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Automation of the air conditioning system for aseptic rooms of pharmaceutical production

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ABSTRACT

As modern control systems are becoming more complex, and the implemented technology more sophisticated, the importance of the different characteristics of those systems, such as reliability, availability, security, and protection, is increasing. In this article, an automation design for the air conditioning system of classified areas of the Parenteral solutions plant of the eastern pharmaceutical laboratory company of Santiago de Cuba province, Cuba, is proposed because there is a lack of optimal environmental conditions for development and production of pharmaceuticals at a large scale. The proposal is focused on the design of a supervision system and automatic control of the environmental variables that influence the drug production process. The entire algorithm for the design was developed to monitor critical and non-critical variables and control values of temperature, relative humidity, differential pressure, and air velocity according to standards established by pharmaceutical companies. The design of the automation system includes, apart from the control and supervision algorithm for operation efficiency, the necessary instrumentation.

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1. INTRODUCTION

According to the production process that is carried out in an entity, the air conditioning system must fulfill specific environmental conditions. Nowadays, very modern and sophisticated air conditioning units function in a stable way and distribute, through ducts, clean and purified air with specific values of temperature and humidity [1]–[3]. On the other hand, air conditioning systems for spaces requiring rigorous temperature and humidity control, usually consume a lot of energy and cause significant energy losses because of inadequate design and control of the systems [4]–[6].

The Oriente Pharmaceutical Laboratory Company, located in Santiago de Cuba province, Cuba, is an entity of the BioCubaFarma Business Group, with the social and economic aim of producing and selling medicines. Additionally, there is a Parenteral Solutions Plant for production of large-volume plastic bags, and it is the only plant of this kind in the country. Its technology is unique, and sodium chloride and dextrose in different formats are produced and distributed throughout the Cuban national health and medical care system. Because of the quality of its products, the prestige of this company is, nationally and internationally, high [7].

The absence of favorable environmental conditions is observed in the air conditioning system of classified areas C and D, which are clean areas to carry out less critical phases to manufacture sterile products or develop stages where the product is not directly exposed. For that reason, the inspection of "Good Practices for the Manufacture of Sterile Products," carried out by Auditors of the Company, and the State Center for the Control of Medicines, Medical Equipment and Devices (CECMED), concluded in "non-conformities" due to no fulfillment of the regulations established for air conditioning systems [8]–[10]. Consequently, the design of an automation system for the supervision and control of specific environmental variables for the areas object of study is proposed in this paper following the standard parameters established for air conditioning systems to obtain high-quality productions and save considerable energy.

2. MATERIALS AND METHOD

The technological flow of the air conditioning system of the plant studied, comprises air handling units (AHUs), water coolers or chillers, cooling towers, and pumps for driving water [11], [12]. For handling units to supply air at the required temperature, cold water is needed, which is provided by water chillers. In turn, for operation, the coolers require less cold water to absorb the generated heat, a condition guaranteed by cooling towers. At the end of the process, pumping stations deliver the necessary amount of water for the correct functioning of the system [13], [14].

Since April 1989, CECMED has been in charge of promoting and protecting the public health system in Cuba by means of a regulatory system capable of guaranteeing appropriate access to the national and international market for pharmaceutical products fulfilling conditions like quality, safety, efficiency, and real information about their rational use. CECMED is also responsible for executing functions of control access to national laboratories, regarding drug registration, medical equipment and devices status, clinical trials, activities of surveillance and post-marketing, good practice inspections, batch release, and licensing [7]. Parameters and standard values for air conditioning systems established by CECMED are shown in Table 1.

Table 1. Values established by CECMED for critical parameters

Parameters	Nominal value	Range
Cold water temperature at the handler inlet	7 °C	-
Water temperature at the handler outlet	12 °C	-
Temperature in rooms of classified areas C and D	22 °C	± 2 °C
Relative humidity in classified areas C and D	65 %	± 5 %
Differential pressure (dp) in the handler filters	-	0 < dp < 180 Pa
Differential pressure in rooms of classified areas C and D	12.5 Pa	± 2.5 Pa

