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Development of Experimental Setup to Investigate the Control System for Infusion Solutions Dosing Process

Fedir Matiko*, Volodymyr Shaleva

Lviv Polytechnic National University, 12 Stepana Bandery St., Lviv, 79013, Ukraine

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Abstract

The paper presents the results on developing an experimental setup for the research into the control system for the solution dosing process based on the weighing method of dosing. According to the results of the dosing process analysis, in the dosing systems of materials or solutions, the critical parameter is the speed of the controller and the time of its communication with peripheral devices. At the same time, it is necessary to ensure the possibility of implementing the necessary control algorithms, as well as supervision of the process. Taking into account these criteria, the authors selected a programmable logic controller (PLC) and developed a pilot plant for the study of the solution dosing process control system. The experimental setup makes it possible to study various control system structures and their dynamic characteristics depending on the characteristics of the programmable logic controller and weighing modules. According to the analysis of the technical characteristics of controllers from well-known manufacturers Siemens, Rockwell Automation and Mitsubishi Electric, the Siemens CPU 1215C DC/DC/DC controller with ET-200SP remote input/output station and SIWAREX WP321 weighing module were selected for the implementation of the experimental setup. Research on the selected programmable logic controller and the dosing process control system was performed. The results of research confirmed that using CPU 1215C DC/DC/DC controller, it is possible to achieve the same speed and productivity of the dosing line as when using control systems based on single-chip processors, while significantly expanding the functional capabilities of the system. The algorithm for controlling the process of dosing the infusion solutions was also improved in order to adapt it to controlling the process of dosing the solutions of different viscosities into bottles of different capacities. The effectiveness of the control system based on the PLC, which is part of the experimental setup, was assessed, in particular, the cycle time of the developed algorithm was estimated. Based on the results of evaluating the duration of the controller program cycle, it was concluded that the use of the developed control system as part of the WDM 8002 type infusion solution dosing line will make it possible to achieve the required line productivity and integrate the control system into the process and production control levels.

Keywords: infusion solution; dosing; programmable logic controller; control system; experimental setup.

1. Introduction

Scientific work on the development and modernization of technological lines for dosing infusion solutions involves the implementation of a large amount of experimental research on all components of such lines.

There are strict requirements for automation systems regarding resistance to malfunctions and failures. In production systems, interruptions as a result of device defects are undesirable, but mostly non-critical, since the processed information remains intact. On the contrary, dangerous situations can arise due to faulty devices within the process automation system. One of the most common sources of failures in production automation is the failure of

* Corresponding author. Email address: fedir.d.matiko@lpnu.ua

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sensors, converters and control devices [1]. In automatic control systems designed for dosing materials or finished products, the critical parameters of the programmable controller are its performance, namely its speed (execution time of program blocks) and communication time with peripheral devices. When choosing a programmable controller, it is important to take into account the available programming language and the availability of libraries of ready-made functions, which will ensure the possibility of implementing the necessary control algorithms, and will also affect the overall speed of the controller.

Taking into account the above criteria, it is advisable to choose a microprocessor controller and conduct research on a prototype of the control system. For this purpose, the authors have developed an experimental setup on which it is possible to study various structures of the control system and their dynamic characteristics depending on the characteristics of the programmable logic controller and weighing modules. The main criterion for choosing a controller and weighing modules is to maintain the same performance as when using control systems based on single-chip processors, while significantly expanding the functional capabilities. This setup is convenient for studying and correcting the algorithm of the dosing process, which covers several stages of the process. In this article, the authors present the results of research carried out by the authors during the improvement of the control system for the WDM 8002 infusion solution dosing technological line.

2. Analysis of recent publications and research works on the problem

In the paper [2], the authors considered the problem of filling syringes and vials with high-viscosity monoclonal antibodies (mAbs). The aspects of the refusal to use a mass filling machine are indicated, since this solution is neither an efficient nor a cost-effective long-term option due to tight production schedules and the corresponding resource requirements. In the work, it was decided to focus on developing the dosing process on a small-scale bottling line, which was used to determine the optimal parameters of the bottling process, support technology transfer, and develop strategies to mitigate current or potential problems with minimal disruption to the normal production process. The small-batch filler was selected taking into account several aspects. Key aspects considered include the intended filling mechanism (e.g. peristaltic pump, rotary piston pump or pressure-time-based filling mechanism), existing in-house filling machinery and the ability to simulate aspects of filling at scale using a small-scale filler, as well as small-scale filling capabilities and adaptability for future upgrades. The impact of process parameters on filling performance was assessed using a modified benchtop setup/filler or a large-scale filling machine.

In [3] the author reviewed trends in the development of sterile pharmaceutical production, namely the introduction of closed processing equipment. One option for closed processing is the restricted access barrier system (RABS). RABS are a relatively easy retrofit to implement in existing cleanrooms and can have lower capital costs than isolators, but are more expensive to operate. RABS are most useful as a retrofit to an existing facility, as the investment can be spread over several years and some of the existing infrastructure and utilities can be reused without modification. Another trend is the increasing use of robotics instead of traditional automation, especially for material handling in a closed system, as well as for front-end and off-loading component handling. Robotics are more efficient and flexible, and they reduce the number of parts needed in a closed system, which improves cleanliness. While traditional automation is still best for high-speed applications (e.g., more than 300 vials/minute), robotics is useful for flexibility in handling different container sizes and for reducing the number of rejections, which is more important for expensive products such as personalized medicines.

