinical Laboratory Standards (NCCLS) ISO 13485 Should be clear without any particle	clear	1 bottle has particle

	PH check	MDR/ Directive 98/79/EC The National Committee forClinical Laboratory Standards (NCCLS) Should be 7	7.1	7.19
	Labeling and packing(figure2)	label skew, label wrinkles, Package without damage, aligned label with barcode and lot number, without cap skew	40 bottle confirmed by the quality control department	3 bottles not confirmed cap was skewed and Detects label is not placement within 1mm of desired location
	Counting(figure1)	Every carton 40 bottles	40 bottles	40 bottle In 10 carton number of 8 bottles is different

Table 2 Quality Control Chart

3.4. Suture wires

Today, different models of suture wires and needles are available for surgery. In this paper, we have mentioned a wire model to check the accuracy of quality control parameters, which is called Sternum Stainless Steel Non-Absorbable Sutures. This wire includes two pieces: the first part is steel wire, and the second part is a curve needle. These parameters are important, as shown in the below table (table 3). In the table, sampling was not random and only 20 samples were produced to be sent to the laboratory.

Type of the needle is Regular reverse cutting edge[7]. ½ circle used for cardiovascular surgery. In the below table

This quality parameters are according to GG-N-211b PEDERAL SPECIFICATION NEEDLE, SUTURE, US Pharmacopeia [8] ,ASTM F1840, Standard terminology for surgical suture and ISO 9001.

Needle Strength Testing /Bend Moment testing of straight or curved needles/ASTM International F1874-98

Needle Sharpness Testing/Penetration testing of straight or curved needles/ASTM International F3014

[7] (Rose & Tuma, 2022)

[8] (Radhakrishna & Tirumalaie, 2007)

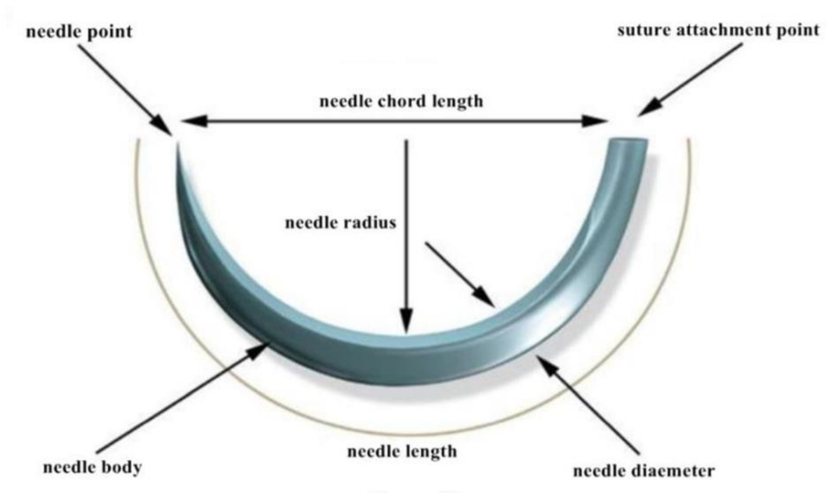

Figure 4 Needle Stracture

3.5. Evaluation of manual quality control of suture needle (table 4)

Index	parameters	Measurement in the quality department in the factory	Measurement by the APKA IRAN HIGH TECH LABORATURY NETWORK
1	Diameter and length (figure3)	Diameter 0.9mm Length 45mm	0.925 mm 45.03cm
2	Needle configuration and shape (figure4)	½ circle Regular reverse cutting edge chord length needle radius 180˚	1/2circle Regular reverse cutting edge needle radius 180˚

3	Penetration testing	Observational method not measured	1.60N
4	Labeling and packing (figure5)	Confirmed	Confirmed
5	Counting	Not available high quantity	Not available quantity

Table 3 Evaluation of manual quality control of suture needle

3.6. Checking diameter and shape by visual inspection system

About needles and wires, they are steel components that can be inspected using visual inspection machines. First, capture images of the things using high-resolution cameras and lighting. Also, you should prepare a reliable place for the camera and lighting in order to capture images without reflection from the lighting. Lighting is critical for visual inspection. The lighting should provide consistent and uniform illumination, without shadows or reflections. Image processing with edge detection and image threshold to identify and measure the diameter of the components. The visual inspection machine uses algorithms to measure the diameter of the components based on the processed images. The algorithms can be based on computer vision techniques, such as blob analysis in Matlab or OpenCV, or machine learning algorithms, such as neural networks. The visual inspection machine compares the measured diameter of the components to predefined specifications to determine if the components are within acceptable tolerances. If the components are outside the tolerances, the machine can flag them for further inspection or rejection. Analysis data and report of the measured diameters and their compliance with the specifications and standards.

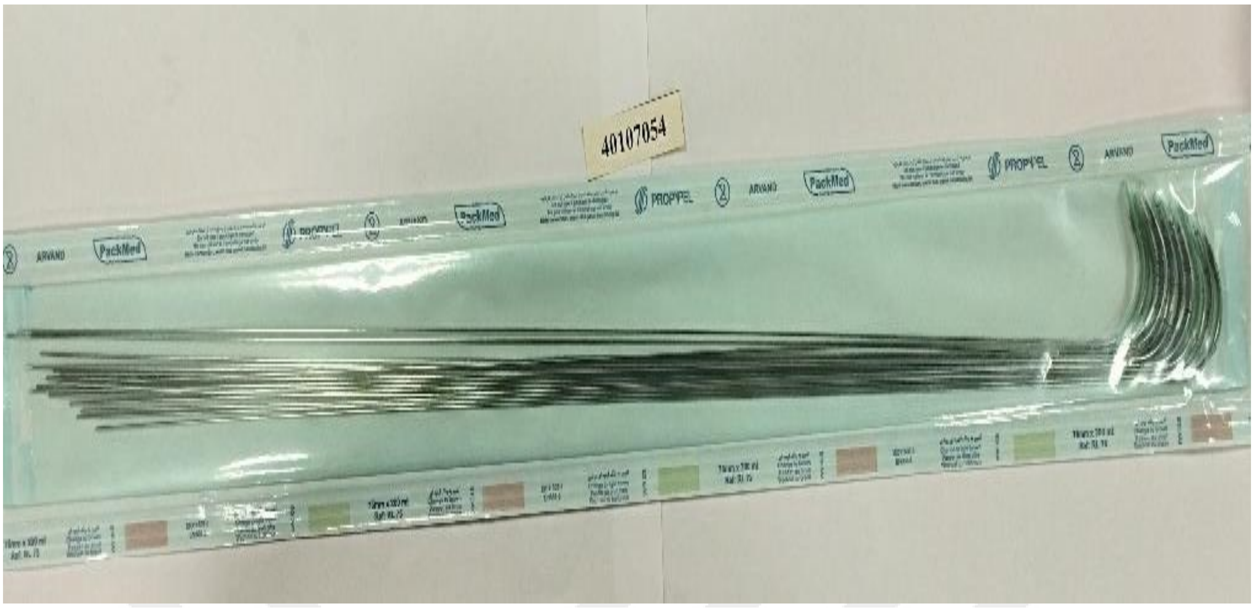

Figure 5 packing of suture needle with wire

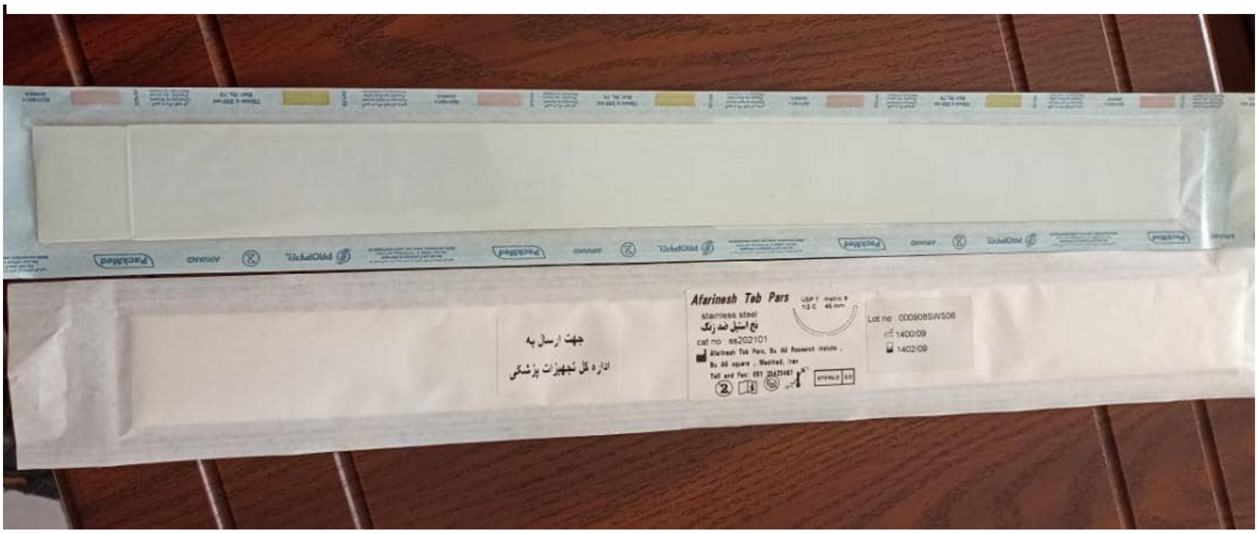

Figure 6 labeliong of suture needle with wire

3. Strategy

Early in the concept or planning phase, a manufacturer must identify the applicable General Safety and Performance Requirements, outlined in EU MDR Annex I, to which the product principle of quality of medical device. Regarding MDR classification (Medical Device Regulation), implantable devices such as suture sternal wire.

