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Automated IV Bag Filling and Sealing System

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Abstract

Intravenous (IV) therapy plays an important role in modern healthcare, providing patients with a direct and efficient way to administer fluids, medications and nutrients. This paper examines the design and development of a new and innovative automated IV bag filling system, highlighting its main features and advantages it provides valuable insights into the various challenges faced on the use of IV bags and to maintain high quality throughout the procedure.

Keywords: Automated system • Articulated robot • Filling • Intravenous fluid bag • Modular gripper • Perilstaltic pump • Pneumatics • Programmable Logic Controller (PLC) • Sensors

Introduction

The role of Intravenous (IV) fluid bottles in modern medicine is crucial. They are the primary means of supply of vital substances to the human body. The pouch itself is usually made of a soft plastic that allows for safe storage, transportation and administration of intravenous fluids. The filling process of the IV bags is a crucial stage in the manufacturing of these fundamental units of modern healthcare and thus maintaining a high degree of sanitation and quality as well as minimizing or elimination of errors is of paramount importance. Traditionally, the filling process has been done manually, making the process timeconsuming, slow, and expensive due to high labor costs and alos have a high risk of errors. Improvements in automation technologies give us the opportunity to do the work more efficiently and ensure that sterility and quality standards are met [1].

The goal of the project is to develop a system that uses high levels of automation to ensure the smooth running and efficiency of the system. Through the use of articulated robots and other automation strategies, the system aims to follow all the stringent protocols and guidelines followed by the pharmaceutical industry. The high productivity that's aimed to be achieved through this system. In this paper we shall navigate through the various components and their interactions with the other subsystems that's required for the ideal operation of the system such as articulated robots, intelligent dispensing mechanisms, heat-sealing mechanisms, manipulation mechanisms among others. Recognising the fact that there are IV bags of varying sizes and thus the system should be designed with the flexibility needed to accommodate all the sizes for the system to be effective. This is done by modular gripper that can be manually adjusted for through a variety of bag sizes. By using the detailed illustrations, flowcharts and block diagrams and elaborate descriptions the paper aims to bring clarity to the system's architecture. The modular nature of the system makes it suitable for use in compact spaces as well as makes it possible to be easily adapted into existing production setups. Keeping the tight space constraints often encountered in these manufacturing facilities in mind, the layout of the system has been cleverly executed with the goal of minimizing the footprint of the system without compromising on its capabilities.

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This paper stands testament to the impact modern methods of manufacturing when used in healthcare, where compromises in precision or sterility could have severe repercussions can have. The synergy between automation and healthcare has a large scope in improving the quality of treatment provided and thus by extension enhancing the quality of life that people can experience [2,3].

Existing Systems and their Limitations

Studying the current state of IV design is critical when designing a system for automated IV bottle filling A number of systems that already exist or have already been implemented in the market are identified are analyzed in order to better understand the process. This literature review focuses on the automation of IV bag filling and sealing in the context of the current systems and their inadequacies. The study looks at many publications and research articles in an effort to provide a thorough picture of the state of knowledge in this area as of right now. This investigation of present products and systems provides important insights into possible improvements and alterations of the current concepts, enabling a comparison of the current systems with the suggested novel solution.

Bausch Advanced Technology Group's IV bag filler, namely the Type 529 semi-automatic equipment of the second generation is one of the systems that's available in the market that's similar in function to the system we aim to create. The machine showcases a high degree of versatility, convenience, ease of cleaning among other things make it a good choice for securely packing IV bags. However it is not the most effective machine among the ones under consideration.

The next machine under consideration, 'Dara Pharma's IV bag filling and closure machines,' which are modular devices designed for processing flexible bags in the biotech and pharmaceutical industries. They are semi-autonomous and are quite popular These machines are capable of producing up to 3,200 units per hour and comply with the strict cGMP and US-FDA norms. These machines have three dosing systems, a flexible dosing range of 50 to 10,000 cc and CIP/SIP construction components that make cleaning and sterilizing simple. Thermal/high-frequency welding and port/connector insertion are two sealing techniques. Laminar flow units, or RABS, are incorporated to remove particles and bacteria while maintaining sterility [4].

