To meet the increasing customer demand in the field of medical technology, the Masterflex Group has extended its facilities to include another clean room.

Masterflex Group: New clean room commissioned

The new clean room at Halberstadt

The new clean room meets the high specifications of the EN ISO 14644 standard for class 7. "In comparison", explains Axel Schuchmann, General Manager of the Masterflex subsidiary Novoplast Schlauchtechnik GmbH, "a room of this class is a hundred times cleaner than an operating theatre in a hospital. Coupled with several other important investments in new extrusion facilities, our production lines are now running better than ever before."

Designed as an extension of the existing extrusion production lines for different areas within medical technology, the new clean room will see the production of Novoplast Schlauchtechnik special hoses for applications in the fields of diagnostics, dialysis, drainage, urology as well as for hearing-aids.

Dr. Andreas Bastin, CEO of the parent company Masterflex SE: "In the field of medical technology, there is a steady growth in demand across the entire market. As this segment is not subject to larger economic fluctuations and has allowed us to gather valuable know-how, we have been able to push this field of production as industry-leading manufacturers of special

p. 2: Masterflex ...

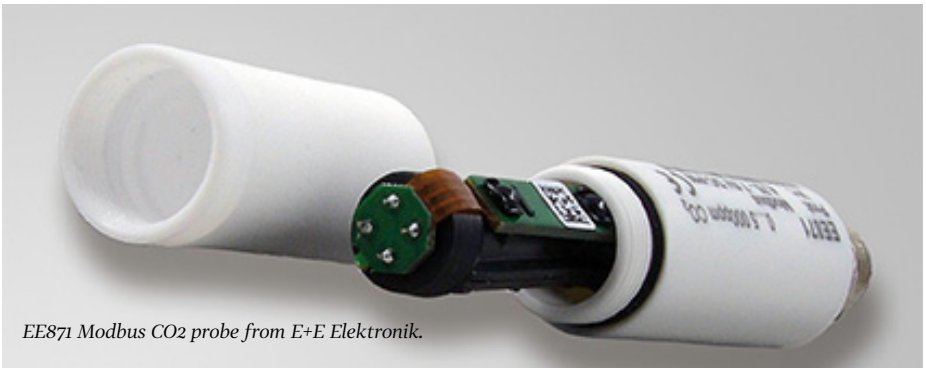
hoses. That has paid off today. The demand for our high quality medical products is rising constantly."

With the extension of the production capacity for medical technology at the site in Halberstadt, the Masterflex Group is not only meeting the needs of the customer head-on, but also safeguarding current and newly created jobs at the same time. This provides a significant benefit to the Halberstadt region in the German state of Saxony-Anhalt. Bastin: "The growth trajectory of our group is the result of our successful business strategy and an answer to the increasing demand for high-tech hoses throughout the entire world market. That's why we see great potential for the future."

Masterflex SE
D 45891 Gelsenkirchen

The EE871 CO2 probe from E+E Elektronik is designed for maintenance-free use in demanding OEM applications. The Modbus protocol permits easy retrieval and further processing of measurement values and facilitates simple integration into custom applications.

Modbus CO_2 probe for demanding OEM applications



EE871 Modbus CO2 probe from E+E Elektronik.

Highest measurement accuracy

The compact probe measures CO2 concentrations up to 10,000 ppm. Thanks to the multipoint CO2 and temperature adjustment, temperature compensation ensures excellent measurement accuracy over the entire operating range of -40... 60°C.

Excellent long-term stability

The CO2 measurement cell of the probe is based on infrared technology (NDIR) and uses a dual-wavelength auto-calibration procedure. Thus, the EE871 is maintenance free and highly resistant to environmental influences. Ageing effects are automatically compensated, thus ensuring excellent long-term stability.

High resistance to pollution

The IP65 enclosure and the replaceable filter ensure optimal protection from contamination. Therefore, the EE871 can also be used in harsh environmental conditions.

Easy assembly

Its compact design, M12 electrical connector and optional mounting flange facilitate the installation or replacement of the CO2 probe.

Due to its very low power consumption, the CO2 probe is particularly interesting for use in battery-powered devices such as data loggers, handhelds and wireless sensors. Other applications can be found, among others, in greenhouses, stables, fruit and vegetable storage facilities, hatchers and incubators.

E+E Elektronik GmbH
Langwiesen 7 A 4209 Engerwitzdorf
Telefon: +43 7235 605 0
Telefax: +43 7235 6058
E-Mail: info@epluse.at
Internet: http://www.epluse.com

Dear readers, dear subscribers,

it has been a pleasure for me to have the opportunity to work with you last year and I am looking forward to 2014.

2014 we will have again a lot of new information, articles and contacts.

Yours sincerely

Reinhold Schuster

The map shows where the readers of the cleanroom online newsletter are coming from: if you want to get in contact with these readers please contact us.

Ecolab Contamination Control has launched a process match assurance mark for their Klercide range of contamination control products.

Process match gives stamp of assurance

The company which produces products and services for the control of microbial contamination in the cleanroom environment has introduced the mark to highlight that its manufacturing processes match those of their customers.

Andy Newsome, Global VP, Ecolab Contamination Control, said: „The last thing customers need in a cleanroom environment is doubt about the validity of products or to compromise their procedures and protocols. The process match assurance shows we are totally confident that our own manufacturing processes, which also take place in cleanrooms, are directly comparable to those of our customers."

The process match assurance is being communicated in all advertising material, sales collateral and new packaging by a special graphic device. Mr Newsome said: „When customers see the logo they will know that the way we manufacture products is as carefully monitored as their own."

Ecolab Contamination Control manufactures a fully validated range of contamination control products for life science cleanrooms worldwide, which are produced to the requirements of cGMP, in their own purpose built cleanroom facility in South Wales.

These include alcohol and biocide sprays which feature the SteriShield Delivery System (SDS), the only validated system on the market, along with an extensive range of pre-impregnated and dry wipes, dry goods and additional service options.

ECOLAB CONTAMINATION CONTROL
1 Wernddu Court, Van Road
CF83 3SG Caerphilly
Vereinigtes Königreich Großbritannien und Nordirland
Telefon: +44 2920 854 390
Telefax: +44 2920 854 391
Mobile: +44 7557 190597
E-Mail: emily.buck@ecolab.com

Vaisala Acquires Renewable Energy Assessment and Forecasting Services Company

Vaisala strengthens its position in the renewable energy market through the acquisition of 3TIER Inc., a US-based company with USD 9.0 million net sales in 2012 and 55 employees. The value of the deal is EUR 10.7 million. Vaisala is using its existing cash balance to finance the transaction. This acquisition will not have a material impact on Vaisala's 2013 financial result or balance sheet. Market guidance for 2014 will include also 3TIER's impact on Vaisala's financial result and it will be disclosed on February 10, 2014 in Vaisala's financial report for January-December 2013.

3TIER provides project feasibility, asset management and forecasting services to companies operating in the renewable energy market globally. While the majority of 3TIER's business comes from the wind energy market, the company also serves customers in the solar and hydro energy markets. 3TIER complements Vaisala's strong environmental sensing business, and its international distribution network will provide significant growth opportunities in Brazil, Nordic countries, China, Australia, India and the USA.

„The renewable energy market is a focus area of Vaisala's Weather business, and the acquisition of 3TIER with its wind and solar energy emphasis, aligns perfectly with Vaisala's strategy. Wind energy represents an extensive market with long-term growth opportunities. 3TIER brings Vaisala valuable capabilities in renewable energy assessment and forecasting services applicable across our other segments as well," tells Kai Konola, Executive Vice President of Vaisala Weather Business.

Vaisala's strategic intent has been to build a stronger position in the renewable energy sector. The acquisitions of Second Wind in August and 3TIER today are logical steps, and together with Vaisala's offering create a full service renewable energy observation and information services business.

Vaisala GmbH
Adenauerallee 15
D 53111 Bonn
Telefon: +49 228 249710
Telefax: +49 228 2497111
E-Mail: vertrieb@vaisala.com
Internet: http://www.vaisala.com

The new Innovative Sensor Technology IST AG headquarters are located in eastern Switzerland. The building offers nearly 100 employees of the high-tech company a modern work envi-ronment.

Dr Mirko Lehmann, Managing Director of Innovative Sensor Technology IST AG.

Each sensor is measured to ensure it meets the customer's requirements. Annually, more than ten million sensors are produced and distributed worldwide.

Swiss sensor manufacturer moves into modern production and office facilities

Innovative Sensor Technology IST AG dedicates new building

Innovative Sensor Technology IST AG has invested more than 14 million Swiss francs in its new headquarters in Ebnat-Kappel, Switzerland. The new building offers nearly 100 employees of the high-tech company a modern work environment, ensuring the production, development, sales and administration departments can work efficiently.

The company develops, manufactures and markets world-class sensors for measuring temperature, humidity, flow and conductivity. These high-quality products are used in a broad range of applications such as HVAC, medical technology, process automation and aerospace. The company, with more than 160 employees in Ebnat-Kappel, (Switzerland), Roznov, (Czech Republic), and Las Vegas, (USA), manufactures more than ten million sensors annually and sells them on all five continents. "We are a global company to the core," emphasizes Managing Director Dr Mirko Lehmann.

Added flexibility in development and manufacturing

The company specializes in sensors based on thin-film deposition. "The production processes place high demands on the work flow and the infrastructure," explains Dr Jörn Lützen, member of the management board and head of the new building construction project. "This new, dedicated facility provides the ideal conditions for meeting these challenges." Roughly half of the 5,000-square-meter floor space is reserved for production and development with 800 square meters set aside for the clean room. "Because the presence of even the tiniest impurities makes it impossible for us to manufacture sensors with micrometer precision, an absolutely pure environment is essential," adds Jörn Lützen.

Given that IST boasts around 4,000 different products and adds more than 200 new ones each year, the Managing Director emphasizes that "the new production facilities increase our flexibility." Last but not least, the expansion allows the company to drive the development of new products such as biosensors or sensors for gas analysis. "We have a reputation for quickly understanding what the customer wants and tackling and rapidly implementing new developments. This calls for effective communication between all of the departments, which the new building facilitates thanks to a creative interior design," says Mirko Lehmann.

