Optimization of a Packaging Work Cell in a Medical Devices' Manufacturing Plant

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Abstract ***—*** *This project was focused in the optimization of a packaging process within a medical device industry. The purpose was to improve secondary packaging process case packing, from a totally manual process to a fully automated. The term "medical devices" covers a wide industry. From sophisticated computerized devices with elaborated mathematical algorithms to rudimentary wooden tongue depressors. The medical device under the subject of this project is manufactured, and packed at the same manufacturing facility, using hi-end packaging machines. The process of packaging the medical device consists of two major steps: primary packaging and secondary packaging. The secondary packaging take a Polypropylene (PP) dewdrop shaped shell strip and accumulate it in three different boxes presentation. The actual process uses two operators to fill shipping cases with the boxes ejected by the secondary packaging machine. This optimization project will add automation machinery to eliminate the manual case packaging process. The intention is to reduce the human interaction and provides an electronic verification of the quality of the boxes and the information included in the case' label.*

Key Terms ***—*** *Medical device, packaging line, manufacturing, Packaging Improvement.*

INTRODUCTION

This project will be conducted in the secondary packaging line of a Medical Device Company located in Atlanta, Georgia, United States. A medical Device is "any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of: diagnosis, prevention, monitoring, treatment or alleviation of disease" [1]. The structure of the manufacturing facility has established two packaging process: The primary packaging unit, which is installed within the production line. The production line is a fully automated system capable of packaging 150 contact lenses per minute into polypropylene shells. a packaging machine is a "mechanism that is used to produce, decorate, identify, fill, weigh, inspect, close, or seal a container or package or used to convey and/or coordinate the packaging functions that must take place in sequence on the production line" [2]. The primary packaging line takes the medical device from the production line and performs the initial packaging by filling a dewdrop shaped PP shell strip with quality controlled liquid for controlled hydrolysis, and finally closing the shell strip with a pre-printed, multi-layer aluminum web stock (sealing foil). Once in the plastic shell the device is sterilized and then transported to the secondary packaging line. The secondary packaging unit is an automated, multi-step system, with software and PLCs for packaging contact lens strips into cartons for distribution. A PLC-programmable logic controller- is a special form of microprocessor-based controller that uses a programmable memory to store instructions and to implement functions such as logic, sequencing, timing, counting and arithmetic to control machines and process and is designed to be operated by engineers with perhaps a limited knowledge of computers and computing language [3]. The process packages strips into cartons for housingThe PLC program receives the carton information and sends it to the side laser printers. The vision system then verifies that the information on the side panel is correct and if not, rejects the carton.

The PLC program also verifies that the weights of the cartons are within specification and if not they are rejected as well. In this section the shells are grouped, packed in consumer cases, labeled with corresponding lot and expiration date, inspected and then manually packed in shipping cases.

Two operators are used to pack the consumer boxes into shipping cases. This project will focus on the installation of a new Case Packer (CP) machine. This new machine will fully automatize the process of case packaging. The management has the intention of improve the process installing three new CP machines at the end of three of the six secondary packaging systems, nevertheless, to simplify the results, only one of these machines will be consider for the purpose of this project.

The secondary packaging lines are designed to pack three different configurations of customer cartons: 5 packs, 30 packs and 90 packs. See Figures 1, 2 and 3 for details.

Figure 1
Five Pack

Figure 2
Thirty Pack

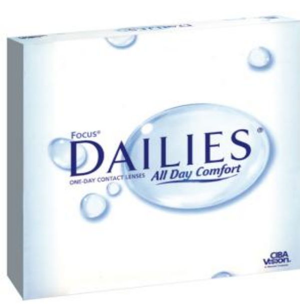

Figure 3
Ninety Pack

Different case sizes are used to pack these three cartons presentation. Table 1 illustrates information about the case sizes used.

Table 1
Case Size per Carton

Carton Size	Internal case size (in)		
	Width	Height	Length
90	12.31	6.19	17.5
30	12.31	4	17.5
5	12.31	4	17.5

Note that the process uses the same cases for 30 packs and 5 packs. The actual packaging process utilizes two operators per shift to manually fill the cases, seal it, and stack it into pallets.

This manual process involves the two operators in a repetitive execution of opening cases, introducing boxes into cases, sealing cases and then stacking into pallets, which represent an ergonomic challenge to the personnel.

The process was evaluated and a User Requirement Document was generated to acquire a new system that can perform the whole process with minimum human intervention.

The new system was thought having in consideration the space available, the dimension of the case, and of course the flow of the process.

In terms of quality the new CP will have the capability of inspect all the items for defects and the presence of all the critical process information as Lot number and expiration date.

This project supports the compliance goal by adding new automatic quality controls to the final packaging process. It will represent a safety improvement by reducing the ergonomic risk associated to the manual process. In addition will support the business unit goals by reducing the head count.

Literature Review

The objective of this section is to describe the terminology and main concepts associated to this project. In addition to establish the methodology to be followed, and the main criteria for measuring the outputs.

Process Flow

The production environment of this Medical Devices Company consists of a linear table machine, a primary packaging unit, and secondary packaging unit.