The IV Express, a high-capacity IV bag-making equipment from Kiefel, brings cutting-edge capabilities to the industry. With capabilities ranging from 2400 to 7200 bags per hour and three different configurations, this machine is notable for its small footprint and compliance with GMP Class C standards. An attached clean-room cabin that complies with GMP Class C regulations may be provided with the machine, providing ideal conditions and integrated pure-air units. It has an integrated station for highly accurate automatic bag filling. Robotic technology is used to seal bags, and because there are multiple sealing options, less floor area is needed [5]. BFM 007, BFR 018, and BFL 852/854 are the three PLUMAT machines that are evaluated in the literature survey. With options for automated closure loading, handling O_2 -sensitive solutions and tolerating bags with one or two open fill tubes, the BFM 007 is a modular, semi-automatic bag filling and sealing machine. The BFR 018 is a rotational filling and sealing device that works with a range of containers and closure ideas. It can handle flexible or semirigid bags and has vacuum and nitrogen gassing options. The BFL 852/854 is a fully automated linear bag filling and sealing machine designed for IV bags. It can handle a wide range of liquid solutions and offers customization options for sealing techniques and handling of O_2 -sensitive solutions [6].

These are some of the various systems that already exist. Though each of the systems have their own advantages, most of the lack modularity. It also lacks adaptability. Most systems are also only semi-automated and still require human intervention. Thus, we aim to address these issues with our proposed system.

Proposed System

The system, from its conceptualization has been conceived with the aim of addressing all the shortcomings and providing a comprehensive solution. The modular architecture of the system has been established keeping in mind that the needs between manufacturers may vary resulting in the requirement of equipment of different specifications. The modular architecture facilitates this effectively.

System design

The proposed system design for the automated IV bagfilling system is meticulously designed to optimize precision, adaptability and efficiency. The primary components of the system include the input area where the bags are fed to the system. This is executed through a simplistically designed racks or fixtures with 5 guide ways where stacks of empty IV bags are placed. The guide ways are positioned such that the IV bags are self aligned in the optimal orientation for the robot gripper to pick them up and mount in the filling stations. The bags in this particular setup are assumed to be placed in the racks manually, however it can easily be swapped out for a conveyor belt based feeding mechanism as well. In this setup we have utilized a twin rack setup as we intend to parallel process two IV bags at the same time so as to enhance productivity. The gripper design and the design of the various stations reflect this (Figure 1).

The filling station and plugging itself consists of a 4-channel peristaltic pump that is responsible for delivering the IV solution in the precise quantities and also sequentially purges the bags by filling the bags with nitrogen gas in appropriate quantities. This is done to completely fill the bag with solution and eliminate the possibilities for air bubbles. The peristaltic pump has 2 dedicated channels for each bag, 1 for IV solution and the other for the nitrogen purging. The pump can seamlessly change channels making it suitable for our need. The other important component is the bowl feeder that feeds silicone plugs to the system through a custom made track. The track diverges into two separate tracks so as to feed the twin towered station [7,8].

The filling and plugging station consists of a tower with two arms – one for filling the bags with IV solution and nitrogen gas and is connected to the peristaltic pump while the other arm is responsible for picking up the silicone plugs from the track and inserting them precisely into the opening of the IV bags to plug them. The arms are and the tower itself which is capable of rotating on its axis are all pneumatically actuated. The clamps on the station are responsible for holding the IV bags in position until the entire filling and plugging process is completed.

The final station of the system is the heat-sealing station. It consists of one heat-sealing machine that can accommodate two separate bags simultaneously. Bins are placed directly below the machine to collect the bags once they are heat sealed. These bins too can easily be swapped out for a conveyor belt based system to boost the productivity further highlighting the systems' modular nature (Figure 2). The system requires the bottles to be packed and filled by hand once the bottles are heat sealed is placed in

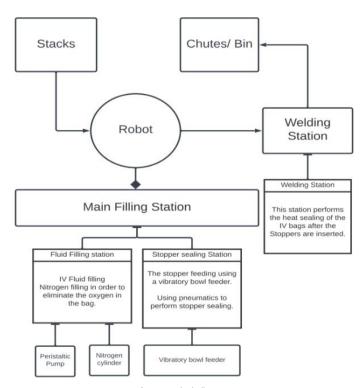


Figure 1. Block diagram.

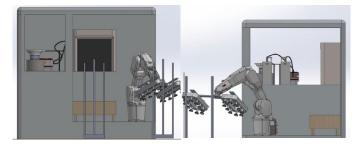


Figure 2. Conceptual design.

the bins. The system is thus simple in its design and layout and does not require a skilled workforce to operate. Therefore, this system has high chance of bringing down the labour cost.

