Minebea intec
The true measure

Hygienic design

Principles and guidelines for open processes in food production

EHEDG GMP HACCP

Cost saving Micro-organisms

NSF Cleanability Environmental protection

BRC Foreign objects

Product Safety Act

Surfaces 3A Materials

academy
by Minebea Intec

- Hygienic design on the production line
- Cleanability as an economic factor
- Conformity with international standards
- Real-life examples

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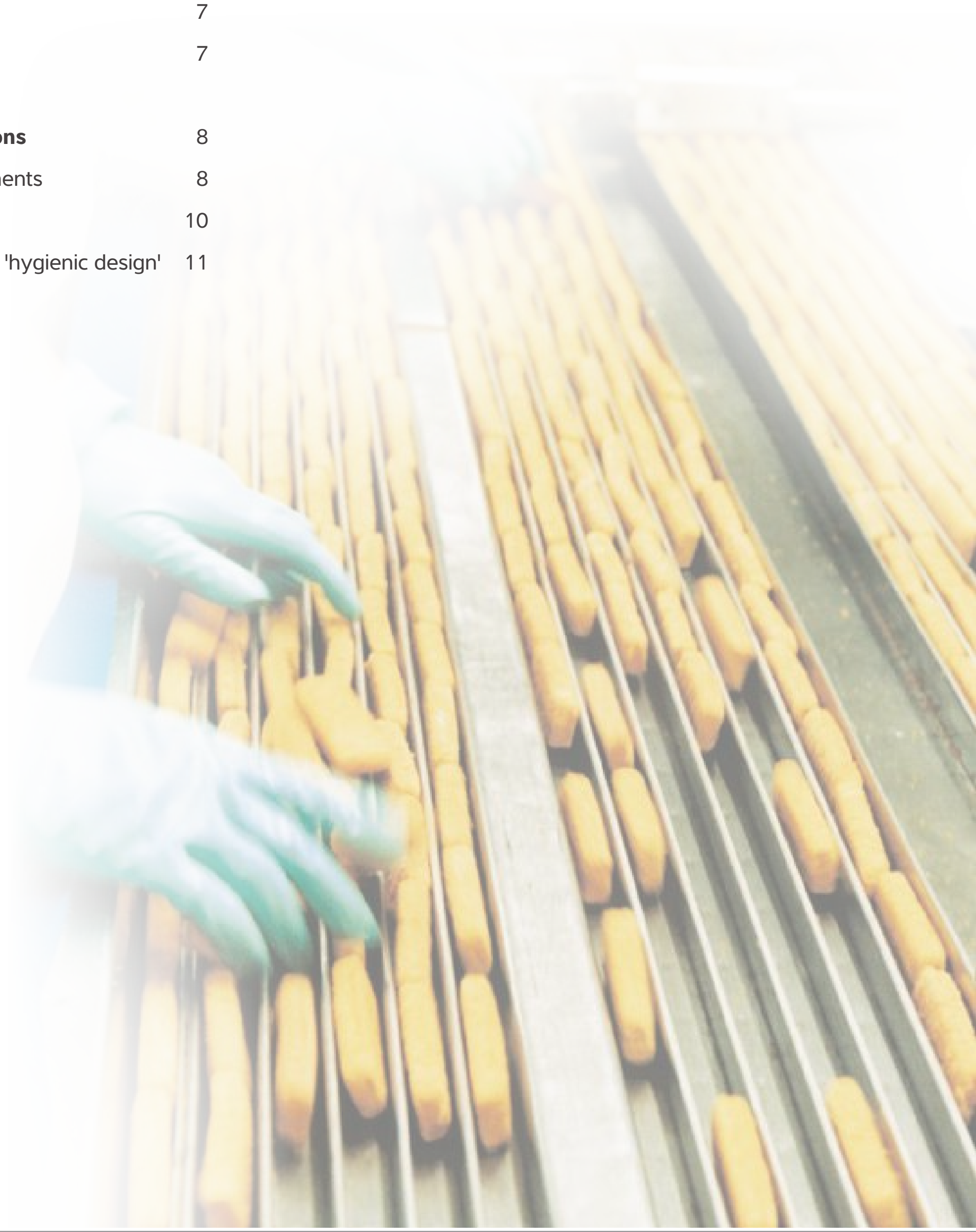