2.1. Status of the air conditioning system in classified areas C and D

The air conditioning system of the parenteral solutions plant in Santiago de Cuba consists of two handlers, one for areas C and another one for area D, which have one single zone for air distribution, and mixed air at the handler inlet. Those AHUs also comprise a filter battery having two filters, one primary, and another secondary, a hot/cold battery, and a fan. Currently, in the air conditioning system of those classified areas, the temperature of the water entering and leaving the AHUs is unknown. Therefore, deterioration of the surfaces of the cooling coils is not detected, losses of airflow can't be estimated, and thermal load in the main supply ducts can't be determined when the filters of the handlers are dirty. In addition, it is impossible to guarantee the entrance of polluted air with positive pressure into the areas for critical products and to control the speed of the clean air impulse into the main ducts of the AHUs, the temperature values are not controlled, and the relative humidity. Another problem with the air conditioning system for the classified areas is the absence of the respective motorized gate in the supply or return conduct. That gate has been replaced by a manual valve located in the water inlet pipe of each AHUs to let cold water pass into the corresponding heat exchanger.

To detect deterioration on the surfaces of the cooling coils for maintenance, it is necessary to measure the value of the water temperature that enters and leaves through the metallic pipes of the handlers. According to the requirements of the process, water entering the AHUs must be between 5 °C and 7 °C, if exceeding the maximum value, a warning signal is issued on the control panel. In addition, water leaving the AHUs must be at 12 °C; in that way, the temperature difference between the water entering and leaving is 5 ºC. When the temperature difference is equal to or less than 4 °C, it means deterioration in the surfaces of the cooling coils, and a warning signal is sent to the control panel.

To estimate the thermal load losses in the main supply ducts, it is necessary to measure the temperature values at the ends of the main outlet duct of the air handlers. Thermal load losses are considered to be present when the measurement difference exceeds 2 °C for at least 2 minutes. If this condition occurs, a warning signal is issued on the control panel, and the possible causes have to be assessed, such as a fault in the supply conduct or an erroneous reading from a measuring instrument.

To determine if the filters of the handlers are clogged or dirty, values of the differential pressure in each one has to be measured. The pressure taps must be located in front of or behind each filter, and if the difference between them exceeds 180 Pa, a warning signal is issued on the control panel for the filter to be changed. The airspeed at the ends must be calculated to estimate pressure losses in the main supply ducts taking into account the value of the maximum airflow. Pressure losses are present when the airflow difference exceeds 2.08% of the maximum value that can circulate through the duct for at least 2 minutes.

In the case study analyzed in this paper, the maximum airflow of the AHU for classified area C is 4000 m^3/h, with 500 m^3/h (Q), while for area D, the maximum airflow of the AHU is 12,000 m^3/h, with 250 m^3/h (Q); in both areas those values correspond to 2.08%. In (1), (2), and (3) are used to determine the airspeed that circulates through the ducts (V) feeding areas C and D. The cross-sectional area (A) of the main air supply duct in area C is 0.192 m^2 and 0.11 m^2 in area D. To solve V, values corresponding to Q and A have to be substituted. In area C, the highest loss permitted is 2173.44 m^3/h, and in area D is 131.68 m^3/h because in normal (automatic) operation mode, the highest airflow permitted for AHU in area C is 23,500 m^3/h, and in area, D is 11,800 m^3/h, with the aim of avoiding motors blow out when fans of the handlers work at maximum values.

$$Q = V * A \tag{1}$$

$$V = \frac{Q}{A} = \frac{500\ m^3/h}{0.192\ m^2} = 0.72\ m/s \tag{2}$$

$$\frac{Q}{A} = \frac{250\ m^3/h}{0.11\ m^2} = 0.63\ m/s = V \tag{3}$$

2.2. Temperature control in classified areas C and D

To keep the temperature at the specific range of 22 °C ± 2 °C, in the clean rooms of classified areas, temperature values have to be measured in each room. Measuring instruments need to be at the most optimal position to achieve the thermal balance of the corresponding space. For the variable Temperature, an on-off control with hysteresis is implemented in the programmable logic controller (PLC) algorithm, knowing that the action of the actuator for relative humidity control represents a disturbance of the temperature control loop. AHU corresponding to area C, supplies clean air to 14 rooms and two corridors, while clean air is supplied to 14 rooms and one corridor in area D. Principles for implementing automatic control are the following:

- A motorized damper in the supply duct of all 28 clean rooms.
- Motorized supply gates never to remain closed to allow constant air renewal in the rooms.
- When the thermal load increases to a degree higher than or equal to 24 °C in one of the rooms of the classified areas, the PLC control algorithm will order the total opening (100%) of the gate to facilitate airflow to the room, the same as for the motorized valve of the AHU.
- When the thermal load decreases to a degree less than or equal to 20 °C in one of the rooms, the PLC control algorithm will order partial closure (50%) of the gate for airflow to that room, the same as for the motorized valve of the AHU.

