Pressure propagation in encapsulated pressure sensor systems

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1 Introduction

All kinds of sensors can be found in many fields of our daily life: Motion and luminance detectors in our homes, temperature sensors in dish washers and coffee machines, CCD image sensors in digital cameras or gyro sensors in the Electronic Stability Control (ESC, also referred to as Electronic Stability Program or Dynamic Stability Control) of modern cars, to mention only a few. Sensors have become necessary and indispensable in various sectors, commodities or production processes and will gain even more importance in the foreseeable future. The evolution of silicon microsystems in the last decades offered new possibilities in sensors and chips. [1] Silicon pressure sensors are among the most common and commercially highly successful micro electrical and mechanical systems (MEMSs). Their technology is presented in detail in chapter 2.

Every application brings along individual needs of protection for the sensing element to avoid parameter shift or even destruction. Because an encapsulation has to meet commercial and technical needs a lot of different techniques have been developed in the past [2, 3]. A strong emerging market for MEMS is medical technology. The enormous potential and the special challenge of biomedical encapsulations have already been identified 30 years ago [4]. During the last years research in many areas of medical technologies has been driven resulting in different systems and applications [5].

Among others, the Institute for materials in electrical engineering 1 (IWE 1) at RWTH Aachen University (RWTH) has developed and presented various medical implants. One of these systems designed to invasively monitor blood pressure, is presented in detail in chapter 4. The construction of this special encapsulation triggered the theoretical reflection of the signal propagation inside of the encapsulation material,
presented in chapter 3.

In general high demands are made on all implantable systems with pressure sensing units. The encapsulation must be edgeless and biocompatible, in order to protect the body from contamination and injuries, and it must protect the electronics from corrosion and mechanical destruction [6]. Despite from these high protective demands, the encapsulation has to realize the pressure signal propagation. A commonly used material fulfilling all the expectations are silicones, as presented in more detail in chapter 2. Due to their incompressibility combined with a high flexibility, they are ideal for the use of pressure propagation. The high variability of various properties are given by the chemical structure of the silicone. Silicones are composed of siliconoxide chains in various lengths, that are linked by differed mechanisms. Thus various amorphous solid-states can be achieved, or, in case of oils or gels, uncured chains can sustain liquid materials with various viscosities. The addition of different organic groups linked to the base silicone chains also influence the mechanical and chemical parameters to a high degree. This way, characteristics like the Young’s Modulus or the transparency can be varied in a wide spectrum. Many kinds of silicones are classified as biocompatible and show a very good long term stability, qualifying them for the use in medical products. Even thin films of silicones can realize the necessary protection. The whole sale price as well as the processing of silicones are comparatively cheap to other biocompatible materials. Using various potting techniques, silicones allow encapsulation in the scale of small batch series or automated mass production [2].

The aim of this thesis is the examination of various influence parameters of the encapsulations material silicone on the pressure propagation. Different geometries are modelled and simulated using the Finite element method (FEM) to derive principle rules and help designing encapsulating structures. Because necessary parameters can not be found in literature or are poorly documented, they had to be determined first for the used materials. The postulated simulations were validated by assemblies with a variation of the same parameters. Finally the findings are used to simulate the sensing unit of the Hyper-IMS system
to show possible improvements in the system design.
2 State of the art

In this chapter the basics and state of the art of relevant technology is depicted. In addition to pressure sensor technology and the physical and chemical properties of the encapsulation material silicone, an overview of available pressure sensing implants is given.

2.1 Pressure sensor technology

A pressure sensor measures pressure, typically of gases or liquids. Pressure is stated in terms of force per unit area. The SI-unit is Pascal (1 Pa = 1 kg/m s^2) or bar (1 bar = 100 kPa). Other units in use include standard atmosphere (atm), pounds per square inch (psi), millimeter of mercury at 0 °C (mmHg) and millimeter of water at 4 °C (mmH₂O). Especially in medical environments mmHg or torr are the typically used unit. A conversion between the various units can be found in table 2.1.

Pressure sensors are used for control and monitoring in thousands of everyday applications. They can also be used to indirectly measure other variables such as fluid or gas flow, speed, water level, and altitude.