1. Why the focus is on hygienic design

1.1 Safety and efficiency as growing criteria in food production

In the food production industry, product contamination by micro-organisms such as bacteria or fungi presents a potential and omnipotent risk. It is therefore important to prevent any type of contamination and to facilitate its removal. The public's access to multimedia also makes it more sensitive to the importance of hygienic design. This is why more and more facility and machine builders as well as manufacturers of individual components of these face this increasing challenge.

The term hygienic design comprises the hygienic design of structural elements, components and production facilities in the food industry under the following premises:

- visible contamination
- easy cleaning

The design principles of hygienic design help to optimise designs to ensure the comprehensive cleanability of the materials, surfaces and constructional elements. In this way, hygienic design supports the food industry in its endeavours to sustainably increase product quality and safety.

Conclusion: hygienic design significantly contributes to quality assurance

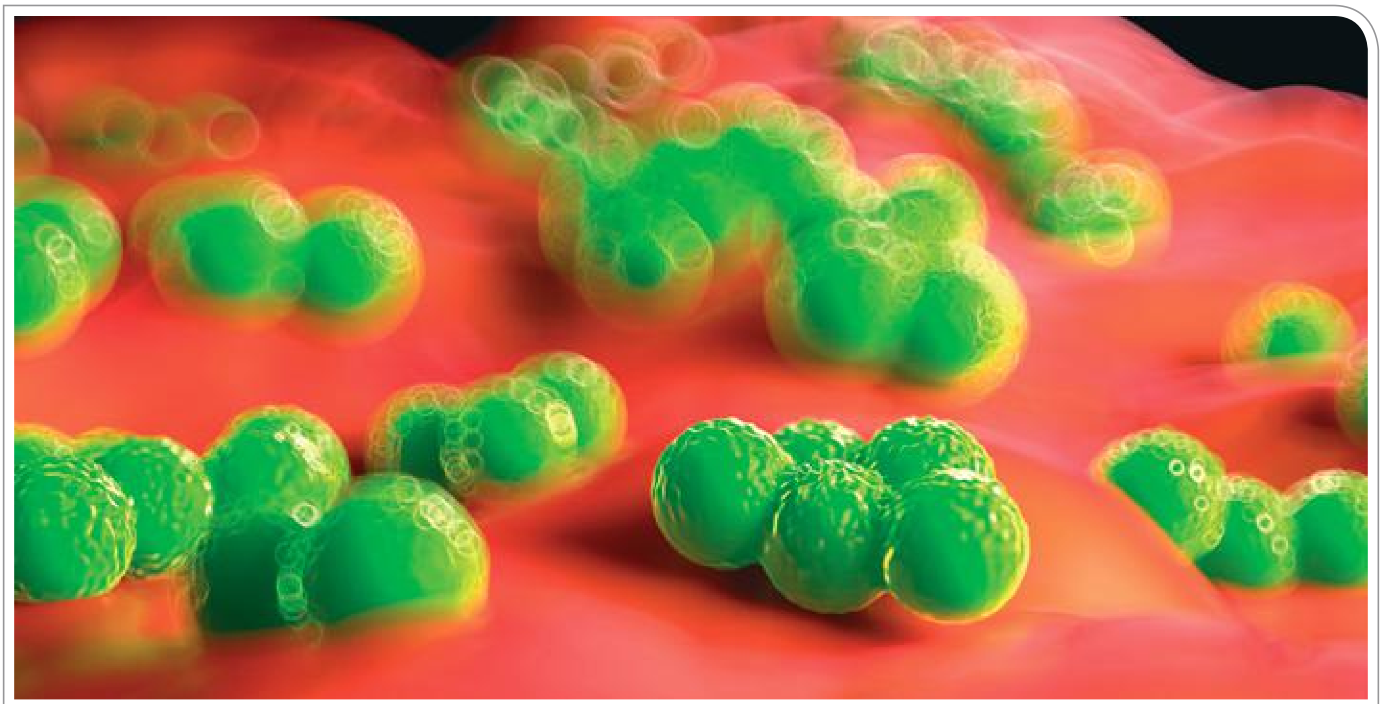
Increasing costs for wages, energy and quality assurance means that the daily cleaning of plant facilities and machines in the food industry is not an inconsiderable cost factor. In addition, the efficiency of production is reduced due to cleaning-related downtimes. The less contamination estimated on machines and facilities, the shorter the cleaning times and downtimes thus lowering the total operating costs.