A visible commitment to the region

IST shared rented premises with other companies in the adjacent community of Wattwill until 2012. The operation was

During deposition, a ceramic substrate is sputtered with high purity platinum inside IST AGs new clean rooms.

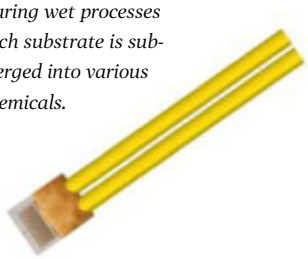
p. 2: Innovative Sensor Technology IST AG dedicates new building

spread over several floors. Managing Director Mirko Lehmann felt it was important for the company to remain in eastern Switzerland. "Apart from the fact that most of our employees live here in the region of Toggenburg, the new building is in a very beautiful, quiet and natural setting that motivates us to be even more productive while attracting job seekers. Our business partners also enjoy visiting us."

The company celebrated the dedication of the new facility on 6 September 2013 in the presence of numerous guests. The three-story building was erected in less than 18 months. More than half of the investment for the construction of the building went to regional companies. The third-floor cafeteria features a glass façade with a magnificent view of the Churfirsten mountain range, part of the eastern Swiss Alps and landmark of the Toggenburg area. Mirko Lehmann: "This region still has tremendous potential for continued growth."

Innovative Sensor Technology IST AG
CH 9642 Ebnat-Kappel

During wet processes each substrate is submerged into various chemicals.



Innovative Sensor Technology IST AG offers more than 4.000 different sensors and develops more than 200 new products every year covering temperature, humidity, flow and conductivity.

Each meeting room is named after a local mountain of the Swiss Alps one can see through the window.

POWTECH looks forward to welcoming powder and bulk solids experts from all over the world

POWTECH 2014 in Nuremberg

The Exhibition Centre Nuremberg invites the industry to POWTECH again from 30 September to 2 October 2014. The 2013 event once again consolidated its position as World-Leading Trade Fair for Processing, Analysis and Handling of Powder and Bulk Solids. Every third exhibition visitor and every third exhibitor travelled to Nürnberg from abroad. Eight per cent more visitors* is also a clear indication of the great response from all branches of industry. The initial figures for 2014 are promising as well.

30th Sept. - 02rd October 2014: POWTECH 2014, Nuremberg (D)

"POWTECH registered its best result so far in 2013 and this positive trend is continuing: We have already received more applications than at the same time before the last event," reports Willy Viethen, Director Exhibitions POWTECH at NürnbergMesse. "Exhibitors who would like to be there in 2014 should contact us now to stake their claims to the desired stand positions."

POWTECH in Nuremberg in autumn 2014 will focus on cutting-edge technologies for screening, mixing, milling, dosing and conveying powder and bulk solids. All the associated processes from analysis and packaging to control and instrumentation are, of course, also present at the exhibition.

Over 700 exhibitors from more than 20 countries are expected at POWTECH 2014. This makes the exhibition the world's biggest presentation of mechanical processing technologies. The exhibitors at POWTECH benefit from extra synergies resulting from the parallel TechnoPharm, Europe's leading trade fair for sterile production processes in the pharmaceutical, food and cosmetic sectors. The unrestricted access of visitors to both exhibitions opens up extra opportunities for contact with these sectors too.

Visit to Nuremberg – the perfect round tour

POWTECH and TechnoPharm are known for very efficient and concentrated information exchange between manufacturers and plant operators. This will not change in 2014 either.

"After last year's changes, POWTECH 2014 is now geared to consistency: the hall allocation remains unchanged. So a tour of our exhibition park again opens up access to the whole world of powder and bulk solids technology," reveals Viethen. The two main entrances to the exhibition site will be open again in 2014 – one in the east of the site, the second directly opposite the underground station. POWTECH occupies halls 1, 4, 4A and 5, and TechnoPharm hall 9. Hall 6 is the mixed products hall again, as POWTECH and TechnoPharm exhibitors are mixed here.

NürnbergMesse GmbH
D 90471 Nürnberg

Beladeseite Sterilisation (HWP Planungsgesellschaft mbH, Fotograf: Peter Horn)

Entladeseite Sterilisation (HWP Planungsgesellschaft mbH, Fotograf: Peter Horn)

Increased Patient Safety through Optimized Hygienic Conditions

New Central Sterilisation at Füssen Hospital

The new, modern central sterilisation facility at Füssen Hospital which came into service at the turn of the year 2012/2013 was achieved after only eight months of planning and implementation, during ongoing operations and for an overall cost of 1.3 million Euros. With high standards of hygiene, new technology, improved sterilisation processes and ideal, spatial access to the surgical department; the project which was planned by HWP Planungsgesellschaft mbH (HWP) in Stuttgart and realized by the General Contractor Münchner Medizin Mechanik (MMM), delivers a solution which ensures the highest level of patient hygiene safety.

The sterilization of instruments at Füssen Hospital had previously been an outsourced activity taking place within the hospital's premises. Following the end of a business arrangement, the hospital management took the opportunity to restructure and fully integrate the sterilization within its own operations. In order to optimize processes, the new 300-square-meter central sterilization could now be attached directly to the surgical area, which is where central sterilization had been previously and successfully carried out in the 1970s.

Project Challenges

An essential challenge of the modernisation project was that the existing central sterilisation had to be gutted and rebuilt in close proximity to the surgical area and in-parallel to the ongoing surgical operation. Furthermore, the construction area had to be hygienically separated from the surgical area using of dust walls and the existing media supply needed to be completely dismantled, technically updated and rebuilt. Although the dismantling of the existing media installations led to numerous technical and structural restrictions, the new central sterilization went live, on schedule and within budget.

Central Improvements

Because the new central sterilisation is adjacent to the surgical area, clean and unclean transports are no longer necessary between the two areas in Füssen hospital. This proximity has also made communication between surgical and sterilization staff more direct, smoother and easier.

Furthermore, since the new spaces benefit from natural day lighting and views of the rural area, the sterilisation staff have experienced considerable ergonomic improvements in the workplace. „Considering that our team previously worked in interior rooms with no natural lighting, this is obviously a significant improvement and a motivational factor for us." says Deputy Head of Department Central Sterile, Yvonne Stuhlreiter, about the new work environment.

The renovation and relocation of the sterilisation unit offered further opportunities for employee orientated improvements. These included HVAC improvements and the procurement of height-adjustable tables, which increased employee comfort. Advanced storage options for the interval-storage in the packing area, and hygienically perfect storage of administrative documents could also be realised.

With the creation and expansion of the new space, hygienic standards could also be significantly increased. „Füssen Hospital now contains the latest technical equipment available that we have fully technically connected." says Walter Bischoff, medical equipment planner at HWP „With this the sterile documentation in terms of a continuous, seamless patient-related sterile documentation underwent a full update." With this shor-

p. 2 : New Central Sterilisation at Füssen Hospital

ter and improved sterile goods logistic, the effectiveness of the internal processes of the hospital are increased At the same time, the new design and layout of the central sterilisation allows the strategic, future possibility of being able to supply external parties, such as GPs‘ offices, with their sterile goods.

Summary and Outlook

The reconstruction of the central sterilisation unit constitutes the first fundamental steps towards the modernisation of the Füssen Hospital. This longer term development plan will see the service spectrum of the facility become both further specialised and extended.

HWP Planungsgesellschaft mbH
D 70190 Stuttgart

Interview with Hospital Director Martin Wiedemann

“Central Sterilisation leads to Numerous Improvements.”

Since February 2013 Martin Wiedemann, in addition to his role as Care Manager, has taken on the function of the Hospital Director at the Füssen location, part of the network of hospitals in the Ostallgäu-Kaufbeuren. In an interview answers to the following questions were given:

What challenges did the new central sterilisation project face and how did you overcome them?

One major challenge was that we had very little time available for the project, from planning to completion. Thanks to the tightly integrated cooperation and continuous coordination between HWP and MMM, we were able to keep our tight schedule.

Other challenges resulted from the fact that we had to rebuild directly on the OR during on-going operation. This task required a lot of mutual understanding between the staff and the planning team, as conversion activities and noise pollution was inevitable.

What changes does the new central sterilisation bring to Füssen Hospital?

The new system technology increases our sterilisation efficiency and hygiene standards. The new concept for material and personnel locks also improves hygiene conditions overall. On top of that, due the close proximity the new central sterilisation to the surgical department, the transport routes for surgical instruments, for example are drastically shorten. Simultaneously, the new spatial arrangement also ensures closer links between our surgical department and the central sterilisation. The surgical staff can, for example, survey the prepared instruments before surgery and gain insights into the central sterilisation preparation processes. In addition to the personnel synergy, we‘ve achieved a more deliberate material disposal for the surgical instruments. As you can see, with the new central sterilisation, numerous improvements for the staff and to the processes have already been achieved, aspects which we want to develop further in the future.

What are your firm plans for here in the future?

With the new central sterilisation and its proximity to the surgical department, communication and processes between the personnel of both departments have been so promising that we are planning a new organisational structure. We are striving for a common team structure for the central sterilization departments, surgical and anesthesia.

Z.ZYKLON - the new all-round system for making non-glued disposable syringes

The working model of the Z.ZYKLON system shown at the Zahoransky stand enjoyed a very favourable reception among the technically versed visitors to the K Fair. The new Z.ZYKLON system for making disposable syringes is an integral automation solution in modular construction. The system serves the separation and non-glued encapsulation by injection molding of disposable syringes. Both the NFS (needle feeding system) and the injection molding unit are integrated in the Z.ZYKLON system.

Visitors to Zahoransky's trade fair stand were thrilled with the system on display. They showed a keen interest in the integrated all-round solution, beginning with the needle isolation via the mold, the actual injection process right through to the individual control with integration capability of the non-glued disposable syringes. Experts were equally fascinated by the easy exchangeability of the NFS with other types of needles and applications. Visitors were amazed at the silent running of the unit in function and were also full of praise for its environmental friendliness. The unanimous opinion among the visitors to the fair was that, all in all, the Z.ZYKLON unit features innovative engineering and crucial advantages compared with many competing systems.