In the publication [4] the authors considered improving the quality of the pharmaceutical manufacturing process, namely the production of sterile liquids. A comparison was made of modern aseptic technologies for blowing, filling and sealing (BFS) ampoules with traditional aseptic methods. The latest methods of aseptic production are dominated by the use of sterile plastic instead of traditional glass for drug packaging. After all, the proposed BFS technology involves forming a container for the product immediately before dosing and significantly reduces human contact during manufacturing, which has a positive effect on the sterility of the method as a whole.

The production of infusion solutions belongs to the pharmaceutical industry. These are solutions intended for parenteral use; they can have very different physical and mechanical properties: different viscosity, specific gravity, different foaming ability, can crystallize and oxidize. The main requirements for their production are maintaining high sterility and accurate dosing of their quantity in the bottle. The latter requirement is due to the fact that other medical preparations are added to infusion solutions.

According to the type of operating cycle, dosing can be continuous or batch; and according to the principle of action, it can be volumetric or weight. With continuous dosing, the product flow that comes out of the dispenser is continuously weighed and, depending on the weighing results, the dispenser's performance is constantly adjusted. When packaging products, as a rule, batch dosing is used, which consists in periodically repeating cycles of measuring the dose of the product and feeding it to the packaging. For portion dosing, volumetric and weight dosers, volume and mass meters of products, as well as dosers of identical piece products are used. Pharmaceutical product dosing equipment includes volumetric and weight dosers specially designed to measure the amount of substance that is fed into a separate consumer container.

Weight dosing is one of the most accurate and popular dosing methods today. Dosing is a very important part of production, since the quality of future products often depends on the accuracy of dosing components. It is very impractical to dose materials manually, so special machines, i.e. dosers are used in production. Dosers provide the ability to dispense a precisely specified portion of a substance.

The most common and accurate method of dosing infusion solutions is weighing during dosing and fixing the weight of the solution after the completion of this process. A number of technological lines have been built on this method, one of which is WDM 8002. This technological line has a well-developed mechanical part and is often modernized in order to use more modern equipment for the control system. In technological lines with weight dosing, it is most often used to place stations for dosing in a straight line and to these dosing stations periodically feed vials by a screw or side belt conveyor in an amount corresponding to the number of these stations. For the WDM 8002 technological line, the number of dosing stations is eight.

Fig.1 shows a schematic diagram of a weight filling machine. The sequence of operation of the equipment is as follows. Before starting work, all equipment drives are positioned, and all components are set to the initial, so-called “zero” position, after which the equipment is ready for operation. The next step is to transport the bottles using transport screws (5), which place the empty bottles at the weighing station (6), where the empty bottle is weighed and its presence at the corresponding station is recorded on the condition that the specified limit weight is reached. After this, the filling station (8) fills the bottles to the specified weight limit. The specified weight is calculated using theoretical methods depending on the type of dosed liquid so that the weight corresponds to the required volume to be dosed. After the successful completion of the dosing stage, the transport screws (5) move the filled bottles to the output conveyor, which transports them to the next stage of production, and feeds new, empty bottles to the dosing stations.

