Natural foods without added preservatives and without the use of thermal processes – this is what modern end consumers want. At the same time, the demand for longer shelf life and absolute product safety is also growing.

Longer shelf life for foods – avoid contamination

Organic yoghurt filling process. CleanFlowCell® laminar flow housing, clean room class ISO-7.

It is possible to do both by using specifically selected clean room technology. High-performance particulate filters offer filter performance so high that even microbiological risks like bacteria and moulds can be kept away from the production process. Whether bread, sausage, yoghurt, vegetables or beverages – in the manufacturer, processing, filling and packaging of sensitive goods, contamination can be completely eliminated. The practically germ-free processing of foods not only permits a significantly longer shelf life for the products, the safety increase is also reflected in lower numbers of complaints.

In the past few years in the food industry, there has been a clear reorientation of hygienic production. More and more food producers rely on the advantages offered by processing in a clean room. The investment in clean room facilities amortises quickly due to the advantages it brings.

Good planning in advance is essential, taking the special features of the specific production process into consideration. The Baden-Wurttemberg company SCHILLING ENGINEERING specialises in the development and installation of clean room systems and has increasingly been working with customers in the food industry over the past few years. Every clean room installation is customised to the needs of the customer and planned with close coordination. Managing Director Günther Schilling is happy about trends in the food industry:

„For some time we've noticed a significant increase in investment. Clean room technology offers great advantages in food production, since the open product is protected from germs during processing. Constant, precision-directed air flows force contaminated air away from the process. The clean room enclosures used are designed for the smallest size needed for safe production. We plan every project on a customer-specific basis and provide support through the qualifica-

Longer shelf life for foods – avoid contamination

Packing sliced bread in a large-scale bakery. The CleanSteriCell® closed system in clean room class ISO-7 meets requirements for pharmaceutical production.

Packing of organic spread. CleanFlowCell® laminar flow housing, clean room class ISO-7.

tion stage. Our customers have had very good experiences with clean room production. Since we use only high-quality materials and the latest technology, the maintenance costs of our systems are very low. The investment amortises very quickly".

SCHILLING ENGINEERING offers different clean room solutions for food production

CleanFlowCell® laminar flow housings and clean room tents are flexible, cost-effective clean room systems in which directed air flows are used to replace contaminated air with filtered air free of moulds and bacteria. The systems consist of load-bearing frame structures of aluminium and are protected from the environment using PVC sheet curtains.

Product safety at the highest possible level offered by CleanSteriCell® closed clean room systems, developed for the strict requirements of the pharmaceutical industry. These are a free-standing „room in room" system usually installed within production buildings. Using a built-in air circulation process within the clean room walls and a permanent air exchange, constant particle cleanliness, temperature, humidity and pressure conditions can be maintained throughout the room. Employees can only enter the clean room through lock systems and with suitable clean room clothing. Microbiological contamination is reliably eliminated.

With flexible options of the latest standards, cleanroom technology can even be integrated into smaller plants and can contribute to further increases in the safety and longer shelf life of food production.

SCHILLING ENGINEERING
Industrial Handling
Cleanroom Systems

Schilling Engineering GmbH
Industriestrasse 26
D 79793 Wutöschingen
Telefon: +49 7746 9278971
E-Mail: i.doerffeldt@schillingengineering.de
Internet: http://www.schillingengineering.de

Dear subscribers,
2016 is ending soon and thus this is the last newsletter of cleanroom online this year. In retrospect we can say that this was a good year – for the sector in general and for cleanroom online in particular. Our web-based platform under www.reinraum.de was 365 days disposable for you as an information portal and advertising platform and we are pleased to inform you that you have used the possibilities we offered here quite numerous. Furthermore with our newsletter we have given you 12 times the most important information, trends and developments of the sector and we are very proud of the active reading participation and your feedback which was always quite complaisant and encouraging. Many thanks for that. We also want to say thank you for the numerous visits at our fair boothes on the Lounges and the Cleanzone.
Please look forward not only to Santa Claus but also to the new printline which is our printed magazine as an annual issue of cleanroom online. It will be published right in time for the Lounges 2017.
We wish you a wonderful Christmas and a good start in the new year.
Your
Reinhard Schuster

Clean room technology continues to grow unabatedly

The Cleanzone 2016 has shown it again: more and more branches cannot forego clean room technology. Therefore the international trade fair with a congress for clean room technology which took place from 8 to 9 November 2016 in Frankfurt recorded a growth of national and international visitors and exhibitors. Thus the industry event has become in its fifth year of its existence a platform of exchange for users, producers and developers of clean room technology.

According to a statement of the Frankfurt fair the exhibitors booked nearly 30 per cent more exhibition area this year. The number of visitors which amounted to 759 visitors from 35 countries was lightly higher than in the previous year (734 visitors from 32 countries). This growth of internationality was also a pleasure to the 86 exhibitors from 12 countries who were supposed to be all highly satisfied with the quality of the trade visitors. Reinraum online has asked around and was able to determine a similar mood, although there were also quite critical comments. The trade visitors of the Cleanzone came from all industries which are producing in clean rooms or controlled areas like the automobile or semiconductor industry, aerospace, laser and optics, surface technology, food and pharmaceutical industry.

The product range of the represented providers varied from planing and construction to air conditioning and ventilation technology, consumables, clean room clothes and cleaning, measuring technique and control systems as well as monitoring systems. Besides the exhibiting companies three important industrial associations were also represented in Frankfurt: the association „Verein Interessengemeinschaft Pharmabau 3000“ (VIP 3000), „Cleanroom.de“, a cooperation of companies which offer solutions for microtechnology, and the „Cleaning Excellence Center Leonberg“ (CEC) concerned with technial cleanliness. Thus the offer of the Cleanzone ranged over all production sectors under controlled conditions.

The Cleanzone congress which came up with a quite international and eminent program informed a total of 103 participants about up-to-date topics in the clean room technology like new norms and guidelines, dealing with crises in production as well as liability in the digital era. The program was splitted in four congress modules: “access to clean room technology”, “planning, layout, construction”, “qualification” and “modern clean room production and optimization while the process is running”.

The Cleanzone Plaza which was installed in the middle of the fair hall 4.0 served as a central contact point and communication platform where topics like industry 4.0, promotion of young talents and the question how one can recognize a good supplier were discussed. Furthermore the Cleanroom award was awarded there already for the fifth time by the ReinraumAkademie in Leipzig. This year the audience voted that the prize which is worth 3.000 euros was awarded to the Adriatic Institute of Technology for the mobile clean room unity “Shellbe”. This module which is made out of an innovative plastic construction qualifies for being used as a hospital, laboratory or epidemic center in conflict areas and economically underdeveloped regions in the world. “Shellbe” distinguishes itself by an extremely high hygiene standard for a mobile unity and thanks to autarkic supply it is possible to also use it in desert regions or in the perpetual ice. Thus the prototype module which was exhibited in the Frankfurt fair hall attracted the attention of all visitors.

Industry 4.0 as a chance for the future and innovation

One of the most important topics and trends of the fair was without doubt that what has recently been summarized under the buzzword “industry 4.0”. Here the question arises whether this buzzword is more a marketing strategy or whether it is in fact a big contribution to the competitiveness of the technology location Germany. The progressive digitalisation for all branches which are producing in clean rooms has become undoubtedly a central topic. In a world in which more and more parts of the production process take place in clean environ-

Reinraumtechnologie auf ungebremstem Wachstumskurs

ments questions like this have to be asked: Is industry 4.0 a chance for further generations to secure the future technologically? How it is possible to integrate the clean room production in a digital way in the total production process? What chances are offered by the digitalisation? What is the difference between Smart Grid and I 4.0? Is digitalisation the driving force for innovations in clean rooms?

Experts tried to answer these questions on the podium, in press conferences as well as with customers and users. Thus Prof. Gernod Dittel from Dittel Engineering pled in this matter for more courage as far as new ways are concerned. Working in clean rooms will be drastically changed by the technical possibilities of industry 4.0. Out of the human-machine-communication the machine-machine-communication will develop; regulations are more and more adjustable and can be better controlled. But the most decisive and in part also the limiting factor is and remains for Dittel the human being. Innovations don't come from alone, but they have to be triggered off actively. Many companies avoid the risk of new ways. The internet of things provides many possiblities which could give the clean room sector another advance. But according to Dittel: Only the companies which tackle with determination the future tasks can remain on the market.

