HYGIENIC PRESSURE AND TEMPERATURE MEASUREMENT

Principles  Design  Applications
## CONTENTS

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>About LABOM</td>
<td>2</td>
</tr>
<tr>
<td><strong>Measuring Technology in Sensitive Environments</strong></td>
<td></td>
</tr>
<tr>
<td>Hygienic Design of Pressure and Temperature Measuring Equipment</td>
<td>4</td>
</tr>
<tr>
<td>Objectives and Principles of Design at LABOM</td>
<td>6</td>
</tr>
<tr>
<td><strong>Integration in Processes</strong></td>
<td></td>
</tr>
<tr>
<td>Temperature Measuring Process Connections</td>
<td>12</td>
</tr>
<tr>
<td>Pressure Measuring Process Connections</td>
<td>14</td>
</tr>
<tr>
<td><strong>Glossary of Terms</strong></td>
<td>16</td>
</tr>
<tr>
<td><strong>Made to measure</strong></td>
<td>18</td>
</tr>
</tbody>
</table>

---

**WITH EXPERIENCE ...**

LABOM – FROM STANDARD TO SPECIAL REQUIREMENTS

LABOM is one of the leading quality manufacturers in industrial pressure and temperature measurement. We have specialised in the measurement and monitoring of pressure and temperature, as well as derivable variables, like level and flow.

Besides a wide range of standardised products, our strength lies in meeting customers' individual requirements. Working in partnership we develop “Made to measure solutions”.

---

MiniTherm resistance thermometer  
PASCAL CV pressure transmitter  
Hygienic diaphragm seals
HYGIENE REQUIREMENTS

Strict national and international regulations govern products, which can directly or indirectly influence the health of humans. The requirements include the protection of health and environment, reproducible quality and traceability.

The hygienic design of the measuring equipment is the prerequisite for the production of flawless products.

GIVING GERMS NO CHANCE

Select the design and layout of the measuring equipment for reliable operation to ensure that components can be properly cleaned.

The equipment must eliminate the possibility of the product becoming contaminated, as germs cannot be allowed to penetrate nor multiply.

With closed systems, this means that automatic cleaning (CIP) and sterilisation (SIP) processes are safe and reliable to use.

EXCLUSIVELY FOR FOOD, PHARMACEUTICALS AND BIOTECHNOLOGY

Hygienic solutions are of key importance for users in these sectors. LABOM specifically produces special “HY-labelled” products on its in-house production line for these sectors.

Fundamentally, we guarantee outstanding precision and long-term reliability for all LABOM-brand measuring equipment.

EVERYTHING FOR SAFE PRODUCTS

- Use of a dedicated in-house production line (HY)
- Production almost exclusively at our plant in Germany
- Suitable materials, like high-quality steels, FDA-listed sealing materials, plastic coatings and diaphragm seal oils
- Traceability of the materials used
- Traceability of the production and test stages
- Inspection certificates by independent staff
- DIN EN ISO 9001:2008 QM certification
LABOM offers a whole range of solutions that meet “hygienic design” requirements to meet hygienic and aseptic demands. The equipment is compatible with Cleaning in Place (CIP) and Sterilisation in Place (SIP) cycles.

The selection of materials, the design of measuring equipment, its production and installation in manufacturing facilities is optimised and tailored to the respective application.

LABOM hygienic measuring equipment is EHEDG-certified and produced on the basis of well-defined principles.

### KEY MEASURES:

- Avoidance of constructive dead zones, gaps and edges
- Flawless surfaces with minimal roughness
- Flush-mounted components
- Use of non-corrosive steel
- Use of suitable sealing materials and seal shapes
- Self-draining design of measuring equipment
- Enhanced assembly and dismantling of measuring equipment

### DIVERSE CUSTOMER APPLICATIONS

LABOM measuring equipment can be used in the most diverse applications: from pressure measurement in cross-flow filtration systems to sterilisation temperature monitoring in the production of anti-cancer drugs to the measurement of the filling level of beverage concentrates in the food industry.
SMOOTH SURFACES

The structure and roughness of a surface is a crucial factor in the cleaning of dirt and micro-organisms. Only a flawless surface without scratches, pores, fissures and cracks can be cleaned and sterilised by automated processes. The differences can only be seen under a microscope.

An average roughness value of $Ra < 0.8 \mu m$ on flat surfaces and in welding seam areas is generally sufficient to ensure good surface cleanability. It is hard to achieve improved cleanability at roughness values below $Ra = 0.4 \mu m$. The wetted areas of LABOM equipment are supplied with the adjacent surface roughness classes.

Surface roughness is not necessarily improved by electropolishing but generates a homogeneous passive layer with minimal adhesion for dirt.