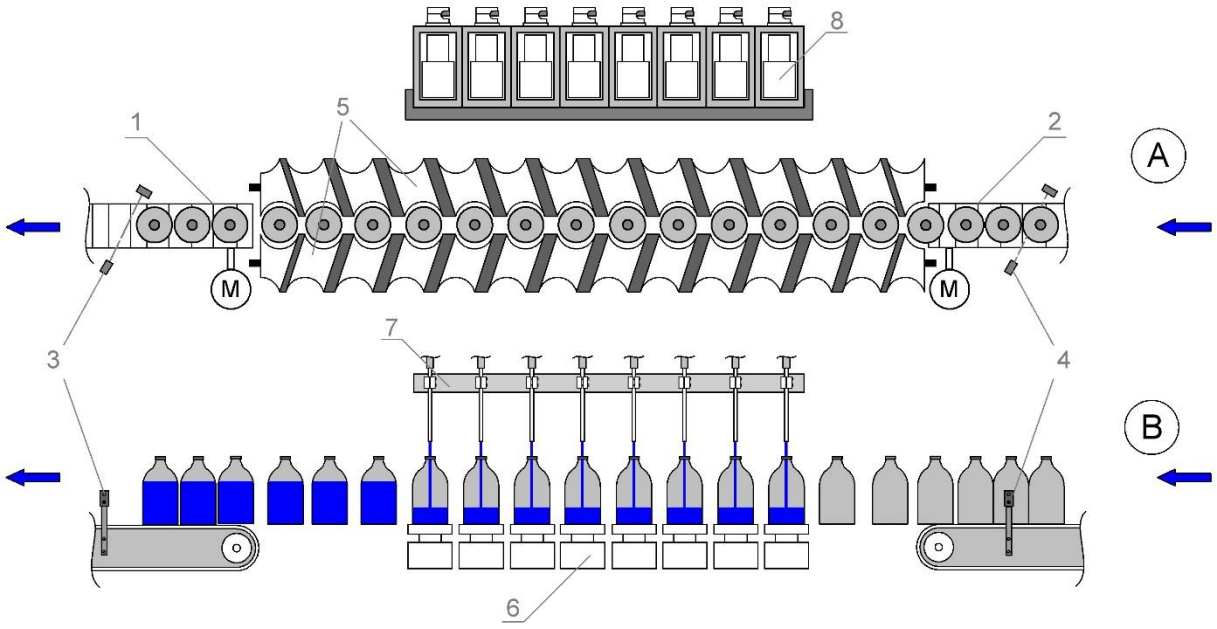

Fig.1. Simplified schematic diagram of a weighing vial filling machine:
1 – receiving conveyor belt; 2 – output conveyor belt; 3, 4 – discrete sensors; 5 – transport screws;
6 – weighing stations; 7 – needle holding device; 8 – filling stations.

Dynamic weighing processes are described in “Dynamic Load Cell Technology” (METTLER TOLEDO) [5]. For this purpose, load cells with magnetoelectric compensation are used. Such cells are less sensitive to mechanical disturbances from the operation of the drives of the technological line and shock disturbances from the flow of infusion fluid, but their much larger dimensions disproportionately increase the dimensions of the dosing area. Therefore, they are used in lines that have one branch for dosing or in checkweighers.

According to the results of comparing the described dosing methods, the authors selected the weight (mass) method of dosing liquid substances as the most promising method for further research.

3. Formulation of the goal of the paper

The purpose of this paper is to use the developed experimental setup to study the technological process of dosing infusion solutions. A positive result from the modernization is possible with a research into the selected programmable logic controller and its additional modules for the control system, research into the developed structural diagram of the control system, reproduction and improvement of the algorithm for dosing infusion solutions. Based on the results of experimental studies of the process of dosing drugs, the main solutions for the modernization of the technological line for dosing infusion solutions of the WDM 8002 type were formed.

4. Selection of a programmable logic controller and its additional modules

To modernize the technological line for dosing infusion solutions, it is necessary to replace the existing control system based on single-chip processors by a control system using a programmable logic controller. Such a replacement provides a significant expansion of the control system functionality in terms of visualization of the dosing process, archiving and processing of dosing results from each dosing station, and diagnosing malfunctions. The only but significant problem with such a replacement is the problem of ensuring the speed of the control system when performing the dosing procedure to maintain the productivity of the technological line. Until recently, control systems based on single-chip processors had a significant advantage in speed compared to control systems using programmable logic controllers. Therefore, the main task when choosing the structure of the control system and the type of programmable logic controller is to maintain the productivity of the technological line.

When selecting a programmable controller and expansion modules (input/output), the products of three most popular companies on the market were analysed, namely: Siemens, Rockwell Automation and Mitsubishi Electric.

For Siemens products, the programmable controller CPU 1215C DC/DC/DC, 6ES7 215-1AG40-0XB0, as well as the remote I/O station type ET-200SP, IM 155-6 PN HF, 6ES7 155-6AU00-0CN0 with the SIWAREX WP321 weighing module, 7MH4 138-6AA00-0BA0, were selected.

Advantages of the selected configuration [6]:

- High-speed compact controller with 200 kB working memory, with built-in discrete inputs and outputs, and 4 built-in high-speed outputs that support stepper motor driver control;
- Availability of 2 high-speed Ethernet ports with the ability to communicate with control panels or remote I/O stations;
- Library of ready-made functions (about 1000 functions);
- Support for modern programming languages (LAD, SCL);
- Availability of a ready-made functional block for processing data from the weighing module;
- Ability to connect quickly to a software control panel deployed on a PC and developed in a single software;
- Ability to configure weighing module parameters directly from the control panel.

The disadvantage of this configuration is the high cost of the software and high requirements for the hardware characteristics of the PC.

From Rockwell Automation products, the SLC 500 Controllers series programmable controller with the HI 1746-WS weighing module was selected.

Advantages of the selected configuration [7],[8]:

- Built-in RS-232/422/423 communication port;

- Available Ethernet PLC-5 controllers and Ethernet interface module (1785-ENET) provide built-in web services;
- Support for programming languages: LAD and Structured-text;
- Extended instruction set, including file processing, sequencer, diagnostics, shift register, instantaneous input/output and program control instructions;
- Presence of built-in ports that can be configured for Data Highway Plus™ (DH+) or Universal Remote I/O.

Disadvantages:

- Small available instruction set: 71 instructions;
- Lack of built-in Ethernet port;
- Lack of built-in analog and discrete inputs/outputs;
- No built-in high-speed outputs for controlling stepper motor drivers;
- Inconvenient software, individual modules of which are specialized for individual components of the control system.

The Q13UDEHCPU programmable controller and Q61LD weighing module were selected from the Mitsubishi Electric catalogue.