As supplier of systems with a broad range of products and items of equipment, Zahoransky AG delivers a large number of upstream and downstream assemblies for the fully automated production of non-glued disposable syringes, under the motto "all from a single source" - from the granule infeed to wrapping and packaging the finished parts. All from a single source also means: all peripheral modules are fully controlled via the central, user-friendly SPC process control.

The NFS integrated in the complete system features a modular structure, capable of handling both needles and puncture aids of varying lengths and different diameters. As an option, even needles with ground surface can be automatically aligned and eventually be transported to downstream processing. Needle singularizing from the magazine follows the first-In – first out principle (FIFO), ensuring that the needles are not stored for excessively long periods. Also, retracing the batches is made a great deal easier, if this should be required.

The needle feeding system (NFS), the ideal singularization for small to medium batch sizes, is available to segregate between 4 and 16, optionally also as many as

Glueless produced disposable syringes

32 needles or puncture aids. Currently, the maximum output is 400 syringes per minute, with the annual output of the Z.ZYKLON system adding up to as many as 55 million units. It is made to comply with clean room specification 8, which usually allows production in the medical categories 1 and 2. With additional equipment and outlay, production in medical category 3 is also possible.

Using a specially developed horizontal rotating table with eight stations, the singularized needles are automatically fed to the various processing steps. In station 1, the singularized needles are placed into a terminal socket strip via the NFS system, the center piece of the Z.ZYKLON total system, and carried to station 2 where the needles are camera-inspected and checked for completeness, correct position and integrity. The next station (3) features the injection molder with the injection mold built in-house. This is where the needles are placed into the mold for sheathing and removed after the injection molding step. Stations 4 thru 6 serve more optional needle checks and inspections, for example checking the pull-out force. Station 7 delivers the good parts to the downstream automation. NOK parts (bad parts) are ejected in station 8. With the appropriate requirements and specifications, NOK parts can also be transferred in a controlled way before being handed over to the downstream automation unit. In one more automation unit, good parts are processed further for siliconing, assembling, final control right through to blister packing.

Complete value added chain from a single source

With its new Z.ZYKLON system, the company is superbly positioned to handle a wide variety of different applications in needle and lancet applications. From mold-making via system engineering with various different solutions for automating processes right through to blister wrapping the finished parts, the company offers the complete production sequence and therefore the whole value added chain from a single source. This system approach is unique worldwide: chaining processes speeds up the production process, creates process stability and enhances productivity - all of these offering a decisive competitive edge.

ZAHORANSKY AG Systemtechnik
D 79108 Freiburg

Z.ZYKLON automized system for disposable syringes

Faster and more differentiated than turbidimetry

Quality control of potable water through Automatic Particle Counting

The German company Pamas develops, manufactures and distributes Automatic Particle Counters for fluid cleanliness control, e.g. of hydraulic or lubricating oil, fuel, pharmaceutical liquids like infusion solutions, WFI (Water for Injection) and process water. For dedicated water applications, the company offers both portable and online measuring instruments. Portable instruments for water applications are the particle counters of the Pamas S4031 product series. For online measurement of water, the Pamas product range provides the Pamas WaterViewer fulfilling the specific requirements for water quality control: This online particle counter is the ideal instrument for the analysis of potable water, process water, purified waste water or raw water. The Pamas WaterViewer has been tried and tested for water applications throughout Europe for many years and has become the trusted measuring instrument for use in water treatment plants and water distribution networks. Pamas Automatic Particle Counters (APCs) deliver faster and more accurate measuring results than turbidimeters or nephelometers. They also provide a more sensitive, differentiated measuring result: Beyond the collective amount of particles, an APC detects, counts and measures each and every single particle. In an online environment, the trending of these results shows much more interesting events.

There are various existing methods to determine whether water is clean and free from particulate contamination. In water treatment systems, both particle counters and turbidimeters or nephelometers are used for water quality control. Turbidimeters and nephelometers measure the collective amount of solid contaminants in liquids. The more turbid a liquid is, the higher the measuring value will be. Contrary to this, Automatic Particle Counters do not measure the collective amount of solid particles, they analyse size and quantity of each single particle which is part of that population in the online sample flow. The knowledge of the particle sizes is of paramount importance in water applications, as it helps to quickly identify certain types of bacteria or even a failure in the system (e.g. break-through of a membrane filter in case of an above average number of large sized particles). The Automatic Particle Counter thus gives more versatile and significant results than a turbidimeter.

The company specialises in liquid particle counters and develops, manufactures and distributes Automatic Particle Counters, designed for fluid cleanliness control. The extensive Pamas product range provides more than 20 different particle counting models for multiple applications. Besides the most widely used models, which are applied in contamination control of hydraulic fluids, fuel and insulation liquids there are more specialised models for the determination of filter efficiency (beta-ratio analysis) and parts cleaning. Fluid cleanliness control in the pharmaceutical industry and water quality control in water treatment plants are other applications within the extensive uses of Automatic Particle Counters.

One instrument of the its product range especially designed for water applications is the Pamas WaterViewer. This unit takes measurements online and is installed as a fixed stationary instrument for water condition monitoring. The system is used for the cleanliness control of potable water, raw water and purified waste water or process water. For condition monitoring, the device may be connected to up to 32 measuring points. With the aid of microprocessor controlled valves, it is easy to change between measuring points and bypass connections. The WaterViewer may be fitted optionally with an automatic Sensor Flushing Unit, the Pamas SFU. This attachment will automatically remove mineral deposits (e.g. manganese, calcium, iron oxide, etc.) from the optical cell windows which may otherwise diminish the laser light beam. The instrument stays in action round the clock without anyone having to take care of it. The instrument configuration can be set up according to the customer's requirements: Depending on the user-specific application, the device may be equipped with different particle sensors with different sensor specifications. The sensor Pamas HCB-LD-25/25 for example, analyses particle sizes between 1 and 200 µm.

The Pamas WaterViewer has been tried, tested and trusted for many years and considered by many users as an accurate and reliable measuring instrument for water applications. It was screened and chosen by the Dutch KWR Research Institute (former KIWA) in 2005. Since then, a multitude of existing publications and scientific papers prove that the device is used for scientific research at many universities in Europe (e.g. at the Technical University Delft in the Netherlands, at the University of Lorraine in France and at the University of Kuopio in Finland). As an example, the Pamas WaterViewer helped to identify relevant factors for the ideal construction of water distribution pipeline systems and the most efficient filtration speed required in pool water treatment.

01st - 04th April 2014:
Analytica 2014, Munich (D)

The Pamas WaterViewer is an automatic particle counting system designed for water applications. The instrument has been tried, tested and trusted for particle analysis of potable water, raw water, process water and waste water. For continuous condition monitoring, the measurement is performed online during operation. The online particle counter gives instantaneously alerts if pre-defined limits are exceeded. With the aid of the optional Multiplexer unit, the device may be connected to up to 32 measuring points and thus is able to monitor up to 32 waterlines.

PAMAS Partikelmess- und Analysesysteme GmbH
D 71277 Rutesheim

The Dialog starts: Does medical technology need new concepts for validating cleanliness?

25 February 2014
Fraunhofer IPA, Stuttgart

The aspect of cleanliness is deeply rooted in medical technology and regulations have been in existence for many years now. Despite this, problems due to inadequate product cleanliness still occur. There are also issues related to manufacturing technology where excessive cleanliness requirements are sometimes made. In this field of conflict, the following question arises: how to achieve a compromise on limiting values that ensures maximum patient safety but also allows meaningful and reliable results to be attained in production using validated test procedures?

Topics
- Threshold validation versus practical cleanliness limiting values
- Technical discussion with you as an expert

Goal
To initiate a dialog about new, practice-orientated procedures for assuring the quality of product cleanliness

Target Group
People from the entire supply chain of medical products who are responsible for quality, cleanliness, analytics and certification

Contact
Fraunhofer Institute for Manufacturing Engineering and Automation IPA
Dr. Markus Rochowicz
Nobelstr. 12 | 70569 Stuttgart | Germany

Venue (Workshop Language is German)
Fraunhofer Institute for Manufacturing Engineering and Automation IPA
Nobelstrasse 12, 70569 Stuttgart, Germany
Lecture Theaters A+B

Registration
To register for the event, please use the following link: http://www.ipa.fraunhofer.de/Braucht_die_Medizintechnik_neue_Ansaetze_fuer_die_Reinheitsvalidierung.2581.0.html

Survey on the topic of validating cleanliness in medical technology
www.ipa.fraunhofer.de/medizintechnik

Fraunhofer-Institut für Produktionstechnik und Automatisierung IPA
Nobelstraße 12
D 70569 Stuttgart
Telefon: +49 711 970 1863
E-Mail: nicole.goeldner@ipa.fraunhofer.de
Internet: http://www.ipa.fraunhofer.de

Idaho Transportation Department and Vaisala recognized for exemplary highway program

Vaisala's collaboration with the Idaho Transportation Department has been recognized by the Road Safety Foundation and the United States Federal Highway Administration (FHWA) as winners of the biennial National Roadway Safety Awards. The award winners were chosen for reducing fatalities and injuries on roadways through excellence and innovation in operations, planning, and design.

The Idaho Transportation Department, using Vaisala's pavement sensors that calculate grip or friction values, discovered that this value can also be used to measure the success of the department's winter road maintenance operations. Idaho personnel developed several benchmark indexes that calculated operational performance, and were able to normalize any variance caused by storms and seasons. Vaisala supported this development by integrating the indexes into their RoadDSS Navigator software which allows for quick review of the indexes alongside other decision-making tools.

„Vaisala strives to develop and apply the latest technological advancements, not only on our own, but by helping solve the challenges our customers face", says Paul Bridge, Offering Manager and Meteorologist for Vaisala Roads. „We are very proud to hear that our technology has been acknowledged as the most innovative in the industry. This is very much our goal with regards to providing information services; working with our client to develop additional value from our sensing technology. You know it's a winner when our client refers to us as their partner."

Vaisala's road weather system provides real value to winter maintenance operations in Idaho. „We had a pretty significant year, this year (2012-13), and preliminary estimates, appears that we have had a 10-20% reduction in our seven (7) million dollar chemical usage budget," says Dennis Jensen, Mobility Services-Winter Maintenance Coordinator, Idaho Transportation Department.

