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**Sviluppo e validazione di un sistema automatizzato per la gestione del farmaco in
dose unitaria e standardizzazione delle relative comunicazioni verso i clienti**

**Development and validation of an automatic system for unit dose drugs
management and standardization of the related customer communications**

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Riassunto analitico

La tesi si focalizza sulla gestione del processo che avviene a seguito di modifiche meccaniche apportate su un sistema robotizzato e delle relative comunicazioni ai clienti. La trattazione è il risultato di un tirocinio avvenuto all'interno di un'azienda che fornisce sistemi automatici per la gestione di farmaci in formato monodose all'interno di ospedali.

Gli obiettivi del progetto sono stati di studiare e testare modifiche meccaniche ad un sistema robotico e di standardizzare il processo di comunicazione al cliente. Rispettivamente, il primo obiettivo viene dal bisogno di trovare la soluzione migliore per ottimizzare e migliorare le prestazioni delle macchine a campo e di quelle in produzione. Mentre il secondo obiettivo nasce dalla necessità di tracciare e di comunicare al meglio al cliente le migliorie apportate alle macchine a campo. La ricerca delle soluzioni è avvenuta per mezzo di un software CAD (Computer-Aided Design) e gestite tramite il software di Product Lifecycle Management (PLM). Al fine di spiegare al meglio il lavoro svolto, l'elaborato mostra una descrizione dettagliata del funzionamento meccanico del sistema automatizzato.

Gli obiettivi della tesi sono avvenuti attraverso diversi step e attraverso la collaborazione interna al team aziendale. In particolare, per la modifica meccanica una prima fase di studio è avvenuta a seguito della segnalazione di un problema riscontrato nella macchina. In seguito, dei test a campo della soluzione sono stati svolti per validare la soluzione pensata. Per quanto riguarda la standardizzazione della comunicazione ai clienti, la soluzione della gestione dei bollettini tecnici (strumento usato per comunicare aggiornamenti ai clienti) è avvenuta a seguito di riunioni interne all'azienda.

In conclusione, sebbene determinati processi siano ancora sottovalutazione e non concluse, le modifiche meccaniche studiate dal sottoscritto hanno portato alla fattibilità della soluzione trovata. Il processo di comunicazione ai clienti è avvenuto attraverso la stesura standardizzata di tre tipi di bollettini tecnici, i quali corrispondono a tre tipi di livelli di urgenza del problema da comunicare.

Abstract

This thesis focuses upon the management processes that take place because of mechanical modifications developed on robotised system and the relative communication to customers. It is the result of an internship performed within a company that supplies automatic systems for the management of unit-dose medications within hospitals.

The project goals were to study and test the mechanical modifications of a robotic system and to standardise the process of customer communication. Respectively, the first objective was to find the best solution to optimise the function of the machinery both on site and in production. While the second objective was derived from the need to trace and communicate alterations made to the machinery in the best possible ways. The research and the solution were accomplished with the aid of CAD (Computer-Aided Design) and managed with Product Lifecycle Management (PLM) software. In order to explain the research in the best possible way, this study shows a detailed description of the mechanical function of an automated system.

The objectives of this thesis were achieved through various steps and with collaboration within the company team. As far as mechanical optimisation was concerned, a first phase of research was implemented following a reported problem found in the machine. After which, tests were made in order to validate the conceived solution. In regard to the standardization of customer communication, the solution of the technical-bulletin management (an instrument for communicating updates to customers) was found after a company meeting.

The results show that although some processes are still under evaluation and not yet concluded, the mechanical optimization made by the author provided feasibility to the solution studied. In addition, the process of customer communication took place through the standardisation of three kinds of technical bulletins that correspond to three types of urgency levels in communication issues.

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Table of contents

| | |
|--|----|
| Introduction..... | 1 |
| 1. Company management | 4 |
| 1.1. Company overview | 4 |
| 1.1.1. Company organization | 4 |
| 1.1.2. Company functions | 5 |
| 1.1.3. Product Lifecycle Management (PLM) and Enterprise Resource Planning (ERP) | 6 |
| 1.2. Introduction to PRs related to the mechanical modifications case studies..... | 10 |
| 1.2.1. Problem Report management | 10 |
| 1.2.2. Roadmap approach | 12 |
| 1.2.3. Introduction to cases #51 #61 | 14 |
| 1.3. Hospital pharmacy and drug management overview | 15 |
| 1.3.1. Hospital pharmacy | 15 |
| 1.3.2. Inpatient drug management process..... | 16 |
| 2. TheraPick system | 19 |
| 2.1. TheraPick system overview..... | 19 |
| 2.2. Pharmacy automation process..... | 21 |
| 2.3. Theoretical introduction to robotics | 22 |
| 2.4. TheraPick system cycle | 27 |
| 2.4.1. BoxStation | 27 |
| 2.4.2. All-forms and Blister packager..... | 31 |
| 2.4.3. Storage | 32 |

| | | |
|----------|--|----|
| 2.4.4. | Dispensing module..... | 32 |
| 2.5. | The importance of TheraPick | 34 |
| 3. | Single-dose packaging module and case-filler group..... | 36 |
| 3.1. | Product overview..... | 36 |
| 3.2. | All-Forms Packager | 37 |
| 3.2.1. | Product: detailed description and main processes..... | 38 |
| 3.2.1.1. | Automatic and manual loading..... | 40 |
| 3.2.1.2. | Picking process..... | 43 |
| 3.2.1.3. | Packaging process | 46 |
| 3.2.1.4. | Vision system | 52 |
| 3.3. | Blister Packager | 54 |
| 3.3.1. | Product: detailed description and main processes..... | 54 |
| 3.3.1.1. | Vision system | 55 |
| 3.3.1.2. | Blister-cutting process..... | 57 |
| 3.3.1.3. | Picking process..... | 59 |
| 3.3.1.4. | Packaging process | 59 |
| 3.4. | Case-filler group | 66 |
| 3.4.1. | Case-filler group functioning in the All-Forms Packager..... | 69 |
| 3.4.2. | Case-filler group functioning in the Blister Packager..... | 73 |
| 4. | Mechanical modifications..... | 74 |
| 4.1. | Problem statement..... | 74 |
| 4.2. | Mechanical modification steps | 75 |
| 4.3. | PR standard management for a mechanical modification..... | 77 |

| | | |
|----------|--|-----|
| 4.3.1. | Management of the PRs regarding the cases #51 and #61 | 79 |
| 4.4. | Mechanical modifications for the cases #51 and #61 | 81 |
| 4.4.1. | The mechanical modifications initiative..... | 81 |
| 4.4.2. | TASK 1: study for the barcode-reader (Keyence) positioning | 82 |
| 4.4.3. | TASK 2: validation of the solution (Keyence)..... | 84 |
| 4.4.4. | TASK 3 and TASK 4 | 89 |
| 5. | Standardization of the technical bulletins | 90 |
| 5.1. | Customer care | 90 |
| 5.2. | Technical bulletins and rebuilding kits..... | 91 |
| 5.3. | Standardization of TB..... | 92 |
| 5.4. | Management of the TB in the PLM..... | 94 |
| 5.4.1. | PR1 management..... | 95 |
| 5.4.2. | PR2 management..... | 97 |
| 5.4.2.1. | ECN flow for the finalization of the mandatory RK | 98 |
| 5.4.2.2. | ECN flow for the finalization of the optional RK | 98 |
| 5.5. | Possible management of the RK for the cases #51 and #61 | 99 |
| 6. | Conclusions and future development | 100 |
| | References and bibliography | 102 |
| | References | 102 |
| | Bibliography..... | 102 |

List of Figures

| | |
|---|----|
| Figure 1.1 Engineering organization chart | 5 |
| Figure 1.2 Business unit systems | 5 |
| Figure 1.3 Product Lifecycle | 7 |
| Figure 1.4 Relations between the CAD files with the ERP thanks to PLM (the states of the product in the PLM and ERP are shown better in the following figure) | 8 |
| Figure 1.5 PLM and ERP interconnection | 9 |
| Figure 1.6 PR flow | 11 |
| Figure 1.7 PR management | 12 |
| Figure 1.8 Determination of PR priority | 14 |
| Figure 1.9 Example of the problem occurred in the case-filler group | 15 |
| Figure 1.10 Inpatient drug management (traditional process) | 17 |
| Figure 2.1 TheraPick modules presentation..... | 20 |
| Figure 2.2 Drug workflow within the TheraPick system | 20 |
| Figure 2.3 Links and joints of a robotic manipulator (with the cartesian configuration) made by Swisslog located in the All-forms packager | 24 |
| Figure 2.4 Cartesian robot with its workspace on the left and a gantry robot on the right | 25 |
| Figure 2.5 Cylindrical robot and its workspace..... | 25 |
| Figure 2.6 Spherical robot and its workspace | 26 |
| Figure 2.7 The SCARA configuration and its workspace | 26 |
| Figure 2.8 Articulated robot and its workspace. | 27 |
| Figure 2.9 The BlisterBox on the left and the PillBox on the right..... | 28 |
| Figure 2.10 BlisterBox insert for blisters on the left and BlisterBox insert for phials on the right... | 28 |
| Figure 2.11 Opening and closing system of canisters | 29 |
| Figure 2.12 Pillbox with its Crossframe | 29 |
| Figure 2.13 BoxStation structure | 30 |

| | |
|---|----|
| Figure 2.14 Empty case | 31 |
| Figure 2.15 Pickportal structure | 33 |
| Figure 2.16 Dispensing portal | 33 |
| Figure 2.17 Therapy ring | 34 |
| Figure 3.1 All-Forms Packager integrated vision | 37 |
| Figure 3.2 Canisters loading window location..... | 38 |
| Figure 3.3 The main components of the All-Forms Packager..... | 39 |
| Figure 3.4 Conveyor-belt group..... | 40 |
| Figure 3.5 Possible movements of the lid-opening group | 40 |
| Figure 3.6 PillBox-loading group..... | 42 |
| Figure 3.7 Manual-loading window | 43 |
| Figure 3.8 The steps of the cup movement for the management of the drug: a) the cup is in the loading position; b) the cup is at the stroke end of the pneumatic slide cylinder; c) the pin of the cup is pushed down and the cup is opened, through its own mechanism so that the medication can drop into the bag | 43 |
| Figure 3.9 Pick-and-place group | 44 |
| Figure 3.10 Tool changer and tool assembly coupling..... | 45 |
| Figure 3.11 Tool-change station | 45 |
| Figure 3.12 Rotating table group..... | 46 |
| Figure 3.13 Printer group | 47 |
| Figure 3.14 First station..... | 48 |
| Figure 3.15 Clamp-opening mechanism..... | 49 |
| Figure 3.16 Second station | 49 |
| Figure 3.17 Third station | 50 |
| Figure 3.18 Fourth station | 51 |
| Figure 3.19 Fifth station | 51 |
| Figure 3.20 Sixth station..... | 52 |

| | |
|---|----|
| Figure 3.21 Blister Packager | 54 |
| Figure 3.22 Blister Packager main components | 55 |
| Figure 3.23 Blister picking | 56 |
| Figure 3.24 Movements of the Image-acquisition station | 56 |
| Figure 3.25 Vision system on the left and cutting map generated automatically on the right..... | 57 |
| Figure 3.26 Four-axis robot | 58 |
| Figure 3.27 Cutting system..... | 58 |
| Figure 3.28 Pick-and-place group | 59 |
| Figure 3.29 Rotating table | 60 |
| Figure 3.30 Small BUD on the left and normal BUD on the right | 60 |
| Figure 3.30 First station..... | 61 |
| Figure 3.31 Printer and laser-cut machine above and the plastic card shape at the end of the cut process below..... | 62 |
| Figure 3.32 Second station main components | 63 |
| Figure 3.33 Main components for the lever closing and for the initial folding of the plastic card .. | 63 |
| Figure 3.34 Bending process | 64 |
| Figure 3.35 Fourth station | 65 |
| Figure 3.36 Last station main components | 65 |
| Figure 3.37 Representation of the mobile and the fixed group-Case fillings in the Blister and All-Forms Packager..... | 66 |
| Figure 3.38 Stabilizer assembly | 67 |
| Figure 3.39 Stabilizer assembly cross-section | 67 |
| Figure 3.40 Stem made of carbon fibre | 67 |
| Figure 3.41 Pneumatic cylinder at the stroke beginning on the left, while on the right it is at the stroke end..... | 68 |
| Figure 3.42 Pneumatic grippers on the left and the buffering of ten UD bags due to the closed grippers on the right | 68 |

| | |
|--|----|
| Figure 3.43 Mobile group-Case filling with particular reference to the rodless cylinder | 69 |
| Figure 3.44 Mobile group-Case fillings in the All-Forms Packager | 69 |
| Figure 3.45 Transfer of the UD bag onto the stem while the first gripper is open | 70 |
| Figure 3.46 Passage of the ten bags from one stem to the other | 71 |
| Figure 3.47 Example of two types of case..... | 72 |
| Figure 3.48 Case-filler group with the rotating table provided with only the last station and with the movable shelf on which the three Cases are placed | 72 |
| Figure 3.49 BUD placed onto the stem of the fixed group-Case filling by the cylindrical robot | 73 |
| Figure 4.1 Example of a UD bag that got stuck by the gripper during its movement..... | 75 |
| Figure 4.2 Flow of the tasks of the first ECN | 78 |
| Figure 4.3 Flow of part of the PR regarding the management of mechanical modifications | 79 |
| Figure 4.5 Designed plate for the mounting of the sensor | 84 |
| Figure 4.6 Axonometric view of the solution on the left; Case and mobile Case-filling group provided with the sensor and plate on the right | 84 |
| Figure 4.7 Plate produced through the 3D printer on the left; test with the sensor and plate installed onto the stabilizer assembly on the right..... | 85 |
| Figure 4.8 Mobile Case-filling group in the filling position, sensor inclined by an angle of 20° and one UD bag stacked onto the Case pin | 86 |
| Figure 4.9 Mobile Case-filling group in the position for the UD-bag receiving, sensor inclined by an angle of 20° and one UD bag stacked onto the Case pin | 87 |
| Figure 4.10 Barcode-reading tests with the sensor inclined by an angle of 25° | 87 |
| Figure 4.11 Pneumatic cylinder at the end of stroke on the left; pneumatic cylinder at the beginning of the stroke on the right | 88 |
| Figure 4.11 Optimal configuration for the reading of the barcode printed on the bag | 89 |
| Figure 4.12 Designed plate for the mounting of the new sensor | 89 |
| Figure 5.1 Structure of the customer care | 90 |

| | |
|---|----|
| Figure 5.2 Flow for the communication and verification of the improvement of a customer product | 92 |
| Figure 5.3 Field letter on the top and retrofit letter on the bottom | 93 |
| Figure 5.4 PR flow occurring for the creation of a RK | 95 |
| Figure 5.5 Flow of the PR1 until the task for the RK creation | 96 |
| Figure 5.6 PR1 flow | 97 |

List of tables

| | |
|-------------------------------|---|
| Table 1.1 Company teams | 6 |
|-------------------------------|---|

Glossary

| | |
|--------------------------|--|
| <i>BUD</i> | Plastic card containing a single-dose blistered medication provided with a unique barcode |
| <i>UD</i> | Unit Dose, it refers to the packaging of a unit-dose medication |
| <i>UD bag</i> | Polypropylene bag containing a single-dose medication, provided with a unique barcode |
| <i>QR code</i> | Quick Response code, it is a type of matrix barcode and so a machine-readable optical label. |
| <i>Case</i> | Loading and storage unit for BUD and UD Bags. |
| <i>CPOE</i> | Computerized Physician Order Entry, component of the HIS |
| <i>HIS</i> | System hospital information |
| <i>TheraPick Manager</i> | Software for the complete management of the TheraPick system |

Introduction

Purpose of this study is to present the design process for mechanical changes, from the state of design to the state of release, in an automated system for drugs' management in Unit Dose (UD). In addition, this paper also describes the standard process developed for system changes communications to the customers, so called technical bulletin.

This project was carried out after a thesis internship with *Swisslog Healthcare*. The company deals with the supply of medical services for hospital pharmacies, and more specifically it deals with the installation of automatic systems that dispense drugs in unit-dose format, depending on the patient's therapy. Nowadays, because of the greater demand by citizens for safer and profitable health services, hospital companies are forced to minimize waste in order to increase the organizational quality and increase efficiency and effectiveness of their own services. In this context, *Swisslog Healthcare* has found its space offering technologies for the automated management and transport of pharmaceuticals.

This document will present a mechanical design change for the *TheraPick* system, which is one of the products offered by the company. It is a system that has been designed to automate time-consuming and error-prone activities, such as packaging, picking and stock management, in order to achieve a more efficient flow of drugs and information throughout the hospital pharmacies organization. The system is divided into several modules, which are different units with the aim to cover part of the entire process, in order to reduce the encumbrances in the hospital pharmacy thanks to its compactness and flexibility.

In the first part of this thesis, the organization and policy of the company and the detailed functioning of the *TheraPick* system are described, with interest for the *Blister Packager* and *All-Forms Packager* modules.

The second part illustrates the author's tasks during the internship period and includes: the study of the process for mechanical modifications, from the early stages of design to the release and production; the standardization of the technical bulletin drafting.

The need to make mechanical modifications derives from problems that affect the stability of the *TheraPick* system. In this study, the misalignment in the warehouse with respect to the drugs quantity calculated by the system, with consequent wasting time, is considered. In that case, modules impacted are both *Blister Packager* and *All-Forms Packager*, which are packaging machines for blistered medications and drugs with different formats, respectively. The difficulty consists in the faulty passage of medicines through the stems of the case filler group generating an incorrect filling of the cases. In fact, the stacker crane, a three-axis robot used in every automatic warehouse, positions the cases filled with incorrect single-dose drugs in the warehouse. Once placed in the warehouse, the system realizes that there is an error during the dispensing process, thanks to the scanning of the data matrix codes located on the label of both Unit Doses (UDs) and Blister Unit Doses (BUDs). As a consequence, the case must be realigned or discarded, generating a time increase in dispensing the product to the patient.

In conclusion, the mechanical modifications of interest consist in the optimization of a component and the consequent assembly of a Quick Response code (QR code) reader in order to increase the stability of the system. For systems already on the market, a non-invasive modification will be proposed, while for new systems the related Bill Of Material (BOM) will be updated.

In this thesis the entire study and process that took place is illustrated, thanks to which, the modifications are developed and validated. As mentioned previously, in addition to the description of the mechanical modifications, the second part of this paper deals with the description of the standardization process of customers communications. The technical bulletins are communications that the manufacturer shares to Customer Care functions (who deal with assistance to local customers) when an unexpected problem with a product that has already been sold to a customer is detected. These technical bulletins briefly describe the problem that affect the system, its cause, the impacted module/function and which type of intervention needs to be implemented. As it will be explained in more details in the following chapters, it has been decided to standardize the technical bulletins.

The final part of the thesis includes an illustration of the activities during the whole internship, the results obtained, and the main expertise achieved by the author following the internship.

1. Company management

1.1. Company overview

1.1.1. Company organization

This chapter briefly describes the *Swisslog Healthcare* organization.

The company is a global provider of integrated logistics solutions of material handling and best-in-class automation solutions for warehouses, distribution centers and hospitals. It is part of the *Kuka Group*, a German robotics and automation solutions supplier.

The *TheraPick* system, studied throughout this work, is a product developed by the *Healthcare Solutions* division and, as mentioned in the introduction, deals with the packaging, storage and dispensing of unit-dose medications. *Swisslog Healthcare Solutions* division is headquartered in Italy, in Cuneo (Cuneo, Italy), that deals with automated solutions for retail pharmacies, and in Maranello (Modena, Italy) that deals with automated solutions for hospital pharmacy and where the *TheraPick* system is developed.

As far as the system organization is concerned, the author of this thesis is part of the Business Unit Systems (described in the following paragraph) and the Engineering area, interacting with and supporting the Mechanical Engineering team located in Maranello.

The engineering team of the Systems Business Unit is composed of various professional profiles from the different branches of engineering who report directly to the Engineering Manager that manages day-to-day resources activities as well as systems development programs and maintenance. As shown in the figure below, the team is composed of:

- The Project leader who deals with the product development (this professional figure is also the supervisor of this thesis and the professional figure with whom the author of this thesis responds to);
- The Tier 3 support which is the part of the staff that supports the customers and the Customer Care function for systems potential issues;

- The mechatronic and software groups are responsible for research and development as well as sustaining activities on systems/products.

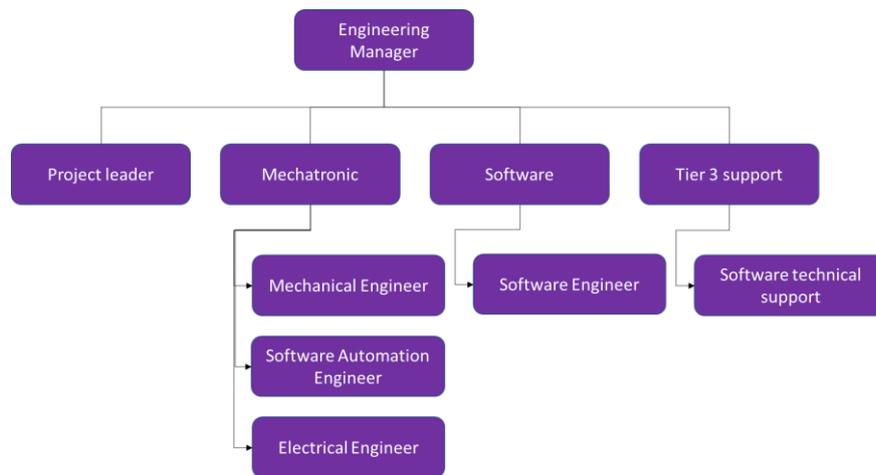


Figure 1.1 Engineering organization chart

The head of the engineering team is part of the Business Unit Systems that focuses on systems/product within the pharmacy automation.

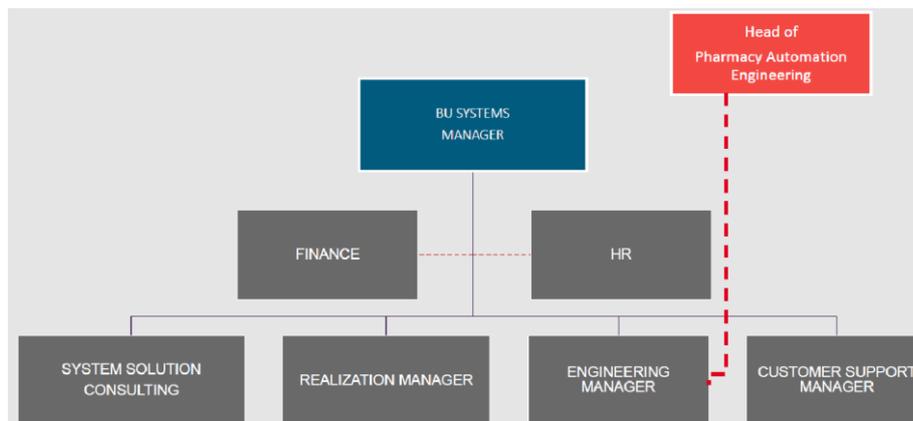


Figure 1.2 Business unit systems

1.1.2. Company functions

For the study of the process needed for a problem report (PR), the knowledge of the company teams and their interaction during the PR process gains importance. The author of this thesis is part of the Research and Development (R&D) team.

Nowadays, with the industry 4.0, companies are prone to follow strategic policies to improve efficiency through the integration of new production techniques and of the interconnection

between machines, devices, sensors and employees of different teams. Internal communication is the flow of information that involves an organization and ensures its operation, giving a fundamental contribution to the motivation and distribution of knowledge among the employees, improving the efficiency of the company. Within this context, *Swisslog Healthcare* has structured the internal communication between different functions through the integration of a Product Lifecycle Management (PLM) and Enterprise Resource Planning (ERP) tools, which are described in more details in the following paragraphs.

| Function | TASK |
|--------------------------|--|
| R&D | Develop technological innovation to improve new and already available systems/products/process |
| SUSTAINING | Maintain and secure production of products/systems already on the market |
| DOCUMENTATION | Develop products/systems documentation (installation, maintenance, assembly) |
| NORMALIZATION | Standardize of the database data to avoid redundancies and to facilitate research of data within the company tools |
| PROCUREMENT | All activities with the aim of researching and purchasing goods, services or works necessary for the organization |
| QUALITY | Manage all quality control activities for production process, to ensure that raw materials, processes, and finished products achieve and fulfill company requirements and applicable standards |
| INDUSTRIALIZATION | Define production cycles, taking care of production technologies and process optimization |
| PRODUCTION | Produce products/systems according to business strategy and plans |
| MATERIAL MANAGEMENT (MM) | Ensure supply chain and secure materials availability for production departments based on sell forecast |
| FINANCE | Define project costs and secure company businesses |

Table 1.1 Company teams

1.1.3. Product Lifecycle Management (PLM) and Enterprise Resource Planning (ERP)

The ERP and PLM tools play an important role in manufacturing companies.

PLM is a product development process, from concept to disposal. It controls the life cycle of the products/systems company. The life cycle of a product is a marketing model traditionally used to describe and analyze the phases that a product goes through during its lifetime, from its market introduction to its removal. The duration of the entire product life cycle is determined by the sales trend. There are four phases in which the product life cycle is divided: introduction, growth, maturity and decline, as shown in the following image [1].

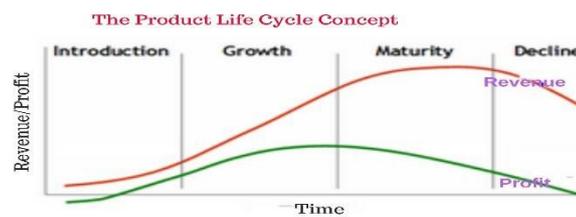


Figure 1.3 Product Lifecycle

PLM is a strategic tool for managing the goods as they move through the typical stages of production. In fact, as mentioned before, conditions in which a product is sold changes over time, so PLM is a necessary structured tool for products management through their lifecycle stages. In conclusion, it represents an all-encompassing vision for managing data relating to design, production, support and the ultimate distribution of manufactured goods.

On the other hand, ERP is a management tool that integrates all the relevant business processes of companies, such as sales, purchases, warehouse management, accounting, etc. ERP systems track business resources and the status of business commitments, such as orders, purchase orders, and payroll. ERP also facilitates the information flow between all business functions and manages connections to outside stakeholders and facilitates error-free transactions and production, thereby enhancing the organization's efficiency.

To keep up with a growing market and face growing competition, PLM and ERP integration is the correct way to reduce costs and improve operational processes for a lean and efficient organization. The integration between the PLM and ERP reduces manual activities, improves automation and limits the number of human errors, leading to time savings in terms of design and production

efficiency, allowing the company to release products more quickly, improving quality and reducing scraps and revisions.

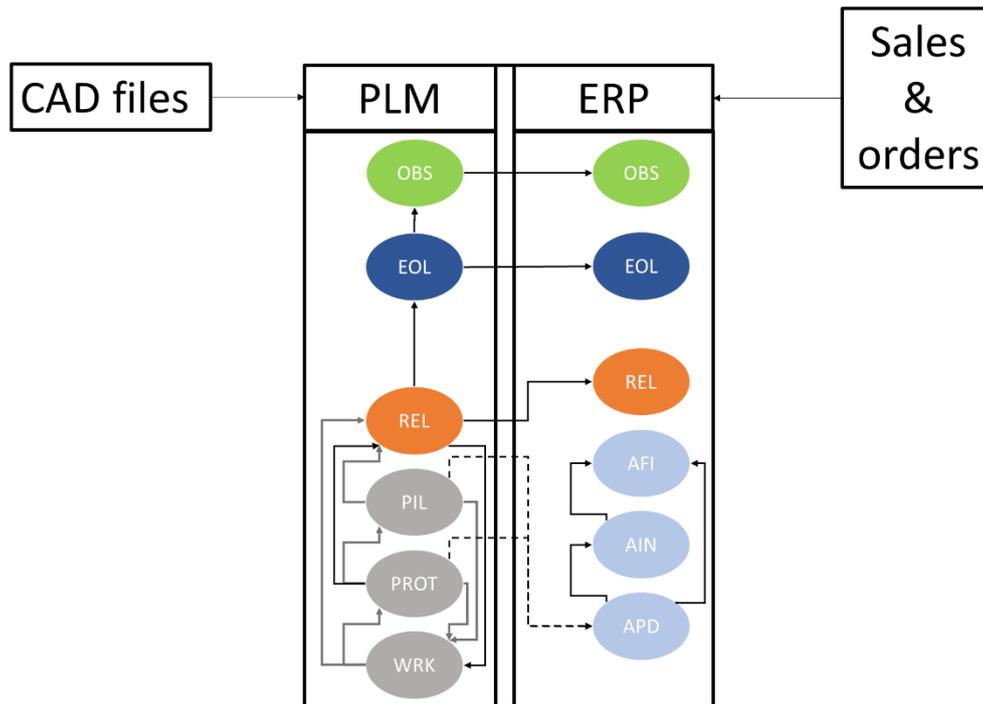


Figure 1.4 Relations between the CAD files with the ERP thanks to PLM (the states of the product in the PLM and ERP are shown better in the following figure)

As shown in the figure above, the importance of the PLM is to link the design part containing the CAD (Computer Aided Design) files with the tasks performed by the ERP, such as orders and sales. By doing so, the PLM becomes a unique location where all the design data are collected without redundancies in order to make them always available to all members of the organization, producing a lean communication between them. This interconnected system is well represented in the following figure:

belonging from several business teams, such as the Finance, Procurement, Material Management and Production teams.

The ERP phases are:

- APD (Approval Procurement Department): Procurement includes the attributes for the article of its competence, mandatory for its release. At the end of this step, the article can go:
 - Directly to Finance, if it is a commercial one or parts;
 - Directly to Industrialization if it is an assembly;
- AIN (Approval Industrial Engineering): Industrialization defines production cycles, takes care about the adaptation of production technologies and of the possible use of external resources for the article production;
- AFI (Approval Finance): Finance defines the article costs;
- REL (RELeased): the article is valid for production.

Once the article stands in the decline phase of the product lifecycle, it can be found in two states:

- EOL (End Of Life): the product is at the end of its life for various reasons (item no longer available, item no longer usable, item with an incorrect unit of measurement, etc.) and there is no possibility to purchase it;
- OBS (OBSolete): the article code can no longer be used for any purpose. The OBS state is settable only if the stock in all warehouses are equal to zero.

