

Irvin D Morales Quiñones  
 Advisor: Hector J. Cruzado, PhD, PE  
 Master in Engineering Management Program  
 Polytechnic University of Puerto Rico

## Abstract

This poster presents an innovative and automated system to improve the current inspection process of the balloon of the catheters. The human factor could affect the product quality because the operator output and accuracy are variable. The proposed inspection process includes a Keyence system, a rotary fixture, a Z-axis system, and an additional vision system that will identify defects. The new inspection process provides consistent quality and accuracy of the products.

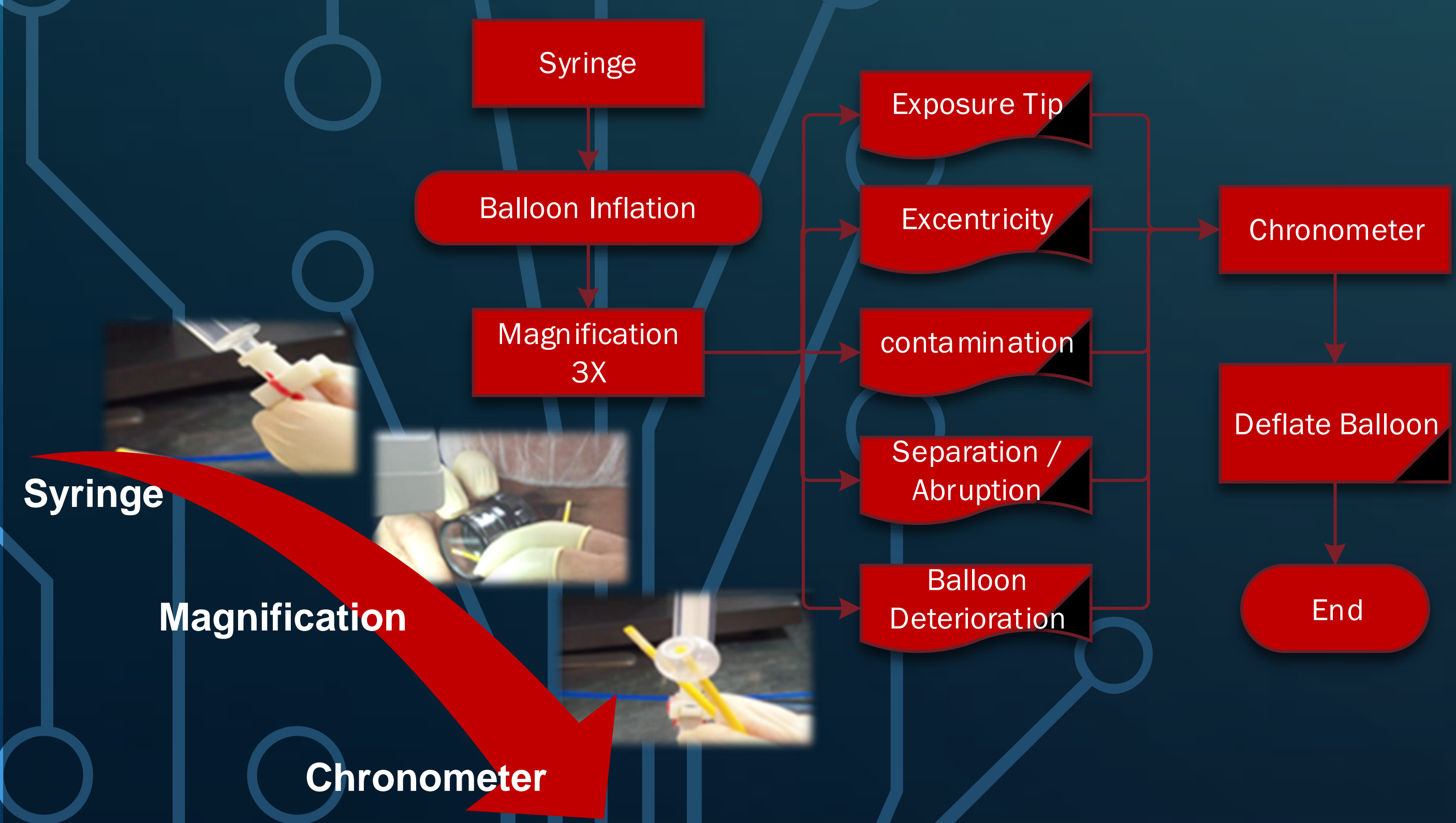
## Introduction

The current inspection process for the balloons of the catheters in a medical devices company is performed by an operator who accepts or rejects the product after visual inspection. For this reason, the product quality could be adversely affected by the human factor which is not the most suitable option in the pharmaceutical or medical devices industry. Emerging new technologies can improve this process to make it more effective. Using a combination of devices to capture and record product defects will make the inspection process more accurate. As a result, the use of a device with all these features will improve product quality and company profit.

## Problem Statement

The current inspection process for the balloons of the catheters in a medical devices company is performed by an operator who accepts or rejects the product after visual inspection.

## Current Inspection Process



## Analysis Approach

My approach to convince the team as well as the manufacturing supervisor was taken the current operator and requested to pull out his glasses and performed the inspection. That means that the operator should not forget their glasses even though the supervisor used another person that shows that the process is variable. As part of this analysis, it took the equipment (Magnification) and it could see that the lens has scratches which can cause distortion in the image during the inspection. Something that helps enough to convince the team was to repeat this exercise with two other operators and the way of each operator perform the inspection it was completely different.