Conclusion: hygienic design saves resource costs

More and more production companies are changing their way of thinking when it comes to energy management and environmental protection (keyword DIN EN ISO 50001). For production facilities which can be cleaned easily, quickly and effectively, the consumption of energy and cleaning agents can be reduced.

Conclusion: hygienic design supports companies in their efforts to reduce energy consumption and protect the environment

The topic of hygiene is increasingly becoming a hot topic of discussion, not only within food production. In the healthcare industry, the incidence of multi-drug resistant micro-organisms is increasing, which poses an incalculable risk to health. MRSA (methicillin-resistant Staphylococcus aureus) is resistant to many antibiotics (multi-resistant), enabling illnesses to progress to a more severe form. The only way to prevent MRSA is through comprehensive hygiene practices. Hygienic design helps minimise the risk of contamination.



MRSA bacteria under the electron microscope

2. What is hygienic design? Where does it come from?

2.1 The evolution of hygienic design

The Machinery Directive ISO 14159, which was published for the first time in 1989, constitutes the legal basis of hygienic design in Europe. Renewed many times since then, this European Directive defines the legal frameworks for constructing safe machines. It refers to requirements for, among other things, materials, cleanability, surfaces, connections, draining fluids, contamination and operating materials.

From a historical perspective, the dairy industry should be seen as the first industry to recognise the need for constructive hygiene solutions. Milk processing takes place in a closed system. Because of this, deposits are difficult to see and inaccessible, and therefore remain inside the system. Raw milk which spends too long in unfavourable conditions in a single location quickly becomes sour and contaminates the entire production. Therefore, a self-cleaning system was considered essential for the milk industry.

Today, avoiding food contamination and increasing product safety are the objectives of all food producers. In particular, due to the steadily increasing globalisation and digital transformation of communications, an enhanced quality standard now goes hand in hand with the awareness of having to protect their own brand and sub-brands. A product defect can quickly gain international awareness and cause damage to the brand image, as well as a loss of profits. The benefits of hygienic design are not only apparent in closed systems – clear advantages also exist in open processes and systems. Many companies and sectors already have recognised the benefits of hygienic design:

- food and beverages
- pharmaceuticals
- biology
- medicine
- chemistry
- cosmetics

2.2 International directives

Hygiene regulations are individually formulated and filed in each country. The objective is always the same: to ensure hygienic production conditions to protect consumers. The following guidelines, in particular, define the requirements for hygienic design:

- EHEDG (European Hygienic Engineering and Design Group)
- 3A Sanitary Standards
- NSF (National Sanitary Foundation)
- FDA (Food & Drug Administration)
- GMP (Good Manufacturing Practice)
- HACCP (Hazard Analysis and Critical Control Points)
- BRC (British Retail Consortium)

In Europe, the *European Hygienic Engineering & Design Group (EHEDG)* disseminates the hygienic design guidelines. The organisation was founded in 1989 to raise awareness of hygiene in the food industry. The EHEDG creates guidelines and provides advice to the industry and is therefore a transferrer of knowledge regarding hygienic construction and design in the process.

The EHEDG supports the European legislature in developing EU Directives on handling, processing and packaging food. The bases for this are EC Directive 2006/42/EC for machines, EN 1672-2 and EN ISO 14159. Further information on the organisation can be found on the homepage at www.ehedg.de.

In America, the organisation 3A stands for the interests of hygienic design. "3A Sanitary Standards Inc." is based on the first standards, which were introduced in the 1920s for components used in processing milk. The objective of 3A is to improve consumer safety by means of hygienic development, education and training. Further details can be found at www.3-a.org.