In order to prepare parameters and prediction by using software during quality control, some chain processes should use virtual quality control.

For a detailed review, we have considered two different medical products. The first product is IVD in vitro diagnostic, and the second product is stainless steel non-absorbable suture wire, in the direction of achieving accuracy and quality control in the factory. Two ways were available to investigate, so about the IVD kit, we checked the quality and inspection three times, and for the suture wire, we delivered it to the laboratory under the government. The tables show two columns: the first column to check the measurement in the quality department in the factory and the second column to check after three inspections, and the second table shows the same column according to the laboratory result. As shown in the above tables, manual inspection has a high defect rate and human inspection takes more time. Concerning precise inspection and quality control of every parameter and process, we utilize a visual inspection production line. When looking at other papers, consider checking the accuracy of the inspection and quality control by using a visual inspection system. There are several techniques for automatic visual inspection and the image analysis system.

4. Techniques

Base of all techniques focuses on the key VIS and its visual inspection system. A moving sheet production line that has a conveyor belt comprise camera beneficial to capture photo from products, Optic illumination aiming to keeping product for best illumination Computer system and image processing system. In our system general modules and second image processing has been used. During checking the weight of the substance, at the beginning check the weight and transparency without particle is important for liquid Laboratory diagnostic liquid kits in pharmaceutical, intending for weight measurement, check the level of the substance also the cap closure with an explanation of an algorithm in C++ programming language and system classifies condition and situation the level of the liquid and cap clouser and the most recent article brings the technique its Feature Extraction (FE) technique. The bottle is glass to reduce reflection; it is better to use LED light; second is filtering to image enhancement; next step is image segmentation with applying the appropriate threshold for better edge detection; then morphological technique to remove noise; in the next step is feature extraction as shown in the picture.

An algorithm is defined as being separated into two main categories of cap checking and liquid level detection. Find the region of interested reg1 (Yellow box) and define the reference line (blue line) and region 2 is Reg 2 (red box) what should be considered to find the level and closer cap is the image pixels in Reg 2. The next average line should be the same as the prototype line. Average lines are calculated to be compared with prototype lines.[9] (figure7)

[9] (Yazdi, Satria, & Golkar, 2011)

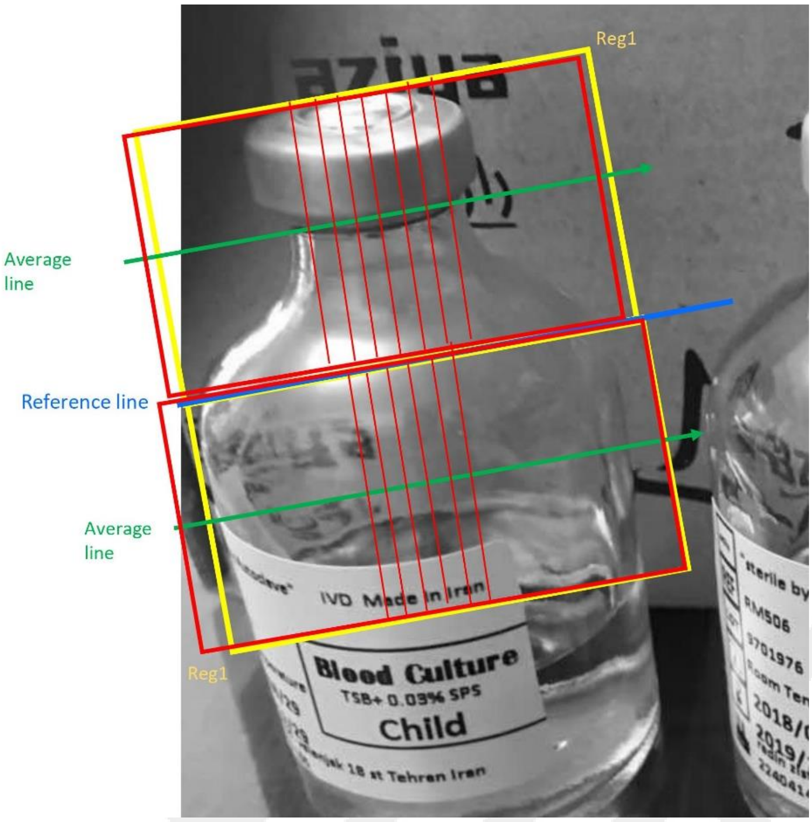

Figure 7 Liquid volume measurement

In order to check product color and particle recommend real-time PVIM for product defect by CCD camera and LED light illumination capture sequence of images, analysis images and possible defects can be detected by related algorithms. The design of this inspection for particle detection is based on an improved binary local descriptor for imaging registration, a defect segmentation algorithm based on fuzzy cellular neural networks (FCNNs) and a robust object tracking algorithm using a collaborative model named as adaptive local weighted-collaborative sparse model (ALW-CSM). To improve the binary local descriptor, use the non-maximal suppression, Hessian matrix, entropy difference and distance constraint to select stable feature points.

A horizontal direction search strategy is used to find the best matching parameters for image matching. Moreover, in mechanical use the fast-moving mechanism system shake the bottles randomly. In this result, evaluate the performance of ALW-CSM algorithm, we conducted experiments and analyzed the results both qualitatively and quantitatively and track the objects feature on image sequence. For quantitative evaluation we evaluate algorithm by using the center position error. For qualitative evaluation we evaluate algorithm under the circumstances of interference, and present tracking results on each image sequence.[10]

For the purpose of inspection all size, shape, angle and diameter of needle machine vision system can be integrated into the manufacturing system. The body of the suture needle is complex, and many objects to check through quality control also manufacture produce high quantities, so it is necessary to implement the new automated machine vision system. This vision inspection consists of a checkpoint vision processor installed in the computer. The panel is composed of several monochrome cameras and LED with the best position for capturing photos from a needle, and a multiplexer is required to connect the cameras to each processor. 3D capture is more effective to check all sides of the product. To manage duration and capture PLC connect it to the vision processor and send a discrete trigger signal.

Another part of the station was captured by the camera. Vision PC communicates with the PLC by using Visionlinx software from Cognex and Rslinx from Rockwell Software. Inspection of the needle is shown by the graphic drawn on the image in (figure8)[11].

On the other hand, for checkpoint vision to cut the exact parts, it finds a trained pattern and locates features that employ PatMax pattern matching measurement characteristics from a needle to meet the approved pattern.

---

[10] (Zhang, Zhong, Yang, & Li, 2018)

[11] (Jia, 2009)

