【GMP005】
Air Cleanliness Monitoring of Cleanroom
SMARTDAC＋　GX10/GX20

■ Background

Cleanrooms in the pharmaceutical industry requires to monitor and record air cleanliness during manufacturing process operation. Manufacturer have to measure fine particles such as dust and impurities in the air with the particle counters. This measurement is widely used by many industries such as pharmaceutical, semiconductor, films and foods.
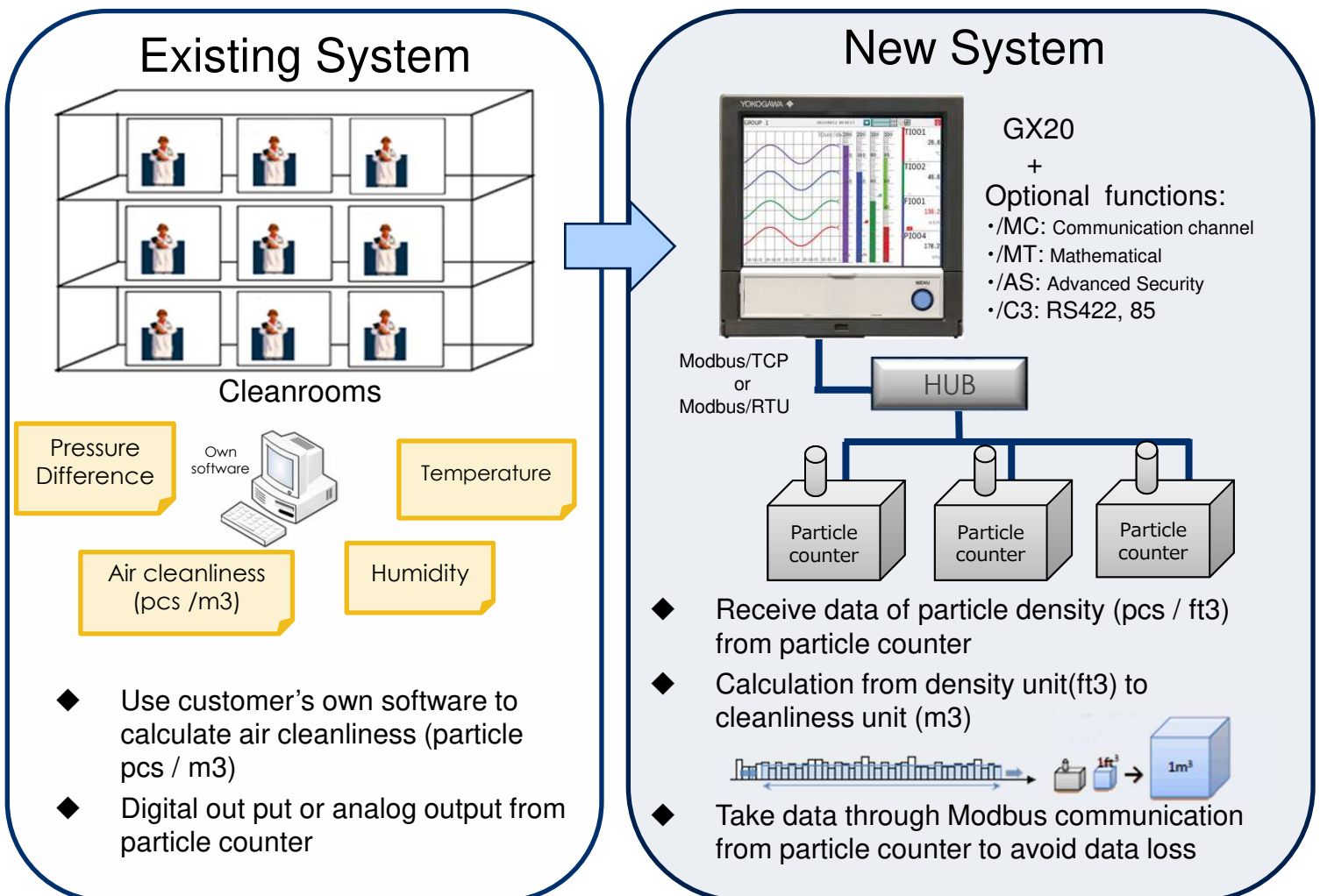
■ Regulations

For pharmaceutical industry, there are several guidelines which determines cleanliness of clean room.