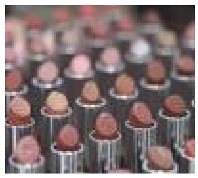
Food and beverages

Pharmaceuticals

Biology

Medicine

Chemistry



Cosmetics

Today, hygienic design is used across numerous industries

NSF stands for National Sanitation Foundation International. The organisation was founded in 1944 in Michigan (USA) and has been globally active since 1990 for public health and the safety of products for people. With over 2100 employees globally, technical experts are available for interviews, conferences, training sessions and various other public health information events. The NSF Standards follow the American National Standards Institute (ANSI) Standards. More detailed information can be found at www.nsf.org.

FDA stands for Food & Drug Administration. This agency has been under the authority of the American Ministry of Health since 1927 and is tasked with ensuring the protection of public health in the USA. FDA monitors the effectiveness and safety of products for the improvement of public health. More information at www.fda.gov.

Good manufacturing practices *(GMP)* are quality assurance guidelines for the production processes associated with medicines, active substances, cosmetics, food for humans, and animal feed. These are defined by the Food & Drug Administration (FDA).

The Hazard Analysis and Critical Control Points *(HACCP)* concept is a clearly structured tool for the food industry, which focusses on preventative measures, and was initially designed by The Pillsbury Company, based in America, in cooperation with the NASA Space Agency. The concept was developed in 1959, at that time with the aim of developing safe foods for the US aerospace industry. In 1998, the concept was anchored in German law by means of the Regulation on the Hygiene of Foodstuffs. Since the beginning of 2006, it has only been possible in the EU to trade and import products which are compliant with the HACCP.

The *BRC* Global Standards are a British certification system for the food industry. Headquartered in London, the British Retail Consortium started out in 1992 to represent the interests of its members vis-à-vis governments, authorities and EU institutions. Meanwhile, the Consortium also informs consumers on topics such as price developments, environmental protection and healthy nutrition. Details can be found at www.brcglobalstandards.com.

3. Principles of hygienic design

3.1 Hygienic design certification

Some directives, such as in Europe, for example, the EHEDG have developed a certification system and issue hygienic design certificates for individual structural elements as well as for entire facilities. Individual structural elements and system components, which are subject to particularly stringent purity requirements can therefore be certified if they meet the hygienic design guidelines and pass specified cleaning tests. Questions relating to design, the materials used and the cleanability of components must be answered in accordance with the guidelines.

Certifications for entire facilities (HDW certified systems) assess the degree of implementation of the hygienic design requirements across the entire facility. In terms of scoring, all components are assessed with regard to their degree of fulfilment at structural element level. The higher the degree of hygienic implementation, the lower the risk of food contamination and the better the ability to clean the facility.

Certification according to the design guidelines for hygienic design is not yet legally required but is instead carried out on a voluntary basis.

In practice, the term hygienic design is often associated with or confused with IP protection classes.
The terms are defined on page 11.

3.2 Materials science

The selection of materials plays an important role in developing components, structural elements and production facilities. Although stainless steel is commonly considered to be the best choice of hygienic materials, even high-quality stainless steels can corrode, for example, in chemically aggressive environments. Even the chlorides contained in cleaning agents may trigger the corrosion process. The corrosion depends on the quality of the material and its condition or, more precisely, the smoothness and flawlessness of the surfaces. The smoother the surface the better. The EHEDG recommends passivation, e.g. by means of electropolishing, and defines a mean roughness depth of max. 0.8 µm for this.

On the right is a load cell made from stainless steel 1.4542 which is commonly used in weighing technology; and, on the left, in comparison, is one made from stainless steel 1.4418 with similar surface qualities

3.3 Cleanability

The quality of cleanability is contingent on the structural design of structural elements, components and facilities. It is important to exclude residues of contaminants, which result in the growth of micro-organisms. Areas with zones which are structurally difficult to clean should also be avoided as cleaning these is associated with high expenditure.

The result of an easy-to-clean facility is increased hygiene and reduced cleaning expenditure (cost savings, environmental protection). For this, no distinction is made between the cleaning methods. The same degree of cleanliness should be achieved for dry cleaning as for wet cleaning.