Advantages of the selected configuration [9]:

- Total memory capacity: up to 32 MB;
- Program memory capacity: 130 kilosteps (520 kB);
- Multiprocessor operation (max. 4 CPUs);
- Built-in Ethernet port for communication and programming;
- Maximum number of inputs/outputs: 4096/8192.

Disadvantages:

- Lack of built-in discrete inputs/outputs;
- Lack of built-in high-speed outputs for controlling stepper motor drivers;
- Software not optimized for the user;
- High price of the programmable controller;
- Lack of integrated software for debugging all functions.

Taking into account the above-described advantages and disadvantages of each control system configuration, the existing experience with the company's products and its dominant positions in our region, Siemens products were selected for the implementation of the experimental installation, namely:

- Programmable controller CPU 1215C DC/DC/DC, 6ES7 215-1AG40-0XB0;
- Remote input/output station type ET-200SP, IM 155-6 PN HF, 6ES7 155-6AU00-0CN0;
- Weighing module SIWAREX WP321, 7MH4 138-6AA00-0BA0.

With the advent of an affordable and high-performance programmable logic controller type CPU 1215C DC/DC/DC, 6ES7 215-1AG40-0XB0 on the market with the following parameters [6]:

- Processor working memory for program processing: 200 kB;
- Data storage memory: 4 MB;
- Data transfer interface: PROFINET IRT;
- Bit performance 0.08 μs / instruction;
- Performance for operations with word data types: 1.7 μs / instruction;
- Performance for floating-point arithmetic typ. 2.3 μs / instruction.

This controller managed to combine all the functions and provide the necessary speed. The most important additional modules of the controller for automating the dosing process are the weighing modules. The new structural diagram uses a weighing module of the Siwarex WP321 type with the following parameters [10]:

- Permissible input signal per test interval: 0.5 μV/d (d=e);
- Sampling rate: 600 Hz;
- Input signal resolution: ±500,000 parts per mV/V;
- Maximum sensor connection length: 500 m, when using the SIWAREX 7MH4702-8AG cable.

5. Development of the experimental setup

The authors have developed an experimental setup for testing the main components of the control system, such as a programmable controller, a remote input-output station, and a weighing module for processing signals from a strain gauge. The implemented setup completely reproduces the hydraulic scheme of the technological line.

Consider the structural diagram of the experimental setup, which is shown in Fig.2. The setup includes a simplified control system for the dosing process of infusion solutions, which simulates the operation of only one dosing station. The control system should consist of the equipment that is planned to be used in the modernization process, and it should also implement the main control algorithms, primarily the dosing algorithm, which will consist of several stages.