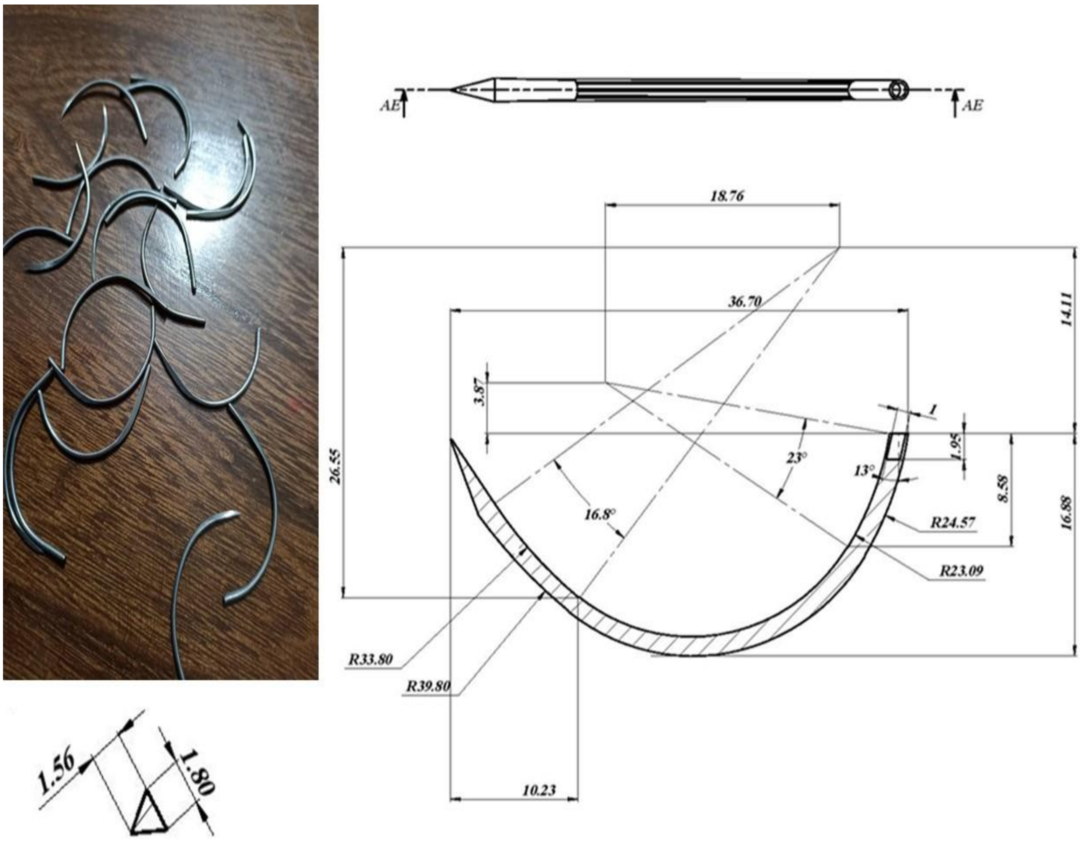

Figure 8 Different parts of the needle

In an effort to check sharpness, a needle penetration test should be performed. The needle is fixed in a stable position by a clamp. The clamp arm moves automatically in the direction of a certain line towards the surface of the medium. The needle clamping fixture shall be rotated at a continuous and constant speed of 4° 6 2°/s, needle curvature is ½ so the range is 156°-200° and the approximate rotation is 60°, the portion of the full body diameter has fully passed through the medium. The needle has passed so far that the entire process has been approved in accordance with standard ASTM F3014, data be collected as a function of force and the maximum penetration force of each needle is collected by the software. During workflow, the software panel on screen brings graphs and reports. The developer software offers smarter tools with a multi-step testing sequence to define its functionality for the user.

For the purpose of checking labels and packages put on the convey, a camera with LED captures pictures from labels and packages. After image acquisition, images are filtered and segmented on the computer. Label inspection and package inspection are two processes to check the labels and area of labels, collect pictures and send them to the application, and compare each image to confirm variable information matching with traceability system data. The best way to inspect labeling and packaging is to convert the image to gray-scale version, then clarify details to compare with the pattern in the software in the system, to check box defects such as spots, blurs, and stain acquisition images. After the process, binarize the image and recognize it according to the set threshold. Sobel edge detection and image subtraction method are used to calculate the difference threshold between the detected image and the template image. The current recognition results can be classified into ‘‘SVM training samples. Determine defects and objects in SVM and prepare the SVM training machine for the supervised classification algorithm. It is an automatic learning feature from large data sets. SVM is used for image processing by some features like Nonlinear mapping, the optimal hyperplane, the support vector, the final decision function and a few support vectors that determine the final result. [1] In this section, we mentioned the methods of inspection by several visual inspection methods regarding the articles that were inserted.

5.1. Image processing

First, choose suitable software in order to process images. The choice of image processing software will depend on the specific requirements of the visual inspection system, such as the complexity of the algorithms to be implemented, the desired processing speed, and the budget. Deep learning-based approaches are becoming increasingly popular for image processing, such as object recognition and shape analysis for needles. Also, it is important to depend on the expertise of the person developing the visual inspection system, as well as the availability of support and resources for the software. Some popular image processing software packages include PYTHON, OpenCV and NI Vision. In this study and every related study, the preferred first use is PYTHON with the second is OpenCV. PYTHON AND GOOGLE COLAB is a powerful image processing tool that is widely used in academia and industry. It has a comprehensive set of image processing functions and is easy to use for prototyping and testing image processing algorithms. We use CV2 in regard to Open Cv in GOOGLE COLAB.

Here is the steps by Pyton to a visual inspection system to check the shape of needle objects :

In this program we didn't use Neural Network, and we wanted to see the difference between two needles, and we used common tools in Python. The first step was to import the image by opening CV2 then image processing, converting Rgb to Gray, then threshold. In order to create a binary image based on the thresholding technique. Then by combining of Contour analysis, Feature Filtering and validation it's calculating the length of contours, and identifying and analyzing the lengths of needles in an image by detecting contours, approximating them, fitting lines to the approximated contours, and calculating the lengths of those lines. The code structure suggests that it expects to find exactly 2 significant contours, and the lengths of the lines are stored in the needle_lengths list.

```
import cv2

import numpy as np

import matplotlib.pyplot as plt
```

```
input_path = input('Open file: ')

image = cv2.imread(input_path)

image_gray = cv2.cvtColor(image, cv2.COLOR_BGR2GRAY)

image_gray_blur = cv2.GaussianBlur(image_gray, (3, 3), 0)

image_thresh = cv2.threshold(image_gray_blur, 0, 255, cv2.THRESH_BINARY_INV + cv2.THRESH_OTSU)

contours, _ = cv2.findContours(image_thresh, cv2.RETR_EXTERNAL, cv2.CHAIN_APPROX_NONE)

lens = [len(i) for i in contours]

maxes = np.array(lens)[np.argsort(lens)][-2:]

contours = [contour for contour in contours if cv2.contourArea(contour) > maxes.min()]

if len(contours)!=2:

exit()

needle_lengths = []

for contour in contours:

epsilon = 0.01 * cv2.arcLength(contour, True)

approx = cv2.approxPolyDP(contour, epsilon, True)

[vx, vy, x0, y0] = cv2.fitLine(approx, cv2.DIST_L2, 0, 0.01, 0.01)

length = np.sqrt(vx**2 + vy**2)

needle_lengths.append(length)

c=contours[0].  # Selects the first contour
```

plt.plot(c[:,0,0],c[:,0,1],c='k',label=str(needle_lengths[0])) # Plots the contour points and labels it with the first needle length

c=contours[1]. # Selects the second contour

plt.plot(c[:,0,0],c[:,0,1],c='b',label=str(needle_lengths[1]))

Plots the contour points and labels it with the second needle length

plt.legend(). #Adds a legend to the plot to label the different contours

output_path = input('Save to: ') # Asks the user for the path to save the plot image

plt.savefig(output_path) #Saves the plot as an image file

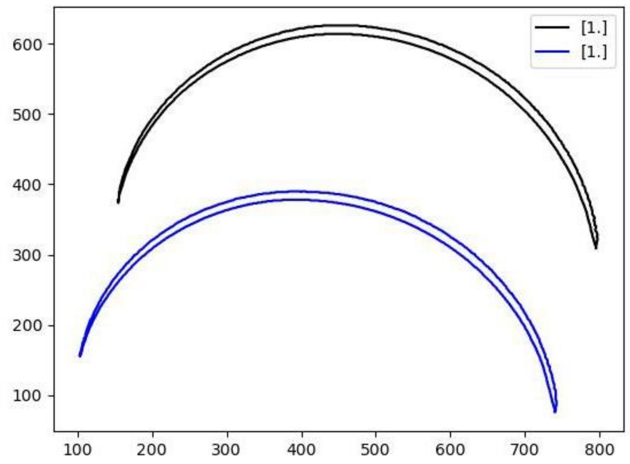

Figure 9 Needle Length

This code generates a visualization that overlays the two extracted contours on the same plot, with each contour's points plotted using lines of different colors. The lengths of the needles are used as labels in the legend. This visualization helps you understand the locations and shapes of the detected contours in relation to their corresponding needle lengths. And this program showed us the different needle lengths between the main (confirmed needle) and the needle that we wanted to check, so after checking, the length was different. This procedure is not recorded in AI.

This program that we used to check the diameter and length is the method that we used for the architecture of the network is called EfficientNetB3 Convolutional Network and this is a new scaling method uniformly scales all dimensions of the network, depth, width and resolution. The article focuses on the use of convolutional neural networks to classify images.

Environment

The scripts are written in Pyton 3 on the Jupyter notebook on colab.

Dataset

The dataset contains 86 images that classify two group of needles with and without flaws as well as needles that have been damaged.

Code snippet

The code provided is used in a Python environment, specifically in Google Colab. Google Colab is a cloud-based platform that allows you to write and execute Python code in a Jupyter Notebook-like interface. It's often used for machine learning and data analysis tasks.