Vaisala GmbH
Adenauerallee 15
D 53111 Bonn
Telefon: +49 228 249710
Telefax: +49 228 2497111
E-Mail: vertrieb@vaisala.com
Internet: http://www.vaisala.com

Vaisala releases the Advanced Total Lightning sensor, the latest in Precision Lightning Geolocation Technology

Vaisala introduces its new Advanced Total Lightning(TM) sensor, the LS7002, offering the latest in precision lightning technology. It is the first, non-VHF, lightning detection sensor to detect Total Lightning and, at the same time, correctly differentiate between cloud and cloud-to-ground lightning. The sensor is designed to operate as part of a network to provide real-time data for operations focused on tracking cloud and cloud-to-ground lightning threats to ground-based and airborne assets. The sensor is suitable for meteorological and climatological measurements, as well as applications in aviation, telecommunications, power utility, defense and forestry.

Unparalleled Lightning Detection Efficiency

The Vaisala LS7002 sensor detects low frequency (LF) electromagnetic signals generated by lightning. The sensor is designed with extremely precise geolocation capability, as well as industry-leading measurement accuracy of lightning strength and lightning type classification. The LS7002 also offers calibrated lightning parameters, and the sensor does not require calibration during normal operations, which leads to cost savings without any operational breaks.

An LS7002 network uses a patented combination of time-of-arrival and magnetic direction finding techniques to deliver superior detection efficiency, optimal location accuracy, with excellent system redundancy, while still utilizing fewer sensors - no other company provides this blend of cost efficiency and scientifically validated best performance. Vaisala lightning technology means that a larger area of coverage can be monitored with fewer sensors, providing a detection system with lower lifetime network ownership costs than any other technology.

In addition, an efficient, lightweight electronics module allows for easy installation and maintenance with stand-alone, rooftop and indoor electronic mounting options. When working in severe weather locations, the sensor electronics can be installed separate from antenna installation.

Advanced Total Lightning(TM) Network

Whenever a new Vaisala lightning sensor is introduced, such as the LS7002, Vaisala also uses the opportunity to update its Total Lightning ProcessorTM (TLP). This processor is used within Vaisala's lightning detection networks and is designed to provide data for a wide range of applications. The TLP allows users the flexibility to select features that are best suited for their requirements. Licenses are available for the following TLP(TM) features, including: system and sensor performance monitoring; network performance mapping; as well as detection efficiency (DE) and location accuracy (LA) projections. There is also an advanced lightning type classification option for „burst" processing and advanced waveform parameters.

These features provide more efficient network operations, stabilized performance, and deliver advanced information with regard to geolocated lightning events. The TLP100(TM) Series processes data from Vaisala's low frequency (LF) sensors delivering unmatched performance; detecting, characterizing and classifying cloud pulses and cloud-to-ground strokes. The TLP200(TM) Series processes data from both Vaisala's LF and very high frequency (VHF) sensors providing Total Lightning Mapping solutions, including the full spatial extent of any lightning threat.

Vaisala GmbH
Adenauerallee 15
D 53111 Bonn
Telefon: +49 228 249710
Telefax: +49 228 2497111
E-Mail: vertrieb@vaisala.com
Internet: http://www.vaisala.com

Christian Pum, CSO of the Engel Holding GmbH in Austria, has decided to resign from his position and will leave the company at the end of this year to accept new challenges in a different industry. Dr. Christoph Steger, former Vice President for Engel's Business Unit packaging, has been appointed as the new CSO.

Engel Appoints New Chief Sales Officer

Christian Pum joined the company in 1991 and has been CSO since 2006. During his time as CSO, Mr. Pum contributed significantly to the worldwide success of Engel. „We thank Mr. Pum for his great achievements and his commitment", highlights Dr. Peter Neumann, CEO of the Engel Holding. „We regret to inform you of his departure, but of course we respect his decision and wish him good luck and all the best in his new challenges."

Dr. Christoph Steger takes over all responsibilities from Christian Pum effective immediately. Mr. Steger joined the company at the beginning of 2012 and had since lead the Business Unit packaging with great success. Under the leadership of Christoph Steger, Engel packaging has experienced a continuous substantial growth, providing injection moulding solutions to the plastic packaging sector.

Together with Dr. Peter Neumann, third-generation-member of the Engel family holding, now the fourth generation in management with Dr. Christoph Steger and Dr. Stefan Engleder (CTO) bears operational responsibility. Since its foundation in 1945, the company has been 100 percent family-owned.

ENGEL AUSTRIA GmbH
A 4311 Schwertberg

Dr. Christoph Steger, formerly Vice President Business Unit packaging, has been appointed newly CSO of the Engel Group.

Arburg demonstrates production efficiency at Swiss Plastics

- **Established team: electric Allrounder 370 E and servo-electric Integralpicker V as high-performance unit**
- **Always efficient: plastic parts production with Arburg solutions**
- **Exciting specialist presentation: Herbert Kraibühler, Managing Director Technology & Engineering, introduces the new Freeformer**

Production-efficient manufacture can only succeed with the appropriately configured machines. Arburg consistently puts this philosophy into practice in its product range. At the Swiss Plastics trade fair, which will take place in Lucerne from 21 to 23 January 2014, the company will present an cost-effective injection moulding solution for technical precision parts: an electric Allrounder 370 E injection moulding machine with servo-electric Integralpicker V. Furthermore, visitors to the Swiss Plastics fair will have an opportunity to see the new Freeformer for themselves as part of a specialist presentation. This unique system for additive manufacturing will be introduced by one of its creators, Arburg Managing Director Technology & Engineering Herbert Kraibühler.

21st - 23rd January 2014: Swiss Plastics fair Lucerne (CH)

"The production of moulded parts in optimal quality at minimum unit costs and the search for potential optimisation measures are important issues for our customers," explains Marcel Spadini, Managing Director of Arburg's Swiss subsidiary: "That's why the topic of production efficiency is always a priority for us. All potential for enhancing energy efficiency, reducing cycle times and optimising manufacturing organisation contributes to the improvement of part production. This is precisely what will be demonstrated by our exhibit, an electric Edrive series Allrounder with a servo-electric Integralpicker V. The electric drives and the precise coordination of all components produce benefits in terms of energy efficiency, precision and cycle times."

Edrive: cost-effective entry into the world of electric machines

Edrive (E) is the entry-level machine series into Arburg's electric machine world. These machines can be used to solve demanding injection moulding tasks precisely and cost-effectively. The clamping force range extends from 350 to 5,000 kN and can be combined with the various sizes of the injection unit on a modular basis. Energy requirements of up to 50 per cent less than with hydraulic machines, combined with an attractive cost/benefit ratio, make the Allrounder E a functional alternative to hydraulic machines.

The exhibit on show at Swiss Plastics is an Allrounder 370 E with a clamping force of 600 kN and a size 170 injection unit, which is equipped with a highly wear-resistant thermoplastic cylinder and a 30 millimetre screw. The machine operates with a precision mould made by Stamm and produces two 8.5 gram housings for knife sharpeners in a cycle time of 23 seconds.

Automation: servo-electric Integralpicker V for fast interventions

The Integralpicker V is the perfect complement for the powerful Allrounder 370 E with its fast vertical intervention options. The robot system offers low-cost entry into automated part removal. Three servo-electric axes permit fast, precise intervention. The features of this picker include simultaneous, freely-programmable machine movements, as well as high dynamics, repeat accuracy and energy efficiency. The standard teach-in function is a quick and easy way to program the picker, resulting in short set-up times.

Individual solutions ensure production efficiency

"Production efficiency calls for customised solutions. However this is not to say that mean that these can't be economical and cost-effective," explains Marcel Spadini. "We're providing a good example of this with the combination of electric Allrounder 370 E and servo-electric Integralpicker V. Here, energy efficiency, speed and precision are brought together in a configuration that is also extremely attractive in terms of price. Anyone looking to get started in automated production and wishing to use high-end injection moulding technology will be able to

pick up some interesting tips from Arburg live at the Swiss Plastics. By talking to our specialists, they will also find out about alternatives that we can precisely tailor to achieve production-efficient manufacturing at their plant."

Expert presentation: an in-depth look at the Freeformer

Another highlight from Arburg will be the Freeformer presentation on Wednesday 22 January 2013 at 3.20 p.m. in Forum 1. This unique additive manufacturing system will be introduced by one of its creators, Arburg Managing Director Technology & Engineering Herbert Kraibühler. The Freeformer and the Arburg Plastic Freeforming process (AFK) caused a sensation in the international plastics world when they made their international debut at the K 2013. With AFK, 3D CAD files are processed directly, standard plastic granulate is melted in an integrated manner as in the injection moulding process and droplets are generated from the liquid melt. These droplets are then used to additively build up the fully functional component layer-by-layer, without requiring a mould. This enables the cost-effective individual manufacture of parts completely without injection moulds, either as one-off parts or in small-volume batches.

ARBURG GmbH + Co KG
D 72290 Loßburg

ACREX India 2014 takes a stand for eco-friendly building services

- **HVAC&R with related building services at ACREX India 2014**
- **More than 450 exhibitors and 50,000 visitors expected**
- **fensterbau/frontale india parallel to ACREX India 2014**

When South Asia's largest exhibition on Air Conditioning, Refrigeration & Building Services, ACREX India 2014, will open its doors February 27 to March 1, 2014 it will set an example for moving towards a carbon-neutral HVAC&R industry. ACREX India is going to reduce its carbon footprint with the help of its exhibitors from Asia, Europe and North America. 10,000 trees will be planted all over India to compensate CO2 emissions created in the course of the event. ACREX India 2014 is organized by the Indian Society of Heating, Refrigeration and Air Conditioning Engineers (ISHRAE) and NürnbergMesse India.

27th February - 01st March 2014: ACREX India 2014, New Delhi (India)

The construction industry is India's second largest industry after agriculture, which has traditionally been the country's largest economic factor. With its expanding economy and its high urbanization rate, India is in need of extended infrastructure, a requirement strongly supported by government funding. Today, 32 million people in India are employed by the construction industry, whose growth is expected to stay strong over the coming years.