Another expert opinion comes from Dr. Jörg Blechschmidt from the Future Management Group AG. His theses: Industry 4.0 is based on a comprehensive inquiry and real-time analyses of machine and process data as well as their decentralized communication. In order to increase the potentials of industry 4.0 for the clean room a paradigm change is necessary. The clean room does not only create a specific environment for the production but it also has to be understood as an integral part of the production plant. Thus the single modules of a clean room have to fulfill the same requirements as far as data collection, real-time analyses and decentralized communication are concerned. In the future the clean room will adjust itself independently to each of the process steps currently carried out and their requirements, clear-sightedly optimize parameters as well as affect actively the production if necessary.

Here are some interviews of exhibitors we questioned in Frankfurt:

Jiri Hrubon, product manager of the Czech company Block Clean Room Solutions which was for the first time among the exhibitors of the Cleanzone, was highly satisfied with the prominent location near the entran-

ce of his booth and the strong visitor attention which the company exhibit attracted. He also expressed quite positively about the fair conversations. Particularly on the first day of the fair the feedback was good and outstripped all expectations. One will tie in with this success on the Cleanzone next year, said Hrubon.

MK-Versuchsanlagen und Laborbedarf was also for the first time as an exhibitor on the Cleanzone. The company was with

its metal-free clean room which was established at the Carl von Ossietzky Universität Oldenburg also nominated for the Cleanroom Award. Dr. Dirk Rosencrantz who is responsible for business development and distribution in the management of the company expressed himself very positive about the first participation of his company: "We are very positively surprised. The feedback which arrived us from niche market players is overwhelming. We are nearly unable to finish explaining and demonstrating. It is a successful combination of image building and positioning on the one hand and real contracts on the other." Dr. Rosencrantz will join the Lounges at the end of January 2017 as well, but as a visitor not as an exhibitor.

As a speaker of AIT (the Adriatic Institute of Technology SpA), the winner of this

year's Cleanzone Award, Felix Altenbach was very impressed by the feedback of the fair. "The fair at Frankfurt has managed to gather all deciders. The feedback on our system is huge. For us the acquisition of the Award with the Shellbe System is a strong support in order to start distribution now with the prototype. We are excited and we will also participate in this fair next year."

For Cédric Spörry from the Swiss Vali. sys GmbH this was the fifth Cleanzone and the exhibition received marks of 1 from him without hesitation. Being three-times represented by the two cooperations with mycleanroom.de and the participation with regards to Shellbe the company was able to increase its visibility considerably. Many new contacts and visits by existing customers have therefore marked the decision to participate again in the fair next year.

For Dr. Udo Gommel of the Fraunhofer Institut IPA this year's Cleanzone has attracted many visitors. The numbers of visitors was similar to last year but the contacts became more international, he said. Dr. Gommel didn't like to promise a participation next year but he confirmed being represented on the Lounges at the beginning of next year which is a home match for the Stuttgart institute.

Rino Woyczyk as well came out as a "repeat offender" with his community of interest VIP 3000. It's the third time for them and they were quite satisfied with the results of these two days. "This year we decided to make a common booth in addition to the sin-

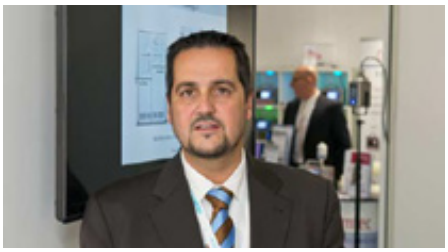
Reinraumtechnologie auf ungebremstem Wachstumskurs

gle boothes in order to enable our members to sample the fair. But the feedback is quite different: Those with products in their product range got very good feedback until now, but the service providers have it harder." As far as the service offer of the fair in Frankfurt for exhibitors and visitors is concerned Woyczyk has some good ideas for improvement: "A water dispenser in every corner of the hall would be good. The air at the fair is dry and one would be able to get something from the water dispenser from time to time." But in total Woyczyk encourages the fair to "do like this" in the future.

The German clean room institute (Deutsches Reinraum Institut) which was for the first time represented with an own booth at the Cleanzone was content with the fair results. Egon Buchta said: "We had the goal to take position to the topic industry 4.0 and to handle the question how far this topic influences the clean room sector. Generally speaking the fair visit is very good. Some projects appear to be concrete, especially in the training under the aspect of the clean room. Furthermore I think that the German clean room institute will be represented again at next year's Cleanzone." Not without a critical undertone Buchta wished that the fair in Frankfurt would "pick up" the visitors a bit better in the future what wasn't the case this year given the huge fair area in relation to the small fair Cleanzone.

Reiner Hummel of Aeropur GmbH estimated the fair as "good given the fact that it took only two days und only half of the fair hall was occupied". In his opinion more customers who build a clean room or want to purify air could have found the way to the Cleanzone. "We had many contacts but unfortunately too less real customer contacts. Nevertheless we go home with a good feeling," he concluded.

Meik Syring of Tresolid as well said that



he was very satisfied. Besides his participation at the VIP booth he was represented by an own small booth and given the international contacts he went quite into rhapsodies. He gave a positive feedback as far as the lightning and the fair ambience (for a design-orientated supplier only consequent) was concerned.

Professor Gernod Dittel of Dittel Engineering recognized the Cleanzone as a "small trade fair but quite nice" and for his company he stated that the quality of the visitors was increased. In the fifth year of the fair he is as an exhibitor in Frankfurt and he also wants to participate in 2017. Dittel is with his engineering company an essential project partner of the award-winning prototype of "Shellbe" and due to good contacts he sees

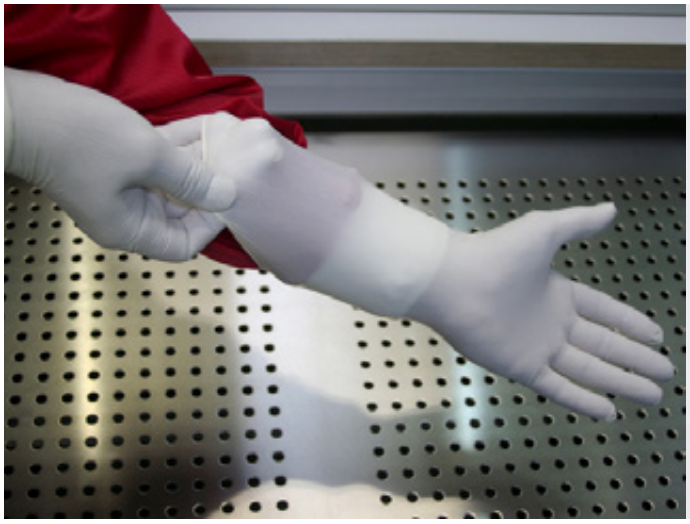
the chance to launch the system until this summer.

All in all the Cleanzone 2016 was a success – for the fair in Frankfurt as well as for the exhibiting companies and their visitors. The next Cleanzone will take place from 17th to 18th October 2017 in Frankfurt am Main.

17th. - 18th Oct. 2017: CLEANZONE 2017, Frankfurt am Main (D)

reinraum online

reinraum online
Mozartstraße 45 D 70180 Stuttgart
Telefon: +49 711 9640350
Telefax: +49 711 9640366
E-Mail: info@reinraum.de
Internet: http://www.reinraum.de



Clean room nitrile gloves

When is a cleanroom glove a „cleanroom glove“?

Validation of any glove used in a cleanroom is typically a long and demanding process. In the face of an increasingly stringent environment, the needs for disposable gloves have changed dramatically. Two decades ago it was common practice to accept standard gloves in PE packaging for use in the cleanroom. Likewise vinyl gloves were widespread particularly in the micro-electronics industry, but a better understanding of the contamination and barrier issues posed by these types of glove have largely contributed to their disappearance. Meanwhile, in the pharmaceutical industry, the practice of using standard surgical gloves (i.e. those where the wallets and outer packing are both made of paper) continued even in aseptic environments.

The adoption of ISO 14644-1 at the beginning of the decade introduced a single standard for cleanroom classification and made it much easier to understand airborne particulate cleanliness. A similar convergence was taking place in Europe for the pharmaceutical industry, with the publication of the Guide to Good Manufacturing Practice for Medicinal Products and its Annexes (EC GMP). Specific areas such as the manufacture of sterile medicinal products are covered in the annexes. Whilst none of these developments give a specific focus to disposables for use in the cleanroom, the trend towards the adoption of cleaner practices in an increasingly regulated environment was clear. Possibly as a way of trying to fill potential gaps, the VDI-Society Civil Engineering & Building Services in Germany began publishing a series of guidelines known as the VDI manual of Cleanroom Technology. With reference to consumables to be used in the cleanroom, this is covered in Annex H of VDI 2083 Part 5.1 “Cleanroom technology- Cleanroom operation“.

