

cleanroom technology for plastics moulding



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1. Agenda

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1. Agenda

Company

alpha ionstatex operate world-wide
and was already awarded 2003 for permanent expanding with the
innovation fund "Pioniergeist 2003".

The core competences are consultation, planning and
development and besides execution, support, acceptance and
certifying.

Our Activities

Development, manufacture, production and mounting in the range
of modular cleanroom technology

Our Strength

Because of clever strategic planning we are able to offer feasible
and cost - favourable solutions, specific to the individual
requirements of our clients.

We give top priority to investment, maintenance charges and
operating expenses.



1. Agenda

alpha ionstatex gmbh provides

ready to use concepts with planning including development up to production, mounting and certifying:

Cleanroom assembling

Startup

Service and maintenance according to VDMA

Planning and specification

Qualification, particle measurements, cleanroom classifying

Personnel qualification and employee training



2. Basic considerations

Decision for a cleanroom

A lot of products only become possible because of cleanrooms.
They are a dominating part for quality and safety during a production.

Use of the cleanroom - areas

Our environment is full of particle and microbes.
Cleanroom areas protect products and processes against influences of the environment to reduce errors.

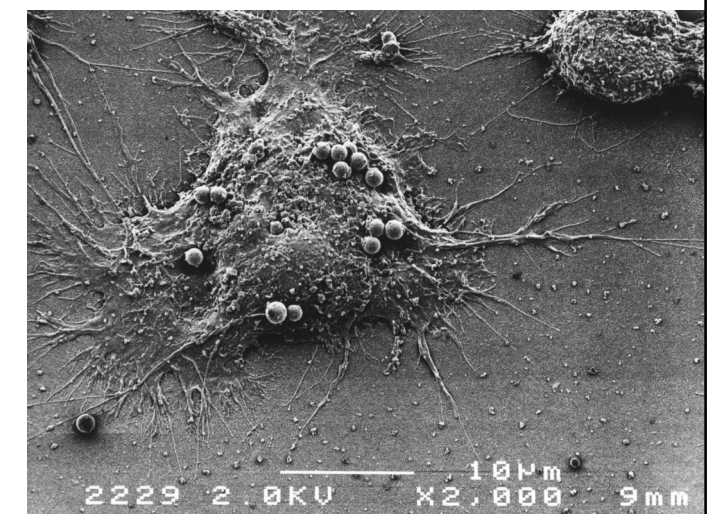
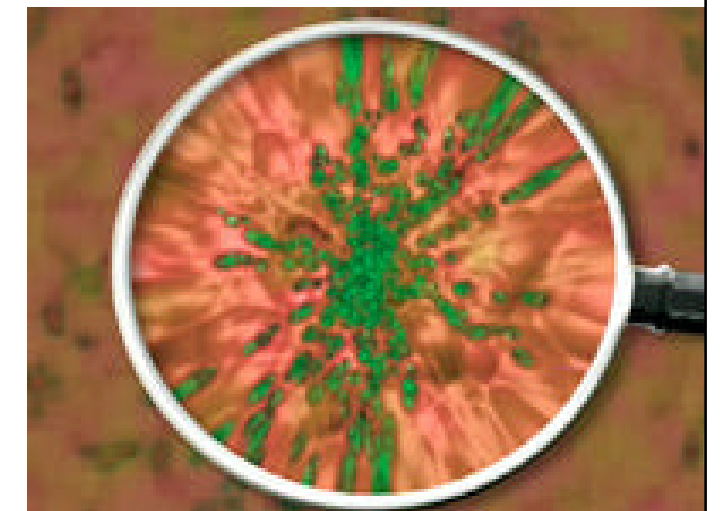
Absence of particles, absence of germs

Absence of particles

Lenses, prisms, mirrors, coated surfaces, design parts, discs

Absence of particles and germs

Medical technology, cosmetics, pharmacy, foodstuffs



3. Humans in cleanrooms

People are a major source of contamination in the clean room.

(Notice the number of particles produced per minute during these activities)

Humans as particle „carriers“

People activity	particles / minutes (0.3 microns and larger)
Motionless (Standing or Seated)	~ 100.000
Walking about 2 mph	~ 5.000.000
Walking about 3.5 mph	~ 7.000.000

Humans with clothes

with normal clothes	~ 80.000 particle / sec. ($\geq 0,5 \mu\text{m}$)
with cleanroom clothes	~ 700 particle / sec. ($\geq 0,5 \mu\text{m}$)
reduction	~ 1/ 100....1000

Humans as germ „carriers“

1 x Sneeze	~ 100
Scalp	~ 1.500.000
Forehead	~ 200.000
Cleanroom class A (GMP)	max. 1 germ / m ³



4. Standards and regulations

European standards ISO 14644

GMP Goods manufacturing processes

FDA US surveillance authority

Association of German Engineers VDI 2083

US Federal Standard 209 e

German Industrial Standard (DIN)

Regulations and Guidelines:

Workplace regulation,

fire protection regulations, ...