1.2. Introduction to PRs related to the mechanical modifications case studies

1.2.1. Problem Report management

As far as the strategic management approach is concerned, Windchill is the integrated PLM software used. This software, as mentioned previously for the PLM, helps the organization to overcome the increased complexity and engineering challenges of developing new products and solve different problems for products that are on the market. The added value of the PLM is the

traceability and the possibility of retracing the history of the modifications made in order to increase the quality of the process.

Within the Windchill tool, Problem Reports (PR) are opened to report and keep track of problems/requests coming from different functions. To solve a PR, one or more Engineering Change Notice (ECN) are required.

ECNs contains the actions that are needed to solve the PR, either in part or completely, and the deadline to close the task. Each 'ECN' contains specific activities and each activity belongs to a specific 'ECN'. In order to complete an 'ECN' all its 'tasks' must be complete.

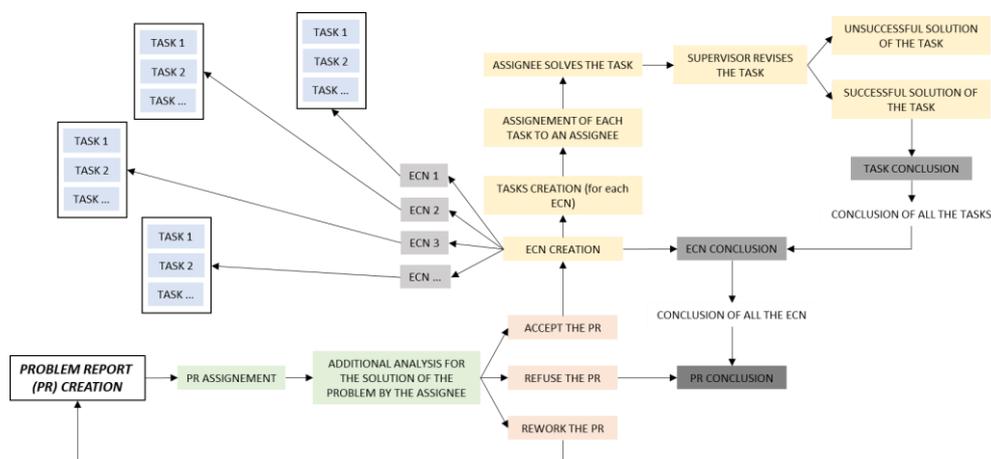


Figure 1.6 PR flow

As far as the *TheraPick* system is concerned, several products are already available on the market. As already mentioned, communications regarding products improvements are shared by Customer Service that represents the interface with the customers for installed systems on the field. These communications are developed and traced within specific PRs.

As shown in figure 1.7, problems are reported by internal functions, for example by technicians during internal testing of the machine or production engineers during assembly and production processes, or external functions, for example by customers while the machine is running within a hospital pharmacy.

Once the problem is detected, the related PR is created with its ECN. ECN are composed of several tasks that are solved sequentially, and each one of them is assigned to a specific function. A supervisor revises the work done by the assignee and either decides to end the same task if it is

well carried out, so the following task can be assigned and the PR can continue flowing through the organization, or on the contrary the same task is assigned again to the previous assignee.

The ECN is released only when all its relative tasks are completed and the PR is released when all its ECN are concluded. The PR flow is reported in the following figure.

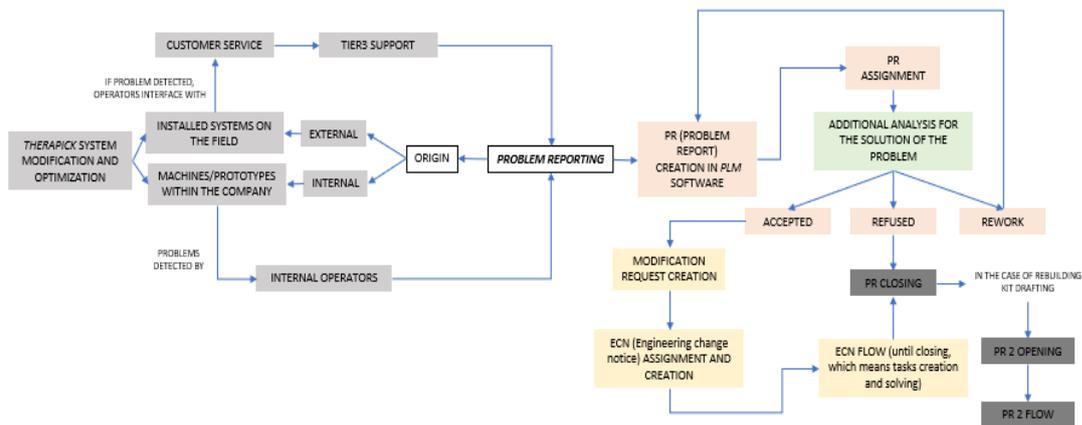


Figure 1.7 PR management

1.2.2. Roadmap approach

The scope of the TheraPick project is to finalize the TheraPick system development to allow deploying ongoing and upcoming projects. To do so, various problems regarding the automated solution are pointed out, analyzed and solved. The task of the author of this thesis is to solve one of the TheraPick system problems that affects the stability of the system, which is the misalignment of the warehouse due to incorrect filling of the cases.

The PR flow is an efficient process that involves various functions. Nowadays, with the industry 4.0, time to market plays a key role in increasing competitiveness against direct competitors. As mentioned previously in the “company overview” chapter, business unit systems take decisions regarding the quality and competitiveness improvements for TheraPick system, such as the guidelines to solve PRs. In fact, the engineering team and project leader issued a roadmap approach to follow, in accordance with the rest of the team, in order to increase the quality of the PRs resolving process.

Within the *TheraPick* project, whose main aim is to complete the *TheraPick* system development ensuring the successful “go live” for already available systems on the market, the so-called Roadmap Approach defines the categories based on which problems reported or new developments are released. Defined categories are:

- Stability
- Flexibility
- Performance

PRs are classified within these three categories.

Within each category, the priority level is defined considering the impact and frequency with which the problem affects and occur within the system. The term impact is referred to a potential stop of the machine or in general to the seriousness of the situation that has been created by a problem. While the term frequency is referred to how often the problem occurs during the use of the machine. Impact and frequency have been defined qualitatively by a cross-functional team constituted by different functions considering that *TheraPick* is a new system and the historical data available do not allow to define those levels quantitatively. The impact and frequency are measured as follows:

- Very low;
- Low;
- Medium;
- High;
- Very high.

The combination between impact and frequency determine the priority levels according to the picture below:

- Very High (red cells)
- High (brown cells)
- Medium (yellow cells)
- Low (green cells)

Based on this evaluation, PRs are solved from very high priority to the low ones.

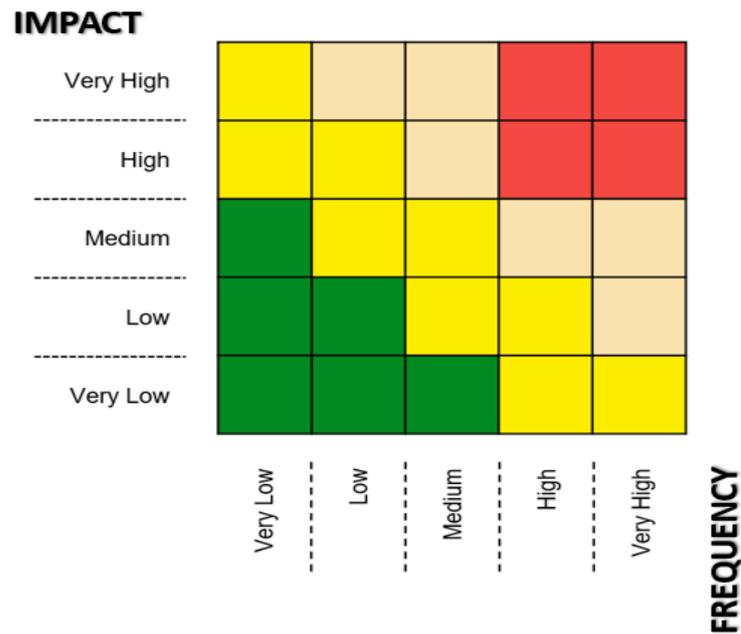


Figure 1.8 Determination of PR priority

1.2.3. Introduction to cases #51 #61

The mechanical modifications described in this thesis are part of two PRs. By referring to the previous chapter, the PRs must be solved in a certain order based on the *TheraPick* roadmap.

The two PRs regarding this study are numbered as cases #51 and #61. As mentioned in the introduction, the problems detected are related to the *Blister Packager* module for BUDs production and the *All-Forms Packager* module for UD bags production. In some cases, the wrong movements of these UD's on the stem in the *case filler* group causes an incorrect filling of the cases. Warehouse misalignment is the result of the #51 and #61 cases, which compromise the stability of the system.

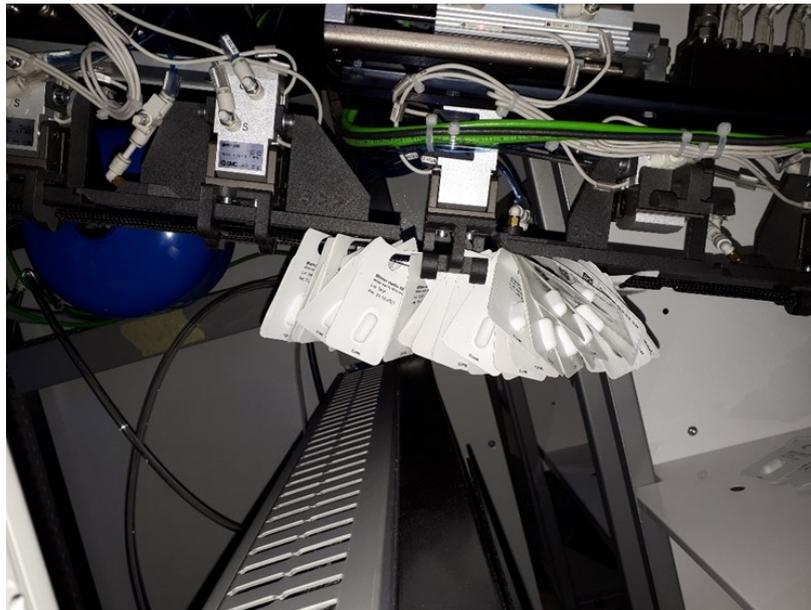


Figure 1.9 Example of the problem occurred in the case-filler group

The priority given to the two PRs is very high, also because of the very high impact and frequency that affect the *TheraPick* system.

The proposed solution and the related process to solve the two PRs mentioned above, are described in later chapters.

1.3. Hospital pharmacy and drug management overview

1.3.1. Hospital pharmacy

This chapter is a brief introduction to the hospital pharmacies, aimed at providing the reader with essential knowledge in terms of pharmacy processes. This information is significant to better understand the benefits of an automated packaging and dispensing system.

Over the past decades, automated machinery has increasingly been exploited within the hospital environment accomplishing tasks previously carried out by operators. These systems are tailor-made solutions improving both patient safety and operation efficiency, which were the key reasons for the growing use of automated drug management systems. *Swisslog Healthcare* provides automated systems for both retail pharmacy and hospital pharmacy, which have different features.

The retail pharmacy works as a drug store and pharmacists provide their direct service to public customers, handling small amounts but a great variety of products in packages almost daily supplied to replenish the pharmacy stock. Instead, the hospital pharmacy manages high amounts of products, usually replenished monthly, and deals with hundreds of prescriptions per day that must be filled correctly and given to the correct patient. In this context, the medication pathway is a complex process that incorporates clinical risk issues as well as logistics aspects. The main areas where medication errors might occur are prescribing, transcribing, preparation, dispensing and administration. Hospital pharmacies dispense hundreds of thousands to millions of medication doses annually, and therefore even low dispensing error rates can generate many errors [2]. In this context, automated drug management systems find its space reducing errors thanks to the nurse's workload reduction to manage and administer medication via easy-to-handle unit doses, thus improving patient safety and efficiency.

In particular, the lower the manual intervention, meaning a high level of automation, the better the therapies administration is. Moreover, the reduction of inventory, expired drugs, storage volumes thanks to automated systems, improves hospitals efficiency and reduce costs.

The Swisslog Healthcare automated drug management system presented subsequently is a tailor-made solution conceived for the inpatient service¹ and it is built around the two targets mentioned before: safety and efficiency inpatient drug management process improvement.

1.3.2. Inpatient drug management process

For the inpatient drug management process three key professionals' figures are involved: pharmacists, nurses and physicians. Each of these professionals involved must accomplish their duty aiming at a patient safety-oriented management of the therapy.

¹ An inpatient is a patient admitted to the hospital for treatment requiring at least an overnight stay. On the contrary, outpatient is a patient not residing in the hospital where he is being treated or that has been dismissed but needs home-treatment.

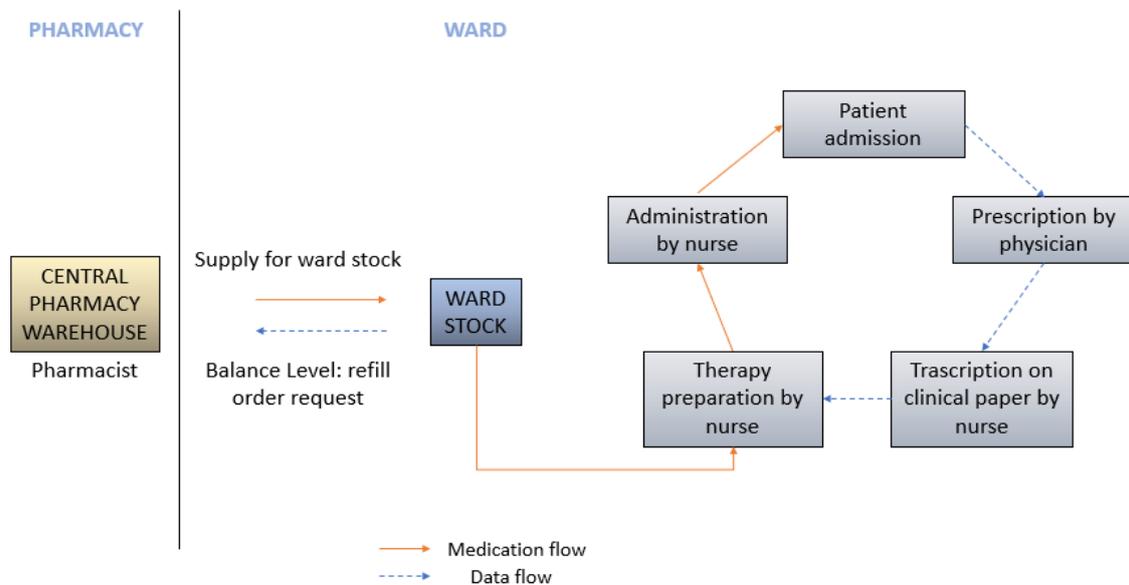


Figure 1.10 Inpatient drug management (traditional process)

The process refers to traditional drug management, that ordinarily begins with the patient's admission to the hospital. The physician, after a diagnosis, examines the patient and decides the correct therapy and prescriptions. The nurse transcribes the therapy on clinical paper and assemble the treatment that is consequently administered to the patient. The rest of the drug management process is up to the pharmacists who supply the ward with medicine refilling from the central pharmacy warehouse. With automated drug management systems, main risks related to human errors such as transcription, preparation or manual therapies administration are prevented. Errors could have different causes and could significantly affect patients' life. Studies show that the most frequent errors are [3]:

- *Administration errors*, such as the drug administered to the wrong patient and at the wrong time, and *therapy preparation errors*, such as nurses' wrong interpretation and drug exchange, are the most common errors;
- The remaining errors include *prescriptions* such as dosage calculation, wrong molecule, drug interactions, wrong therapy duration, and errors of *transcription* such as manual errors, the wrong interpretation and incomplete information.

High-tech hospitals take several measures to avoid these kinds of errors, which are: CPOE Computerized Prescription Order Entry (CPOE) software for the electronic recording of the patients

therapy, robotics, automated distribution devices, bar-code technology and measurements such as bedside verification² to support the medication management process in improving safety inpatient care.

Depending on therapy preparation, it is possible to distinguish two types of hospital management: *centralized* and *decentralized* solution. To briefly introduce the differences, the *centralized* therapy preparation management contemplates a patient-specific therapy prepared inside the hospital pharmacy staff, while the *decentralized* procedure relies on a totally different concept since the patient-specific therapy is assembled directly within the ward by nurses. The *TheraPick* system is designed for centralized therapy preparation management, even though thanks to its flexibility and modularity it can be used for decentralized therapy preparation management too. The role played by the *TheraPick* system in the inpatient drug management process compared to the traditional process is described in the following chapter.

² Bedside verification is a safe procedure which consists of an electronic bar-code check matching the patient and the medication immediately prior to the administration.

2. TheraPick system

2.1. TheraPick system overview

The *TheraPick* system is a customizable, versatile and configurable pharmacy automation solution developed by Swisslog Healthcare for hospitals automated unit-dose drug management. The benefits of the machine, such as the increase of safety and the reduction of operational costs, have been already discussed in the previous chapter.

The system is a configurable solution thanks to its modularity. As it is shown in the following figure, The TheraPick system is composed by four modules:

- 1) *Blister Packager*: fully automated module for blisters cutting and Blister Unit Dose (BUD) packaging which are then placed into cases and stored in the warehouse; this module is integrated within the system;
- 2) *All-Forms Packager*: automated module for the Unit Dose (UD) bag packaging of drugs that are not compatible with the BUD model such as vials and pills. This module can be integrated into the system, which means that the UD bags are automatically loaded into the warehouse; it can also operate autonomously, which means that the UD bags are loaded into the warehouse by filling and moving the cases manually;
- 3) *Storage (or warehouse)*: integrated module in which cases with BUDs/UD bags as well as Blister, Pills and Phial Boxes are located;
- 4) *Dispensing module*: combines BUDs and UD bags on a plastic ring that represents the patient's therapy. On this ring there is a label (Patient Label) that describes the composition of the therapy and the delivery destination.



Figure 2.1 TheraPick modules presentation

The system is conceived to secure therapy management by tackling recurring human errors during the preparation and dispensing phases. A presentation of the system is important in order to explain to the reader how the system manages medications in unit doses.

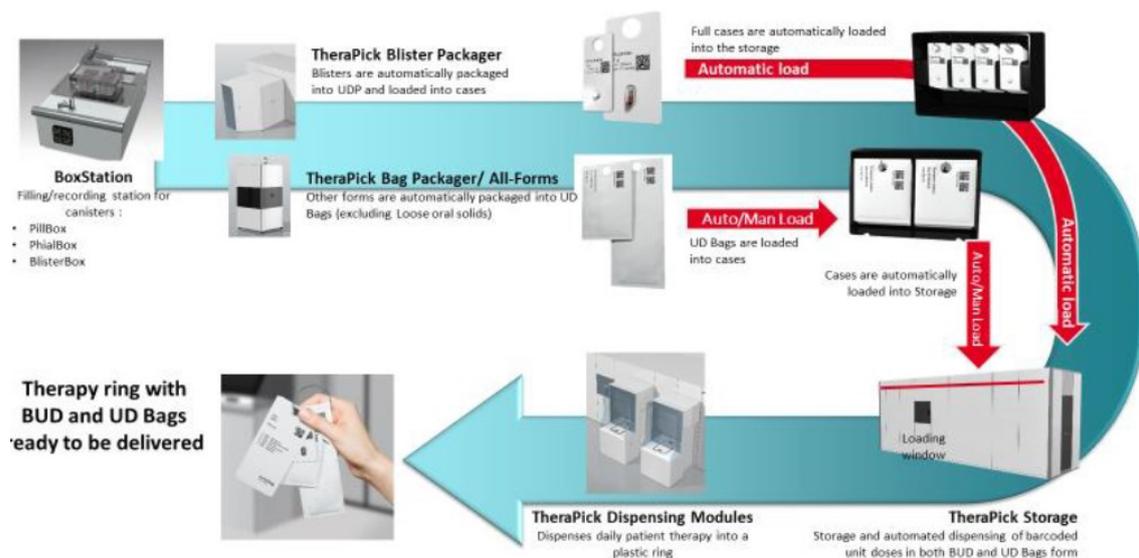


Figure 2.2 Drug workflow within the TheraPick system

The figure displayed above shows the steps of the drug process within the system. The packaging process begins at the BoxStation, where different types of medications are placed and properly

arranged in special canisters. The following step is then carried out through the *Blister Packager* and the *All-Forms Packager*, whose main tasks are to package BUDs and UD bags, respectively. On BUDs and UD bags barcodes are printed containing all drugs information (type of drug, expiry date) and a unique progressive number that allows to trace the drug from preparation to administration to the patients. The mono-dose medications are then loaded into cases, which are then placed in the warehouse thanks to the stacker crane. The last step is carried out by the dispensing module, which gathers all the unit-dose drugs for the patient-specific therapy through a plastic ring.

The system is provided with a loading window which is an automated warehouse access door for loading or unloading cases and canisters (except from the PillBox) manually. This is due to various reasons such as therapies that return to the pharmacy or for the loading of canisters into the system. The system is customizable depending on the hospital requirements such as the number of beds served, the organizational set-up of the pharmacy, the average number of unit-dose bags and so on. In fact, the system is not always equipped with all modules and the layout is defined based on the customers' needs.

The following chapter describes the *TheraPick* system process and shows the best configuration achievable considering all the modules of the system.

2.2. Pharmacy automation process

The *TheraPick* system, as discussed in the previous chapter, fits with the centralized management of the therapy while at the same time it is adaptable to a decentralized one.

Within the inpatient drug management process, the *TheraPick* system allows a fully automated drug workflow in order to help nurses and pharmacists to patients care activities reducing the time for operational ones. The pharmacy automation process performed through a *TheraPick* system starts with the implementation of the prescription made by the physician through a software-guided procedure, more precisely, through a Computerized Prescription Order Entry (CPOE) application. In this contest, the pharmacists must put the medications into the system when their quantity in the warehouse falls below a certain threshold. Once the therapy has been received via

software, the pharmacists validate the therapy order and launch the patient-specific therapy production. The UD bag and BUD in the system are then produced, assembled and delivered into the ward stock with the therapies prescribed by the physician in the right quantity and at the right time. Finally, nurses have to administer the ring therapy created by the *TheraPick* system to the patient. To further improve patient safety, nurses could check that the right therapy is administered to the right patient through the bedside verification. In fact, when a patient is admitted into the hospital, a dedicated barcode could be assigned to him or her. At the moment when the physician prescribes the patient's therapy through a CPOE, the *TheraPick* system creates a new barcode, which will be printed on the patient label on the therapy ring and it will correspond to the patient one.

2.3. Theoretical introduction to robotics

The *TheraPick* system is a robotized system for the automatic packaging of single-dose medications and for this reason the following paragraph aims to describe the general functioning of robotized systems in industries.

A robot is a machine capable of carrying out human tasks independently and automatically. The robotics is the engineering discipline that studies and develops methods with which robots can carry out their tasks so as to replace humans in an automatic way. Industrial robots are used for manufacturing processes. Their applications in the *TheraPick* system include welding, punching, pick and place for medications, product inspection, packaging and labelling; all accomplished with high precision and carried out in a safe way. The main advantages of robot usage within industries are [4]:

- Manufacturing costs reduction;
- Productivity increase;
- Product quality improvement;
- Elimination of risky or alienating tasks.

Robots are complex hybrid systems which consist of various subsystems such as computers. That is an electronic hardware suitably programmed via software that controls a mechanical part made of servomechanisms for the performing of desired mechanical tasks. The mechanical structure of a robot is controlled to perform tasks and involves three distinct phases:

- Perception;
- Processing;
- Action.

Sensors give information about the perception and so of the environment or of the robot itself (like the position of the internal components). This information is derived from the sensors and then processed to calculate the appropriate signals to the actuators or motors which move the mechanical system. Industrial robotized systems are equipped with many components, such as motors for the robot movement and sensors for the environment perception. *TheraPick* system robots are powered by a pneumatic system that uses compressed air that, with electric motors and actuators, perform several robotic movements. For the cutting process in the *Blister Packager*, an ultrasonic motor performs the vibration of the blade which cuts the blister into single doses.

The *TheraPick* system is also provided with several sensors such as position, speed and vision sensors.

Many of the several operations that take place within the *TheraPick* system are carried out by manipulators that play an important role in robotized systems. A robotic manipulator is an electronically controlled mechanism composed of an assembly of links interconnected through mechanical joints.

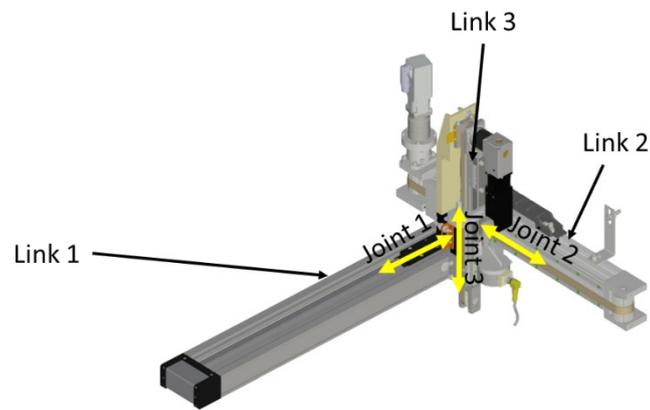


Figure 2.3 Links and joints of a robotic manipulator (with the cartesian configuration) made by Swisslog located in the All-forms packager

The most important types of joints used in the *TheraPick* system are the:

- Revolute joint that allows relative rotation between two links along one axis;
- Prismatic joint that allows relative translation between two links along one axis;
- Cylindrical joint that allows relative rotation and translation between two links along one axis.

The manipulator is mounted on a base which can be fixed or movable. It is composed of an arm that ensures mobility and reachability, a wrist that confers orientation, and an end-effector that performs the required task [5]. The manipulators within the *TheraPick* system are provided with several end-effectors; the most common ones are the pneumatic grippers and the suction cups.

The two most relevant parameters with which a robot is defined are the workspace and the degrees of freedom. The first one provides important and helpful information to optimize the dimensions of a robotic manipulator. It is defined as the set of points in the space that can be reached by its end-effector that depends on the joints with which it is provided. The second one is the number of movements that the robot can perform in a space.

The robots can be classified in many different ways according to several parameters, which can depend on its:

- Functional criteria (for manipulation, for processes or for assembly);
- Geometrical structure;
- Mobility (manipulator mounted on a fixed or movable base);

- Precision (high, medium or low precision);
- Speed (rapid or slow manipulators).

The most commonly used commercial manipulators are the three-axis robots, which means that they have three degrees of freedom. The types of movement that manipulators can perform inside its workspace are defined by its joints. As far as the geometrical structure classification is concerned, the types of three-axis robot are:

- The cartesian robots or the gantry robots, which are composed of three prismatic joints and its workspace is cuboidal. The three links are perpendicular to each other. The gantry robot has the same operating principle and it is used for heavy loads movements;

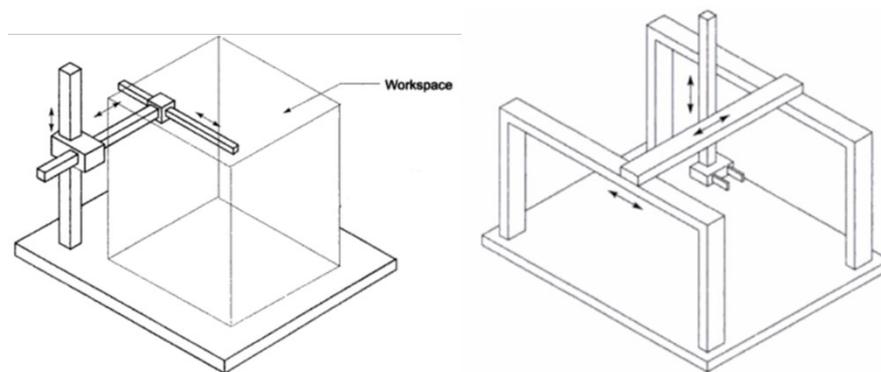


Figure 2.4 Cartesian robot with its workspace on the left and a gantry robot on the right

- The cylindrical robots, which are composed of two prismatic joints and a revolute joint. The workspace of the robot is a cylinder as described in the picture below:

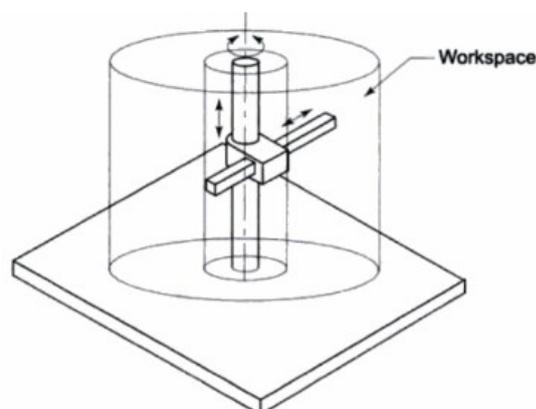


Figure 2.5 Cylindrical robot and its workspace

- The spherical robots, which are composed of two revolute joints and one prismatic joint. The workspace of the robot is a sphere in this case;

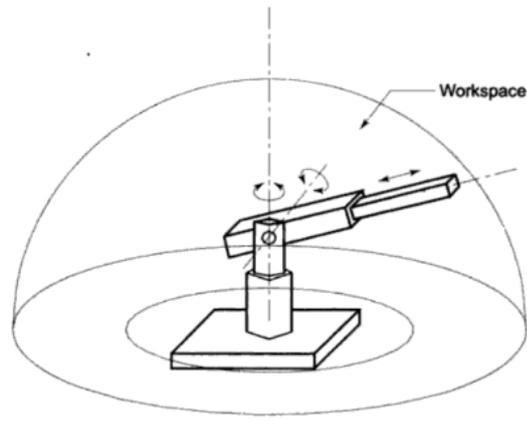


Figure 2.6 Spherical robot and its workspace

- The SCARA robot is a combination of the cylindrical and spherical robots as a result of a manipulator with revolute motions confined to the horizontal plane. In fact, the SCARA robot has the same kind of joints of the spherical robot but with three motion axis that are parallel;

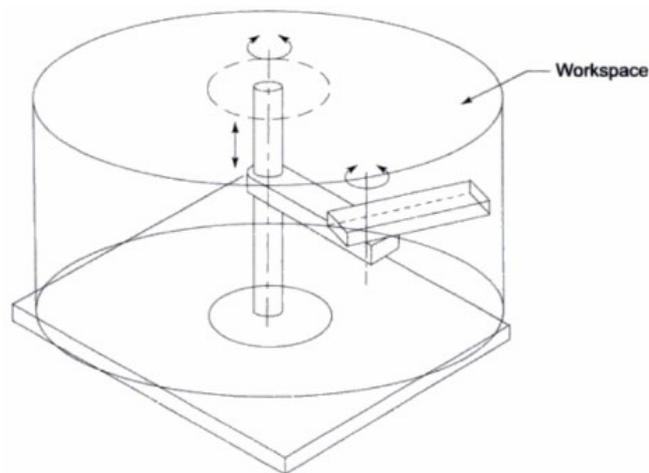


Figure 2.7 The SCARA configuration and its workspace

- The articulated robots are also called anthropomorphic robots for its similarity to the human arm. It is composed of three revolute joints.