Throughout the electronic, aerospace and solar industries, evaluation procedures have undergone a significant transformation. The same pace of change does not appear to have been mirrored in the pharmaceutical industry, where in some sectors surgical and medical examination gloves continue to be used in respectively sterile and non-sterile areas. Some hospital pharmacies, where cytotoxic drugs and parenteral products are prepared, may view personal safety as the main priority followed by cleanliness of the product. However under the influence of ISO 14644 and especially the EC GMP, these areas are undergoing change.

Why do cleanroom applications need a specific glove?

In many case the primary purpose for wearing gloves is to avoid contamination of the product.. Apart from the costs associated with high batch failure rates, contamination by biological agents of parenteral drugs can have serious consequences for patients. A similar concern is the need to maintain the cleanliness of the surrounding cleanroom environment, as this can contribute to product contamination.

Material	Material properties	Cleanroom (CR) suitability
Vinyl/PVC	Low strength and elongation. Poor flexibility and ergonomics. High non-volatile residues and wet particle counts.	For use in CR with low sensitivity to particle contamination and where there is minimal need for protection from micro-biological hazards.
Natural Rubber Latex	High tensile strength, with good elastic properties. Prone to shedding particles in-use. Responds well to extra rinse cycles to produce gloves low in particles and ionic extractables.	For CR applications where there is a need to avoid particulate and ionic contaminants. Excellent barrier properties to biohazards. Compatible with gamma-irradiation for sterile gloves.
Synthetic Latex: Nitrile, Neoprene (Polychloroprene), Polyisoprene and Polyurethane	Good to acceptable elongation and high tear resistance. Good abrasion resistance. Following additional laundering, possible to produce glove with very low ionic and particle residues.	**Nitrile:** Ideal for CR seeking highest cleanliness levels in terms of low particulate and ionic contaminants. **Nitrile/ Neoprene/Polyisoprene/PU:** Excellent barrier protection to biohazards. Suitable for gamma-irradiation in sterile gloves.

Table 1: Summary of main features of glove materials

The first step in the evaluation is the choice of glove material

Where electrostatic discharge (ESD) is a concern, the following should be borne in mind:

- Natural Rubber Latex gloves are static insulative – static insulative materials are considered as having a surface resistance of higher than 1 x 10^{12} ohms/square. The danger here is that the charge is held to a certain point then released in an uncontrolled fashion. Even with high surface residues such as ionic contaminants, the gloves appear to remain static insulative.
- Nitrile gloves are in terms of surface resistance considered to be on the border between the insulative and static dissipative ranges. Extensive cleaning especially in deionised water may reduce the

When is a cleanroom glove a „cleanroom glove"?

glove's dissipative properties. Static dissipative means that the electric charge bleeds out in a controlled manner and does not affect the properties of an item. A glove that is static dissipative has a surface resistance of more than 1 x 10^5 but less than 1 x 10^{11} ohms/square.
- Vinyl gloves (often referred to in the past as ESD gloves) offer the best dissipative qualities, by virtue of the high level of surface contaminants.
- Neoprene may exhibit similar ESD behaviour to Nitrile. Furthermore as many Neoprene gloves have an inner coating (often polyurethane or silicone) to facilitate donning, it is unlikely that they will have undergone rinsing in deionised water to enhance cleanliness. Therefore any favourable static dissipative properties are likely to be derived from high levels of surface contaminants.

Why is it important to consider the cleanroom classification?

Based on ISO 14644-1, the lower the ISO Class the lower is the permitted concentration of airborne particles. Whilst the electronic industry will tend to focus on particles and extractables, the pharmaceutical sector will give particular attention to bacterial contamination. For those operating under sterile conditions, the potential for endotoxin contamination will be of special interest. However for both non-sterile and sterile applications, the potential of a glove to cause particle contamination should be a source of interest as these particles could support microbial life. Glove manufacturers can ensure that the lowest contamination levels are maintained, by laundering gloves in deionised water, drying under HEPA filter driers and adopting cleanroom protocol for packing and sorting the gloves. The latter stage is often done in an ISO 5 or even 4 cleanroom.

Other criteria for selection of cleanroom gloves

Whilst operators' comfort when wearing gloves and their personal safety are clearly significant factors, any validation process will also want to consider the valuable contribution that can come from supporting documentation.

Feeling and comfort

Feeling and comfort are important, as an operator who experiences discomfort and is unable to perform correctly various tasks may cause errors. However: just because a glove is comfortable does not automatically mean that it is the right choice. Natural rubber latex is probably the most comfortable glove material, but brings with it the risk of natural rubber latex allergy and poor abrasion resistance leading to potential shedding of particles in-use. Gloves with an inner-coating may be viewed as desirable by users, as they offer effortless donning. However these gloves are unlikely to have been subjected to the extensive laundering (particularly in deionised water) needed for a cleanroom glove, in order to render them low in particles and extractable contaminants. In contrast nitrile gloves may not provide the same level of comfort and dexterity, but multiple rinses in deionised water can produce a glove with the lowest levels of particle and extractable contamination. Additionally compared to natural rubber latex, nitrile offers superior abrasion resistance coupled with more favourable ESD properties.

Availability of documented performance

A glove manufacturer's ability to provide comprehensive and insightful documentation will not only facilitate the validation process, but could ultimately lead to the reduction or even elimination of incoming inspection. In this respect, lot-specific data is often preferred to periodic tests, such as those done annually or every quarter. For many years, the electronic industry has been using such data as part of their Standard Operating Procedures (SOPS). Increasingly the pharmaceutical industry has been requesting information of this nature to support at least the evaluation process. Specific data that could be requested is as follows:

- Particle residues by lot for sterile and non-sterile gloves. Tested in accordance with IEST – RP – CC005.4
- Endotoxin testing by lot for sterile gloves to confirm low endotoxin content claim. Testing to be based on the Limulus Amoebocyte Lysate kinetic tubidimetric technique (LAL)
- Sterilisation by lot confirming that gloves have been sterilised to SAL (Sterility Assurance Level) of 10^{-6} in accordance with ANSI/ AAMI/ EN ISO 11137:2006

Product data sheets that are frequently found on manufacturers' websites will often give a snapshot of the quality of the data available. To assess the potential of the manufacturer to deliver documented consistency, requesting copies of certificates of analysis or conformance for three or more recent lots could be helpful. An example of a certificate of conformance is detailed below. Under "Physical Test Data", the number of total samples of final product is shown for various physical tests. The column referred to as "barrier defects" gives important information in terms of the incidence of pinholes. Lots are accepted on the basis of whether or not the number of defects exceeds the number of statistically permitted defects (as determined by AQL). Thus "Pass" will be shown when the number of permitted defects was not surpassed. It will be noted that particle contamination analysis is defined both by concentration (i.e. average particles/ cm^2) and distribution (i.e. particle size range expressed in µm). (see Certificate of Conformance)

Those operating in sterile environments will seek reassurances as to sterility of the gloves. A certificate of irradiation is outlined below and shows the minimum and maximum doses of irradiation to which the gloves have been subjected. Often as part of the initial evaluation process, additional information will be sought covering sterilization validation procedures. The latter is most likely to include dose-mapping, GMP audits of the contract sterilization facilities etc. (see Certificate of Irradiation)

Regulations and Norms

If as part of a risk assessment disposable gloves are being used for personal protection, then only those gloves that are registered according to the Personal Protective Equipment (PPE) Directive (89/686/ EEC) should be used. Additionally if the gloves are being used for personal protection against chemical splashes, then selection of gloves that are registered as Complex Design (Category III) according to the PPE Directive would be appropriate.

Gloves that are Category III and designed for micro-organism resistance must achieve at least an AQL of 1.5 (Level 2), based on the water penetration test. Gloves of this type may also exceed this minimum performance requirement for micro-organism resistance by having an AQL of less than 0.65 (Level 3). AQL (Acceptable Quality Level) is a crucial parameter for assessing the barrier performance of a glove and specifically with regard to pinholes. Through a process of random sampling, an AQL of less than 0.65 assumes a statistical probability that no more than 0.65% in any given batch can have pinholes. It is therefore significantly more stringent than an AQL of less than 1.5 which would permit up to 1.5% having pinholes. AQL also has important implications for protecting the product as pinholes

When is a cleanroom glove a „cleanroom glove“?