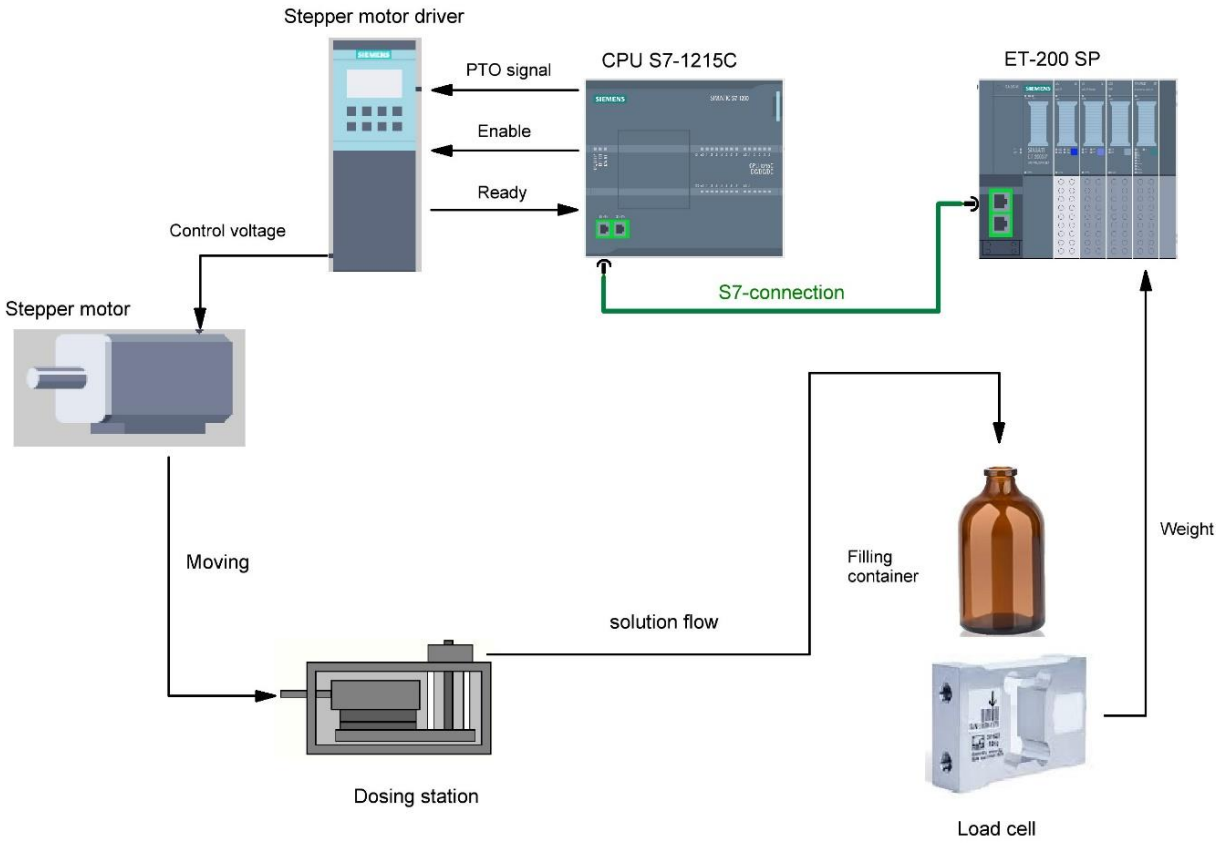

Fig.2. Structural diagram of the experimental setup for the study of the process of dosing infusion solutions.

From the above diagram it follows that the main means is the programmable controller CPU 1215C DC/DC/DC in which the control algorithm is embedded. The controller is connected to the remote input/output station ET-200SP, IM 155-6 PN HF via Profinet network cards using the S7-connection protocol. This connection forms a measuring and control complex in which the remote input/output station is a measuring unit, and the controller is a data processing center and a control device. To change the opening position of the dosing station in accordance with the embedded algorithm, the controller generates a control action on the stepper motor driver and receives data about its

state through high-frequency outputs and discrete inputs of the system. The stepper motor driver, in turn, generates a signal to move the stepper motor, which, by rotating the shaft, changes the degree of opening or closing of the dosing station, which changes the degree of hose clamping, and accordingly its patency. Further, through the filling needle, the dosed solution enters the dosing container, which is installed on the weighing cell to measure the weight of the dosed solution. The value from the weighing cell is sent to the SIWAREX WP321 weighing module. The weighing module transmits the data to the programmable controller, in which the exact weight is determined in the configured software block.

On the developed experimental setup, studies of the stages of the dosing process were carried out: the beginning of filling, the main filling, the end of filling.