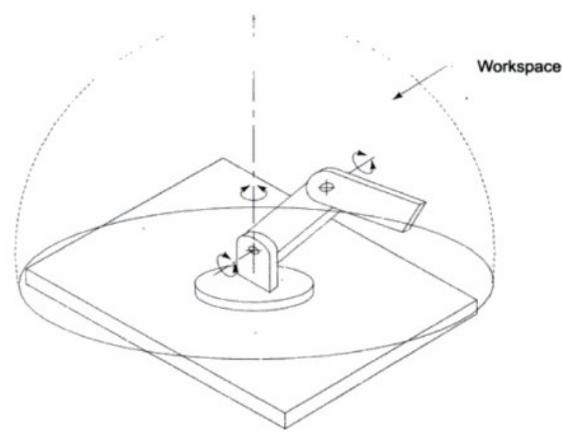


Figure 2.8 Articulated robot and its workspace.

2.4. TheraPick system cycle

2.4.1. BoxStation

As described previously the *TheraPick* system cycle begins with canisters filled at the BoxStation, which is a control device for the filling and registration of the BlisterBox and the PillBox. It allows a secure transfer of medications from their original packs to specific canisters.

The BlisterBox and PillBox are Swisslog Healthcare's patented locked canisters for loading medications into the packaging station. As shown in the figure below, these boxes consist of three main components:

- *Safe closing lid*: a special lid equipped with a safety closure that can be only opened from the BoxStation;
- *RFID tag*: an electronic chip positioned both on the case and on the canister. The chip records all the information related to the box and thanks to both the system and BoxStation TAG reader, the machine knows all the main data of the medications contained both in the case and in the canister;
- *Box code*: an identification code printed on a label applied on the box's main body. This code is also registered on the RFID tag.

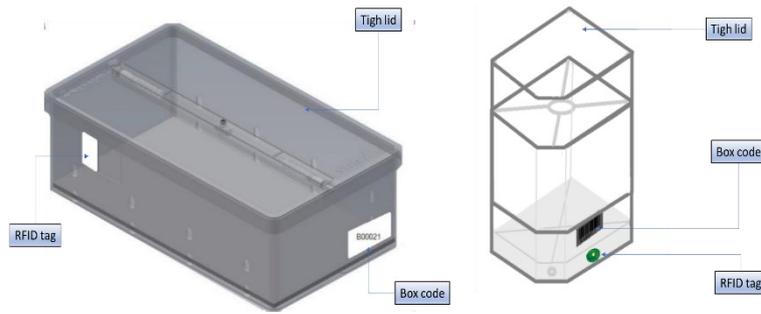


Figure 2.9 The BlisterBox on the left and the PillBox on the right

The BlisterBox is the dedicated container for the loading of blisters (not in the single-dose format) into the *Blister Packager* or for the loading of other kinds of drugs (such as phials) into the *All-Forms Packager*. The Pillbox is used for the loading of solid bulk medications for oral use into the *All-Forms Packager*. Each one of the canisters can accommodate an insert, which is an element placed in the box and used for the drugs filling and handling.

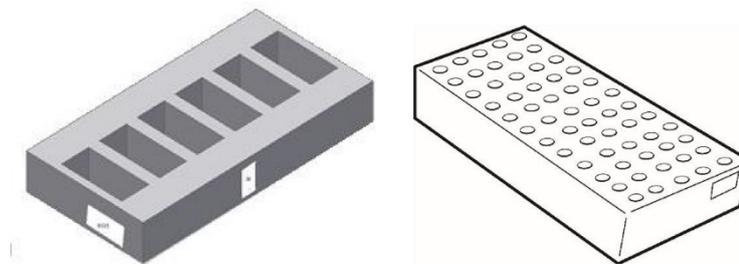


Figure 2.10 BlisterBox insert for blisters on the left and BlisterBox insert for phials on the right

The canisters can only be opened from the BoxStation tools through a controlled and tracked procedure. In order to increase the safety of the medications inside the boxes, their opening and closing can be only carried out through a suction cup which creates the vacuum within the box lid. This operation is used to move the pin, which is attached to a compression spring as shown in the following figure. As a result, this movement locks and unlocks the connection between the lid and the box. Therefore, the compression of the spring creates the vacuum and consequently the connection between the lid and the container is released. On the other hand, the spring is in the rest position for the closing of the canister.

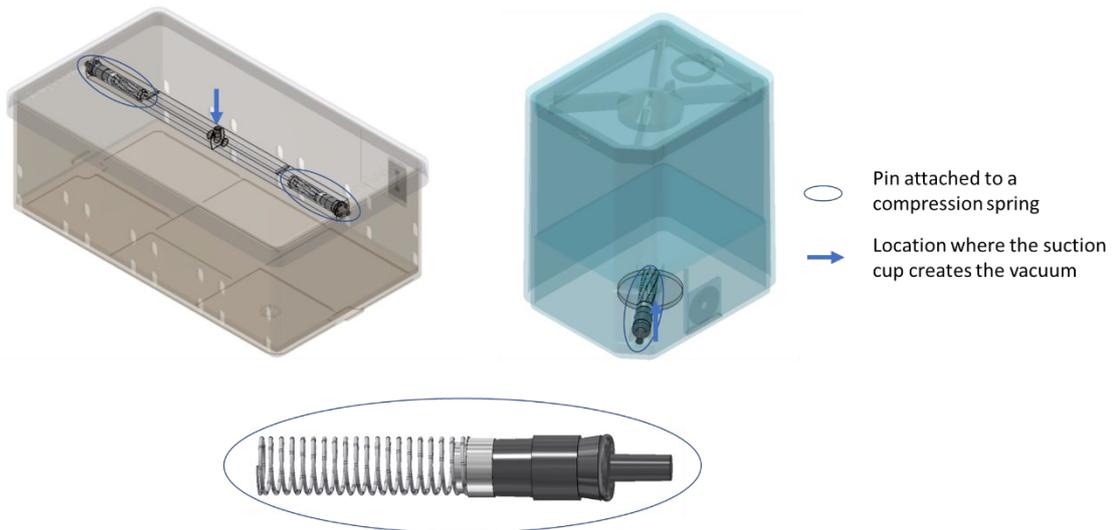


Figure 2.11 Opening and closing system of canisters

The Pillbox is also provided with a “crossframe” that allows the picking of a single solid-bulk medication contained in the box. When the box is loaded into the *All-Forms Packager*, a cannula attached to a cartesian robot comes into contact with a hole located onto the crossframe in order to create the vacuum through a suction system. By doing so, the cannula proceeds with the suction and the single-dose medication is collected.

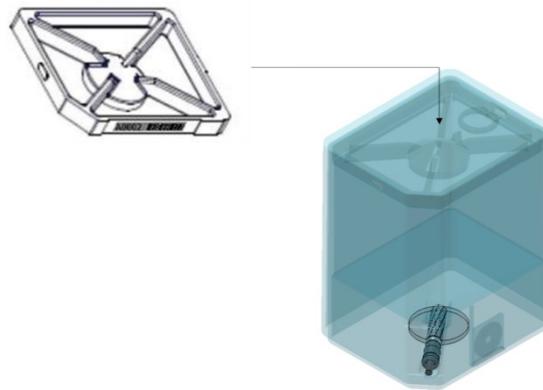


Figure 2.12 Pillbox with its Crossframe

The BoxStation has the tools for the correct opening, closing, tracking and software registering of canisters. To do so, the module, as shown in the figure below, is constituted by:

- Vacuum pump for canisters opening and closing;
- Pressure gauge;
- Barcode reader;
- Tag reader.

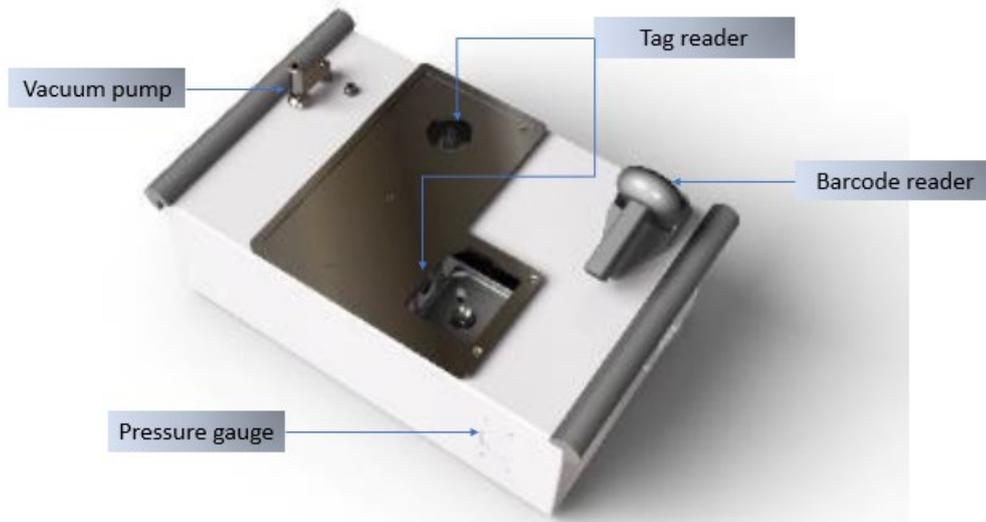


Figure 2.13 BoxStation structure

In the BoxStation, a software application guides the operator through the canister filling and recording procedure, requiring a barcode scan for each relevant step. Two operators carry out data checks in order to ensure accuracy and safety. Three main steps are carried out in this module:

- *Initialization*: the canisters and their relative inserts are registered in the software application through the box code and RFID tag barcode reading. The inserts are positioned in the canisters and are elements in which drugs are contained;
- *Box filling*: the canisters are placed in their appropriate location at the BoxStation and filled with drugs. Each box is only filled with a product with the same batch number and the same expiry date. Medication codes are uploaded on the software through barcode reading in order to track and handle products within the TheraPick system process;
- *Check box*: a second validator operator, different from the first, validates the insertion of the canister data loaded into the software by the first operator.

After the software-supervised canister filling procedure, the operator moves towards the loading window where the packaging cycle begins.

2.4.2. All-forms and Blister packager

The *All-Forms Packager* and the *Blister Packager* are the two dedicated modules of the *TheraPick* system for the packaging of unit-dose drugs. The packaging process starts with the introduction of the medications in the unit-dose packaging modules.

As far as the *Blister Packager* is concerned, since it automatically portions blistered medications into blister unit-dose (BUD), only the BlisterBox (containing blisters) can enter this module. Instead, all the Swisslog Healthcare's patented canisters different from the BlisterBox, can enter the *All-Forms Packager* module.

After the checking step is completed at the BoxStation, the canisters are placed into their loading window. At this point, the stacker crane in the storage moves the BlisterBox up to the packaging machine, while the PillBox has its loading window located directly in the *All-Forms Packager*. Once the canisters enter the system's module, the packaging process can start, as explained in more details in the following chapter.

At the end of the packaging cycle, the unit doses are either transferred automatically into the *Storage* or handled by an operator (this is possible only in the *All-Forms Packager*). In the first case, BUDs or UD bags are placed into the case located on a storage shelf. In the other case, UD bags can be handled by an operator thanks to what is called "side-sliding production".



Figure 2.14 Empty case

2.4.3. Storage

The *Storage* is the automated module for the stock of medications in unit-dose format. The cases containing packaged single-dose drugs are automatically loaded and unloaded from the *Storage* through a stacker crane, able to carry out both operations.

The stacker crane has a crucial role, not only for managing the movement of cases and canisters, but also for tracking the objects through the tag reader which is placed on it. The stacker crane is a three-axis robot, which means that it is a mechanism with three degrees of freedom, used in automated storage and retrieval systems. It is composed of a mobile frame that moves along a vertical column and carries the head of the stacker crane, which is the end-effector of the mechanism that comes directly into contact with the canisters (excepted from the PillBox) or cases. It is able to carry up to five cases at the same time and one canister at a time. The stacker crane is equipped with toothed belts for the lifting motion of the mobile frame and for the translation motion of the vertical column along the track in the aisle of the warehouse. The head of the stacker crane can rotate around the perpendicular axis of the mobile frame plane in order to line up with the warehouse shelves that house the cases and canisters. It is provided with a system for the tag reading of the objects with its clamps.

The *Storage* module is provided with a return window, through which non-administered medications (coming from the ward) and cases containing wrong medications are re-loaded into. It is also used for the loading and unloading of canisters from the *Storage*.

2.4.4. Dispensing module

The last step of the *TheraPick* system cycle is represented by the dispensing module, also called *PickRing*.

The dispensing cycle starts when a medication order is received through the HIS (Hospital Information System) and the *PickPortal* collects the appropriate medication from the *Storage* area. The *PickPortal* is the robot for the loading of BUD and UD bags into the *PickRing* module. It is provided with two vertical guides in order to enable the vertical movement of the horizontal axis.

The head of the PickPortal can move along the horizontal axis and rotate around the parallel axis of the vertical guides. It is the end-effector of the robot and is equipped with a barcode reader and suction pipes that pick up the single dose medication bags.

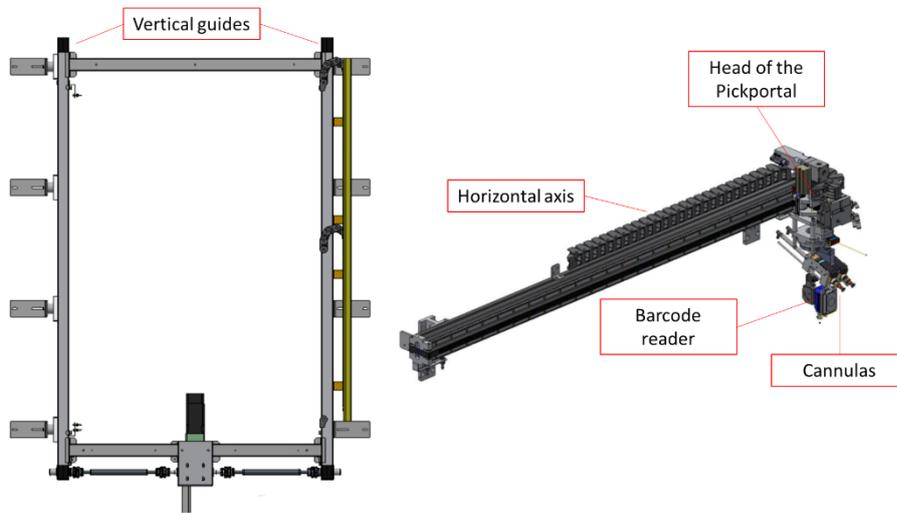


Figure 2.15 Pickportal structure

The stacker crane removes the appropriate cases from their location in the warehouse to move them towards the dispensing portal. Here, the cases containing drugs with a high dispensation number per day, are placed on the Pinwall, while the cases containing drugs with a low dispensation number per day, are placed on a shelf by the stacker crane when the order is received. The Pinwall is the trade name referring to the panel in the *Storage* near the *PickRing* module, where cases with the most widely consuming drugs are located.

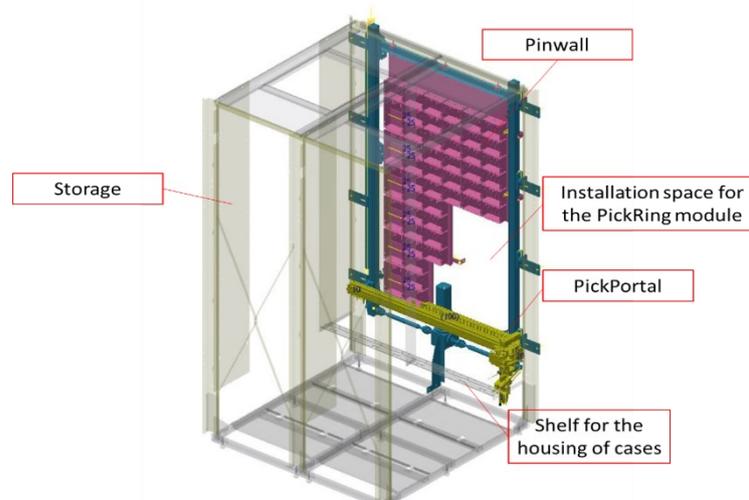


Figure 2.16 Dispensing portal

The BUD and UD bags are picked up from the cases with a suction pipe placed on the end-effector of the PickPortal. The bags containing the single-dose medications of the patient-specific therapy are then placed on a stem of the *PickRing* module.

The *PickRing* module allows the collection of all unit-dose medications that make up the patient's therapy and binds them together with a label in a plastic ring. At the end of the binding process, the ring is patient-specific containing the label with all patient data and the list of drugs constituting the patient's therapy.



Figure 2.17 Therapy ring

The rings are then sent to the ward either by hand or through a pneumatic tube system. Once the therapy rings are transferred into the ward, the nurses organize the administration phase.

2.5. The importance of TheraPick

The *TheraPick* system project comes after the development of the *PillPick* system. The latter is the pharmacy automation system that packages, stores and dispenses unit-dose format medications.

The need for the development of the *PillPick* system derives from the high request in the hospital of large amounts of single-dose medication management that mainly deals with drugs that are not in the blister format. For this reason, the *PillPick* system was initially developed as a machine for the management of high amounts of medication in original packs or in unit doses. In fact, the *PillPick* system is provided with a module called *AutoPhial* for the automatic loading of unit-doses in the medication packaging machine called *PillPicker*. The *AutoPhial* has been improved as *AutoPhial Plus*, able to cut blisters automatically. This new module was developed because of the diffusion of

the blistered medications, especially in Europe. However, the PillPick system was designed for the management of high amounts of medicines, not in blister format. Nowadays the *PillPick* system is still on the market and it is sold in different hospitals around the world.

The diffusion of blistered medications prompted the Swisslog Healthcare technical experts to focus on the developing of a unique solution for the management of all kinds of single-dose medications in order to improve the hospital pharmacy workflow and to reduce operational costs. This is the reason the *TheraPick* system has been designed.

3. Single-dose packaging module and case-filler group

3.1. Product overview

Over the past years, industry 4.0 has increased the production and profit of automatic packaging machines in the pharmaceutical field of application. Surveys demonstrate that 85% of the total amount of solid drugs in Europe are packed in blisters [6]. Both manufacturers and consumers recognize the benefit of blisters packaging, such as product integrity, product protection and reduced possibility of accidental misuse.

Hospital pharmacies distributing medications are challenged by the large number of prescriptions to be packed in unit doses (not only in blisters) with the consequent risk of potential dosing errors, increase operational costs and decrease product safety. To reduce these kinds of mistakes and improve efficiency, the Swisslog Healthcare technical experts have focused on developing solutions to improve the automation of the complete unit-dose management process. To do so, the team focused on handling the widest range of galenic forms, with special focus on blisters singularization and identification. Swisslog Healthcare developed the *TheraPick system* with two modules for the packaging of unit dose medications which are the *All-Forms Packager* and the *Blister Packager*.

As described previously, the All-Forms module is an automated module for the UD bag packaging of drugs that are not in blister format, such as vials, ampules, syringes and cups. It is a complex machine composed of several functional groups all aimed at providing the correct packaging of drugs in unit doses. Depending on the customer's needs of the system, as already mentioned, there are two versions of the *All-Forms Packager*: the stand-alone one which is autonomous that means that UD bags are manually loaded into the warehouse with respect to the integrated version which has additional functional groups for the automatic loading of UDs into the *Storage*.

The *All-Forms Packager* design is based on the previous version called the Semi-Automatic Bag (SAB). This UD packaging machine is still available on the market and it is similar to its latest version.

The main difference between the two modules lies in the lack of the conveyor-belt group in the

SAB. This is because the entry of all the canisters (apart from the PillBox that are not managed) takes place manually in the loading window located directly on the SAB, while in the latest version of the machine packager, the entry of the boxes (except from the PillBox) is automatic.

Firstly, the *All-Forms Packager* is innovative in two ways:

- The space optimization within the machine where the functional group for the box loading is substituted with the conveyor-belt group;
- The management of larger amounts of different kinds of drugs, since the introduction of the boxes into the system is automatic.

Secondly, the *Blister Packager* is the automated module completely integrated in the *TheraPick* system for the automatic portioning of blisters into single doses that are then packed into BUDs. This module contains more functional groups with respect to the *All-Forms Packager* due to the blister cutting process. The loading of blisters into the module is only automatic and must be performed using the BlisterBox. The canister is placed on the loading window located on the *Storage*, where a stacker crane grasps it in order to start the BUD packaging cycle.

3.2. All-Forms Packager

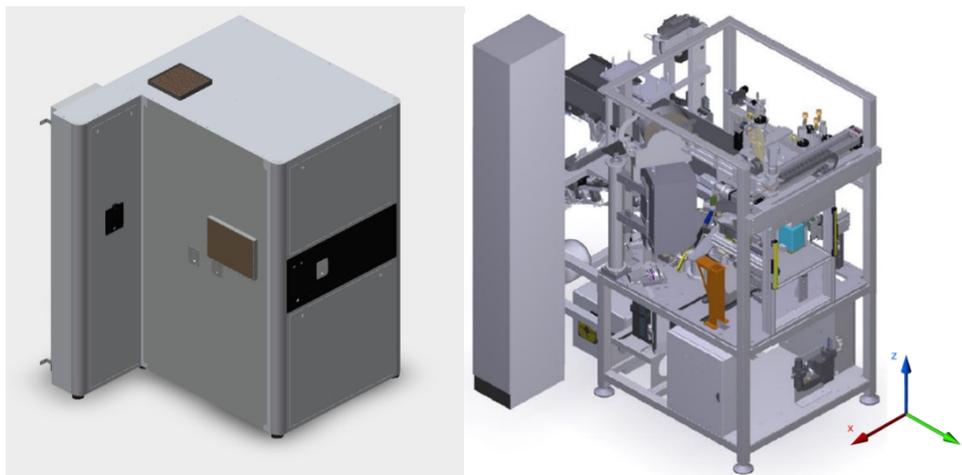


Figure 3.1 All-Forms Packager integrated vision

3.2.1. Product: detailed description and main processes

The packaging process starts with the introduction of the medications in the *All-Forms Packager*. Drugs can enter the module concerned through both automatic loading (using the canisters) or manual loading (exploiting the dedicated access area).

Drugs whose shape and size are not supported by the canisters must be loaded manually. In this case, drugs are inserted by hand through the provided window.

As far as the automatic loading is concerned, canisters are placed manually in their dedicated loading window. The PillBox enters the system's module through the dedicated loading group located in the *All-Forms Packager*. BlisterBox (filled with specific type of drugs, blisters excluded), on the other hand, enters the module through the conveyor-belt group. Canisters, after the check made at the BoxStation, are placed by the operator in the loading window located on the *Storage*, as shown in the following figure.



Figure 3.2 Canisters loading window location

Once the BlisterBox is placed in the dedicated loading area, the canister is moved up to the conveyor-belt group by the stacker crane. The tag reader on the head of the stacker crane reads the RFID tag of the canister in order to check and track the drugs movements within the *Storage*. When the canister enters the *All-Forms Packager* module, a robot with the end-effector consisting of a suction cup opens the boxes. The medications in the canister are then picked up through a cannula and placed in a bag located in one of the rotating table group stations. The bag is then closed and placed on the stem of the case-filler group, ready to be transferred into the case located

on the shelf of the *Storage*. Differently from the *Blister Packager*, the *All-Forms Packager* can package the single-dose medications without necessarily storing them in the automatic warehouse. In fact, the *All-Forms packager* module can perform what is called the “side-sliding production”, which means that the UD bags are ready to be dispensed after being wrapped and placed in a container. The immediate production of the UD bag through the “side-sliding production” is requested for the immediate or urgent use of the medications.

In order to increase the stability and the efficiency of the *TheraPick* system during the packaging process, the machine packager checks the integrity and the correct packaging of the drug through the barcode reading and the use of the vision system. The module is provided with two containers, one for the waste and the other one for the “side-sliding production”.

The *All-Forms Packager* operations are controlled by the *TheraPick Manager* (TPM) software and via the user interface, available on a dedicated monitor.

The following picture displays the main parts of the *All-Forms Packager*.

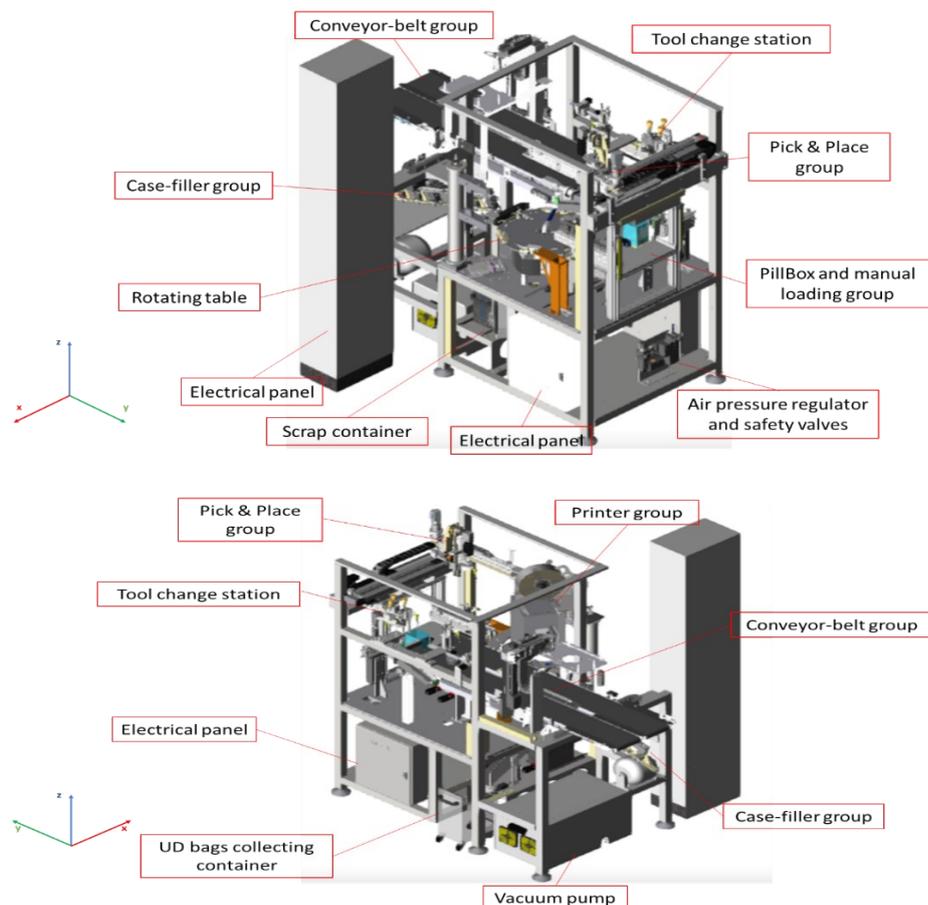


Figure 3.3 The main components of the *All-Forms Packager*

3.2.1.1. Automatic and manual loading

The process starts when the operator places the canister in its loading window. As mentioned before, the stacker crane automatically picks up the box, recognizing it by reading the box RFID tag. After this recognition and data recording phase, the canister is automatically placed onto the conveyor-belt group of the *All-Forms Packager*.

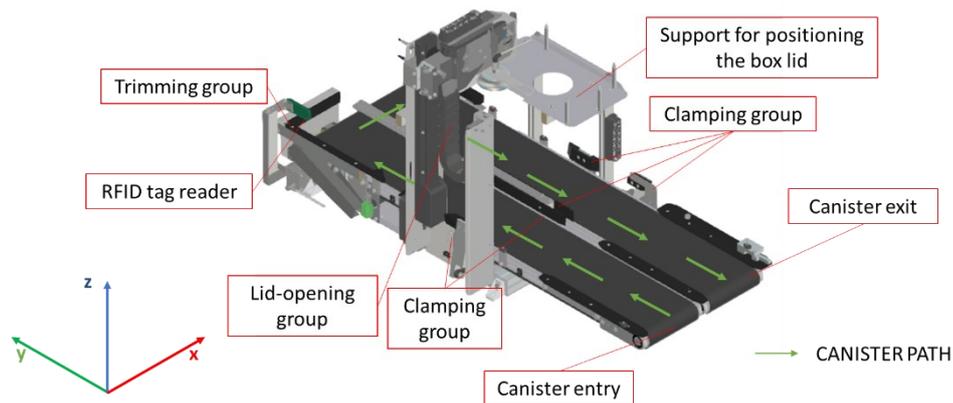


Figure 3.4 Conveyor-belt group

Once the canisters are placed onto the conveyor-belt group, as shown in the previous figure, the box is moved up to the lid-opening group and blocked by the movement of the clamping group. Here the head of the two-axis robot opens the box through a suction cup located on its end-effector. Then, the lid of the canister is placed on its dedicated support and the canister is moved towards the end of the conveyor-belt in order to begin the picking process.

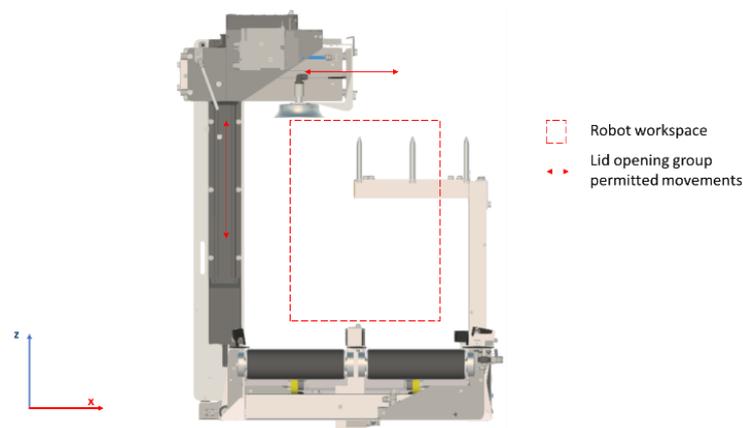


Figure 3.5 Possible movements of the lid-opening group

When the canister is empty at the end of the picking process, the box is moved onto the other conveyor belt through the trimming group and then carried under the support of the box lid, in

correspondence with the lid-opening group. Here the box is blocked again through the clamping group and then closed with the lid that was previously placed onto the support. In fact, after the return of the empty box, the lid-opening group grasps the lid from its location and places it onto the box. After this step, the closed empty box is moved up to the canister exit so it can be handled by the stacker crane which will transfer the box to the return window of the *Storage*.