SHIELD Scientific

CERTIFICATE OF CONFORMANCE

Product Description: SHIELDskin XTREME™ Sterile White Nitrile 330 DI'
Catalogue numbers: 69 8761, 69 8762, 69 8763, 69 8764, 69 8765, 69 8766, 69 8767, 69 8768, 69 8769

Lot number(s): 274R10B201, 274R10B202, 274R10B203, 274R10B204, 274R10B205, 274R10B206, 274R10B207
Date of Manufacture: February 2010

Physical Test Data				
	Dimensions	Barrier Defects	Minor Defects	Major Defects
Sample size	200	200	200	200
AQL Level	1.5	0.65	1.5	1.5
Defects allowed	7	3	7	7
Defects found	0	2	2	0
Pass/Fail	Pass	Pass	Pass	Pass

Test method: EN 374-2:2003

Particle Test Data		
Particle size in µm		Average particles/cm²
0.5 - 1.0		789
1.0 - 2.0		28
2.0 - 5.0		18
5.0 - 10.0		8
10.0 - 20.0		3
> 20.0		0
TOTAL per Sample		846

Test method IEST-RP-CC005.3

Extractable Test Data		
Extractable Ions		Test result
		ug/cm²
Ammonium	NH_4	0.022
Bromide	Br	<0.006
Calcium	Ca	0.214
Chloride	Cl	0.158
Fluoride	F	<0.006
Magnesium	Mg	<0.006
Nitrate	NO_3	0.075
Nitrite	NO_2	<0.006
Potassium	K	0.082
Phosphate	PO_4	<0.006
Sodium	Na	0.048
Sulfate	SO_4	0.063

Test method IEST-RP-CC005.3

Endotoxin Data
<20 Endotoxin Units / pair of Gloves (EN455-3:2000)

Test method: Lumulus Amoebocyte Lysate kinetic turbidimetric test
Detection limit: 0.5 EU/ml

SHIELD Scientific

CERTIFICATE OF IRRADIATION

Product Description: SHIELDskin XTREME™ Sterile White Nitrile 330 DI'
Lot number(s): 274R10B202, 274R10B203, 274R10B204, 274R10B205
Date of Manufacture: February 2010

Certificate Number: 090050
Irradiation Lots: 10031111
Date of Irradiation: 09.03.2010

Product Details			
Lot number	Product description	Size	Quantity cs
274R10B202	SHIELDskin Xtreme™ Sterile Nitrile 330 DI'	6.5	20
274R10B203	SHIELDskin Xtreme™ Sterile Nitrile 330 DI'	7.0	51
274R10B204	SHIELDskin Xtreme™ Sterile Nitrile 330 DI'	7.5	80
274R10B205	SHIELDskin Xtreme™ Sterile Nitrile 330 DI'	8.0	100
		TOTAL	251

Irradiation Facility Information		
Irradiation Facility	Irradiation Method	QA Manager
SterilGamma (m) SDN. BHD. Rawang Integrated Industrial Park 48000 Rawang, Selangor MALAYSIA	Gamma Irradiation	Abdul Rahman Ghani

Irradiation Dose Information*		
Dose Requested Minimum	Dose Delivered Minimum	Dose Delivered Maximum
25.0 kGY	29.2 kGy	33.6 kGy

*SterilGamma has confirmed that the products have successfully been irradiated and have received the minimum dose requested (as the above stated) within the precision and accuracy of the dosimetry system employed.

provide a passageway for human-borne contaminants. Accordingly in those areas where protection from microbial contamination is a key priority (e.g. aseptic areas), seeking gloves with an AQL of <0.65 may be prudent.

For applications where there is exposure to potentially harmful viruses, it should be noted that the above claim of micro-organism resistance does not extend to protection to viruses. This may be a particular concern to vaccine manufacturers that routinely use live viruses. If there is a specific need for viral protection from viruses, then gloves which have additionally been tested for viral penetration may be the solution (e.g. bacteriophage test as defined in ASTM F1671 or ISO16604:2004).

Need for special packaging

Standard gloves packed in cardboard boxes are not compatible with most cleanrom environments. Gloves packed in this way will be prone to shedding cardboard particles, whilst it will be noted that the action of taking the gloves out of the boxes will often exacerbate the risk. For the above reasons removing the gloves from the cardboard box and depositing them in plastic dispensers will not eliminate the risk of particle shedding in-use. Consequently it is standard practice to only accept gloves in PE packaging for use in cleanrooms. Often these are double-bagged to facilitate safe transfer to the cleanroom. The use of ink on the packaging that is resistant to isopropanol (IPA) helps to reduce an additional contamination risk.

For sterile areas the continuing use of surgical gloves with PE outer-packing but inside a paper wallet may provide a further source of contamination. Often these gloves are registered according to Medical Device Directive (93/42/EEC) and may not be suitable where a risk assessment has identified personal protection as the principle intended purpose for wearing the gloves.

Conclusion

In order to minimize contamination of the environment and product, it may be desirable to select only those gloves that have been washed in deionised water, dried under HEPA filter driers and packed in a cleanroom (preferably ISO class 5 or 4). It will have been noted that not all glove materials are compatible with the rigorous washing process involved with multiple rinses in deionised water. Consequently if a high level of cleanliness is sought avoiding vinyl gloves may be necessary. In the less critical environments (e.g. ISO class 8 or D, based on the EC GMP classifications), it may be common practice to use shorter-length gloves such as those of 240mm. However the potential shedding of human-borne contaminants especially from the exposed wrist area should not be under-estimated. Accordingly it may be preferable to use longer gloves such as those with a length of 300mm to provide complete coverage of bare skin.

The discussion on selection criteria for cleanroom gloves has highlighted the value for personal and product safety of documented performance. In this respect the test overview may provide a useful summary of the key test data that could be requested. (see table 2: Summary of key test data for cleanroom gloves)

References:

1) ISO 14644-1:1999 “Cleanroom and associated controlled environments – Part 1: Classification of air cleanliness”
2) VDI 2083 Part 5.1 (September 2007) “Cleanroom technology – Cleanroom operation” (VDI-Society Civil Engineering & Building Services)
3) EC Guide to Good Manufacturing Practice [Available from European Commission Enterprise Directorate General on ec.europa.eu/health/documents/eudralex/]
4) IEST-RP-CC005.3 “Gloves and Finger Cots used in Cleanroom and other Controlled Environment” (Institute of Environmental Science and Technology)

When is a cleanroom glove a „cleanroom glove“?

5) ISO 11137:2006 “Sterilization of health care products – radiation”
6) EN374-1:2003 “Protective gloves against chemicals and micro-organisms – Part 1: Terminology and performance requirements”
7) EN374-2:2003 “Protective gloves against chemicals and micro-organisms – Part 2: Determination of resistance to penetration”
8) EN374-3:2003 “Protective gloves against chemicals and micro-organisms – Part 3: Determination of resistance to permeation by chemicals”
9) ASTM F1671-97b /ISO16604:2004 “Standard Test Method for Resistance pf Materials Used in Protective Clothing to Penetration by Blood-borne Pathogens using Phi-X174 Bacteriophage Penetration as a Test System”
10) EN455-2:2009 + A2:2013 “Medical gloves for single-use: Part 2: Requirement and testing for physical properties”
11) EN455-3:2015 “Medical gloves for single-use: Part 3: Requirements and testing for biological evaluation”
12) ISO 10993-10 “Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersenstivity”
13) ASTM D257-14 “Standard Test Methods for DC Resistance or Conductance of Insulating Materials”
14) EN1149-1:1996 “Protective clothing, electrostatic properties, surface resistivity (test methods and requirements)”

SHIELD Scientific B.V
D 84184 Tiefenbach

Test Overview

Personal and Product Safety		people	production		Lot-specific
Regulation/Norm			sterile	Non-sterile	
89/686/EEC	Declaration of Conformity –PPE Cat III	x			
EN374-2:2003	AQL – resistance to penetration from micro-organisms & chemicals	x	x	x	x
ASTM F1671-97b/ ISO16604:2004	Viral Penetration Test		x	x	
EN16523-1:2015	Chemical Permeation Tests	x			
EN455-3:2015	Latex protein test – cannot claim below 50µg/g, but note requirement from BGIA - Institute for Occupational Safety and Health in Germany (BGIA) for <30 µg/g	x			
EN455-3:2015	LAL Test to substantiate low endotoxin content claim	x	x		x
ISO11137:2006	Sterilisation Guide lines		x		x
EN455-2:2009 + A2:2013	Elongation and Tensile strength	x	x	x	
ISO10993-10:2010	Biocompatibility of material, specifically with reference to irritation and Delayed Type Hypersensitivity	x			
ASTM D257-14	surface resistance	x	Sometimes	x	
EN1149-1:1996	surface resistance	x	Sometimes	x	
IEST RP CC 005.4	Particle release and extractable matter		x	x	x

Table 2: Summary of key test data for cleanroom gloves

With the new brand architecture, OEKO-TEX® is reinforcing its role as a global full-service partner for implementing greater sustainability throughout the textile value-creation chain. The current OEKO-TEX® portfolio consists of six certifications and services for manufacturers, sourcers, brands, and retailers throughout the textile market.