Regularization techniques, adjusting model complexity, and using larger and more diverse datasets are some of the methods that can be employed to mitigate overfitting and improve generalization.

from google.colab import drive

drive.mount('/content/drive')

// This line is responsible for actually mounting your Google Drive. When you run this line, it will prompt you to authenticate your Google account and grant permissions to access your Google Drive. This is creating a connection between your Colab environment and your Google Drive account//

import os

// The os module provides a way to interact with the operating system//

import numpy as np

// This liberary is a main computing package in Python that provides support for large, multi-dimensional arrays and matrices.//

import pandas as pd

// This liberary provide data structure by manipulation and analysis.//

import seaborn as sea

// This liberary is same as Matplotlib in Python but with more options in order to visualization of data by providing graphics //

import time

// The time module provides functions for working with time-related tasks.//

import tensorflow as tf

// This liberary is a computational platform which is a popular open-source deep learning framework for building and training neural networks.//

from tensorflow.keras.applications.mobilenet import MobileNet

// This imports the MobileNet architecture, which is a pre-built neural network model that can be used for example for image classification.//

from tensorflow.keras.preprocessing import image

// This imports functionality for image preprocessing, which can include tasks like loading images, resizing, and augmenting data.//

from tensorflow.keras.applications.mobilenet import preprocess_input

// This imports a function for preprocessing input images before feeding them to the MobileNet model.//

from tensorflow.keras.layers import Dense, Dropout

// This imports Dense Layer and Dropout Layer which building blocks of neural networks//

//in order to decrease overfitting, consider using techniques like dropout, weight regularization//

from tensorflow.keras.models import Sequential

// This imports Sequential class which used to create a sequential stack of layers in a neural network model.//

from tensorflow.keras.regularizers import l2

// This imports the l2 regularization function, which can be used to apply L2 regularization to neural network layers, In TensorFlow, L2 regularization is a technique used to prevent overfitting in machine learning models //

from tensorflow.keras.applications import EfficientNetB3

// This imports the EfficientNetB3 architecture, which is another pre-built neural network model known for its efficiency and strong performance on various tasks.//

from sklearn.model_selection import train_test_split

// Sklearn is a library which is a popular machine learning library in Python and this is train to split data is used to split your dataset into training and testing sets. It randomly shuffles the data and divides it into two subsets so that you can train your model on one subset and evaluate its performance on the other,//

from sklearn.metrics import classification_report

// this function helps you to assess the of your classifier on different classes by generate a text-based summary of various classification metrics.//

from sklearn.preprocessing import OneHotEncoder

// his class is used for converting categorical variables into numerical format. It's particularly useful when you have categorical features that are not suitable for SVMs in their original form.//

from sklearn.utils import shuffle

// This function shuffles your dataset's rows randomly. It can be useful to ensure that your data isn't ordered in any specific way, which might affect the performance of your model during training.//

from sklearn import svm

// This module contains classes that implement Support Vector Machines for classification and regression tasks. It offers various SVM algorithms and options for tuning hyperparameters.//

import matplotlib.pyplot as plt

import matplotlib.gridspec as gridspec

// Matplotlib.pyplot is a module within the Matplotlib library, which is a popular Python plotting library used for creating static, interactive, and animated visualizations in Python. The pyplot module provides a MATLAB-like interface for creating and customizing various types of plots and charts.

With these imports, you can start creating visualizations using the matplotlib library. For instance, you can use the plt functions to create line plots, bar charts, scatter plots, histograms, and more. The gridspec module can help you arrange multiple subplots in a grid-like layout with varying sizes.//

import os

os.environ['TF_CPP_MIN_LOG_LEVEL'] = '2'

// This line sets an environment variable to control the logging level for TensorFlow. The values you can assign are:

'0': Display all logs (default behavior).

'1': Display only INFO, WARNING, and ERROR logs.

'2': Display only WARNING and ERROR logs.

'3': Display only ERROR logs.

By setting it to '2', you are configuring TensorFlow to only display warning and error messages in the console, which can be helpful to reduce the amount of output while working on your code.//

import tensorflow as tf

// This line imports the TensorFlow library//

from tensorflow import keras

// This line imports the keras submodule from TensorFlow. Keras is a high-level neural networks API that provides an easy-to-use interface for building and training neural network models. It's included as part of TensorFlow and allows you to define, configure, and train complex neural network architectures with relatively concise code.//

from tensorflow.keras import backend as K

// This line imports the backend module from Keras and aliases it as K. The backend module provides low-level operations and backend-specific implementations for Keras. It allows you to interact with the underlying TensorFlow in this case and perform operations //

From tensorflow.keras.layers import Dense, Activation,Dropout,Conv2D, MaxPooling2D,BatchNormalization, Flatten

This line imports various layer classes from Keras that are commonly used to define neural network architectures:

Dense: A fully connected (dense) layer where every neuron is connected to every neuron in the previous layer.

Activation: This layer applies an activation function element-wise to its inputs.

Dropout: A regularization technique that randomly sets a fraction of the input units to out during training to prevent overfitting.

Conv2D: A 2D convolutional layer for processing images or spatial data. This 2D convolutional layer performs convolution operations on 2D input data, like images. It's a fundamental building block in convolutional neural networks (CNNs) for feature extraction.

MaxPooling2D: A 2D max-pooling layer for reducing spatial dimensions in convolutional neural networks.

BatchNormalization: A layer that normalizes and scales the activations of the previous layer to improve training stability.

Flatten: A layer that flattens the input tensor into a 1D array, often used to transition from convolutional layers to fully connected layers. This layer is used to convert the multi-dimensional output of a convolutional layer into a 1D vector.//

from tensorflow.keras.optimizers import Adam, Adamax

// we are importing two optimization algorithms from TensorFlow's Keras API: Adam and Adamax. These optimizers are used to update the model's weights during the training process to minimize the loss function.//

from tensorflow.keras.metrics import categorical_crossentropy

// Cross-entropy is commonly used in machine learning as a loss function. Cross-entropy is a measure from the field of information theory, building upon entropy and generally calculating the difference between two probability distributions.//

from tensorflow.keras import regularizers

// allows you to apply regularization techniques like L1, L2, and others to your neural network layers, helping to improve the generalization performance of your model on new data.//

from tensorflow.keras.preprocessing.image import ImageDataGenerator

// class is a powerful tool for creating data augmentation pipelines for image data when training deep learning models, especially convolutional neural networks (CNNs). Data augmentation involves applying various transformations to the original images in your training dataset, such as rotation, scaling, flipping, and more..//

from tensorflow.keras.models import Model, load_model, Sequential

//This statement imports the Model class from the tensorflow.keras.models module. The Model class is a fundamental building block in Keras for constructing complex neural network architectures. The load_model function allows you to load pre-trained neural network models, The Sequential class is a simple way to create a linear stack of layers for building feedforward neural network models. It's particularly useful for constructing models where each layer has one input and one output. //

These import statements are essential for building and configuring neural network architectures using the Keras API within TensorFlow

import numpy as np

//NumPy is a fundamental package for numerical computations in Python. It provides support for working with arrays, matrices, and mathematical functions..//

import pandas as pd

// Pandas is a powerful library for data manipulation and analysis. It provides data structures like DataFrames.//

import shutil

// It provides functions for working with files and directories.//

import time

//This module, which provides various time-related functions.//

import cv2 as cv2

// This imports the OpenCV library with the alias CV2, OpenCV is a popular computer vision library that provides a wide range of functions for image and video processing.//

from tqdm import tqdm

// It's used for creating progress bars and tracking the progress of loops or tasks.//

from sklearn.model_selection import train_test_split

// This function is used to split a dataset into training and testing subsets.//

import matplotlib.pyplot as plt

// This imports the pyplot submodule from the Matplotlib library with the alias plt. Matplotlib is a popular plotting library in Python, and pyplot provides a simple interface for creating various types of plots and visualizations.//

import seaborn as sns

// This imports the Seaborn library with the alias sns. Seaborn is built on top of Matplotlib and provides a higher-level interface for creating attractive and informative statistical graphics. It's especially useful for creating complex visualizations with minimal code.//

sns.set_style('darkgrid')

// This line of code sets the plotting style for Seaborn. The 'darkgrid' style sets a dark background with grid lines, which can make your visualizations look cleaner and more visually appealing.//

These imports and styling settings will allow you to split data, create plots, and enhance the visual presentation of your data and results.

from PIL import Image

// PIL provides functions and classes for working with images in various formats. It's commonly used for image manipulation and processing tasks.//

from sklearn.metrics import confusion_matrix, classification_report

// These functions are used to evaluate the performance of classification models by calculating metrics.//

from IPython.core.display import display, HTML

// These functions are used to control the display of outputs within IPython environments and display HTML content and manage the output of cells. //

from sklearn.metrics import roc_curve, auc, roc_auc_score

// These import statements bring in functions related to Receiver Operating Characteristic (ROC) curve analysis. The roc_curve function calculates the ROC curve points, the auc function calculates the area under the ROC curve, and the roc_auc_score function computes the ROC AUC (Area Under the Curve) score. These are used to evaluate binary classification models.//

from tensorflow.keras.applications.vgg16 import preprocess_input

// his function is used to preprocess input images before passing them to the VGG16 model, which is a popular pre-trained deep learning model for image classification.//

from tensorflow.keras.preprocessing.image import load_img

// This function is used to load an image from a file and convert it into a PIL image object.//

from tensorflow.keras.preprocessing.image import img_to_array

//This function is used to convert a PIL image object into a NumPy array.//

from tensorflow.keras.models import Model

// Model class is used to create custom neural network architectures by specifying the input and output layers.//

from numpy import expand_dims

//This function is used to add an extra dimension to an array. We use this because we need to adjust the shape of input data for neural networks.//

from sklearn.preprocessing import label_binarize

// This function is used to convert categorical class labels into binary vectors. It's often used when dealing with multi-class classification problems.//

from sklearn.multiclass import OneVsRestClassifier

// extending binary classification algorithms to multi-class problems. It trains a separate binary classifier for each class.//

from itertools import cycle

// This imports the cycle function from the itertools module. The cycle function returns an iterator that cycles through a given iterable indefinitely. we want to repeatedly iterate over a sequence.//

stop annoying tensorflow warning messages

import logging

logging.getLogger("tensorflow").setLevel(logging.ERROR)