5. Clean-room classes

ISO	US.	GMP	0,3 +		0,5 +		1,0 +		5,0	
14644	Fed.									
class			um / Volumen		um / Volumen		um / Volumen		um / Volumen	
			m ³	ft ³	m ³	ft ³	m ³	ft ³	m ³	ft ³
1										
2			10		4					
3	1		102	3	35	1	8			
4	10		1.020	30	352	10	83			
5	100	A	10.200	300	3.520	100	832		29	
6	1.000		102.000		35.200	1.000	8.320		293	7
7	10.000	C			352.000	10.000	83.200		2.930	70
8	100.000	D			3.520.000	100.000	832.000		29.300	700
9					35.200.000		8.320.000		293.000	

6. Ventilation and air conditioning system

Systems for air heating, air cooling, humidifying and dehumidifying,
e. g. for the adherence to the dewpoint for areas for tools

include:

Air – filtering, two-stage filter system (prefilter)
absorbing duct (before and behind the ventilators)
ventilators
air duct system with Hepa – Filters at the end of system
cooling (chilled water set, cooling pipework systems)
Heating (over water, electrical heating element)

.....



6. Ventilation and air conditioning system

Air rate / Air change

Clean room class – (at rest / in operation)

Dimensions (cleanroom)

Pressure maintenance

Type of area (mould, handling, personnel)