OEKO-TEX® Brand: **Expanding and Refreshing**

Textile manufacturers, sourcers, brands, and retailers around the world know that every January there will be an update to the OEKO-TEX® test methods and limit values for harmful substances. This January, the textile industry can expect the same but they will also see the complete roll out of the new, cohesive OEKO-TEX® branding strategy that was previewed a few months ago. In addition, OEKO-TEX® plans to unveil new products in January as well.

With the portfolio of OEKO-TEX® products growing rapidly in response to textile industry needs—the most recent addition was DETOX TO ZERO by OEKO-TEX® to help eliminate hazardous substances by 2020—the new brand architecture comprehensively aligns all services and independent certifications under the OEKO-TEX® banner in a way that is recognizable throughout the global market. OEKO-TEX® will prominently feature the brand's tag line, CONFIDENCE IN TEXTILES, in every product logo to connect to the OEKO-TEX® heritage for protecting consumers and supporting sustainable products and manufacturing processes.

"OEKO-TEX® has worked for twenty-five years to help textile product companies reduce hazardous chemicals and to increase the sustainability of the industry," says OEKO-TEX® General Secretary, Georg Dieners. "Our OEKO-TEX® product range will continue to expand with the worldwide textile supply chain and the increasing challenges it poses for our customers. We are proud of the confidence we have earned through that work as well as the confidence the OEKO-TEX® brand gives to consumers everywhere."

The new OEKO-TEX® brand identity kicks off OEKO-TEX's 25th Anniversary, which will be celebrated next year. Founded in 1992 in direct response to public outcry against dangerous chemicals in textiles, the International OEKO-TEX® Association has grown to sixteen member textile testing and research institutes with offices in more than 60 countries. The OEKO-TEX® product portfolio has expanded with textile supply chain globalization and will grow as the textile market and the public's expectations change. "OEKO-TEX® has evolved over twenty-five years but our values remain constant and deeply rooted in safety, quality, and sustainability," continues Dieners.

The new OEKO-TEX ® brand identities will begin rolling out immediately and will be in full force with the annual January update. The STANDARD 100 by OEKO-TEX® and STeP by OEKO-TEX® design updates have been completed by the end of October. Updated certificates and label templates are available now for the 10,000 companies around the world who currently work with OEKO-TEX®.

Hohenstein Laboratories GmbH & Co. KG
D 74357 Hohenstein

Andy and Lawrence Whittard celebrating 45 year anniversary with some of the Cherwell team.

Pharmig annual conference plays integral role in Cherwell's celebrations on Stand 9

Cherwell Laboratories Celebrates 45th Anniversary

Cherwell Laboratories is celebrating its 45th anniversary this November. The specialist suppliers of products for environmental monitoring, cleanroom bio-decontamination and process validation for healthcare, pharmaceutical and industrial applications was initially set up as a veterinary diagnostic laboratory in 1971 by Lawrence Whittard. Since then, maintaining strong customer and industry links has played a fundamental role in the achievements of the Company and therefore, Cherwell will be marking their anniversary at Pharmig's 24th annual conference on Stand 9.

Over their 45 years in business, Cherwell has built a reputation for providing high-quality products, expert advice and excellent customer service to meet the specific requirements of environmental monitoring and process validation. Cherwell attribute their success in these areas to the strength of relationships that they have built with customers and on their ability to work closely with them to provide the best solution for their individual needs.

Andy Whittard, Cherwell's Managing Director, commented, "We pride ourselves on our willingness and ability to work with customers. Our industry knowledge, expertise and readiness to discuss requirements allow us to fully understand the individual challenges faced by our customers and to hopefully fulfil their needs. Our employees are a vital part of our business - they are the ones who go the extra mile because they care about our customers."

He continued, "Attending and supporting key industry events has played an important part in building these relationships and keeping in touch with regulatory changes and customer requirements. Therefore, we thought it fitting that we celebrated our 45th anniversary at Pharmig's annual conference. We will be running a competition on our stand for delegates to enter for the chance to win a hamper."

Pharmig's annual conference will be held on the 16th and 17th November at the Nottingham Belfry Hotel and will provide the opportunity for individuals to keep up-to-date with the latest hot topics in microbiology. This year, the topics covered will include: Annex 1 updates; environmental monitoring risk assessment and the lean approach and the use of HACCP for reducing microbiological contamination.

Experts from Cherwell Laboratories will be at the conference to demonstrate Cherwell's product range and to share and develop their own expertise. Notably, Cherwell's Microbiology Product Specialist, Andrew Ramage, will be contributing on the Culture Media: Back to Basics discussion sessions led by Dr Tim Sandle, BPL on Wednesday 16th November at 12.15 p.m. and Thursday 17th November at 11 a.m.

Cherwell's range includes Redipor prepared media - such as petri dishes, settle plates, bottled media, broth bags, vials and ampoules; SAS microbial air samplers for environmental monitoring and Mar Cor bio-decontamination solutions. Also ensuring that Cherwell is able to respond efficiently to changing industry and customer requirements, the Company has implemented a flexible manufacturing process for its Redipor range.

Cherwell Laboratories Ltd
OX26 4XB BICESTER Vereinigtes Königreich

parts2clean 2017 (24–26 October)

Parts cleaning: cleanliness alone is not enough

– Cost-effective cleaning and consistent results call for the right solution for each particular job
– parts2clean 2017 features all the latest technologies and trends

Whether we are talking about intermediate or final cleaning, the purpose of industrial parts cleaning is to ensure the necessary degree of cleanliness for subsequent processing, or for the long-term, trouble-free functioning of the relevant part or component. Although the required standard of cleanliness (meaning the absence of particulate residues and/or surface films) can vary greatly depending on the particular operation and sector involved, the ultimate aim is to achieve – and in many cases also to document – the desired outcome consistently, quickly, and at the lowest possible cost. Another challenge often faced is to maintain the condition of a work-piece's surface until it undergoes further processing.

Prospective buyers from around the world will be able to find all the right solutions at the next parts2clean, which takes place from 24 to 26 October 2017 at the Stuttgart exhibition center. "Among industrial users, parts2clean is internationally valued as the No. 1 source of information and market-ready solutions. This is underscored by the fact that 85 percent of the show's attendees are decision-makers", remarked Olaf Daebler, Director of parts2clean at Deutsche Messe.

The reason why the Leading International Trade Fair for Industrial Parts and Surface Cleaning is so attractive to users from virtually every field of the manufacturing industry, as well as from the MRO sector (maintenance, repair and overhaul), is that the show provides comprehensive coverage of each and every link in the process chain. The range of exhibits spans plant and installations, processes, process media and their conditioning for the degreasing, cleaning and pre-treatment of parts and components, handling and process automation, washer baskets and pallets, clean room technology, quality assurance, test methods and analytical procedures for cleanliness inspection, corrosion protection, preservation and packaging, as well as contract cleaning. In addition, various special formats focusing on specific themes are planned for the show, including deburring and cleaning in electronics production and the cleaning of work-piece containers. But it's not just about the latest technology; it's also about the challenges and the solutions that are being driven by global trends such as electromobility. So experts are predicting that the selective cleaning of functional surfaces will be a key growth area over the coming years. At parts2clean, industrial users will not only get a complete overview of processes, media, and available measures for optimizing processes and costs, but will also be able to make direct comparisons between different, competing technologies. "Our Guided Tour program will also be a big help to trade visitors here," added Daebler.

Guided Tours – the fast track to know-how and contacts

These Guided Tours, which are offered in two languages (English and German), will run twice daily throughout the show, taking in selected exhibitor stands. They give visitors the opportunity to gather information about specific areas of interest in industrial parts and surface cleaning. For them it is a quick and easy way to discover relevant solutions and innovations and identify likely suppliers who can solve their problems. The Guided Tours also give participating exhibitors an excellent opportunity to pitch their products and innovations directly to a choice, pre-selected target audience, right at their stands, resulting in new leads and potential sales.

All there is to know about industrial parts and surface cleaning

When it comes to knowledge-sharing, parts2clean likewise sets the standard with its three-day Industry Forum. The focus here is on technology basics, strategies for optimizing processes and reducing costs, and quality assurance. There will also be first-hand reports on best-practice applications, as well as discussion of the latest trends and innovations. All presentations given in the parts2clean Industry Forum will be simultaneously translated (German <--> English)

24.10. - 26.10.2017: parts2clean 2017, Stuttgart (D)

Deutsche Messe AG
D 30521 Hannover

Nahtloser Übergang von der Entwicklung in eine robuste Großserienfertigung

Gerresheimer at Compamed

Gerresheimer manufactures innovative drug delivery systems as well as medical devices and diagnostic products for brand name customers all over the world. It is a full-service provider covering all stages of the supply chain up to finished CE-marked product, from concept development, industrial design, product development, production equipment engineering, mould engineering and special equipment production to FDA and GMP-compliant large and small series production, assembly, pharmaceutics assembly and filling, sterilization and packaging.