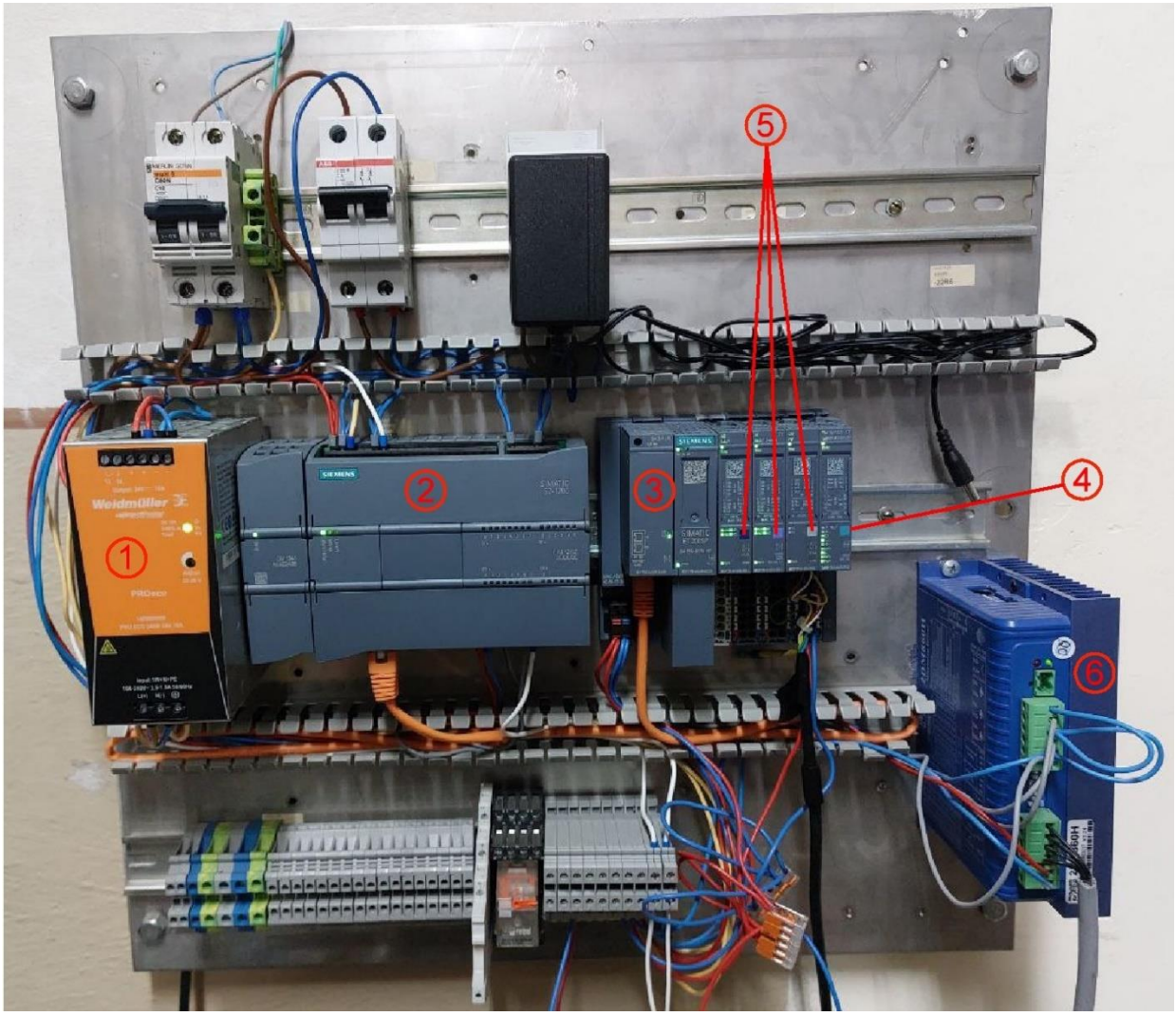

Fig.3. General view of the experimental setup for investigating the control system for infusion solution dosing:
1 – 24 V power supply; 2 – Siemens CPU 1215C PLC; 3 – ET200 SP remote station; 4 – SIWAREX WP321 weighing module;
5 – discrete input module, discrete output module and analog input module; 6 – stepper motor control driver.

6. Experimental study of the control system for the infusion solutions dosing process

When choosing the main element of the control system of the technological line for dosing infusion solutions, i.e. a programmable logic controller instead of a single-chip processor, it is important to reproduce the dosing algorithm as closely as possible and maintain the specified line performance. When carrying out modernization work, it is not always possible to read the existing control algorithm of the technological line, given that

application programs are written in machine code languages. In the end, this is not necessary, since the features of controller programming do not allow applying the existing control program to another type of controller, even from the same manufacturer. Therefore, it is more expedient to conduct separate experimental studies of the dosing process on the developed experimental setup and form a dosing algorithm for the selected controller and adjust its parameters.

According to the results of the analysis of the process of weighing vials, this process is divided into three stages (see Fig.4): the beginning of filling, the main filling, the completion of filling. The total duration of the dosing process, excluding the time of moving the vials to the dosing section of the technological line, should not exceed 8 s for infusion solutions with low viscosity. This duration of the dosing process is provided by the line control system based on single-chip processors. It is obvious that for viscous infusion solutions, the dosing time increases.

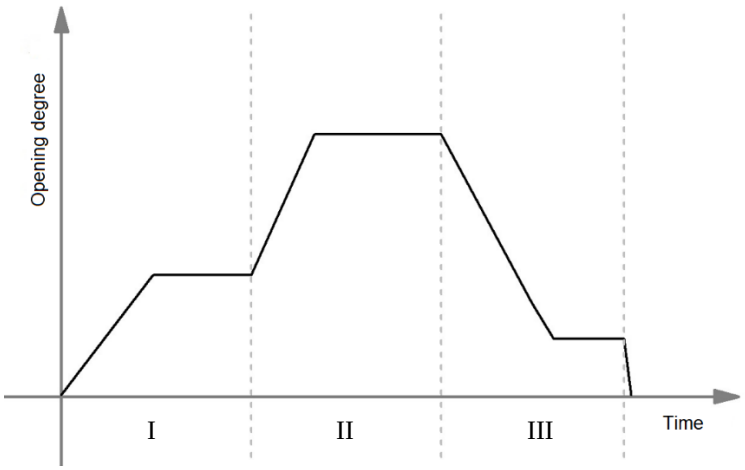

Fig.4. Graph of changes in the opening degree of the dosing station during bottle filling:
I – pre-dosing stage; II – rough dosing; III – precise dosing.

A feature of the first dosing stage is that when the dosing station is opened, the infusion solution flow hits the bottom of the bottle and creates a jump-like disturbance for the weighing channel. Therefore, for this dosing stage, it is necessary to choose the opening speed of the dosing station to reduce the jump-like disturbance on the weighing cell. The distribution of control pulses for the stepper motor driver in time will be different for different values of the infusion solution doses and for solutions with different viscosities.

During the second dosing stage, the solution level in the bottle slows down the flow flowing out of the dosing needle. The force from the dynamic flow pressure acting on the weighing cell will be constant. It depends on the infusion solution flow rate, which is determined by the degree of opening of the dosing station, the viscosity of the infusion solution, the pressure of the infusion solution in front of the dosing station, and the structural dimensions of the dosing needle. This force can be measured in an experimental setup and should be taken into account before proceeding to the third dosing stage.

The third dosing stage is the final and most important, as it is during this stage that the exact weight of the infusion solution in the vial must be established. During this dosing stage, the station is gradually closed using a series of control pulses acting on the stepper motor driver. It is necessary to close the dosing station a little before reaching the final weight value.

During experimental research, for given values of the volume (weight) of infusion solutions in vials, transition points between stages were determined for all three stages of dosing. Each transition point corresponds to a certain degree of the organ dosing station, which, in turn, depends on the number of opening/closing pulses that are supplied to the stepper motor driver from the controller. Having implemented the control algorithm in accordance with the dosing schedule shown in Fig.4, the dosing cycle was performed, and a graph of the change in the weight of the infusion solution in the vial during dosing was recorded. Fig.5 shows such a graph for an improved solution dosing process control system.

