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 the multiple computerized systems that composes the Cell Operating System (COS) assembly line at Medtronic Juncos Campus as part of the Project Synergy. This equipment is capable of executing three subprocess without human intervention: attaching an adhesive patch to the Synergy sensor, engaging the Synergy sensor to a serter, and inspecting the flatness of the assembly. However, manual placement of all components must be performed to trigger the automatic process. To reduce the human dependency, an opportunity to automate part of the Patch and Serter Installation System manual process was identified. As the final step of this equipment's manual process, the Synergy sensor must be transferred from point A to point B using a vacuum drone tool. This step was optimized by replacing the vacuum tool drone with a selective compliance assembly robot arm, commonly used for assembly and/or pick-and-place applications.*

Key Terms *— Automation, Chronic, Diabetes, Glucose.*

INTRODUCTION

According to the World Health Organization (WHO), the number of people with diabetes increased from approximately 100 million in 1980 to over 400 million in 2014 [1]. Annually, about 1.5 million deaths worldwide are reported with direct attribution to this disease. Currently, it is estimated than nearly half of the people with this condition are unaware of it.

The Origin of Glucose

When humans and animals eat, food travels through the digestive system to the consumer's stomach, where food is broken down into different nutrients. Sugar (or glucose) is one of these nutrients derived from food, and as shown in Figure 1, it is directly released into the consumer's bloodstream (or capillary), where it afterwards moves (from the bloodstream) into the interstitial fluid surrounding the body's cells [2].

Figure 1
Glucose Moving from Bloodstream into Interstitial Fluid [2]

Insulin: The Master Key of Cells

The pancreas, the organ responsible for the digestion of food, produces a hormone known as insulin. This hormone, as shown in Figure 2, acts as a key to open or unlock cells, allowing glucose to move out of the blood and into the body's cells [2]. As a result, the amount of glucose in blood decreases.

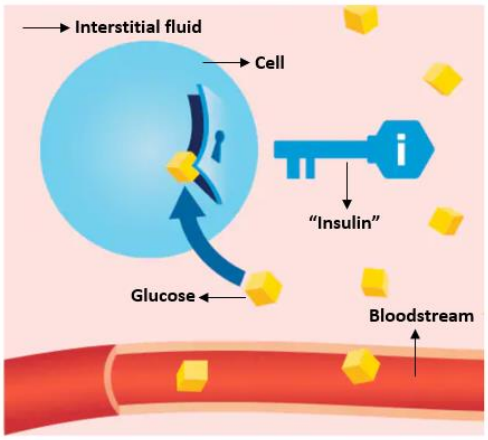


Figure 2
Glucose Moves into Cells with the Help of Insulin [2]

Once glucose enters the different cells distributed throughout the body, it is converted into energy, which is used by the cells to execute work. If any glucose remains in the blood after the demand for energy has been satisfied, the body stores it in the liver, as illustrated in Figure 3.

However, cells are not capable of storing glucose in absence of key-acting insulin, causing glucose to stay in the blood and hence, increased levels of glucose in blood.

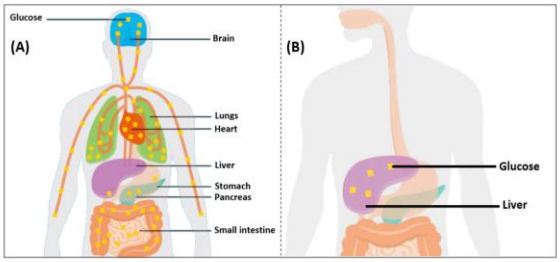


Figure 3
Every Cell in the Body Uses Glucose for Energy [2]

Brother Glucagon

Glucagon is another hormone produced by the pancreas and is released when the body detects that the levels of glucose in blood are low. Glucagon allows the liver to release stored glucose into the bloodstream.