The linear table obtains the raw material from a previous process to produce the device utilizing 22 stations that function in sequence with 16 mechanical tools. The mechanical tool contains the molds that ultimately form the device itself. Each station has a specific function in the production process. The functionality of each station eventually affects the efficiency of the whole linear table and the quality of the product. Once the device is formed then is automatically transferred to the primary packaging line. The primary packaging line is a fully automated packaging system responsible for placing the device, produced in the linear table, into polypropylene shells strips, dosing the packaging liquid, sealing the shells with foil, and printing the product information into the foil. The following information is printed in the foil: the base curve, power, lot number, and expiration date. See Figure 4 for details.

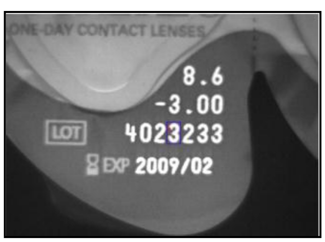

Figure 4
Example of a Product Foil

Each critical section of the process is inspected by a vision inspection system. Product that does not comply with the quality standards are rejected automatically.

The device strips produced by the primary packaging machine is stacked in a transport cartridge. This cartridge holds the product during the sterilization process and while delivering the strips to the secondary packaging machine.

The secondary packaging machines pack the strips produced by the primary packaging line into cartons. Each strip is comprised of 5 devices held in polypropylene shells sealed with a foil cover. Depending on the work schedule determined by the Manufacturing Management System (MMS), the secondary packaging machine is configured to inspect and pack 1 blister, or 6 nested, or 3 sets of 6 nested blister strips into one carton, resulting in cartons containing 5, 30, and 90 devices respectively. See Figure 5, for a top view of the secondary packaging machine.\

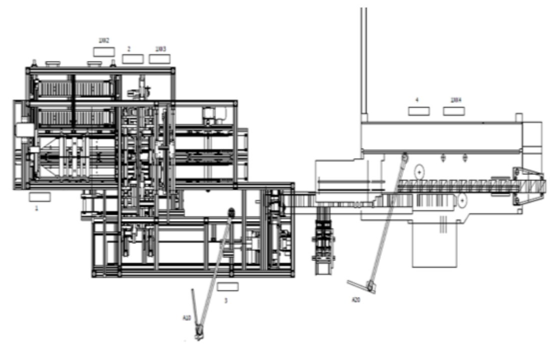

Figure 5
Top View of the Secondary Packaging Machine

The secondary packaging, which is controlled by a dedicated PLC and monitored using a HMI, is made up of the following sub-systems:

- Magazine Handling
- Strip Loading
- Strip Nesting
- Carton placing/ erecting
- Carton loading
- Carton printing
- Check weighing

The above sub-systems are designed to automatically feed strips of desired product, and determine the configuration to be cartoned. This include verification of incoming magazines, carton blanks, printed information and carton weight. Any strip or carton not meeting specification is discarded prior to exiting the line.

First the strips are fed into the secondary packaging machine, and then the product information is verified against the information pulled from the MMS. If the information is not according to the scheduled lot information charged from the MMS, the strip is rejected. If the strips contains the right information then the secondary packaging machine pack the strips into the corresponding carton configuration. Once the carton is sealed the unit uses laser marking systems to print the corresponding product information on the side and bottom of the cartons. The information printed in the side of the box includes the base curve, power, center thickness, and the diameter of the device. In the bottom the system prints the lot number and the expiration date. The vision inspection system verifies the information printed in both side of the box reducing the risk of a product recall due to labeling issues.

Process Improvement

This project will optimize the process by installing a new CP machine. The new CP consists (in that order) of three major components: an independent vision system, the case packer itself, and a label printer.

- The Vision System: inspects the cartons coming out of the secondary packaging line before feeding the CP machine. A configurable sampling station is available to collect boxes before entering the CP.

The lot run is initiated on the CP by the secondary packaging line PLC. The machines are synchronized to avoid product jamming and to communicate the relevant lot information and machine statuses. At the same time the lot critical information is sent to the CP, which hand shake the data received. The cartons is then accepted and inspected by the vision system. The vision system is designed to verify carton structure quality and print quality including glue residue defects. Up to 20 tools of each tool group may be placed on the combined image of all five exposed sides of the carton.

The system is used to detect open carton flaps, missing carton flaps and/or glue on the exterior of the carton. This vision system was designed to improve the quality of the product responding to internal customer complains. In addition inspecting the entering cartons for defects described before, reduce the downtime of the new CP, since the defects could cause product congestion.

The first vision tool executed locates a model target on the carton within the image. The model can be used to identify the correct carton is being run. After training the vision system, the defined tools are then executed to locate and verify objects of interest on the carton [4]. The defect analysis allows control of what is considered a defect from the resulting difference image produced. Boxes with Images that do not comply with predefined acceptance range are rejected before entering the case packer conveyor.

- The CP: The CP will collect the cartons (5-pack, 30-pack and 90 packs) coming from the vision system; feed, set up and load trays (without applying lids). The magazine for trays/cases accommodates a minimum of 100 blanks. See Figure 6.

