TECHNICAL WHITE PAPER

On

Automatic IP Cleaner

Author:

Mahantesh Gowda Patel
Director
Envisys Technologies Pvt. Ltd.
#32, Ligadi Mansion,
Muthurayaswamy Layout,
Sunkadakatte,
Bangalore – 560 091
Ph: +91 80-65770603
E-mail: patel@envisystech.com

INTRODUCTION/ BACKGROUND:

Envisys Technologies Pvt Ltd designs and manufactures Environmental Test Chambers for simulating various environmental stress conditions like temperature, humidity, salt fog, rain, dust, altitude, solar radiation etc., for component level and as well as end product testing applications in various industries viz., automotive, electronics, defence, aerospace etc., Envisys also provides custom engineering solutions in testing, automation and other applied engineering areas of various industry applications. As a part of its ongoing research and development work Envisys has recently developed an automated system for complete isopropanol based chemical cleaning of medical devices/equipment an innovative and cost-effective cleaning solution of sensitive medical devices of varied dimensions and shapes with outstanding features/benefits as a substitute to existing tedious manual process used in the said industry.

PROBLEM STATEMENT:

Currently many manufacturers of medical equipment/devices use the process of filling oil in the equipment/device which acts as an insulation media in the equipment/device manufactured by the factory. However, after the manufacturing process of such oiled equipment/device there is a need for cleaning of such assembled end products after the production cycle to qualify/validate the same as cleaned equipment/device (free from oil dirt's/stains/deposits) for packing and dispatch.

In order to perform the cleaning activities of these equipments/devices there has been a dedicated workforce assigned to manually clean the line-products before dispatching them for packing departments. In the process many man-hours were allocated for this process and also it is found that, there is a substantial loss of chemical (isopropanol) used for cleaning during the process.

As a process it is considered as a time-consuming activity involving many man-hours and chemical consumption, wastage etc., and as a whole it is found to be a high-cost affair. Also, it is against the safety measures in terms of its noise and air pollution hazards due to the usage of air-compressor in the methodology applied and a chemical inhalation exposure leading to multiples health complexities as the isopropanol used is of strong odor and irritant to skin.

The need for a machine which can automate the process of cleaning under safe conditions which shall avoid the human intervention and effectuate the optimum use of chemical and time for the defined statement of problem is the fundamental objective of this study to develop a system which may act as a substitution for the current tedious process adopted by the industry.

EVALUATION OF THE CURRENT PROCESS OF CLEANING:

Medical equipment/devices are designed with different geometric dimensional structures of un-even surfaces/shapes, projections, heat transfer slots, receptacles, electronic PC boards etc., During the oil-filling process of these equipments/devices oil spills out from these equipments/devices and gets deposited/accumulated on the surface/interiors of the body of equipment/device. Hence cleaning of these oil deposits/stains from the equipment/device is a challenging task for the work-force assigned for this job.

The manual cleaning process requires the use of isopropanol chemical, compressed air of high pressure (10bar), white cotton cloth, and exhaust ionizer etc., the manual cleaning methodology applied in this context involves three stages viz., the manual spray of isopropanol on the device, bursting of high pressure compressed air and wiping the equipment/device with white cloth. The process is repeated three or more times until the device is fully cleaned before qualifying/validating the particular equipment/device for necessary packing and dispatch.

The study on the consumption rates of cleaning process of one equipment or device is evaluated as below: In order to clean one equipment/device using the manual process below are the details of consumptions estimated*:

- Man hours: 25-30 mins
- Isopropanol: 100-150 ml
- Compressed air : 250-300 cfm
- White cotton cloth: 250-300 gms

*data collected from the users/operators/process managers

Few of the hazards undergone during the each cleaning process are investigated as below:

- Exposure to chemical inhale due to the polluted air in the surrounding vicinity
- Exposure to noise pollution emitted from the air-compressor of noise level up to 80-85 dba.
- The cleaning agent isopropanol is considered to be dangerous in terms of its flammability and other health problems due to its harmful characteristics

CHALLENGES:

In the manual cleaning since human involvement is the basis, organizations develop methods to control performance parameters, document performance, and maintain competence through training. Manual cleaning processes cannot be taken for granted. As the risk analysis becomes common practice in medical equipment manufacturing, manual cleaning procedures are increasingly being recognized as a high risky activity. If manual cleaning processes are not adequately controlled through a comprehensive program, the reliability of such process is questionable.