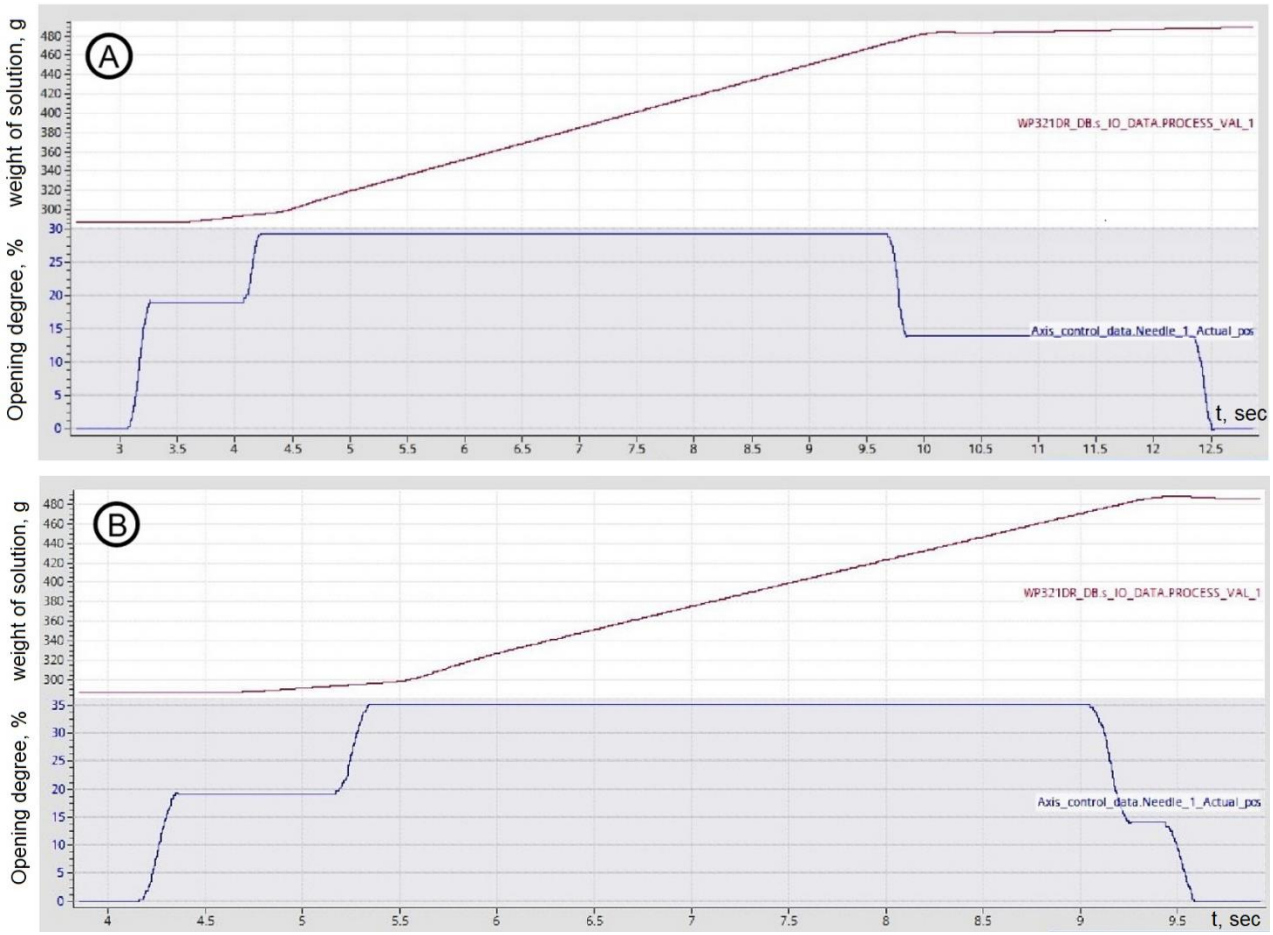

Fig.5. Curves of changes in the weight of the infusion solution in the vial during the dosing of an infusion solution with low viscosity (red line – weight of the solution vial, blue line – the degree of opening of the dosing station):
A – set value of the solution weight is 200 g, dosing time is 9.2 s, the stepper motor acceleration time is 0.5 s;
B – set value of the solution weight is 200 g, dosing time is 5.9 s, the stepper motor acceleration time is 1 s.

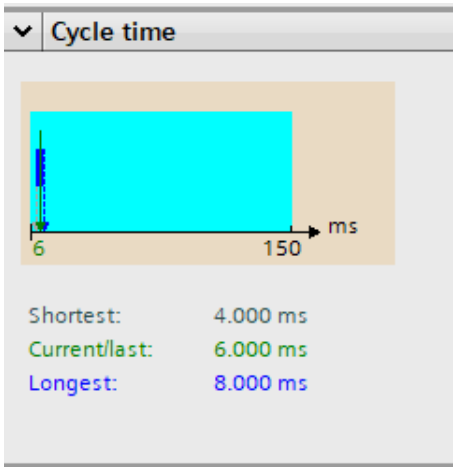

Fig.6. Processing time of the full program cycle.