Tools for dry cleaning:
- cloths
- brushes
- vacuum cleaner

tools for wet cleaning (IP54/IP65):
- damp cloths
- chemicals

tools for wet cleaning (IP69):
- high-pressure cleaner
- chemicals


Floor scales with lift mechanism make cleaning easier


Hygienic weighing solution with load cell and mounting kit under a sleeve made from FDA-compliant special silicone

3.4 Access

Many production facilities in the food industry are cleaned without dismantling. Access to problem areas should therefore be provided. Here, the economically and technically expedient and justifiable expenditure for achieving the required level of cleanliness must be defined.

In areas which require wet cleaning for production reasons, partial dismantling of the facilities for cleaning purposes can´t be be avoided. Therefore, it is necessary that disassembly can be carried out easily, preferably without tools.


Example: belt changed without tools on a dynamic checkweigher

3.5 Cost considerations

The benefits of hygienic design are often offset by increased capital expenditure. However, the comparably increased costs for equipment and facilities using a hygienic design should be addressed in relation to their associated benefits:

- time saving when cleaning the facility
- reduced cleaning agents
- lower energy requirement
- lower staff and maintenance costs
- simple fulfilment of/compliance with regulations/requirements

Considering all factors neutrally proves that hygienic design facilities are a long-term investment. They ensure both optimal line efficiency and environmental protection. The TCO (total cost of ownership) is therefore comparatively lower for facilities using hygienic design as not only the purchase costs are included in this statement of account but also all of the expenditure associated with subsequent use, such as

- Resource costs (water, waste water, chemicals, etc.)
- Energy costs (electric, thermal)
- Maintenance/repair costs
- Staff costs
- Minimised risk of production failure, rejection etc.

Conclusion: hygienic design has a positive influence on many areas of the TCO, providing safe food with a good and positive image while at the same time protecting the environment.

4. Design principles

4.1 Factors for hygienic design

For the development and construction of structural elements, machines and production facilities, hygienic design is the design principle used to ensure that designs satisfy cleaning regulations as well as being easy to clean. The following manufacturing levels are affected by this:

- design
- material selection (material pairings)
- manufacturing processes
- surface treatment
- connection techniques

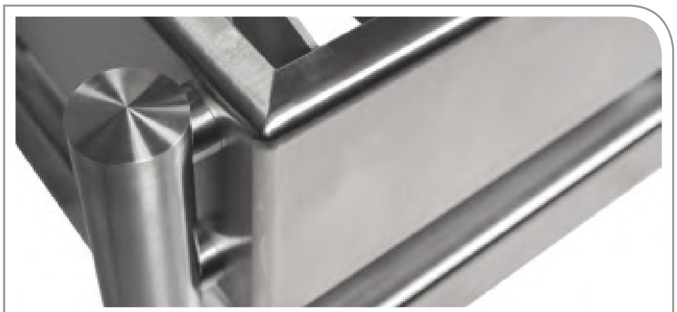
The design principles for hygienic design define the following parameters. Points to consider include a high surface quality, food-safe (suitable) materials and a corresponding environment for food production, which also includes the soil condition.

- No horizontal surfaces
- Smooth surface finish/self-draining surfaces
- No sharp corners/angles (radii min. 3 mm, better > 6 mm)
- No unnecessary holes
- No avoidable contact surfaces, screws and gaps
- No hollow part
- No dead spaces
- Few structural elements
- Open design
- High ground clearance
- Easy inspection
- Good accessibility

Furthermore, the surface must meet the following requirements. Material selection is an important factor for this: the use of stainless steel is often considered to be hygienic design. Even though stainless steel is a better choice than standard steel, its suitability depends on the application and design. The following parameters must be considered for surfaces:

- corrosion resistance
- water impermeability
- no cracks or crevices
- flawlessness of the surface ($R_a < 0.8$ µm)
- resistance, durability (maintenance-free)
- quality of the connection points, in particular welded joints

Important: in terms of risk assessment, hygienic design distinguishes between surfaces which come into contact with the product and those which do not. A hygienic design assessment is therefore possible depending on the areas.



