

Innovative into the Future – BOY-Injectioneering



Economic clean room concepts

Knowledge of the cleanness required

The requirement for a clean manufacturing environment is very common in medical technology. Also, for the production of mostly very small, highly technical parts, especially in the automotive and communications industries, as well as in precision equipment manufacturing, foreign particle-free production environments are becoming more and more inevitable.

For the planner of such a production line, this means that in addition to the procedural processes, the development of a suitable environment for the production is required. With a variety of products with correspondingly different production processes and cleanness requirements in production, it is understandable that the implementation of a clean environment cannot be a ready-made standard that is available „off the peg“ – this has to be planned according to the requirements.



Planning principles for a clean manufacturing environment

The basis for the planning is the knowledge about the requirements for cleanness.

Cleanness means that no foreign particles exist in a volume in which production will take place.

This means for the technician that a maximum of particles that can be tolerated in the production environment must not be exceeded. In addition to the quantity, the size of the particles is also important.

Different **cleanness classes** are defined by the number of tolerated particles in different size ranges.

This quantification is done in medical technology and in the food sector according to the **US Federal Standard 209 E**, which is implemented by the FDA (US Food & Drug Administration). In Europe, the comparable **EN ISO 14644-1** was introduced (image 1).

Cleanroom classification according to EN ISO 14644 - 1							
EN ISO 14644 - 1 Classification number (N)	Highest value of the concentration of particles (particles per m³ air / per cft) Equal or higher than the considered quantities shown below.						old US-Federal Standard 209 E
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm	
ISO Class 1	10	2	-	-	-	-	-
ISO Class 2	100	24	10	4	-	-	-
ISO Class 3	1.000 28	237 7	102 3	35 1	8 0	-	1
ISO Class 4	10.000 284	2.370 67	1.020 29	352 10	83 2	-	10
ISO Class 5	100.000 2.841	23.700 673	10.200 290	3.520 100	832 24	29 1	100
ISO Class 6	1.000.000 28.409	237.000 6.733	102.000 2.898	35.200 1.000	8.320 236	293 8	1.000
ISO Class 7	-	-	-	352.000 10.000	83.200 2.364	2.930 83	10.000
ISO Class 8	-	-	-	3.520.000 100.000	832.000 23.636	29.300 832	100.000
ISO Class 9	-	-	-	35.200.000	8.320.000	293.000	-

While the **EN ISO 14644-1** refers to the particle size 0.1 µm and the classification is made on the permitted power-of-10 of the number of particles / m³, **the US Federal Standard** refers to the maximum number of particles of the size 0.5 µm only in a volume of 1 cft (cubic foot) (= 0.0284 m³).

Image 1: clean room classification according to EN ISO 14644-1 and FDA US Fed.Std. 209 E

Function of a clean room

Typical clean rooms operate with air-conditioned, filtered air that is consistently transported into the room from the ceiling at a low overpressure. This air should flow through the room in a laminar flow and escape via outlets which are in the floor area.

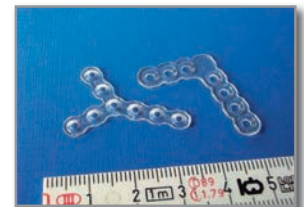
Turbulences are to be avoided.

A lightly higher air pressure in the clean rooms prevents the penetration of foreign particles. The expenditure of the air conditioning is very complex, especially for high cleanness classes, due to the necessary regular replacement of filter elements. This is the reason to keep the clean room volume low.



When selecting machines for the manufacturing in a clean environment, attention must be paid whether these machines are suitable for the process.

- Are particles delivered into the environment, e.g. abrasion?
- Are there any machine areas that tend to get dirty, e.g. bearing points that need to be lubricated?
- Are air flows created by fans or convection?
- Is the machine easy to clean, e.g. due to a smooth-surface design?
- How often is maintenance to be carried out in the clean environment and how complex is it?
- Does the machine have a high heat emission that has to be compensated by the performance of the air conditioning?
- Do high temperatures on the machine cause convection flows, which disturb the downward "laminar flow" and thus cause air turbulences?



In order to achieve economically sensible and ergonomically favourable solutions, compact and smoothly enclosed machines are therefore the obvious choice. BOY injection moulding machines already comply with almost all criteria in the standard version.

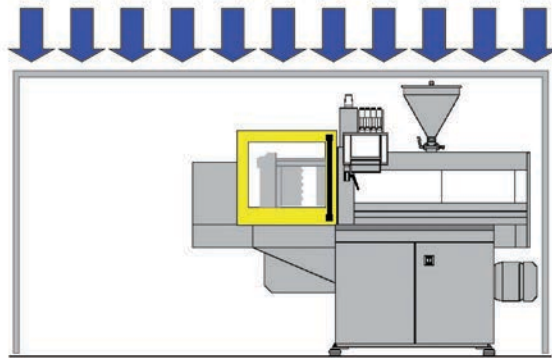
- If the machine is operated correctly, there are no abrasion points. Servo-hydraulic machines, for example, are not equipped with toothed belts.
- If required, optional water-cooled servo drives can be used in order to avoid undesirable cross-flows and turbulences in the laminar-flow-area.
- BOY injection moulding machines are fully enclosed, which makes an easy cleaning possible.
- Only a minimum maintenance is required. Lubrication points are completely eliminated.
- The servo drives work extremely energy-efficient. Combined with the possibility to almost reduce the hydraulic oil temperature to room temperature, the heat emission into the production environment is minimal.
- Modern Econplast-plasticising units optimally bundle the energy for the preparation of the plastic by means of heating elements which are integrated into the cylinder and a precisely designed insulation. The temperature of the smooth-surface housing of the plasticising cylinder is drastically reduced compared to conventional plasticising units. Convection flows are thus reduced to a minimum.