flow rate (air change) 10 - 500 (1000) 1/h

Air filter classification

Filterclass

G1 – G4

F5 – F9

H10 – H14

U15 -

Type

coarse

fine

HEPA

ULPA

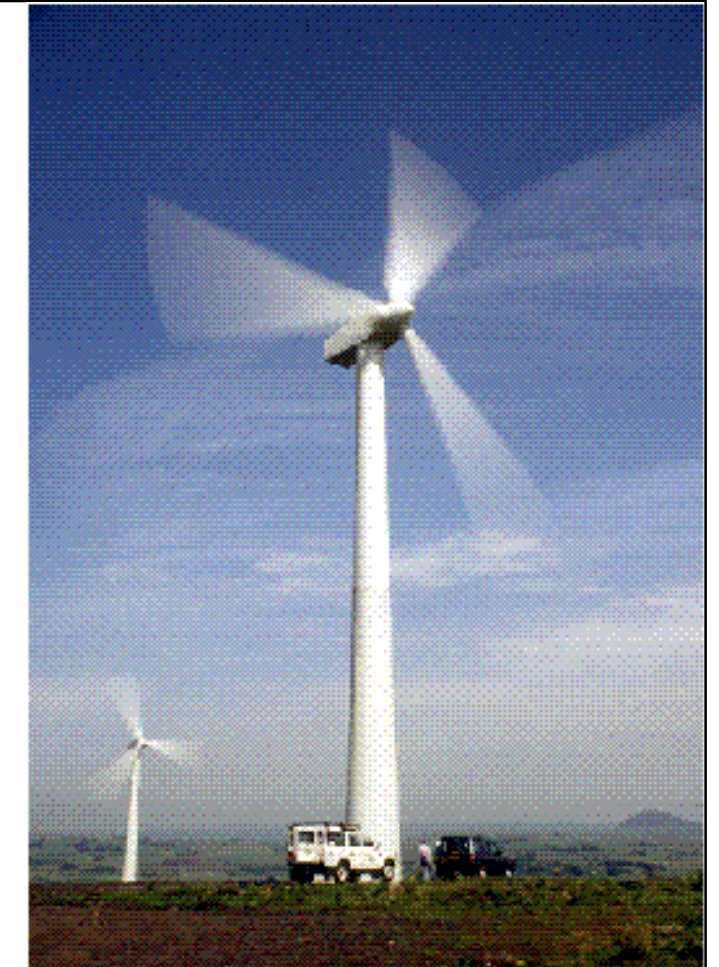
Norm

EN 779

EN 779

EN 1822

EN 1822



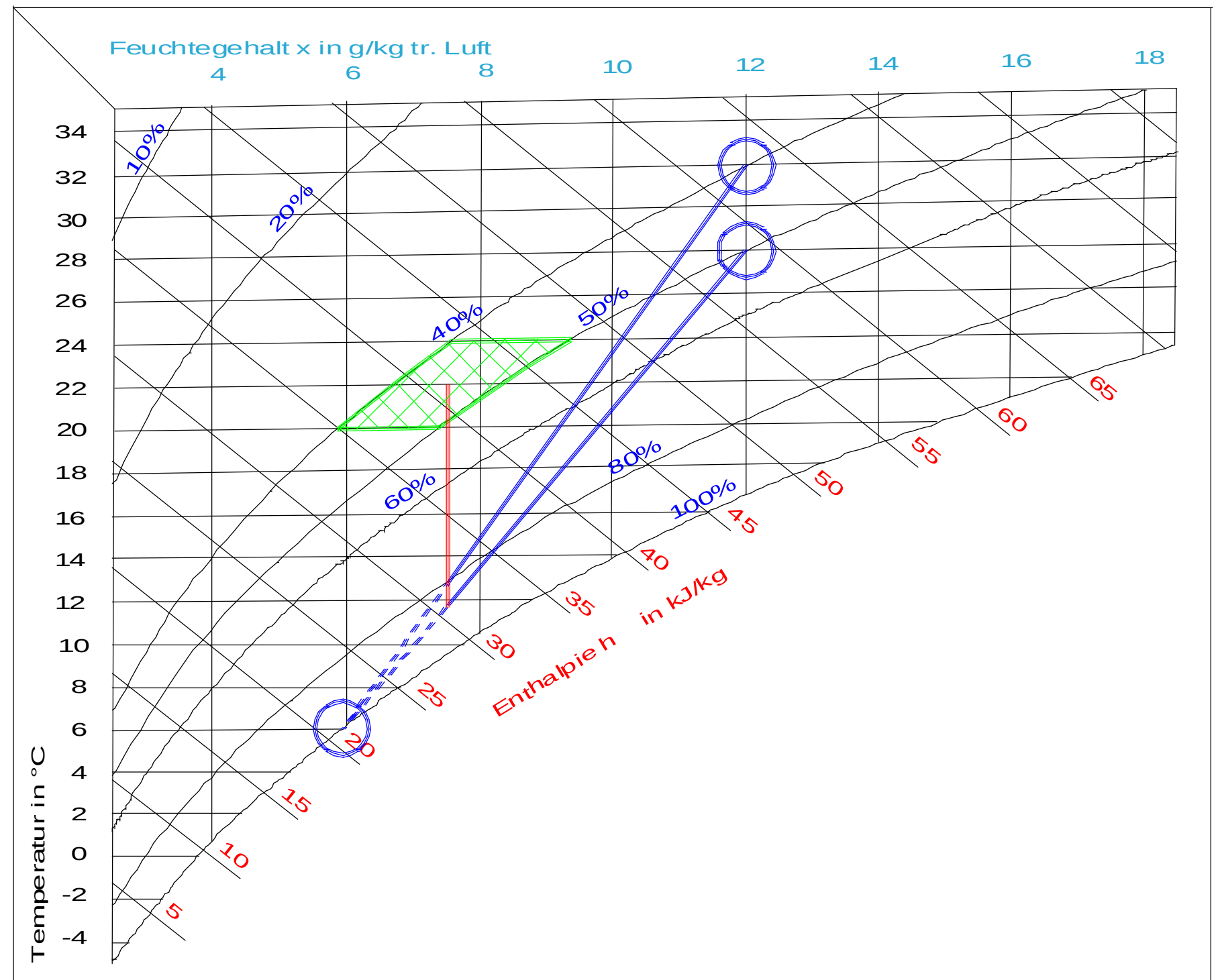
6. Ventilation and air conditioning system

Relative air humidity %

Dehumidification / humidification

Outer air

h x – diagram (Mollier)



6. Ventilation and air conditioning system

Humidifying systems

Steam air moisturizers (electrical / gas)

Humidification over atomization (VE water / silver ions)

Dehumidifying system

Cooling and re-heat up

also by high outside temperatures

Cooling

dependent on:

Machines inside, lighting

Persons

Sun exposure

Heat emission by products

Air flow rate, Dehumidifying

Heating

Regulation over working places regarding minimum ambient temperatures



7. Control technology and electrical measurement

Systems for:

Air conditioning

Filter control

Interdependent door locking of the locks

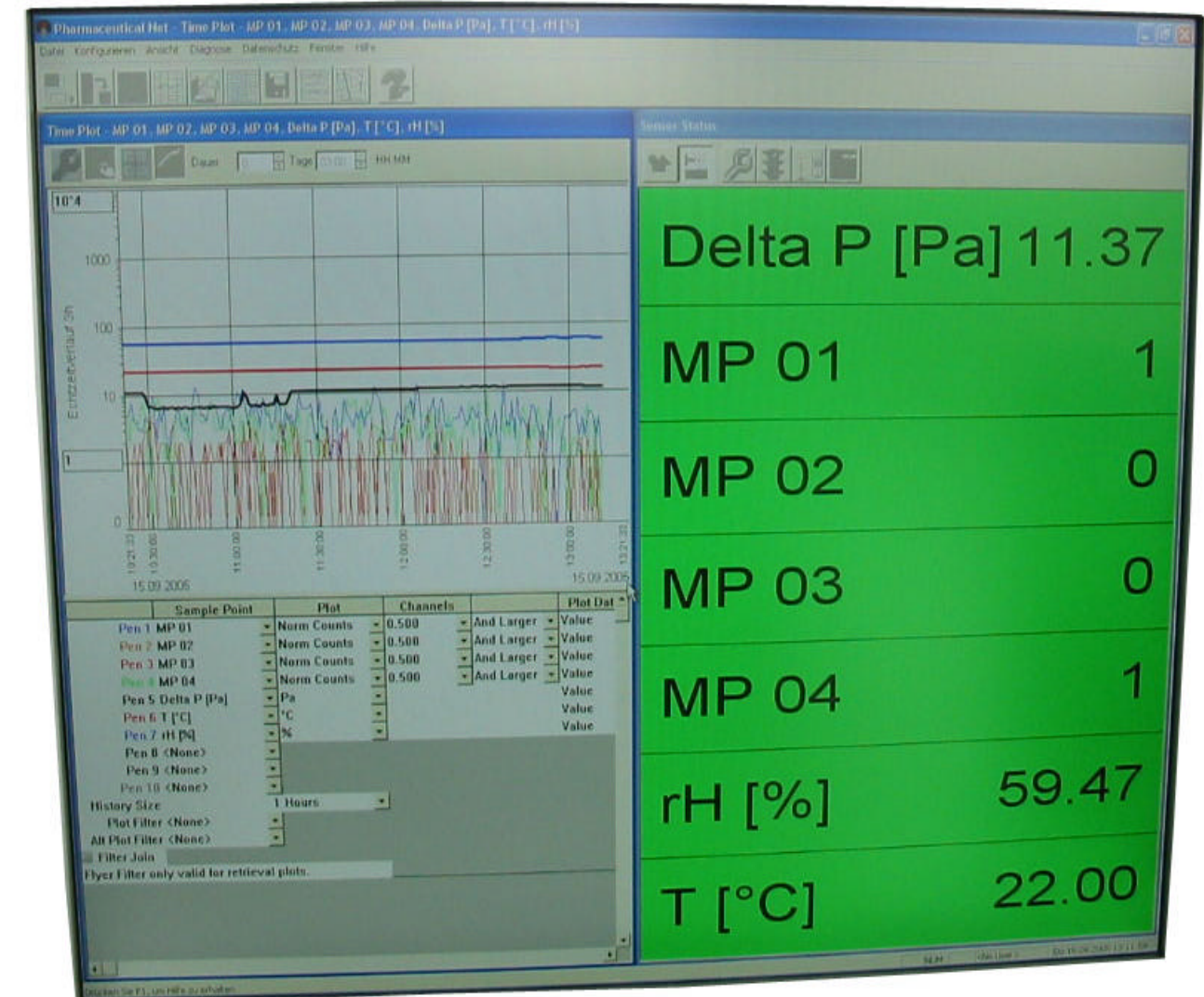
Personal admission systems with provable documentation

Intercom systems between inside and outside of the cleanroom

Online monitoringsystem

Online particle measurement, data logger

Data logger for recording and storage of the data (temperature and/or humidity and/or pressure)



8. Furnishing, cleanroom equipment

Lock persons

Sit-Over Bank

Wardrobe

Clothes rail

Washbasin

Contactfree water tap

Disinfectant spender

Soap dispenser



8. Furnishing, cleanroom equipment

Clothing

Cleanroom clothing prevents that the persons working in the cleanroom contaminate these with particles – hair, dust at the clothes

Overalls, gloves, overshoes, caps

equipment

Disinfectant, cleaning materials, tables, chairs, ...



9. Modular cleanroom system

Injection moulding machine: inside cleanroom

All in one system

All machine parts in one cleanroom area



Injection moulding machine: outside cleanroom

Every machine parts as a cleanroom area:

Mould area of injection moulding machine

Handling-, robot system

Conveyor belt

Cleanroom (person - working area / automatic assembly machine)

Locks for persons (male / female) and material



9. Modular cleanroom system

System KM:

Injection moulding machine
outside cleanroom

Mould area
inside cleanroom

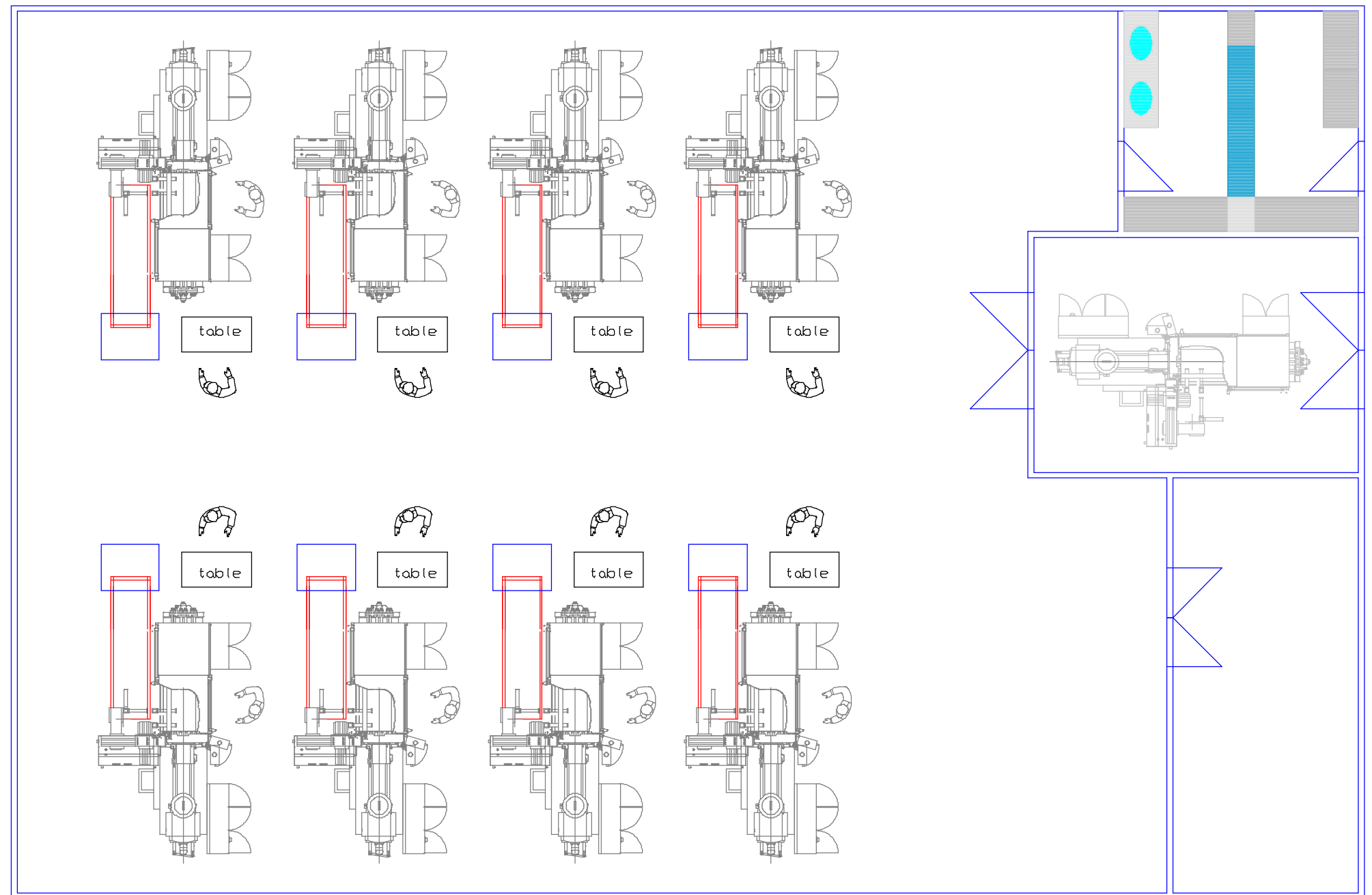


9. Modular cleanroom system

Modular clean room CAA

8 x Injection moulding machine
inside cleanroom

Area: 330 m²

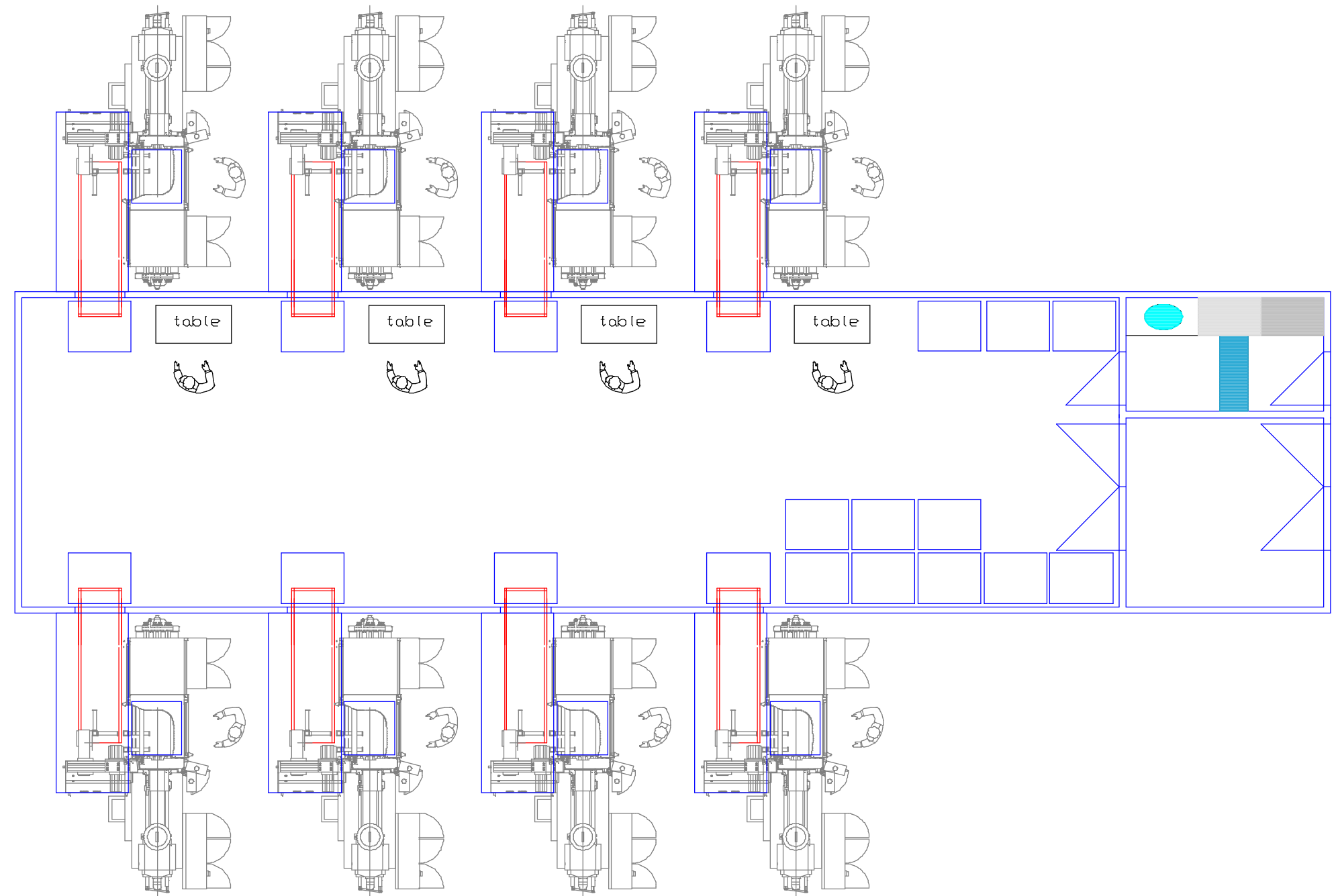


9. Modular cleanroom system

Modular clean room CAA

8 x Injection moulding machine
outside cleanroom

Area: 90 m²



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9. Modular cleanroom system

injection moulding machine		8	8
		inside	outside
Cleanroom	Area m ²	330	90
	Height m	4,5	2,8
	Volume m ³	1.485	252
	Air change 1/h	40	40
	Air rate m ³ /h	59.400	10.080
Locks	Persons area m ²	16	4
	Material area m ²	24	7
	Total m ²	40	11
	Height m	3	3
	Volume m ³	112	31
	Air change 1/h	20	20
	Air rate m ³ /h	2.240	616
Cleanroom incl. locks	m ³ /h	61.640	10.696
Cooling power (min.)	kW	260	50
Heating power	kW	120	40



9. Modular cleanroom system

Cleanroom assembling

Wall and ceiling

Single sided or double sided structure

Windows, double-glazed window

Doors - electrical system of door – interlock

Lights, serviced either from clean room

Safety lights

Ports in wall for implementation (conveyers, ...)