The automatic load of solid-bulk medications for oral use in the module is carried out in the PillBox-loading group. As shown in the following figure, the PillBox is placed by the operator onto the cross-frame support where the box is opened by a vacuum pump. After this step, the manipulator called the picking-up lid clamps, moves the PillBox lid from its initial position. Before these operations, the TAG reading process is performed in order to check and track the canister. The PillBox lid-opening group can move onto the vertical plane (along the z-axis for the lifting motion and along the x-axis in order to move the lid from above the opened box) so it can lift and remove the PillBox cover. The PillBox-loading group is also provided with a single-action cylinder for the shaking of the PillBox when a single-dose medication is not picked by the pick-and-place group. The cylinder concerned moves along the y-axis towards the negative direction and returns in its resting position thanks to a spring, in order to hit repeatedly a plate on which the PillBox is placed. By doing so, the PillBox shakes because the plate rotates around a pin of small angles. The shaking is performed when the cannula of the pick-and-place group cannot pick up the single-dose medication. Once the PillBox is

emptied, the lid-opening group puts the box lid back into its own position so that the PillBox is closed thanks to its dedicated mechanism.

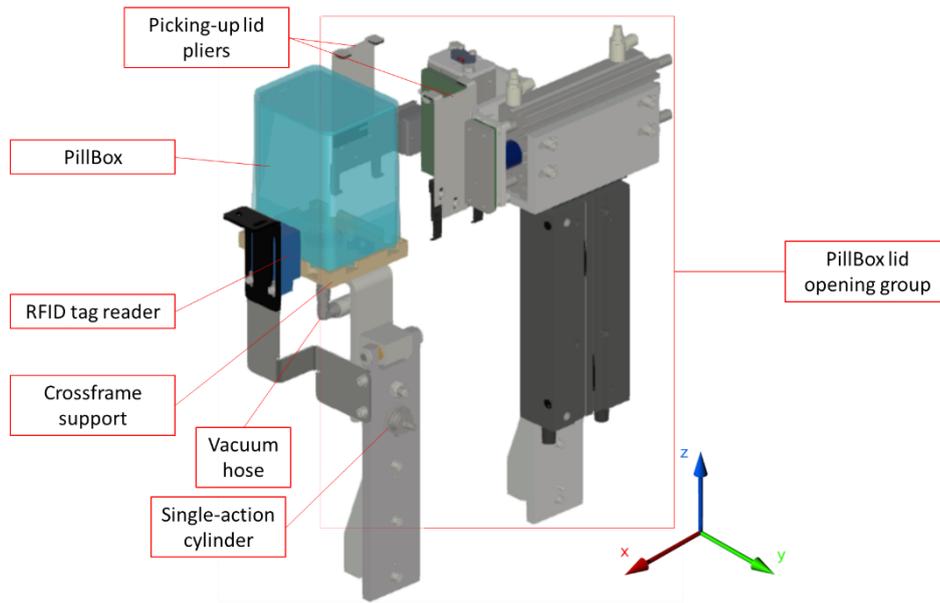


Figure 3.6 PillBox-loading group

The medications which cannot be introduced automatically in the system are manually loaded into the *All-Forms Packager* through the manual-loading group. The drugs concerned are those blistered medications which are incompatible with the *Blister Packager* and other kinds of medications, such as syringes.

The manual loading takes place when the operator scans the barcode on the original medication pack. Thanks to this scanning operation, the medication data is registered in the *TheraPick Manager* software and the introduction of the medication into the *All-Forms Packager* can take place. To do so, the operator places the single-dose medication one at a time into the dedicated cup, as shown in the following figure. A photocell system recognizes every time that the operator introduces a single-dose medication into the loading window. The photocell system can track all the medications that are introduced, detect any kind of errors and block the moving components within the machine in order to increase the operator safety.

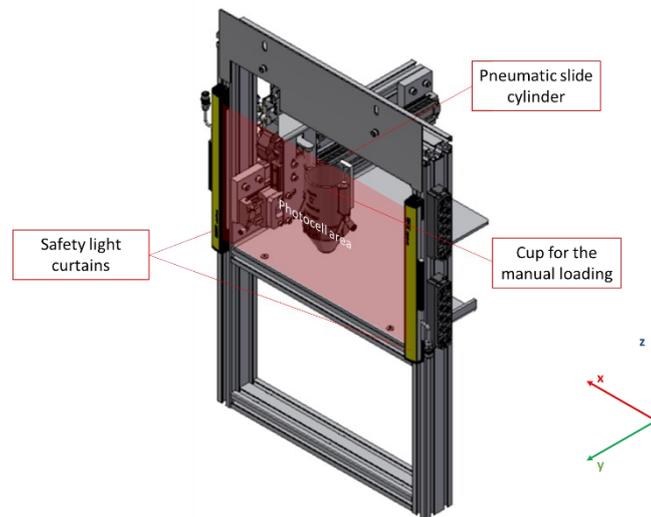


Figure 3.7 Manual-loading window

The role of the cup is to move the single-dose medication up to the stroke end of the pneumatic slide cylinder. Once arrived in the position concerned, a compact guide cylinder pushes down a pin which opens the cup in order to drop the medication into the bag that is located in one of the stations of the rotating table group.

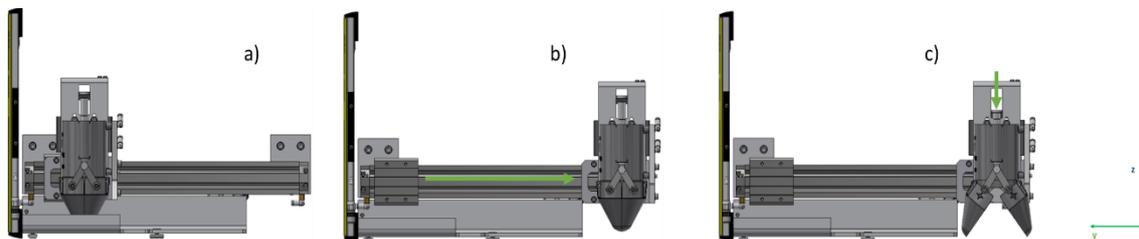


Figure 3.8 The steps of the cup movement for the management of the drug: a) the cup is in the loading position; b) the cup is at the stroke end of the pneumatic slide cylinder; c) the pin of the cup is pushed down and the cup is opened, through its own mechanism so that the medication can drop into the bag

3.2.1.2. Picking process

The picking process in the *All-Forms Packager* consists in moving the single-dose medication from the canister into the UD bag located in one of the stations of the rotating table group (which is described in the following paragraph). The process is carried out by a manipulator which is a cartesian robot called the pick-and-place group. The three-axis robot workspace contains the location of the canisters, the tool change station and the stations of the rotating table where the UD bag is located during the filling task. Since the pick-and-place group can move along the three-axis of the space, it is provided with three motors on which are mounted the encoders that calculate

the position of the links to avoid the possibility of colliding with other elements within the module. It is also provided with proximity sensors, for reporting to the system the initial position of the links.

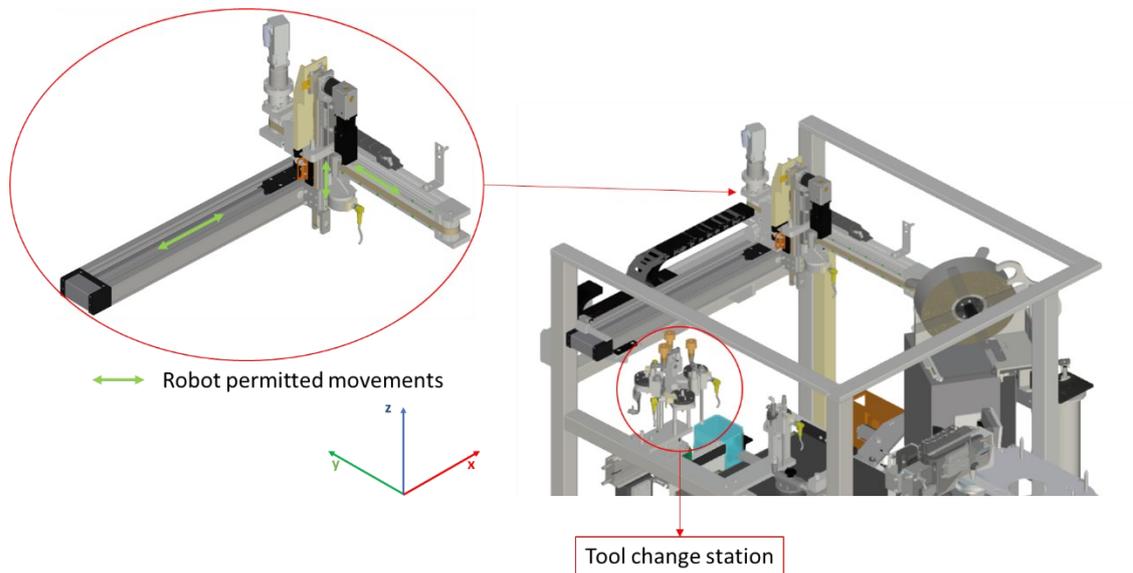


Figure 3.9 Pick-and-place group

Before the picking process can take place, the tool changer, which is the end effector of the robot, must grasp one of the tools located in the tool-change station. The three-axis robot grasps the proper cannula depending on the type of medication that must be handled. To do so, as shown in the following figure, the tool changer is designed to grasp the cannula assembly through a mechanical and electrical quick-coupling connection between the same tool changer and the disc where the cannula is attached. In fact, the central pin geometry of the tool assembly is designed for the quick coupling connection to be held during the picking process, while the two side pins prevent the rotation of the tool assembly. The cannula holds and moves the single-dose medication through the creation of the vacuum. In fact, the cannula assembly is provided with a bellows suction cup which is connected to a coordinate system integral with the robot motion.

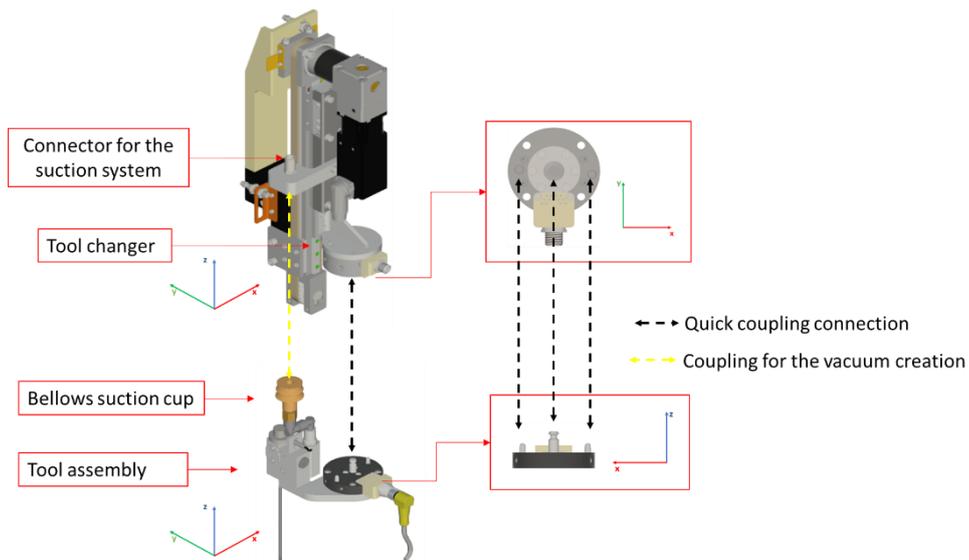


Figure 3.10 Tool changer and tool assembly coupling

The tool-change station is provided with an engine that allows the rotation of the support where the three tools are placed. The role of the engine is to align the tool assembly with the end-effector of the pick-and-place group.

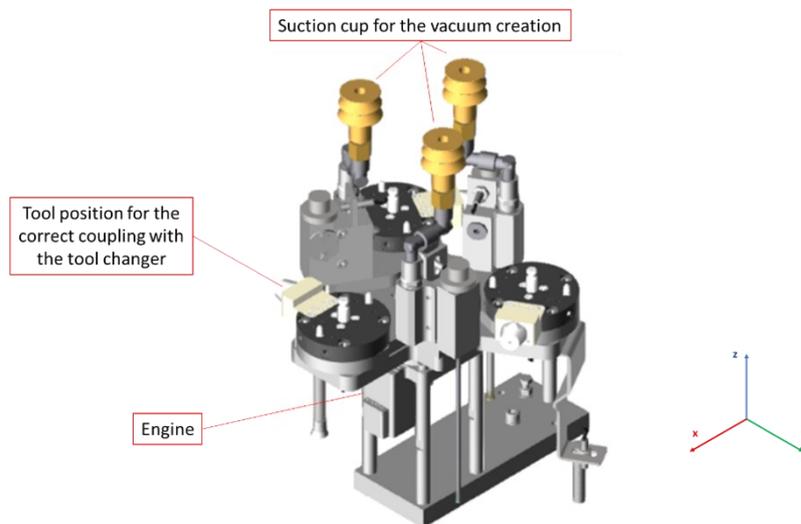


Figure 3.11 Tool-change station

Once the right tool is grasped, the picking process can start. The cannula extracts the single-dose medication and keeps it attached to the end of the tool during the entire movement. The suction through the cannula is interrupted when the drug is dropped into the desired location. At the end of the process, when the canisters are emptied, the pick-and-place group puts the cannula back into the tool change station.

3.2.1.3. Packaging process

The rotating table group is the assembly within the *All-Forms Packager* where several operations are carried out and finalized for the correct and safe UD bag packaging. It is composed of six stations located uniformly at the edge of the circular table and in each one of them a different operation is performed. The benefit of the rotating table is that it can perform the indicated operation simultaneously at each station, therefore it can deal with more than one single-dose medication contemporaneously. The rotating table is provided with a stepper motor and with an incremental encoder which divides a full rotation into several equal steps that ensures the precision of the angular displacement of the rotating table. In this way, every time that all the operations are concluded in each station, the rotating table rotates by 60° thanks to the stepper motor, so that the operations can be carried out again. The rotating table is also provided in each station with clamps which are opened thanks to a guide, as shown in the following figure:

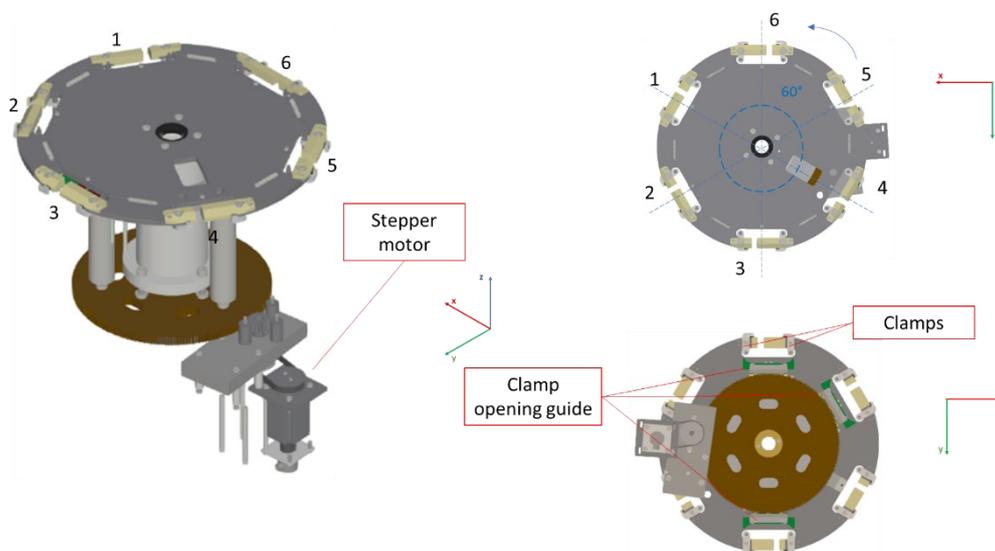


Figure 3.12 Rotating table group

To simplify the description of the packaging process, the stations are numbered from one to six as shown in the previous figure.

The packaging process starts at the first station where the lower part of what is going to be the UD bag is welded. The groups that carry out the operations at this station are the welder and the printer groups. Information and barcode are printed on a propylene tubular film.

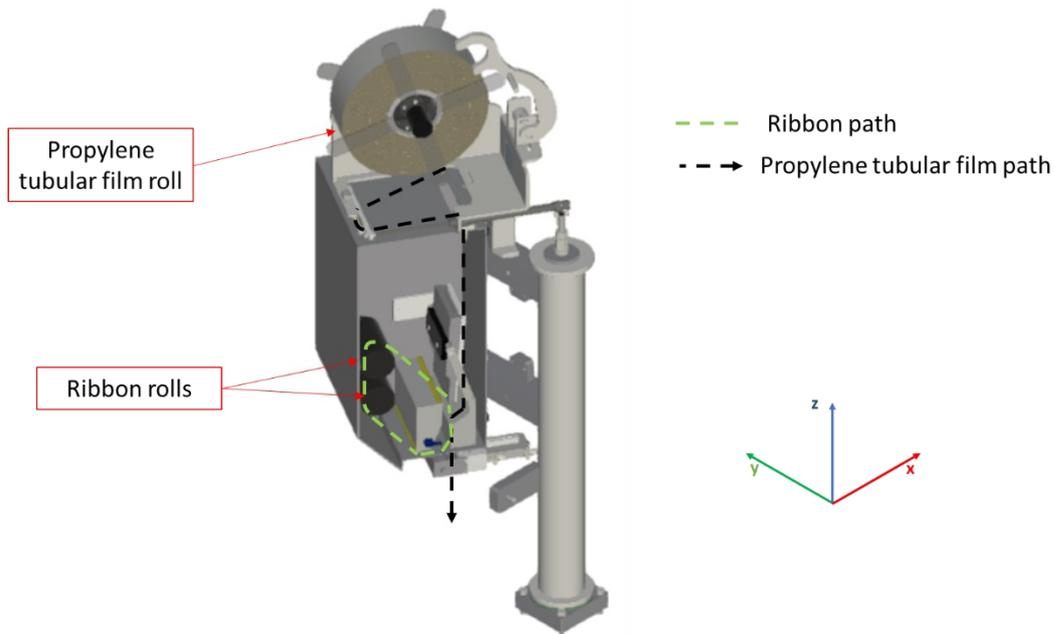


Figure 3.13 Printer group

Once the tubular film comes out from the bottom of the printer group, the lower welder group moves from its resting position up to the stroke end of a sliding carriage in order to weld the propylene tubular film. After this step, the propylene film is pulled down by the welder group and cut by an automatic cutter. The first station ends its operations with the movement of the empty open UD bag by the pusher group towards the clamps, where the bag is grasped and transferred to the second station.

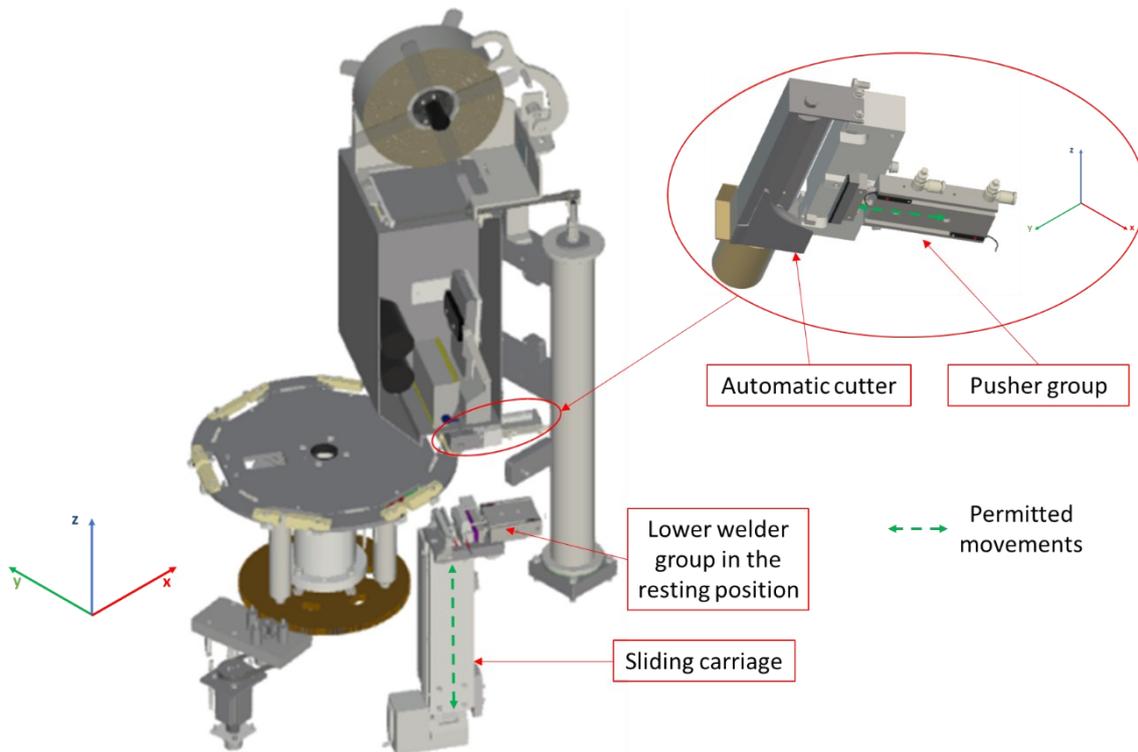


Figure 3.14 First station

As far as the opening guides of the clamps are concerned, they are present in three of the six stations and they remain still during the rotation of the rotating table. The opening of the clamps is performed through a pneumatic cylinder that moves the guide in the radial direction and forces the two lower pins to follow the guide shape, as shown in the following figure. By doing so, the guide forces the clamps to rotate around their upper pin, which has the cursor function, and are thus opened. When the pneumatic cylinder moves back to the resting position, the clamps return to the resting position too thanks to a spring system attached to the lower pin.

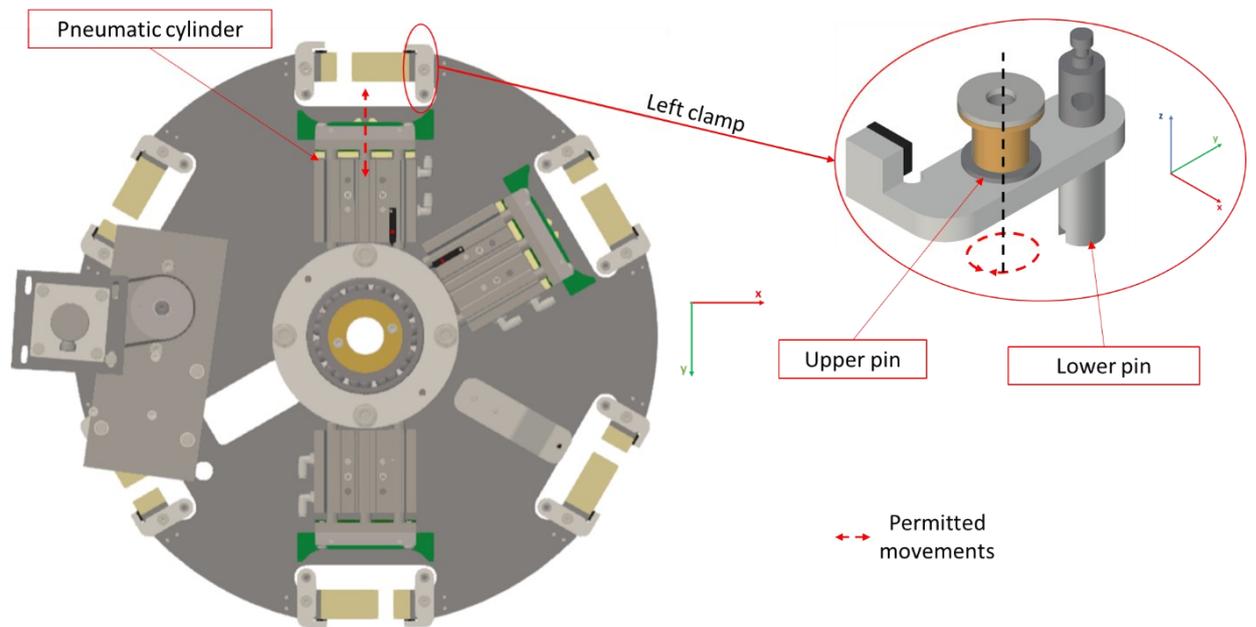


Figure 3.15 Clamp-opening mechanism

In the second station the correct cut and printing of the UD bag are verified. During the rotation from the first to the second station, a bag guide places the UD bag correctly into the second station where the barcode printed on the bag is read by the dedicated sensor. This device is attached to a beam as other static components of the module.

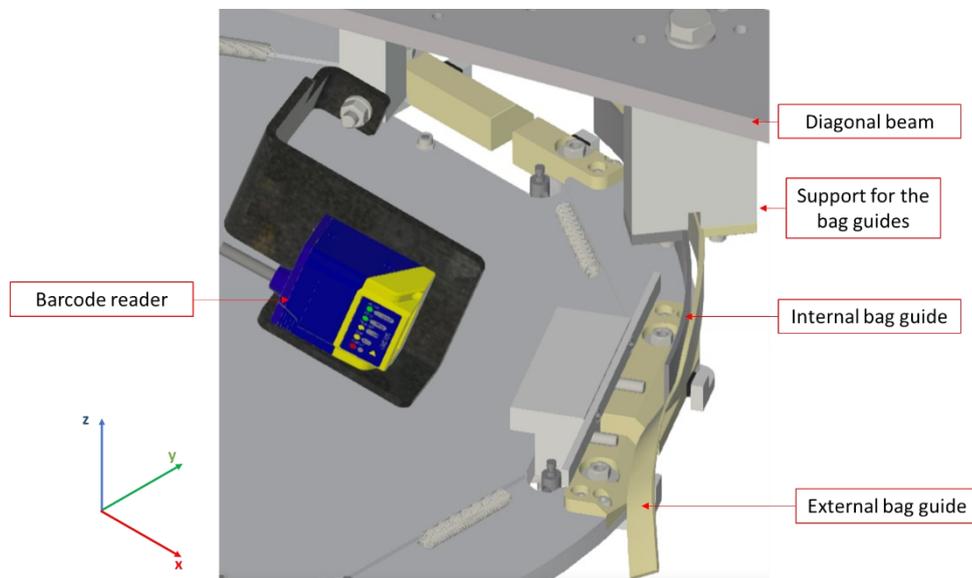


Figure 3.16 Second station

The third station is where the bag is filled with the single-dose medication. Once the bag has arrived in this location, four suction cups grip the plastic envelope on the side facing the rotating table. In the meantime, the other side of the bag is gripped by another four suction cups that are movable

in the opposite side with respect to the previous ones. In fact, two pneumatic cylinders perform the linear movement of the suction system in the radial direction of the rotating table. After the bag is gripped on both sides, the clamps are opened, and the movable part of the station moves away from the rotating table while it is still holding one side of the UD bag. At this point, the bag is opened and the pick-and-place group drops the medication into the bag. The third station is provided with infrared barriers, which detect the passage of the single-dose medication when it is dropped into the UD bag. It is also provided with a container located under the station for the collection for any medications, which for various reasons did not enter the bag.

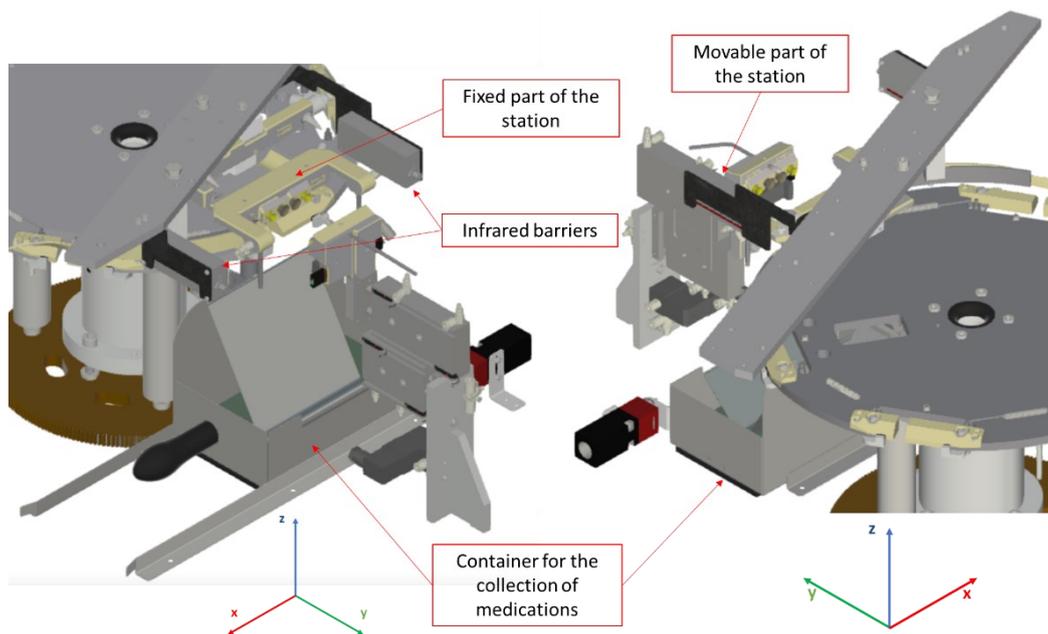


Figure 3.17 Third station

The fourth station is where the upper part of the UD bag is welded. The plastic envelope arrives in the location with the aid of two guides. Once the UD bag is placed correctly in the fourth station, which means the bag is between the two sealing jaws, the bag is ready to be welded. In fact, the sealing jaw is heated and moved through a pneumatic cylinder until it hits the positioner. After the welding operation is carried out, the sealing jaw returns to its resting position and the bag can be moved towards the fifth station.

