

To support Air-conditioning Validation for
Sterile Pharmaceutical production

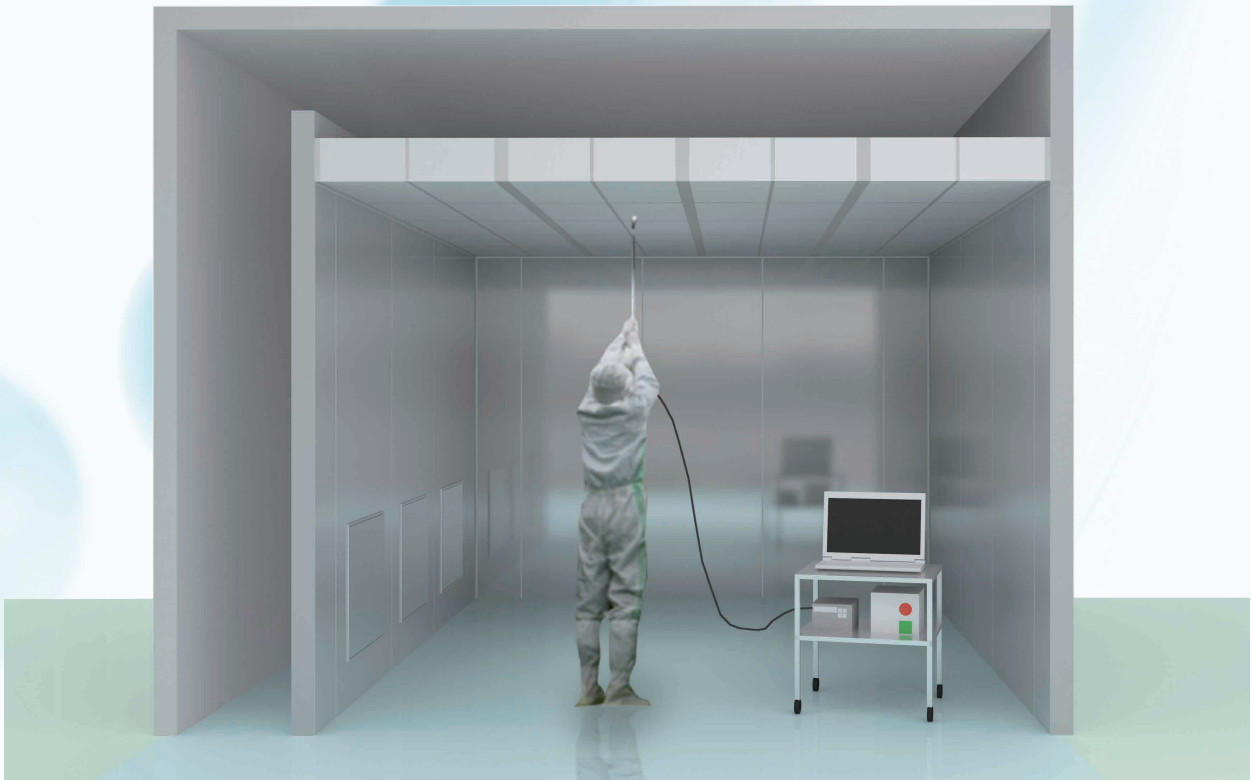
Validation Ace-M

Features of Validation Ace-M

- Support of validation measuring process
- Automated acceptance and recording process
- GAMP5 (including Part 11) compliant

This system supports the validation measuring process, enables data processing and record output of the measured results.

The automated acceptance and recording process allows for confirmation of the measurement results on the measurement screen, and reduces the record totaling work. (1/2 of work load compared to the conventional manual measurement)



Features of Validation Ace-M

■ Filter Leak Test

Since the filter surface can be scanned according to the audio guidance, the reproducibility of measurements can be improved.

■ Record Management Function

Booth records: The filter information can be managed for each room.

Air-conditioning system records: The room information can be managed for each system.

■ CSV

Performs computerized system validation (CSV) based on GAMP5.

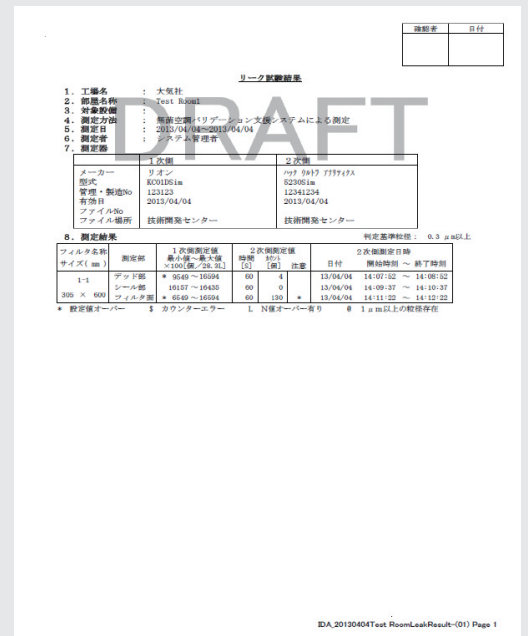
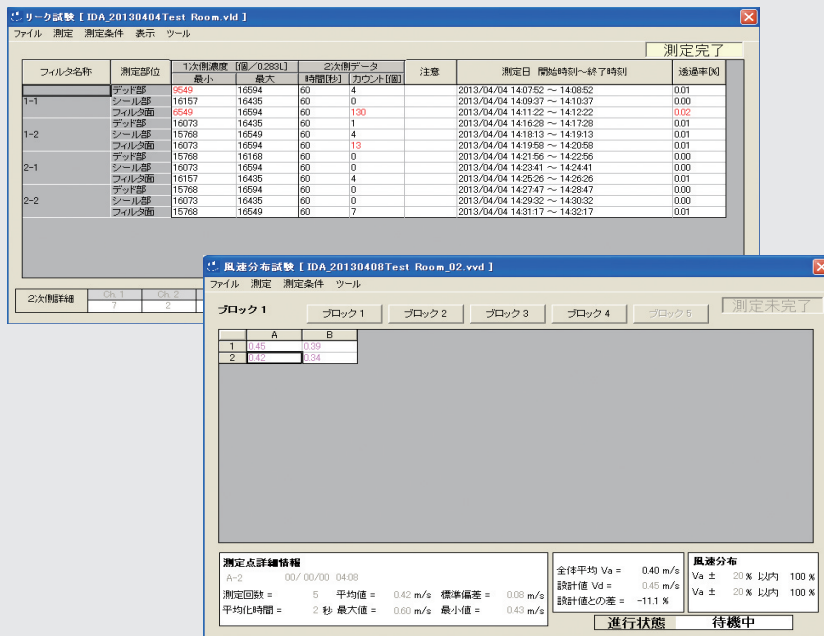
■ Air Velocity Distribution Test / Air-Circulation Frequency Test

The memory data in the anemometer can be acquired.

■ Security

Comply with 21 CFR Part 11. (Electronic signature, alteration prevention, audit trail, etc.)

Since operation authority can be added for each user, the loss of data by unexpected operation can be prevented.



Validation Ace-M Sample Screen

Usable Measuring Devices

Primary Side Particle Counter

Rion

KC-01E

Secondary Side Particle Counter

Hach Ultra Analytics

A2400 Series

A3400 Series

Anemometer

KANOMAX JAPAN

Model 65 Series

OS

- Windows 7
- Windows XP

Contact

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