Fig.6 shows the processing time data for the full program cycle from the Online & diagnostics tab of the TIA Portal software, where we see that the shortest processing time was 4 ms, and the longest time was 8 ms. The

obtained cycle time values confirm that the applied technical means satisfy the requirements for the dynamic characteristics of the dosing technological process.

The curve of the change in the weight of the infusion solution in the vial during dosing versus time is shown in Fig.5. This figure was obtained in the process of studying the control system in the installation for two values of the stepper motor acceleration time: 0.5 seconds and 1 second. Based on the results of processing the obtained data, the parameters for setting the dosing algorithm were determined, and it was also established that the selected technical means ensure the productivity of the technological line which is not less than that of the line operating under the control of single-chip controllers.

7. Conclusion

In automatic control systems designed for dosing materials or solutions, the critical parameter is the speed of the controller and the time of its communication with peripheral devices. When choosing a programmable controller, it is also important to ensure the possibility of implementing the necessary control algorithms, as well as supervision of the process.

Taking into account the criteria described above, the authors selected the controller and developed an experimental setup for studying the control system for the solution dosing process. The setup makes it possible to study different control system structures and their dynamic characteristics depending on the characteristics of the programmable logic controller and weighing modules.

Based on the analysis of the technical characteristics of controllers from well-known manufacturers Siemens, Rockwell Automation and Mitsubishi Electric, the Siemens CPU 1215C DC/DC/DC controller was selected for the implementation of the experimental installation, as well as a remote input/output station of the ET-200SP type, IM 155-6 PN HF with a SIWAREX WP321 weighing module 7MH4 138-6AA00-0BA0.

Experimental research on the selected programmable logic controller and the dosing process control system was performed. The results of experimental research confirmed that using a PLC-type controller it is possible to achieve the same speed and productivity of the dosing line as when using control systems based on single-chip processors, while significantly expanding the functional capabilities of the system. The algorithm for controlling the process of dosing infusion solutions has also been improved in order to adapt it to controlling the process of dosing solutions of different viscosities into bottles of different capacities. The effectiveness of the developed control system based on the Siemens CPU 1215C controller has been evaluated; in particular, the cycle time of the developed algorithm has been evaluated. Based on the results of evaluating the cycle time of the controller program, it was concluded that the use of the system developed by the authors for controlling the WDM 8002 infusion solution dosing line makes it possible to achieve the required line productivity and integrate the control system into the process and production control levels.

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Розроблення експериментальної установки для дослідження системи керування процесом дозування інфузійних розчинів

Федір Матіко, Володимир Шалева

Національний університет «Львівська політехніка», вул. С. Бандери, 12 , Львів, 79013, Україна

Анотація

В статті представлено результати розроблення експериментальної установки для дослідження системи керування процесом дозування розчинів на основі вагового методу дозування. За результатами аналізу процесу дозування встановлено, що в системах дозування матеріалів або розчинів критичним параметром є швидкодія контролера та час його комунікації з периферійними пристроями. Одночасно потрібно забезпечити можливість реалізації необхідних алгоритмів керування, а також диспетчеризації процесу. Враховуючи ці критерії, авторами виконано вибір програмованого логічного контролера (ПЛК) та розроблено експериментальну установку для дослідження системи керування процесом дозування розчинів. Установка дає можливість дослідити різні структури системи керування та їх динамічні характеристики в залежності від характеристик програмованого логічного контролера та вагових модулів. За результатами аналізу технічних характеристик контролерів відомих виробників Siemens, Rockwell Automation та Mitsubishi Electric для реалізації експериментальної установки обрано контролер компанії Siemens CPU 1215C DC/DC/DC, віддалену станцію вводу/виводу типу ET-200SP та ваговий модуль SIWAREX WP321. Виконано експериментальні дослідження обраного програмованого логічного контролера та системи керування процесом дозування. За результатами експериментальних досліджень підтверджено, що застосовуючи контролер CPU 1215C DC/DC/DC можна досягти такої ж швидкодії та продуктивності лінії дозування, як і при застосуванні систем керування на основі однокристальних процесорів, при одночасному суттєвому розширенні функційних можливостей системи. Також удосконалено алгоритм керування процесом дозування інфузійних розчинів, з метою його адаптації до керування процесом дозування розчинів різної в'язкості у флакони різної ємності. Оцінено ефективність системи керування на основі ПЛК, яка входить до складу експериментальної установки, зокрема оцінено час циклу виконання розробленого алгоритму. За результатами оцінювання тривалості циклу програми контролера зроблено висновок про те, що застосування розробленої системи керування у складі лінії дозування інфузійних розчинів типу WDM 8002 дасть можливість досягнути необхідної продуктивності лінії та інтегрувати систему керування до рівнів керування процесом та виробництвом.

Ключові слова: інфузійний розчин; дозування; програмований логічний контролер; система керування; експериментальна установка.