<table>
<thead>
<tr>
<th>to convert into</th>
<th>Pa</th>
<th>bar</th>
<th>atm</th>
<th>psi</th>
<th>mmHg</th>
<th>mmH₂O</th>
</tr>
</thead>
<tbody>
<tr>
<td>multiply ... by</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pa</td>
<td>1</td>
<td>1.00 * 10⁻⁶</td>
<td>9.87 * 10⁻⁶</td>
<td>1.45 * 10⁻⁴</td>
<td>7.50 * 10⁻⁴</td>
<td>0.10197</td>
</tr>
<tr>
<td>bar</td>
<td>1.00 * 10⁵</td>
<td>1</td>
<td>0.9872</td>
<td>14.5039</td>
<td>750.2838</td>
<td>1.02 * 10³</td>
</tr>
<tr>
<td>atm</td>
<td>1.01 * 10⁵</td>
<td>1.01295</td>
<td>1</td>
<td>14.696</td>
<td>760</td>
<td>1.03 * 10³</td>
</tr>
<tr>
<td>psi</td>
<td>6.89 * 10³</td>
<td>0.068948</td>
<td>0.068046</td>
<td>1</td>
<td>51.71</td>
<td>7.03 * 10³</td>
</tr>
<tr>
<td>mmHg [0 °C]</td>
<td>133.28</td>
<td>1.33 * 10⁻³</td>
<td>1.32 * 10⁻³</td>
<td>1.93 * 10⁻²</td>
<td>1</td>
<td>1.36 * 10²</td>
</tr>
<tr>
<td>mmH₂O [4 °C]</td>
<td>9.8067</td>
<td>9.81 * 10⁻⁶</td>
<td>9.68 * 10⁻⁵</td>
<td>1.42 * 10⁻³</td>
<td>7.36 * 10⁻²</td>
<td>1</td>
</tr>
</tbody>
</table>
Drastic variations in technology, design, performance, application suitability and cost are common in this market segment. A conservative estimate would be that there may be over 50 technologies and at least 300 companies making pressure sensors worldwide.

A pressure sensor usually acts as a transducer generating an electrical signal as a function of the pressure applied. Pressure sensors can be classified with regard to pressure ranges they measure, temperature ranges of operation and most importantly the type of pressure they measure. There are various kinds of sensors and thus multiple definitions how to group them properly. The most general definition is to differ between

1. Absolute pressure sensors

The pressure relative to perfect vacuum (0 bar or no pressure) is called absolute pressure. Absolute pressure sensors measure pressure against a reference chamber at vacuum. In relation to the measured pressure, this reference vacuum should negligible.

2. Relative pressure sensors

The relative or gauge pressure sensors measure a pressure relative to a given atmospheric pressure at the actual location. A tire pressure gauge is an example of gauge pressure indication, reading the pressure relative to atmospheric pressure. When the tire pressure gauge reads 0 mbar, there is really atmospheric pressure (typically 1013.25 mbar) in the tire.

3. Differential pressure sensors

Differential pressure sensors measure the difference between two pressures introduced as inputs to the sensing unit. These sensors can be used to measure the pressure drop across a barrier like in an oil filter. Another application would be to measure flow or level in pressurized vessels.
Pressure sensing technology

Various physical principles to transform pressure into an electrical signal allow a wide range of different sensor types. The most common principles shall be listed here, to give a broad overview. The two most important principles are explained in depth in the following sections. There are two basic categories of analog pressure sensors.

**Force collector sensors** generally use a force collector (such a diaphragm, piston, bourdon tube or bellows) to measure strain (or deflection) due to applied force (pressure) over an area.

1. **Piezoresistive strain gauges**

Uses the piezoresistive effect of bonded or formed strain gauges to detect strain due to applied pressure. Common technology types are Silicon (Monocrystalline), Polysilicon, Thin Film, Bonded Metal Foil, Thick Film, and Sputtered Thin Film[7]. Generally, the strain gauges are connected to form a Wheatstone bridge circuit to maximize the output of the sensor. [8] This is the most commonly employed sensing technology for general purpose pressure measurement. Generally, these technologies are suited to measure absolute, gauge, vacuum, and differential pressures. This sensor principle is the most commonly used and is described in depth in section 2.1.1

2. **Capacitive**

Uses a diaphragm and pressure cavity to create a variable capacitor to detect strain due to applied pressure. Common technologies use metal, ceramic, and silicon diaphragms. As this technology is used in the project Hyper-IMS (see section 4), it is described in section 2.1.2.