Floor covering with / without groove (floor – wall)



9. Modular cleanroom system

Cleanroom system for injection moulding machine

Every machine parts as a cleanroom area

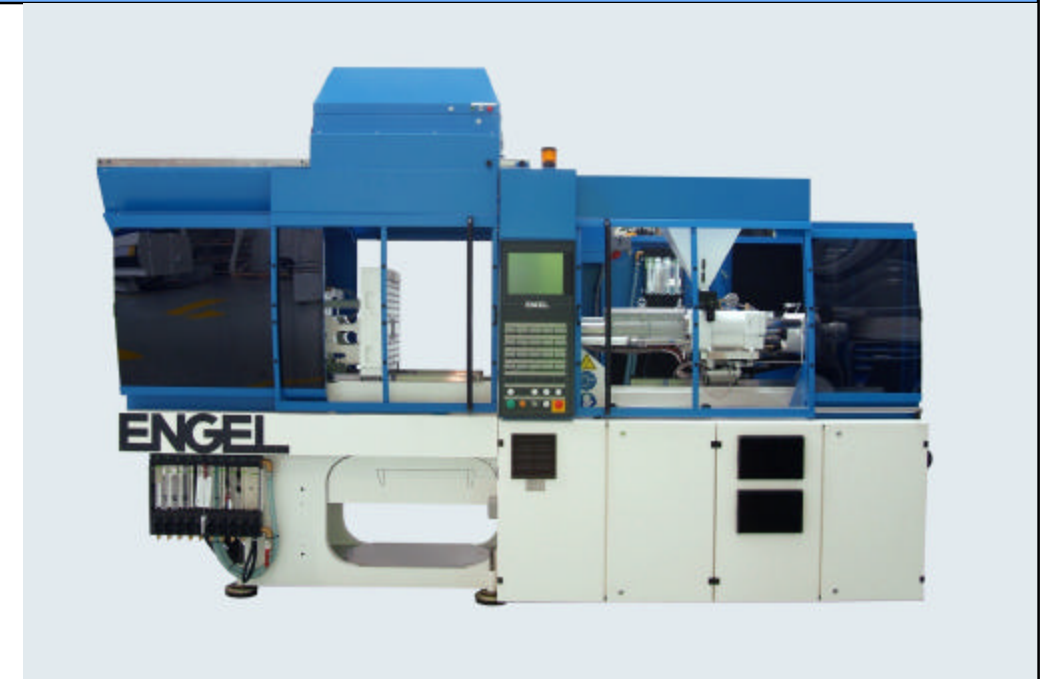
Ventilation system over Clean Air Modules CAM

Mould area of injection moulding machine

include moveable frame for the mould changing

Handling-, robot system

Conveyor belt



9. Modular cleanroom system

Cleanroom system for injection moulding machine



10. Planning fundamentals

Machines in / out clean rooms

Person in clean rooms

Cleanroom quality, cleanroom classes

Change of air, volumetric air flow

Positive pressure attitude

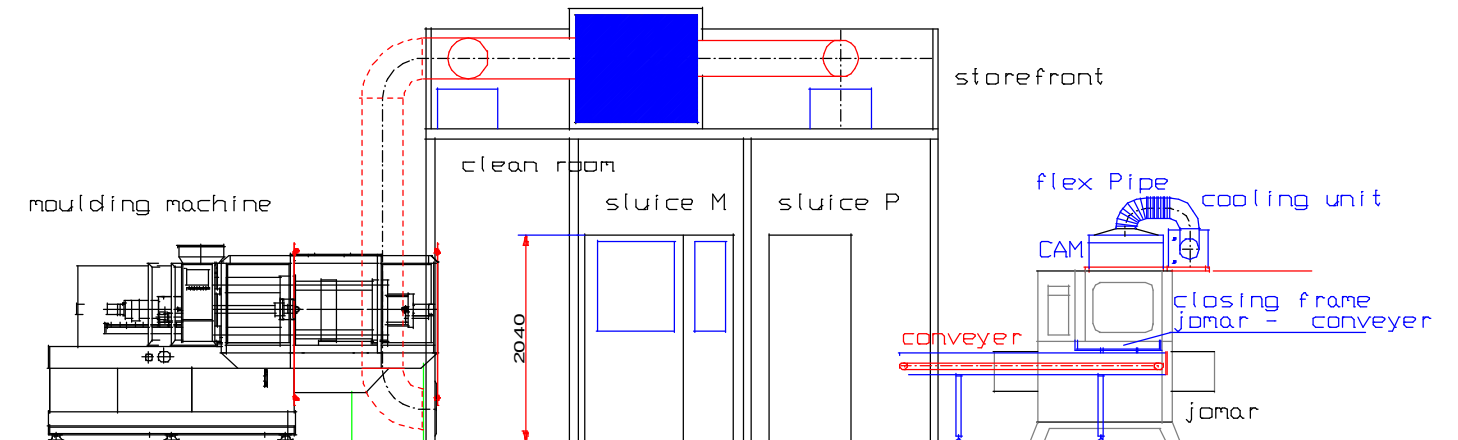
Temperature (inside)

Relative air humidity (dehumidification / humidification)

Inside and outside heat loads,

Cooling and heating capacity

.....