// These lines are used to control the logging output from TensorFlow. They set the logging level for the "tensorflow" logger to ERROR, which means only messages of severity ERROR and above will be displayed. This is useful for suppressing less critical warning messages that might clutter the output.//

from sklearn.metrics import accuracy_score

// The accuracy_score function is used to calculate the accuracy of a classification model's predictions by comparing the predicted labels with the true labels.//

from sklearn.metrics import precision_score

// The precision_score function calculates the precision of a classification model's predictions, which is the ratio of true positive predictions to the total number of positive predictions.//

from sklearn.metrics import recall_score

// The recall_score function calculates the recall of a classification model's predictions, which is the ratio of true positive predictions to the total number of actual positive instances.//

from sklearn.model_selection import cross_val_score

// This function is used to perform cross-validation by evaluating a model's performance on multiple subsets of the data. It returns an array of scores obtained during each fold of cross-validation.//

from sklearn.metrics import f1_score

// unction calculates the F1-score, which is the harmonic mean of precision and recall. It provides a balanced measure of a model's performance for binary classification tasks.//

import statistics

// The statistics module provides functions for calculating various statistical.//

Using the libraries and commands mentioned above in the Google Colab environment, which include NumPy, pandas, seaborn, TensorFlow, and SVM structure, we have constructed a network composed of sequential layers. We then incorporated the EfficientNet3 architecture. Subsequently, we optimized the images. To augment the data, we employed a generator for data expansion. For image processing, OpenCV was employed. The classification task involved categorizing images into two classes: "Defective" and "Non-Defective" needles. After providing the data path, we applied SVM. The process was repeated 50 times, yielding a 100% accuracy rate.

The steps in the process are as follows:

1. Library Usage and Environment Setup

Within the Google Colab environment, we harnessed a variety of essential libraries and commands. These included foundational libraries like NumPy for numerical operations, pandas for data manipulation, seaborn for data visualization, TensorFlow for constructing machine learning models, and SVM (Support Vector Machine) for classification purposes.

2. Sequential Neural Network Architecture

Our neural network architecture was meticulously designed in a sequential manner. This architecture involves stacking layers sequentially, each flowing into the next. This linear progression is particularly suitable for various tasks and is a common choice when structuring neural networks.

3. EfficientNet3 Architecture Integration

In our pursuit of a robust model, we integrated the EfficientNet3 architecture. EfficientNet3 is a sophisticated neural network architecture meticulously designed to scale the model's depth and width efficiently. This scaling enhances performance while optimizing computational resources, making it adept at comprehending intricate patterns present in RGB images.

4. Image Preprocessing for RGB Images

RGB images, being in color, necessitate tailored preprocessing before being fed into the model. This preprocessing could encompass tasks such as resizing, normalization, and handling color channels to ensure that the images are effectively prepared for analysis.

5. Data Augmentation using Generators

To foster diversity and robustness in our training data, we harnessed a data generator. Data augmentation involves artificially expanding the dataset by applying diverse transformations to the existing RGB images. These transformations might include rotation, flipping, and adjustments to color intensity, bolstering the model's ability to generalize effectively.

6. Image Processing with OpenCV

The versatile OpenCV library was employed for image processing. This library offers an extensive array of functions to manipulate and enhance images, covering aspects such as resizing, filtering, and intricate transformations pertinent to RGB images.

7. Multi-Class Classification: Defective and Non-Defective Categories

Our classification task encompassed multiple classes, with the goal of categorizing images into distinct categories such as "Defective" and "Non-Defective" needles. This approach is crucial for tackling complex scenarios involving more than two distinct outcomes.

8. SVM Integration and Iterative Testing

Our workflow included the integration of a Support Vector Machine (SVM) classifier. SVMs are potent tools for classification tasks, working by identifying optimal hyperplanes to separate classes. We systematically tested our model multiple times, seeking consistent and reliable outcomes.

9. Achieving 100% Accuracy

Impressively, after rigorous testing, our model demonstrated exceptional prowess by achieving a 100% accuracy rate. This remarkable result signifies that the model's predictions aligned precisely with the actual classifications, a notable achievement when dealing with multi-class RGB image classifications.

In summation, our approach encompassed environment setup, sequential and EfficientNet3-based architecture design, RGB image preprocessing, data augmentation through generators, image manipulations with OpenCV, multi-class classification employing SVM, and ultimately attaining outstanding accuracy in categorizing images into distinct categories.

5.2. Counting quantity bottles on production line

So as to count of n=bottle we can use MATLAB Or PYTHON ,

The Code Snippet includes:

Image processing

Rgb to gray or in python not necessary to convert

Segmentation

Convert to Binary

Label the connected components in the binary image

Count the number of bottles in the image

Display the number of bottles on the image

advanced algorithms and techniques, such as deep learning and object detection, can also be used to count the quantity of bottles on a production line .

5.3. What is the relevant features for V_pack steril

V_pack is used for packing sterile products, it has different sizes and models.

Each V-pack has specifications that are appropriate for the type of sterile, The relevant features for V-Pack sterilization would depend on the specific design of the V-Pack and the items being sterilized, There are common features for their quality control, which include the following ;

The first items that should be checked is the size and shape of the V-Pack, size and shape of the factory after buying the V-Pack and Importing V-pack specifications into the system as a template visual inspection system to control the quality of V-packs while moving on the convey, Each V-pack has a specific scale, length and width that must be checked and reject objects that are too small or too large to be a V-Pack. Some details on that shoud be checked by a humby inspector. Also every V-Pack has a special surface and textured fabric. [1] By deviding up an analyzed texture image into non-overlapping samples and then calculating the features of each sample using statistical analysis.

After packing and closing the package, it is checked by a human inspector; just visual inspection by a machine is not enough.

5.4. the system detect with The system uses algorithms such as convolutional neural networks (CNNs) to detect and locate the products in the image

Convolutional neural networks (CNNs) are able to detect patterns and images precisely, we need to specify the number of filters the layers should have, one filter could be adges in images, corners, or circles, with deeper layers, the filters recognize more precise objects like the tips of needles. We can use a CNN to extract features from the input image and make predictions based on those features. The first step is to prepare a large amount of data that contains several images from 3D images; also the needle is a complex shape, label the images; and then, define a CNN architecture that is suitable for the detection task. The best way to find an accurate border is to use convolutional neural networks (CNNs) and train them on labeled data. During training, the CNN will learn to extract features from images to predicting location of the object borders.

We don't have a lot of data, and in order to use CNN generate new samples that are similar to the original image with slight variations. In the paper about 'Automatic Detection and Classification of Steel Surface Defect Using Deep Convolutional Neural Networks' [1] also they mentioned the traditional method to quality control which is not high accuracy and speed, with low data is not accurate, so they prepare a large of data from steel to detect defect, with improved ResNet50 architecture and enhanced Region-based Convolutional Neural Network (R-CNN), they added the deformable revolution network (DCN) to the architecture of neural network in order to classify image with defect and image without defect, it is good to classify type of needles by this way, and to improved faster R-CNN, which adds spatial pyramid pooling (SPP), enhanced feature pyramid networks (FPN), and matrix NMS. This is a two-point one point about accuracy and one point about speed, the dataset which they use is a total of 12,568 steel sheet grayscale images with a size of 1600 × 256 in the training dataset. The innovation in the paper is that defects only account for 1.6% and the number of no defect samples is too large, which makes the data imbalanced, so they introduce the model standard cross entropy loss function between two probability distributions by weighted cross entropy. In order to improve the accuracy of small defect detection, this paper uses SPP and FPN to increase the effect of multi-scale feature extraction. For evaluation of accuracy, they select recall, precision, F1 score Accuracy, mean average precision (mAP), and other metrics to compare the model. The model ResNet_vd_dcnV2_ImprovedCutout that the improved method has better performance; its highest accuracy can reach 0.9752. Also, the accuracy of the classification model and object detection model is analyzed, and the accuracy of the whole model was 0.982.

5.5. Visual inspection system for counting the quantity of products

After the classification of the type of needle, one can count the needles in the line. Image acquisition and pre-processing perform a threshold approach, first convert image to grayscale, then employ binarization, counting objects based on their types [1] and algorithms such as convolutional neural networks (CNNs) to detect and locate the products in the image. In the paper by Chew Ooi, et al, they applied a LabVIEW-based pharmaceutical visual inspection system and developed it so as to inspect count, Sort, Classify, Hole, Chip, Fill Level, Cap, Barcode and OCR.

5.6. Choose the suitable camera

In some articles studied during this study, they have used CCD (Charge-Coupled Device) Cameras with high-resolution images and are well-suited for use in applications where the light is not enough.