The articulated robot is the primary element of this system and sits at the centre of the work cell. It is responsible for the movement of the bags from one station to another. It is important for the robot to be precise and accurate as deviations could lead to IV bags not being mounted on the stations. The end effector itself is equipped with a faceplate that can accommodate two different modular grippers. The gripper uses a vacuum cup to hold the IV bottle. Vacuum cups have been used because they are suitable for handling the contents and fragility of the IV bottle. The modular nature of the gripper means that the size of the gripper can be manually adjusted so that it can accommodate all of the most widely used size IV bags in the industry [9].

In today's fast-paced and increasingly modularityoriented world, adaptability and efficiency are more important than ever. As the healthcare industry continually evolves to meet the demands of an ever-growing patient population, the need for innovative solutions becomes paramount. Manipulation of IV bags of various sizes effectively has its own set of challenge sand limitations. Hence we designed the concept gripper to suit our needs. It has the principles of modularity, adaptability and efficiency at its key element. Along those lines, the gripper's structure allows for its dimensions to be adjusted manually. The 4 key features of the gripper are:

Modular design: At the heart of the modular gripper's ingenuity lies its modular design. This feature allows users to effortlessly tailor the gripper's size to accommodate a wide spectrum of IV bag dimensions. With the Modular Gripper, an automated manufacturing system can quickly adapt the gripper's

dimension to securely grip the IV bags of all sizes from the smallest to the voluminous larger ones. This adaptability empowers the system with the ability to handle a diverse array of IV bags without the need for multiple specialized tools (Figure 3).

Suction cup integration: A unique feature of the modular gripper is its cleverly integrated suction cups. These cups are positioned strategically with respect to the gripper configuration to ensure proper grip and secure attachment to the IV bags. These Festo suction cups form an airtight seal, eliminating the risk of accidental spills during operation.

Manual size adjustment: Perhaps the easiest feature of the modular gripper is its effortless manual size adjustment. Resizing the gripper to exactly match the size of the IV bag is a simple process.

Safety: The gripper reduces the need to handle IV bags by directly handling various procedures thus eliminating various potential sources of contamination of IV bags. The suction grippers also ensure the bags are not damaged by utilising the appropriate amount of force on each IV bag.

Flowchart

The proposed system has a carefully explains the workflow that ensures sterile and precise production of bags. The process aims to be efficient and thus has a defined sequence of actions. Empty IV bags are arranged first, stacked and safely stored in fixtures made specifically for this purpose. These fixtures are designed to hold the bags in place without interfering with the robotic arm's motions. The system's main component, the articulated robot, uses suction grippers on its end effectors to carefully remove the empty IV bags from the neatly arranged stacks. The gripper's design is especially remarkable because it makes it possible for the fixtures with individually regulated suction cups to precisely and dependably grab and handle each bag. The IV bags are then moved to workstations that are made especially for that purpose. They go through a special step in this process where they are wrapped in self-facing clamps. This clamp plays an important role in ensuring stability in the next stages of bag manufacturing.

Two separate arms, the filler arm and the stopper access arm, constitute the work piece itself. A pneumatic actuator is used to touch the cap of the handle to start IV bag, which is placed exactly above the opening of the fourth barrel. A 4-channel peristaltic pump, which delivers the IV solution and nitrogen gas in precisely calculated amounts ensures the accuracy and precision of the filling process. The stopper-insertion mechanism works in tandem with the filling arm as it completes its mission. In unison with the other arm, it retracts after removing a silicone plug. When filling is successfully completed, both arms swing into place on a pivotal mount that rotates 90 degrees to place the insertion arm exactly above the IV bag opening. This is a calculated move that makes it easier to insert the plug and seals the bag securely. The gripper of the robot plays a vital role in the final stage of the process as it handles the filling and sealing of IV bags efficiently. These bottles are then taken to a dedicated heat sealing facility, where a process is performed that ensures a hermetic seal, preserving the IV bag throughout its useful life [10,11].

In conclusion, the automated IV bag-filling method that has been suggested is a thoughtful fix that overcomes the drawbacks of the current manual procedures This fixture, robotic arm with precision receiver, and specialized workshops combine well to emphasize efficiency, sterility and accuracy in IV bag preparation. Maximum precision levels are guaranteed by synchronized operation of stopper and access fill arm with constant fluid delivery *via* peristaltic pump the gripper's versatility and safety features make it even more effective at handling different-sized IV bags with the least amount of contamination risk. The design of this system provides context for the next parts, where we will examine the operational flowchart and block diagram, giving us a thorough understanding of how it functions to achieve sterile and accurate IV bag preparation (Figure 4).