Diabetes Type 1

According to the Centers for Disease Control and Prevention (CDC), diabetes is classified as a chronic health condition – condition that last 1 year or more and require ongoing medical attention or limit activities of daily living or both – that affects how the body turns food into energy [3][4]. There are cases where the pancreas is unable to create enough or any insulin at all, causing cells a glucose deficit and hence, energy. This condition is diagnosed as diabetes Type 1. Currently, there is no prevention, delay, or cure for diabetes Type 1. Patients of diabetes Type 1 must take insulin every single day to be able to convert food into energy.

Diabetes Type 2

Diabetes Type 2 is diagnosed when a patient's pancreas can still produce insulin, but either it does it at levels lower than required or the body's cells are resisting to react to the insulin, avoiding glucose to be converted into energy. This is the most common type of diabetes. About 92% of the patients of diabetes suffer of Type 2.

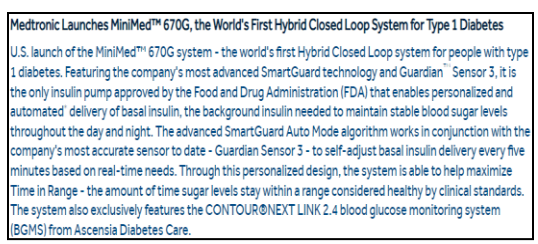
Prediabetes

Patients diagnosed with prediabetes has higher-than-normal blood glucose levels, but not high enough to be diagnosed with diabetes. However, prediabetes raises the risk of developing diabetes Type 2 if not treated correctly. Fortunately, and contrary to diabetes Type 1 and 2, it can be reversed.

Medtronic: Diabetes

Through the years, Medtronic has been one of the pioneer companies providing the latest technologies for diabetes management. After acquiring MiniMed™ Inc, Medtronic introduced the world's first wireless and automatic insulin pump in 2003. A year later, the Food and Drugs Administration (FDA) approved the patient use of Guardian Continuous Glucose Monitoring (CGM) system, a medical device designed to notify the patient potentially dangerous glucose fluctuations [5]. In 2006, the FDA approved the MiniMed™ Paradigm REAL-Time CGM, the world's first integrated diabetes management system. After the launch and approval of these technologies, the way for the next generations of integrated systems of pump and CGM systems was paved. One of these next generations was launched in 2017: Medtronic's MiniMed™ 670G, the world's first hybrid closed loop (HCL) system. Figures 4 and 5 contain the Medtronic's official description of the world's first HCL system and a look at the combined system, respectively.

Currently, Medtronic Juncos Campus (MJC) is developing a next generation of the CGM system to level up the previous Guardian Sensor 3 (GS3). The project addressing this new sensor generation is internally known at MJC as Project Synergy.


Medtronic Launches MiniMed™ 670G, the World's First Hybrid Closed Loop System for Type 1 Diabetes

U.S. launch of the MiniMed™ 670G system - the world's first Hybrid Closed Loop system for people with type 1 diabetes. Featuring the company's most advanced SmartGuard technology and Guardian™ Sensor 3, it is the only insulin pump approved by the Food and Drug Administration (FDA) that enables personalized and automated* delivery of basal insulin, the background insulin needed to maintain stable blood sugar levels throughout the day and night. The advanced SmartGuard Auto Mode algorithm works in conjunction with the company's most accurate sensor to date - Guardian Sensor 3 - to self-adjust basal insulin delivery every five minutes based on real-time needs. Through this personalized design, the system is able to help maximize Time in Range - the amount of time sugar levels stay within a range considered healthy by clinical standards. The system also exclusively features the CONTOUR®NEXT LINK 2.4 blood glucose monitoring system (BGMS) from Ascensia Diabetes Care.

Figure 4
The World's First Hybrid Closed Loop System [5]

Figure 5
MiniMed™ 670 G and Guardian Sensor 3 Combination

Problem Statement

Currently, in order to trigger the automatic processes of the Patch and Serter Installation System, the Synergy sensor must be first manually transferred from point A to point B using a vacuum drone tool. Any error that occurs from the sensor transference forward, whether human or machine, will result in scrap since no rework can be performed for this process.

