Clean room technology

Clean solutions for a clean production environment
If you wish to use the many opportunities now offered by clean room technology in your company, you need to be able to rely on a partner who can offer you all the necessary technical components. And this would be advantageous, because it is apparent that the manufacture of innovative technical medical items, such as biodegradable human implants, is gaining in market potential. However, technical applications in the automotive, optical or micro-electronics sectors show that a wide range of options is available for high-quality clean production. There is one figure that shows that we at ARBURG can offer you full support in this area: several thousand ALLROUNDERS are already working reliably in a variety of clean room applications. If that's not proof enough...

**Special equipment for ALLROUNDERS for clean room applications**

<table>
<thead>
<tr>
<th>Part of equipment packages</th>
<th>Options</th>
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<tbody>
<tr>
<td>Mobile clean air module</td>
<td>Powder coating in “light grey”</td>
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<tr>
<td>with ionising unit installed above the clamping unit</td>
<td>Tunnel cover around conveyor belt</td>
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<tr>
<td>Raised machine feet</td>
<td>Stainless steel sorter unit</td>
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<tr>
<td>Tunnel cover around conveyor belt</td>
<td>Cover of the hydraulic system</td>
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<td>Stainless steel sorter unit</td>
<td>Contact of the cooling water distributor</td>
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<td>Cover of the hydraulic system</td>
<td>Clamping unit in stainless steel finish</td>
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<td>Nickel-plated mounting platen with covered bores</td>
<td>Media connections on the mounting platens</td>
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<tr>
<td>Sealed guarding for robotic systems in transparent PC including clean air module</td>
<td>Log book for the qualification and validation of the machine capability</td>
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<td>Sliding guard with suction connection for injection nozzle tip</td>
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Realise all your requirements
For medical and technical applications, ARBURG offers a clean room solution tailored to specific requirements and catering to every wish. The modular product range covers hydraulic, hybrid and electric ALLROUNDERS, different complementary clean room concepts, tailored equipment packages and flexible expansion options. When implementing turnkey systems, ARBURG, as a main contractor, cooperates with leading manufacturers of automation and clean room technology in order to bring together functions and solutions that are as individual as possible. Because application-specific requirements need precise responses, no two clean room solutions from ARBURG are the same.

Targeted emissions minimisation
In the case of clean room applications, it is particularly important that emissions should be kept to a minimum, so as to be able to achieve continuous, high-quality production. ARBURG offers highly specialised system solutions for a clean production environment. The basis for this is the low-emissions, standard machine technology, such as liquid-cooled drives or control cabinets, combined with numerous options for meeting the most stringent cleanliness requirements, e.g. through
• mobile clean air modules with ionisation for a high-level of air circulation
• the special stainless steel cover version for the best cleaning conditions
Unique solutions are required when working under clean production conditions – ARBURG has them.

In-depth consultation
However, ARBURG offers even more, because clean room concepts can only be as good as the expertise that lies behind them. An interdepartmental team of clean room specialists ensures that even unusual solutions can be implemented: machines are always specified in accordance with requirements and customer support pays equal attention to machine and applications technology and assists with mould design. In addition, ARBURG provides its customers with a perfectly equipped clean room laboratory where extensive individual customer trials can be carried out. It couldn’t be better!

Take OR lamps for example: when producing LED lenses, it is not just high part quality that counts, but also an ultra-clean production environment.
Application-specific: required clean room conditions

<table>
<thead>
<tr>
<th>Class according to EN ISO 14644</th>
<th>Maximum value for particles per m³ of air</th>
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<tbody>
<tr>
<td></td>
<td>0.1 µm</td>
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<tr>
<td>ISO 1</td>
<td>10</td>
</tr>
<tr>
<td>ISO 2</td>
<td>100</td>
</tr>
<tr>
<td>ISO 3</td>
<td>1,000</td>
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<tr>
<td>ISO 4</td>
<td>10,000</td>
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<td>ISO 5</td>
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<td>ISO 6</td>
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<td>ISO 7</td>
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<td>ISO 8</td>
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<td>ISO 9</td>
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The clean room classes set down clear guidelines for the number of particles permitted in one m³ of air.