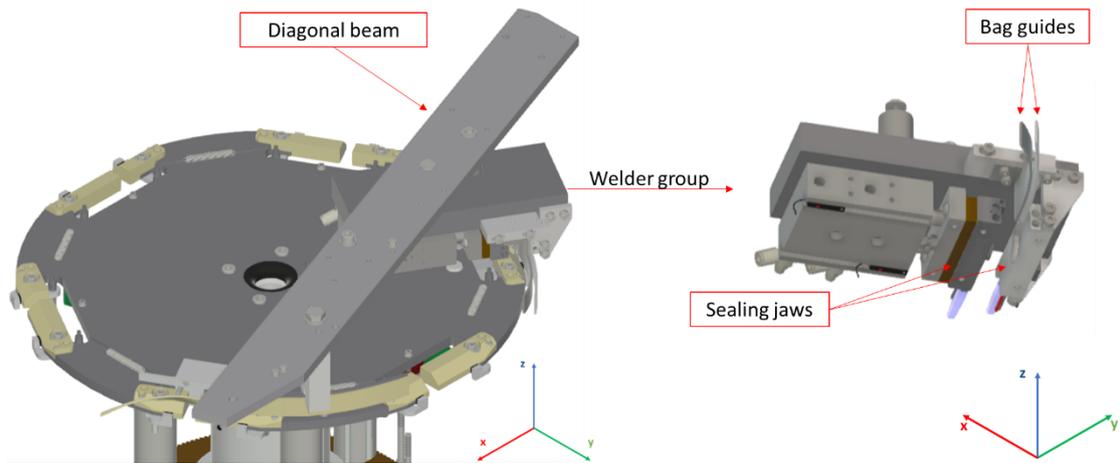


Figure 3.18 Fourth station

The fifth station is where a punching machine pierces the UD bag. When the UD bag arrives, the punch is forced through the plastic envelope to create a hole. The punching machine is provided with a pneumatic system which blows the scraps that are produced during the process into a tube. It is also provided with an anti-static brush in order to reduce the electrostatic charge of the UD bag.

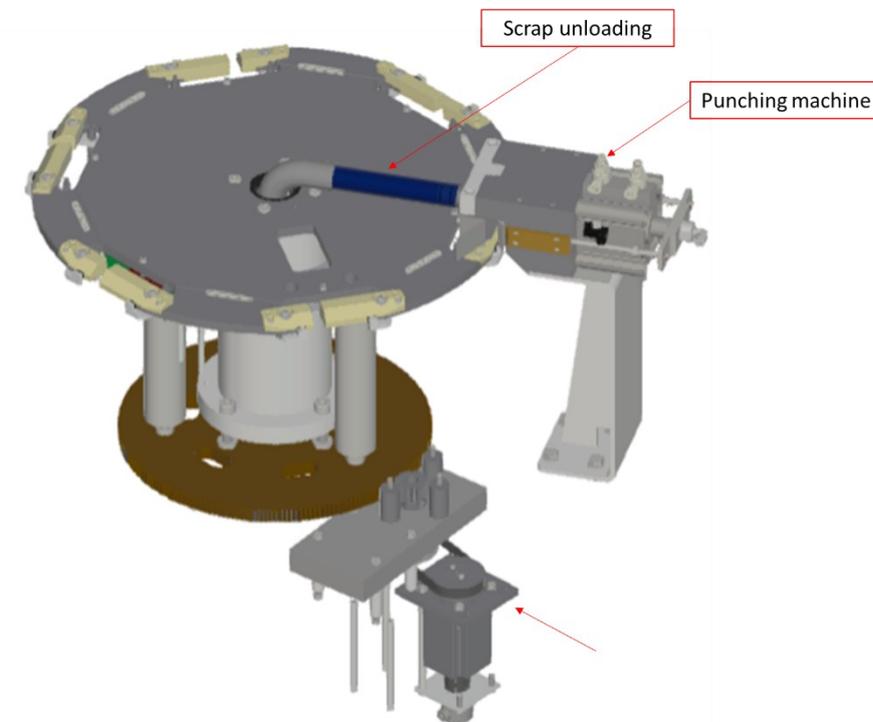


Figure 3.19 Fifth station

The last station is where the UD bag is moved either to the *Storage* through the case-filler group or, depending on the UD bag conditions, it can be dropped onto a slide or into a waste container.

The sixth station is provided with five fibre-optic sensors for the detection and for the verification of the correct position of the UD bag.

If for any reason the vision system detects an anomaly during the UD packaging, the system lets the bag drop into the waste container located under the station. Otherwise, if the integrity and the wrapping of the UD are in line with the expectations, the UD bag can be sent into the *Storage* or dropped onto a slide for the “side-sliding production”, which is located under the station. It is attached to a plate which in turn is connected to a cylinder through a fork. The slide is movable thanks to the pneumatic cylinder, which depending upon its position, allows the fall of the UD bag either into the waste container or onto the slide itself.

If the UD bag is expected to be stocked in the *Storage*, the stem of the Case-filler group gets near to the UD bag hole in order to move it into the pins of the Case.

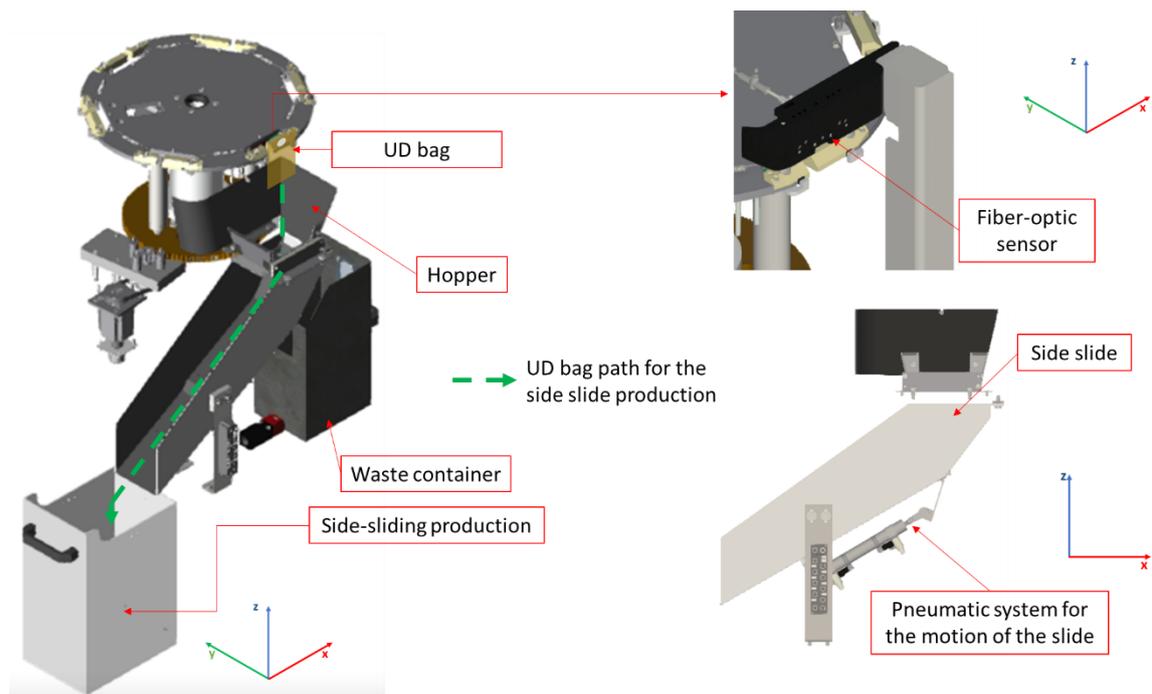


Figure 3.20 Sixth station

3.2.1.4. Vision system

As mentioned previously, the vision system checks the integrity and the correct packaging of the drug through capturing the image of the UD bag during the packaging process.

The acquisition and the processing of images is widely used in several processes in the manufacturing industries, mainly in quality control processes. The techniques used for the image processing during the packaging process of the UD bag are the:

- Edge detection which identifies the edges of an object;
- Pattern matching which identifies objects or parts of them by correlating them to a template.

The capturing of images involves several components which are the:

- Illumination system;
- Sensor (camera);
- Processing system.

The image processing of the UD bag takes place in two steps of the packaging process, more precisely one in the fourth station and the other one between the fifth and sixth station.

In the first case, the image is captured in a stationary way while the UD bag is welded onto its upper part and illuminated by a light. The camera takes a picture of the UD bag reflection in the mirror in order to check the integrity of the medication from its shadow.

During the rotation of the UD bag between the fifth and sixth station, a camera takes a picture while the bag is rotating around the table. This check is made to make sure the UD bag is correctly packed.

If the vision system detects an error, the system discards the defected UD bag.

3.3. Blister Packager

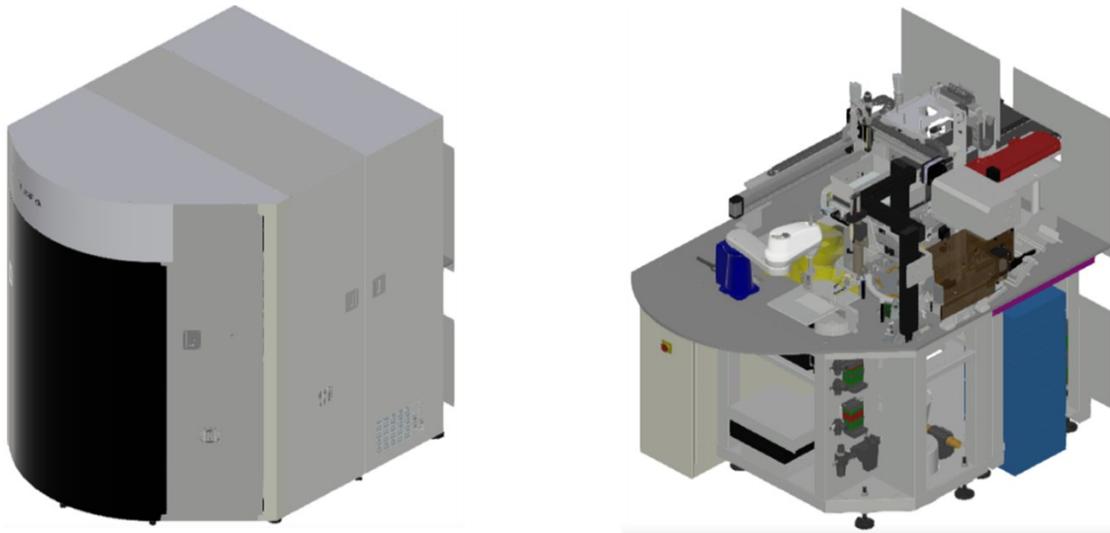


Figure 3.21 Blister Packager

3.3.1. Product: detailed description and main processes

The *Blister Packager* is the essential element of the *TheraPick* system. In fact, it is fully integrated with the system and it also performs different and more complicated operations compared to the *All-Forms Packager*.

The blisters are only loaded in an automatic way using the *BlisterBox* which enters the robotized system through the dedicated loading window located on the *Storage*. The *Blister Packager* is provided with a conveyor-belt group similar to the *All-Forms Packager* one. It is used for moving the *BlisterBox* in and out of the module. The description of the conveyor-belt group is outlined in the previous chapter.

The way that the canister is transferred from the loading window into the packager machine is the same as described for the *All-Forms Packager*, which is through the stacker crane.

The blisters introduced into the system are first analysed, cut into single-doses and then wrapped at the rotating table. On this component the blister is packed and sent automatically to the *Storage* through the case-filler group just like in the *All-Forms Packager*. In order to cut the blisters into single doses, the system acquires the cutting pattern automatically through a dedicated vision device ensuring a correct cut. The *Blister Packager* can cover up to 90% of the blisters types on the

market including odd shapes and patterns [7]. The operations are controlled by the *TheraPick* Manager software and via the user interface available on the dedicated monitor.

The following picture displays the main parts of the *Blister Packager*:

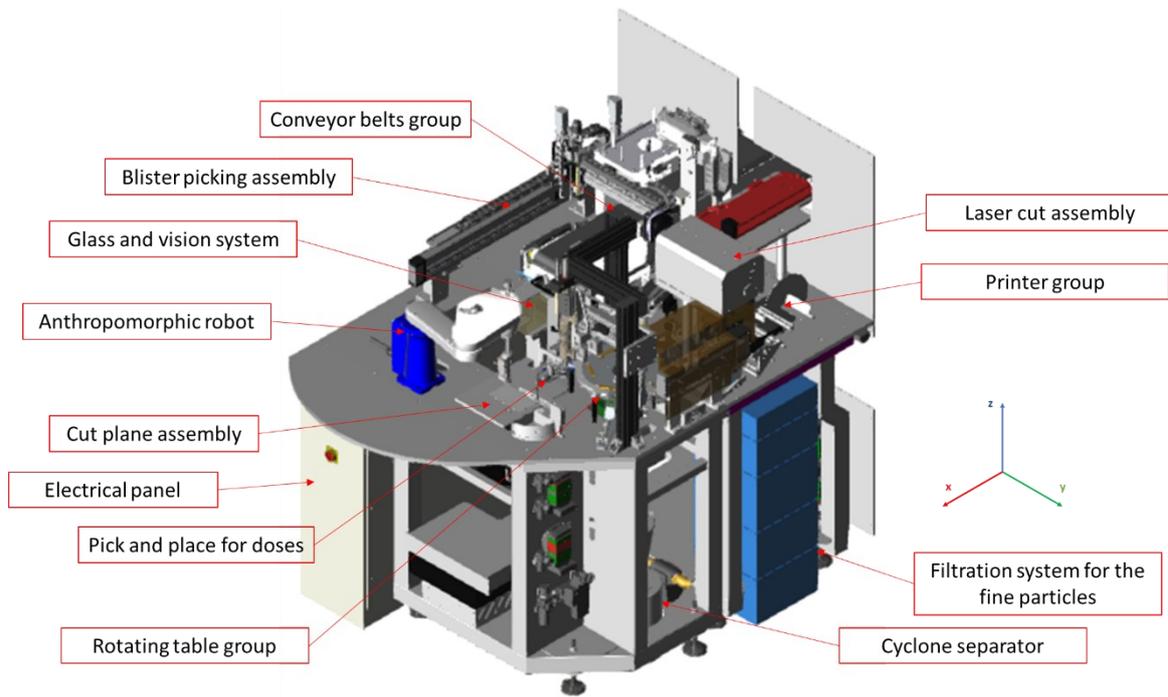


Figure 3.22 *Blister Packager* main components

3.3.1.1. Vision system

The *BlisterBox* enters the module through the conveyor-belt group where it is opened and then moved up to the end of the same conveyor belts where it is read by a tag reader and then emptied by the assembly for the blister picking. This component is a cartesian and a three-axis robot, similar to the pick-and-place group described previously in the *All-Forms Packager*. The assembly for the blister picking is provided with a cannula as an end-effector which can rotate around its own axis in order to handle the blisters. The cartesian robot picks the blister from inside the canister and places it, with the medications facing down, on a glass located in the image-acquisition station where the blistered medication is analysed by the vision system.

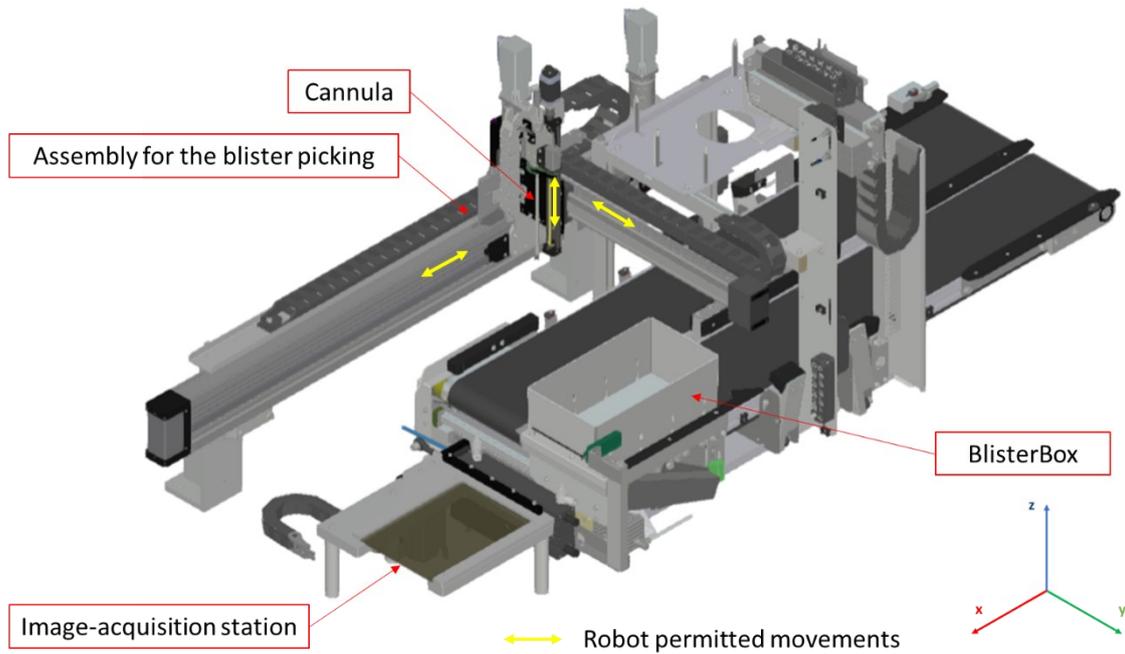


Figure 3.23 Blister picking

Before the blister is placed onto the glass plate, the upper part of the image-acquisition station is moved from its resting position by both a pneumatic and electric cylinder. When the blister is placed correctly onto the fixed part of the station, the movable part can return to its resting position so the vision system can analyse the blister which is located between the two glass plates.

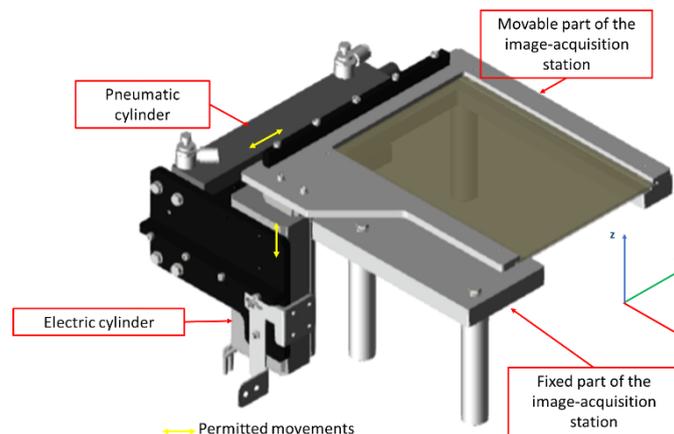


Figure 3.24 Movements of the Image-acquisition station

The vision system allows the identification and validation of almost all blisters available on the market by taking advantage of the photometric stereo³ technique. The system concerned is composed of four led projectors for the illumination of the blister and of a camera for the image

³ Photometric stereo is a technique in computer vision for estimating the surface normal of objects by observing that object under different lighting conditions [8].

capturing. Once the picture is taken, the vision system allows the detection and analysis of the layout of the blister pills by processing one or more cutting patterns which are automatically generated and proposed by the machine to the user that can manually edit them.

The blister cutting map is validated and recorded in the database, so the software application associates a pattern to the related drug which implies no further operations for a recognition phase when processed.

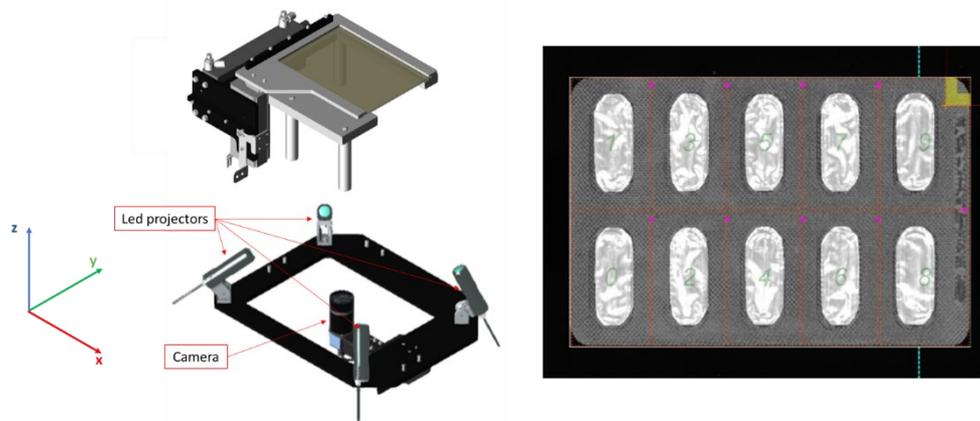


Figure 3.25 Vision system on the left and cutting map generated automatically on the right

If it is not possible to create a cutting map due to the particular shape of the blister, the system automatically discards the medications by placing them into the dedicated container through the aid of a robot. Otherwise the process goes on with the cutting of the blister.

3.3.1.2. Blister-cutting process

The *Blister Packager* cutting device is a tool conceived to singularize almost all types of blister typologies available on the market.

After the image processing of the blistered medications, a four-axis robot grasps the blister and places it correctly onto the cut plane. The manipulator has a similar configuration to the SCARA one but with the difference of having a cylindrical joint instead of a simple prismatic joint. The end-effector of the robot is provided with grippers which can rotate around its own axis.

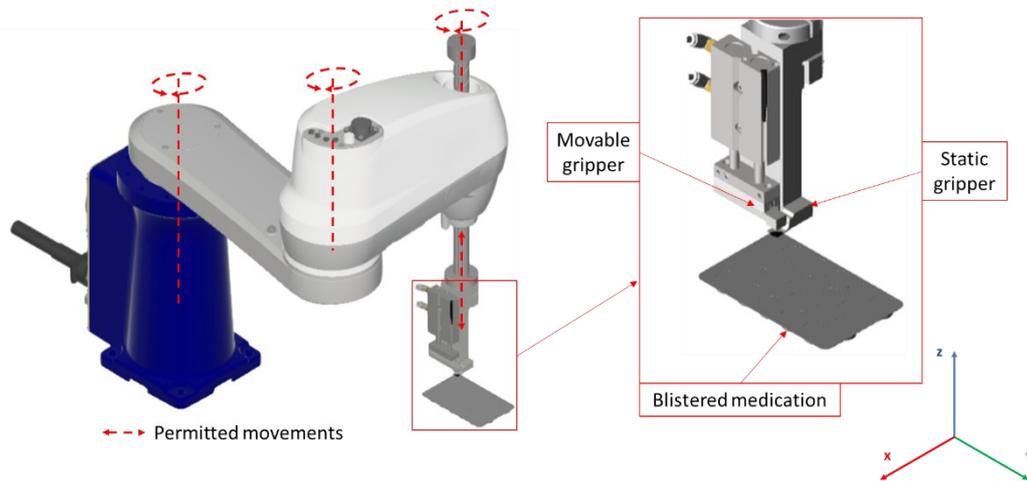


Figure 3.26 Four-axis robot

The cutting of the blisters into single doses is carried out by an ultrasonic cutting technology, which is provided with a blade that is mounted on a cutting sonotrode. An electrical actuator moves the cut plane vertically in order to press the blister against a mechanical stop which ensures a correct cut of flexible blisters. The blade goes through a hole located in the cut plate and performs the necessary cut with a vertical vibration thanks to an ultrasonic generator. While the cutting operation is carried out, the blister is oriented and held with the aid of the robot. The mechanical stop is provided with a hole for the passage of the blade during the cut.

If the cut is not performed correctly the medication is moved into the scrap container, otherwise the BUDs are picked and placed into the third station of the rotating table.

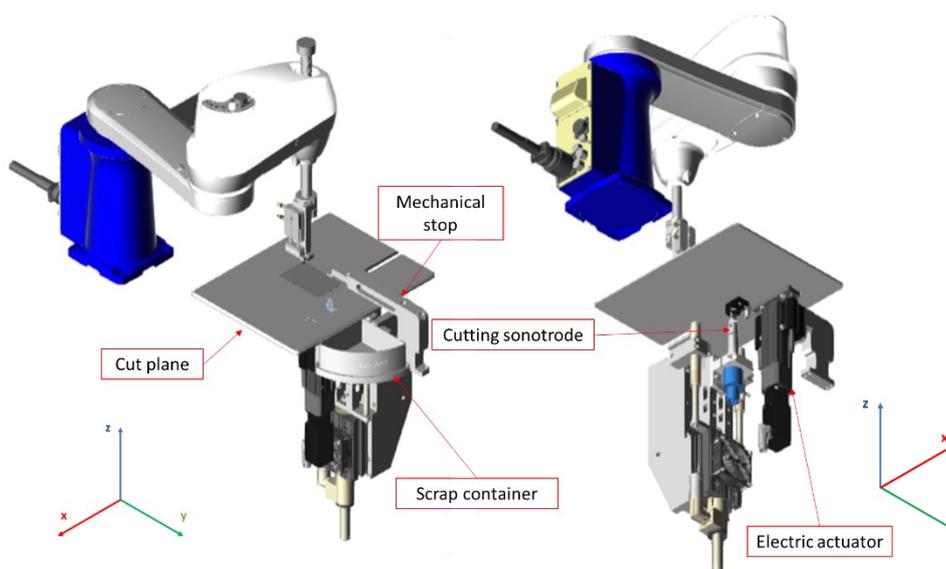


Figure 3.27 Cutting system

3.3.1.3. Picking process

The picking process consists in moving the single-dose medication from the cut plane to the third station of the rotating table where it is wrapped. This operation is carried out by what is called the pick-and-place group for doses which is a cylindrical manipulator with the end effector consisting of a cannula. So, the robot is composed of one revolute joint and two prismatic joints and the cannula can rotate around its own axis in order to place the blistered single-dose medication into the plastic card in the third station of the rotating table correctly.

The following picture shows the robot and its movements:

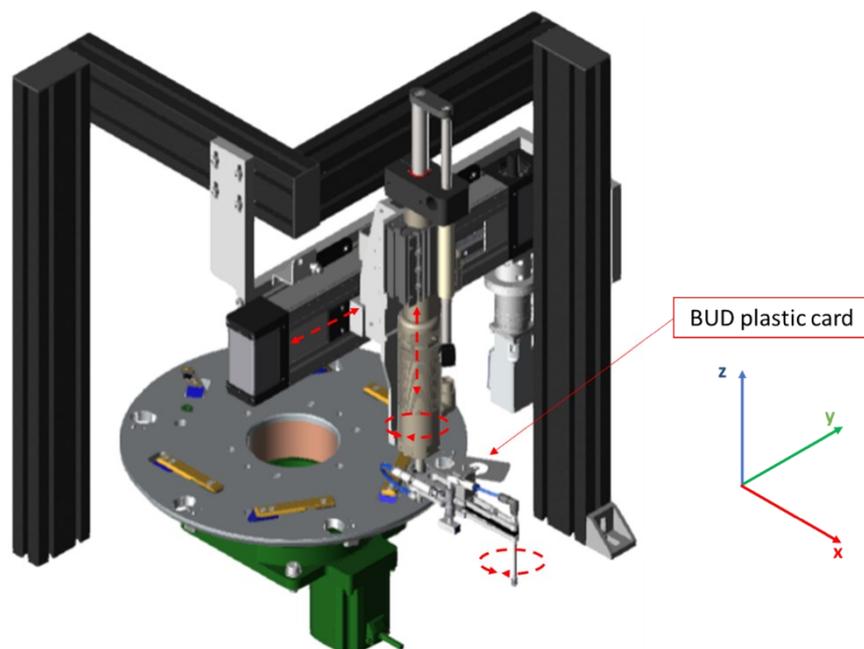


Figure 3.28 Pick-and-place group

3.3.1.4. Packaging process

As in the *All-Forms Packager*, the rotating table within the *Blister Packager* is the assembly where the set of operations for the correct and safe BUD packaging are carried out. It is very similar to the previous one, with the same benefits but it performs in different way. The rotating table is composed of five stations located uniformly at the edge of the circular table and the rotation is performed by a commercial motor which ensures the precision of the angular displacement of the rotating table. The mechanical components that performs the BUD gripping are different from those of the *All-Forms Packager*. In fact, the opening and closing mechanism of the lever takes place

respectively in the last and second station thanks to a cylindrical component located under the table in the first and second station. The mechanical element responsible for the opening and closing of the levers moves vertically in order to hit the lever body during the rotation. Moreover, a magnetic disc that is located in each station of the table keeps the lever closed.

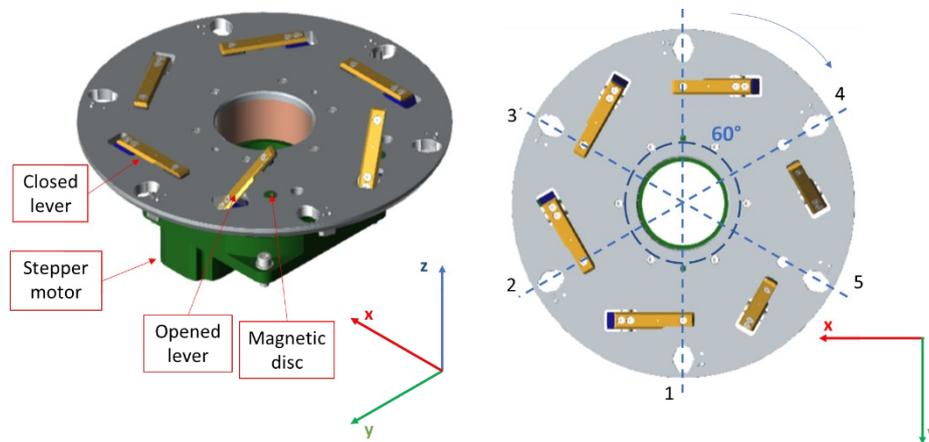


Figure 3.29 Rotating table

The *Blister Packager* produces two kinds of BUDs, a small one (28.5x75mm) and a normal one (42x75mm).



Figure 3.30 Small BUD on the left and normal BUD on the right

Each station is provided with a cursor and a pin in order to block respectively the rotation of the small BUDs and the normal ones during the packaging process. The pin remains fixed relatively to the table, on the contrary the cursor is movable. Since the small BUD is narrower than the normal one, the pin is too far away to block the small BUD rotation while the cursor accomplishes the task concerned. In the first station, two pneumatic cylinders move vertically in order to move the cursor

up and down depending upon which of the two types of BUDs are needed to be produced. If the cursor is moved up by the vertical movement of the pneumatic cylinder located under the table, it means that the small BUD needs to be produced. In this case the head of the cursor emerges from the rotating table. Otherwise if it is moved down by the vertical movement of the pneumatic cylinder located above the table it means that the normal BUD is needed to be produced. In this case the head of the cursor does not come out from the rotating table and so the pin blocks the normal BUD rotation.