- GMP (FDA)
- EU-GMP Annex-1
- PIC/S GMP Annex-1
- WHO-GMP

Maximum permitted number of particles per m3 equal to or grater than the tabulated size				
	At rest		In operation	
Grade	0.5μm	5.0μm	0.5μm	5.0μm
A	3 520	20	3 520	20
B	3 520	29	352 000	2 900
C	352 000	2 900	3 520 000	29 000
D	3 520 000	29 000	Not defined	Not defined

EU-GMP Annex-1 *Manufacture of Sterile Medicinal Products*

■ Application overview

Existing System

Cleanrooms

Pressure Difference

Own software

Temperature

Air cleanliness (pcs /m3)

Humidity

- ◆ Use customer's own software to calculate air cleanliness (particle pcs / m3)
- ◆ Digital out put or analog output from particle counter

New System

GX20
+
Optional functions:
- ·/MC: Communication channel
- ·/MT: Mathematical
- ·/AS: Advanced Security
- ·/C3: RS422, 85

Modbus/TCP or Modbus/RTU

HUB

Particle counter | Particle counter | Particle counter

- ◆ Receive data of particle density (pcs / ft3) from particle counter
- ◆ Calculation from density unit(ft3) to cleanliness unit (m3)

- ◆ Take data through Modbus communication from particle counter to avoid data loss
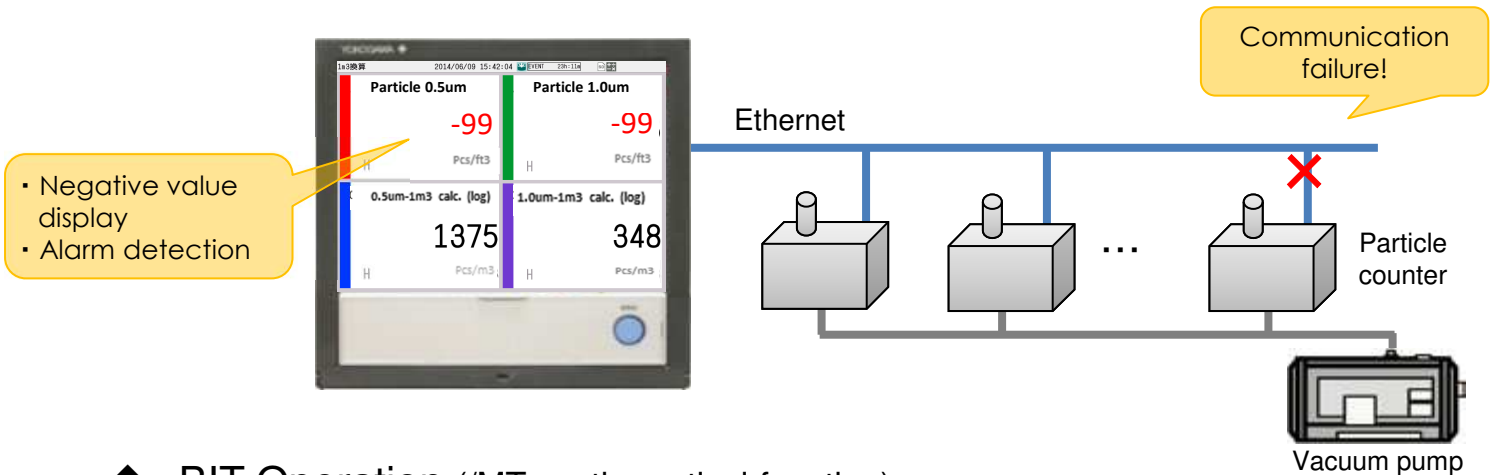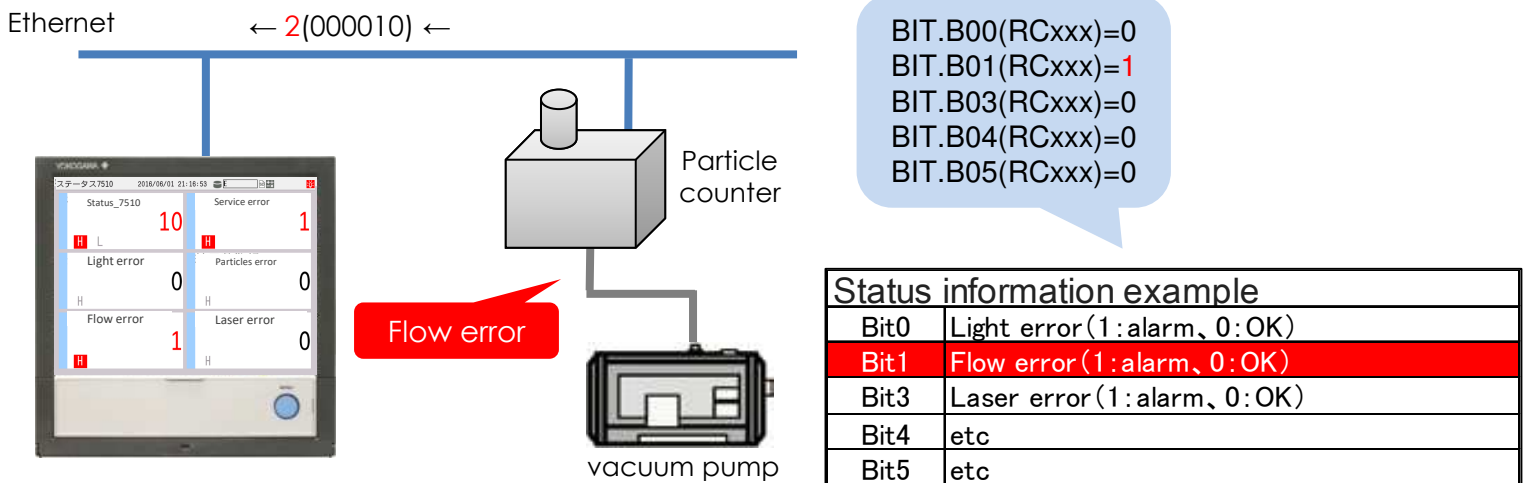
■ Additional features to support safe monitoring