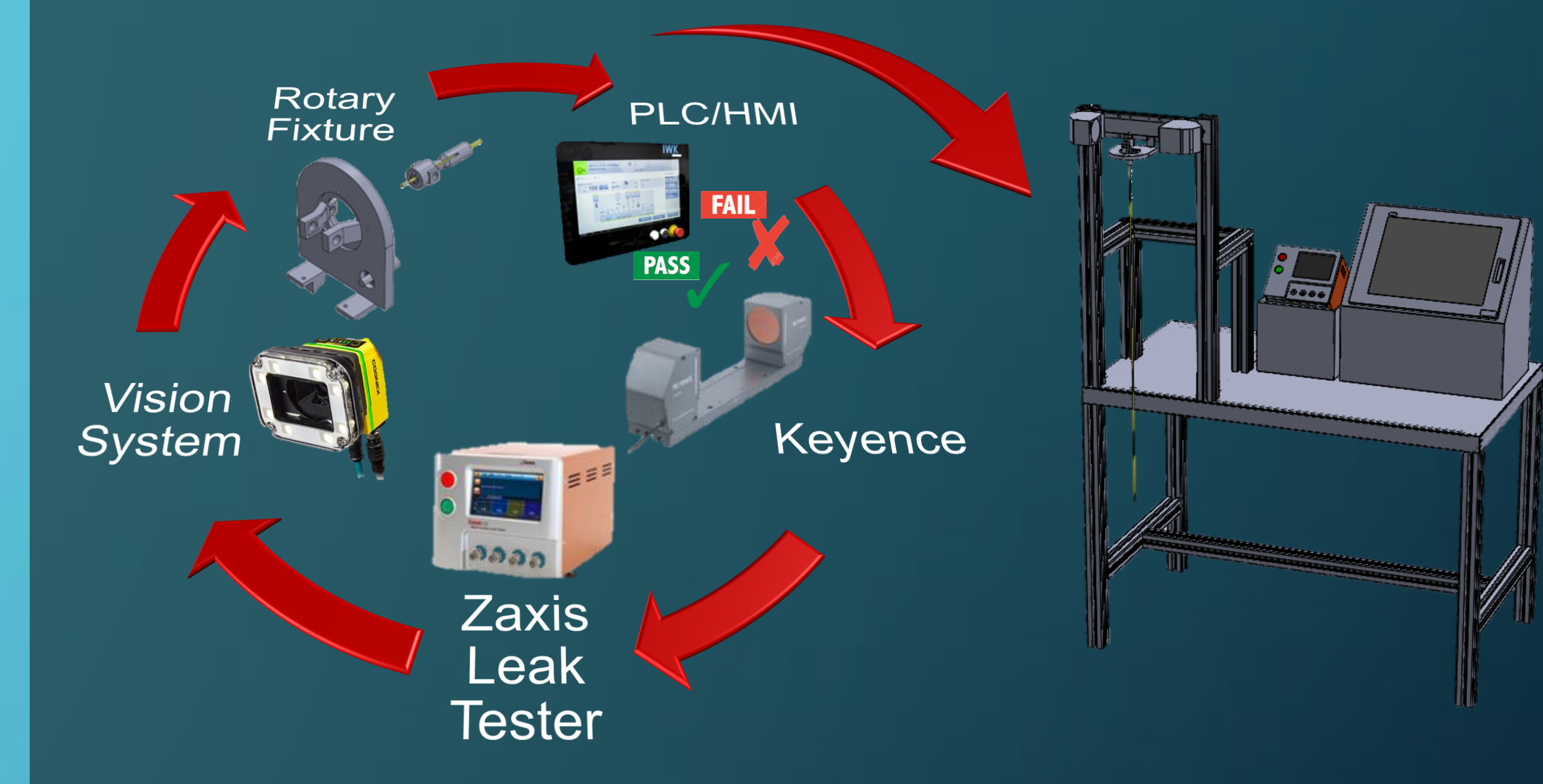
## Equipment Featuring

Equipment	Featuring	Cost \$
Keyence	Gaps between shoulder Eccentricity Tip exposure Storage data	\$23,000.00
A-axis Leak Tester	Leak Test Inflation Volume Deflation Time	\$25,000.00
Cognex Vision System	Defect (deterioration/abruption/particles) Presence of primer	\$13,600.00
PLC/HDMI	Communication between equipment's Accept or Reject Units notification	\$ 7,300.00
Rotary Fixture	Hold Catheter Rotate 180°	\$ 3,000.00
Workstation/Validation	N/A	\$12,200.00

## Results and Discussion

It was not established yet a test to perform a number of units to prove the variability of the process. For example, when the operators measure the gap between the balloon edge and shoulder of the tip. The measures were different for each operator even though, it was close between them and those measurements were into the specification. Possible alternatives to correct and improve the inspection process were discussed. First, it captures the dimensions during the inspection it will be using the Keyence system. Some advantages of this system are that it can record the images and store them if is necessary to review them later. Also, the system saves the data into a spreadsheet that can be used to do some statistical analysis of the variability of the measurement inspected. The programming, as well as the maintenance of this equipment, is easy to learn and do it without a specialized operator. Second, the Zaxis can be communicated with the system to inflates the balloon and to save the deflation time. The Cognex vision system which got the defect particles and primer presence is another system that is easy to program and do maintenance.