Example: no sharp corners, reduced contact surfaces

Example: no hollow spaces, easy inspection

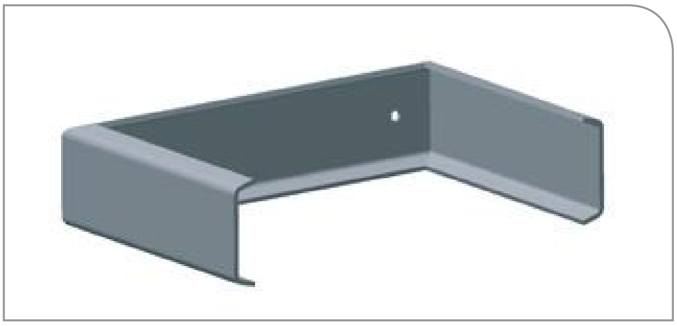
Example: good accessibility – good inspection capability, no sharp corners

Example: high ground clearance, no dead spaces due to solid material design

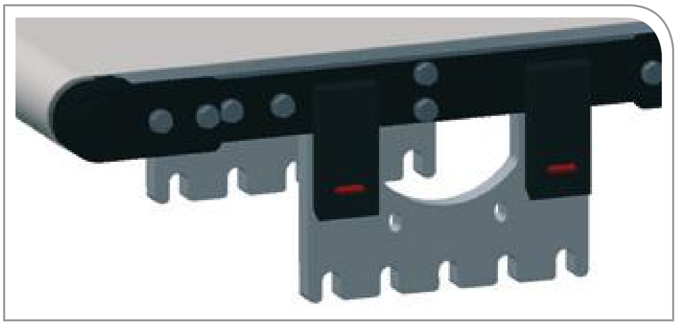
5. Design examples and recommendations

5.1 Consideration of individual requirements

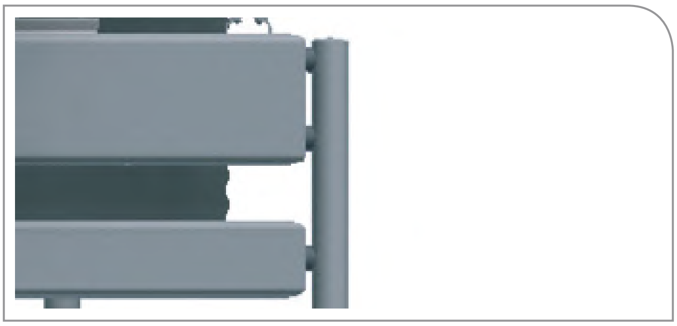
Hygienic design is becoming increasingly important in the design of process lines, facilities and equipment and has become a systematic field of work, especially in the pharmaceuticals, food and biotechnology industries. In doing so, the individual requirements and aspects are first identified and analysed. Here are some examples of how hygienic design can be realised in the aforementioned industries.



Example of frame structure
Hygienic design does away with hollow profiles. *Bending edges* are necessary, for technical reasons, to increase rigidity. These are *open and visible* (obtuse opening angle 90° < 180°) and designed *with large radii* (larger than R3). The bevelled bending sides prevent the adhesion of deposits. All welded joints are executed using *continuous welding*.



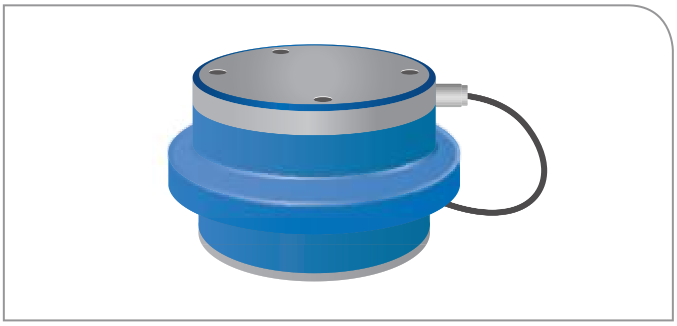
Example of conveyor belt uptake
The *contact surfaces* in direct connection with the conveyor belt are *reduced* to a required minimum. The *absence of horizontal edges* minimises deposits. The elongated holes below are technically required to ensure sufficient adjustability. The elongated holes are designed to be *open at the bottom*.