2.3. Airspeed control in the main supply ducts of the AHUs

A proportional control is implemented in the PLC algorithm for controlling the airspeed in the main supply ducts of the AHUs. The airflow reference value comprises the room's required airflow values and the minimum value needed for the room. The sum of the airflow values is carried out in automatic mode and the implemented algorithm takes into account that, when a supply damper is fully opened, the airflow value required in the room is added, subtracting a calculated value of 178.5 m^3/h for area C and 89.28 m^3/h for area D.

To carry out the airspeed control in the main supply ducts, the variable Value has to be measured at a point before the ramifications. Location of the airspeed sensor at that point measure pressure losses in the corresponding supply duct, which constitute a disturbance of the input to the control loop of that variable. The difference between the airflow reference value, corresponding to the design proposed, and the value measured in the room is added to the real airflow value, which must be the same when there are no thermal load losses. With that reference value (real), the speed of the fan motor of the corresponding controller is modified by a frequency inverter that receives the control signal. Using (4), the value of that signal is obtained.

$$\frac{(I_{Máx.T} - I_{SV})}{I_{Máx.T} - I_{Mín.T}} = \frac{F_{Máx} - F_{VRR}}{F_{Máx} - F_{Mín}} \tag{4}$$

In the previous expression, $I_{Max.T}$ is the maximum value of the current at the output of the transmitter, $I_{Min.T}$ is the minimum value of the current at the output of the transmitter, I_{SV} is the value of the current supplied to the frequency inverter (control signal), $F_{Máx}$ is the maximum airflow of the AHU, F_{min} is the minimum air flow of the AHU (0 m^3/h), and F_{VRR} is the real airflow value. The value of I_{SV} as a function of F_{VRR} is obtained when using (5).

$$I_{SV} = I_{Máx.T} - \left(\frac{F_{Máx} - F_{VRR}}{F_{Máx} - F_{Mín}}\right) * (I_{Máx.T} - I_{Mín.T}) \quad (5)$$

2.4. Control of relative humidity and differential pressure in areas C and D

To keep the value of the variable relative humidity at the appropriate range, the clean air inlet must have the established relative humidity percentage, which is achieved by controlling the voltage value received from a bank of heating resistors located internally in the AHUs. When energizing those resistors, the temperature of the air supply increases, and, consequently, the relative humidity value also increases, creating then a disturbance for the relative humidity control, which can be reduced by de-energizing the resistors. To keep the value of this variable within the established range of 65% ± 5%, a control on-off with hysteresis has to be to implemented in the PLC algorithm, where resistors turn on when the measured value is equal to or less than 60%, and shut down when it is equal to or higher than 70%. For that reason, a bank of heating resistors working with a 440 V AC three-phase power supply, nominal power of 9 kW, cyclic frequency of 60 Hz, and current consumption of 13 A is proposed to be used.

A control on-off with hysteresis is also implemented in the PLC algorithm to control the differential pressure in the different rooms. That control in area C is carried out in the room called “Filling” (room with positive pressure) and in the room called “filling corridor” (room with negative pressure). In area D, the control is carried out in the room called “formulation” (room with positive pressure) and in the room called "concentrated reactors" (room with negative pressure). In the most critical room in each area, a pressure tap must be placed; the same must be done in the room with negative pressure. Therefore, the algorithm used to control the differential pressure is the same for both areas, decreasing the pressure in the “filling” room and in the “formulation” room and increasing the pressure in the “filling corridor” and in the “concentrated reactors” room when the differential pressure is higher than or equal to 15 Pa. When that occurs, the PLC control algorithm orders the 100% opening of the airflow of area C3 and 50% of area C4, see Figure 1. When the differential pressure is less than or equal to 10 Pa, the PLC control algorithm orders the 100% opening of the airflow in area C4 and 50% in area C3. Then, the pressure will increase in the “filling” and “formulation” rooms, and decrease in the “filling corridor” and “concentrated reactors” rooms.