"One of our strengths is that we offer a seamless transition from development to robust mass manufacturing," said Peter Wallrabe, Managing Director of Gerresheimer Item in Münster, Germany. At Compamed in Düsseldorf, the international trade fair for suppliers and manufacturers of medical technology, Gerresheimer will be demonstrating its expertise in usability engineering, industrial design, product development, mould engineering, automation technology, injection moulding in clean room environments, assembly, finishing, pharmaceutics assembly, packing and filling.

Medical products are becoming increasingly complex. Patients using the products are also getting older, and an increasing number of people are self-medicating in the home. Medical personnel are faced with time constraints and pressure to work more efficiently. Various factors can contribute to mistakes being made in the use of medical products, which is why usability engineering is coming to play a key role. The FDA's audits today have a stronger usability focus, so Gerresheimer's specially trained usability engineers work with its customers to incorporate usability considerations at an early stage of the product development process. They analyze users, use context and products that are already available in the market, interview experts, conduct user tests, draw up interaction specifications and perform many other activities. At the end of the product development process, Gerresheimer's customers don't just get a medical device that is optimally geared to patient requirements – user friendly, intuitive and safe – but can also be mass manufactured.

13th - 16th Nov. 2017: COMPAMED 2017, Duesseldorf (D)

Gerresheimer AG
D 40468 Düsseldorf

Cleaning and disinfect in hard-to-get-to areas

Customers asked Vileda if it is possible to disinfect and clean hard-to-get-to areas such as floors, walls and ceilings behind equipment or piping. It is also not possible to clean and disinfect tanks and isolators with normal mopping equipment.

Vileda has listened to this request and took advantage of its CleanTech foam material with microfiber from CE Duo mops and have transferred this technology a sponge.

This material is already validated for CE with proven cleaning efficacy. Foam construction is also excellent for small spill pick-ups and disinfecting hard to reach areas.

The CE sponge has a size 4¨x7¨ and the double sided construction with RF welded "clean" edges. You can have the CE sponge in a non-sterile and in future in a sterile disposable version.

The sponge is a perfect solution for end-users who want to clean and disinfect hard-to-get-to cleanroom areas at once.

Vileda GmbH
Im Technologiepark 19 D 69469 Weinheim
Telefon: 0172/6218117
E-Mail: juergen.lederer@fhp-ww.com
Internet: http://www.vileda-professional.com

Busy times on exhibition stand „13A13": With a total of twelve exhibits, Arburg succeeded in drawing the crowds at the K 2016.

Arburg world premiere (right to left): On the eve of the K 2016, Managing Director Sales Gerhard Böhm, Managing Director Technology & Engineering Heinz Gaub, Managing Partners Juliane Hehl and Michael Hehl and Managing Director Finance & Controlling Jürgen Boll presented the new hybrid Allrounder 1120 H large machine.

„Wir sind da."

Arburg makes a big impact at the K 2016 international trade fair

– World premiere: New Allrounder with a clamping force of 6,500 kN, new control system and new design
– Crowd-puller: Ten thousand visitors experienced the highlights at first hand on the exhibition stand
– Everything from Arburg: Allrounder, Freeformer, Industry 4.0 and innovative applications

Those wanting to find out about innovations and trends in injection moulding and industrial additive manufacturing at the K 2016 leading international trade fair in Düsseldorf (Germany) could not afford to miss Arburg. From 18 to 26 October 2016, over 400 employees and trade partners from 53 countries presented twelve innovative exhibits on the company's own exhibition stand, while a further fifteen machines were on show on partner stands. The major attraction was the new hybrid Allrounder 1120 H – with a clamping force of 6,500 kN, the largest injection moulding machine in Arburg's product range. Pioneering features included its visionary Gestica control system as well as the aesthetic and functional new design in which this world premiere was presented. According to the exhibition magazine, the most popular give-away at the K 2016 were the Arburg silicone wristwatches.

16th - 23rd Oct. 2019: K 2019, Duesseldorf (D)

„Our pioneering large machine heralds the next generation of Allrounders. The response was overwhelming. We are extremely satisfied. Evidently, we have perfectly fulfilled the wishes of our customers," summarises Michael Hehl, Managing Partner and Spokesperson for the Management Team at Arburg: „Virtually no other manufacturer offers such a wide range of solutions for the efficient production of plastic parts. From high-volume items to batches as small as a single unit, we have shown innovative applications and techniques, once again impressively demonstrating our innovative strength."

New „Wir sind da." brand promise

„However, our offering extends far beyond these technological services," emphasises Managing Partner Juliane Hehl: „At the K 2016, we combined our brand promise with a special key visual - ‚Dare to Dream. Wir sind da.' This is intended to express the fact that we are always there wherever the customer may be – in geographical, technological, mental and physical terms. You can rely on us, just like a trusted family-member. We promise our customers and partners that we will never compromise in our commitment to them. This is an idea that was quite tangible in Düsseldorf. We had thousands of international visitors and the mood on the stand was extremely positive. You could hardly ask for more!"

Arburg surprises the trade experts

Following the sensational launch of the Freeformer at the K 2013, this year it was the turn of the hybrid Allrounder 1120 H to make its international début. Arburg has thus extended its clamping force range by 30 percent, now up to 6,500 kN. „Together with the new machine design and the visionary Gestica control system, we genuinely succeeded in surprising the trade experts once again, giving us plenty to talk about in our discussions," adds Managing Director Sales, Gerhard Böhm. „Our exhibits covered a wide range of industries and applications and were very well received by the visitors. All-in-all, we have rarely had so many high-quality discussions at a trade fair before." International interest in high-end injection moulding technology „Made in Germany" is still very high. From the entry-level electric machine to complex turnkey systems and the Freeformer for industrial additive manufacturing, Arburg had production-efficient

„Wir sind da." – Arburg makes a big impact at the K 2016 international trade fair

solutions for every industry and application.

Industry 4.0 trend topic

Everyone was talking about Industry 4.0 at the K 2016. Managing Director Technology & Engineering Heinz Gaub explains the idea behind the Arburg exhibit in the context of this trend topic: „We used the example of a ‚smart' luggage tag to demonstrate the potential of spatially distributed production and the individualisation of high-volume parts in batches as small as a single unit. For this purpose, an Allrounder injection moulding machine was combined with a Freeformer for industrial additive manufacturing and the product was individualised on a customer-specific basis."

After the two parts were moulded using a vertical Allrounder 375 V and an NFC chip was integrated, the order data for the subsequent production process was stored on the chip and the product thus became an information and data carrier, identifying itself at the various stations and controlling its own further manufacturing process. The subsequent processes included the addition of the address data of a QR code by laser and the additive application of a 3D graphic using the Freeformer. The Arburg host computer system stored all process and quality data on a central server. The individual website of the personalized product meant that all process and quality data could be traced on a 100 percent basis at all times. At the central „Industry 4.0" information point, the last of five stations, Arburg also illustrated the benefits of Industry 4.0, as well as some possible business models. In addition to traceability, this also includes other data-supported actions using the NFC chip integrated in the luggage tag, such as the online ordering of brochures.

As an example of „smart service", a hydraulic Allrounder 270 S was used to introduce a new remote maintenance tool that enables fast, efficient and reliable online support. The injection moulding machine was equipped with a service router and integrated firewall for this purpose. Malfunctions and process sequences can be efficiently analysed and optimised through online support. This reduces unnecessary waiting times, machine downtimes and therefore costs.

New machine technology

An Allrounder Cube 2900 was presented for the first time in Düsseldorf, using a 32+32-cavity cube mould from partner Foboha to produce two-colour flip-top closures for Pril washing-up liquid bottles from Henkel in a cycle time of 8.5 seconds. The moulded parts were removed including fitting of closures without impacting on the cycle time. This output for this application was increased by ten percent, despite a 25 percent lower energy requirement. Arburg tailored the new series, which is available with clamping forces of 2,900 and 4,600 kN, to high-speed applications using cube moulds weighing up to 16 tonnes.

The Golden Electric series was launched in spring 2016 to facilitate economically efficient entry into electric injection moulding production. The new electric machines with clamping forces of 600 to 2,000 kN offered an excellent price/performance ratio thanks to consistent standardisation. At the K 2016, an Allrounder 470 E Golden Electric with a 32-cavity mould produced protective covers for a health care product.

The new Allrounder 2000 T vertical rotary table machine with 2,000 millimetre table diameter was also presented on the stand of Arburg's partner Lauffer Maschinenfabrik. The new machine concept features a very compact installation area, an ergonomically efficient table height of just 850 millimetres and space for larger moulds.

