Automatization of the Patch and Serter Installation System's Sensor Transference Step

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Abstract

The Patch and Serter Installation System is one of several semiautomated equipment composing the Cell Operating System Assembly Line of Medtronic, Juncos for Project Synergy. To trigger its automatic process, all required components must be manually placed into their respective nests. Once components placement has been completed, the Synergy sensor must be manually transferred to the patch nest using a vacuum drone tool. Any error that occurs from the sensor transference step forward will result in scrap. Through this project, it was intended to identify an automated solution capable of replacing the vacuum drone tool to reduce the human dependency and the potential human error during the Synergy sensor transference. Using as reference another system with similar application and discussing with an automated solutions manufacturer, a SCARA was identified as a potential replacement option and thereupon ordered. Currently, the SCARA is installed and within the official design of the system.

Introduction

When humans and animals eat, food travels through the digestive system to their stomach, where food is broken down into different nutrients. Sugar (or glucose) is one of these nutrients derived from food. Glucose is directly released into the consumer's bloodstream, where it afterwards moves into the interstitial fluid surrounding the body's cells [1]. The pancreas – the organ responsible for the digestion of food – produces a hormone known as insulin. As presented in Figure 1, insulin hormone acts as a key to open or unlock cells and allow glucose to flow into the cells [2]. As a result, reduced levels of glucose in blood are obtained.

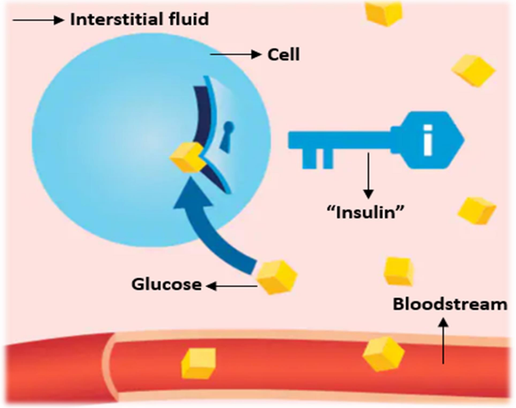

Figure 1
Glucose Flows into Cells with the Help of Insulin [2]

Once glucose enters the cells distributed throughout the body, it is converted into energy, which the body uses to execute work. However, in absence of insulin, cells remain closed and thus glucose remains in the bloodstream, causing increased levels of glucose in blood. This can occur either when the pancreas does not produce enough or any insulin at all (type 1 diabetes), or when the cells resist to react to the produced insulin (type 2 diabetes). As defined by the Center for Disease Control and Prevention (CD), diabetes is a chronic health condition that affects how the body turns food into energy [3]. According to the Pan American Health Organization (PAHO), about 1.5 million deaths worldwide are attributed to diabetes [4]. It is estimated that only half of the over 400 million people who suffer from this condition are aware of it.

Background

Medtronic, one of the pioneer companies providing the latest technologies for diabetes management, launched in 2017 the world's first hybrid closed loop system, the *MiniMed*^{TM} 670G. The *MiniMed*^{TM} 670G is a personalized automated insulin pump that works in conjunction to the *Guardian Sensor 3* (GS3), a continuous glucose monitoring sensor capable of notifying potentially dangerous glucose fluctuations (refer to Figure 2) [5].

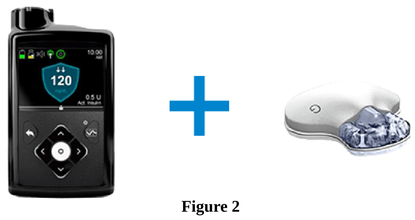

Figure 2
MiniMed^{TM} 670 G and Guardian Sensor 3 Combination

Currently, Medtronic Juncos Campus (MJC) is developing a next generation of the GS3 by means of Project Synergy. Project Synergy consists of a new completely disposable sensor device with a significant volume reduction in comparison to GS3, as shown in Figure 3. It leverages the GS3 flex design in a new form factor that greatly reduces user burden for insertion, wear, and replacements.

Figure 3
Next Generation of GS3: Project Synergy

Synergy sensor will not require over-tape since it will have an adhesive patch that will adhere to the patient's skin. Also, it has a new serter design for a simpler insertion process. Figure 4 illustrates the main differences between the Guardian and Synergy sensors and serters.

Figure 4
Next Generation of GS3: Project Synergy

The Patch and Serter Installation System is the second last computerized system used within the Synergy Cell Operating System (COS) Assembly Line at MJC. This system is responsible for three subprocesses:

1. The bonding of the Synergy sensor to the adhesive patch
2. The engagement of the serter assembly and the Synergy sensor
3. The planarity inspection of the final assembly

These three subprocesses are performed automatically. However, for the automatic process to begin, four manual subprocess must be executed before:

1. Carrier must be placed in its nest
2. Serter must be placed and locked in its nest
3. Adhesive patch must be placed in its nest
4. Synergy sensor must be transferred to patch nest

Problem

Before this work, the last manual subprocess of the Patch and Serter Installation System (hereinafter P&S) was performed using the customized vacuum drone tool presented in Figure 5. Whether human or machine, any error from this subprocess onwards resulted in scrap. Therefore, to reduce both the human dependency and the potential human error during the sensor transference, the main objective of this work was to identify an automated solution capable of replacing the vacuum drone