Research Description

To reduce the potential human error during the operation of the Patch and Serter Installation System, it is expected to replace the current manual mechanism to transfer the Synergy sensor with an automated one. Therefore, through this research, automated solutions capable of replacing the vacuum drone tool will be identified, analyzed, and potentially implemented.

Research Objectives

The objectives of this research study are:

- To identify automated solutions capable of replacing the vacuum drone tool.
- To select and implement (if possible) the identified automated solution.
- To reduce the human dependency and potential human error during the sensor transference.

Research Contributions

In alignment with the mission of the Organization, contribution to human welfare will be made by applying engineering techniques to automate the Synergy sensor transference mechanism. In terms of quality, both the process and the product itself will be beneficiated as the automated solution to be selected will be logic-based programmed, allowing the reduction of variability and (potentially) cycle time. Besides adding versatility, theoretically, the automated solution shall increase the efficiency of the transference subprocess. Therefore, a yield improve is expected. Finally, this optimization favors the ergonomic standpoint. Occasional muscular fatigue reported by direct labor workers during the continuous transference of the Synergy sensor will no longer occur if the automation under discussion is performed.

Literature Review

For the purpose of this article, the main information source used was the MJC's quality system.

Project Synergy

Project Synergy consists of a new, completely disposable sensor device with a significant implantable volume reduction in comparison to GS3, as shown in Figure 6. The Synergy sensor leverages the existing GS3 flex design in a new form factor which greatly reduces user burden for insertion, wear, and replacements.

Figure 6
Next Generation of CGM: 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 7 illustrates the differences between the Guardian and Synergy sensors and serters.

Figure 7
CGM sensors: The Old and New Generation

Process Description

The overall Synergy process at MJC is divided into five main lines, each consisting of a group of equipment:

1. Synergy Cell Operating System (COS) Assembly
2. Serter Assembly
3. Tyvek to Cap Sealing
4. Pre-Sterile Bulk Packaging
5. Final Pack

Each manufacturing line consists of a group of equipment. For the purpose of this article, emphasis will only be placed on one of the equipment within the Synergy COS Assembly line. More specifically, on the Patch and Serter Installation System.

Patch and Serter Installation System

The Patch and Serter Installation System is the second last of nine (9) custom-built semiautomated machines used in the Synergy COS Assembly line. This system is responsible for three (3) subprocesses:

1. The installation and bonding of the CGM Synergy sensor to the adhesive patch.
2. The engagement of the serter assembly and the Synergy sensor (with bonded adhesive patch).
3. The planarity inspection of the engaged Serter-Synergy sensor assembly.

These three subprocesses are sequentially and automatically performed. However, for the automated sequence to begin, all required components must be first manually placed into their respective nests. This is, the carrier (used to transport units from one system to another) must be placed on the carrier nest, the serter must be inserted and locked into the serter nest, and an adhesive patch must be placed on the patch nest.

Vacuum Drone

After all components have been manually placed into their respective nests, also manually, an operator must transport the Synergy sensor from the carrier to the patch nest using a vacuum drone tool (see Figure 8 for reference). Once the sensor transference is completed, the operator must clear the safety curtains to start the automatic process.

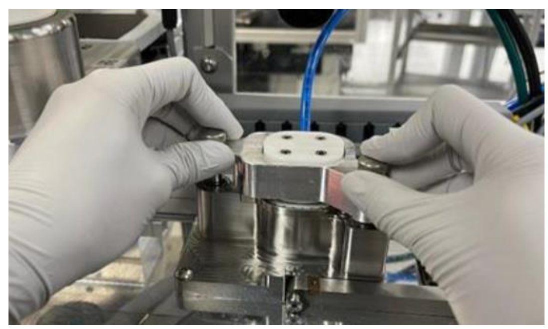


Figure 8
Patch and Serter Installation System's Vacuum Drone Tool

Once a unit passes through the entire Patch and Serter Installation System's process, it cannot be reworked. Errors obtained during and after the sensor transference subprocess will automatically result on scrap. The vacuum drone tool – the current manual pick-and-place mechanism used to transfer the Synergy sensor from the carrier to the patch nest – depends on human intervention. Despite the Patch and Serter Installation System was validated in 2021 and personnel destined to use it is adequately trained, this dependency factor increases the probability of human error.