Innovative applications

One of the application highlights was the „ready-to-use" LSR/LSR wristwatch in Arburg design. The associated expertise in multi-component injection moulding, automation and the processing of liquid silicone (LSR) was demonstrated with an efficient turnkey system. An electric two-component Allrounder 570 A produced two two-coloured wrist straps from liquid silicones (LSR) Silopren 2670 and 2620 fully automatically in a 75-second injection moulding cycle.

No less impressive was the production of ready-to-use designer folding step stools. The idea, design and implementation of this application all originate from Arburg. The centrepiece of the turnkey system was the new hybrid Allrounder 1120 H high-performance machine with a clamping force of 6,500 kN, which produced a 1,092 gram step stool in a cycle time of around 60 seconds. The new Multilift V 40 robotic system removed the eight individual pieces from the family mould and placed them on a rotary transfer table. There, the two halves of the step stool were pre-assembled and then transferred by means of a turning station to a six-axis robot, where the stoppers were added to the feet and the finished step stool was placed on a conveyor belt. In this concept the linear robot and six-axis robot worked hand-in-hand, i.e. the six-axis robot communicated directly with the Multilift V 40, which in turn was connected to the Gestica machine control system.

Physical foaming with Profoam was an innovative lightweight construction application in which plastic granulate is mixed with a gaseous blowing agent in a granulate lock upstream of the injection unit. A hydraulic Allrounder 630 S with a new, five-litre granulate lock produced a structured cover for car interiors from PC (GF) in a cycle time of around 60 seconds. Dynamic mould temperature control enabled a high-gloss surface to be produced also with foaming technique.

The visible part was consistently designed for foaming and, with a wall thickness of only 1.8 millimetres, met the same requirements as a moulded part with a thickness of 2.5 millimetres produced using compact injection moulding. At around 213 grams, the structured cover was therefore around 24 percent lighter than an equivalent compact part.

The example of Petri dishes was used to demonstrate a cost-effective, compact and productive solution for the production of high-volume medical technology items: An electric Allrounder 470 A in a clean room version produced around 4,500 bases and lids per hour, corresponding to an output of around 16 million parts per year. The bases and lids of the Petri dishes were made from PS and were produced using a 2+2-cavity stack mould in a cycle time of 3.2 seconds, brought together in a conveyor system, assembled and stacked.

The current status of additive manufacturing

As well as the Freeformer, which individualised „smart" luggage tags at the K 2016, Arburg also presented two other Freeformers. One was used to process a new material, PEI high-temperature plastic. One of the remarkable features of this application was the layer depth of around 0.14 millimetres and the associated part quality. 70 spacers used in Allrounder injection moulding machines and weighing just 0.09 grams each were produced in a small-batch operation. The third Freeformer produced a model of a toggle model (1:16). Consisting of around 100 million drops, the resulting „block" almost filled the entire build chamber. After the support structure had been dissolved in the warm water bath, the 738-gram model had around 30 moving joints – just like the toggle of a „real" injection moulding machine.

ARBURG GmbH + Co KG
D 72290 Loßburg

K 2016: **BOY- innovative in all categories**

With its appearance at the K 2016 the specialist of injection moulding machines up to 1,000 kN clamping force hit the mark and impressed the visitors with its exhibits and applications at the worldwide most important Trade Fair for Plastics and Rubber. For BOY this event in Düsseldorf is and remains the base of relevant and future-oriented decisions for product-, process- and problem-solutions.

Whether the smallest BOY injection moulding machines – as the BOY XXS with 63 kN clamping force, which was presented to the public for the first time – or the new machine control Procan ALPHA ® 4 with graphic sequence programming – the presentation of the new products of the family-run company from Neustadt-Fernthal were persuasive.

Automation solutions 4.0

The premiere of the new BOY-linear handling LR5 as well as the successful presentation of the most modern automation technology with two interlinked working robots on a BOY 35 VV completed the successful trade show presence of BOY with an "Industry 4.0"-application. The process- and visitor data were printed by a QR-Code on individually personalized beer glasses (filled on request). Visitors could receive their refreshment directly from the robot hand.

Blow moulding in an injection moulding machine

On a BOY 60 the blow moulding technology was impressively demonstrated. In a 4+4-fold mould bottles for eye drops were pre-injected, then – after a 180° rotation of the mould core in the form – blown up and airtight packed in an integrated clean room.

Multi-Drive – the logical extension of Servo-Drive

Already with the launch of the servo-electrical pump drive BOY has set new energetic standards in the drive technology of injection moulding machines. With the new function Multi-Drive two energy-efficient servo-drives take over the drive function (either parallel or together). With the Multi-Drive technology applications with high injection volumes or -speeds or high-speed applications with short cycle- and cooling times can be performed more efficiently.

The operating times of both pumps can be individually configured in the injection moulding cycle. This means that simultaneous movements as for example opening of the mould and parallel ejector movements, core pulls etc. or processes of the different axes can be combined without any problems. In contrast to the electromechanically driven injection moulding machines – which require a separate servo-motor for each axis and thus have a high connected load – the BOY Multi-Drive operates with two drive motors only, which offers energetic advantages.

World premiere of the BOY XXS Table Top

For the first time BOY presented another new development – the new Table Top machine BOY XXS. The advancement of the BOY XS with a clamping force of 63 kN has been specially designed for the production- and laboratory area. All microforms of well-known manufacturers of standard mould units can be easily installed into the two-plates clamping system. The BOY XXS is equipped with a worm plasticizing in the diameter range of 8 – 18 mm (max. injection volume of 10.2 cm^3). Short dwell times of the material within the plasticizing unit and a more gently material processing acc. to the FiFo-principle (First in – First out) offer advantages when processing temperature-sensitive materials. All proven features of the BOY injection moulding machines such as an industrial permanent use, the intuitive machine control Procan ALPHA ® and the compact dimensions can be rediscovered in the BOY XXS. Optionally the table machine can be ordered with a movable base frame which will further improve the flexible field of applications of the BOY XXS.

A quick recap

„The K 2016 was the perfect platform to present the BOY-innovations to an international expert audience. We could find out that Industry 4.0 is more and more gaining ground in the plastics- and rubber industry. Many visitors at our booth were particularly interested in the new BOY XXS, the individual automation solutions, the "Industry 4.0 – application" and our new control Procan ALPHA ® 4," explained Alfred Schiffer, Managing Partner of Dr. Boy GmbH & Co. KG, and he added: "The K 2016 has been one of the most successful trade fairs so far. Numerous business transactions during the eight-day fair and a large number of promising projects are very positive prospects for BOY."

16th - 23rd Oct. 2019: K2019, Duesseldorf (D)

Dr. Boy GmbH & Co. KG
D 53577 Neustadt-Fernthal

Innovative pharma packaging in excellent quality

Reputed pharmaceutical customers procure Gerresheimer primary packaging products to cover their global requirements. The Gerresheimer Group's subsidiaries, Triveni and Neutral Glass, provide it with an excellent positioning in the Indian market. This year Gerresheimer will be presenting glass and plastic pharmaceutical packaging products that are FDA-registered and manufactured to stringent quality standards to the trade public at CPhI in Mumbai.

"All of our products are manufactured in compliance with the very highest quality standards. These standards apply to both glass and plastic packaging because all the Gerresheimer production processes are standardized and certified," said Subodh Gupta, Managing Director at Triveni in India.

Glass and plastic are the first choice primary packaging materials for solid and liquid dosage pharmaceuticals, a fact that is reflected by the Gerresheimer products on exhibit at CPhI Mumbai (India).

Pharmaceutical primary packaging plastic

Gerresheimer is one of the world's leading suppliers of plastic eye drop bottles. It recently modified the closure system on its Type A dropper bottle to the FDA's new requirements. Now the tamper-evident ring stays firmly affixed to bottle once it has been opened.

Does a tablet container always have to look like a pharmaceutical container? The Duma Pocket's oval shape makes it look more like a box of sweeteners or peppermints. Gerresheimer is introducing a new member of the Duma Pocket product family at CPhI in India: Duma Pocket 100 ml.

Now the popular Triveni Round family has been extended by a 60 ml container with a multilayer design for the US market. The Protect features delivers enhanced protection against water vapor and oxygen to sensitive pharmaceutical drugs. It is the first plastic container with a multilayer sandwich structure manufactured in an injection blow molding process.

Pharmaceutical primary packaging glass

Gerresheimer offers a fully comprehensive portfolio of glass pharmaceutical packaging extending from the smallest glass cartridges made from tubular glass up to 5000 ml acid-resistant chemicals bottles. There are also vials, ampoules, cartridges and other specialty products in transparent and amber borosilicate glass types I, II and III, as well as vials that are specifically manufactured for the Indian market.