Control Systems

Programmable Logic Controllers' (PLCs') ladder logic

A carefully thought-out ladder logic program and the use of a Programmable Logic Controller (PLC) enable the automation of the IV bag-filling mechanism.

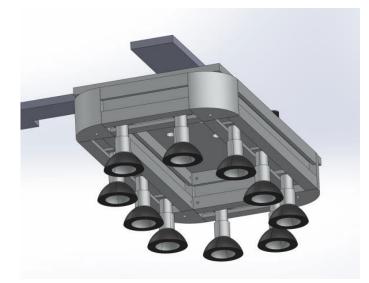


Figure 3. Gripper design.

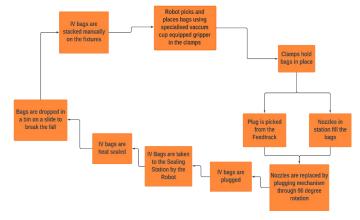


Figure 4. Flow chart.

The PLC is the main control unit in charge of organizing and managing each step of the bag-filling procedure. The PLC's ladder logic program coordinates the sequence of events in the system, guaranteeing a seamless and effective workflow. An explanation of how the PLC manages each stage is provided below:

Bag placement and retrieval: Picking empty bags from the input tray which doubles as the bag stack marks the start of the operation. The PLC gets this input and starts the Filling Station when the bags are detected by Infrared (IR) sensors at the nozzle.

Filling station: After turning on, the Filling Station fills the bag with the necessary IV fluid. This procedure is controlled by the PLC, which also keeps time. The filling operation is essentially stopped when the PLC delivers a signal to close the nozzle after a predetermined amount of time.

Transfer to head seal station: The Manipulator takes the bag out of the Filling Station after it has been filled. The bag is placed in the Head Seal Station thanks to the PLC's continued supervision. The heat seal station's infrared sensors make this transfer possible.

Heat sealing: The PLC initiates the Heat Seal procedure when the bag is detected by the IR sensors at the heat seal station. This procedure guarantees that the bag is tightly sealed. Like the filling process, the PLC keeps track of time and after a specified delay, it allows the sealed bags to move forward.

Conveyor transfer: The PLC is in charge of supervising the movement of the sealed bags from one conveyor to another. The filled and sealed IV bags are delivered to the end bin by the conveyor, which is essential for their subsequent usage or distribution. The PLC's ladder logic software, which drives this complex control system, makes sure that every stage of the IV bag-filling procedure is executed in a timely and well-coordinated manner. It keeps the IV bags' integrity and quality intact during the whole operation in addition to improving system efficiency (Figure 5).

Electrical wiring using Eplan

The electrical wiring diagrams help us represent the linking between the different components in the system. It includes the various sensors, solenoids etc. The main elements of the wiring diagram are given below:

PLC Signals to solenoid valves (Y3.0-3.7): The electrical circuit plays an important role in controlling the solenoid valve (Y3.0-3.7). These valves control the airflow in the system. Signals from the PLC go to these solenoid valves, ensuring precise and synchronized operation of the components. The information PLC receives from sensors helps the PLC decide when to send signals to specific actuators.

Contact control: Contactors are used to control motors, heaters and other high voltage components. Electrical circuit wiring involves contactor connections. These interfaces allow the PLC to control these devices. This ensures that motor-driven actions, such as the rotation of the two-arm tower housing, are properly controlled and in accordance with the system requirements.

Sensor integration: Sensors are also connected to the electrical circuit to provide real-time feedback to the PLC. Various sensors such as pressure sensors, position sensors, limit switches, IR sensors continuously monitor important parameters. For example, a pressure sensor resides in the vacuum level of the gripper and picking mechanism, while a position sensor ensures perfect alignment when rotating the two-arm system. The PLC continuously

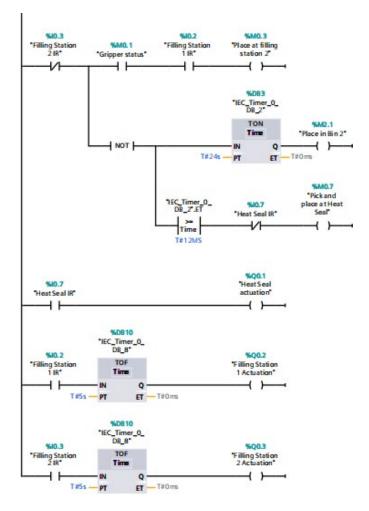


Figure 5. PLC ladder logic.

processes data from these sensors, enabling dynamic adjustments to improve system performance [12].