Example of adjustable foot supports
The design guidelines for hygienic design recommend designs made from round, *solid material*, to avoid sealed hollow spaces or dead spaces on the inside and deposit surfaces on the outside. *Round spacers* reduce contact surfaces and prevent deposit surfaces. The top sides are designed with *chamfers/curves*, to prevent horizontal deposit surfaces. An attachment on the outside of the frame minimises non-visible areas. Installation should take place *at ground level and without a pit*.

Example of dust covers
In order to avoid horizontal deposit surfaces and to increase rigidity, the *upper surface of dust covers should be designed with a pitched roof shape*. Positioning at a *distance to the upper framework* minimises the contact surfaces and facilitates inspection. For larger dust covers, a *design with cutouts* is recommended to minimise the contact surfaces.

Example of signal lamp
Since cable routing is to be avoided on the exterior, the design should make provisions for signal lamps *directly on the switch cabinet*. Cable routing *inside the structural elements* avoids complicated hygienic cable routing and concomitant in/outlets to the structural elements which require sealing. Deposits on the exterior are therefore minimised.

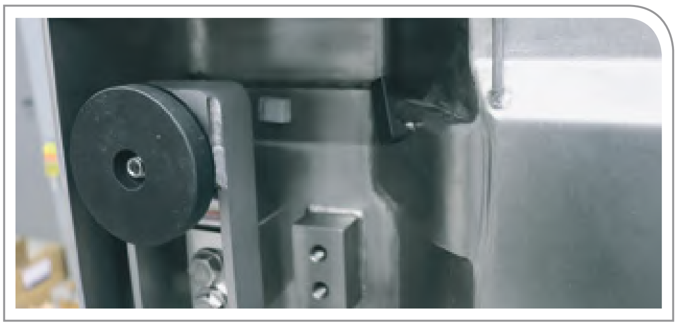


Example of sealing contact surfaces
A specially developed connection geometry between the silicone protective sleeve and the connection plates ensures reliable sealing of the dust-proof and water-proof interior.

Example of surface design
No sharp corners, no hollow spaces, no horizontal surfaces and a mean roughness of R_a = 0.8 µm

Example of cable routing
Easily accessible cable routing below a flat-bed scale. After installation, the cable is tensioned using a winged screw and can be loosened at any time for easy cleaning.

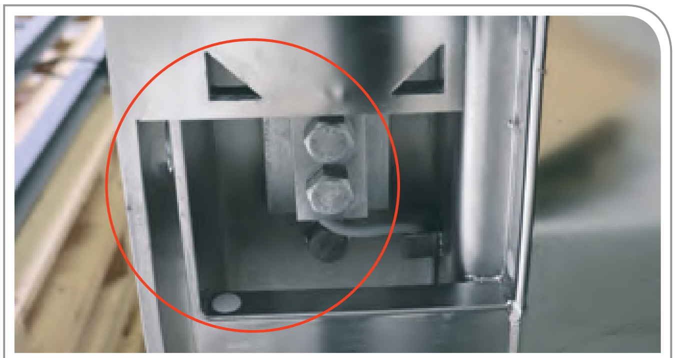
Example of corner design
Constructional angles larger than 90 degrees ensure easy cleaning, as shown here in this example of a flat-bed scale. The satin-finished surface has a surface roughness of less than 0.8 µm.



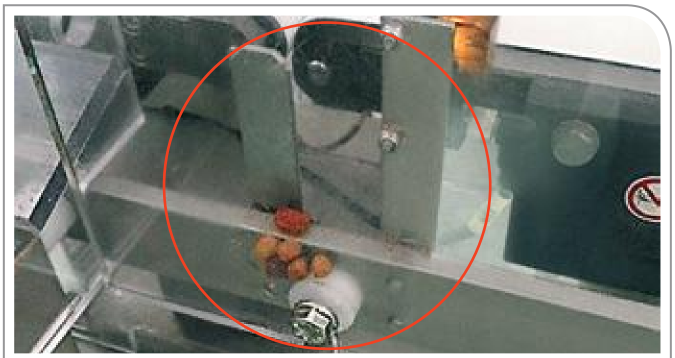
Example of integrated feet and lifting mechanisms
The integrated feet and the lift mechanism of this flat-bed scale are located below the platform and are therefore less susceptible to contamination. However, the open design ensures easy cleaning if necessary.