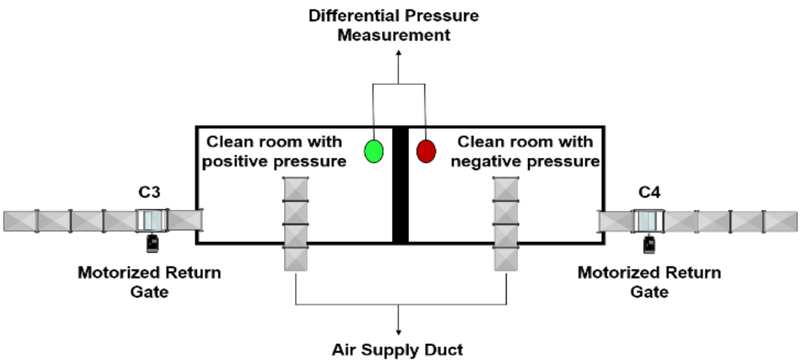

Figure 1. Location of the pressure taps and motorized return gates

3. RESULTS AND DISCUSSION

The Kimo brand transmitter, model TH 110, having the characteristics detailed in [15], [16] and a temperature range from 0 to 50 °C, and from 5 to 95% of relative humidity, is proposed to measure those variables at the different measurement points. The HK Instruments brand transmitter, model DPI±500-1R-AZ, whose technical specifications can be found in [17], is also proposed to carry out the differential pressure measurement in the filters of the handlers and to guarantee activation of a warning light signal inside the room. For differential pressure control in the rooms, the HK Instruments brand transmitter, DPT-R8 series, model DPT 250-R8-AZ-D-S [18] is proposed. Additionally, the HK Instruments brand transmitter, DPT-Flow series [19], is proposed to measure airspeed due to the characteristics of the design and the speed limit values in classified areas. Maximum and minimum airflow values of areas C and D are given by (6), (7), (8), and (9). Peak flow in area C,

$$\frac{Q}{A} = \frac{24000\frac{m^3}{h}}{0.192\ m^2} = 34.72\ {}^{m}/_{s} = V \quad (6)$$

peak flow in area D,

$$\frac{Q}{A} = \frac{12000\frac{m^3}{h}}{0.11\ m^2} = 30.30\ ^{m}/_{s} = V \quad (7)$$

minimum flow in area C,

$$\frac{Q}{A} = \frac{10000\frac{m^3}{h}}{0.192\ m^2} = 14.47\ ^{m}/_{s} = V \quad (8)$$

minimum flow in area D,

$$\frac{Q}{A} = \frac{5000\frac{m^3}{h}}{0.11\ m^2} = 12.63\ ^{m}/_{s} = V \quad (9)$$

To continue with the plant's existing line of frequency inverters and fulfill the technical requirements, the Danfoss VLT HVAC Drive FC 102 brand equipment, model 131B6772, is proposed as an actuator for airspeed control. Technical specifications of the frequency inverter can be found in [20], [21]. According to the requirements of the air conditioning system, the Belimo brand motor, model LF24-SR, is proposed to be used in the dampers of areas C and D. Due to the advantages of using solid-state relays, a Kudom three-phase solid-state relay, model KSQF480D25, whose characteristics are found in [22], is also proposed for the connection between the PLC and the bank of heating resistors. On the other hand, an ANV brand solid-state relay, model SSR-10DA, with technical specification in [23], is used for the connection between the motorized valves and the PLC, and between this last one and the set of gate actuators of each classified area.

3.1. Proposal for selection of control instrumentation

Technical criteria, characteristics of the process, requirements of each application, and the economic amount allocated by the Investment Department of the Eastern Pharmaceutical Laboratory Company were taken into account to select the control instrumentation and the data acquisition system. For the data acquisition system, the output voltage and current range of each measurement instrument, as well as the distance between its location and the control system were analyzed by using the channeling scheme of the Parenteral Solutions Plant. Analysis results showed that the distance of the instruments with current output oscillates between 25 m and 80 m, while the distance of the instruments with voltage output oscillates between 20 m and 35 m. Taking into account that the highest value of the conductor resistivity at 20 °C is 0.84 Ω, and knowing that 1.5 mm^2 is the highest value of the cross-sectional area of the conductor, it was obtained that 0.0084 V is the value of maximum voltage loss along conductors, which is considered negligible, guaranteeing, therefore, the reliability of current and voltage measurements.