ACREX India 2014 offers the construction industry the perfect platform to link its various sectors with international partners. The exhibition, which has grown rapidly over the last few years, will host country pavilions from the USA, Germany, Italy, Korea and China. Additionally, exhibitors from Czech Republic, France, Malaysia, Netherlands, Saudi Arabia, Switzerland, Thailand, UAE, UK and Ukraine have already signed up for participation. "With ACREX India, we provide a platform for our local products and services while also exchanging expertise and information in the building services sector internationally," says Sonia Prashar, Managing Director of NürnbergMesse India.

ACREX India 2014 not only showcases products and developments from the HVAC&R industry but also from allied building services including plumbing and fire safety, and window and facade products. These are at the centre of the concurrent exhibition fensterbau/frontale india, which ACREX India participants can visit free of charge.

Plant a tree for carbon neutrality

In line with ACREX India's traditional focus on energy-efficient technologies, its organizer ISHRAE will set an example for responsible use of natural resources. The organizer will sponsor the planting of 10,000 trees across India, resulting in a huge reduction of the trade show's carbon foot print. The trees will be planted by the Indian NGO Sankalp Taru. ISHRAE is subsidizing the costs for most trees, supplemented by contributions from the exhibitors. The trees can be located via GPRS supported tags and their growth can be monitored over time. The names of those contributing will be tagged on the trees which will be looked after by local farmers, who will in the end also harvest the yield.

By planting a tree, exhibitors therefore not only reduce the carbon emissions of the trade fair, but also contribute to the environment on a long-term basis, while supporting local farmers and their families. "With this initiative we want to set an example not only for our show, but for the whole industry. At ACREX India 2014, we are taking a great step towards the future," explains Ashish Rakheja, Chairman of ACREX India 2014.

Focus on renewable energies

In addition to reducing its carbon footprint, the exhibition also focuses on renewable energies, such as photovoltaic, tidal and wind energy, and their use and application fields in the HVAC&R industry. To visualize this endeavor, the organizers of ACREX India will be establishing an Innovation Gallery – a pavilion constructed from reusable bamboo poles and jute rope, showcasing India's first (Self-) Sustainable Township of its kind. The pavilion will highlight both passive and active design strategies to be used on an architectural as well as on an urban design scale. Furniture made from waste material will decorate the pavilion along its axis, transforming the passage into a comfortable stay. Interplay of corridor space and niches on both sides, created by varying the width of the structure, will provide zones where one can rest and enjoy the local scenery and exhibition. Ashish Rakheja says: "It is our aim to encourage the industry to follow the principle of three Rs in their business as much as possible: Reduce, Recycle and Reuse!"

Thinking the future at ACREX India 2014

The exhibition not only provides an internationally renowned setting to showcase products and developments; concurrent to ACREX, India ISHRAE also organizes a rich workshop and conference program. One of the key conferences is on "Green Buildings", supported by the Indian Ministry of New & Renewable Energy. Its aim is to raise interest among engineers, students and industry experts towards energy-efficient buildings. There will be several other workshops on topics like Geothermal Systems – Design Considerations, Energy Security – Renewable or Hydrocarbon, Hospitals & Critical Healthcare Facilities – HVAC systems design, Cool Thermal Energy Storage in the Era of Sustainability, BIM – Building Information Modelling and Seismic Considerations in Building Design.

A powerful duo: ACREX India in parallel to fensterbau/frontale india

fensterbau/frontale india will again be held concurrent to ACREX India at the Pragati Maidan Exhibition Centre in New Delhi. The international exhibition for windows, doors, façades and related technologies, machinery and services is organized by NürnbergMesse India. With their complementary themes they are equally appealing to architects, planners and building experts. In 2013, 70 international exhibitors presented their latest products and technologies to an increased audience of about 5,640 qualified visitors.

NürnbergMesse GmbH D 90471 Nürnberg

Leading-edge technologies for hygienic processing

TechnoPharm 2014 in Nürnberg

TechnoPharm takes place again in the Exhibition Centre Nuremberg from 30 September to 2 October 2014 under the motto of "Pharma. Manufacturing. Excellence". Europe's leading innovation forum for sterile processing technology in pharmaceuticals, food and cosmetics tackles serious issues: What is the pharmaceutical industry developing to cure the problem of steadily rising costs? What can be done against the growing regulatory pressure? How do food manufacturers meet the consumers' need for more safety? Plant manufacturers and production specialists meet at TechnoPharm to discuss the latest developments ranging from sterile processes to packaging. One of the focuses of the trade fair is on cleanrooms. TechnoPharm 2014 takes place again together with POWTECH, the World-Leading Trade Fair for Processing, Analysis and Handling of Powder and Bulk Solids.

30th Sept. - 02rd October 2014: TechnoPharm 2014, Nuremberg (D)

"TechnoPharm stands for a concentrated specialist pharmaceutical exhibition with a focus on food and cosmetics. The claim and last year's relaunch of the event attracted a very good response among exhibitors and visitors. We want to use these positive signals in 2014 to establish Nürnberg even more firmly as Europe's gathering for pharmaceutical production experts," reports Willy Viethen, Director Exhibitions at NürnbergMesse. "So far more exhibitors have registered that at the same time for the previous year's event. So companies wanting to be there as exhibitors in 2014 should contact us now to make sure of the best places."

The Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik (APV – International Association for Pharmaceutical Technology), which supports the trade fair as honorary sponsor, is also already working flat out on the programme for TechnoPharm. "The requirements for pharmaceutical production call for investment – above all in more efficient processes and plant. And these are exactly the industry's hot topics that we must discuss in 2014," says APV President Prof. Dr. Jörg Breitkreutz. "We are working on a presentation programme that is broader and larger than ever before at TechnoPharm."

Products at TechnoPharm 2014 in Nürnberg:

- Plants and equipment for the manufacture of solid, semi-solid and liquid products
- Sterile and biotechnology plants
- Peripherals for sterile process technology
- Active ingredients and auxiliary materials
- Instrumentation, analytical and control systems
- Packaging technology, filling technology and packaging materials,
- Cleaning and hygiene products
- Industrial safety

The parallel POWTECH, World-Leading Trade Fair for Processing, Analysis and Handling of Powder and Bulk Solids, creates valuable synergies. The trade fair duo registered a large eight per cent more visitors in 2013.

NürnbergMesse GmbH
D 90471 Nürnberg

Vaisala Signs a Contract for Seven Weather Radars to Turkey

Vaisala has signed a contract to deliver seven dual polarization weather radars to Turkey. The contract with the Turkish State Meteorological Service includes WRM200 weather radars, installation services and training. The deliveries start during the summer of 2014 and will be completed by the end of 2016. The value of the deal is EUR 6.3 million.

„The Turkish State Meteorological Service is a long-term customer of Vaisala with whom we have been cooperating since 1990. We have earlier delivered six weather radars to Turkey. After the implementation of the new radars the Turkish State Meteorological Service will be able to serve the whole nation with high quality meteorological data and weather forecasts," tells Kai Konola, Executive Vice President of Vaisala Weather Business.

A weather radar is the single most effective device to observe rainfall. A dual-polarized radar distinguishes between different types of rainfall and between rain and non-meteorological objects, such as birds and insects. It also measures the intensity of precipitation more accurately, providing valuable information for local short-term weather forecasts, for example.

Vaisala GmbH
Adenauerallee 15
D 53111 Bonn
Telefon: +49 228 249710
Telefax: +49 228 2497111
E-Mail: vertrieb@vaisala.com
Internet: http://www.vaisala.com

parts2clean 2014 already growing strongly

- **12th parts2clean meeting with strong demand for stand space, both by German exhibitors and from abroad**
- **Added value from parallel staging of O&S and other trade fairs**

24th - 26th June 2014: parts2clean Stuttgart (Germany)

Following its record staging in 2013, parts2clean is headed for more growth in 2014. Demand for exhibition space appears to be even stronger due to the simultaneous staging of parts2clean alongside O&S and other related shows. By early December 2013, as many as 121 exhibitors had already reserved space for the 12th edition of the flagship trade fair for cleaning of industrial components and surfaces to be held from 24 to 26 June 2014 at the Stuttgart Exhibition Center.

"Four weeks after our participation in parts2clean 2013, we already have a number of excellent business deals in the making and soon to be closed. The previous year's fair went very well for us, but the total number of valuable business contacts we made this time is even higher," reports Gerhard Koblenzer, Managing Director of LPW Reinigungssysteme. Similarly positive feedback about post-show business could be heard from many other parts2clean 2013 exhibitors. This is certainly one reason why at the start of December, two-thirds of the available exhibition space has already been firmly booked. The exhibitor lineup already includes virtually all the market and technology leaders in each of the areas covered: systems, processes and process media, and their conditioning for degreasing, cleaning, deburring and pretreating of components, parts hoppers and workpiece containers; cleanroom technology; corrosion protection; conservation and packaging; contract cleaning services; quality assurance, test methods and analysis procedures. As a cross-industry and cross-materials showcase, the most recent parts2clean attracted some 4,982 trade professionals to Stuttgart – nearly 14 percent more than in 2012. These visitors hailed from a total of 49 European, American and Asian countries. Fully 90 percent of the visiting trade professionals are involved in purchasing and procurement for their organizations. No wonder exhibitors boast of such good post-fair business.

Parallel implementation with O&S raises attraction

Another reason for the high interest in stand space, according to Olaf Daebler, parts2clean General Manager for Deutsche Messe, is the parallel staging alongside O&S, the flagship trade fair for surface treatments and coatings. "Decorative and functional coatings play a significant role in all industrial sectors today, and properly cleaned surfaces are key to the quality of these coatings, whatever the processes used," explains Daebler. "That is why nearly every visitor to O&S is also a potential customer for parts2clean exhibitors, which opens up new market opportunities for these companies." This is also true for the two other trade fairs being held together with parts2clean and O&S in 2014 at the Stuttgart Exhibition Center: LASYS, the flagship trade fair for laser materials processing, exhibits the full spectrum of laser technology for every industrial application and type of material. Here too, clean surfaces are often of mission-critical importance. For some of the international audience at AUTOMOTIVE Expo – a combination of five trade shows aimed at the automotive sector – cleaning is also a key manufacturing process.

