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SECURING CLEAN AIR DEVICES

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Clean air device validation is becoming increasingly important. This narrative covers validation methodology, testing modes, and device types. Factors affecting device performances are discussed as well as other testing procedures to characterize systems security.

Filter performance is evaluated by different criteria. It is desirable that filters, or filter media, be characterized by low penetration across the filter of contaminants to be filtered. At the same time, there should exist a relatively low-pressure drop, or resistance, across the filter.

The use of magnehelic-type analog indicators, that rely on bellows and the blind reliance on them as on-line monitors for clean room filtration and scavenging airvolumes is a mistake.

The credence placed on these devices is a set-back for **current Good Manufacturing Practice conformance**. Their readings mislead. That hurts controlled workspace integrity.

Context

A depth media filter is a deep, relatively uniform density media, i.e. a system in which the solidity of the depth media remains constant throughout its thickness. If the percent solidity of the depth media is sufficiently high, relatively large particles will tend to collect in only the upstream portions of the media, tending to **load** on the front end of the media, and not penetrate very deeply. Those that occlude the air passage ways are termed **retained solids** i.e. retention of solids within the filter media.

Penetration, often expressed as a percentage, is defined as : **Pen = C/ Cδ**, where C is the particle concentration on exit through the filter and **Cδ** is the particle concentration before entry through the filter.

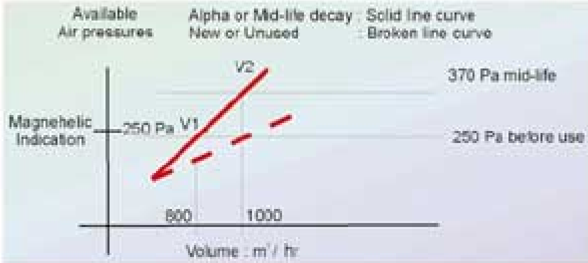
Filter efficiency is defined as : **100% minus Penetration**.

Because it is desirable for effective filters to maintain values as low as possible for both penetration and pressure drop across the filter, they are rated according to value termed **alpha (α)**, which is the slope of penetration versus pressure drop across the filter. Steeper slopes or higher **alpha** values are indicative of better filter performance.

Alpha is expressed according to the following formula : **α = 100 log (C/C δ) Δ P**, where, **Δ P** is the pressure drop across the filter.

Filter lifetime

A filter will have reached its lifetime, when a limiting pressure drop across the filter media is reached. For any specific application, the **limiting** pressure drop will be the point at which the filter needs replacement, as set forth in specifications applicable to the system, or through regulatory requirements. With magnehelic type differential pressure gauges, these filter characteristics are ignored. The essence of their misapplication is revealed by the curves shown in **Figure 1**.



HEPA Status	Volume	Pressure Drops	Magnehelic
New	1000 m^3 / hr	250 Pa	OK
Mid-Life V1	800 m^3 / hr	250 Pa	Anomaly
Mid-Life V 2	1000 m^3 / hr	370 Pa	OK

Figure 1 : Anamolous readings.

Note : The anomaly stems from the probes transducing pressure and not air-volumes which are inversely proportional. Unless, the air handling systems respond with tip-speeds to sustain air-displacement, the magnehelic readings would hypothetically and detrimentally remain unchanged.

Retrospectives

Device performance analysis has been defined as the reconciliation, rectification, and interpretation of performance. The measurements are rectified to identify and eliminate those measurements that contain bias i.e. systematic errors sufficiently large to distort conclusions. The results are used to discriminate acceptable performance, including the techniques of linear systems which are restricted in use to the linearized versions of real systems.

In fact, for many control applications the linear systems have produced excellent results which are supported experimentally. For such systems we must necessarily employ special analytical, graphical and numerical techniques which take account of system non-linearities. The most fundamental property of a linear system is the validity of the principle of superposition. It is on account of this property that it can perhaps be guaranteed that a linear system designed to perform satisfactorily when excited by a standard test signal, will exhibit satisfactory behavior under any circumstance. Furthermore, the amplitude of the test signal is unimportant since any change in input signal amplitude results simply in change of response scale with no change in the basic response characteristics. In contrast to the linear case, the response of non-linear systems to a particular test signal is no guide to their behaviour, to other inputs, since the principle of superposition no longer holds.