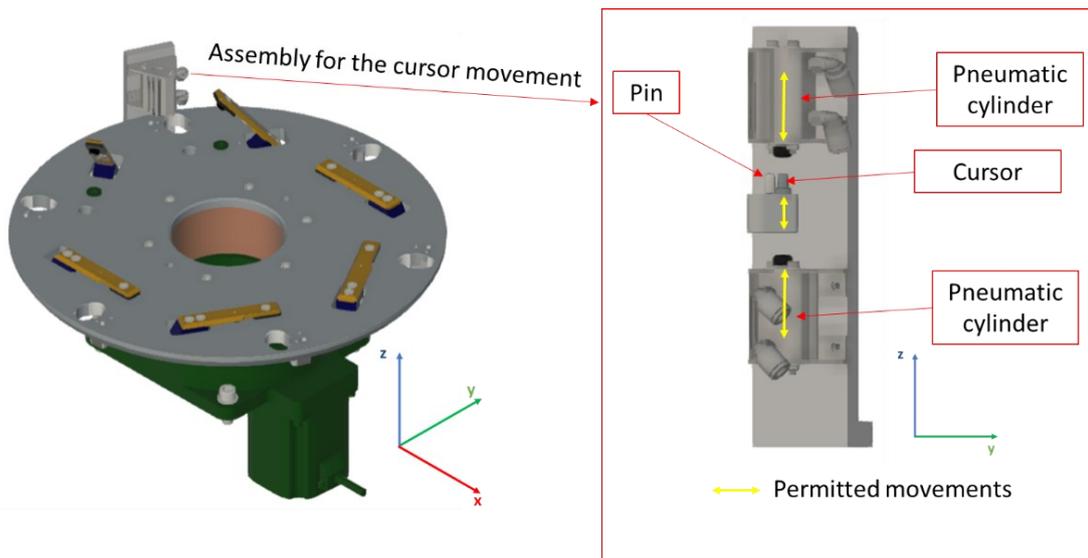


Figure 3.31 First station

The second station is where the empty BUD is placed by a manipulator after the plastic card is printed and processed. The groups that are involved in this step are the printer, the laser-cut machine, and the entry-bud group. The information and the barcode regarding the single-dose medication are printed on the plastic material which comes out from the printer. Once it is out and on the cut plane, the laser cut performs the cutting and the drilling of the plastic card as shown in the following figure:

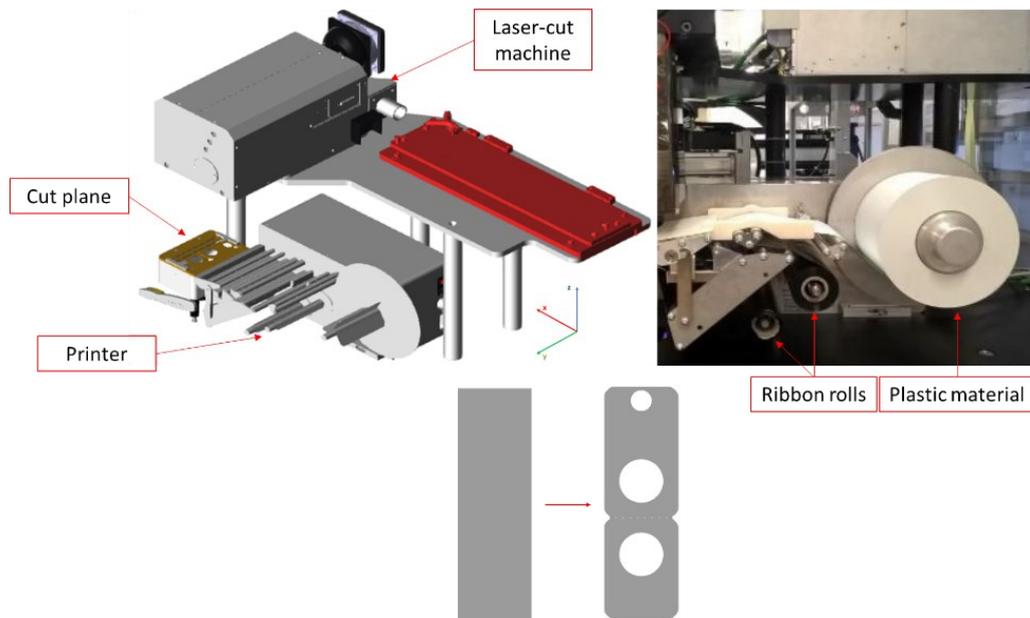


Figure 3.32 Printer and laser-cut machine above and the plastic card shape at the end of the cut process below

During the cut operation, scraps are produced and extracted from under the cut plane by a suction system, while for safety reasons, another suction system extracts the heat and the products generated from the vaporization of the plastic material during the laser cut. During the laser-cutting process, fine particles are generated by the vaporization which are extracted and then filtered by a filtration system. Once the cutting process is carried out, the plastic card is read by a barcode reader and if it is produced correctly without problems, the entry-bud group places the plastic card onto the first station of the rotating table. Otherwise the same entry bud group drops the plastic card onto a slide where it glides out into the waste container. The entry bud group is a two-axis robot manipulator with an end effector consisting of a set of suction cups.

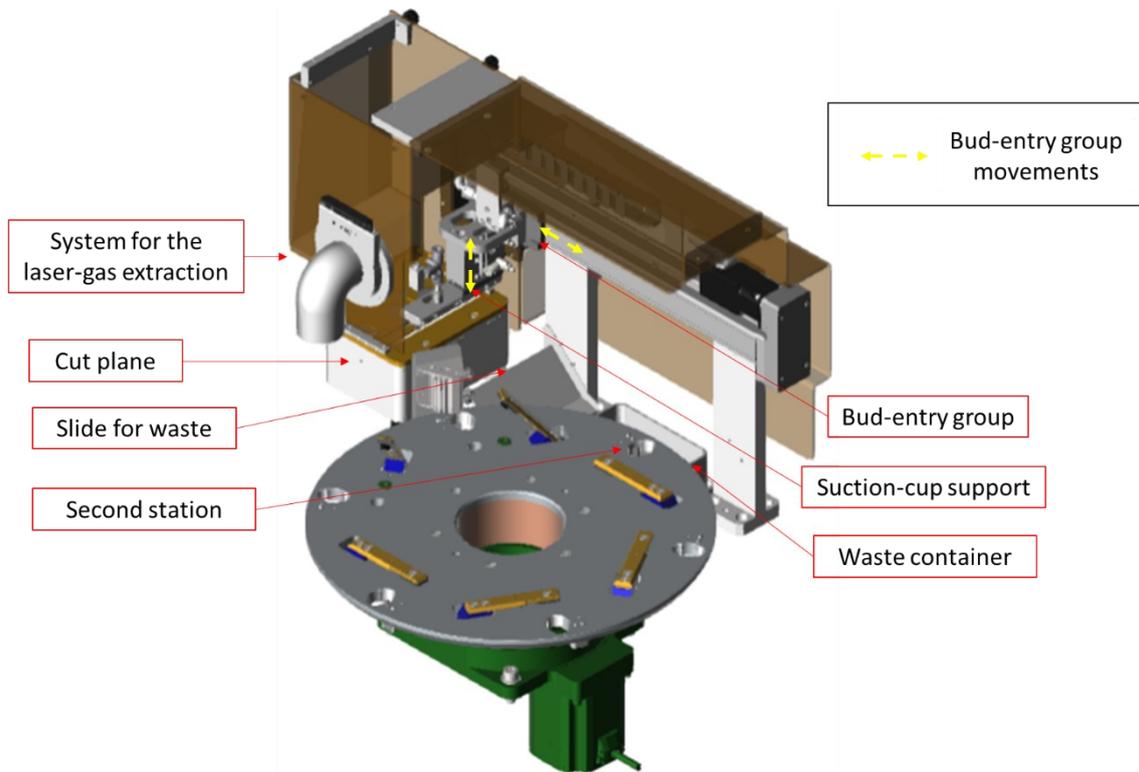


Figure 3.33 Second station main components

During the rotation of the table from the first to the second station, the lever hits a component and begins to close. The plastic card is placed in this station through the bud-entry group and is then held by the lever which is closed by the cylindrical mechanism placed under the table as described previously. The empty BUD is then moved to the third station by a guide in order to perform a pre-fold as shown in the following figure:

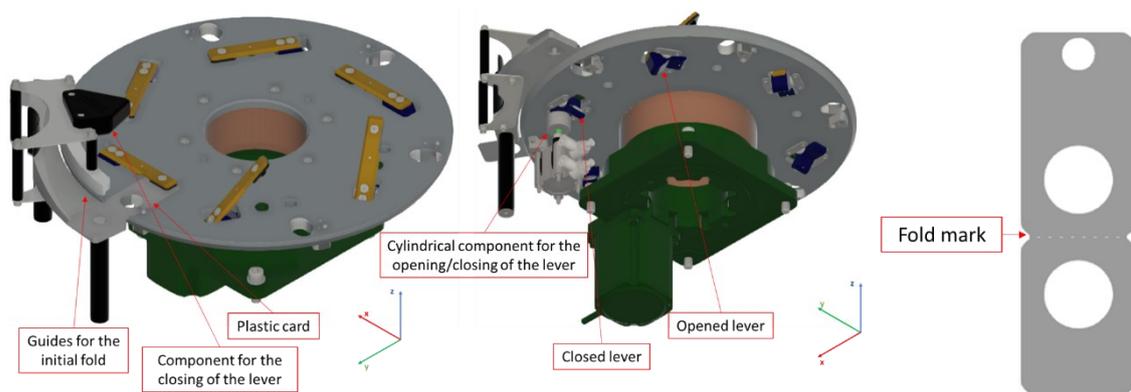


Figure 3.34 Main components for the lever closing and for the initial folding of the plastic card

The third station is where the plastic card is filled with the blistered single-dose medication and then folded over. The drug is placed, with the medicine facing down, into the hole in the plastic card with the aid of the pick-and-place group, as mentioned previously. After this step, the plastic

card containing the medicine is folded through the bending assembly. This latter machine is composed of two parts which are the mechanical block and the tipper. The first one is composed of a steel sheet which rotates thanks to a linear movement of a pneumatic cylinder and hits the BUD in order to keep it still. The second one has the same composition of the mechanical block and during the movement folds the bud in on itself. Once these operations are carried out, the bag is moved towards the fourth station passing through a guide that keeps the BUD folded.

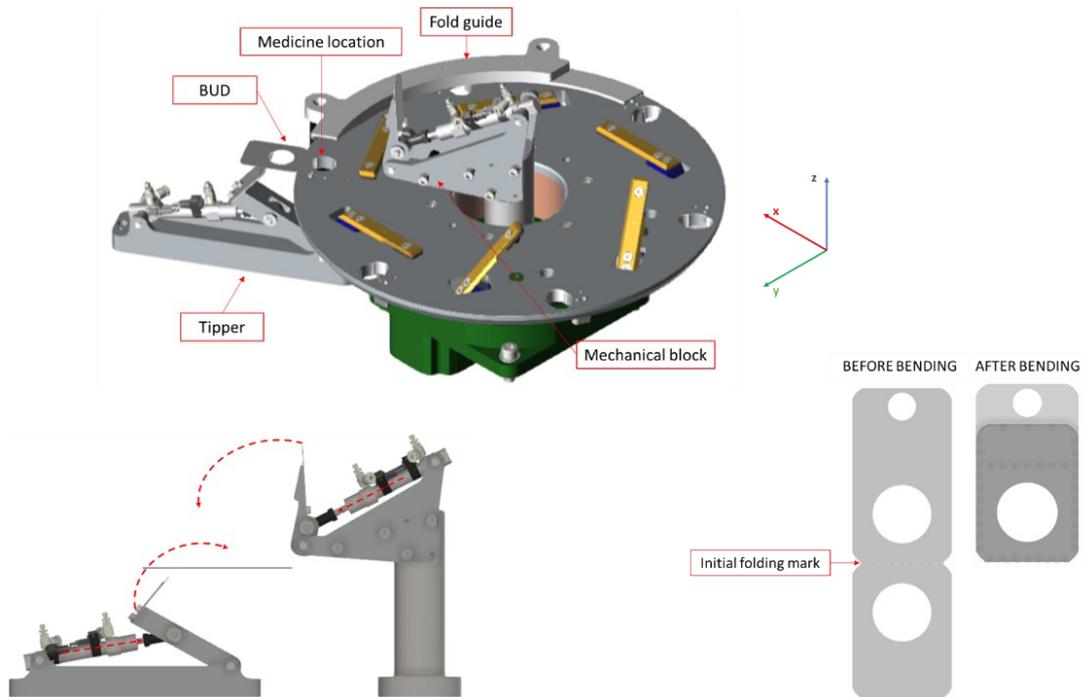


Figure 3.35 Bending process

The fourth station is where the BUD is welded through an ultrasonic welder. This robotized component is provided with two welding sonotrodes, one for the welding of small BUDs and one for the normal ones. The two welding sonotrodes can move vertically thanks to two pneumatic cylinders and it can slide on a guide through another pneumatic cylinder, depending on which of the two welders will perform the welding process. It is also provided with a shovel to keep the BUD folded after passing through a fold guide. When one of the two welding sonotrodes arrives above the station, the shovel rotates thanks to a pneumatic rotary actuator in order to give the possibility to the welding sonotrode to lower and to weld the BUD.

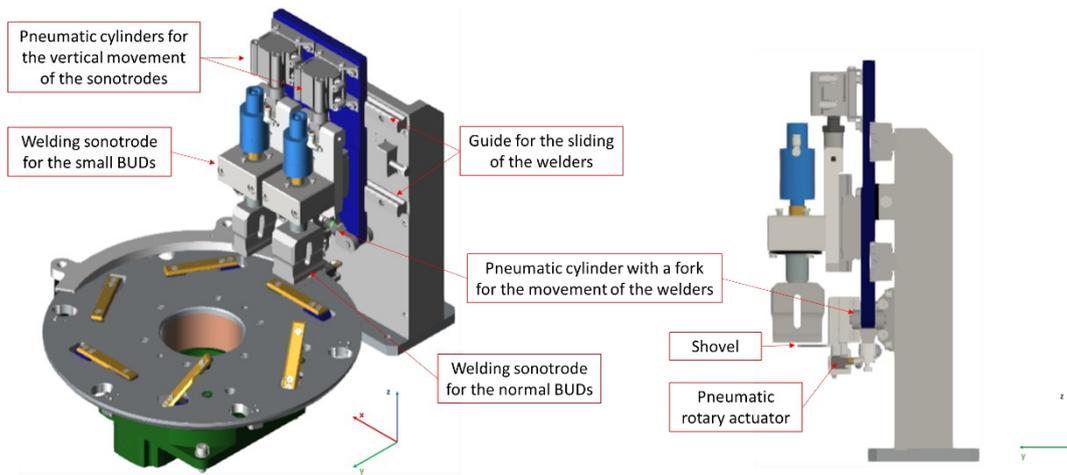


Figure 3.36 Fourth station

The last station is where the BUD is transferred from the rotating table onto the stem of the case filler. Firstly, the lever is opened thanks to the mechanism mentioned previously, then the BUD is picked up and placed onto a stem by the assembly for the outgoing rotation of the BUD which is a cylindrical robot. The robot movements are performed thanks to pneumatic cylinders, except from the horizontal movement along the x-axis which is performed by an electric motor. The end-effector of the robot consists of six suction cups for the collection of the BUD, as shown in the following figure:

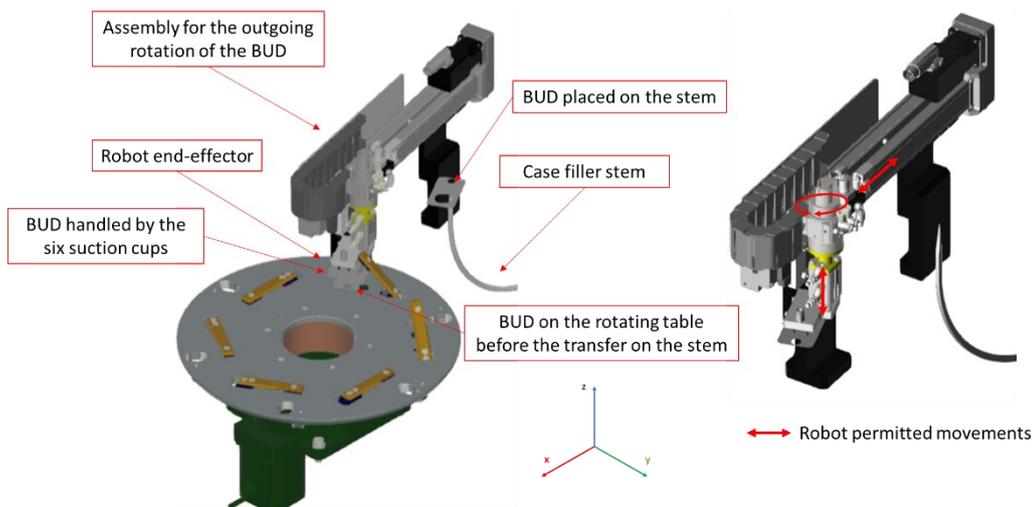


Figure 3.37 Last station main components

3.4. Case-filler group

The case filler group is the object of this study. In particular, aim of this paper is the understanding of the potential problems related to the UD bags and BUDs management on the case filler, in the *All-Forms Packager* and *Blister Packager*, respectively, and consequently their potential solution.

The case-filler group is the automated assembly for the transfer of UD bags and BUDs from the rotating table into the case and it performs the same task in both packagers modules of the *TheraPick* system, even though they are not exactly the same. In fact, the difference between the two case-filler groups in the *All-Forms Packager* and in the *Blister Packager* lies in the fact that the first one is composed of two mobile case-filler groups while the second one is composed of one mobile and one fixed case-filler group. The term mobile case-filler group refers to the assembly composed of the stem, the stabilizer, the pneumatic cylinder and the grippers, while the fixed case-filler group does not have the pneumatic cylinder since it does not move.

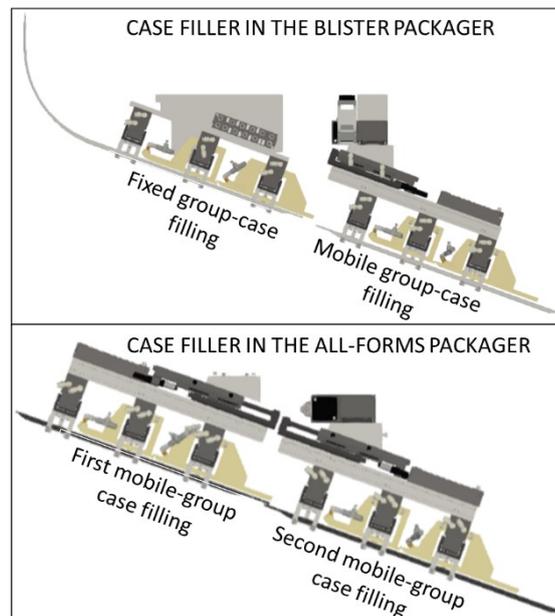


Figure 3.38 Representation of the mobile and the fixed group-Case fillings in the Blister and All-Forms Packager

Apart from the differences described above, the two case-filler groups are composed by the same components, which are:

- Stabilizer assembly: a set of components for the facilitation and maintenance of the correct orientation of the BUDs and UD bags during their transfer into the cases. All the stabilizer

assemblies are composed of two parts obtained through 3D printing and of several pneumatic components such as the elbow connector, the tube and the flow regulator, as shown in the following figure:

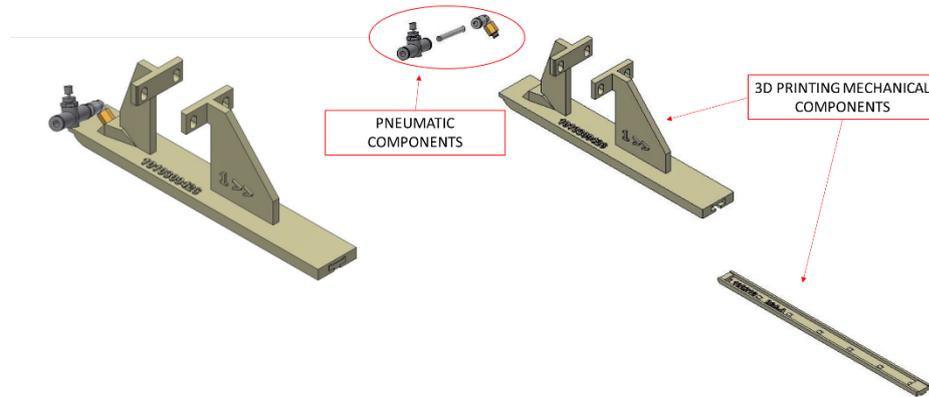


Figure 3.39 Stabilizer assembly

The compressed air comes in from the elbow connector which enters the crawl space between the two assembled 3D printed components and comes out through the inclined slits in order to facilitate the sliding of the bags through the stem.



Figure 3.40 Stabilizer assembly cross-section

- Pneumatic system for the compressed air production;
- Stems where the UD bags and BUDs go through;



Figure 3.41 Stem made of carbon fibre

- Pneumatic cylinders for the linear motion of the mobile group for the case filler along the stems axis;



Figure 3.42 Pneumatic cylinder at the stroke beginning on the left, while on the right it is at the stroke end

- Pneumatic grippers for the gripping of the stems and for the buffering during the movement of the BUDs or the UD bags along the same stems. Each mobile case-filler group is provided with three pneumatic grippers. The buffering is performed when one of the grippers is closed to block the passage and to regulate the flow of the UD bags;

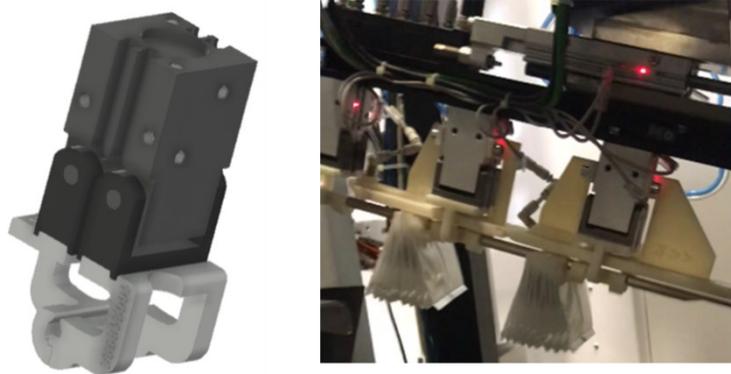


Figure 3.43 Pneumatic grippers on the left and the buffering of ten UD bags due to the closed grippers on the right

- Rodless cylinder powered by an electric actuator for the linear movement of the stem that deposits the UD bags or BUDs on the case.

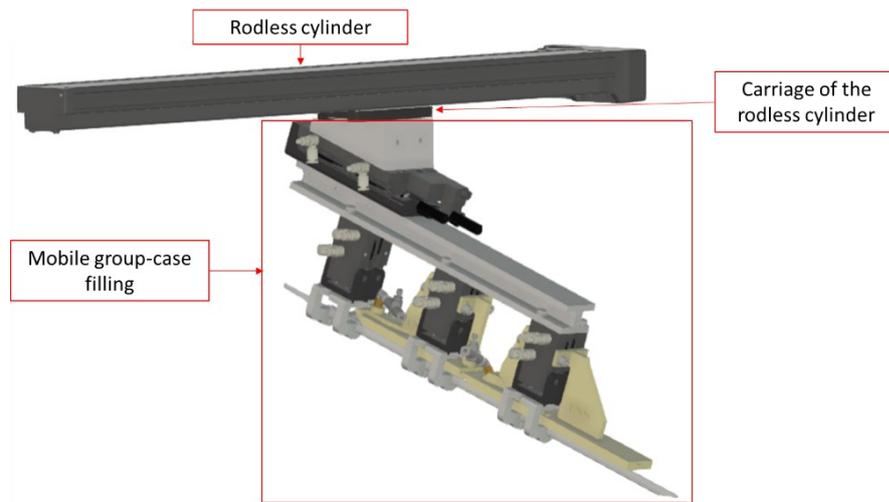


Figure 3.44 Mobile group-Case filling with particular reference to the rodless cylinder

3.4.1. Case-filler group functioning in the All-Forms Packager

The *All-Forms Packager* case-filler group is composed of two mobile subassemblies.

In order to facilitate the description of the case-filler group function, the grippers and the buffering locations are numbered as shown in the following figure:

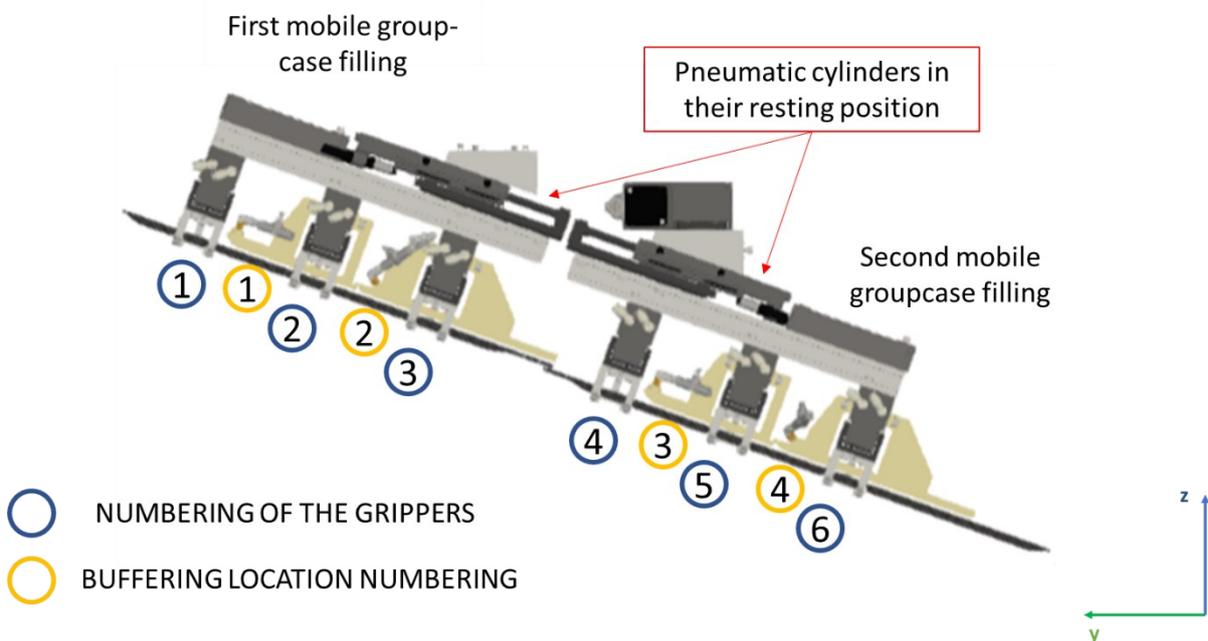


Figure 3.45 Mobile group-Case fillings in the All-Forms Packager

The two mobile group-case fillings have different roles: the first one receives the UD bags from the last station of the rotating table and transfers them to the other mobile group-case filling; the second one moves the UD bags received from the first one into the case.

As mentioned previously, the role of the UD bag buffering is carried out by the pneumatic grippers which remain closed in order to block the passage of the medications. It is important to point out that the second pair of grippers are not opened until the number of UD bags in the first buffering location reaches a certain amount. In particular, the number of the UD bags must correspond to the quantity of UD bags that must be stacked onto a single pin of the case, which is decided before the start of the machine packager operations. The opening of the pairs of grippers, from the second onwards, can take place only if the following buffering location is empty.

After the correct position check of the UD bag made at the last station of the rotating table by the fibre-optic sensors, the pneumatic cylinder of the first mobile group-case filling moves from its resting position in order to reach the UD bag hole. Once the movement is performed, the UD bag is released from the grip of the rotating-table clamps and goes into the stem while the first pair of grippers are opened. By doing so, the first pair of grippers allow the bags movements which slide up to the first buffering location. Subsequently, the pneumatic cylinder returns to the resting position so that the rotating table can rotate and bring another UD bag to the last station. The operation described above is repeated as many times as needed to reach the quantity of UD bags that must fill the buffering location.



Figure 3.46 Transfer of the UD bag onto the stem while the first gripper is open

The second gripper is opened in order to let the UD bags glide up to the second location buffering while the first and the third gripper remain necessarily closed.

When the second mobile group-case filling is ready to receive UD bags, the two pneumatic cylinders return to their resting position, the third and fourth grippers are opened and the UD bags are moved to the third buffering location as shown in the following figure:

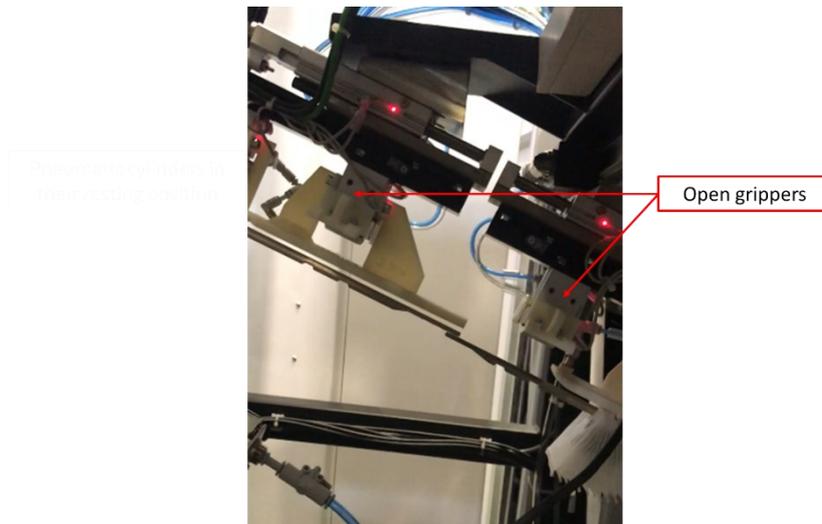


Figure 3.47 Passage of the ten bags from one stem to the other

The second mobile group-case filling is ready to stack the UD bags onto the pins of the case when the UD bags have arrived into the last buffering location. The pneumatic cylinder moves up to the stroke end when the mobile group deposits the UD bag into the case and the last pair of grippers are opened. Apart from this movement, the second mobile group has an additional degree of freedom. In fact, the rodless cylinder on which the group is attached, carries out the linear movement along the x-axis in order to line up the stem with the pin of the case.