METHODOLOGY

In order to reduce human dependency on this system (and with it, the risks of failure), an automation opportunity was identified for the Patch and Serter Installation System: replacing the current transference mechanism with an automated one. Using as reference another semi-automated equipment with similar application within the Synergy COS Assembly line, the possibility of replacing the vacuum drone tool for a selective compliance assembly robot arm (SCARA) was presented to upper management for evaluation.

SCARA robots are programmed polyphase manipulators most commonly used for pick-and-place and/or assembly operations requiring both high accuracy and speed. The equipment that was used as reference has a SCARA by Epson responsible of picking up the serter from point A, completing the assembly, and then placing it into point B. In the case of the Patch and Serter Installation System, the SCARA would only be used to perform the sensor transference from the carrier to the patch nest.

Theoretically, the proposed optimization could be performed since SCARA robots are mainly designed for pick-and-place applications, as the subprocess under evaluation. However, there are other specific factors (or specifications) that shall be analyzed in order to select a suitable and compatible SCARA. Some of the specifications that will be evaluated to select a SCARA suitable for the Patch and Serter Installation System include (but are not limited to) payload, axis, motion range, size, effectiveness, cost, and safety.

Implementation Plan

Project Synergy has a production target of over 500 units per shift. In order to meet this production output target, it is required to replicate more than ten (10) times each of the equipment within the Synergy COS Assembly line. Therefore, Project Synergy will count with multiple COS lines. In other words, there will be multiple Patch and Serter Installation Systems.

For the purpose of this automation project, once an automated solution is identified as capable of replacing the vacuum drone tool, if ordered, it would be installed in the first Patch and Serter Installation System replica. This means that what should be the first Patch and Serter Installation System replica, will actually be treated as a new (Patch and Serter Installation System) equipment since it should have a SCARA solution. This will allow to have at site two (2) Patch and Serter Installation Systems with different sensor transference mechanism for comparison purposes. In the end, the transference mechanism that proves to be the most appropriate will continue to be the official design of the Patch and Serter Installation System and thus, the rest of its replicas will be ordered to be manufactured with such transference mechanism.

RESULTS AND DISCUSSION

Since the engineering and programing team of Project Synergy was already familiarized with the SCARA options offered by Epson, it was a business decision to filter the search for the automated replacement by "Epson SCARA robots". At the moment that the research was initiated, there were four (4) different series of SCARA robots offered by Epson potentially capable of replacing the vacuum drone tool: T-series, LSB-series, RS-series, and G-series (refer to Figure 9 for visual reference of each SCARA option).

Figure 9
Epson's SCARA Robots [6]

A general description from Epson of each series is contained in Figure 10.

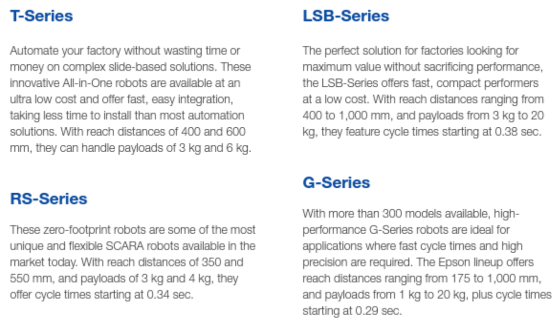


Figure 10
Epson SCARA Robots Overview [6]

Due to the design of the Patch and Serter Installation System, the mounting type of the SCARA to be selected must be tabletop. Since RS-series are SCARA designed for ceiling mounting, they were discarded as replacement options for the vacuum drone tool. Therefore, the research was focused on SCARAs T-series, LSB-series, and G-series.