Bilingual technical forum – Cleaning expertise for added value

parts2clean draws users from around the globe not only as an information and purchasing platform, but also as a source of specialized know-how. They gain valuable expertise from the bilingual forum with simultaneous interpretation (German<>English) of presentations covering every aspect of industrial components and surface cleaning. Record participation of 2,181 attendees at parts2clean 2013 showed that international demand for cleaning expertise continues to be very high.

Deutsche Messe AG / Presse
D 70825 Korntal

This article presents how a good understanding of basic steam sterilization principles can help with avoiding most common mistakes made when using autoclaves.

Steam Sterilization Principles

Autor: Marcel Dion und Wayne Parker

Steam sterilization has been used for more than a century to sterilize items that can withstand moisture and high temperature. Steam is water in the vapor state; it is therefore non-toxic, generally readily available, and relatively easy to control. A good understanding of basic steam sterilization principles and cycles is necessary to avoid mistakes that can lead to non-sterile load items, poor performance of the equipment, personnel injury, lower productivity, higher operation and maintenance costs, and damage to load items. Steam sterilizers are used for numerous applications in the pharmaceutical and medical device industries. The focus of this article is saturated steam applications, such as laboratory media sterilization, decontamination, and general component sterilization. Terminal sterilization of parenteral liquid products or devices containing liquids may require processes using steam-air mixtures or super-heated water-air mixtures. These processes, as well as in-situ sterilization of tanks, filters, etc., are not addressed in this article.

Steam Sterilization Principles

Six factors are particularly critical to assure successful steam sterilization:
1. Time
2. Temperature
3. Moisture
4. Direct steam contact
5. Air removal
6. Drying

1. Time

The exposure (sterilization) time is a critical factor simply because all the organisms do not die at the same time. A minimum amount of time at sterilization temperature is required to kill all the organisms. Geobacillus stearothermophilus (Bst) spores are generally used to test steam sterilizer cycles because they are extremely resistant to moist heat sterilization. They are also non-pathogenic and commercially readily available. The number of survivors is usually plotted on a logarithmic scale. A straight line survivor curve such as the one shown in Figure 1 is typical.

The D-value (time to reduce the microbial population by 90%) for Bst should be 1.5 to 3.0 minutes at 121.1° C (250° F) (1). For purposes of discussion, we will use a D121 value of 2.0 minutes and a sterilization temperature of 121° C (250° F). A typical sterilization cycle will include an exposure phase of at least 20 minutes at 121° C (250° F) for a Sterility Assurance Level (SAL) of 10-4, assuming a starting population of one million (106) organisms. This means there is a one in ten thousand (10-4) chance of a single viable Bst spore surviving the process. For each additional two minutes of exposure at 121° C (250° F), the SAL is decreased by a factor of ten. The required SAL varies with application. Care should be taken to assure the correct SAL is targeted prior to cycle development. The actual bioburden of the products being sterilized will logically be killed faster than Bst. The resultant "overkill" is an accepted method for sterilization of durable items and should be used when possible(2).

2. Temperature

The second critical factor in steam sterilization is the temperature of the saturated steam controlled in the chamber of the sterilizer. Fi-

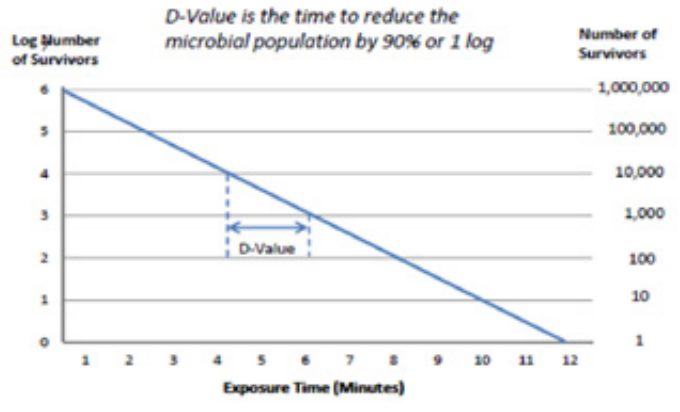


Figure 1. Typical survivor curve

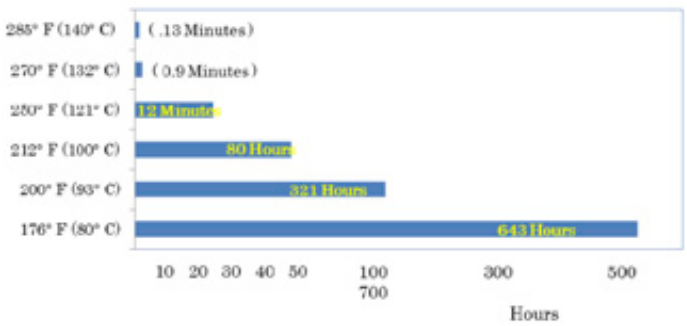


Figure 2. Sterilization time versus temperature

p. 2: Steam Sterilization Principles

gure 2 below clearly demonstrates how increasing the temperature dramatically reduces the time needed to achieve sterilization. Figure 2 illustrates approximately how much time is required to achieve equivalent microbial lethality (SAL 100 with a starting population of 106, D121 value 2.0 minutes) at different moist heat exposure temperatures(2). The temperature of saturated steam is directly related to the pressure at which it is controlled. The pressure-temperature relationship values are shown in saturated steam tables(4). A typical cycle at 121° C (250° F) will require 15 to 17 lbs of gauge pressure (103 to 117 kPa) in the chamber of the sterilizer. The gauge pressure required will be higher than the pressure shown in the saturated steam table due to air mixed with the steam and elevation above sea level. The maximum pressure in an autoclave is limited by the specifications (ASME pressure rating) of the pressure vessel (chamber and jacket).

3. Moisture

Moisture in the steam has a major impact on its ability to denature, or coagulate proteins; hence the importance of using saturated steam. Saturated steam is at equilibrium with heated water at the same pressure, which means it contains the maximum amount of moisture without liquid condensate present. Saturated steam is recommended for steam sterilization. Not all steam is acceptable for use in a sterilizer. A dedicated clean steam supply is recommended. Superheated steam, steam containing excessive liquid water, and steam containing excessive boiler additives or contaminates (such as rust) should be avoided. Superheated steam is defined as steam that is above its saturation temperature. Superheat occurs in steam distribution systems when the line pressure is dropped across a pressure reducing valve (PRV). The larger the pressure drop, the more superheat is created. Superheated steam does not contain the required moisture necessary to assure sterilization. The excess energy in superheated steam is transient and is eventually dissipated by the items in the sterilizer chamber, but can cause difficulty when validating the sterilizer to the empty chamber temperature stabilization requirements of the European Standard EN285(5). The ideal clean steam system for steam sterilizers is regulated at 30-35 psig (207 to 241 kPa) at the source. EN285 indicates the steam supply pressure should not be more than twice the chamber pressure at the desired temperature. Superheat is also created when saturated steam passes over a surface at a higher temperature. The sterilizer jacket temperature should always be set slightly below the chamber sterilization temperature to avoid superheating of the steam as it enters the chamber.

4. Direct steam contact

Direct steam contact with the surface of the object to be sterilized is required for the steam to transfer its stored energy to the object. Without direct steam contact to all surfaces, the item will not be sterilized. The amount of energy stored in steam is much higher than dry air or water at the same temperature. From the saturated steam table mentioned above, one can see that it takes 419 kJ/kg (180 Btu/lb) to heat water from 00 C to 1000 C (320 F to 2120 F). This is the enthalpy of water (hl). It takes an additional 2,257 kJ/kg (970 Btu/lb) to create steam at atmospheric pressure (1000 C or 2120 F). This additional energy stored in the steam is the enthalpy of vaporization (he), and is the key to steam sterilization. In order for the steam to transfer its stored energy, it must condense on the surface of the object being sterilized.

5. Air Removal

Air is the biggest deterrent to steam sterilization. Air must be removed from the chamber and the load before direct steam contact and sterilization can occur. This is accomplished in a steam sterilizer by a series of vacuum pulses prior to sterilization (pre-conditioning phase). A small amount of air will always be present in the autoclave chamber, but must be minimized. Insufficient air removal, sterilizer chamber vacuum leaks and poor steam quality (excess non-condensable gases) are the most common causes of sterilization failures.

6. Drying

Wrapped items must be dry before they can be aseptically removed from the sterilizer. Condensation is the natural result of steam contact with the cooler surfaces of the load during the heating and exposure phases. The presence of condensation (wet packs or pouches) can cause re-contamination of the load when removed from the sterilizer. A steam sterilizer dries the load after sterilization by drawing a deep vacuum in the chamber (post- conditioning phase). A vacuum level of 1.0 to 2.0 psia (6.9 to 13.8 kPa) is recommended for efficient drying. At 1.0 psia (6.9 kPa) chamber pressure, water boils at 38.7° C (101.7° F). Therefore, the condensate will boil and be removed as steam through the sterilizer's vacuum system. The energy required to boil the condensate comes from the load itself. As the temperature of the load cools due to evaporation of the condensate, evaporation (drying) decreases. When the load temperature cools to the boiling point of water at the drying vacuum level, drying is negligible. Adding further drying time past this point will not provide any further drying. Optimal load drying times depend primarily on load density and packaging. Due to their low density, plastic and rubber items may require additional drying, as they cool rapidly (pulsed air or heated pulsed air drying post-conditioning processes). The amount of residual moisture in a package can be determined by weighing the package before and after the sterilization process. Typically, verification of the absence of visible water droplets on or in the package is sufficient.

Steam Sterilization Basic Cycles

Steam sterilization cycles typically consist of three phases:

1. Pre-conditioning: during this phase, air is removed from the chamber and the load is humidified by means of alternating vacuum and pressure pulses.

2. Exposure: during this phase, the chamber temperature is raised to and held at the programmed sterilizing temperature for the programmed exposure time (both are user selectable). The exposure may also be controlled by accumulated Fo for liquids if a load probe and appropriate sterilizer controls are used. Refer to point #7 in common mistakes section below for more information on Fo.

3. Post-conditioning: during this phase, dry goods loads are cooled and dried or a liquids load is cooled. The chamber pressure is brought to atmospheric.

Over the years, various cycles have been developed for different applications. It is critical that the proper cycles be used.