11. Qualification

Qualification conform to regulations such as
ISO 14644 / GMP for:
Design (DQ), installation (IQ), operation (OQ)

Evaluation of:

Particle count and size, clean room class,
air velocity, change, volume flow rate,
pressure, temperature, relative humidity,
luminosity, noise level,



12. Investments

Strongly dependent upon:

Clean-room class,
size and volume of the clean room area,
such as heating, cooling and humidification
incl.

Wall and ceiling, doors, lights, floor covering
ventilation and air cooling system, control technology and electrical measurement

Orientation price (EUR / m²)

class (ISO 14644)	Area incl. locks (height: 3,2 m)				
	25	50	100	200	500
	m ²	m ²	m ²	m ²	m ²
8	2.500	1.500	1.000	800	500
7	2.900	1.800	1.200	950	600



13. Particles during injection moulding process

Valuation criteria

Cleanroom class to EN ISO 14644

Particle size

Measuring points (representation and realization)

Operating condition (no-load operation, supply, production)

Tool

Cycle time (s)

Stroke (mm)

Stroke time, opening (s) and closing (s)

Tool temperature, surface (°C)

Dimension of the tool range



13. Particles during injection moulding process



Measured data

Volume, size in micrometer			cleanroom
moulding area	0,5	5,0	class
	ft ³ /min.	ft ³ /min	ISO 14644
without ventilation system	450.000	1.000	(9)
with ventilation system, at rest	1.200	2	7
with ventilation system, in operation	11.000	60	8

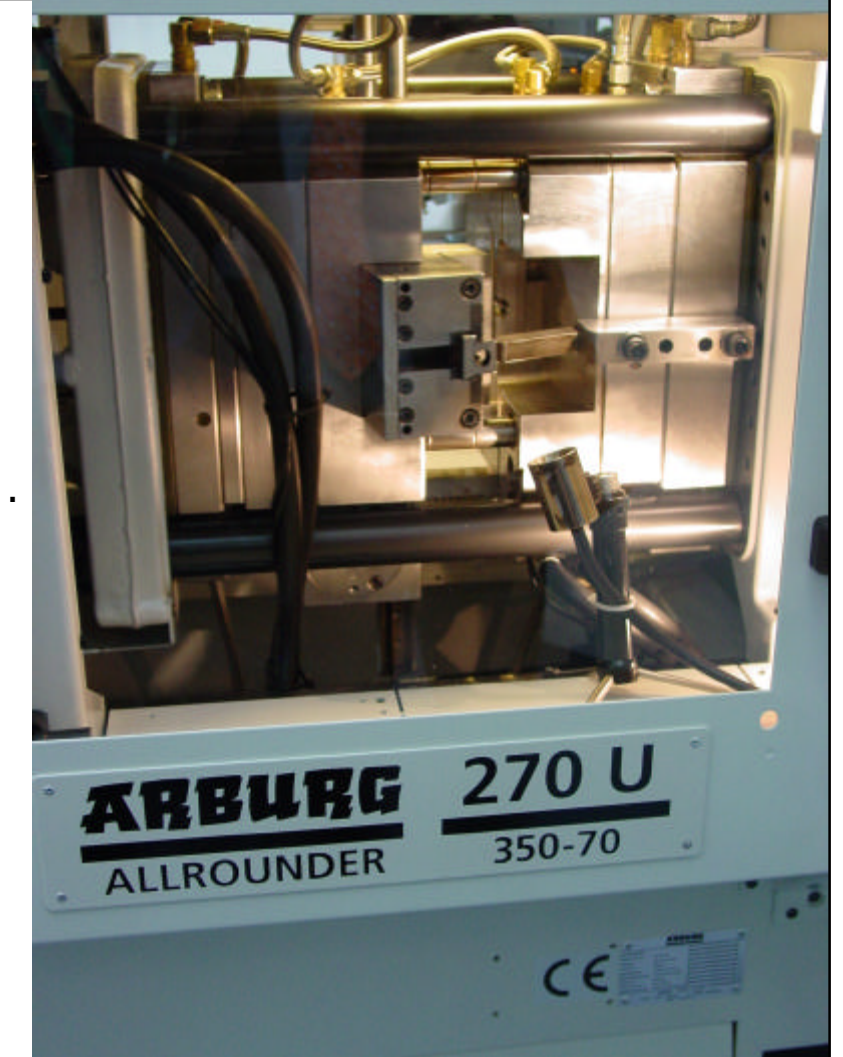
13. Particles during injection moulding process

Experiences

Within a cleanroom area particle, as e.g. during injection moulding from movements,
The cleanroom technology can reduce the particle concentration.

The moulding machine must correspond to the general requirements regarding a cleanroom manufacturing.

The production areas must represent a clean condition.



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