Finally, one part of the maintenance is the calibration which is important for the quality of the product and which was mentioned during the discussions about the things that can improve the quality of the product.



## Conclusion

The main goal of this project is to eliminate the human error, increase the quality and accuracy of the inspection process of the balloon into the catheters. To improve the quality is necessary to use a semi-automated or automated sophisticated equipment. Due to the new technologies is necessary to be less dependent on the humans to perform process like inspection or process in where there is needed to reject or accept any product. Some implications of the process that it was dependable of humans being rationale are: increase the price of products, poor quality and variability on the process. An important fact while developing a system as this one is combining different factors like vision, metrology, and leak test system that makes the project an expensive one. However, the final product will have a better quality which will guarantee that the customers trusted in the product.

## Bibliography

- Food and Drug Administration FDA. 1999 Guide to Inspection of Quality System, Quality System Inspection Technique, August 1999.
- Guardiola, B, A, *et al.*, "Machine Vision System: Automate.
- Food and Drug Administration FDA 1996 Medical Devices; Current Good Manufacturing Practices CGMP Final Rule; Quality System Regulation.
- Inspection & Metrology, *A thesis Submitted to the Faculty of the Graduate School of Western Carolina University in partial fulfillment of Requirements for the Degree of Master of Sciences.*
- Petkova, H 2010 World Health Organization 2010 Barriers to innovation in the field of medical devices August 2010.