3. **PSFET**

During the last years some efforts were undertaken to build pressure sensors with single MOSFET- technology. A pressure sensitive field effect transistor (PSFET) is realized by placing parts of the transistor on a silicon membrane, thus deforming the gate capacitance [9, 10] or the gap between the channel and the gate [11]. This deformation
causes a drift in the transfer characteristic of the FET, that can be detected. This Technique was first presented in 2001 by Sumito and Ko [9] and has not yet found its' way into mass production.

4. Piezoelectric

Uses the piezoelectric effect [12] in certain materials such as quartz to measure the strain upon the sensing mechanism due to pressure. The major drawback of this technology is that no static measurements can be made because even the best isolation can not prevent a leakage current thus loosing the separation of charge caused by outer force. On the other hand highly precise and very fast sensors can be realized.

5. Electromagnetic

The displacement of a diaphragm can be measured for example by means of changes in inductance or the Hall effect [13].

6. Optical

Uses the physical change of an optical fiber to detect strain due to applied pressure. A common example of this type utilizes Fiber Bragg Gratings [14].

7. Potentiometric

Uses the motion of a wiper along a resistive mechanism to detect the strain caused by applied pressure.

Other types of electronic pressure sensors use other properties (such as density) to infer pressure of a gas, or liquid. These sensors is also called passive pressure sensors because the primary cause (the pressure) is not transformed directly into electrical energy.

1. Resonant

Uses the changes in resonant frequency in a sensing mechanism to measure stress, or changes in gas density, caused by applied pressure. This technology may be used in conjunction with a force collector, such as those in the category above. Alternatively, resonant technology
may be employed by expose the resonating element itself to the media, whereby the resonant frequency is dependent upon the density of the media. Sensors have been made out of vibrating wire, vibrating cylinders, quartz, and silicon MEMS [15, 16]. Generally, this technology is considered to provide very stable readings over time.

2. Thermal

The thermal conductivity of gas changes the density allows conclusions to the applied pressure. A common example of this type is the Pirani gauge [17].

3. Ionisation

Measures the flow of charged gas particles (ions) which varies due to density changes to measure pressure. Common examples are the Hot and Cold Cathode gauges.

4. Others

There are numerous other ways to derive pressure from its density (speed of sound, mass, index of refraction) among others.

2.1.1 Piezoresitive pressure sensors

The most common principle for micro-electric pressure sensors in available market is the piezoresistive pressure sensor. As these sensors are nowadays used in large numbers for example in the automotive industry, the availability and the range of obtainable specifications are enormously high at comparatively low costs.

Piezoresistivity

The piezoresistive effect describes the changing resistivity of a semiconductor due to applied mechanical stress. In contrast to the piezoelectric effect, the piezoresistive effect only causes a change in electrical resistance and does not produce an electric potential. The change of resistance in metal devices due to an applied mechanical load was
first discovered in 1856 by Lord Kelvin. With single crystal silicon becoming the material of choice for the design of analog and digital circuits, Charles S. Smith reported for the very first time the discovery of the piezoresistive effect in the cubic semiconductors germanium and silicon in his paper published in the journal Physical Review on April 1, 1954 [18]. This discovery entailed development of discrete silicon strain gauges with sensitivities up to 50 times higher than that of conventional metallic ones. The excellent mechanical properties of silicon could be used aside from the well know electronic ones by the integration of diffused resistors into the silicon and by creating pressure-sensitive deformable regions directly within the silicon sensor chip. Since then piezoresistive sensor technology has decisively influenced the development of microsystem technology and micro electro mechanical systems (MEMS) for some time. [1] An on-chip production of complementary metal oxide semiconductor (CMOS) is possible to realize, but not in a single wafer process line. So typically piezoresistive sensors are build up in multi-chip systems. In semiconductors, changes in inter-atomic spacing resulting from strain affects the bandgaps changing the affinity of electrons to be raised into the conduction band. This results in a change in resistivity of the semiconductor. Piezoresistivity is defined by

$$\rho_\sigma = \frac{\frac{\delta\rho}{\rho_0}}{\sigma}$$  \hspace{1cm} (2.1)$$

where $\delta\rho = \text{change in resistivity}$, $\rho_0 = \text{original resistivity}$ and $\sigma = \text{mechanical strain}$.