Optimal parametric control system

There are two approaches to the design of control systems. In one we select the configuration of the overall system by introducing compensators and then choose the parameters to meet the given specification on performance. In the other, we find an overall system that meets the given specifications and then compute the necessary compensators. Peak overshoot, settling time, gain margin, phase margin and steady-state error, are among specifications used. These design specifications are selected because of convenience in graphical interpretation.

These are generally many designs that can prognosticate these among causes for deterioration of device performance.

Figure 2 describes linear functions of Parametric Controls and is the one currently favoured by end-users.

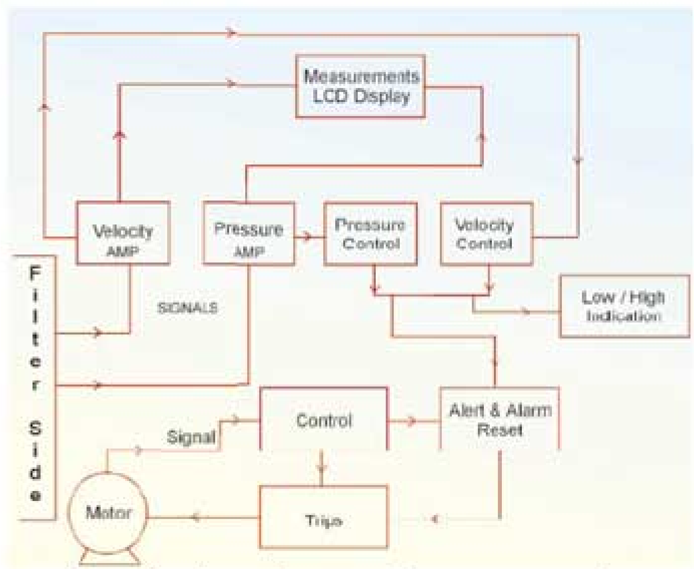


Figure 2 : Linear functions of parametric controls.

Prospectives

Validation is the procedure of comparing a measurement to one or more of the following :

- Another measurement
- An expected range
- Equipment status
- Equipment relations.

If the comparison shows that the measurement is inconsistent with the comparison information, the measurement is considered suspect. It is important to note that validation, typically only brings a measurement under suspicion. It does not verify that the measurement is incorrect. Safety is paramount. Some validation analysis can mislead and contraindicate the measurements are invalid when, in fact, the comparison information is invalid. It is not difficult to extrapolate that actions could result from this erroneous conclusion which would place maintenance and operating personnel in jeopardy. Validation merely raises suspicion; it does not confirm errors of measurement.

Feedback and non-feedback systems

These are increasingly being adopted to perform their assigned tasks automatically. A *non-feedback – open-loop – system* represented by the block diagram and signal flow graph in **Figure 3**, is activated by a single signal at the input – for singleinput systems . There is no provision within this system for supervision of the output and no mechanism is provided to correct – or compensate – the system behavior for any lack of proper performance of system components. On the other hand, a *feedback –closed-loop – system* represented by the block diagram and signal flow graph in **Figure 3** is driven by two signals – more signals could be employed – one the input signal and the other, a signal called the feedback signal derived from the output of the system. The feedback signal gives this system the capability to act as a self-correcting mechanism. The output signal c is measured by a sensor **H**(s), which produces a feedback signal b. The comparator compares the feedback signal b with the input – command – signal r generating the actuating signal e, which is a measure of discrepancy between r and b. The actuating signal is applied to the process **G**(s) so as to influence the output c in a manner which tends to reduce the error e.

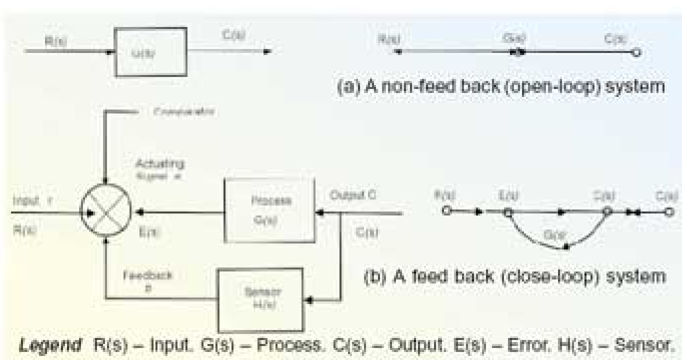


Figure 3 : Open-loop and close-loop systems.

