



Cleanroom environment meets GMP guidelines

KS 98plus / RM 200 / ADAM / PPC-153 /MSI software application

Temperature and humidity control

Cascaded control of air circulation

Access control system

Sequence control of pass-through interlocks

KEY WORDS

Cleanroom, grey room, air shower, quality management, GMP,

air conditioning, temperature control, humidity control,

baby pacifiers, turbo halers, asthma sprays, injection ampoules, pharmaceutical products,

CANopen, industrial PC, touch-panel PC, communication modules, batch reports

DESCRIPTION

Using the following products from PMA, an air conditioning concept was implemented for the manufacture of plastic parts for pharmaceutical use (e.g. turbo halers for asthma sprays, injections ampoules, baby pacifiers, etc.) under Class A cleanroom conditions, including pressure, temperature and humidity control:

Several RM 200 I/O modules linked via CANOpen, and a KS 98plus multi-function controller together with pressure sensors and combined humidity/temperature sensors are connected to a touch-panel industrial PC (type PPC-153) by means of ADAM communication modules. The industrial PC also runs PMA's MSI software package, and the system meets the US quality management guidelines GMP (good manufacturing practice) for the production of pharmaceutical products.

Just one KS 98 multi-function unit operates the entire aircon system, together

with the safety interlocks for pass-through access to the cleanroom.

The MSI software for data acquisition is used for system operation as well as storage of measurement data, including batch reports and recipe management.

IMPLEMENTATION

CONTROL OF THE AIRCON SYSTEM

The plant described here operates on the recirculating air principle with admixed fresh outside air.

Depending on the outdoor temperature and humidity, and under consideration of the energy consumption, the controller module decides whether the plant is to

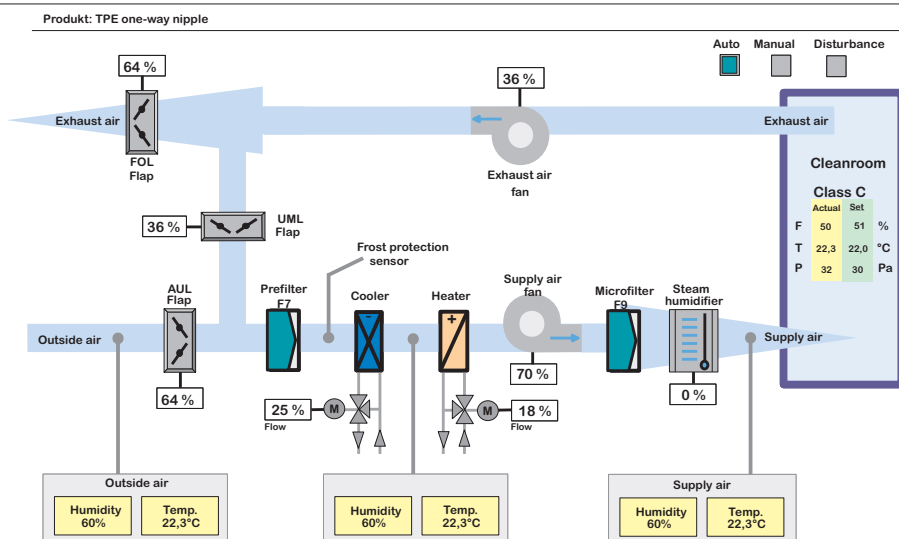
be operated with circulated air or fresh outside air.

In both cases, the required temperature in the cleanroom is used as the setpoint. Additional measurement values for the control system are provided by the combined humidity/temperature sensor fitted in the supply air duct.

Air humidity is controlled by means of an air drier (dehumidification through condensation in a cooler) and the steam humidifier.

A fixed speed is set for the supply air fan. The required pressure in the cleanroom is maintained by controlling the speed of the exhaust air fan.

Control diagram



After passing through a prefilter and a microfilter in the aircon system, the circulated air is kept clean by means of a filter fan unit (FFU) installed in the cleanroom ceiling.

Possible damage to the cooling/heating equipment is prevented by a frost protection sensor.

A hygostat monitors the supply air leaving the aircon system and thus detects any malfunction of the steam humidifier. The following measurement values ensure reliable and optimum system operation:

- Outdoor temperature
- Outdoor humidity
- Temperature and humidity ahead of the aircon system
- Temperature and humidity at the exit of the aircon system
- Temperature and humidity in the cleanroom
- Pressure in the cleanroom
- Pressure in the material pass-through
- Pressure in the personnel pass-through
- Monitoring of door and window contacts

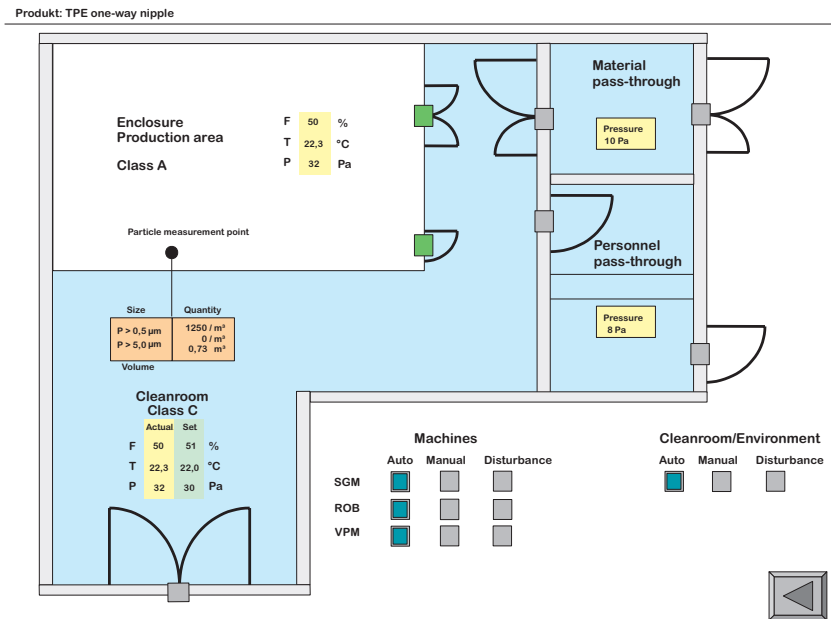
ACCESS CONTROL SYSTEM

The entrance doors of the personnel and material pass-throughs are fitted with an access control system. By means of an ID number, every employee can open the door for access. If one door is opened, the opposite door is locked.

This ensures that unfiltered air cannot enter the cleanroom via the pass-throughs. The employee ID number is used to record the date and time whenever the personnel or material pass-through has been operated. All interlock functions of the pass-throughs are also controlled by the KS 98plus.

The MSI software provides three process diagrams for operating the system.

Cleanroom concept



The first page is a survey showing the control diagram with the airflows and all the aircon equipment. All the setpoints and measured values for air temperature and humidity are displayed, including those in the cleanroom itself.

The second page is a plan view of the cleanroom showing all the door and window contacts.

The third page enables all the min/max limit values to be adjusted, together with the associated alarm functions. Data entry is password-protected. If a value is changed, this is recorded in the event log with date, time, and user name.

The same applies for the acknowledgement of alarm messages.

The historic trend display shows the variations of the measured values during a freely selectable time period, and with freely selectable measurement point combinations.

The batch protocol can be used to generate a batch report with customer number, user ID, batch start, and batch end. The stored data can be printed out and attached to the delivery as a quality report.



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