5.2 Negative examples

Horizontal deposit surfaces increase the effort required for cleaning



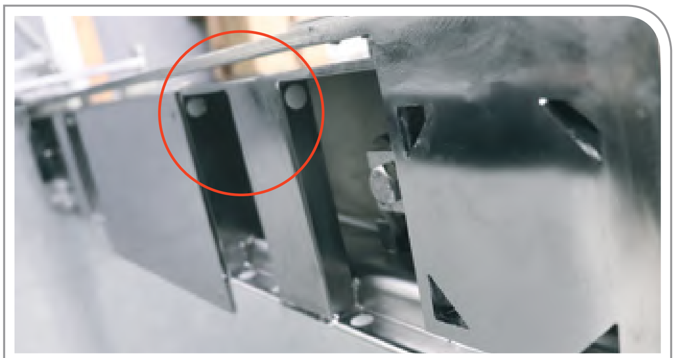
Corners, edges and gaps allow dirt to accumulate. Poor accessibility complicates cleaning.



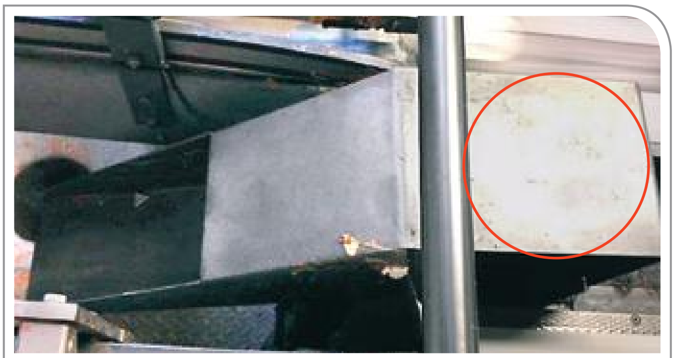
Deposits in difficult-to-access areas equate to effort in cleaning

Screws, angles and spaces are susceptible to contamination and difficult to clean.

Large-scale deposits in areas which do not come into contact with the product mean less risk of contamination, but still necessitate increased cleaning effort.



Sealing rubber caps are only safe to a limited extent, as these can fall out. The semi-open design of the flat-bed scale complicates cleaning.



Soiled horizontal surface on a dual-track checkweigher.
No open design.

The externally mounted lift mechanism of the flat-bed scale requires additional space and represents a trip hazard for the operating personnel.

5.3 Incorrect interpretations of the term 'hygienic design'

Hygienic design is often talked about, but it isn't always what is meant. For example, caution should be exercised when hygienic design is associated with IP protection classes. Here, the parameters of constructional design are confused with the parameters of cleaning.

By way of comparison: if a facility withstands the high pressure of protection class IP69, this does not imply that the facility complies with the hygienic design guidelines.

IP protection classes (acc. DIN 40 050 part 9):
IP: International Protection (ingress protection)

First identification number: protection against foreign objects and against contact

- 0 – no protection
- 1 – protection against foreign objects with a diameter of min. 50 mm
- 2 – protection against foreign objects with a diameter of min. 12.5 mm
- 3 – protection against foreign objects with a diameter of min. 2.5 mm
- 4 – protection against foreign objects with a diameter of min. 1 mm
- 5 – protected against dust in a damaging amount
- 6 – dust-proof

Second identification number: protection against water

- 0 – no particular protection
- 1 – protection against dripping water falling vertically
- 2 – protection against water dripping at an angle
- 3 – protection against spray water
- 4 – protection against splash water
- 5 – protection against jets of water
- 6 – protection against flooding
- 7 – protection against immersion
- 8 – protection against submersion
- 9 – protection against 100-bar water pressure

We make daily life safer

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