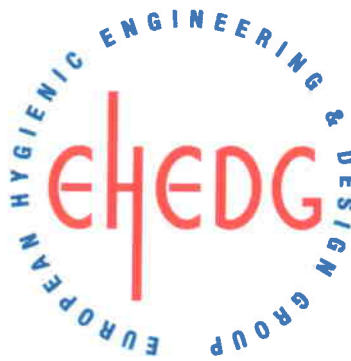


Accreditation for hygiene tests by the German Accreditation Service



EVALUATION REPORT

**Verification of the cleanability
of the optical sensor series 53
in accordance with EHEDG guidelines**

Report-No. 151/20.11.2007

Leuze electronic GmbH + Co. KG
73277 Owen / Teck, Germany

The report comprises of 10 pages, including 5 illustrations.
The evaluation relate exclusively on the examined components listed in this report.
The report was compiled by trained personnel working in compliance
with the EHEDG-Guidelines.

Freising-Weihenstephan, 07. January 2008

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DAR Registration No. DAP-PL-3480.00
Accreditation complying with DIN EN ISO/IEC 17025:2000 for:
"Microbiological tests for cleanable equipment used
in the food production"

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1 Task

Leuze electronic GmbH + Co. KG, In der Braike 1, D-73277 Owen / Teck, Germany, asked the Research Center Weihenstephan for Brewing and Food Quality (Forschungszentrum für Brau- und Lebensmittelqualität, BLQ) of the Technical University of Munich (TU München), Life and Food Science Center Weihenstephan to evaluate the hygienic design of the optical sensor series 53 in a number of variations. The following models were evaluated: stainless steel housing with and without teach button, each with an M8 connector at the housing or with a cable tail of 200 mm and M8 connector.

The evaluation was carried out abiding decisively by the EHEDG guideline no. 8 "Hygienic Equipment Design Criteria", second edition, April 2004.

The assessment was made by inspecting the equipment in 2007.

2 Description of the optical sensor series 53

The 53 series of optical sensors (Fig. 1) are stainless steel versions manufactured especially for use in the food and pharmaceutical industry. The photoelectric sensor can be used in both wet and dry processing areas. Accordingly, wet or dry cleaning may be required. A complete and safe cleaning is essential in both cases to minimise the danger of product contamination.

The optical sensors of the 53 series consist of a housing which contains the electronic parts. This housing is made of stainless steel alloy with material code 1.4404 or AISI 316L and is manufactured via a MIM (Metal Injection Moulding) procedure. It has a blasted surface with a regular structure. Glued to the front is a scratch- and diffusion-proof PMMA plastic window coated with inorganic polymers. It is flush with the housing such that no edges or steps are created. Only the epoxy-glued joint has a small groove that cannot be avoided from a technical perspective. The top side of the housing is bevelled such that water cannot accumulate. The entire housing is kept at a very small size, minimising the possibility of dirt contamination. A teach button may be integrated at the top of the housing. This is often required to configure or reconfigure the sensor during operation. The teach button is made from TPV-PE plastic seals the hole at the top of the housing with an elastomer (TPV). The connector or cable exits at the bottom side of the housing. A stainless steel sleeve is welded to this as well. The weld seam was created via laser process and does not show any faults. The cable connection on the bottom side of the sleeve is sealed and held down with a spring washer. The PVC cable is approved for coming into contact with food. The connector is a conventional M8-sized round connector with a screw sleeve that has a gap and edges. In the version without cable, the connector is directly welded to the bottom side of the sleeve. No transitions are visible.

The device can be wet cleaned by lathering in common alkaline and acid detergents. A low pressure hose may be used as all electric components are designed dustproof and waterjet-proof according to IP67 or IP69K. The use of high pressure hoses is however not recommended as the loosened dirt is distributed and contaminates neighbouring production areas. A cleaning requires dirt to be removed.

The optical sensors are part of the area that does not come into contact with the product as no products (food) make direct contact with the surfaces. However, they are installed in the direct vicinity or even directly above the product or product containers. In these cases, the surfaces may be soiled and thus there is an indirect risk of contamination for open product containers.

This evaluation neither considers the attachment option of the photoelectric sensor at the machine nor auxiliary components such as reflectors.