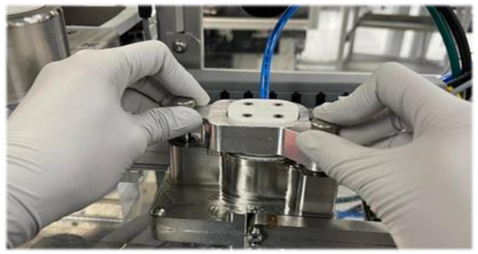

Figure 5
Vacuum Drone Tool

Methodology

To meet the production output of Project Synergy, each computerized system within the Synergy COS Assembly Line must be replicated several times, including the P&S. For the purpose of this work, the selected automated solution would be installed in the first P&S replica. This will allow to have two P&S with different transference mechanisms for real-time comparison.

Results and Discussion

Using another system with similar application (within the Synergy COS Assembly Line) as reference, the opportunity of replacing the vacuum drone with a selective compliance assembly robot arm (SCARA) was identified and presented for evaluation. SCARA robots are programmed manipulators used for pick-and-place and/or assembly operations requiring high accuracy and speed. Project-wise, MJC is familiarized with SCARA solutions by Epson®. Therefore, it was decided to evaluate the four Epson's SCARA series offered at the time: T-Series, RS-Series, LSB-Series, G-Series (refer to Figure 6).

Figure 6
Epson® SCARA Series [6]

Due to the actual design of the P&S, RS-Series were immediately discarded as potential replacements since these series are for ceiling mounting and the P&S requires tabletop mounting. In terms of payload, the SCARA shall be capable of transferring a weight of 2kg (Synergy sensor approximate weight). Additional specifications were directly discussed with the manufacturer. Based on their feedback, an Epson's SCARA T-Series was identified as the best option to replace the vacuum drone. An order was placed for the identified solution, which will be installed in the first P&S replica. The integration of this automated solution triggers additional design changes. Some of them can be appreciated in Figure 7, nests relocation and larger dimensions for example.

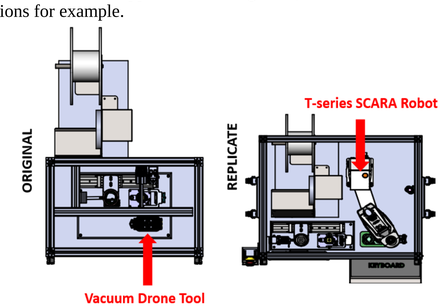

Figure 7
Schematic Top View Comparison of Original and Replica P&S

Conclusions

In early March 2022, a Factory Acceptance Test was performed to the new P&S (with SCARA). Overall, the results were satisfactory; the SCARA satisfactory replaced the vacuum drone. Besides reducing the potential human error, the ergonomic factor of the transference subprocess improved. There were no findings to attend related to the new transference mechanism. By the end of March 2022, the P&S replica arrived at MJC. Currently, the Installation Qualification (IQ) execution for this replica is underway. Figure 8 presents an actual image of the SCARA installed in the P&S replica.

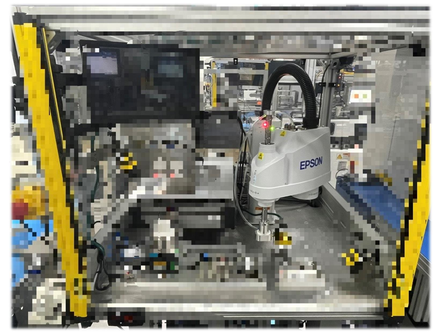

Figure 8
Schematic Top View Comparison of Original and Replica P&S

Based on the noticeable improvements, the P&S replica was standardized as the official design for this system. Therefore, all P&S replicas shall have the replicate design of Figure 7.

Future Work

After completing the IQ of the first P&S replica, yield and time studies will be carried out by Business Optimization Department to identify potential opportunities. As of today (October 2022), there are five more P&S replicas (with SCARA) at MJC under preparation for validation. Regarding the original P&S (with vacuum drone), a retrofit will be eventually performed to update its design to the current one.

Acknowledgements

The automation of the P&S sensor transference subprocess was accomplished with the support of MJC's technical and engineering teams, an external assembler contracted by MJC, and the feedback of Epson®.

References

1. "Diabetes", World Health Organization, September 16, 2022.
   Available at: https://www.who.int/news-room/fact-sheets/detail/diabetes
2. "Diabetes and How the Body Works", Medtronic.
   Available at: https://www.medtronicdiabetes.com/about-diabetes/what-is-diabetes
3. "Diabetes", Centers for Disease Control and Prevention. Page last reviewed: December 16, 2021.
   Available at: https://www.cdc.gov/diabetes/basics/diabetes.html
4. "Diabetes", Pan American Health Organization.
   Available at: https://www.paho.org/en/topics/diabetes
5. "Innovation Milestones", Medtronic.
   Available at: https://www.medtronicdiabetes.com/about-medtronic-innovation/milestone-timeline
6. "Robot Specification 2020 Catalog", Epson Robots, 2020.