Abstract—This document deals with explanation of the design, creation and testing of a new automated machine for the production of ureteral catheters for a company producing medical equipment. The work is a continuation of the diploma thesis of a student of the College of Polytechnics Jihlava, whose work only concerned the design of the mechanical part of the machine and the analysis of the actual manual production process.

Keywords—PLC, TIA Portal, HMI, machine safety, EPLAN

I. INTRODUCTION

This work deals with the creation of a machine for the automation of the production process of ureteral catheters. The machine is divided into two parts. A manual process shortens ureteral catheters to the desired length. An automated process assembles the support wire designed to transport the catheter. This wire is also called a stylet. Part of the assignment for the this work is the creation of an electrical project with the selection of electrical components, the creation of a risk assessment according to applicable legislation, the design of software equipment together with visualization, the practical connection of electrical components based on the design, the creation of visualization and control software and, finally, the verification of the entire solution in operation [1].

A. Urological catheter

A ureteral catheter is used in patients when it is not possible to drain urine naturally from the body. If we talk about draining urine from the body in a way other than natural, then we talk about urine derivation. The catheter is most often made from a polymer, specifically from polyvinyl chloride known under the abbreviation PVC. In appearance, it is a hollow thin long tube. The tip may include drainage holes for power derivation, or depending on the application, it may include a differently shaped tip [1].

When introduced into the patient's body, the catheter may include a support wire for transport. This is to prevent deformation and bending, as the catheter is very flexible. This support wire is called a stylet and includes a crimped end cap. This end is located on the side of the catheter that the healthcare professional holds during insertion. The stylet passes through the catheter and must not protrude from the catheter on the side for application into the body [1].

Fig. 1. A stylet produced by the company commissioning the production of the machine.

B. Purpose

The original production process is only manual and divided into several steps, where each production operator is in charge of one part of the process.

Among the biggest suggestion for building the machine was the process of shortening the wires for the stylets, as this is a possible safety hazard for the operator. When cutting, small parts of the wire can fly off and injure the operator. At the same time, the automation of the process apart from safety will also solve time savings, increase accuracy and reduce costs. By combining the process of shortening and crimping the stylet, there will again be savings due to the efficiency of the material flow, which again leads to a reduction in costs [1].

C. The concept of creating a new machine

The machine was developed to include an automatic and a manual part. The whole machine works as a whole, so it has common control and safety. The safety of the machine works in such a way that if there is a breach in one of the workplaces, the whole machine stops and is brought to a safe state. But if a process failure occurs, when, for example, a step of the state machine is not completed in the required time, the machine control will set a failure at the given station, which will stop only the part of the machine where the given station is located. This means that if there is a malfunction, for example, on the automatic part, the operator on the manual part can continue and her work is not affected.

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D. Automatic part of the machine

The automatic part of the machine has the task of completing the stilet. The task of this part is to remove the wire from the magazine, shorten the wire to the length according to the recipe and then crimp the end. The finished piece will be thrown into the sink with the finished pieces, where the operator will then pick them up. The machine can also recognize some poorly made pieces. When a bad piece is detected, the process stops and must be removed by the operator. The machine has no sinkhole for bad products. The automatic part is divided into four independent stations with possibility exchange information with each other.

E. Manual part of the machine

This part of the machine is used to manually shorten ureteral catheters to the required length. In the layout of the machine by stations, it is station 5 for manual shortening of catheters. The station is located in front of the automatic part. The process begins by inserting the catheter into the trough and waiting for an activated optical sensor to detect the end of the catheter with a shaped tip. The sensor is located in a small house, which is attached to the board of the manual workplace. There are pre-prepared mounting positions for the houses, where the position is directly prepared for a specific length to be shortened. The operator therefore does not have to measure the distance for shortening. After switching on the sensor, there is a wait for the shortening process to be activated. The process can be started by pressing a button or pressing a foot pedal.

II. WORK PROCESSING

A. Electro project

1) In general

An electrical project was created using the EPLAN 2023 tool and at the same time suitable components were selected. Since the selection of elements is huge, only the most important parts will be listed.

2) Control system

A Siemens SIMATIC S7-1214FC DC/DC/RLY PLC was chosen to control the machine. The reason for choosing this PLC with Fail-safe function was the possibility of programming machine control and safety in one program, when variables can communicate with each other. This is a more convenient solution for the programmer. At the same time, the PLC can communicate using the standard PROFINET communication protocol as well as its PROFIsafe superstructure, which enables communication with safety elements at the PLe level according to the ČSN EN ISO 13849-1:2023 standard. The S7-1500 PLC was not used, as it is a smaller machine and the chosen PLC is sufficient for the needs.