Whether for medical or technical applications, cleanliness is necessary in many sectors, in order to bring products onto the market successfully. Does your medical clean room application require you to meet all the necessary standards and guidelines? Do your own quality standards necessitate a technically clean production environment? In both cases we are the right partner for you. That’s because our extensive experience and perfect injection moulding technology enable us to meet every conceivable requirement, so that you can manufacture smoothly, reliably and, above all, cleanly.

Cleanliness requirements
The list of requirements can be long: Moulded parts must be protected from airborne contamination such as dust particles, pollen, bacteria, cell residues, viruses or organic aerosols. For this purpose, negative influences arising during production must be limited and prevented from coming into contact with the product. In practice, this can be achieved through high-quality ventilation and air-conditioning for example. The central set of regulations for defining clean rooms is the EN ISO 14644 standard. Injection moulding production generally takes place in classes ISO 7 and ISO 8. For the highest standards, clean room conditions up to ISO 5 are possible. Other EN ISO, VDI and VDA standards and EU directives also apply. These are derived from GMP (Good Manufacturing Practice), other directives from the US FDA (Federal Drug Administration) and individual specifications and factory standards.

Medical applications
Due to their advantages, such as biocompatibility, sterilisability and chemical resistance, plastics have also become an essential material in the field of medical technology. A correspondingly wide range of applications thus exists for the moulded parts. It extends from mass volume or disposable items via instruments through to implants, which are temporarily or permanently implanted in the human body. For the success of a product, it is not just production under clean conditions (norm-controlled absence of particles and germs) that is decisive. Other important factors include the precision and reliability of the injection moulding machine, which is required to produce the parts to the highest quality standards.
Technical parts: high-level cleanliness guarantees high quality.

Technical applications

The hygiene demands that apply to technical applications are also continuously increasing. Visible defects can occur in decorative parts through the inclusion of particles, for example. Good examples of this are optical components such as lenses and sensors, parts with downstream finishing through chroming or painting and items with in-mould labelling (IMD, IML).

In micro-technology applications, fine micro-textures are applied to the plastics. The inclusion of particles would lead to malfunction here.

The key to the absence of particles in the entire sector is individual quality assurance in each injection moulding company and a machine and clean room concept tailored to the requirements.

Essential: regular cleaning

Regular cleaning and disinfection of the clean room and all production facilities are essential if a clean production environment is to be maintained. ARBURG provides injection moulding technology that is easy to clean and that makes operation correspondingly efficient.

In addition, specific hygiene measures for personnel are decisive. Special work clothing and working guidelines (compliance with cleaning procedures before and after working in the clean room) are required with no exceptions.

Qualification and validation

Comprehensive qualification documentation is available for all ALLROUNDERS in order to meet the documentation requirements under ISO 13485 and GMP. This includes the following standard documentation:

- Machine configuration
- Operating instructions
- Functional descriptions
- Maintenance intervals
- Cleaning instructions
- Setup plans and circuit diagrams
- Spare parts lists

The inspection log book may also be included as evidence of machine capability. Compliance with limit values and tolerances is checked in detail and documented. In order to maintain the reproducibility of an injection moulding machine, ARBURG offers an inspection contract that ensures regularly qualified re-validation.
Precisely tailored: modular machine technology

Ionisation: clean air modules ensure low-particle air in the working area.
Clean: tunnel covers ensure that parts can be transported free of contamination.
Tidy: covered cooling water distribution systems limit the risk of possible contamination.

For us, perfect clean room conditions start with injection moulding technology adapted precisely to your individual requirements. After all, the clean room, production and items can only meet the highest quality requirements if the production components used operate with low emissions. In order to exclude sources of contamination and to establish a sufficiently clean production environment, our ALLROUNDER injection moulding machines can be adapted individually by means of highly-flexible expansion options. Perfectly moulded parts from the clean room – we make it happen!

Basis: low-emission technology
All aspects of ARBURG clean room technology are subject to continuous further development. This includes detailed analyses, such as particle measurements, flow visualisations, static charging tests as well as thermography.
The high-grade standard equipment of the ALLROUNDER effectively combats contamination and emissions. The machines come with an abrasion and scratch-resistant powder-coating as standard. Liquid-cooled drives and control cabinets prevent air turbulence and cause only a very low level of heat dissipation. Dispensing with belt drives prevents particle contamination due to abrasion.