- A basic gravity cycle (cycle without pre-vacuum) can be used for items such as unwrapped metal components, glassware, or non-porous items that do not entrap air.

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- Liquids require modified gravity cycles to prevent liquid loss from boiling over. Liquids in open or vented containers or in bottles with loose caps can be processed in a "basic" liquid cycle (with slow exhaust). The cooling (exhaust) phase of this cycle allows for the chamber to slowly return to atmospheric pressure to prevent boil-over as seen in Figure 3. Nominal liquid loss due to evaporation during the slow exhaust phase is typically 10 to 15%. The time required for the slow exhaust phase can vary considerably depending on the volume of liquid per container and per load. Larger volumes require slower exhaust rates. Use of a load probe and F0 exposure control is recommended. Vented containers only are to be used with this process.

Liquids are at or near boiling temperature at the end of a slow exhaust cycle and must be allowed to cool before the load can be safely removed from the sterilizer. Liquids in sealed containers require an air overpressure cooling cycle to prevent explosion of the container(s) during the cooling phase or unloading process as seen in Figure 3. Clean, dry compressed air (process air) is admitted to the sterilizer chamber at the end of the exposure phase and controlled at a pressure higher than the pressure of saturated steam at the temperature of the load probe. As the air flows over the load, the load is cooled and the chamber pressure starts to drop due to condensation of steam in the chamber. The supplied compressed air flow rate must be sufficient to maintain overpressure during the entire cooling phase. This "Air Cooling" process is highly recommended for sterilization of liquids in sealed OR vented containers because it eliminates evaporation and boil-over during the cooling phase. In addition, liquids can be cooled to a temperature safe for handling (600 C to 800 C or 1400 F to 1760 F) during the process by flowing water through the sterilizer jacket during the cooling phase. The load can be safely removed immediately upon cycle completion. The American Society of Mechanical Engineers (ASME) pressure rating of the sterilizer limits the amount of overpressure than can be utilized. Fill volume has a significant effect on the internal pressure of the sealed container. The lower the fill volume, the lower the internal pressure will be due to compression of the air in the head space of the container. The approximate internal pressure of a sealed container can be calculated using Robert Beck's equation (6).

- Since air is generally a deterrent to sterilization, a "Prevacuum" cycle (alternating vacuum and pressure preconditioning pulses) is recommended for all loads other than liquids.

(Figure 4)

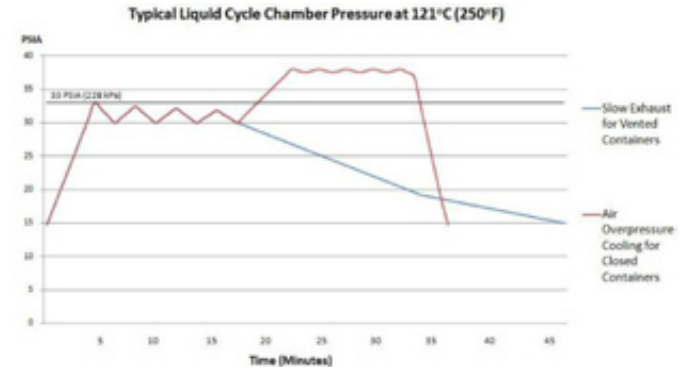

Figure 3. Typical liquid cycle chamber pressure at 121 °C (250 °F)

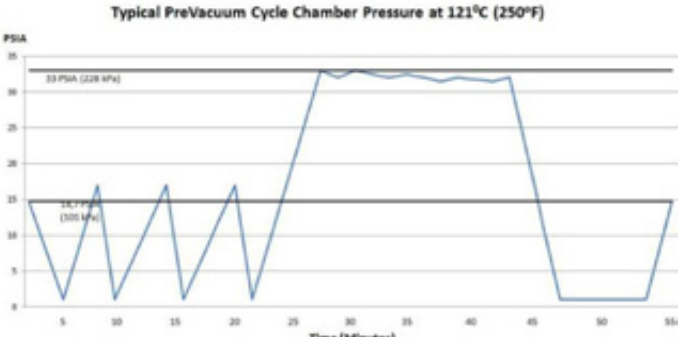

Figure 4. Typical prevacuum cycle chamber pressure at 121 °C (250 °F)

Measuring performance

Several methods can be used to verify the efficacy of the sterilization process. Typical methods use biological indicators (BI's) and chemical indicators (CI's) that are placed in worst case positions in the load and/or in test packs.

- Biological Indicators provide the best test for sterilization and are used to establish the efficacy of the cycle. In this category, we can find:

> Inoculated spore test strips. The strips must be aseptically transferred to an incubated growth media soon after the sterilization process is complete.

> Self-contained biological indicators (SCBI) (Figure 5). Because they are self-contained, SCBI's reduce chances for false positives due to poor aseptic transfer technique. They are typically used to monitor the effectiveness of steam sterilizing process.

> Glass ampoules are also used when the indicators must be placed in a liquid product to be sterilized (culture media as an example). (Figure 5)

- Chemical indicators provide immediate proof of steam penetration (not necessarily of sterilization). In this category, we can find:

> Autoclave tapes that show the process has occurred with no correlation to time/temperature.

> Chemical Integrators that are correlated to time and temperature. These particular indicators can help reduce cycle development time by providing immediate indication of sterilization efficacy.

- Steam penetration studies: Temperature sensors can be placed in hard to reach locations to provide indication of steam penetration.

Prevacuum sterilizers should be tested routinely for air leaks and air removal capability. Automatic chamber leak tests (vacuum hold

Figure 5. Self-Contained Biological Indicators (SCBI)

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tests) are typically provided in the software of modern prevacuum sterilizers, and should be run daily after a warm-up cycle. The sterilizer chamber is evacuated to the limit of the vacuum system (<1.0 psia or 6.9 kPa) and the chamber and associated piping are isolated (valves closed) for a hold period. The difference between the absolute pressure at the beginning and end of the hold period is the total leak rate. The leak rate should be < 1.0 mm (0.039 inches) Hg/minute (2). Hold time varies per procedures, from 10 to 30 minutes. It should be noted that a pressure rise during the hold phase is not always indicative of a chamber vacuum leak. Wet steam can cause condensate to be introduced into the chamber during the test preconditioning pressure pulses. Any condensate in the chamber will evaporate at the test vacuum level, causing a rise in chamber pressure. One practical way to determine the source of the pressure rise is to observe the leak rate during the vacuum hold phase with an absolute pressure gauge connected to the sterilizer chamber. An air leak rate will be fairly constant over the vacuum hold period. A pressure rise from evaporation of condensate will result in a high rate at first, and then will diminish as the condensate is evaporated.

In addition to the vacuum hold test, a challenge test such as the Bowie-Dick test should be run periodically as seen in Figure 6. The challenge test is different from a vacuum hold test in that it challenges the sterilizer to remove the air from within a dense package and displace the air with steam. It is fairly uncommon for a sterilizer to pass a vacuum hold test and fail a challenge test, but it has been observed. Insufficient air removal during the prevacuum phases and/or poor steam quality (excess entrained non-condensable gases, superheated steam or wet steam) can cause this anomaly. Challenge tests are temperature specific, and tests designed for 1320 C (2700 F) will not function properly in a 1210 C (2500 F) test cycle.

The Ten Most Common Mistakes in Steam Sterilization

Most mistakes regarding the programming and operation of typical steam sterilizers are related to the basic principles of steam sterilization.

1. Containers with closed valves, empty glass bottles with tightened screw caps or secured aluminum foil are placed in the sterilizer.

As a result, steam cannot directly contact the inside surfaces and sterilization does not occur. This problem can be resolved by assuring that all items in the sterilizer have a way for the steam to get in and the air to get out. If there is uncertainty about whether an item's configuration, set-up, packaging, or orientation will allow adequate steam penetration, a thermocouple, chemical and/or biological indicator can be placed inside the item to be certain.

Figure 6. Bowie-Dick test pack

2. Pouched and/or heavily wrapped items are tightly packed in the chamber.

As a result, air may remain trapped in the items after the preconditioning phase and prevent sterilization. Items should not be overwrapped, and sufficient space should be maintained between load items. The preconditioning vacuum and pressure pulses must be set correctly to attain complete air removal from the load. Typically, four (or more) preconditioning vacuum pulses should be programmed to reach at least 28 in (711 mm) Hg vacuum ((1.0 psia or 6.9 kPa (absolute)) to assure sufficient air removal for worst case loads. Some very dense loads may require a short (2 to 5 min) hold phase at peak preconditioning vacuum to allow time for trapped air to be removed. Preconditioning pressure pulses should be programmed for 3 to 5 psig ((21 to 34.5 kPa (gauge)). Higher pressures set for prevacuum pressure pulses can result in an excessive amount of superheat and difficulties with temperature stabilization during the first few minutes of the exposure phase.

3. Heavier items are placed on top shelves.

Water droplets and/or stains are observed on the outside of wrappers of items placed on the mid to lower shelves after the sterilization cycle is complete. Because the items are not dry, they cannot be aseptically removed from the sterilizer. Condensation is the natural result of steam contact with the cooler surfaces of the load. The condensate will fall from shelf to shelf. The denser the load item, the more condensate is created. Therefore, place heavier items on the bottom shelf. In addition, consider placing a cotton sheet or lint free towels on each sterilizer loading cart shelf prior to loading to allow the condensate to be absorbed. This also aids in drying. As the condensate wicks into the sheet or lint free towels, the condensate surface area is greatly increased and evaporates much more rapidly during the drying phase than the same amount of condensate in a droplet or a puddle.

4. Load is too dense or items are positioned incorrectly in the load.

As a result, wet or damp items are observed at the end of the cycle. Wrapped items positioned so that condensate is allowed to collect will not be dried. Items should be positioned so that the condensate is allowed to flow downward. Items (wrappers, pouches, filters, or other porous biological barriers) that remain wet at the end of cycle cannot prevent contamination of the load when removed from the sterilizer. As the load cools outside the sterilizer, the water in the wrapper will be drawn into the wrapped item. Any contamination that is present in the environment can be drawn through the sterile barrier along with the water. There are numerous other possible causes for wet loads. The most common are:

a. Insufficient drying vacuum level or time programmed

b. Rubber or plastic items in pouches

(i.e., rubber stoppers, plastic tubing) may require additional drying (a pulsed-air or heated pulsed-air drying process is recommended for these items)

c. Wet steam:

While there is no single solution to eliminating wet loads, it's likely that experimenting with drying time, repositioning items, reducing load density, modifying cycle settings, and investigating steam quality will resolve the problem.