As mentioned in the previous chapter, the stacker crane places the empty cases on a shelf of the *Storage* that must be filled by the case-filler group. A maximum of three cases can be placed on the shelf simultaneously. In the *All-Forms Packager*, with respect to the *Blister Packager*, the shelf concerned is movable because of the different types and dimensions of cases that can be filled in.



Figure 3.48 Example of two types of case

In fact, while the *Blister Packager* deals only with cases of the same dimensions, the *All-Forms Packager* can deal with bigger cases too, depending on the type of medication that the packaging process require. For this reason, the shelf of the *Storage* on which the cases are placed is provided with two pneumatic cylinders that carry out the vertical movement of the shelf in order to keep the pins of the cases at the same height whatever the type of case to be filled.

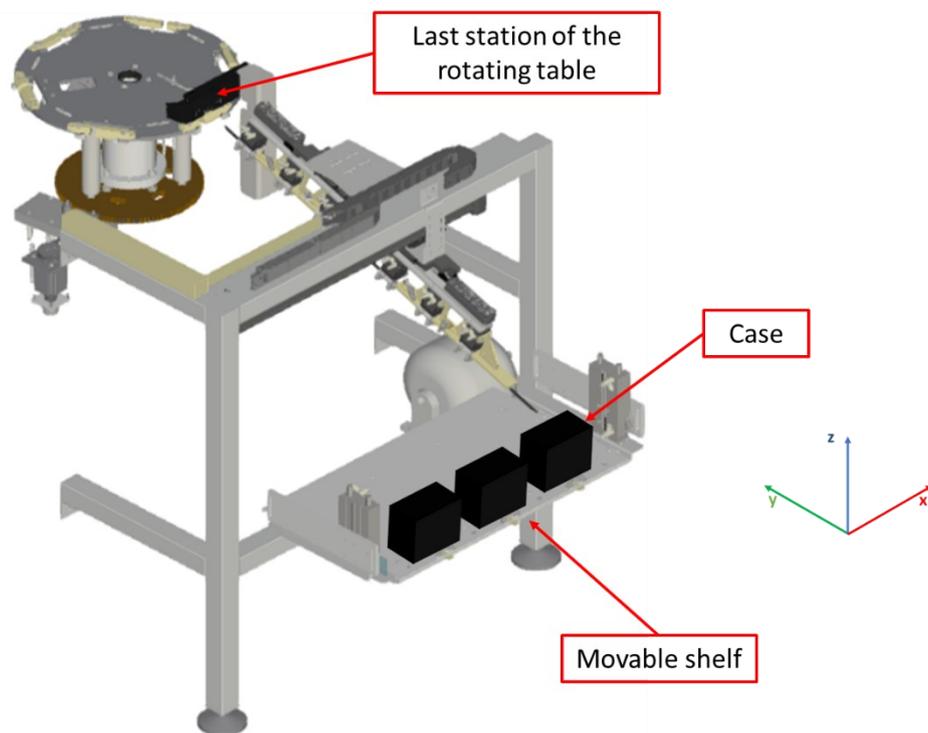


Figure 3.49 Case-filler group with the rotating table provided with only the last station and with the movable shelf on which the three Cases are placed

3.4.2. Case-filler group functioning in the Blister Packager

The *Blister Packager* Case filler group is composed of one fixed and one mobile group for the case filling.

The case-filler group in the *Blister Packager* has the same function as the one in the *All-Forms Packager* that was described previously. The difference lies in the presence of the fixed group-case filling which is not movable. In fact, while in the *All-Forms Packager* the first mobile group-case filling moves towards the last station of the rotating table in order to reach the UD bag hole, in the *Blister Packager* the BUD is stacked into the stem of the fixed group-case filling by the cylindrical robot, as described previously and as shown in the following figure:

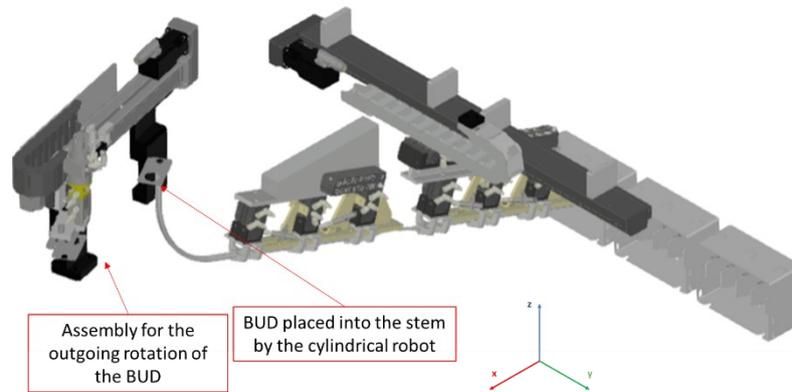


Figure 3.50 BUD placed onto the stem of the fixed group-Case filling by the cylindrical robot

The process proceeds as described previously. The cases used for the *Blister Packager* are all with the same shape and dimension, and for this reason the shelf of the *Storage* on which the cases are placed is not provided with the pneumatic cylinders as in in the *All-Forms Packager*.

4. Mechanical modifications

4.1. Problem statement

The incorrect filling of the cases is mainly due to the difficult movement of BUDs and UD bags on the stem that causes the misalignment of the warehouse drugs quantity. This error takes place when the UD is transferred from the last station of the rotating table to the pin of the case by the case-filler group. This problem is caused by several reasons:

- The BUD and UD bags containing the single-dose medications undergo several processes before reaching the case-filler group that increase their electrostatic charges. This increase determines the rotation of the UD leading to a chaotic and difficult movement of them on the stems of the case-filler group. As a result, the sliding of one or more bags along the stem is incorrect since they are only partially transferred from a buffering location to the following one, or in some cases, are not transferred. This is the main reason for which some cases are filled with the incorrect number of bags;
- The uneven blowing of the compressed air through the slits of the stabilizer does not help the UD bag or BUD to slide along the stem in certain points. Therefore, some packed medicines can get stuck during their movement along the stem;
- The incorrect alignment of the stem with the case pin causes the incorrect filling of the bags that could be lost partially or completely.

An example of an error that took place in a prototype of the *TheraPick* system is represented in the following figure, where a UD bag got stuck during the movement from a buffering location to the following one:

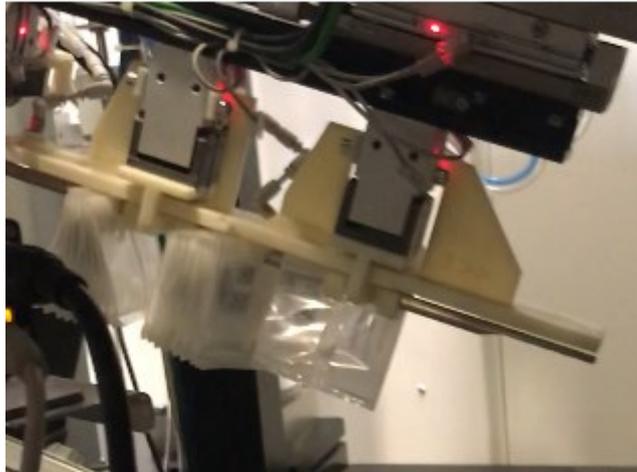


Figure 4.1 Example of a UD bag that got stuck by the gripper during its movement

The incorrect filling of the *cases* is detected by the barcode reader during the dispensing operations. When the cases are transferred to the dispensing portal, the cylindrical robot detects an error in the case due to the lack of medications or to the wrong medication. In the worst-case scenario, the stacker crane cannot replace the wrong case with another one from the warehouse, because, for example, it is the only case containing that type of drugs. This scenario can cause an increase of the dispensation time or even the abort of the dispensation process of the therapy to the patient. In the best-case scenario, the detection of the wrong case takes place during other operations and not during the dispensing of the therapy, such as the refill of the Pinwall made by the Pickportal. In this case, there is no loss of time for the therapy dispensation to the patient.

Another example could be if the wrong case detected by the Pickportal is replaced by another one stored in the warehouse. In this case, the stacker crane moves the wrong case to the loading window located in the *Storage* and the right one is moved to the dispensing module. When this happens, even though the therapy is administered correctly to the patient, the increase of time for the therapy dispensation is a disadvantage for the patient.

4.2. Mechanical modification steps

The purpose of this paragraph is to describe the steps for a potential mechanical modification to solve the issue.

The mechanical modifications are developed using the Problem Report (PR) process within the PLM software, after being reported, as described briefly in the first chapter. In details, the set of Engineering Change Notices (ECN) and their own tasks describes the actions to be executed to solve, track and manage the mechanical modification. The PR process define all the actions of different functions that have to be addresses in order to solve the problem efficiently. Once a problem or a possible product/process optimization is detected, the PR with its ECN and related tasks are created and assigned to different functions. Tasks related to mechanical modifications are assigned to the R&D team, as well as for the cases #51 and #61 that are treated in this thesis.

Generally, the design of a mechanical modification takes place through different steps in order to optimize a machine. As a first step, the study of the mechanical structure and the functioning of the machinery are carried out. Secondly, an analysis of the problem and the study of the solution is performed. Finally, one or several tests are performed in order to meet the initial requirements. In this case, the related PR is solved and the mechanical modification is released within a structured workflow, as it is described in the following paragraph. On the contrary, another solution has to be defined and tested until the issue is properly solved. Tasks management involve different functions in a structured and coordinate way.

Every manufacturing company makes use of the Bill Of Material (BOM)⁴ for the warehouse management and for the supply organization. When a mechanical modification takes place, the addition, the removal or the substitution of a new part (components without a structure) or assembly (set of components) in the system must be updated into the BOM. By doing so, the upcoming productions of the *TheraPick* system contain the improvements released. Instead, the machineries that are already functioning by the customers can or must be equipped with the improvements made through the delivery of rebuilding kit, as described in detail in the following chapter.

⁴ The BOM (bill of material) is a document where are described in a hierarchical way the list of components, sub-assemblies, semi-finished components and raw materials of each needed to manufacture an end product.

Many factors are taken into consideration during the study and the design of the solution of the problems met. In this phase, several solutions can be carried out and the task of the mechanical designer is to find the best one in order to perform the mechanical modification in the quickest and in the most efficient way.

4.3. PR standard management for a mechanical modification

In this paragraph the standard flow of a generic mechanical modification within the PLM is described. It is important to point out that the standard process of the PR flow can be tailored depending on the specific case of the mechanical modification. This means that the tasks illustrated in this paragraph are the ones that must be performed, and the ones to which it is possible to add other tasks.

As mentioned briefly in the first chapter, the PR is composed of several ECNs which in turn contain several tasks. The aim of this paragraph is to describe to whom the tasks that must be fulfilled are assigned in order to release the PR and thus, to release to mechanical modification solving the problem.

After the problem is detected, the first step is to create the PR in the PLM tool with its ECN and tasks. The ECNs involved in order to carry out the mechanical modifications are mainly two: a first one deals with the planning and the creation of the necessary modifications for the release of the new code related to new parts or assemblies; a second one deals with the insertion of the new parts or assemblies in the BOM.

The first ECN includes the study of the problem reported. It consists of a first task which is assigned to R&D. Depending on the nature of the problem, the task is assigned to the technician (e.g. if the problem derives from a mechanical difficulty, the task is assigned to a mechanical engineer). In this task, after a first analysis phase, the purchase request for the components needed for the testing of the solution is carried out. The purchase request is not always performed because some components are already available (in the warehouse) or could be produced by a 3D printer. Therefore, once the purchase request is performed, the consequent phase is the validation of the solution executed by R&D (usually the assignee coincided with the one of the first tasks). Once the

tests are carried out, if the testing performed is passed with positive results, the task is ended, and the flow of the ECN move forward. On the contrary, if the test performed is not passed, the process is repeated starting again from the first task where a different study for the solution must be performed.

Once the validation is completed, the following task is assigned to Normalization who standardize the description of the new assembly/code. This task is performed in order to define the proper name of the parts or assemblies and to facilitate its research within the IT system. The modifications can either consist in the addition of a new part or assembly (so a new code must be created for the new part) or in the addition of a part or assembly that already exists in the system.

Procurement is the owner of the following task that is to make a request for an order from the dealer in order to receive the cost of the components that need to be added into the system.

At this point, the task can be assigned directly to the finance team unless it needs to be evaluated by the industrialization team. This will be necessary when an assembly needs to be added into the system. In this case the assignee of the industrialization team has to optimize the manufacturing process by organizing the work cycles and by managing and defining the assemblies of the machinery with which the same machine is composed. If the mechanical modifications imply the introduction of drawing or commercial components into the system, the task can skip the industrialization team.

The last task of the ECN is assigned to finance who evaluates the financial impact related to the purchase and to the warehouse management of the new parts or assemblies.

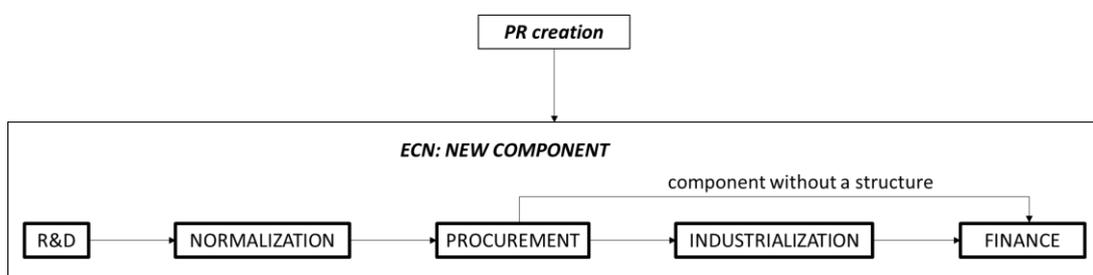


Figure 4.2 Flow of the tasks of the first ECN

Once all the tasks of the first ECN are concluded, the second ECN regarding the insertion of the new components into the BOM can start. The flow of the tasks contained in this ECN starts in the R&D

team where the assignee of the related task revises and updates all the CAD files (for mechanical modifications) or the electrical diagrams (for electrical modifications) involved in the modification. Then, two different tasks are then assigned simultaneously to both normalization and documentation functions. The assignee of the normalization team imports the updated BOM (with all the CAD files revised) from the PLM software into the ERP one. While, the other task is assigned to a member of the documentation team only if an electrical modification is carried out from the R&D team. The assignee of the team publishes the documentation regarding the electrical diagrams to share this documentation to internal customers (like Customer Service).

The third step of the ECN for the insertion of new components into the BOM is carried out by the procurement team that updates the purchase orders. The following task is assigned to a member of the material management team who updates the ongoing orders according to the modification in progress.

The ECN ends with the task performed by a member of the normalization team that releases the new updated BOM.

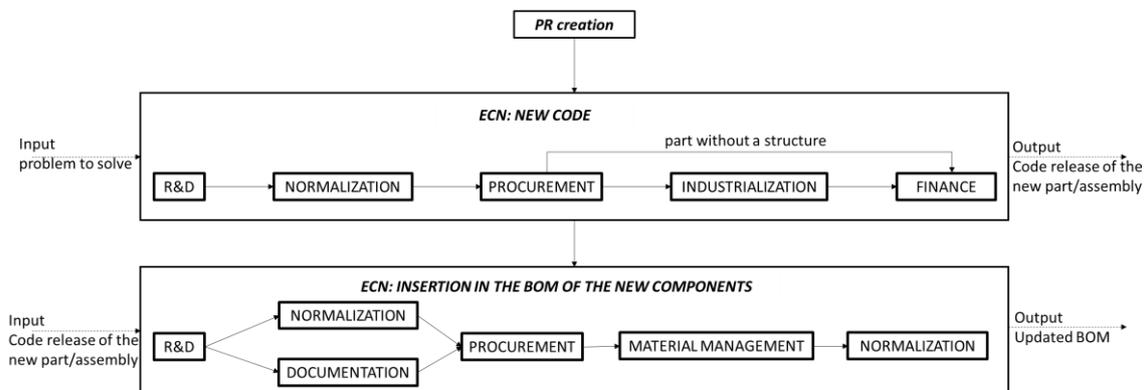


Figure 4.3 Flow of part of the PR regarding the management of mechanical modifications

4.3.1. Management of the PRs regarding the cases #51 and #61

The solution developed to solve the already described problem that affects the TheraPick system was to equip the case-filler group with a barcode-reading sensor. The study and design of the solution is described in more details in the following paragraphs.

The PRs of the cases #51 and #61 of the product roadmap do not strictly follow the standard flow described in the former paragraph.

For both cases #51 and #61 of the product roadmap a PR was opened describing the problem encountered and the ECNs that need to be followed in order to solve the problem. As mentioned previously, the problem was detected within the company by technicians during internal testing.

The flow of the PRs relative to cases #51 and #61 starts in the R&D team, as do all the mechanical modifications. Before the opening and the carrying out of the ECN regarding the new code creation, another ECN regarding the study and the validation of the solution to the problem was created.

This ECN involves only the R&D team and it is composed of four tasks:

- Task 1: study for the barcode-reader (Keyence) positioning;
- Task 2: validation of the solution (Keyence);
- Task 3: study for the alternative barcode-reader positioning;
- Task 4: validation of the solution (alternative barcode-reader).

The first task was carried out by the author of this thesis. In fact, the mounting of a high-performance sensor using a 3D modelling software was studied. The identification of the correct sensor is derived from the project data which are the:

- QR code dimension and resolution;
- Reading distance;
- Reading angle.

In order to study the positioning of the sensor through a 3D modelling software, a 3D model of the device was obtained by contacting a supplier. The output of the task is the 3D CAD file with the case-filler group in which the commercial sensor is mounted.

The second task deals with the validation of the first task. This means that a test on the prototype was performed. A day for testing with Keyence supplier was planned at the beginning of March (the supplier for the sensor with whom it was the test was carried out). The specifications of the tests are described later. The output of this task is the result of the tests made, which demonstrate the feasibility of the solution studied.

The third and fourth tasks deal with the same two previous tasks with the difference that the study and the validation of the solution are performed with alternative sensors. The output of the tasks

concerned are a 3D CAD file with the case-filler group in which the alternative commercial sensor is mounted and the result of the relative test.

4.4. Mechanical modifications for the cases #51 and #61

4.4.1. The mechanical modifications initiative

To solve the already described issue, it was decided within the System Program to modify part of the case-filler group for the cases #51 and #61 without making significant changes to the original design of the machine to ensure systems upgrade on the field. As mentioned before, the following chapter deals with the description of the rebuilding kits creation.

In order to solve the misalignment of the *TheraPick* warehouse in an efficient way, it was decided to provide the case-filler group with a barcode-reading sensor to be retrofittable also for system already available on the market. This decision was taken because of several reasons.

The hypothesis of redesigning the stabilizer in order to optimize the blowing of the compressed air coming out from the slits was discarded because of the uncertainty of the results and the complexity of the modification itself from a retrofit strategy point of view. For this reason, the introduction of the barcode-reading sensor was defined as first option being possible to implement it on both new and already available systems.

Another reason for introducing the barcode-reading sensor was to receive precise statistical data regarding the frequency of the error that occurs when the system is working. So, the introduction of the sensor is not only the solution for the warehouse misalignment, but it can also be a tool for the study and the analysis of the error that occurs in the case-filler group.

A further reason for introducing the barcode-reading device in the case-filler group was because other similar sensors are used to ensure the correct packaging of the medications in both the *All-Forms* and *Blister Packager* modules. So, with the introduction of a sensor which is already part of the BOM, the amount of work, costs and time to perform the mechanical modification is reduced.

Another idea was to introduce other kinds of sensors, such as the fibre-optic sensors instead of the barcode reading one, in order to count the number of the UD bags or BUDs that passes along the

stem. A previous study was carried out through the use of a system called Light Detection and Ranging (LIDAR) which measures the position of the bags by illuminating them with a laser and measuring the reflection with the sensor. The results were reliable regarding the position of the BUDs or UD bags along the stem, but the sensor and the computer that manages the imaging system significantly impacted the cost of the machine. In addition, other sensors with low performances could have given uncertain results considering that the UDs rotate while moving on the stem.

After a first step of analysis and research of the best solution to be implemented, it was thought that the problem would have been solved implementing a barcode-reading sensor on the case-filler group checking if the last BUD or UD bag stacked onto the pin of the case was the right one. In this way, if the last UD stacked on the Case pin does not correspond to the right one, the case is sent back to the loading window avoiding the misalignment in the warehouse and, in case of a missing BUD or UD bag, the intervention of an operator is requested.

Alternative sensors were also taken into account. In particular, a commercial sensor with high performance was considered in order to verify the feasibility of the solution. If the sensor fulfilled the expectations, the solution would have been feasible, otherwise another kind of solution would have been analysed.

Therefore, an initial study and research of the commercial sensor with which the case-filler group could be modified was carried out by the author. Once the device concerned was selected, the following step was to study where and how to mount the sensor through the aid of a 3D modelling software.

4.4.2. TASK 1: study for the barcode-reader (Keyence) positioning

The first task of the first ECN was carried out by the author of the thesis, whereby a commercial sensor offered by the Keyence company was added to the 3D CAD file of the case-filler group. Thanks to the operating and technical specifications of the sensor provided, it was possible to carry out the study for the correct mounting of the sensor into the case-filler group.

The choice of the Keyence sensor comes from the need to search for a device on the market with low overall dimensions capable of reading a 2D code, with a certain resolution and from a certain distance. As mentioned before, the identification of the correct sensor derives from the project data which are the:

- QR code dimension: 8 x 8;
- QR code resolution: 0.5 mm;
- Reading distance: from 100 mm to 150 mm;
- Reading angle: from 20° to 100°.

In order to choose the suitable barcode-reader for the solution, it is necessary to study the parameters of interest which are the:

- Distance range for the correct reading of the 2D code;
- Focal length;
- Field view;
- Minimal resolution;
- Mounting configuration.

By knowing these parameters, it was possible to study the positioning of the sensor in the case-filler group. The study revealed that the best configuration for the mounting of the sensor into the case-filler group was on the mobile case-filling group that interacts with the cases. In addition, a plate to be mounted on the stabilizer assembly was designed to implement the barcode-reading sensor on the right position. The idea of the plate comes from the fact that a barcode-reading sensor has to read the data matrix from a specific distance. Furthermore, the design of the plate comes from the need to perform the same mechanical modifications in both case-filler groups of the *Blister* and *All-Forms Packager*. The alternative solution was to mount the sensor directly onto the stabilizer assembly, but with the risk that the sensor would not have been able to read the BUD or UD bag barcode because too far from the case.

The plate is provided with two holes for the connection with the stabilizer assembly and with another hole and a slotted one for the mounting of the sensor. It is also provided with a ribbing to

increase bending resistance and facilitate the mounting of the plate for a possible RK. The following figure shows the designed plate:

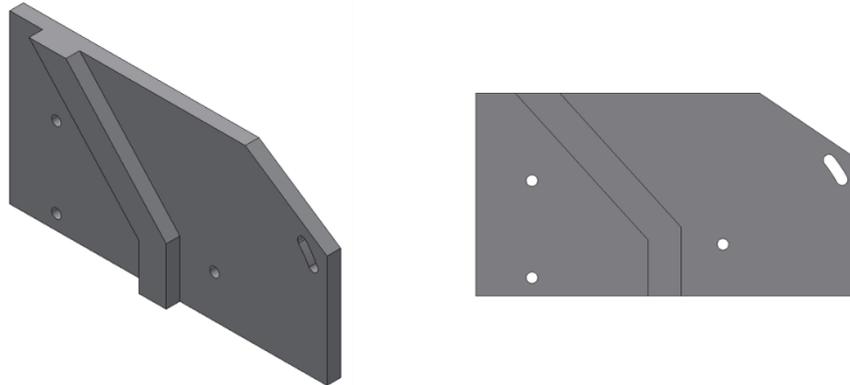


Figure 4.4 Designed plate for the mounting of the sensor

The task ends with the uploading of the 3D CAD file into the PLM software, containing the case-filler group where the plate with the commercial sensor is mounted.

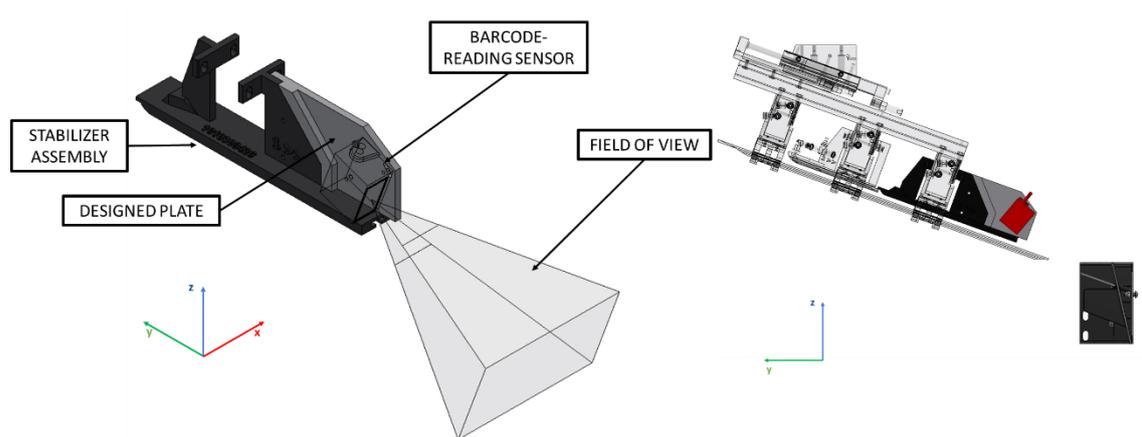


Figure 4.5 Axonometric view of the solution on the left; Case and mobile Case-filling group provided with the sensor and plate on the right

4.4.3. TASK 2: validation of the solution (Keyence)

The aim of the test is to verify the feasibility of the printed barcode reading of the BUDs or UD bags through the addition of a sensor. Another aim of the test is to verify if the sensor reads the right barcode.

Usually a purchase request task takes place before the solution testing. In the PRs of the cases #51 and #61, a purchase request was not needed, because parts or assemblies needed were:

- The plate which is produced within the company through the fused deposition modelling (FDM) process used by the 3D printer. The process concerned uses a continuous filament of a thermoplastic material which is heated and extruded by a head that moves in two dimensions. The plastic material used is water soluble and deposited on a horizontal plane;
- The screws for the mounting of the plate and sensor;
- The sensor is brought by a Keyence representative who assists and helps the execution of the tests.

The validation of the solution was arranged with Keyence who brought the sensor and managed the functioning test on the system.

As mentioned previously, the plate was designed by the author of this thesis and produced through a 3D printer, as shown in the following figure:

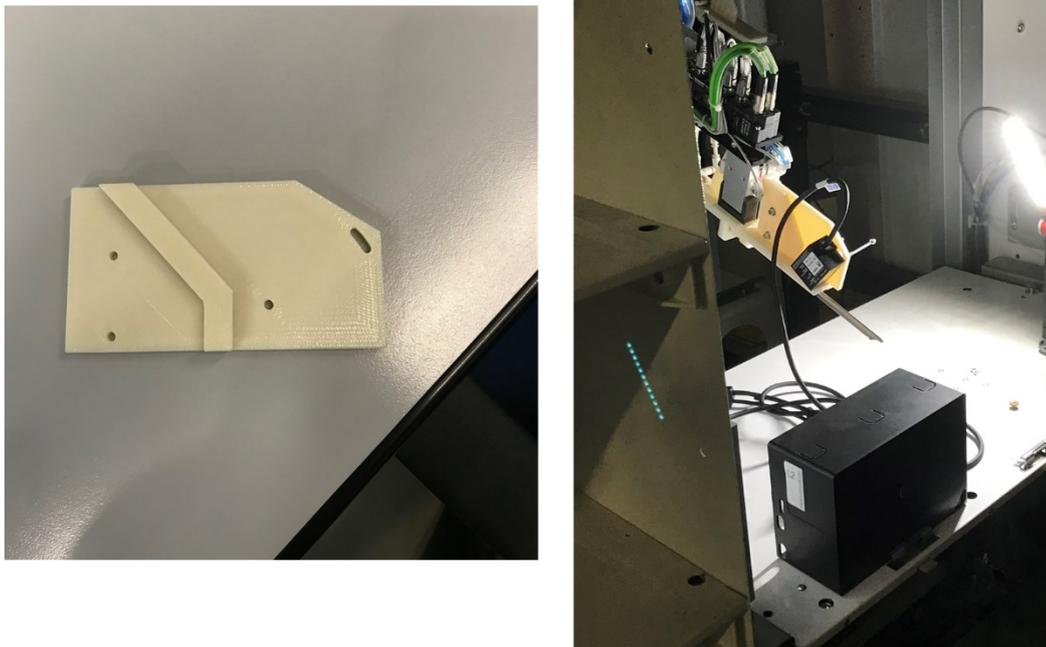


Figure 4.6 Plate produced through the 3D printer on the left; test with the sensor and plate installed onto the stabilizer assembly on the right

The test was performed without the designing of the electrical connection of the sensor, but simply holding the power cable by hand. The sensor was connected via USB to a PC that acted as a host. Through the PC brought by the Keyence representative, it was possible to force the sensor to scan the data matrix and to view the images observed by the lens of the camera of the sensor. Several

tests took place actuating the trigger when the mobile case-filling group was in a position suitable for the relative type of test.

The tests were performed on a prototype of the *TheraPick* system within the company in Maranello, or more specifically, in the *All-Forms Packager*. A PillBox containing more than a hundred pills was introduced in the module. Therefore, the machinery was activated and the UD bags were stacked onto the pins of the cases.