Important: ionised clean air
Clean air modules use radial fans to draw in the ambient air and produce clean air via a pre-filter and an airborne particle filter (HEPA H14). An integrated ionisation system also neutralises electrostatic charging, significantly reducing the number of particles on the moulded parts. The permanent air flow leads to a high level of air circulation in the production area. At the same time, air is displaced, effectively preventing the penetration of particles. Clean air modules enable clean room class ISO 3 to be achieved directly at the air outlet of the airborne particle filter.

Further information:
Injection moulding machines brochure
User-friendly: media connections on both the fixed and moving mounting platen.

Efficient: best possible cleaning thanks to an stainless steel clamping unit.

Flexible expansion options
ARBURG offers a wide range of individual equipment features for optimum clean room production. These include, for example
- raised machine feet for a clean production environment
- a stainless steel sorting unit for the reliable separation of good and reject parts
- a mobile clean air module for fast, convenient setup
- nickel-plated mounting platens with covered bores for the best cleaning conditions in terms of GMP A and ISO 5
- FDA / NSF H1-compliant lubricants

Equipment

In line with the clean room concepts, ARBURG has combined the necessary basic equipment in packages.

Machine docked with clean room
- Mobile clean air module installed above the clamping unit
- Extended conveyor belt
- Tunnel cover around conveyor belt
- Stainless steel sorter unit
- Raised machine feet
- “Light grey” powder coating

Production cell docked with clean room
- Mobile clean air module installed above the clamping unit
- Closed guard for housing the robotic system in transparent PC
- Clean air module installed above the working area of the robotic system
- Tunnel cover around conveyor belt
- Raised machine feet
- “Light grey” powder coating

Production in the clean room
- Specially for hydraulic ALLROUNDERs:
  - Cover for the hydraulic system
  - Raised machine feet
  - “Light grey” powder coating
Multi-faceted: clean room concepts

Our clean room concepts all share one primary characteristic: consistent, practice-oriented design. This means that you always decide which of our versions should be used in your production. That’s because our design depends solely on your part and production requirements.

Our range includes an ALLROUNDER that is directly connected to a clean room, solutions that involve production entirely within the clean room as well as individual clean room cells. The modular design of our entire technology enables simple application-specific adjustments and the addition of new features and functions. There is for sure to be something of interest for you!

Connection to clean rooms

In this concept, the ALLROUNDERs may produce outside of the actual clean room, but production conditions remain absolutely clean. These conditions are created by clean air modules installed above the clamping unit. A conveyor belt, which features a tunnel cover, transports the produced parts without contamination to the actual clean room for further processing. As well as free-falling parts, automated removal is also possible. The robotic system is docked with the ALLROUNDER by means of a guarding made from transparent PC. Together with clean air modules that cover the entire working area, a completely encapsulated production cell is created under clean production conditions. It is also possible to feed in inserts from the clean room. Both of these versions allow the clean room to be kept as small as possible. Because the ALLROUNDER and the associated peripherals are set up outside the clean room, it is not exposed to any additional particle contamination or thermal loading. All downstream processes such as quality control or packaging are performed within the clean room. Access is via personnel and material air locks.
2 Production in the clean room
This version organises ALLROUNDERs and entire production cells in a clean room. It is particularly suitable for injection moulding companies which produce with a very large number of machines under identical clean room conditions. Vertical and rotary table machines can be integrated, as can downstream work processes or processes that require manual insertion.
In this production environment, the machines and robotic systems are open on top in order to use the continuous ventilation within the production hall for generating air flow in the work area. The cover on the hydraulic system limits the risk of possible impurities.

As an option, it may be advantageous to exclude other sources of emissions. This can be achieved in various ways, such as:
- covering the cooling water distributor,
- providing media connections in the vicinity of the mould,
- providing a stainless steel encapsulated clamping unit,
- and, in the case of hydraulic ALLROUNDERs in particular, by providing a liquid-cooled pump motor without a fan.