<table>
<thead>
<tr>
<th>Code</th>
<th>HY</th>
<th>HY06</th>
<th>HY04</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turned parts</td>
<td>$Ra &lt; 0.8 \mu m$</td>
<td>$Ra &lt; 0.6 \mu m$</td>
<td>$Ra &lt; 0.4 \mu m$</td>
</tr>
<tr>
<td>Diaphragm foils</td>
<td>$Ra &lt; 0.4 \mu m$</td>
<td>$Ra &lt; 0.4 \mu m$</td>
<td>$Ra &lt; 0.4 \mu m$</td>
</tr>
<tr>
<td>Weld seams</td>
<td>$Ra &lt; 0.8 \mu m$</td>
<td>$Ra &lt; 0.8 \mu m$</td>
<td>$Ra &lt; 0.8 \mu m$</td>
</tr>
</tbody>
</table>

(Comparison of 500x magnified diaphragm surfaces)
NO GAPS AND EDGES

The design makes the difference: In attempting to ensure that systems and equipment meet the purpose for which they were originally designed, it must be accepted that hygienic necessities can sometimes come into conflict with hygienic requirements. There should be no gaps and edges, but, at the same time, the equipment has to work perfectly.

Hygiene safety always has priority in the search for an acceptable compromise. LABOM has a lot of experience in the process industry and offers a range of different hygienic or aseptic process connections.

FEATURES OF ASEPTIC PROCESS CONNECTIONS

- Self-centring by a cylindrical guide creates a gap-free seal towards the inside of the pipe
- Metallic stops ensure that the seal is subjected to a defined pressure
- Space to allow for thermal expansion on the side facing away from the process
Dead zones are produced by abrupt changes in diameter or the ends of blind pipes, among other things. Hygienic design of measuring points should aim to avoid dead zones, as they can lead to problems during cleaning. Basically the rule is: The higher the flow rate of a cleaning agent, the better the result.

**HOW DEAD ZONES ARE PRODUCED**

- Diameter increases
- Diameter narrows
- Blind pipe end

Improved solutions have to be found for the local geometry for optimum flow. Ideally, there should be no dead zones.

**SOLUTIONS FOR MEASURING DEAD ZONES**

- Measurement of pressure with an inline diaphragm seal (part of the pipe)
- Measurement of temperature with a pipe sensor (part of the pipe)
- Measurement of the surface temperature (external/clamp-on technology)

**SELF-DRAINING**

Self-draining is a key issue in plant and pipe installation. The EHEDG recommendations are as follows: “The interior and exterior of all equipment, components and pipes has to be self-draining or capable of being drained and easy to clean. Avoid horizontal surfaces; ensure that they are always inclined to one side. Design external surfaces so that any fluids can flow away from the product area.”
THE RIGHT MATERIALS

CORROSION-FREE STAINLESS STEEL

Stainless steel provides excellent corrosion protection under the process conditions of applications in the food, pharmaceuticals and biotechnology industries.

The selection of the appropriate stainless steel for the specific application depends largely on the corrosiveness of the process and the cleaning agents. Mechanical stress and mouldability, weldability, hardness and cost are further relevant factors. (In this respect refer to the EHEDG Recommendation on Construction Materials Doc 32)

STAINLESS STEELS USED

- Stainless steel housing 1.4301 (304) and 1.4401 (316)
- Wetted parts: Stainless steel 1.4404 and 1.4435 (316L)
- Higher grades of stainless steel on request, for instance in compliance with the Basle Standard BN2 or with reduced delta ferrite content

FLUIDS AND OILS

- Pressure transmission fluid, FDA-listed silicone-free and synthetic oil as standard
- Other options: medical white oil (FDA-listed), glycerine/water

GASKETS

Instruments and equipment components are adapted to the process using proven connection technology and gaskets. A gasket has to function properly throughout its entire service life under all process and cleaning conditions and can either be designed as O-ring or gasket.

REQUIREMENTS

The gaskets have to have mechanical and chemical resistance to the product and the cleaning agents within the specified temperature range.

Furthermore, controlled compressive loading has to be guaranteed, taking into account the thermal expansion of the seal material.

Smooth surfaces to reduce the adhesion of particles, adequate elasticity and neutrality in terms of colour and taste are further requirements that have to be taken into account in accordance with the guidelines and regulations.

SELECTION CRITERIA

The following must apply to all materials under normal conditions:

- Corrosion-resistant
- Chemically inactive
- Resistant to the fluid to be measured
- Resistant to cleaning agents within the specified temperature range
- Non-toxic
INTEGRATION IN PROCESSES

PRESSURE MEASURING INSTRUMENTS

PASCAL Ci4 pressure transmitter with dairy coupling and inline diaphragm seal
CI4120

Mechanical pressure measuring instrument with inline diaphragm seal
BH42

TEMPERATURE MEASURING INSTRUMENTS

Pt 100 resistance thermometer with inline temperature transducer
GA2200

Pt 100 resistance thermometer with clamp connection and replaceable measuring insert
GA2540
The integration of measuring equipment into production plants is a sensitive undertaking. Any interference in the line can cause risks particularly in the hygienic production of food or medicines. What needs to be taken into consideration?