It is evident from the in-depth study of the current process of cleaning that it is a challenging task for an industry to evolve a substitute process which can completely eliminate the obstacles faced in the current process of manual cleaning practiced on day-to-day basis.

The following challenges are instrumental in finding a suitable solution to the problem:

Major Challenge:

The current manual process of cleaning needs a substitution with an automated solution of non-human involvement in the process under safe conditions.

Derived Challenges:

- ✓ Reduction of noise from air-compressor to allowable limits of safety standards
- ✓ Thorough cleaning of equipment/device using automated cleaning process
- ✓ The time factor to be reduced for each process of cleaning
- ✓ Avoidance of chemical exposure to the surrounding air
- ✓ Limiting the consumption of isopropanol and compressed air
- ✓ Compliance to EHS safety norms

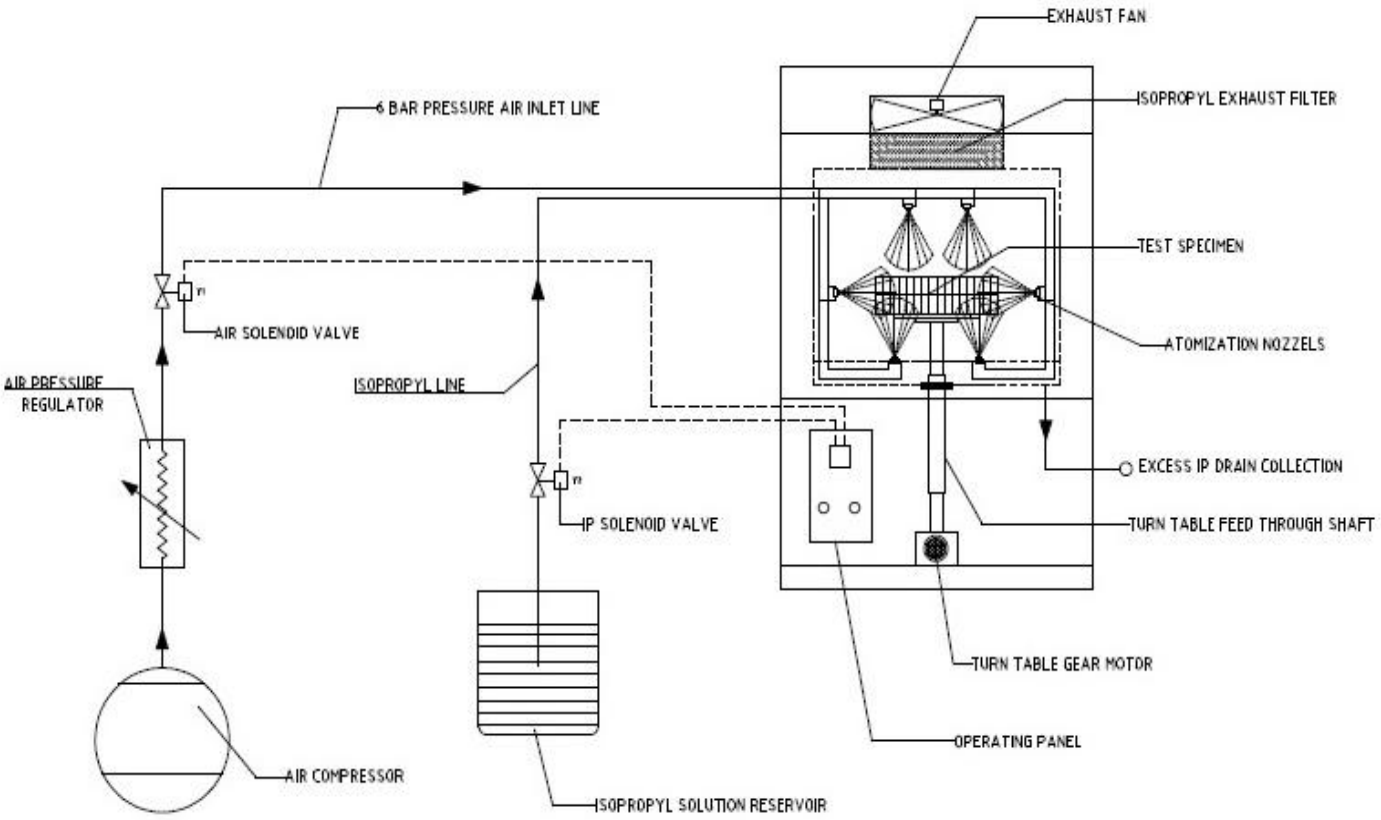
SOLUTION-PROPOSED/ DISCOVERED:

After conducting a thorough evaluation of the current process practiced/in-use by the manufacturer/s of medical equipment/device Envisys R&D team has successfully discovered/developed a suitable & substitutable solution by a concept/solution via its proto-type automated equipment with the following parameters into consideration:

- Cleaning process should happen in the enclosed condition
- Compressed air noise should be reduced by using insulated enclosure
- Automatic cleaning process by providing turn table rotatable in 360 deg directions with height adjustment mechanism
- Controllable speed of rotating table depending on the requirement
- All the side walls in the interiors of the enclosure to be provided with flexible/adjustable spray and air nozzles in all directions
- Common spray and air nozzles shall have conical 25 deg spray angle to ensure 100% spray on the device subjected for cleaning
- Isopropanol collection point / provision in the enclosure to collect the sprayed isopropanol for re-use
- Exhaust provision in the enclosure for sprayed isopropanol exhaust with IP filtration/ionization for environmental safety
- Reduce the consumption of isopropanol and compressed air
- Elimination of manual cleaning process
- Reduce cleaning time

AUTOMATIC IP CLEANER FROM ENVISYS – OPERATING PRINCIPLE

The device for cleaning is kept on the turn-table (made of geometric surface openings) inside the enclosure. The turn-table is pre-configured to level adjustments for suitable specific device dimensions. The following checks needs to be ensured before switching on the cleaning process ie., level of isopropanol in the reservoir, air-pressure and proper door locking of the enclosure.



In order to start the cleaning process press the run/reset button of the pre-configured controller/timer (pre-setting of run-duration, number of cycles, isopropanol, air pressure and spray time is done during trial stage). Once the button is pressed cleaning process will start. In the process Isopropanol and air will get mixed in the atomizer and will be sprayed on the specimen device kept on the turn-table as per pre-set duration. Flow of isopropanol will be stopped after the set time duration is over. Subsequently high pressure air will be burst on the specimen device as per the set duration to clean the sprayed isopropanol and other particles on the device. This process will be repeated 2-3 times depending on the status of cleaning of the device. The number of repeat cycles is then pre-configured in the controller during this trial stage. Cleaning process can be viewed and monitored by see-through full viewing window provided on the door of the enclosure to inspect the process and take out the device from the enclosure after the full cleaning is performed.

The direct spray system approach for removing the stains, deposits etc., both loose and tenacious on the device revolves around the ability to actually impinge upon surface and interiors of the device with the spray nozzles fitted in all directions.

BENEFITS / FEATURES OF AUTOMATIC IP CLEANER

Envisys R&D team has succefully developed an Automated Isopropanol Cleaner with the following features / benefits in the equipment:

- A through and automated cleaning of medical equipment/devices on all sides
- Time setting of the cleaning process for automated shut down of the process after completion
- Reduction in the consumption/usage level of isopropanol to: 25-30ml.
- Reduction in the consumption/usage level of compressed air to: 150-175cfm.
- Reduction in the cleaning time to: 8-10min.

ENVISYS TECHNOLOGIES PVT LTD
Regd. Office: No.32, Ligadi Mansion, Muthurayaswamy Layout, Sunkadakatte
Bangalore – 560 091 Karnataka – INDIA
E-mail: help@envisystech.com Website: www.envisystech.com
CIN: U74900KA2014PTC073998 Ph: +91 80 65770603, 7411455246

- Elimination of usage of white cloth to : 0%
- There is no abnormal compressor air noise during cleaning process as a result of insulated enclosure
- Prevention of hazardous chemical exposure to surrounding area
- Filtration and exhaust of sprayed isopropanol
- Complete elimination of human involvement in the cleaning process except for loading and unloading of the equipment/device subjected for cleaning
- Fulfillment of EHS guidelines
- Overall it is a time-cost saving method/solution of cleaning with complete automation in place

CONCLUSION:

The invention of Automated IP Cleaner has derived phenomenal advantages in overcoming the hazardous cleaning process used in the medical equipment/device manufacturing industry by providing an automated solution to reduce most of the critical processes involved in the cleaning process by using isopropanol as a primary cleaning agent. Moreover it is a cost-time saving solution to clean the equipment/device effectively using an automated system which can perform all the activities under safe conditions to fulfill the purpose. There is a further scope for development of this product in the future after examining the usage results and feedback obtained from the users of this innovative product.

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