5. Pouches are placed flat on the sterilizer shelves or stacked on top of one another.

As a result, pouches may have water droplets inside and cannot be aseptically removed from the sterilizer. Typical cause is when the

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condensate naturally created when steam penetrates the pouch and contacts the surface of the item within is not removed during the post-conditioning drying phase. Pouches should be spaced properly and placed in rack that holds the pouch on its edge (Figure 7) to prevent pooling of the condensate inside the pouch. Pouches should not be placed flat on the sterilizer shelf. Pouches should not be overloaded. Remember that more mass means more condensate.

Sufficient drying vacuum level and time should be programmed to allow for complete evaporation of the condensate. Wet steam should be corrected. Double pouching may require additional prevacuum pulses with dwell time at maximum vacuum and increased drying time. Doubled pouches should never be assembled so that the items inside cannot be seen. Pouch flaps should not be folded over.

6. Liquids in vented containers are placed in a deep pan to catch boil-over (slow exhaust cycle)

The pan will hold water, therefore it will hold air. The steam cannot contact the surfaces within the pan because of the trapped air, and they will not be sterilized. The solution is to eliminate the pan and adjust the sterilizer slow exhaust rate to prevent boil-over. A shallow pan, less than 1" (25 mm) deep, can be used in the event that a small amount of boil-over cannot be eliminated by adjusting the slow exhaust rate.

7. "Overcooked" Media

Over sterilization of media will caramelize the sugars and render the media useless. The typical overkill approach is not recommended for sterilization of media. The exposure phase should be programmed to achieve the desired SAL and no longer. Use of a load probe and F0 exposure control is recommended for sterilization of media in containers larger than 100 ml (3.4 oz). As illustrated in Figure 8, F0 is a calculation of the equivalent exposure at temperatures other than 121.10 C (2500 F). As the liquid is heated, the calculated F0 (from the load probe temperature) is accumulated until the selected F0 exposure value (minutes) is achieved, at which point the cycle proceeds to the exhaust/cooling phase. For example, from the graph we see that the kill rate on the same population of organisms is half as effective at 1180 C (2450 F) as at 1210C (2500 F). Therefore, at 1180 C (2450 F), it will require twice the exposure time to kill the same number organisms.

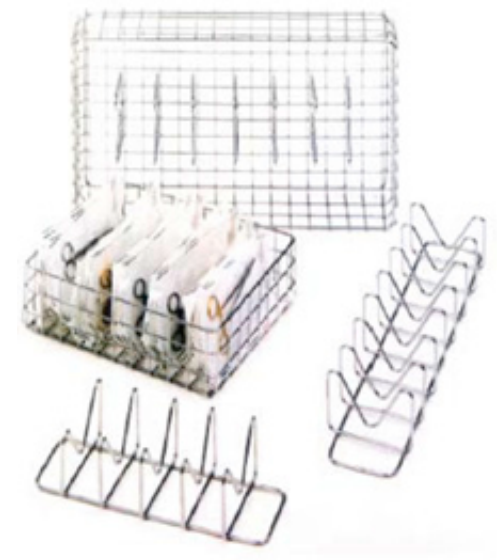

Figure 7. Proper position for pouches

A common formula for calculating the F0 value is:

$$F_0 = \int_0^t L\,dt \quad \text{where} \qquad L = 10^{\left(\frac{T-121.1}{z}\right)}$$

where:
- L is lethal rate of bacterial spores
- t is exposure time, [s]
- T is exposure temperature, [°C]
- z is a constant, [°C]

The constant z describes the slope of the thermal death curve. The widely accepted value for z is 10 °C (18° F) in steam sterilization.

8. Using cold water for vacuum pump that is too hot.

As a result, the vacuum pump may not be able to reach 1.0 psia (6.9 kPa). The heart of the prevacuum sterilizer is the water-ring vacuum pump. The efficiency and maximum vacuum capability of a water-ring vacuum pump are adversely affected by higher water temperatures typically encountered during the summer months. During operation the water within the pump is heated by mechanical friction and heat energy from the sterilizer chamber. If the temperature of the water inside the pump reaches 390 C (1020 F) during the preconditioning or post conditioning vacuum peak, the water inside the pump will boil at ≤1.0 psia (6.9 kPa) and cause cavitation. In this case, the recommended preconditioning vacuum level of 1.0 psia (6.9 kPa) cannot be achieved in the sterilizer chamber. A common "workaround" for this situation is to change the set point of the prevacuum pulses to a level that can be achieved. Insufficient air removal can be the result unless the number of vacuum pulses is increased, causing longer cycle times and less effective air removal. Internal pump temperatures higher than 390 C (1020 F) are often observed during the summer months if the water supplied to the pump is not cooled. Chilled water is ideal, but typically too expensive to use in a sterilizer vacuum pump arrangement in which the water flows from the vacuum pump to drain. The recommended solution is a recirculation/cooling system for the vacuum pump water that uses chilled water in a closed loop heat exchanger. This configuration is eco-friendly as it saves a significant amount of water. In addition, the vacuum pump efficiency is not subject to seasonal water temperature fluctuations.

9. Load probe is available, but not used.

Most modern sterilizers include (optional) an RTD load probe and F0 exposure control for use in liquids sterilization, but many times the probe is not used. If equipped with a load probe, the exposure can be controlled by the temperature of the liquid rather than the temperature in the drain line. Without the load probe, the temperature of the liquid is not known and can only be estimated, resulting in inadequate (non-sterile) or excessive F0 (overcooked). The load

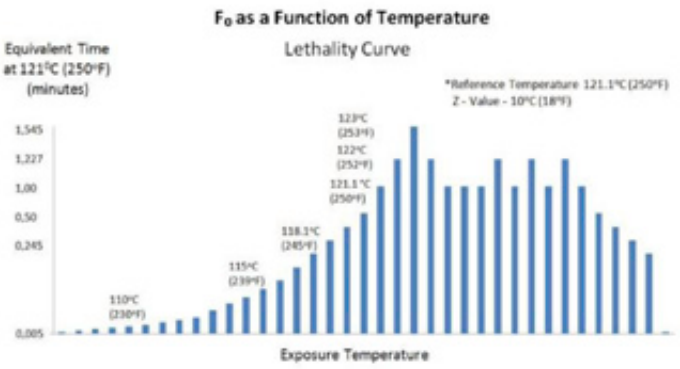

Figure 8. F0 as a function of temperature

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probe should be placed in a container of water approximating the volume of the largest volume of liquid being sterilized. Load probe control/F0 must then be selected in the sterilizer control settings.

10. Pressure/Vacuum rate control is available, but not used.

Most modern sterilizers include (optional) rate control for the vacuum and pressure ramps, but many times the rate control is not used. When no pressure rate control is applied steam will enter the chamber at maximum velocity during the preconditioning pressure pulses, which creates a superheat problem and EN285 compliance problems as discussed earlier. Slowing the pressure rate allows time for superheat to dissipate during the ramp up.

When no vacuum rate control is applied the chamber will depressurize at the maximum rate of the vacuum pump. The typical problem associated with this is burst pouches. Slowing the vacuum rate allows time for the pouch internal pressure to equilibrate and prevents bursting during the preconditioning and post conditioning vacuum phases.

Conclusion

Steam sterilization is a process that is dependent on basic principles that are sometimes unknown or disregarded by the sterilizer user. A large percentage of steam sterilizer failures can be solved by logical and practical application of these basic principles. It should be noted that proper training for sterilizer users should include this education. Proper wrapping and loading techniques are critical for safe and successful sterilization. As with any critical process equipment, proper maintenance and calibration is essential.

STERIS Deutschland GmbH
Eupener Strasse 70 D 50933 Köln
Telefon: +49 (0)821-56996494
Telefax: +49 (0)821-56996496
Mobile: +49 (0)172-5201338
E-Mail: Andrea_Haselmayr@Steris.com
Internet: http://www.sterislifesciences.com

About the Authors

Marcel Dion is Director of Marketing for Washing and Steam Sterilization Systems in the Life Sciences Division of Steris Corporation. Dion holds a diploma in instrumentation and control from Levis-Lauzon CEGEP in Quebec, Canada. He was involved in designing and manufacturing washing systems for the life sciences industry during the first 20 years of his career. For the past 13 years, he has been responsible for developing and bringing to the market innovative and efficient cleaning and steam sterilization systems for critical parts/components that are involved in the drug manufacturing process. Dion has been a member of ISPE, PDA, LAMA and AALAS organizations for several years. He can be contacted by tel: +1-418-664-7512. Steris, 490 Armand-Paris, Quebec G1C8A3, Canada.

Wayne Parker is an independent consultant for moist heat sterilization to the pharmaceutical, biotech, and research industries. Parker graduated from Hillsborough High School in Tampa, FL in 1965 as a member of the National Honor Society. He attended the University of South Florida in Tampa from 1965 to 1968. Parker served in the U.S. Air Force from1968 to 1972 as a Radar Maintenance NCO and continued his education through the U.S. Air Force Extension University. He was employed by the American Sterilizer Co. (now Steris Corporation) from 1972 to 2012, when he "retired." During his career, Parker held numerous positions, including; field service technician, field service cGMP specialist, area sales manager and key pharmaceutical accounts manager. He has provided training and consulting services to numerous companies, and continues as a guest lecturer several times per year at the University of Tennessee, Memphis, College of Pharmacy post-graduate course in aseptic processing. He has been a member of ISPE, PDA, and AALAS organizations for many years. He can be contacted by email: autoclaveman2007@yahoo.com

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Impressum:
cleanroom online / W.A. Schuster GmbH · Mozartstrasse 45 · D 70180 Stuttgart · Tel. +49 711 9 64 03 50 · Fax +49 711 9 64 03 66
info@reinraum.de · www.cleanroom-online.de · GF Dipl.-Designer Reinhold Schuster · Stgt, HRB 14111 · VAT DE 147811997