It is important to note that 18 digital inputs, 78 analog inputs, 16 digital outputs, and 36 analog outputs are needed to carry out the automation proposal. In correspondence with those requirements, the Siemens SIMATIC S7-300 PLC, compact CPU 314C-2PN/DP, model 6ES7314-6EH04-0AB0 [24], was selected. Apart from that, 10 SIMATIC S7-300 SM331 analog input modules, model 6ES7 331-7HF01-0AB0 [25], and 5 SIMATIC S7-300 SM332 analog output modules, model 6ES7 332-5HF00-0AB0 [26] were also selected. For possible updates of the air conditioning system control algorithm, 2 inputs and 4 analog outputs were left free in the last modules of each type. In addition, 5 analog inputs, 2 analog outputs, and 6 digital inputs on the CPU remained free. At the end, a SIMATIC S7-300 IM360 transmit interface module, model 6ES7 360-3AA01-0AA0 [26], and a SIMATIC S7-300 IM361 receive interface module, model 6ES7 361-3CA01-0AA0 [26] were selected.

Consumption of each instrument and possible losses in the electrical circuit have to be known to properly select the electrical power supply. A parallel connection between the instrument or equipment, and the source allows to know the total current consumption, equivalent to the sum of all the currents required by mentioned loads, corresponding to 9.84 A. Therefore, a source with an output of 24 virtual data center (VDC) and 10 A is required for the correct operation of the instrument or equipment. For that reason, the SIMATIC PS 307 10 A switching power supply, model 6ES7 307-1KA02-0AA0 [27] was selected. The control algorithm, and the configuration of the PLC simulation were carried out using the integrated automation portal development software (TIA Portal V13.0) shown in Figure 2.

The SIMATIC HMI Panel KTP700 Basic, model 6AV2 123-2GB03-0AX0 [25] was selected because of the advantages of human-machine interfaces (HMI) for being carried into practice and fulfill the necessary requirements of the Investment Department of the Eastern Pharmaceutical Laboratory Company. The PROFINET communication subnet is established due to the possibilities of communication between the selected HMI panel and the interface of the selected PLC shown in Figure 3.

Figure 2. Configuration of the PLC and input and output modules

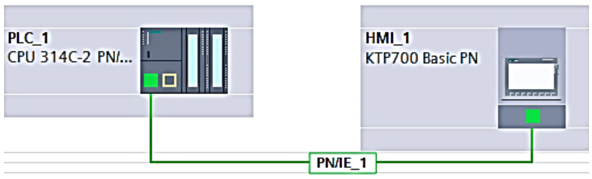

Figure 3. Communication between HMI panel and the PLC

3.2. Control algorithm implemented in the PLC

The selected PLC control algorithm has a Main Organization Block (OB1), where the operating system of the S7 CPU executes the routine contained in this block cyclically. That block is integrated by 15 function blocks and 29 instance data blocks. The function blocks constitute logical blocks that permanently store their input, output, and input/output parameters in the instance data blocks according to the 195 variables declared in the "PLC Variables Table." It is necessary to highlight that the algorithm to control variables of area C is also used for area D, varying only the names of the declared variables. All programming is done in ladder diagram (LD) language [28], [29] and is structured as described below.

The main organization block integrates all the function blocks and executes the tasks the control algorithm implements. Depending on the fulfillment of certain conditions, that OB1 can work in automatic or manual mode; for example, in the start treatment block, the physical outputs allowing power supply of some actuators become activated, the frequency inverter goes into the Run mode, and the stop indicators are disactivated. The stop treatment block indicates the stop state, closing the motorized valve and disconnecting the electric power, as well as reducing the fan motor speed of the AHU to a minimum, and switching OFF the frequency inverter to the stop mode. Some other actions carried out by the OB1 at the following: electrical disconnection of the bank of heating resistances, opening of all motorized gates, and decoction of actuators. When all the previous instructions are executed, the state of the total stop will be indicated.

Manual mode is preferably used for maintenance because the positions of switches for the bank of heating resistances and the AHU fan can be easily verified; if this last one is ON, the frequency inverter goes into the Run mode, increasing to the maximum speed of the AHU fan motor, corresponding to 24,000 m^3/h for area C and 12,000 m^3/h for area D. That mode also gives the possibilities of checking other conditions to guarantee the manual operation of the system. Scaling of all temperature measurements in classified areas and evaluation of conditions in the rooms regarding the temperature of the water entering the AHU, deterioration of the cooling coil, and thermal load losses in the main supply duct are carried out in the automatic operation mode. That mode also gives the possibility of controlling the relative humidity, differential pressure, and airspeed in the classified areas. A single algorithm is used in the "Alarms" function block, which includes the 16 variables of the general alarm signals of the AHU system that become activated when the limit values of the variables are reached or exceeded.