3 Individual clean room cell
ARBURG can also offer its customers complete turnkey solutions, including all the necessary automation and clean room technology, from a single source. ARBURG handles all implementation steps, from project planning, commissioning on the customer's premises and CE labelling, to training and system support. As a main contractor, ARBURG cooperates closely with the leading manufacturers of automation and clean room technology in order to provide production units that are of a genuinely high technical standard.
Individual clean room solutions must exactly correspond to your specific application in order that series production of high-end injection moulded parts is always ensured. We offer you the finest clean room concepts from a single source, providing the same modularity familiar from our ALLROUNDER injection moulding technology. From individual machines and production cells with a removal function to complete project systems, including all clean room applications. Either designed to be used directly for your clean room, docked with the clean area, or as an individual clean room cell. We offer you not only the technology you require, but also the professional support to go with it. From the planning stage to installation on site. Choose high-grade solutions – rely on us!

1 High-quality medical technology

“Complete production in clean room” is the production philosophy followed by B. Braun Melsungen AG at its production facility in Escholzmatt, Switzerland. The ALLROUNDERs run in a large-scale ISO Class 8 clean room in which assembly operations and primary packaging also take place. The multi-way tap system produced in this environment is used in intravenous drip therapy. In order to ensure correct operation of the tap system, extremely stringent tolerances must be adhered to during injection moulding. The individual components, produced are interim-stored in a bag, brought to an assembly station, then packaged in Tyvek foil and transferred out of the clean room via an air lock for sterilisation.

2 Secure encapsulation of inserts

Gira is also involved in the production of medical technology components. When it came to the design and execution of the ISO Class 7 clean room with online particle monitoring, the company placed its full trust in ARBURG’s expertise. Thus, for example, blood flow diverters are produced on a production cell outside the clean room with a horizontal MULTILIFT robotic system. In order to achieve the necessary clean production environment, clean air modules are mounted above the entire working area of the production cell. The insert is separated in the clean room, the finished parts are then conveyed by means of an encapsulated conveyor belt back into the clean room for quality control and packaging.
Sterile OP instruments

Under the motto “Sharing expertise in the operating theatre”, Tuttlingen-based Aesculap AG & Co. KG, a division of B. Braun Melsungen AG, offers its customers products and services relating to core surgical processes. For the production of various surgical instruments, for example clamps, ALLROUNDERs were docked to an ISO Class 7 clean room. After production, the moulded parts drop onto an encapsulated conveyer belt, which transports them to the clean room without contamination. Quality control and packaging take place here, before the assembled part batches leave the clean room again via a material air lock. Finally, the parts are sterilised.

Particle-free lenses

Optical lenses are produced fully automatically under clean room conditions with a production cell built around a hydraulic ALLROUNDER. The configuration operates in conjunction with a MULTILIFT H robotic system arranged at the rear of the machine. Both the clamping unit of the machine and the operating area of the robotic system are covered with clean air modules, which ensure a low-dust atmosphere. The optical lenses, made from PMMA are produced in a 4-cavity mould, are removed by the MULTILIFT together with the sprue and set down onto an encapsulated conveyor belt. This transports the parts to a clean room, where they are further processed and packaged.

Clean system solutions

ARBURG was involved in the project for the production of a vaginal ring (medical implant) for HIV prevention, acting as main contractor for the entire production cell. Thanks to an stainless steel clamping system, the electric ALLROUNDER is adapted to the highest hygiene requirements in accordance with ISO 13485, as well as the specifications of the FDA and the GMP directives. The machine equipment includes nickel-plated mounting platens, the cover for the cooling water distributor, covered media connections routed to the mounting platens and FDA / NSF H1-compliant lubricants. The entire clean room cell is covered over with ISO Class 3 clean air modules.
Distances between tie bars from 170 x 170 to 920 x 920 mm | Clamping forces from 125 to 5,000 kN | Injection units from size 30 to 4600 (according to EUROMAP)

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All data and technical information have been compiled with great care. However we accept no responsibility for correctness. Individual illustrations and information may deviate from the actual delivery condition of the machine. The relevant valid operating instructions are applicable for the installation and operation of the machine.

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