Cleaning procedures for ÄKTAprocess system external surfaces

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Cleaning procedures for ÄKTAprocess system external surfaces

This application note describes studies to determine ÄKTAprocess system compatibility with common cleaning processes for external surfaces, including fogging of the entire system. This study does not detail any microbiological decontamination advantages or disadvantages of any of the methods used.

ÄKTAprocess systems come into contact with a variety of cleaning agents as well as a number of potentially aggressive chemicals (e.g., salts, aldehydes) and this study was designed to test the system's compatibility with several common cleaning agents when cleaning surfaces. ÄKTAprocess systems and components were exposed to common surface cleaning agents, and also tested for response to clean room fogging agents. Tests were designed to assess local (spot) cleaning effectiveness as well as a whole-system method utilizing a common fogging method.

Methods

Customer surveys were used to ascertain the most common cleaning agents used in association with ÄKTAprocess systems and associated clean rooms. The cleaning agents most often used were ethanol, isopropanol, hydrogen peroxide, and peracetic acid in various concentrations and mixtures. While these solutions provide well-documented cleansing effects, they can sometimes also react with surface finishes to cause discoloration. To test the effects of cleaning agents on ÄKTAprocess systems we used two approaches, one involving individual system components, and one involving entire systems. In both cases, surface cleaning and fogging were used.

Fig 1. ÄKTAprocess system.

Component testing

Surface tests

In the manual application tests a wide variety of component surfaces were tested, including most areas subject to exposure to cleaning and/or caustic substances. All surfaces/components were photographed prior to testing and again following testing if effects of cleaning agents were evident. In addition, duplicate components were also left untreated for comparison to treated surfaces. A grading system was used to qualitatively assess the results of the cleaning results. The grading is summarized in Table 1.

Table 1. Grading system used to quantify results

Grade assigned	Observed result
0	Surface has dissolved and is fully or partially visible.
1	Surface has dissolved and comes loose when touched.
2	Surface has dissolved but is otherwise intact.
3	Change in surface color. Stains visible from all directions when the surface is angled towards a light source.
4	Change in surface color. Stains disappear at certain angles when the surface is angled towards a light source.
5	No effect observed.

Experiment 1 – Common cleaning agents

To imitate the manual cleaning of surfaces on ÄKTAprocess systems, we utilized 6% hydrogen peroxide, 70% ethanol, and 70% isopropanol to wipe surfaces. A cotton swab was used to wipe common cleaning solutions on material surfaces for 5 sec, allowing the solution to evaporate, then repeating the wiping procedure for a total of 10 applications. Surfaces were marked showing which cleaning agent was applied.

Experiment 2 – Salt residues from buffer

In normal applications, salt residues from buffers are commonly found on system surfaces. In this experiment component surfaces treated with 2M NaCl and 1M NaOH, which were applied until residue was visible. The resulting residue areas were marked and left to dry for 24 (NaCl) or 72 h (NaOH). Following these incubation periods, the residue areas were gently wiped with 70% isopropanol or 70% ethanol in an attempt to clean away the residue.

Fogging test

ÄKTAprocess components were exposed to salt residues and dry fog to determine any detrimental effects of fogging on material integrity. Salt residues were created by dripping small amounts of 1M NaCl and 1M NaOH onto component surfaces, until residues were established. Two residue contact times were used, a short-term contact of less than three weeks, and a long-term contact of greater than one month. The electronic components were also exposed outside of the normal cabinet environment and then functionally tested.

Fig 2. A nozzle applying fogging solution.

Fogging of system components was carried out with a Mini Dry Fog™ System (Fig 2) dispensing Minncare solution (22% hydrogen peroxide, 4% peracetic acid) according to supplier recommendations (contact time = 1 h).

Environmental conditions during fogging were:

Relative humidity: 70%-90%

Temperature: room temperature (approx. 20°C)

A large number of component surfaces were tested, covering a majority of the exposed surfaces of an ÄKTAprocess system.

System testing

Fogging tests

Large-scale fogging tests on two ÄKTAprocess systems were carried out in a limited space using a Dry Fog system and Minncare solution (as in the component tests described in the previous section). Systems were shut off prior to the fogging tests. For the fogging tests, selected surfaces on an ÄKTAprocess system were exposed to 2M NaCl and 1M NaOH for a period of about one week. Fogging was then performed five times in an attempt to simulate a heavy fogging scenario. As a control, another ÄKTAprocess system was not exposed to salt residues and underwent a single fogging treatment. The fogging system was set for a 15 m^3 room, but carried out in a 9 m^3 space to simulate a "worst case" scenario with respect to fog concentration. The same general testing conditions were used for the fogged system that was not exposed to salts.