3.3. Control algorithm implemented in HMI panel

The "HMI variables" Table was taken into account when programming the HMI panel; 231 variables of that Table were declared, 13 being internal to the HMI programming, and 218 were declared in the PLC. In addition, in the "user administration" window, access is configured for a single administrator, whose name is "Operator," being the only one with permission to supervise all the protected images of the HMI under the default password "1234". In the protected "HMI warnings" window, 16 warnings were programmed in the "alarm" category, corresponding to the 16 addresses of the variables declared in the "Alarms" function block in the PLC.

Figure 4 shows the main screen welcoming the supervision and control of the air conditioning system of the parenteral solutions plant. Figure 5 corresponds to the window containing the buttons of the main panel of area C (MP AC) and the main panel of area D (MP AD), where it is possible to select the manual or automatic mode, and the “start” or “stop” status, as well as the status of “chiller emergency,” “remote mode,” and “Total Stop” of the AHUs corresponding to each classified area. The username (operator) and password have to be entered in the “login,” corresponding to the second function button that refers to the security and protection protocols of the system.

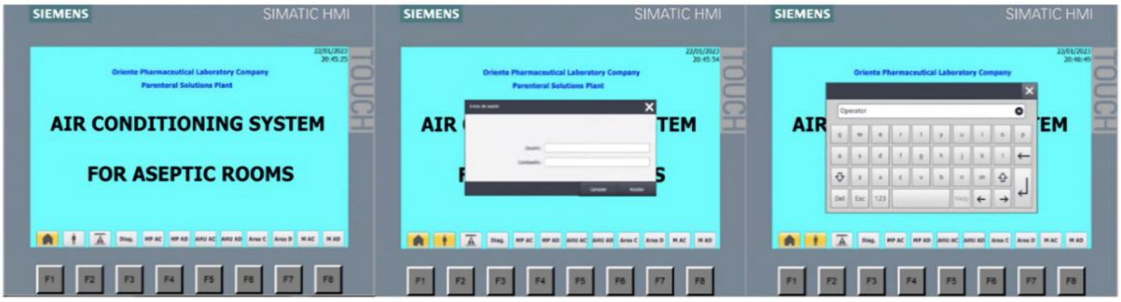

Figure 4. Front page and login screens

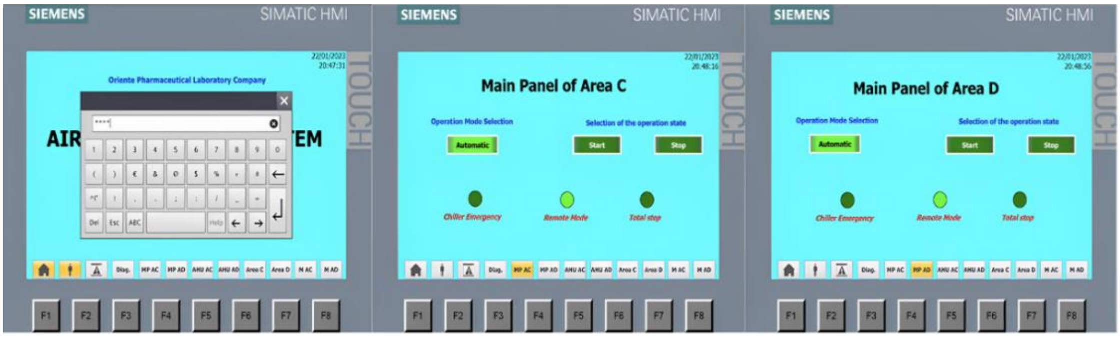

Figure 5. Login screens and main panels for areas C and D

The window represented in Figure 6 corresponds to the air conditioning system of rooms C and D. From the function buttons “AHU AC” and “AHU AD” it is possible to visualize the measurement values, indicators in real-time associated with the AHU, and the airflow of the different systems. Figures 6 and 7 correspond to the window with the function buttons “area C” and “area D” and show the behavior of the air conditioning system in real-time, reflecting the values of temperature and relative humidity values in each classified room, as well as the state of the motorized gates and the differential pressure values. Figure 7 shows the function buttons “M AC” and “M AD”, indicating the status of the AHU fan motor, the motorized valve, the set of 16 actuators for motorized dampers, and the bank of heating resistances of each classified area. The function button corresponding to the active windows is highlighted in yellow. The control algorithm implemented in the HMI panel can also perform other functions to achieve the system's efficiency.