The following figures show details of the optical sensor:



Fig. 1: Front view



Fig. 2: Top side with teach button



Fig. 3: Bottom side with cable exit



Fig. 4: M 8 connector

3 Basis for evaluation

The sensors hygienic design was evaluated in accordance with guideline no. 8 "Hygienic Design Criteria", second edition April 2004 of the European Hygienic Engineering & Design Group (EHEDG). These hygiene criteria were developed as a joint effort by mechanical-engineering and food-processing experts. The requirements are regarded to be state-of-the-art and are essential for the hygienic design of apparatus and structural elements employed in the processing of food. This is important to protect consumers and to preclude the risk of infection, disease, contamination or injury, which can originate in food. Such risks must be reduced to a minimum. The hygienic design principles must be applied especially to surfaces which come into contact with the product being made. All other areas and added on components, which do not come into contact with the product, must be designed and built in a certain way. They must prevent moisture and dirt from accumulating and must prevent varmint from nesting. It must be possible to easily clean, monitor and maintain these areas and added on components.

4 Evaluation in accordance with EHEDG recommendation document no. 8

General

Principally the requirements of the EHEDG guideline "Hygienic equipment Design Criteria", 2004, encompass the provisions of both the European standard DIN EN 1672-2, 2005, DIN EN ISO 14159, 2004 and the European council directive for machinery 98/37/EC, also in the updated version of 2006/42/EC.

Materials – stainless steel

Requirements:

The material's surface must be corrosion-resistant, mechanically stable and non-toxic. It must be resistant to both the product and cleaning agents used under conditions of intended use. Product-contact surfaces should preferably be made of austenitic stainless steel belonging to the AISI 300 series (e.g. 304, 316, 316L). The corresponding German alloys have the material standards 1.4301, 1.4401 or 1.4404 respectively. Castings should be made with the appropriate grade of stainless steel with analogous properties. For areas which do not come into direct contact with the product, the same requirements apply.

Evaluation:

The housing and the sleeve where the cable exits are made of stainless steel alloy with material code 1.4404 / AISI 316L and thus are registered for use in contact with food. This alloy features high corrosion resistance, in particular against chlorides.

Materials – Plastics

Requirements:

Any plastics used must be easy to clean. Various types of plastics are recommended, like PP, PVC, PC, PE, EPDM, HNBR, etc. In the same way elastomer materials must have a closed surface so that cleaning is easy and complete. Typically EPDM, HNBR and silicone is used in contact with food. Plastics and elastomer materials in contact with food must have the appropriate approval.

Evaluation:

PMMA is used as cover for the optics. The teach button and its seal consist of TPV-PE. The cable finish, cable sheathing and the connector are made of PVC. All of these materials are registered for contact with food and a resistant against the common cleaning agents and processes.

Surfaces

All surfaces must be easy to clean and must not pose as a source of risk to foods becoming contaminated. All surfaces that come into contact with product, must be resistant to it and to the cleaning agents and disinfectants used under all conditions of intended use. The contact areas must be made out of non-absorbent materials (see materials) and must satisfy the specified requirements for roughness.

Requirements:

Product contact surfaces should have finishes characterized by a low mean roughness value less than 0.8 µm. Non-product contact surfaces must be smooth enough to ensure easy cleaning.

All surfaces must be free of defects such as holes, scratches and crevices.

Evaluation:

The stainless steel housing has a smooth and fault-free surface. It features a regular surface structure which does not present problems in terms of cleanability. This also applies to the plastic sheet covering the optical sensor. All surfaces are free of imperfections such as holes, grooves, and gaps. The average roughness Ra is smaller than 2.5 µm (measured value: Ra = 1.9 µm). The surfaces not coming into contact with food are thus sufficiently smooth to permit easy cleaning.

Welded joints**Requirements:**

Metal-metal contacts must be continuously welded together, making sure that there are no crevices. The welding process should take place within an inert gas atmosphere. If the welding seam shows major unevenness or tarnishes an after-treatment will be necessary. While welding, no edges or unlevelled surfaces are allowed to not impede cleaning. The welded joint must not have any defects or pores and it should run in a straight line.