Modular clean room concepts

The BOY-typical 2-platen clamping unit allows the use of different clean room concepts which are presented below.

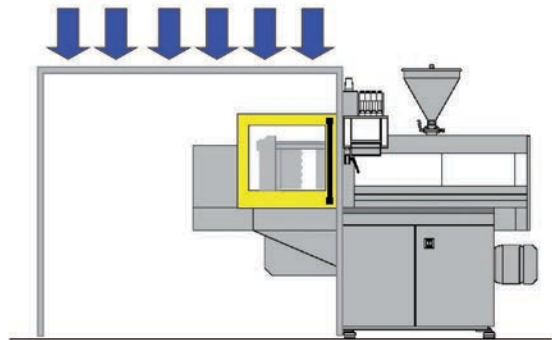
Clean Room
Concept
I



The injection moulding machine is located entirely in the clean room:

The compact design, slightest emissions, full housing and minimum maintenance requirements offer tangible advantages. A clean-room-suitable, self-contained material supply system is available for all BOY machines.

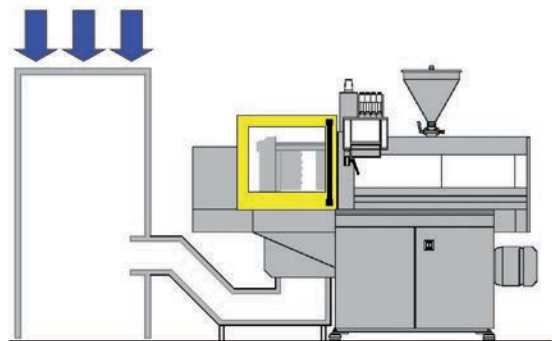
Clean Room
Concept
II



Only the clamping unit of the machine protrudes into the clean room:

This arrangement is possible thanks to the 2-platen clamping unit. Minimum space requirement in the clean room, plasticising unit, drive and material supply are located outside the clean room. The machine can be operated via a second operating unit both from the clean room and from outside.

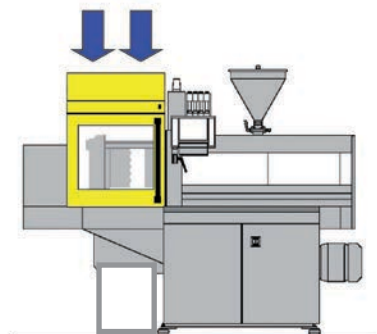
Clean Room
Concept
III



The machine is located outside the clean room: The manufactured parts are transported into the clean room via a completely enclosed conveyor belt or a handling system.

From the clean room, clean air flows through the conveyor belt channel and against the flow of moulded parts through the mould room. Alternatives with the use of a handling system and a transfer gate are possible.

Clean Room
Concept
IV



If the manufactured parts are not fed directly into a follow-up-process, the production area can be limited to a minimum. An air filter box (laminar flow box) mounted on the protective housing of the clamping unit presses a laminar clean air flow through the open injection mould and its surroundings. Directly below the mould, the parts are packed immediately in the clean environment.

Which clean room concept is suitable and when?

Clean room requirements according to **ISO-class 1, 2 or 3** must be considered as highly sensitive. The production facility should therefore be discussed on the basis of a technical specification with the suppliers of the components.

With some adaptations the clean room concepts I and II offer a good basis.

Clean room requirements according to **ISO-class 4 or 5** can be implemented with clean room concepts I and II. Concept III of a cascade-type clean room with the enclosed clamping unit of the injection moulding machine, from which the transport to a higher-class clean room takes place, offers the advantage that the machine is located in a clean area that is less complex to operate, while the high-class clean room can be a smaller design.

Clean room requirements according to **ISO-class 6** can be implemented with less expenditure. Since the filters in these classes are less expensive, clean room concept I is the one that is preferably used. Concept III is also applicable.

Clean room requirements according to **ISO-classes 7 and 8** require minor measures in the environment of the injection moulding machine. The working environment must be adapted to the cleanness requirements. Concept IV ensures that it is protected from contamination.



Image 2: BOY 60 E with laminar-flow-box



BOY injection moulding machines with integrated laminar-flow-box and alternative packaging machine are affordable and efficient alternatives to conventional clean room systems. The cantilevered two-platen clamping unit of the BOY injection moulding machines offers design-related advantages for the clean room production. The requirements of ISO-class 6 are well accomplished by the machine modification according to **clean room-concept IV** (see page 4).



Spritzgiessautomaten

Dr. Boy GmbH & Co. KG

Industriegebiet Neustadt / Wied
Neschener Str. 6
53577 Neustadt-Fernthal
Germany

Tel.: +49 (0)2683 307-0
Fax: +49 (0)2683 307-4555
E-Mail: info@dr-boy.de

www.dr-boy.de



BOY-APP
free of charge at
<http://app.dr-boy.de>