3) Visualization

HMI TX110-00VPST from Turck was selected for visualization purposes. Visualization programming takes place via the TX VisuPro development tool, which is available free of charge. The panel has similar properties to the Siemens HMI of the higher Comfort series at the price of the lower Basic series panel, which is why it was chosen. The price for a similar equivalent would be approximately twice as much [2].

4) Elements for the safety of machinery

Machine safety is controlled using a safety PLC and safety modules, where the greatest risk to human health is the mechanical movements of the pneumatic cylinders and the shearing point in the manual shortening workplace. Data exchange between the safety modules and the PLC is ensured using the PROFIsafe communication bus, which is an extension of the PROFINET network. This network is used both for the transmission of normal data and additionally for the transmission of safety data, when it achieves certification up to the PLe level according to ČSN EN ISO 13849-1:2023.

To prevent access to the machine, all doors are equipped with an RFID Guardmaster 440G-LZ security lock from Allen-Bradley. The exception is the rear wing door, where one wing is guarded by the aforementioned security lock and the other by the SI-RFDT-LP8 SI-RFDT-LP8 security RFID switch from Banner company. The leaf with a safety lock contains an aluminum angle for mechanically preventing the leaf with a safety switch from opening in the event of a lock. If the door is locked and the leaf with the switch remains open, the control system will recognize this and prevent the machine from starting. It will be possible to close only after the locks are reopened.

In order to monitor the cutting site at the manual workplace, a safety RFID switch SI-RFDT-LP8 is placed on the cover, which is active only in the case of an active manual process for shortening the catheter.

There are three emergency stop buttons in total. One is located on the control panel, the other on the left side of the machine near the wire magazine and the last one near the manual workstation. The last emergency stop is equipped with a cover against accidental pressing and the option to lock the LOTO (LockoutTagout) system, which is used by machine maintenance when working on machinery. All emergency stop
buttons are Harmony XB5 RU 22mm detents from Schneider Electric firm.

In the event of a security breach, all safety elements for controlling the action elements will be switched off. It is a BLDC motor to which two STO (Safe Torque Off) signals from the safety output module are connected. In the case of compressed air, on the FRL unit for the treatment of compressed air there are two VP546-5DZ1-M-D safety solenoid valves (SMC company) with gate position monitoring, which are again controlled by the safety output module. Furthermore, all valves for controlling pneumatic cylinders are controlled by the EX260-FPS1 valve terminal (SMC company) with PROFI safe communication protocol. In the event of a fault, the power part of the valve terminal is disconnected via a command sent via the PROFI safe protocol from the safety PLC and all valves return to the middle closed position. Only the safety PLC takes care of turning off all these mentioned safety devices in the event of a malfunction. All physical electrical connections are two-channel with a pulsating signal to diagnose the preservation of the safety function in the circuit.

5) Wire unwinding motor
   A BLDC (brushless direct current) motor BG 66x25 dPro PN 24 V with integrated control and encoder was chosen for measuring the wire. The motor is controlled via the PROFINET communication protocol. The motor is powered of 24 VDC and has a rated current of 8.03 A. The encoder is the incremental type including 4096 pulses per revolution [3].

6) Pneumatic components
   All pneumatic components and associated equipment will be from SMC company.

B. Safety assessment

1) Safety automation builder
   Safety automation builder (SAB) is a tool from Rockwell Automation. It has been used for the design and analysis of security systems. For the purposes of the work, a project was created in this tool, where safety risks were defined and the required PLr was subsequently calculated according to the EN ISO 13849-1:2023 standard. Protective measures were applied to all risks and it was subsequently determined whether the risk was reduced to an acceptable level. The risks were taken into account in terms of the type of danger, the operation performed and the level of operator training [4].

2) Sistema
   The Sistema tool enables safety assessment according to the EN ISO 13849-1:2023 standard. It was used to calculate individual safety functions based on individual device functional data obtained automatically using libraries supplied directly from industrial device manufacturers or by manual input [5].

3) Documents for EU declaration of conformity
   The default revision was created to meet the conditions and requirements of EN 60204-1:2018. For these purposes, a test protocol was drawn up, where electrical equipment was measured to see if it complied with the above-mentioned standard. The measuring device METREL MI 3100 SE and ILLKO REVEX plus were used for this. At the same time, an overall verification of the requirements for meeting the standard was developed. From measurements and development of protocols, it was found that the default revision meets the requirements.