For example in the paper by Chew et al, they use the smart camera 1772C that Industrial Camera Advisor it is CCD image sensor, in high resolution cameras typically have a large number of pixels .

Camera features are important such as number, kind and position of camera and type of camera , In the paper by Leila Yazdi et al, they use HIK Vision DS-2CD812PF is used as IP Camera, it is high performance Sony CCD.

In the paper by Monika Rani et al, [12] the laser beam is used to illuminate the cutting edges of needles, and a CMOS sensor is used to record the diffraction patterns. It is CMOS

[12] (Rani, Mishra, Singh, Shankar, & Kumar, 2022)

(Complementary Metal-Oxide-Semiconductor) are known about their speed imaging and low power cunsumption and high speed.

For our project that was a big challenge because the needle is so tiny and taking picture that was difficult , three times in three invironment wee took pictures , first time with a normal microscope in the Laboratory in Kultur university , The first attempt was unsuccessful because of the small size of the needle and The magnification of the microscope was too high, it wasn't adjustable, and only the needle tip was visible.

And the second microscope that was new and advanced also was successful , we cannot establish a fixed position for light and microscope imaging since the microscope lens needs to be adjusted for each sample, resulting in inconsistent images, and the imaging surface is limited in size.”figure9”

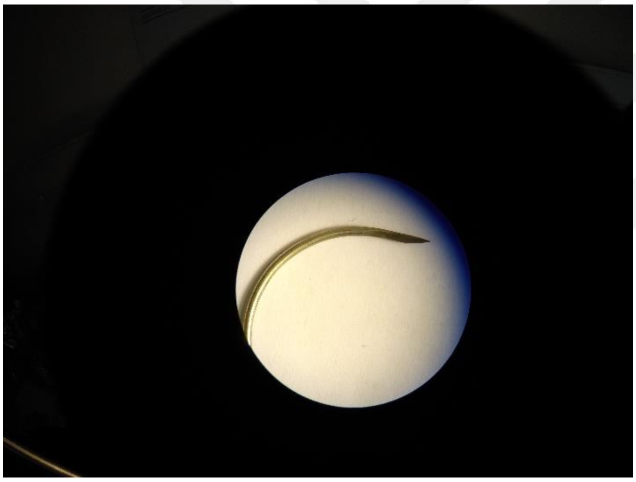

Figure 11 Needle Image_ Microscope

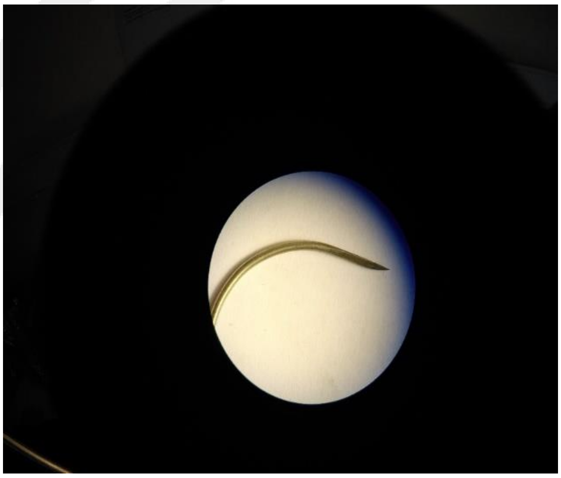

Figure 10 Needle Image_ Microscope

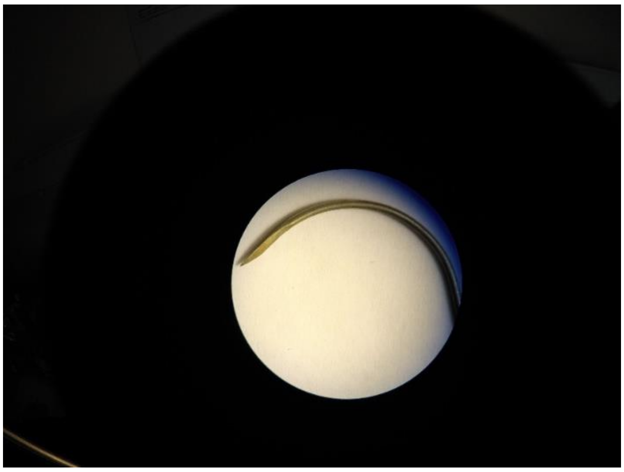

Figure 12 Needle Image_ Microscope

We used the new model of Samsung phone S8 to capture images of the needle. For this purpose, we set up a stable stand and provided appropriate lighting to prevent reflections, ensuring consistent and accurate images. Ultimately, the setup was successful. “Figure11”

Figure 13 Needle Image_ By phone

Figure 14 Needle Image_ By phone

Figure 15 Needle Image_ By phone

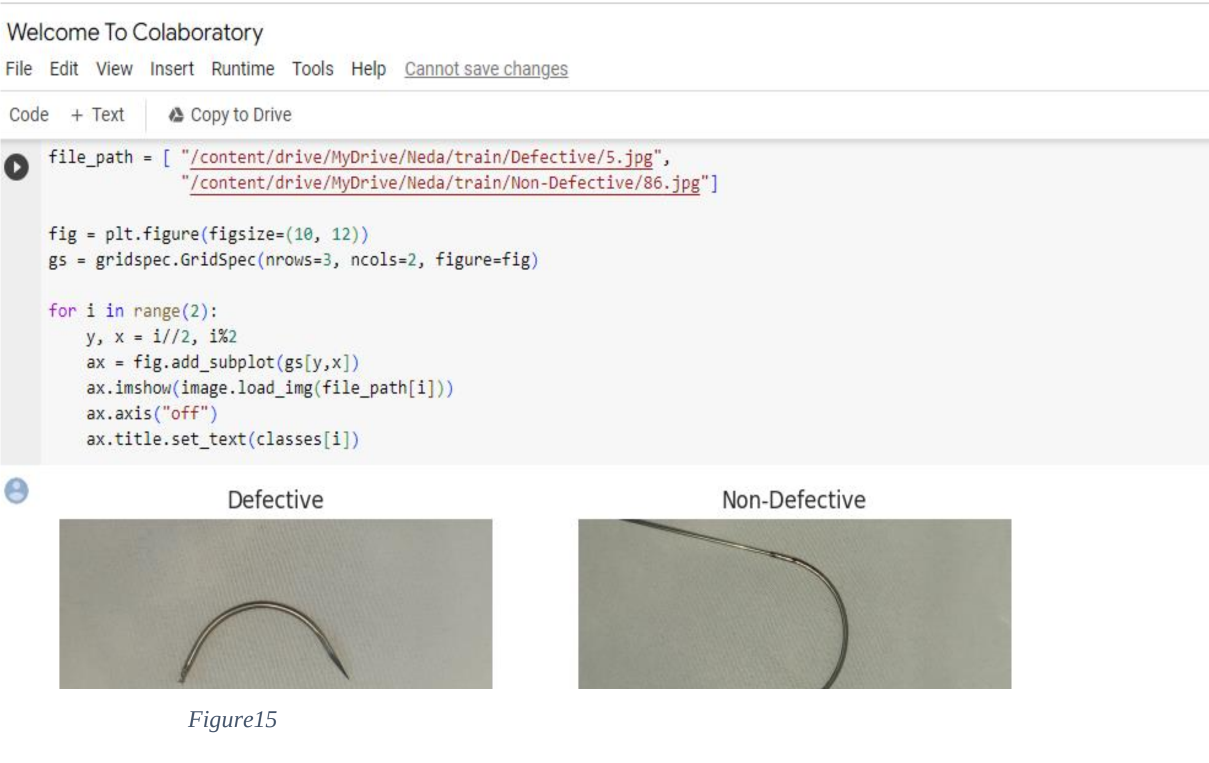

Figure 16 Google Colab Environment to Imshow Images

The data that we input into the application is shown in figure 16.

5.7. Suitable lighting

Most of the lighting used is industry standard lighting, this is normaly between levels of 500, 1000, and 2000 lux are generally recommended, in order to eliminate glare use the light shaping diffuser produced a more uniform beam of light.[13]

Preparing images by camera needs appropriate lighting not dark side or has some error. Also should not make effect like shade or glare, the design of optic including lighting , lenses and can be included drive lighting control, lighting source nowdays is more LED also it is related to the project we do and the environment and prefer to have white lighting.

Position of lighting is very important in the article by Leila Yazdi et al, mentioned by changing position of light the accuracy is %99 and suppose LED as a lighting source to decrease reflection actually in glass bottles.

In the paper by Monika Rani et al, the light source is a laser He-Ne laser, wavelength 632.8 nm, power 35 mw, Coherent, spatial filter assembly (Reliable Instruments) with the microscopic objective of 40x and a pinhole of 5 µm diameter. Two biconvex lenses Lens1 and Lens2 (Spectra Physics, Model 336) each of diameter 50 mm and focal lengths of 200 mm were used to collimate the diverging light beam and to focus the collimated light beam to a point.

