Cleanroom technology

Cleanroom validation studies and maintenance

Kropman bundled and detached its expertise and facilities in the branch of cleanroom in a section called KCC Services, which rapidly became a high specialized team of specialists. This group is capable to support your company from the early validation studies for specific purposes further on.
To ensure that the facilities meet the defined requirements and are fit for the intended purpose as these are agreed in the User Requirement Specification (URS) and the Validation Master Plan, we developed precious monitoring tools. We can actually guarantee the standards you wish.

- **Specific measurement protocol voor each customer**
- **State of the art devices**
- **Problem solving skills en flexibility**
- **Clear reports in short time**
- **GMP trained test engineers**
- **Integrated project approach**

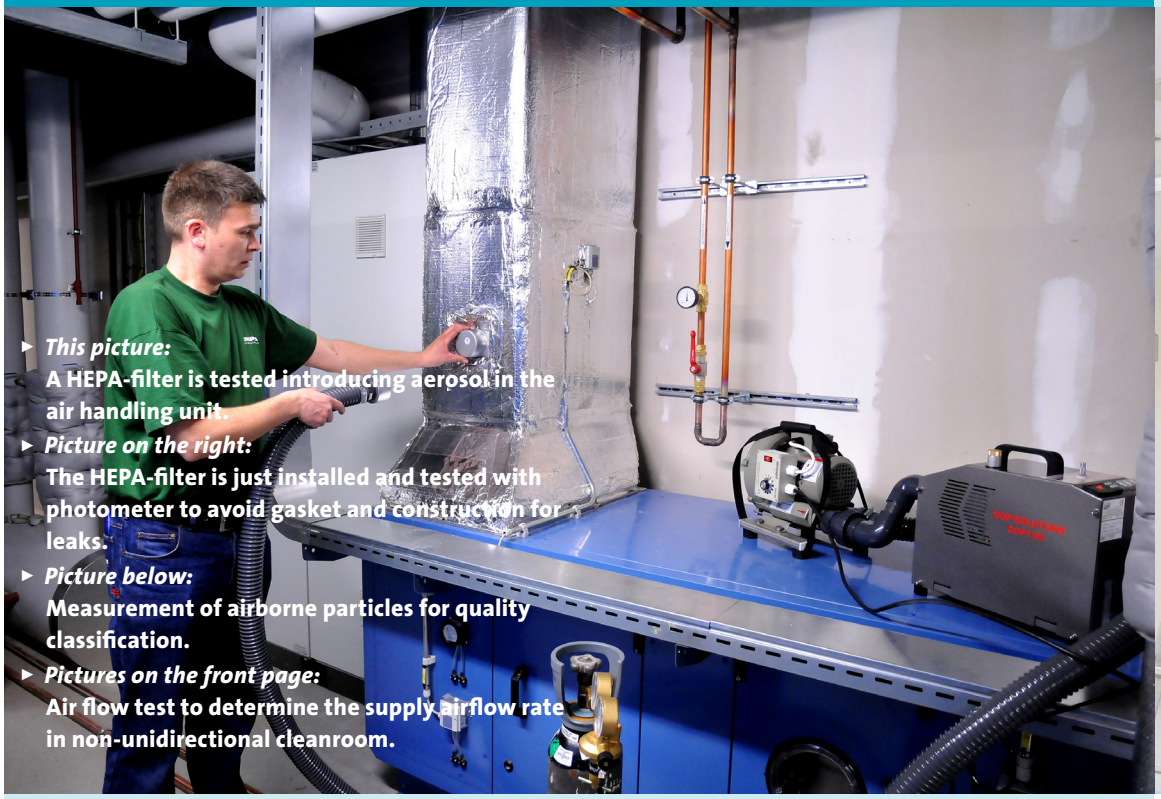
A number of objective references are not only essential when certifications are required by law (to gain official validations, for example, or to be shown to inspectors), but every time in which quality, control, security and reliability need to be proved.
High-technological instruments, driven by specific software, keep microbes, temperature, relative humidity, differential pressure, air flow, airborne particulates and other environmental factors constantly under control.
Due monitoring the equipment and the environmental emissions as well, we can provide you a full insight in nearly any manufacturing processes of scientific researches during the complete lifecycle.

Control and monitor

Cleanroom validation starts with several qualification phases following the most recent norms and the standard guidelines, including c-GMP, GMP of ISO 14644-1, 14644-3, 14698, NEN-z/3. When a class of ISO 14644-1 is chosen and the cleanroom is validated, the study protocol ends with monitoring and control. After the implementation, you will receive a standard documentation list containing data, reports and instructions. These documents, together with the URS and the Validation Master Plan, form the reference for monitor and control phase. When anomalies are reported, we send you a proposal plan in order to correct it. This method prevents problems.

Measurements and tests

- Airborne particle count for classification and test measurement;
- Air flow test to determine the supply airflow rate in non-unidirectional cleanroom and the air velocity distribution in a unidirectional cleanroom;
- Air pressure test to verify the specified pressure differential between separate environments;
- Air pressure difference test for the determination of filter pollution;
- Installed filter system leakage test using aerosol photometer or discrete-particle



- ***This picture:***
  A HEPA-filter is tested introducing aerosol in the air handling unit.
- ***Picture on the right:***
  The HEPA-filter is just installed and tested with photometer to avoid gasket and construction for leaks.
- ***Picture below:***
  Measurement of airborne particles for quality classification.
- ***Pictures on the front page:***
  Air flow test to determine the supply airflow rate in non-unidirectional cleanroom.

counter (DPC);
- Airflow direction test and visualization to check the airflow direction and its uniformity;
- Temperature and humidity test;
- Recovery test to determine the ability of the installation to eliminate airborne particles;
- Containment leak test to determine if there is intrusion of contaminated air into clean zones from surrounding non-controlled areas;
- Bio contamination control to determine the number of colony-forming units (CFU) in the air or on surfaces (active air sampling, sedimentation, and surface sampling);
- Light intensity, sound and CO_2 measurements.

Environments maintenance
- Cleanrooms, pharmacy preparation rooms and laboratories;
- Operation and isolation areas;
- Unidirectional flow clean air devices;
- Microbiological safety cabinets and insulators;
- Fume hoods, fire safety storage cabinets, powder exhaust units and extraction points;
- Medical gases installations.

Your installation is our care

In addition to running the validation studies, the contract administrator of KCC Services advises and coordinates the following services:
- Calibration of sensors and equipment;
- The commissioning of air handling installations;
- Replacing filters, v-belts and other parts;
- Carrying out maintenance and inspections;
- The remedy of malfunctions;
- Perform modifications including change control;
- Moving of installations and equipment.

This is only a selection from the services of Kropman Contamination Control.

More information?

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Kropman Installation Techniques

Kropman belongs to the top of Dutch installation companies. Since the start in 1934 Kropman has evolved into a full technical service provider. The engineering, execution and aftercare to maintenance and technical management are arranged in detail. As a system integrator covers Kropman the areas: mechanical engineering, electrical engineering, measurement and control technology and contamination control. Kropman has its own factory for prefabrication and is particularly active in the health care, utilities and the industry, in Netherlands and in the Euro regions. The ten service sites of Kropman, which lied scattered in the country, form a close network and operate as one firm.