Communication between the PLC and the HMI panel selected is established by a ProfNet network. The main purpose of that network is to exchange information for supervision and control of the process. It also allows communication with another PLC configured as a master to govern the hierarchical control structure and the management of information from all the Plant's control systems.

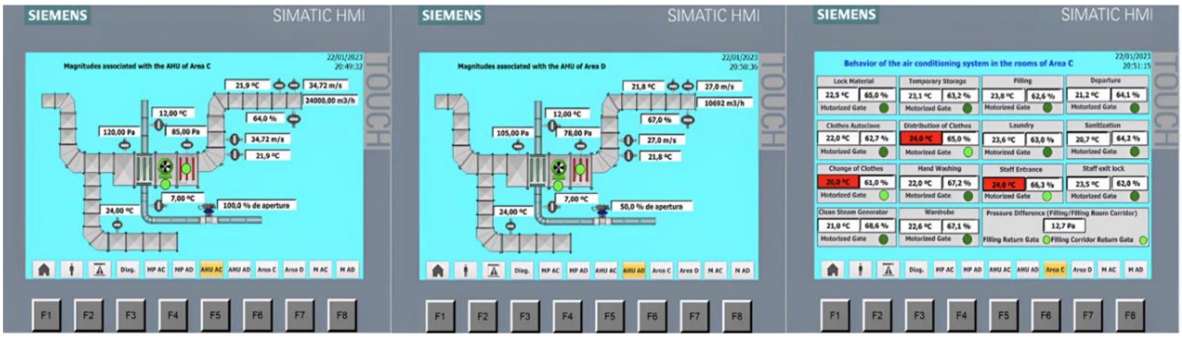

Figure 6. Screens of the air conditioning system in rooms of area C

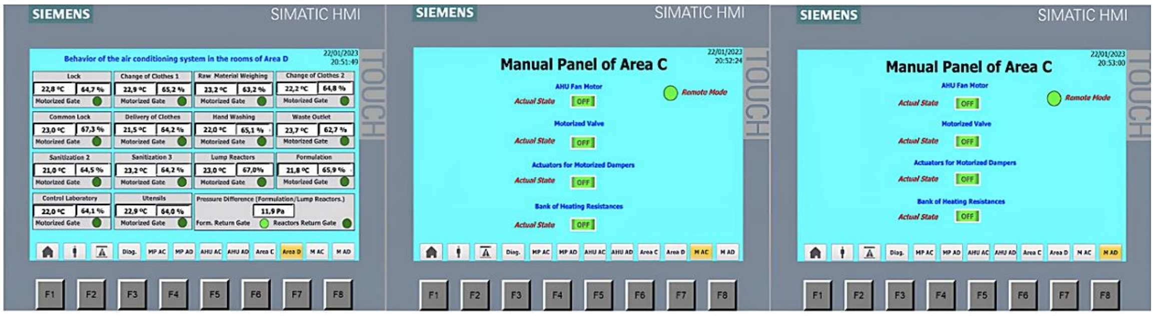

Figure 7. Screens in rooms of area D and manual mode for areas C and D

4. CONCLUSION

The design proposed in this paper for controlling temperature and relative humidity creates favorable climatic conditions for manufacturing pharmaceutical products with higher quality. Furthermore, the design of the differential pressure control system allows a lower environmental contamination rate in critical production areas where all rooms must be aseptic. On the other hand, the design of the airspeed control system supplies the necessary amount of purified air to extend the useful life of the AHUs fans, saving, at the same time, electrical energy and creating a proper economic balance.

This research work demonstrated the necessity of implementing an automatic air conditioning system at the parenteral solutions plant in Santiago de Cuba and confirmed the importance of controlling the fundamental variables of the system. For that reason, a system fulfilling the standards established by CECMED was designed to supervise and control environmental variables in two classified areas of the Plant. The designed protocol of communication gives also the possibility of implementing similar systems of supervision and control to other processes of the Plant object of study. For the efficient functioning of the whole system, the required instruments and algorithm for supervision and control are additionality included in the automatic system proposed. The cost of carrying into practice the complete design can be regularly paid by the possibilities it gives of saving electrical energy. According to the proposed design, future perspectives of supervision and control can be implemented, not only in other areas of that Plant, but for the industrial development of that industry in general by creating SCADA software, or in other similar industries.

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