**GAP-LESS INSTALLATION**

It is crucial that the measuring instrument itself is centred by a cylindrical guide, avoiding edges and projections and producing a gap-free seal towards the inside of the pipe.

**CONNECT  

CONNECTION OPTIONS**

LABOM measuring instruments are available with a range of different connections and can be integrated into the most diverse production facilities.

- Pascal CS pressure transmitter/pressure switch with Varivent connection CS2110

**INSIGHT**

This double page gives an insight into design examples of process connections, as we have often realised for customers in the food and beverage industry, drug production or biotechnology sector.

**CLEANING**

Our equipment is capable of withstanding 140 °C hot steam and complies with the conditions for cleaning & sterilisation in place (CIP/SIP).

It is also simple to install and dismantle, in the event that equipment has to be removed for cleaning. This is a major benefit for systems that need to be taken apart.

**CONNECTION TECHNOLOGIES AT A GLANCE**

- Pipe connection systems for in-line applications
- Flat diaphragm seal
- Thermowells with various process connections for temperature measuring instruments
- Design with threaded, clamp and flange connections
- Metal-to-metal process connections
- Tubus solutions
- Manufacturer-specific process connections and custom solutions
- Clamp-on technologies for non-invasive measurement
Temperature is one of the most commonly measured values in pharmaceutical manufacturing, to monitor and control the production process and also sterilisation procedures with saturated steam (SIP).

**INVASIVE TEMPERATURE MEASUREMENT**

**PREFERABLY ELECTRIC**

Electrical measuring equipment is used almost exclusively to process measuring results and comply with documentation requirements.

**ROBUSTLY INVASIVE**

The most common method of temperature measurement is to invasively introduce a sensor into the process. This measurement technique is robust and proven.

**PRECISELY WITH THERMOWELL**

The conventional immersion probe has been evolved to permit hygienic, invasive measurement using an orbitally welded thermowell system – this technique is precise, has no seals and is sterile.

**INVASIVE CONNECTIONS**

- Conical threaded connection, metal-to-metal seal
- Union nut as per DIN EN 11851
- Clamp DIN 32676
- Clamp ISO 2852
- Tri-clamp
- Varivent
- Ingold
- Neumo BioControl/BioConnect
- Aseptic connections
- HYGIENIC connections without seals
- Other connections on request

**CONNECTION TECHNOLOGIES FOR TEMPERATURE MEASUREMENT**

**Metal-to-metal sealing**

- Orbitally welded thermowell system

---

**MiniTherm**

- Fast response
  - GA2700

**MiniTherm for installation**

- in a separate protective tube
  - GA2730

**Resistance thermometer**

- for in-process calibration
  - GA254

**Field housing with interchangeable measuring insert**

- GA27540
ON THE SURFACE OF THE PIPE

A sensor tip reaching into the process represents a significant obstruction to the flow with very small pipe diameters.

Measuring the surface of the pipe can be the solution specifically with respect to pharmaceutical measuring tasks: Non-invasive and without the associated hygiene risks.

Alternatively, an inline sensor can be integrated in the pipe.

NON-INVASIVE CONNECTIONS

Inline sensor:
- Food pipe threaded connection DIN 11851
- Threaded connection IDF ISO 2853
- Clamp connection, ISO 2852-compliant

Clamp-on measuring instruments with various clamp elements:
- Clamping block (for pipe Ø 4...57 mm)
- Clamping shoe (for pipe Ø 10...300 mm)
- Clamping bracket (for pipe Ø 4...17.2 mm)
Pressure is one of the most commonly measured values in process engineering, and yet virtually no process is identical to another. The use of diaphragm seal technology is useful for measuring in hygienically sensitive environments.

**AT A SAFE DISTANCE**

Diaphragm seals are the first choice if there are exceptional requirements governing a measurement task. They separate the measuring instrument from the process media and prevent it from entering into the measuring system - perfect setup for a hygienic solution.

**NEW SOLUTIONS**

Measuring tasks are being developed and becoming more highly specialised with increasing automation in the process industry. With patented diaphragms and customer-specific designs for diaphragm seals, LABOM is contributing to precise results and greater operating reliability.

**CERTIFIED SAFETY**

A number of LABOM diaphragm seals have been certified by the European Hygienic Engineering & Design Group (EHEDG) as being suitable for cleaning in place (CIP) and sterilisation in place (SIP) applications.