Evaluation:

The welding was carried out using inert gas and a laser process. The weld seam is fault-free and has a typical roughness and structure. No tempering colours have formed.

Geometrical Proportions**Rounding****Requirements:**

Inside corners should preferably be rounded out to a radius of 6 mm or more. The minimum radius is 3 mm. Sharp corners with an angle less than 90° must be avoided. In the event that sharp corners cannot be avoided, or that a radius of less than 3 mm must be accepted, the design characteristics must compensate any loss in cleanability.

Evaluation:

All edges of the casing's top are located on the outside. All sharp edges have been removed. The sleeve of the cable exit is welded to the bottom side. This results in a right angle corner with a weld seam. The good accessibility of this area does however permit cleaning and easy inspection. The cable exit itself is positioned slightly to the back into the sleeve and is not easily accessible or visible.

Self-drainage***Requirements:***

Each piece of equipment must be designed for self-drainage once it is in its installed state. Consequently, horizontal surfaces must be avoided. Instead, care must be taken to provide for an inclination towards one side. It is not allowed that water can accumulate at any area.

Evaluation:

The optical sensors of the 53 series have a inclined roof shape so that no water can collect on a horizontal surface if the device is mounted vertically. In addition, this surface is minimised such that only very small quantities of liquids can adhere.

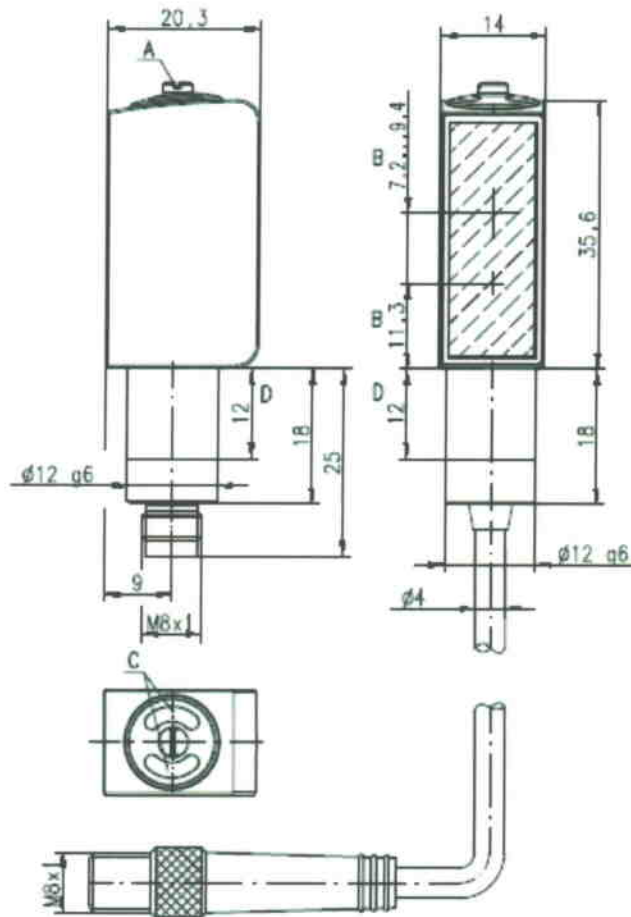
5 Result of evaluation

Basically the design of the optical sensors conform to the hygienic design requirements, which were made according to the EHEDG recommendation. Since the device is used in non-product contact areas, it is not mandatory to meet all requirements for areas coming into contact with the product. Easy and safe cleaning of the surfaces is guaranteed. The cleaned surfaces can also be inspected.

6 Summary evaluation

The subject appraisal shows that the optical sensor series 53 in the different variants with and without teach button and with M8 connector at the housing or with cable tail 200 mm and M8 connector, which were submitted by the company Leuze electronic GmbH + Co. KG, Owen / Teck, Germany, meet the requirements for easy cleanability (Hygienic Design Criteria). The underlying EHEDG document no. 8 is state-of-the-art.

7 Appendix: Drawing



- A Einstellschraube
- B optische Achse
- C Anzeigedioden
- D zulässiger Klemmbereich

Fig. 5: Drawing of optical sensor series 53