Gerresheimer AG
D 40468 Düsseldorf

Microbial Quality of compressed air and gases

The microbiological monitoring of compressed air and bottled gases for microbial contamination is important within manufacturing facilities to ensure that product contact air is contamination free within sterile or aseptic manufacturing process.

The TRIO.BAS GAS is a microbial high pressure sampler according ISO 8573-7 and ISO 14698.

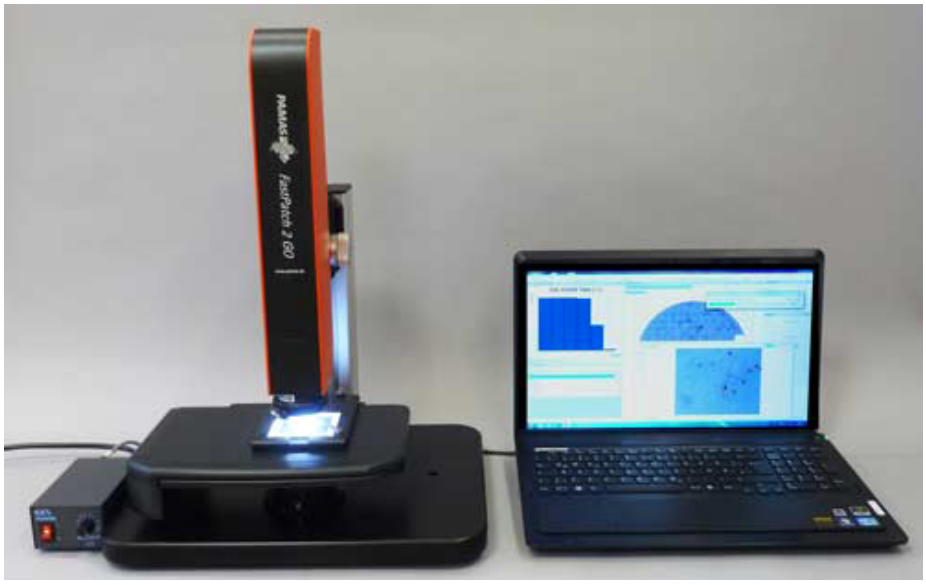
The TRIO.BAS GAS from Orum International S.r.l. in Milan, Italy has been specifically developed and produced to facilitate this microbiological test.

The system is sterilized by autoclaving in a single unique body to avoid possible contamination during the preparation steps.

The viable microorganisms collection is based on impact on culture plate like Petri dish.

Sampling data are transferred via Bluetooth to the P.C. according GMP and GLP.

Orum International S.r.l.
20153 Milano, Italien



The PAMAS FastPatch 2 GO image analysing system is the ideal instrument to measure dark and highly contaminated fluids. The automatic microscope system produces quick and accurate analytic results with the length and width of each particle recorded. (Picture: PAMAS)

Microscope for automatic filter patch analysis as per ISO 4407

PAMAS develops and manufactures automatic particle counters for fluid contamination control. The PAMAS product range includes measuring instruments for long-term condition monitoring of an array of liquids including hydraulic or lubricating oil and for contamination analysis of particulate matter in water, sea water, aviation fuel and pharmaceutical suspensions. At Hanover fair 2017, PAMAS presents an optical microscope image analysing system which is designed to analyse fluids that can prove problematic for automatic particle counters such as emulsions and dark fluids. The PAMAS FastPatch 2 GO microscope system analyses the entire effective filtration area of a filter membrane according to ISO 4407.

Fluid cleanliness can be monitored through optical particle counting. An automatic particle counter detects particulate contaminants in the fluid and measures their size and quantity. Some fluids however cannot be analysed through automatic particle counters. Amongst these are two phase liquids, highly contaminated fluids and emulsions. It is impossible to distinguish the immiscible liquid droplets contained in such samples from the solid particles, i.e. from the relevant particulate matter that is of interest in particle counting. In order for PAMAS to continue to support customers, existing and new, when analysing such fluids, PAMAS offers its own automatic microscope system for the analysis of filter membranes, the PAMAS FastPatch 2 GO.

The PAMAS FastPatch 2 GO system analyses particles trapped on the surface of the filter membrane and measures the length and width of each single particle. The user can capture images of any particles of interest on the filter membrane and add them to the end report with the dimensions of each particle displayed. The end report also includes an overview of the entire effective filtration area analysed depicting the chosen particles location on the filter patch. The PAMAS FastPatch 2 GO system provides results to international cleanliness standards including SAE AS 4059 F, NAS 1638, ISO 4406 and ISO 16232. If the user requires, the instrument is able to measure particles according to any user defined or customer specific standard.

Users of the instrument confirm that the PAMAS FastPatch 2 GO, compared to alternative microscope devices, provides key benefits: Firstly, sample analyses are repeatable and regardless of the filter patch orientation, the results are the same. Alternative microscopes do not allow inserting the filter in another orientation. The membrane filter patch is encased within a slide mount to ensure that the patch is held flat which removes the need for refocussing and more importantly prevents cross contamination. This also enables multiple analyses of the same sample to be carried out at any given stage in the future.

Another benefit is the measuring speed of the PAMAS FastPatch 2 GO: It takes less than 5 minutes to analyse a filter patch with a diameter of 25 millimetres.

Finally, the system incorporates a polarising option for the analysis of specific particle properties. Reflecting particles are categorised as metallic, and are highlighted in the particle results table. Equipped with this particular feature, the PAMAS FastPatch 2 GO enables differentiation of metallic and non-metallic particles, which has proven invaluable with some of PAMAS' existing customers. This polarising feature has detected the early failure of breakdowns in internal components that would have otherwise gone unnoticed.

The integrated polarising option further enables to detect transparent sample components like e.g. gelatinous particles. Their refractive index, which is similar to that of the surrounding air, makes the detection of such particles difficult. The polarising filter absorbs certain light parts and thus can make transparent particles visible.

The PAMAS FastPatch 2 GO system includes its own laptop preloaded with the software application required for analysis. This software programme is designed for membrane analysis and measures a wide variety of parameters, including the measurement of the particles length, width and area. The end report is fully customisable to the customer's requirements, logo and branding. A short English demonstration video on the PAMAS website provides an explanation of the software and shows a full filter membrane analysis. The video can be viewed at www.pamas.de after selecting the product page of the PAMAS FastPatch 2 GO.

PAMAS Partikelmess- und Analysesysteme GmbH
D 71277 Rutesheim

Humidity and Temperature Transmitter with Heated Sensing Probe

Improved Long-Term Stability in High-Humidity Conditions

Continuous high relative humidity (RH) can impair the long-term stability and accuracy of humidity sensors. Therefore, the new EE211 humidity transmitter from the Austrian sensor specialist E+E Elektronik features a heated sensing probe. This leads to best accuracy and long-term stability in high-humidity (>85% RH) and even in condensing environment.

The EE211 is designed for accurate humidity and temperature measurement under continuous high-humidity or condensing conditions. The device is ideal for climate control in fruit and vegetable storage, in greenhouses, incubators, ripening processes or in mushroom growing.

Heated humidity probe

In order to avoid drift effects due to long-term exposure of the sensing elements to high humidity, the sensor head of the EE211 humidity probe is continuously heated. The permanent over-temperature leads to max. 80% RH at the sensor. Condensation-related dirt deposits as well as corrosion of the sensor are thereby prevented.

Furthermore, the unique E+E protective coating also protects the active sensor surface from contamination and corrosive influences.

The combination of these features results in considerably improved long-term stability and increases both the service life and the measuring performance of the sensor.

Measured values and interfaces

The EE211 calculates the dew point temperature (Td) based on the RH and temperature values measured by the heated humidity probe. A separate, interchangeable temperature probe measures the ambient temperature (T). From Td and T the EE211 calculates back the ambient relative humidity as well as additional physical quantities like absolute humidity, mixing ratio, wet-bulb temperature or specific enthalpy.

Figure 1: EE211 Humidity and temperature transmitter with heated sensing probe. (Photo: E+E Elektronik GmbH)

The measured values are available on the Modbus RTU interface or on two analogue current or voltage outputs. The optional backlit display can show up to three measurands simultaneously.

Easy configuration and adjustment

The Modbus RTU parameters, the scaling of the analogue outputs and the display layout can be set with the free configuration software. The user can also carry out one or two-point humidity and temperature adjustment. The temperature probe can also be calibrated separately.

Optimally protected electronics

The IP65/NEMA 4 enclosure offers optimal protection for the EE211 electronics. Additionally, for best performance even in aggressive environment, the measuring electronics inside the humidity probe are fully encapsulated.

E+E ELEKTRONIK

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

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