This includes the DIN 11864-compliant models with flange, clamp or threaded connections, Varivent®, NEUMO Biocontrol® and the LABOM Hygienic Tubus range. There is also a range of other clamp connections or solutions with union nuts available for applications with less stringent requirements.
WITH DIAPHRAGM SEAL

PASCAL Ci4 with Varivent connection
Ci4110

PASCAL CV with clamp connection
CV3010

PASCAL CV with Neumo BioControl connection
CV3010

PASCAL CS with dairy coupling
CS2110

UNIVERSAL CA with dairy coupling
CA2110

COMPACT ECO with clamp connection
CA1110

WITH PIPE DIAPHRAGM SEAL

PASCAL CV with inline diaphragm seal
CV3010

Mechanical pressure gauge with inline diaphragm seal
BH42
FDA Food and Drug Administration. US Health Authority.

US-3A A voluntary association of interest groups representing US industry. Aim: To safeguard public health through a programme of hygiene standards for equipment for the production of food.

HYGIENIC DESIGN Design of equipment, components and parts to meet specific cleaning requirements.

CIP CLEANING IN PLACE Automated cleaning procedure of closed equipment or a closed process system – no dismantling.

SIP STERILISATION IN PLACE Automated sterilisation of a closed process system, which removes or kills micro-organisms, often using superheated steam at 120 °C or more.

ASEPTIC COMPONENT A component designed to comply with cleaning regulations, which can be sterilised and is impermeable to micro-organisms.

CORROSION The interaction of a material with its environment, which leads to a change in the properties of the material and possible failure of the component. This interaction is often electrochemical. There are different types of corrosion depending on the corrosion mechanism and the appearance of the corrosion, including pitting, stress-corrosion cracking (SCC) and crevice corrosion.

FLAWLESS SURFACE A flawless surface is a surface free of defects, like scratches, fissures, pores and holes, where product residue or cleaning agent and relevant micro-organisms can accumulate. Only a surface that is deemed to be flawless can be easily cleaned.

GMP Good Manufacturing Practice: Quality assurance process, mandatory in both the USA and in Europe, in the production of pharmaceuticals and foodstuffs. It covers personnel, premises, documentation, production, quality control and equipment.
European Hygienic Engineering & Design Group, founded in 1989 to promote hygienic processes in food production. The EHEDG is made up of professionals from the food industry, suppliers and system installers, research institutes and government bodies. At an international level, the group publishes guidelines and recommendations on “Hygienic Design” and develops test procedures and assessment criteria.

<table>
<thead>
<tr>
<th>EHEDG CERTIFICATION CLASSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>The respective system components are categorised in Classes I and II, with Class I relating to equipment that can be cleaned in its installed state (CIP cleaning) and Class II relating to components that can only be cleaned in their dismantled state. Furthermore, parts used in aseptic applications, can be certified as “EL Aseptic”, while certificate “ED” relates to components specifically intended for dry cleaning.</td>
</tr>
</tbody>
</table>

**EL Class I**  
Applies to components that can be cleaned in their installed state (CIP= Cleaning in place).

**EL Class II**  
Applies to components that can only be cleaned after they have been dismantled.

**EL Aseptic Class I**  
Applies to components that can be cleaned in their installed state (CIP= Cleaning in place), sterilised (SIP = Sterilisation in place) and are impervious to bacteria.

**EL Aseptic Class II**  
Components for closed processes, which are dismantled for cleaning, can be sterilised with steam and are impervious.

**ED**  
Applies to components used in dry processes, which are cleaned dry. All the provisions of EHEDG documents 8, 22 and 26 have to be met.
MADE-TO-MEASURE SOLUTIONS

THE NORTH GERMAN EXPERTS

As well as manufacturing standard equipment for the process industry, LABOM is also an experienced specialist in measuring instruments that meet customers’ individual specifications. LABOM specialises in solving unusual measuring tasks and is more than happy to advise customers. Development, production and sales are located on the same site at its headquarters in Hude (Oldenburg). The company’s short lines of communication, large inventory and outstanding vertical manufacturing enables it to produce even small quantities of individual measuring instruments.

SELECTION

The LABOM portfolio ranges from smart standard instruments, modular designed measuring systems and high-end measuring transmitters to custom configured measuring tasks.

INNOVATIONS

LABOM solves individual tasks with innovative ideas, like in-process calibration of temperature measuring devices or so-called Kombibar equipment with simultaneous electronic and mechanical pressure measurement.
STANDARDS

LABOM equipment for hygienic use is manufactured in line with GMP (Good Manufacturing Practice) guidelines and meets FDA (Food and Drug Administration) and EHEDG (European Hygienic Engineering & Design Group) standards.

QUALITY

LABOM’s quality management system is DIN EN ISO 9001: 2008-certified and complies with the Pressure Equipment Directive 97/23/EC and ATEX 94/9/EC/IECEx.