All surfaces were then visually inspected and results recorded. After the five fogging treatments, a system functional test was carried out to verify that the fog did not affect system functioning.

Surface test

Separate, complementary surface tests were carried out by wiping surfaces by hand, ten times, with a 3% Minncare solution and 6% hydrogen peroxide. These surfaces included equipment, such as polymers and equipment tags, that were thought to be potentially sensitive to cleaning agents.

Results and Discussion

Component testing

Surface tests

The majority of component surfaces tested showed no detectable effects (grade 5 according to Table 1) of any of the cleaning solutions or the salt residues.

In Experiment 1 - Common cleaning agents, exceptions included: 1) the power supply connection (blue polycarbonate) showed noticeable surface marking when viewed at certain angles; 2) The blue surface color of the Roxtec cable (polymer) bled slightly when exposed to cleaning agents; and 3) the steel surface of the flow meter showed slight bleaching.

In Experiment 2 – Salt residues, exceptions included: 1) the steel surface of the flow meter showed rust spots after exposure to NaCl (but prior to wiping) and slight bleaching when exposed to isopropanol and ethanol; and 2) some EPDM membranes showed slight discoloration when exposed to NaOH.

Fogging test

The results showed that the majority of component parts with NaOH and NaCl residues showed no surface effects after short- or long-term exposure. NaCl caused rust stains in salt residue on some areas of exposed steel, and this effect was amplified in combination with fogging, showing black spots after wiping. Consequently, it is recommended that steel parts are cleaned of any residues prior to clean room fogging treatments with Minncare solution.

Following fogging, functional tests of the system circuit card as well as the CU-960 control box were all successful.

System testing

Fogging tests

Fogging of an entire ÄKTAprocess system gave results similar to the component fogging study - Minncare solution in combination with salt residues tended to exacerbate the rust effect on stainless steel surfaces (e.g., Fig 3).

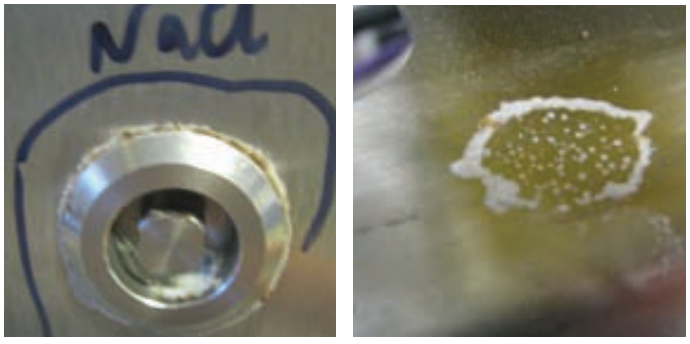

Fig 3. Examples of incipient rust on areas of salt residue on steel surfaces after fogging.

In most cases, residue and rust could be removed with gentle wiping of the surface (Fig 4). No effects were seen on tags, adhesives, or labels.

The results suggest that cleaning of external surfaces (with special attention to steel surfaces) is important before fogging of ÄKTAprocess systems. Although the fog slightly penetrated the electrical system cabinet, no effects of the fogging were seen on system functional performance.

Surface test

None of the tested surfaces were affected by the test chemicals.

Fig 4. Areas of salt residue and subsequent rust (left photo) are normally easily removed with gentle cleaning with water (right photo).

Recommendations

The results of these studies show that common cleaning agents such as 70% ethanol and isopropanol are possible to use on ÄKTAprocess systems. The only case for concern is when steel is in contact with salt residues. In such cases, care should be taken to completely remove salt residues prior to cleaning (step 1 below). This study shows that the following cleaning techniques are compatible with ÄKTAprocess systems:

1. Regularly wipe/wash off system surfaces with water to remove salt and other external deposits. Note that this step is mandatory prior to performing either of the following procedures!
2. Regularly clean system surfaces with 70% ethanol or 70% isopropanol, and also before placing the system in a clean room environment (according to SOPs).
3. Clean room cleaning techniques may include fogging with Minncare solution (hydrogen peroxide and peracetic acid) according to SOPs.

Regular wiping and care of the system will help keep the surfaces unaltered.