Several tests were performed depending on the position of the pneumatic cylinder, on the angle of the sensor and on the quantity of bags stacked onto the pins. The tests made with one UD bag stacked onto the case pin are described below:

- Barcode reading with the sensor inclined by an angle of 20° , the pneumatic cylinder at the beginning of the stroke;

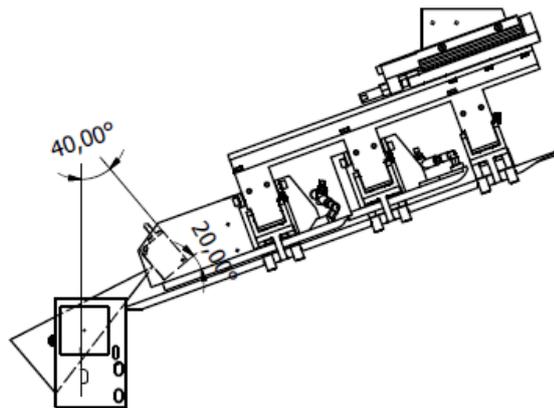


Figure 4.7 Mobile Case-filling group in the filling position, sensor inclined by an angle of 20° and one UD bag stacked onto the Case pin

- Barcode reading with the sensor inclined at an angle of 20° . The pneumatic cylinder is at the stroke end;

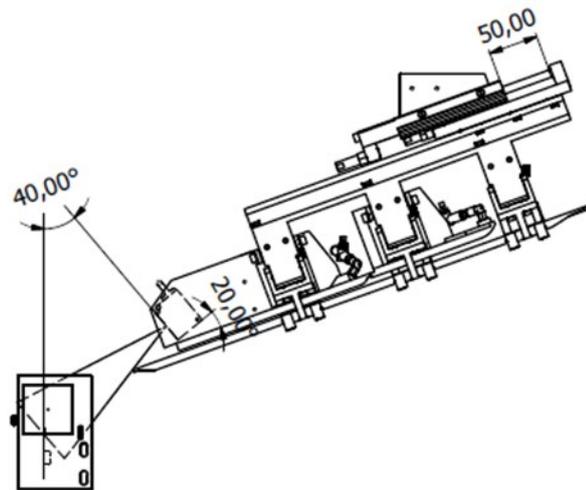


Figure 4.8 Mobile Case-filling group in the position for the UD-bag receiving, sensor inclined by an angle of 20° and one UD bag stacked onto the Case pin

- The same two tests described above were carried out again with the sensor inclined by an angle of 25°;

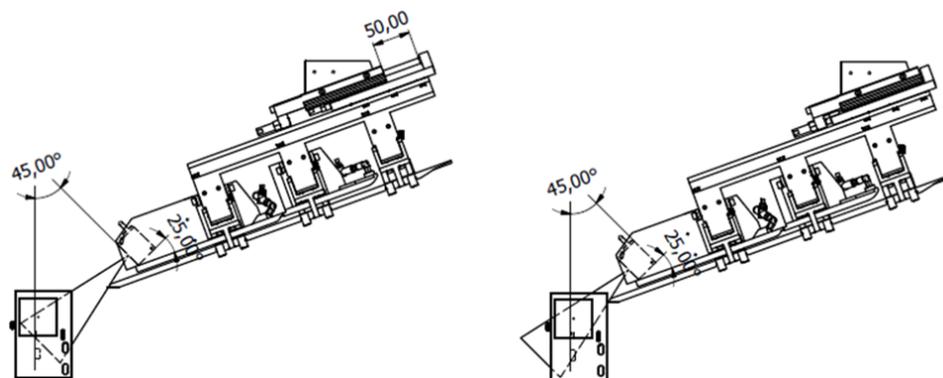


Figure 4.9 Barcode-reading tests with the sensor inclined by an angle of 25°

In addition to the tests described above, the same tests were repeated with the pins filled with ten UD bags instead of one UD bag. These other tests were carried out in order to ensure the correct reading of the BUD/UD bag QR code despite their different inclination. In fact, the electrostatic interaction between bags and the medications volume stacked onto the case pin could affect the position of the last UD deposited on the pin raising the reading angle for the barcode sensor.

In conclusion, all the tests carried out ended with good results and with the successful reading of all the triggers made. Furthermore, it was possible to verify the best configuration of the several tests carried out. The variables involved were the position of the pneumatic cylinder and the angle

of inclination with which the sensor was mounted. As far as the pneumatic cylinder is concerned, the optimal distance was for the filling configuration of the mobile case-filling group, that is, with the pneumatic cylinder at the beginning of stroke. This conclusion comes from the fact that, even though the field of view for the data matrix on the UD bag was smaller, the image of the QR code shown on the PC screen of the sensor was clearer and easier for the sensor to read thanks to the camera.

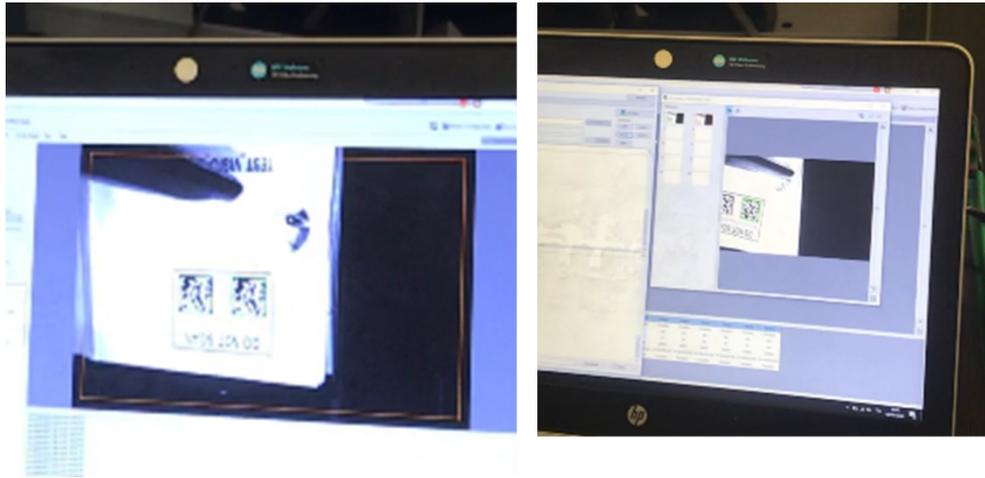


Figure 4.10 Pneumatic cylinder at the end of stroke on the left; pneumatic cylinder at the beginning of the stroke on the right

As far as the angle of inclination of the sensor is concerned, the optimal angle was of 25° . The sensor inclined by an angle of 20° had a greater field of view depth and thus a better view of the QR code when the pin is filled with only one bag. This characteristic was not so relevant for the goal of the test. In fact, the sensor inclined by an angle of 25° not only carried out the reading of the bag in the case of the pin filled with only one bag normally, but it also has a better view of the pins filled with ten bags despite the interaction between them that created a kind of concertina.

In conclusion, it can be deduced by the analysis reported by the several tests, that the optimal mounting is for 25° and the position of the pneumatic cylinder is at the beginning of the stroke, as shown in the following figure:

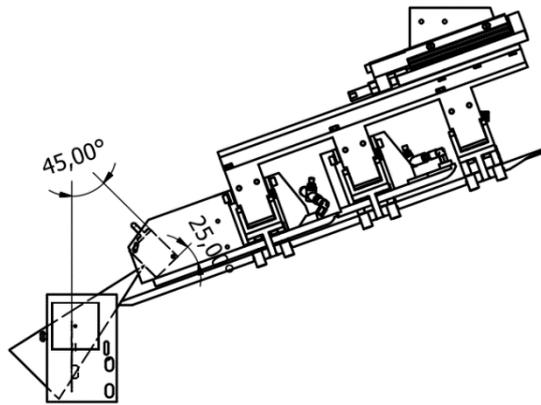


Figure 4.11 Optimal configuration for the reading of the barcode printed on the bag

4.4.4. TASK 3 and TASK 4

The two tasks regarding the study and validation of an alternative solution to the Keyence sensor are carried out with a sensor which is already part of the *TheraPick* system. So, after a feasibility analysis with the Keyence sensor, another device with a lower performance and lower costs already present within the system was studied and validated. As for the Keyence sensor, the new device was installed in the case-filler group through the aid of a new plate. The latter component is similar to the previous one, with the difference that it is redesigned in accordance with the new mounting specification of the barcode-reader sensor. The following figure represents the redesign of the plate for the new sensor:

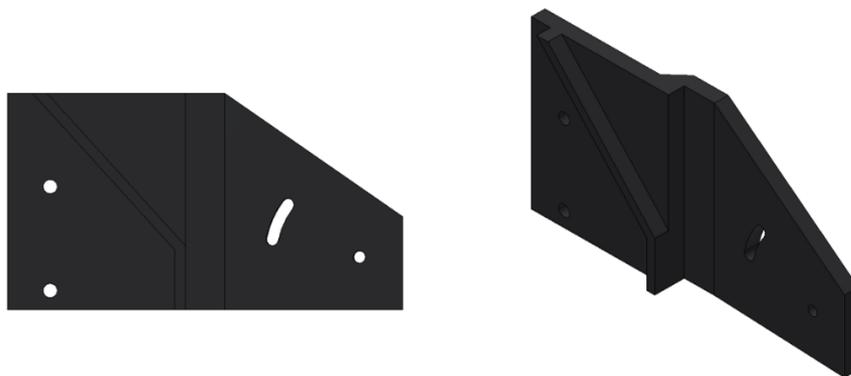


Figure 4.12 Designed plate for the mounting of the new sensor

5. Standardization of the technical bulletins

5.1. Customer care

Nowadays, the strategic approach of many companies is to focus on the customer. When the product or service provided by a company satisfies a customer, it entails his/her loyalty and the spread of their good feedback that can probably attract other customers. On the other hand, if the customer is unsatisfied the company would probably lose him/her causing a decrease in profit. Therefore, what characterizes a successful company is not only the providing of a good product or an excellent service, but also to have an efficient customer care service.

The customer care represents the set of actions taken by a company in order to satisfy the customer before, during and after the purchase and the fruition of products or services. In order to ensure that the products and services meet the demands and expectations of the customers, Swisslog Healthcare provides customers and technical support. The customer care centre is composed of several customer care units that support their customers in their own specific region. The author of this thesis is part of the engineering area and his task is to interact and support the customer care centre by interfacing with the local customer care. The customer care assists clients through part orders, technical support, scheduled maintenance, upgrades and service agreements. Beside other activities, the engineering team supports the customer care centre through the technical bulletins on which are described the upgrades and the technical support for any optimization of a product.



Figure 5.1 Structure of the customer care

5.2. Technical bulletins and rebuilding kits

The technical bulletins (TB) represents the company communication process to inform the customers about mandatory products modifications, optional products improvements or products information only. Once an issue is reported from the field or an improvement on the product is developed, the resolution of the issue or the changes to be implemented to improve the products themselves are communicated to the customers by means of the TB.

A synthetic judgement is assigned to the problem reported in the technical bulletin, depending on the urgency level. For any technical bulletin it is possible to assign three levels of urgency, which, from the least to the most urgent, are described as:

- Information only: information on the products (obsolescence, improved instructions, etc.) communicated to the customers without a specific issue;
- Potential improvement: products improvements (SW upgrade, new functionalities, etc.) communicated to the customers to address issues not impacting significantly the product itself;
- Retrofit activity: products improvements communicated to the customers to address issues significantly impacting the product itself.

As mentioned previously, a PR is opened in the PLM tool for example when a product presents an issue, or a product modification needs to be developed. As for mechanical modifications, the communication to the customer is managed and tracked through the PR.

When a problem is detected and solved, as described in the previous chapter, a mechanical modification is released and, if deemed appropriate, a first ECN is created to define the related rebuilding kit (RK). The RK is a set of components to upgrade products/systems already on the market. The RK also contains the instructions for the implementation of the modifications. Once the RK is created and its relative ECN is concluded, another ECN with the RK documentation is created.

The tracking of technical bulletins and RKs through the PLM tool is useful for ensuring that modifications are correctly developed, communicated and implemented on the field. The RK and

TB workflow for the communication and verification of a mechanical modification is shown in the following figure:

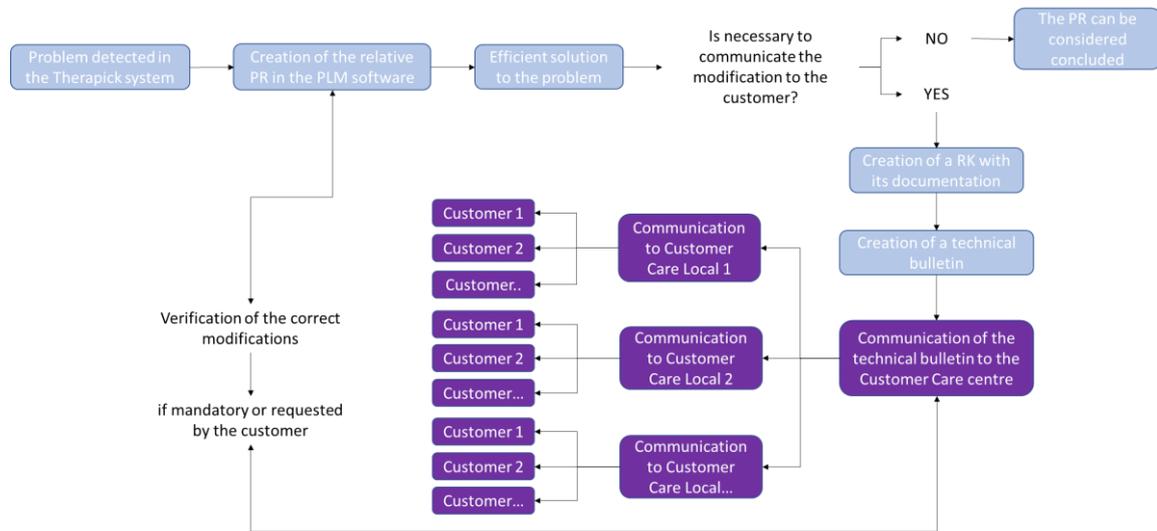


Figure 5.2 Flow for the communication and verification of the improvement of a customer product

5.3. Standardization of TB

The aim of this paragraph is to present how the customers' communication is structured and why it is crucial to standardise this process.

The main reason for the introduction of the TBs standardization is related to the need to improve products on the markets in a structured and efficient way in order to satisfy customer requirements. Before the TB standardization, the RKs were sent to customers only when considered. With the new process, a communication for each RK is sent to the customer, independently from the urgency of the problem. Therefore, the new standardization process improves the connection between the customer and the company.

The standardization of TBs is a way to clarify which of the several onsite machineries have been equipped with the RK and which have not. Three types of TBs, so-called letters, have been defined based on the type of problems with which the machine is affected:

- *Retrofit Letter*: the problem significantly impacts the machine and the implementation of the modification is mandatory;
- *Field Letter*: the problem does not significantly impact the machine and the implementation of the modification has to be required by the customers;

- *Field Notice*: information only.

The three types of letters correspond to the urgency level of the optimization that is needed to be carried out. The main difference between the three letters lies in the fact that the retrofit one is mandatory which means that the modification described in the RK must be carried out in all the machines available on site, while the other two are not mandatory and could depend on the customers' requests. More specifically, the field notice is a simple communication where an update of the machine is described, while the field letter is the communication where a potential improvement is recommended. An example for a retrofit letter and field letter are shown below:

Field letter: FL_002065_2020

| | |
|---|---|
| Date of quality issue / QNC Ref. | Not applicable |
| Region | Asia Pacific, EMEA |
| Feedback | Upgraded part |
| System / Module | Therapick / Dispensing |
| Urgency Level | Medium |
| Safety impact | Not applicable |
| What | Increased pneumatic lift stroke and changed conveyors' sides design to improve rings deposition and transport on conveyors |
| What impacted | Dispensing Module |
| To do: | Please order to Swisslog Orders Italy (orders.slhc.it@swisslog.com) code 1001016527 |
| Prepared By | Francesco Alessandro Bonifacio |
| Approved By | Stefano Marzetta |

Urgency level= "Low" for information only
Urgency level= "Medium" for potential improvement
Urgency level= "High" for retrofit activity

Retrofit letter: RL_002063_2020

| | |
|---|---|
| Date of quality issue / QNC Ref. | QNC-20-000143 |
| Region | Asia Pacific, EMEA |
| Feedback | Design optimization |
| System / Module | Therapick / All-Forms Packager |
| Urgency Level | High |
| Safety impact | Ref. to QNC-20-000143 |
| What | Fan implementation on All-Forms cover to secure inside temperature within the established limits |
| What impacted | All-Forms Packager |
| To do: | Please order to Swisslog Orders Italy (orders.slhc.it@swisslog.com) code 1001016606 |
| Prepared By | Francesco Alessandro Bonifacio |
| Approved By | Stefano Marzetta |

Urgency level= "Low" for information only
Urgency level= "Medium" for potential improvement
Urgency level= "High" for retrofit activity

Figure 5.3 Field letter on the top and retrofit letter on the bottom

As shown in the previous figure, the structure of the two types of letters are similar and they are sent to the customer care who share them with the local customer care, as mentioned previously. TBs template includes the following information:

- Date of quality issue and quality nonconformity code (QNC), which outpoints the problem;

- Region of the local customer care where the letter is sent;
- Feedback that describes briefly the RKs' scope;
- System and module affected;
- Urgency level of the problem detected, and which is described in more detail in the key below the table. "Low" urgency level refers to information only, "Medium" for potential improvement and "High" for retrofit activity;
- Safety impact that is related to the specific QNC;
- Description of the problem detected;
- Part or module of the system impacted;
- RK code and email address to order the specific RK;
- Member of the organization who prepared and approved the standardized TB.

5.4. Management of the TB in the PLM

The previous chapter described the flow of the PR related to mechanical modifications. Two ECNs are opened, the first leads to the creation of a new code for the new part/assembly and the second is related to the insertion of the same part/assembly into the BOM. Once these two ECNs are solved (all tasks are completed by each function), two additional ECNs are opened, if required, to create a rebuilding kit. In fact, not all the mechanical modifications and revisions developed and tracked through PRs are communicated to customers. The need to create a RK depends on the type of modification developed. For this reason, two possible scenarios could occur:

- If the modification does not significantly affect the functioning of the machinery, the RK is not created. This means that the PR is opened together with ECN 1 and ECN 2 which are described in the previous chapter. while the new ECNs related to the creation of a RK are not created and the PR is concluded with the ECN2. This means that the onsite machines are not modified, but the new productions of the *TheraPick* system contain the modifications made through the PR;

- If the modification affects the functioning of the machinery, the RK is created. This means that the PR is opened together with the ECN 1 and ECN 2, a new ECN for the creation of the RK is created and once it is completed an additional ECN for the RK instruction is opened.

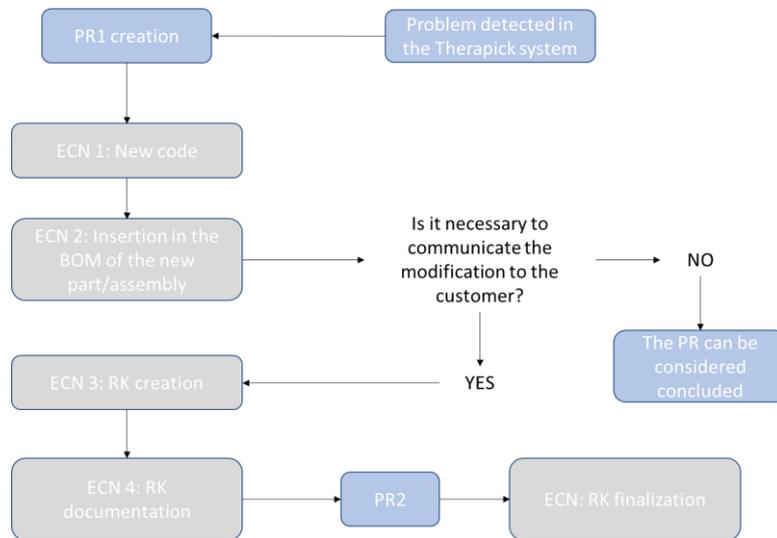


Figure 5.4 PR flow occurring for the creation of a RK

At the end of the ECN 4 a new PR is created for the management and finalization of the RK to trace the onsite systems upgrade, as described in a later paragraph. So, in order to clarify the organization of the PRs, the first PR regarding the mechanical modifications and the creation of the RK is called PR1, while the second one, regarding the communication to the customers, is called PR2. The PR2 is opened once the ECN 4 is closed, as described in more detail in the following paragraphs.

5.4.1. PR1 management

As previously described, for ECN 1 and 2, the standard flow is followed involving all the required functions.

Once decided if the modification has to be implemented or not on the field, a new ECN for the RK creation is opened. The aim of this ECN is to release an orderable code both within the PLM and ERP tools containing all the necessary components/instruction for onsite systems upgrade. The tasks of this ECN follow the same process for the creation of a new code in the ECN 1. The main difference lies in the first task of the R&D team. More specifically, the tasks are assigned in the following sequence:

- TASK 1: the first task is carried out by R&D who drafts two documents. The first one lists the components that will be included within the rebuilding kit BOM. The second one describes the instructions for the correct mounting and regulation of the kit. As for the ECN 1, if the modification involves several areas of R&D (electrical modifications and components additionally to the mechanical ones) the task must be completed more than one R&D team member;
- TASK 2: Normalization standardizes the description of the new RK coming from the R&D and assigns the BOM code to the kit;
- TASK 3: Procurement defines the RK costs;
- TASK 4: Industrialization optimizes the manufacturing process by organizing the work cycles and by managing and defining the assemblies of the RK which will be added in the machinery;
- TASK 5: Finance evaluates the financial aspect related to the RK.

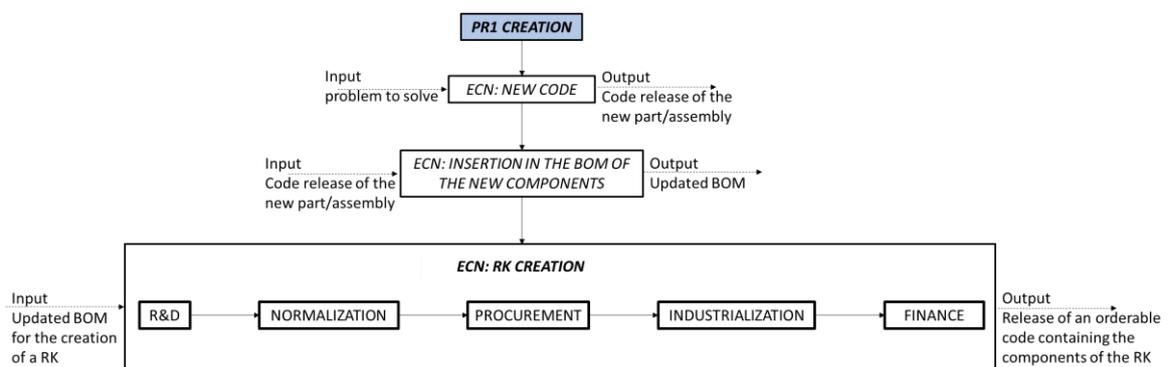


Figure 5.5 Flow of the PR1 until the task for the RK creation

Once all the tasks of the ECN regarding the RK creation are concluded, an orderable code for the RK is released.

After the process for the creation of the RK, a following ECN regarding the RK documentation is started. The opening of the new ECN is needed for the drafting of the official documentation of the RK to be sent to the customers.

The ECN flow starts from an assignee of the documentation team who drafts the official document from the one made by the R&D team in the previous ECN. Then, in the second task a member of

the normalization team standardizes the document that was made the first task and attaches the document in the RK created after the first ECN. The third and last task is carried out by a member of the R&D team who opens the PR2 after checking the previous ECN about the creation of the PR.

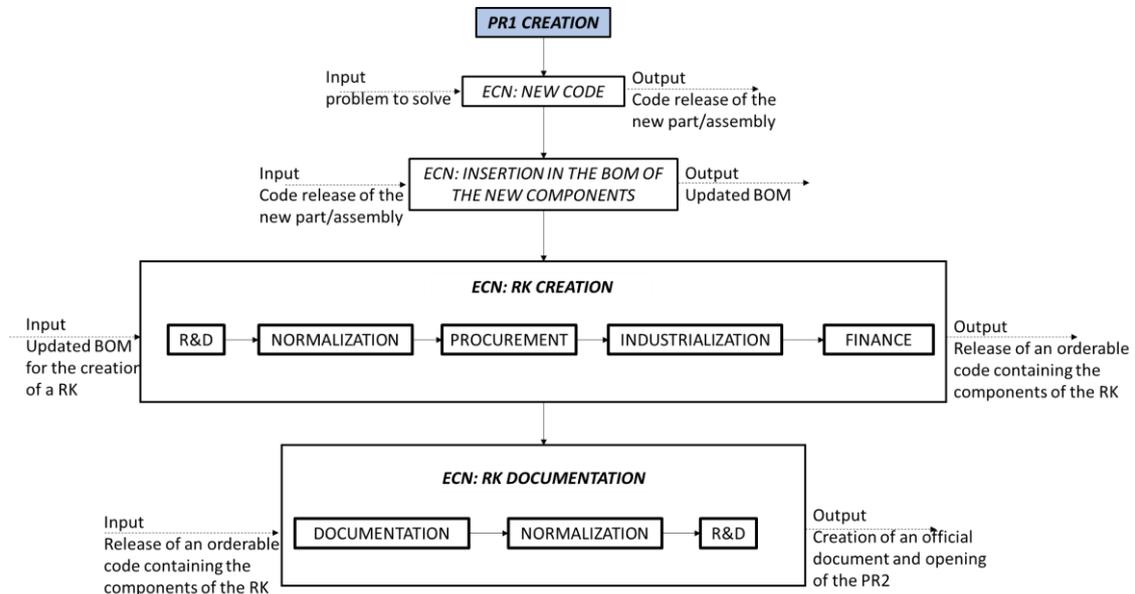


Figure 5.6 PR1 flow

At the end of the PR1 process, the problem for which it had been opened can be considered solved and therefore the tasks of the engineering group can be considered concluded. In fact, at the end of the PR1 process, the problems can be considered solved for the machines that will be manufactured.

5.4.2. PR2 management

The PR2 includes the communication of the possible optimization of the machine to the customers and the tracking upgrade of the systems already available on the market. As mentioned previously, three types of TB are used to communicate an upgrade based on the content of the communication itself. For this reason, two different ECNs can be opened after the PR2:

- The ECN for the finalization of the mandatory RK is opened if the problem that affects the machine is communicated through the retrofit letter;
- The ECN for the finalization of the optional RK is opened if the problem that affects the machine is communicated through the field letter/notice.

5.4.2.1. ECN flow for the finalization of the mandatory RK

The ECN for the finalization of the mandatory RK is composed of seven tasks of which two are carried out in parallel. It is opened if the problem reported in the PR1 significantly affects the *TheraPick* systems running onsite. This ECN is carried out when the RK is mandatory, that means that the installation of the RK must be done.

The tasks included in this ECN are schematically described below:

- Task 1: the first task is carried out by R&D who drafts the retrofit letter according to the template described before;
- Task 2: Quality sends the retrofit letter to the local customer care while Material Management defines the systems impacted by the modification and starts ordering the required components;
- Task 3: Production starts the production of the RKs based on the information received by MM within the TASK 2;
- Task 4: Production also manages the shipment of the RKs to the customer;
- Task 5: Quality verifies that customers received the RKs;
- Task 6: Quality verifies that the RK has been properly installed on the system.

The flow described above ensures that at the end of the process, all the machines are upgraded at the latest hardware configuration and the issue described within the PR1 is solved.

5.4.2.2. ECN flow for the finalization of the optional RK

The ECN for the finalization of the optional RK is opened if the RK is not considered mandatory but optional. This means that the problem reported in the PR1 affects the *TheraPick* system, but differently from the previous ECN, the optional installation is not considered mandatory and it's up to the customers decide to order this kit. In that case, the RK is sent only if the customer asks for it once the field letter/notice has been received.

The two tasks with which the ECN is composed is schematically described below:

- Task 1: the first task is carried out by R&D who drafts the field/notice letter;

- Task 2: Quality shares the field/notice letter to the local customer care.

The flow described above ensures that at the end of the ECN the field/notice letter is sent to the local customer care to inform the customers of the possible upgrade available for the machine.

5.5. Possible management of the RK for the cases #51 and #61

The aim of this paragraph is to provide the reader with the possible management and path of the PR opened as a result of the cases #51 and #61.

During the solution study carried out in the first task of the PR regarding the cases #51 and #61, the possibility of creating the RK of the solution was considered. In fact, the plate designed in the first tasks is provided with the ribbing in order to facilitate the drilling and the installation of the assembly into the onsite machines.

The decision whether the RK has to be mandatory or optional has still not been taken, at this point. This choice is made also after the evaluation of the financial impact for the installation of the RK. In fact, the machine works and carries out all its tasks without the solution found in the first task of the PR, even though it could work more efficiently.

If the installation of the sensor in the *TheraPick* system is considered mandatory, systems on the field will be upgraded with the new sensor. On the other hand, if the installation of the barcode reader is considered optional, the sensor will not be installed on the systems unless the customer requests it. In each case, systems that will be produced once the modification is released will implement the developed sensor. The previous chapter dealt with the design of the mechanical modifications for the correct mounting and positioning of the sensor into the case-filler group. After the first analysis, additional studies have to be carried out to complete the electrical design of the configuration of the sensor. The term electrical design refers to the dimensioning of the cables that are needed to power the sensor and their connection to the electrical cabinets. In addition, another probable task that has to be carried out within the R&D team is the development of the software sensor's commands necessary to communicate with the sensor.

6. Conclusions and future development

This project is a clear example of an engineering approach to the managing of mechanical modifications and their possible communications to the customers.

Although it was not possible to analyse the process of PRs relative to the cases #51 and #61 until the end, a possible solution for the reported problem was found, developed and tested.

The study and the design of the proposed mechanical modification showed that the introduction of a barcode-reader sensor into the system was feasible.

The list below gives a perspective of the phases carried out for the mechanical modifications:

- Study of the machine functioning
- Analysis of the problem that affects the system
- Study of the solution
- Opening of the PR in the PLM with its structure
- Implementation of the tasks assigned concerning the study and test with the Keyence sensor

As a possible future development, a solution of the warehouse misalignment was evaluated within the R&D team that consists of introducing an additional bar-reading sensor at the end of the case pin in order to send the signal when the data matrix at the end of the same case is reading. By doing so, when the data matrix is read, the system knows that the pin is empty and with this check operation, made at the end of the case filling, the misalignment of the warehouse is prevented.

This could be a possible solution to be added with the one studied in this thesis.

The standardization of the communication towards customers took place once decided how to inform in the clearest and effective way on machine improvements. The technical bulletins were defined by three kinds of letters depending on the urgency level of the problem. In each of the three letters the code for ordering the rebuilding kit (RK) to be installed in the onsite machine were reported. It has been decided that communications through the letters could be either with mandatory RK or optional RK, which means in the first case that the upgrading of the onsite machine

must be tracked and carried out while in the second case the possible upgrading is carried out only if requested by the customer. Compared to the previous management of communications, the tracking and clarification with the standardization of the process for the RK installation was introduced.

Within the internship period, the author of this thesis gained useful experiences and expertise in the evaluation and development of technical modifications impacting on robotized system. In addition, other skills regarding the knowledge of the company's processes and tools (such as CAD software and PLM/ERP tools) have been achieved.

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