Figure 6
Trays Magazine

A set of parameters are adjusted in the CP to optimize its performance. Refer to Table 2 for details about some of the system critical parameters.

Table 2
CP Critical Parameters

Device	Parameter
Glue Melter	Temperature
Main Supply	Pressure
Vacuum Generator	Pressure
Label Printer Applicator	Pressure
Auto Feed Regulator	Pressure

The CP includes a number of controls subsystems to guarantee the control of the sensors, conveyors, motors, mechanical arms, and safety devices associated with the machine. PLCs, Frequency drives, Input Output banks, computers and human machine interfaces interact to operate the CP synchronized.

The next step in the process is erecting the case to place the boxes into it. The case is then sealed with hot melt. The tray layout is predefined in the system parameters. The CP machine is capable of process up to 130 cartons per minutes, using 5 packs as the reference. Refer to Figure 7 for details about the CP machine [5].

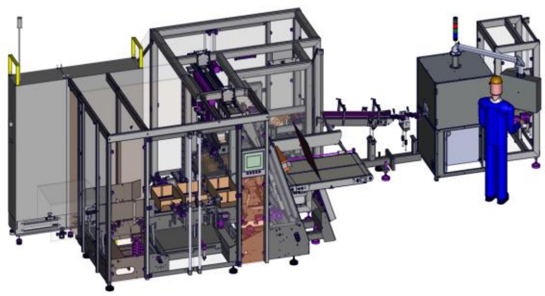

Figure 7
Layout of the CP

The CP is configured to operate according to the manufacturing requirement. All the setup and control are designed to be executed through the system interfaces. Four human machine interfaces are available in the CP: One in the vision system, two in the CP itself, and one in the label printer.

All machine control, configuration, alarms and fault clearance, parameter setup, input/output status, and system tuning is made through the system interfaces. The interface includes machine schematics to easily describe the system status.

In addition to the interfaces, stack lights with red, orange and yellow, and an audible voice alarm are used to communicate the machine status.

Safety devices such as door interlocks, light curtain, and emergency stop buttons will stop the machine immediately in the case they are activated. The machine cannot be restarted without operator intervention.

The Label Printer: The last step in the CP machine is printing label [6]. The label printer prints and applies a label with the batch number, line number and other relevant information to each case coming out of the CP. This label is them verified for accuracy on a vision system. Once the case is released by the printer verification system, then it is exited to the output conveyor. The operator then places a lid on each case coming out of the CP and place the case on a pallet.

Methodology

Before the implementation of the CP, the system was assessed for impact and criticality. Product of this assessment it was concluded that an engineering commissioning was the most suitable process to test and challenge the machine installation, operation and performance. An international vendor was selected. The system was tested in the vendor site and after delivered and installed in its place by the side of the secondary packaging machine, it was successfully commissioned and released for production.

During the testing process some adjustments were required in the vision system and in the CP setup parameters. The PLC program was verified to comply with the local programming standards of annotation, training of the programmer, and absence of dead code.

Results and Discussion

Since the release of the new CP machine it was no longer required to maintain two operators executing the former manual process. Instead just one operator is required per shift. Since the CP was conceived to be mostly autonomous, this one operator is then shared between two operational case packer installed in contiguous packaging machines.

The previous process required two dedicated operators per shift per case packaging process. The new process reduces the human interaction to ½ operators per shift per CP. This headcount reduction represents a savings of $262,080. See Table 3.

Table 3
Labor Saving

Before	Units	After
2	Operator/Shift	0.5
$18	Labor Cost/Hr	$9
4	Shift/Wk	4
52	Wk/Yr	52
$299,520	Total labor cost per year	$37,440
N/A	Savings	$262,080

With the new system a new tray was introduced. This new tray in term of the output, the CP does not represent a significant improvement. The new product output is similar to the output of the previous manual process. Nevertheless the presence of a new vision system that verifies the boxes for defect will reduce the customer complains. At the time of this project no data were still produced to demonstrate this quality improvement.

The count of the tray is being improved because the automated system increases the accuracy of the calculation. The installation of the CP improves the overall ergonomics of the area packaging eliminating the need for manual repetitive movements. The manual erecting of trays and lid was eliminated.

The introduction of the new CP machine reduces the probability of mixed product increasing the quality of the process.

The system use a new single piece, wrap around designed tray. This new tray will represent savings of $210,000 (amount provided).

In Conclusion the new Case Packer Machine represents a total cost saving of $262,080, plus the outcome related to quality improvements that will tend to reduce complaints due to a boxes defects. In addition benefits related to ergonomics improvement will reflect in sick leave reductions and insurance related issues reductions. These numbers were not estimated.

Table 4
Cost Analysis

Machine	Cost
CasePacker	$420,060
Vision System	$106,265
Cartoner and Scada Modification	$20,000
Installation	$27,000
Spare Parts	$15,000
Expenses	$35,000
Total	$623,325

Table 5
Payback Analysis

Machine	Cost
Total Benefits/Yr	$262,080+$210,000 =$472,080
Total Cost	$623,325
Payback Years	1.32

References

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