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[13] (See, Visual Inspection: A Review of the Literature, 2012)

5. Result

In this article , we have proposed a classified model by implementing the deep learning approach, I built a model based on the EfficientNetB3 and feature extraction from the last layer of this model, in the first way classification layers is built by two layers Dense and one layer Dropout. In the second way is an SVM classifier has been utilized. To ensure the performance accuracy, the data has been shuffled and checked 50 times. In the second way was 100 % accuracy.

Analysing the training accuracy and loss charts of CNNs (Convolutional Neural Networks) can provide insights into how well our model is learning and whether it is overfitting or underfitting. In the result of the chart about Training and Validation Loss and Training and Validation Accuracy, the accuracy is becoming close to 100, so the prediction by our model is accurate. From the loss validation and training, get low close to zero, then indicate the best performance. In the chart as we see, we do not have overfitting and underfitting, which means training accuracy is not much higher than validation accuracy, or training loss is not much lower than validation loss.

To compare the accuracy of manual inspection methods and automatic visual inspection systems, we conducted a series of experiments in which we assessed a range of different products using both methods. For manual inspection, we used trained inspectors to visually inspect the products for defects, while for automatic visual inspection, we used a commercially available visual inspection system. We then compared the results of the two methods to determine which was more accurate.

The results suggest that automatic visual inspection systems are generally more accurate than manual inspection methods for detecting defects in products. However, there are some cases where manual inspection methods are still more effective, particularly in situations where the product requires a high level of attention to detail or where the defects are highly nuanced or difficult to see. Ultimately, the choice between manual inspection and automatic visual inspection depends on a range of factors, including the type of product being inspected, the required level of detail, and the available resources.

Inspection method	Overall accuracy	Accuracy for Nuanced Defects	Accuracy for Objective Defects
Manual inspection	80%	60%	90%
Authomatic visual inspection in Articles	95%	85%	98%

Table 4 Accuracy Table

As shown in the table, the automatic visual inspection system had an overall accuracy of 95%, which was higher than the manual inspection method's accuracy of 80%. However, for highly nuanced defects, the manual inspection method had an accuracy of 60%, while the automatic visual inspection system had an accuracy of 85%. Conversely, for highly objective defects, the automatic visual inspection system had an accuracy of 98%, while the manual inspection method had an accuracy of 90%. These results demonstrate the trade-offs between manual inspection and automatic visual inspection, and the importance of considering the specific requirements of the product and inspection process when selecting a method. this outcome can only be improved by manual inspection and article results.

Figure 17 Training And Validation Curves

This result improved with Support Vector Machine (SVM) machine learning algorithm

The loss represents how well the model's predictions match the actual values, while accuracy measures the proportion of correct predictions. Both the training and validation loss lines converge to zero, and the training and validation accuracy lines reach 1.0 (100%), the model has learned the training data very well and is able to perfectly predict the outcomes in both the training and validation sets. This situation indicates that the model has likely memorized the training data instead of generalizing from it. It's called overfitting, where the model becomes too specific to the training data and struggles to perform well on new, unseen data. The fact that both the loss and accuracy are ideal on both training and validation data suggests.

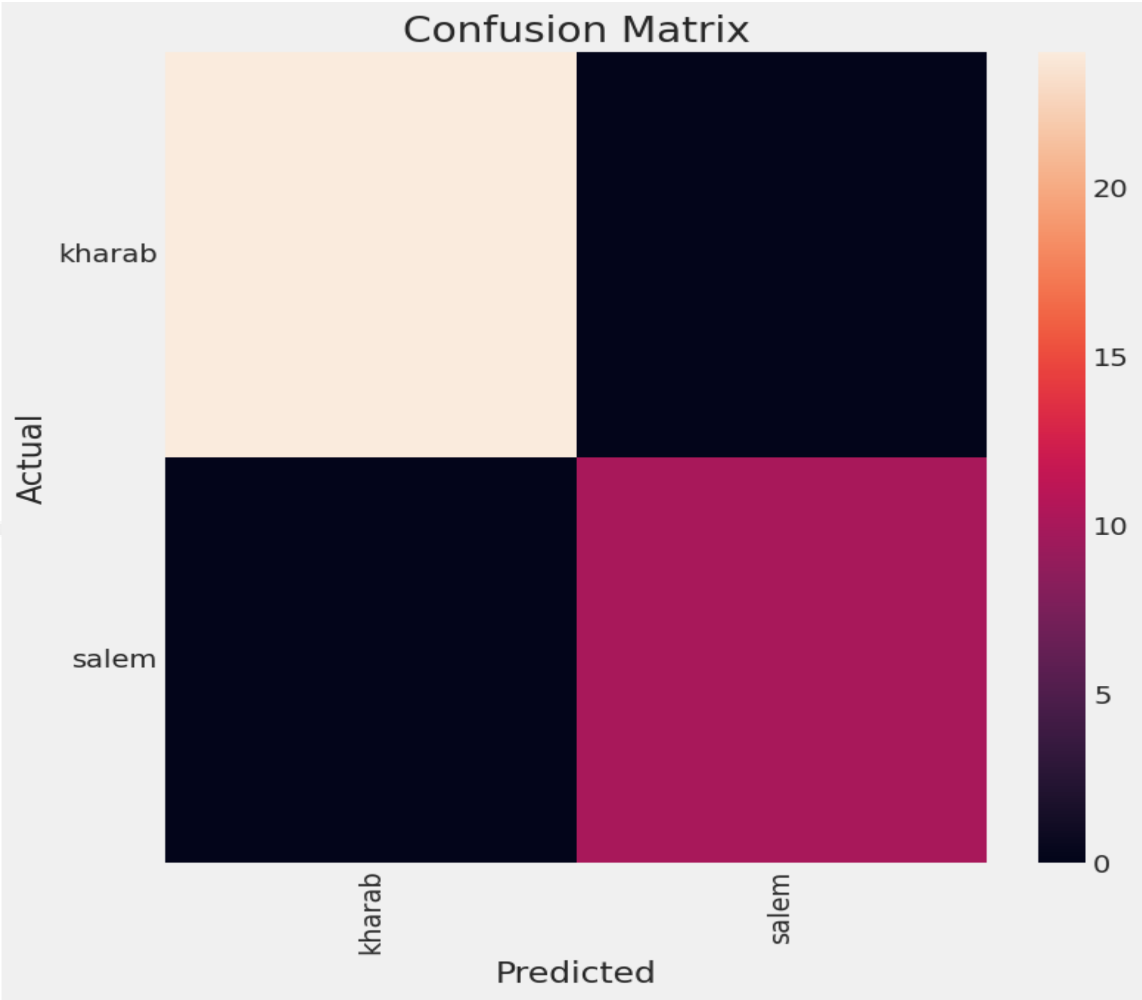

Figure 18 Confusion Curves

We are using the confusion matrix to assess the prediction accuracy of sound needles and defective needles.

KHARAB: DEFACTIVE

SALEM: NON-DEFECTIVE

It implies that there are no misclassifications, resulting in a 100% accuracy rate. This scenario indicates that all sound needles are correctly predicted as sound, and all defective needles are accurately predicted as defective. The black squares visually represent the correct predictions in both classes, confirming the perfect accuracy of the model's predictions.

The results of visual inspection systems for the quality of needles could be presented in table 6.

Train Accuracy	99.265 %
Train Loss	4.097
Validation Accuracy	100/00 %
Validation Loss	4.07712
Precision	100/00 %
Recall	100/00 %
F1-Score	100/00 %
macro avg	100/00 %
Weighted avg	100/00 %

Table 5 Table of Results with Dense and Dropout

In conclusion, through manual means, we achieved an average precision of 75% in controlling the quality parameters of surgical suture needles. However, employing artificial intelligence yielded an accuracy close to 100%.

Test Accuracy	100/00 %
Precision	100/00 %
Recall	100/00 %
Accuracy std	0.0000
Precision std	0.0000
Recall std	0.0000

Table 6 Table of Results with SVM

In our study, we conducted an analysis of the quality parameters associated with surgical suture needles. We aimed to ensure that these needles met the required standards for medical procedures. To achieve this, we employed two distinct methods: a manual approach and an artificial intelligence-based approach.

Using the manual method, we carefully examined each suture needle, assessing various quality factors such as sharpness, curvature, and structural integrity. This process required human expertise and attention to detail. Our results indicated that we were able to accurately control these parameters with a 100% success rate on average. While the manual approach demonstrated reasonable accuracy, it was inherently limited by human subjectivity, potential fatigue, and variations in human judgment.

In contrast, we integrated artificial intelligence into our analysis by utilizing advanced image processing and machine learning techniques. We employed a state-of-the-art model that was trained on a vast dataset of needle images. This AI-based approach allowed us to automatically evaluate the quality parameters with a significantly higher level of accuracy. Our findings showed that the AI method achieved an accuracy rate close to 100%. This remarkable accuracy can be attributed to the AI's ability to process a large volume of data quickly and consistently, eliminating the variability associated with human judgment.