Inter-module communication: The automated system as a whole consists of various modules that work seamlessly. These modules also need to communicate which is possible through this circuit wiring. The circuit wiring includes the communication interfaces for various components such as the vacuum gripper, filling arm and the rotating mechanisms of the tower. This communication ensures all operations are synchronized and well-co-ordinated.

HMI Interface: The Human-Machine Interface (HMI) panel is an integral part of the electrical circuit. It provides a user-friendly interface for administrators to monitor and control system operations. Through an HMI, operators can enter commands, check system status, and receive alerts or notifications if something is abnormal. The electrical circuit facilitates the transmission of data between the HMI and the PLC, enabling seamless interaction.

Emergency stop and safety interlock: The emergency failsafes such as the emergency stop and safety interlocks are also done using this wiring. Safety of a system such as this is a priority concern. These safety features are interconnected with the control system to ensure risk is reduced.

Control logic: The electrical circuit houses the customized control logic that governs the sequence of operations for each component. This logic dictates when and how solenoid valves (Y3.0-3.7) open or close, when motors activate and when sensors trigger actions. It is the brain behind the precise coordination of the entire system, ensuring that IV bags are handled, filled, and sealed accurately and efficiently.

Pneumatic circuits

Similar to the electrical wiring diagrams, the pneumatic circuit diagram provides us with a visual representation of the various components and how they are involved in the pneumatic system of the automated IV bag filling machine. The four primary pneumatic modules used in the system are as follows

Vacuum gripper: The vacuum gripper is critical to the system as it is responsible for handling IV bags from the vertical stack. This is a practical application of a modular receiver.

Solenoid valve- The solenoid valve controls the operation and deactivation of the vacuum generator. This valve is closely integrated with the robotic control system to ensure accurate and reliable bag pickup and release.

Vacuum cups: Vacuum cups or nozzles are securely attached to the gripper arms. These cups establish a reliable vacuum seal, enabling secure bag handling.

Pressure relief valve: Every pneumatic and hydraulic mechanism often has a Pressure Relief Valve to safeguard the gripper mechanism from overloading and to enhance operational safety. Notably, the structured, modular and well-documented nature of the PLC code facilitates streamlined maintenance and enables efficient troubleshooting procedures.

Rubber plug picking mechanism: The arm responsible for picking the rubber plug is also pneumatically actuated. It is specifically designed to retrieve the silicone plug from the feeder's track. Its key components are the Suction Cups, Vacuum Ejector, Solenoid Valve and the Pressure Sensors

Pneumatic actuation and plug insertion: The insertion of the silicone plug into the opening of the IV bag is carried out using the pneumatic circuit. The circuit is designed with certain considerations.

Pneumatic cylinders: The pneumatic cylinders chosen forthis application need to have the appropriate stroke length as well as the right amount of force.

Directional control valves: DCVs decide whether the cylinder expands or retracts and the 5/2 DCV is mostly used in pneumatic circuits.

Flow control valves: Flow control valves ensure the rate of cylinder expansion and retraction controlled to optimum levels and appropriate ensuring the energy is applied.

Rotation of the two-armed tower structure: The two armed tower structure is at the core of the filling and plugging station and thus its optimal functioning is crucial. The primary components used in it are discussed.

Rotary actuator: We have specialized pneumatic rotary actuators that are chosen to achieve precise 90° rotation everytime. This is crucial since this ensures the arms are positioned accurately. The actuator possesses the required torque and angular displacement capabilities to execute this task accurately [13].

Directional control valve: A dedicated DCV is used to ensure this operation is executed smoothly.

Limit switches: These switches act as the sensors and trigger it's the DCV to stop.

Conclusion

With an ever-increasing population, the need for medicines is also increasing rapidly. Automation will help ensure that sufficient quantities of medicines are available everywhere at reasonable costs. We therefore analyzed existing systems in the market with the intention of identifying and fixing deficiencies in existing systems. The system described in the paper aims to effectively eliminate the need for multiple manual steps in the manufacture of IV bags and has a high level of modularity and flexibility that allows for rapid and easy adoption in design of the existing varieties. The system is robust and efficient through the use of robots, innovative gripper design and filling and plugging station design stitched together by an efficient PLC ladder logic system and control wiring. Moreover, because it primarily uses air conditioning, it is also relatively safe compared to other systems.

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Conflict of Interest

No financial interest or any conflict of interest exists.

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