Besides the mounting type, another important factor to evaluate in order to select a SCARA is the payload. The payload is the weight that the robot is capable of lifting. The Synergy sensor – the component to be transferred – has an approximate weight of less than 2 kg. Hence, a high payload robot is not necessary for the transference subprocess of the Patch and Serter Installation System. All robots within series T, LSB, and G with payloads of 6 kg or greater were no longer considered as replacement options. Additional specifications were studied and directly discussed with the manufacturer for guidance and recommendations. Based on manufacturer's feedback, the Epson SCARA T-series was identified as the best option series to replace the vacuum drone tool. Hence, and order was placed.

Replacing the vacuum drone tool for the Epson's SCARA also triggers additional design changes, including components relocation and greater volumetric area, as shown in Figure 11. An external service provider was contracted to develop the new Patch and Serter Installation System.

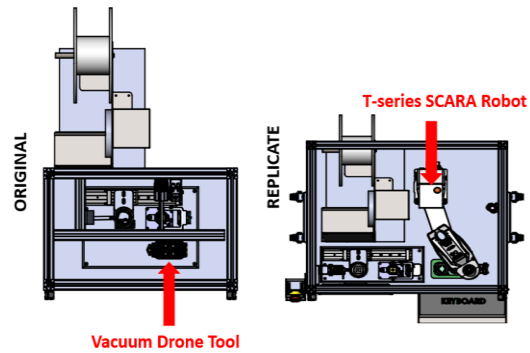


Figure 11
Schematic Top View of the Patch and Serter Installation System: Original vs "Replicate"

CONCLUSION

In early March 2022, a Factory Acceptance Test (FAT) was performed to the Patch and Serter Installation System with SCARA robot to verify if the equipment meets the pre-defined requirements in terms of design and purpose. Multiple tests were performed to the system during FAT, including (but not limited to) verification of hardware components and configuration, inputs and outputs (I/O), screen navigation, faults and alarms, and functionality testing. Overall, the results were satisfactory; the Epson's SCARA T-series successfully replaced the vacuum drone tool. A punch list was prepared and provided to the supplier detailing minor findings to be corrected before delivering the equipment to MJC.

By the end of March 2022, the new system was delivered to MJC. Tests performed during the FAT were repeated at site. Also, additional testing to challenge the communication between the system and the MJC's Manufacturing Execution System (MES) were carried out. Several dry runs were performed as preparation for the installation qualification (IQ). Figure 12 shows an actual image of the Patch and Serter Installation System with Epson's SCARA at MJC.

Multiple improvements were quickly noticed on the Patch and Serter Installation System with the transference mechanism replacement. One of the most important, besides the human dependency reduction, is the ergonomic factor. Given its right cornered location, the previous vacuum drone tool was more comfortable to use for those workers with right-handed dominant laterality. With the automatization of the transference subprocess, this opportunity is resolved since the direct-labor worker will no longer have to manually perform the sensor transference. Thus, the muscular fatigue factor due to the continuous manual transference will also no longer occur.

Figure 12
New Patch and Serter Installation System at MJC

Currently, the IQ execution is underway, with an estimated due date of by the end of October (2022), following the Computerized System Lifecycle Program of MJC. Once the validation is completed, yield and time studies will be performed to the process. However, based on the observed improvements, MJC upper management took the business decision of making the Patch and Serter Installation System with SCARA the official design of the equipment. Therefore, the design requirements of the remaining Patch and Serter Installation System replicates were developed specifying that an Epson SCARA robot T-series capable of transferring the Synergy sensor from the carrier to the patch nest is required. At the present time, there are five (5) more Patch and Serter Installation Systems replicas (with Epson's SCARA) at the Synergy COS Assembly line under preparation for validation. On the other hand, a retrofit will be performed to the original Patch and Serter Installation System (with the vacuum drone tool) at some point after fully validating at least one of the new systems.

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