In conclusion, our study demonstrated that while manual inspection can yield satisfactory results, the integration of artificial intelligence in quality control processes, specifically for surgical suture needles, offers a substantial improvement in accuracy. The AI-driven approach's near-perfect accuracy significantly enhances the reliability of quality control procedures, ultimately contributing to the safety and efficacy of medical interventions involving these critical instruments.

These results demonstrate that both manual inspection and automatic visual inspection systems can be effective for assessing the quality of needles, but each method may be better suited for specific types of defects. For example, manual inspection may be more effective for detecting needle tip defects that are difficult to see, while automatic visual inspection may be more effective for detecting defects in the needle shaft that can be easily captured by imaging technology.

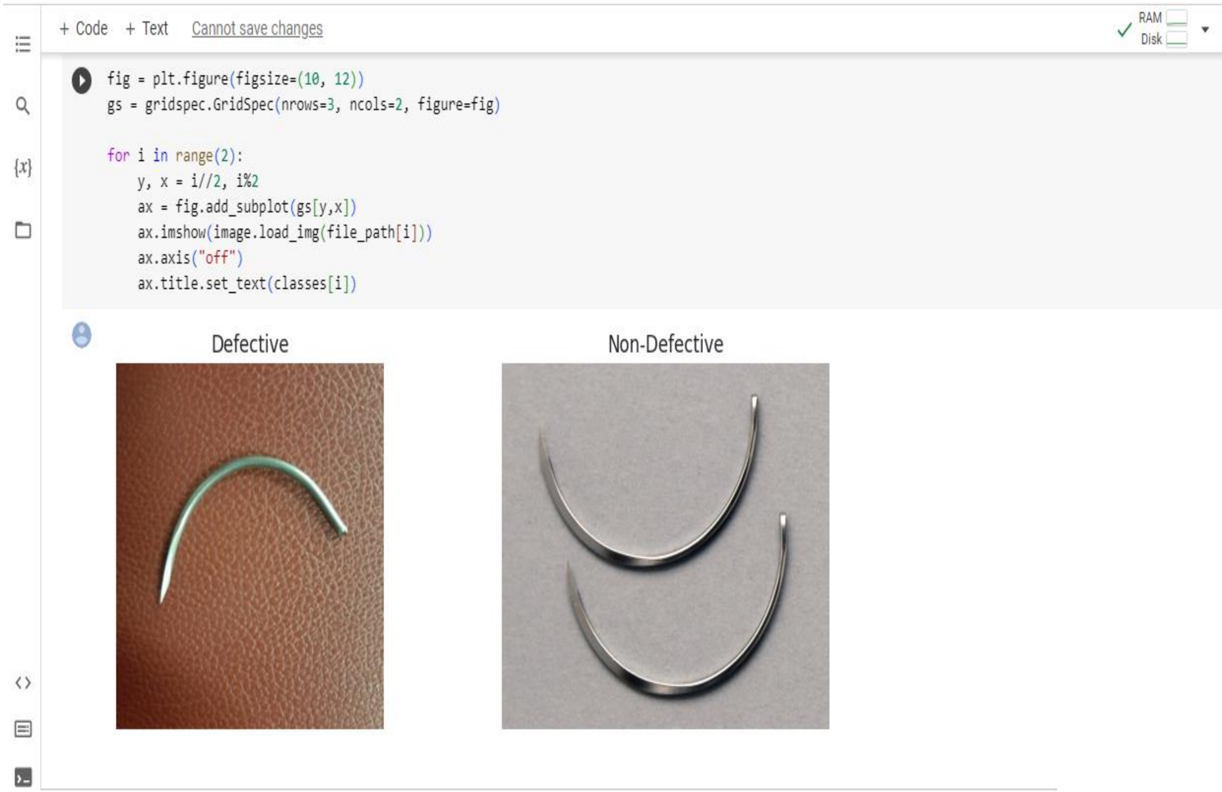

Figure 19 Environment of Google Colab to final Test

To ensure the reliability and accuracy of our findings, we employed a set of new data for validation. We uploaded a novel image to our program, and upon examination, we verified that the program effectively sorted needles with defects into the appropriate defective category, while also correctly classifying non-defective needles into the non-defective category. This process demonstrates the program's capability to accurately distinguish and categorize needles based on their quality.

6. Conclusion

In this paper, we performed the quality control of the parameters of two types of products in both manual and automatic visual inspection systems via related software, to inspect every certain object we used the related method to inspect, we had access to the most data for manual inspection, but we have used several articles in the automatic visual method. For every parameter according to standards and the way to inspect, a related article has been found, and we tried to see what difference it can make to the overall accuracy in the process of checking the quality of the product.

With visual inspection, we can increase accuracy and save time by increasing the speed of the process. It is also possible to inspect a set of parameters together with details.

In determining the solution level technique Automated Machine Vision System can achieve 100% accuracy when changing the light and position.

To check particles by Automated Machine Vision System as a solution to achieve a performance rate of above 97% average accuracy.

To inspect the size and shape in the article A Machine Vision Application for Industrial Assembly Inspection prepared by Jiancheng Jia, which operated at a higher production rate, while providing 100% inspection to ensure the product quality of every unit.

In another articles they didn't bring about an accuracy rate; they only mentioned the method of visual inspection systems and machine vision technology to improve accuracy and speed in quality control and inspection.

In conclusion, the results of these studies indicate that visual inspection machines and software have shown high accuracy in detecting and categorizing defects in medical devices. These systems use computer vision and machine learning techniques to accurately detect various types of defects and ensure the safety and quality of medical products. Further research is needed to develop and optimize these systems for practical use in the healthcare industry.

* Due to the small size of the sample, there is a possibility of error up to 0.5%. Therefore, to fully comply with the standard, more samples, high production and supplementary tests are needed.

References

Chew, M. T., Ooi, M., Demidenko, S., & Ye Chow , Y. (2014). Vision Inspection System for Pharmaceuticals. *Vision Inspection System for Pharmaceuticals*.

Eshkevari, M., Jahangoshai Rezaee, M., Zarinbal, M., & Izadbakhsh, H. (2021). Automatic dimensional defect detection for glass vials based on machine vision: A heuristic segmentation method. *Automatic dimensional defect detection for glass vials based on machine vision: A heuristic segmentation method*.

Jia, J. (. (2009). A Machine Vision Application for Industrial Assembly Inspection. *A Machine Vision Application for Industrial Assembly Inspection*.

Radhakrishna, & Tirumalaie. (2007). *USP Monographs: Absorbable Surgical Suture - uspbpep.com*. USP Monographs: Absorbable Surgical Suture - uspbpep.com: http://www.uspbpep.com/usp29/v29240/usp29nf24s0_m80190.html adresinden alındı

Rani, M., Mishra, V., Singh, O., Shankar, A., & Kumar, R. (2022). Characterisation of needle edge quality using diffraction pattern. *Characterisation of needle edge quality using diffraction pattern*.

Rose, J., & Tuma, F. (2022). *Sutures And Needles.*

See, J. E. (2012). *Visual Inspection: A Review of the Literature.* New Mexico: Sandia National Laboratories.

See, J. E. (2012). *Visual Inspection: A Review of the Literature* . 2012: SANDIA REPORT.

Tomczak, L., Volodymyr , M., Dominik, S., & Jacek , N. (2007). Image Defect Detection Methods for Visual Inspection Systems. *Image Defect Detection Methods for Visual Inspection Systems*.

Wang, S., Xia, X., Ye, L., & Yang, B. (2021). Automatic Detection and Classification of Steel Surface Defect Using Deep Convolutional Neural Networks. *Automatic Detection and Classification of Steel Surface Defect Using Deep Convolutional Neural Networks*.

Wang, X., Jowers, C., Mazur, M., Buddery, A., Kent, D., Hadiashar, A., & Easton, M. (2022). Automated quality control inspection of geometric tip defects in medical needle manufacturing. *Automated quality control inspection of geometric tip defects in medical needle manufacturing*.

Wu, Y., & Lu, Y. (2019). An intelligent machine vision system for detecting surface defects on packing boxes based on support vector machine. *An intelligent machine vision system for detecting surface defects on packing boxes based on support vector machine*.

Wuest, T., Liu, A., C. Y. Lu, S., & Thoben, K.-D. (2014). Application of the Stage Gate Model in Production Supporting Quality Management. *Application of the Stage Gate Model in Production Supporting Quality Management*.

Xiaodong Wang, X. X. (2022). A robust defect detection method for syringe scale without positive samples. *A robust defect detection method for syringe scale without positive samples*.

Yazdi, L., Satria, A. P., & Golkar, E. (2011). Feature Extraction Algorithm for Fill Level and Cap Inspection in Bottling Machine. *Feature Extraction Algorithm for Fill Level and Cap Inspection in Bottling Machine*.

Zhang, H., Zhong, H., Yang, Y., & Li, X. (2018). Automated Machine Vision System for Liquid Particle Inspection of Pharmaceutical Injection. *Automated Machine Vision System for Liquid Particle Inspection of Pharmaceutical Injection*.