Feedback as a means of automatic regulation and control is, in fact, inherent in nature and can be noticed in many physical, biological and soft systems. For instance, the body temperature of any living being is automatically regulated through a process, which is essentially a feedback process, only it is far more complex than the diagram of **Figure 3**.

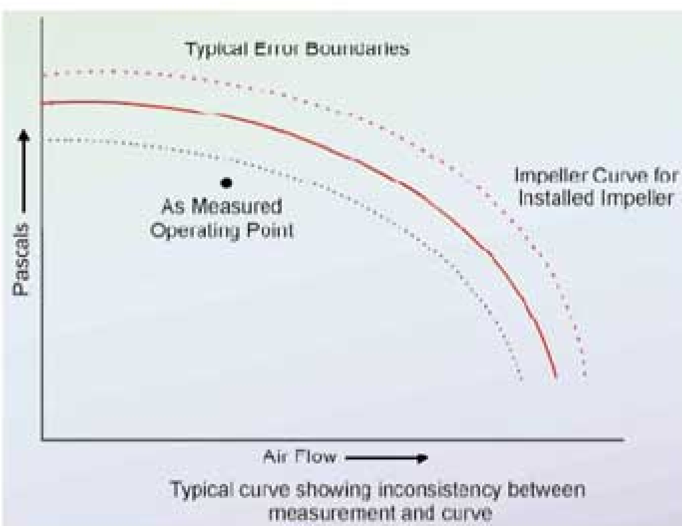
The greater the number of validation comparisons between the measurement and the list, greater the likelihood that the measurement can be identified as valid or invalid.

Measurement versus measurement : In this type of validation, a process measurement is compared against another. For example, if a separate high level alarm indicates that filter Δ P is Lo and the Control Logic indicates that it is in the expected range, one of these measurements is wrong.

Measurement versus expected range : If air steam flow is expected to vary in a relatively narrow range and the flow measurement indicates that it is twice the high value, the flow measurement is then suspect and should be reviewed. A frequent occurrence is when a measurement remains unchanged for a period of time when normal fluctuations should result in a set point. The constant measurement would indicate that this reading is suspect.

Measurement versus equipmentstate : A blower offline should have no flow. If the blower is off and the flow meter indicates that there is flow, the flow measurement is suspect.

Measurement versus equipment performance : Blowers that are in reasonable condition typically operate within 5 percent of their impeller curve. Consequently, pressures and flows that are inconsistent with the blower curve imply that the indicated flow and; or pressure are incorrect. **Figure 4** shows a single impeller curve plotted as head versus flow. The point shown is inconsistent with the blower in operation. Therefore, that pair of flow and pressure measurements is not validated and should not be used in the subsequent steps.



Typical curve showing inconsistency between measurement and curve

Figure 4 : Typical curve.

Validation v/s Rectification

The goal of both rectification and validation is the detection and identification of measurements that contain systemic error. Rectification is typically done simultaneously with reconciliation using the reconciliation results to identify measurements that potentially contain systematic error. Validation typically relies only on other measurements and operating information. Consequently, validation is preferred when measurements and their supporting information are limited. Further, prior screening of measurements limits the possibility that the systematic errors will go undetected in the rectification step and subsequently be incorporated into any conclusions drawn during the interpretation step.

Conclusion

Off-loading or flow-totalization control of space, employs preset linear pressure sensing of final exit velocities in which set values are sacrosanct to fulfill cleanroom objectives. In-tandem blowers do the rest.

There are no compartmentalization controls. Room infiltration and exfiltration rates are a matter of **alpha-balance** and are not subject to transient disturbances like traffic through doors.

- Only one supply system is required to support a space in cascade.
- Minimum air changes per workspace can be easily established and documented.
- Localized air turbulence, that affects **colony-formed units generation** adversely, is avoided. Security Systems derive their worth from being as simple as simple can be.
- They ensure positive separation of zones that must avoid cross migrations.
- Eliminate a need to place remote sensors away from control devices – resulting in a high degree of reliability.
- One cascade supply system, as required by pre-regulated activity to sustain work-space integrity.
- React to differential pressure directly, obeying filtration **alpha values**.
- Least cost to implement.