As part of the analysis, there was a risk assessment according to EN ISO 12100:2010, and EN ISO 13849-1:2023. The assessment is recorded in the risk assessment report. The assessment includes mention of the use of some standards, types of users, machine modes, possible performed actions, ranges of movements, effects of energies and many others.

All requirements for issuing an EU declaration of conformity for machinery have been met. The declaration contains all the standards used in the creation of machinery.

C. Software and visualization design

1) General operation of the program
   The program will be written in TIA Portal V17 from Siemens. According to the proposal, the program will be divided into a control part for the joint operation of the program, a safety part for servicing the safety of the machine and a part for individual stations. Each station will contain a state machine. Individual stations will exchange information with each other for the overall functioning of the machine.

2) Controlling part of the program
   This part of the program will be in charge of general tasks for the operation of the machine. Alarm handling, sensor data processing, control of individual valves and actuators, visualization data handling and various other auxiliary tasks will mainly be carried out here. In general, it takes care of the control of the common parts for the machine independently of the individual station.

3) Safety part of the program
   This is where all the machine safety staff will be. Only certified functions from Siemens will be used for work. There is a limitation of programming instructions as it is a safety part. Furthermore, specially created data blocks will be used to share data between the regular and security programs. Only one function from the safety organizational block will be called to handle the instructions, triggered by a cyclic interrupt with the highest priority compared to the standard program.

   Any modification to this part of the program will result in a change to the checksum, and normal playback to the PLC cannot be performed without consent to the change and a change to a new checksum with a signature.

4) General operation of visualization
   In general, a common background (template) will be created for the entire visualization, which will include the possibility of user management, language change, an overview of active modes, error indications, and the opening of a pop-up window, an overview of the status of security elements, and the current date and time. The visualization will be divided into four main parts.

   The first group of screens will serve the main information about the stations and the operation of the machine. Here will be screens for the main overview and control of individual
stations. In this group of screens, for example, you can change the recipe, set the batch for production, monitor the statuses of individual stations, change the maximum times of individual steps, start the step mode of the state automaton at each station, confirm bad pieces and turn on the lighting.

The second group will be used to control the machine in manual mode. Furthermore, the setting of the parameters of individual actuators and sensors will be included here. In total, there will be seven screens for manual control and adjustment of pneumatic cylinders, valves, BLDC wire gauge motor, camera sensor, vibrating feeder, ITV proportional valve, and sensors.

The third group will be intended for setting up, and monitoring the entire machine. It will be divided into six parts. The first part will be for recipe management. The second one includes the monitoring the inputs and outputs of the machine. The third part will contain the machine monitoring data, where there will be information about the machine operation, calculated OEE (overall equipment effectiveness) of the machine, and compressed air consumption as a function of time. The fourth section contains the settings and information on predictive maintenance of the actuators. The fifth part is the audit trail, where it will be monitored that user made which change. The last sixth part will be the detailed setting of the bed at the station 3 to calculate the values for guiding the wire.

The last fourth group is alarms. Here will be the current alarms, and the total alarm history with filtering.

D. Electrical wiring

The electrical connection was implemented based on the design, and wiring diagram created before implementation. Thanks to the prepared scheme, and board layout, a lot of time was saved.

Fig. 3. Connecting the cabling in the switchboard.

E. Software creation and visualization

The software was created on the design before actual implementation. Thanks to the design, a lot of time was saved and the operation was efficient. The program itself is logically organized and custom functions are used for almost the entire program. The visualization was created based on the design. The goal was to create it in such a way that it was clear and organized for the best possible orientation and detection of all machine states. Emphasis was also placed on the size of text and images. Everything was consulted with potential users.

F. Testing and production rollout

The machine has been successfully tested and debugged to all states. All users have been trained. The production test, validation was successful and now it is waiting to be released to production.

III. CONCLUSION AND EVALUATION

The machine was successfully designed, manufactured, documented and handed over to the client. Now it is ready to start the production for which it was made. A lot of experience was gained from building the machine, when it was possible to build a large machine from start to finish. It was also necessary to think about the future, manage the costs for construction and work. Unfortunately, this work could not be mentioned here in its entirety, as it is very extensive and everything cannot be described here.

Fig. 4. A machine made and prepared at a designated location in production.

REFERENCES