◆ Watchdog Timer (/MC: Communication channel option)

If the data has not been updated for a certain period of time due to communication failure or any troubles, certain value can be set to be displayed. For this application, negative values are displayed as value to tell abnormality to the monitors.

Communication failure!

Ethernet

Particle counter

Vacuum pump

- ・Negative value display
- ・Alarm detection

Particle 0.5um -99 Pcs/ft3
Particle 1.0um -99 Pcs/ft3
0.5um-1m3 calc. (log) 1375 Pcs/m3
1.0um-1m3 calc. (log) 348 Pcs/m3

◆ BIT Operation (/MT: mathematical function)

Possible to obtain the status information of the particle counter by using the mathematical function. Recorder get status information through Modbus communication (alarm/message).

Ethernet

← 2(000010) ←

Particle counter

Flow error

vacuum pump

BIT.B00(RCxxx)=0
BIT.B01(RCxxx)=1
BIT.B03(RCxxx)=0
BIT.B04(RCxxx)=0
BIT.B05(RCxxx)=0

Status_7510 10
Service error 1
Light error 0
Particles error 0
Flow error 1
Laser error 0

Status information example

Bit0	Light error（1：alarm、0：OK）
Bit1	Flow error（1：alarm、0：OK）
Bit3	Laser error（1：alarm、0：OK）
Bit4	etc
Bit5	etc

Product solution for Pharmaceutical

GX20/GX10 Paperless Recorder with Advanced Security Function (/AS)

◆ ...users
- Ad...
- Windows Serv... Active Directory p... management...

◆ Audit trail
- Se...e log
- O...
- W...hat & w...

◆ ...y
- ...inal e...
- M...check wi...

◆ Ele...re
- On soft...
- Thre... sign...et

▶ CV CONTROL

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