In the first years, silicon was used as a substitute for strain gauges by working it out as a thin foil. A first integrated piezoresistive pressure sensor was presented in 1969 [1]. This basic layout has become the de facto standard and is shown in figure 2.1: A cavity commonly processed by anisotropic etching forms a deformable membrane with implanted resistors. This basic element can be used for differential or gauge pressure measurement. For absolute pressure sensors the base element is mounted on a silicon bulk or pyrex glass body by means of
anodic bonding to form a closed cavity with a reference pressure, which usually is vacuum. Typically the chip is orientated in the way that the membrane is parallel to the (100)-crystal layer. As the cavity is build by anisotropic etching, its side walls are located in the (111)-layer, forming the typical angle of 54.74 °C with the membrane. Inside the membrane there are usually four strain gauges. In general Ohm’s law for anisotropic crystals is given by the vector of the electric field \( \vec{E} \), the current density \( \vec{j} \) and the specific resistance (\( \vec{E} = \rho \cdot \vec{j} \)):

\[
\begin{pmatrix}
E_1 \\
E_2 \\
E_3
\end{pmatrix} =
\begin{pmatrix}
\rho_{11} & \rho_{12} & \rho_{13} \\
\rho_{21} & \rho_{22} & \rho_{23} \\
\rho_{31} & \rho_{32} & \rho_{33}
\end{pmatrix} \cdot
\begin{pmatrix}
j_1 \\
j_2 \\
j_3
\end{pmatrix}
\] (2.2)

Due to the symmetries in the cubic silicon crystal, the coefficients on both sides of the diagonal of the tensor \( \rho \) are symmetric \( \rho_{ij} = \rho_{ji} \). Thus the number of independent coefficients reduces to six. As in an unstressed crystal the resistance is isotropic, only one independent coefficient remains: \( \rho_{11} = \rho_{22} = \rho_{33} = \rho_0 \) and \( \rho_{12} = \rho_{13} = \rho_{23} = 0 \). Thus the following correlation between a behaviour under load and
the load-free isotropic behaviour can be formulated:

\[
\begin{pmatrix}
\rho_{11} \\
\rho_{22} \\
\rho_{33} \\
\rho_{12} \\
\rho_{13} \\
\rho_{23}
\end{pmatrix}
= \begin{pmatrix}
\rho_0 \\
\rho_0 \\
\rho_0 \\
0 \\
0 \\
0
\end{pmatrix}
+ \begin{pmatrix}
\Delta \rho_{11} \\
\Delta \rho_{22} \\
\Delta \rho_{33} \\
\Delta \rho_{12} \\
\Delta \rho_{13} \\
\Delta \rho_{23}
\end{pmatrix}
\]

(2.3)

The mechanical stress field in a loaded crystal can be described by the normal \((\sigma_{11}, \sigma_{22}, \sigma_{33})\) and the shear stresses \((\sigma_{12} = \sigma_{21}, \sigma_{13} = \sigma_{31}, \sigma_{23} = \sigma_{32})\). With the help of the piezoresistive coefficients \(\pi_{ij}\) the changes in resistance can be determined from the strain coefficients. Typically this is a 6 x 6 matrix with 36 independent coefficients. But again the number of coefficients can be reduced with the help of the symmetries in a cubic crystal resulting in the dependency on the three piezoresistive coefficients \(\pi_{11}, \pi_{12}, \pi_{44}\):

\[
\frac{1}{\rho_0} \begin{pmatrix}
\rho_{11} \\
\rho_{22} \\
\rho_{33} \\
\rho_{12} \\
\rho_{13} \\
\rho_{23}
\end{pmatrix}
= \begin{pmatrix}
\pi_{11} & \pi_{12} & \pi_{12} & 0 & 0 & 0 \\
\pi_{12} & \pi_{11} & \pi_{12} & 0 & 0 & 0 \\
\pi_{12} & \pi_{12} & \pi_{11} & 0 & 0 & 0 \\
0 & 0 & 0 & \pi_{44} & 0 & 0 \\
0 & 0 & 0 & 0 & \pi_{44} & 0 \\
0 & 0 & 0 & 0 & 0 & \pi_{44}
\end{pmatrix}
\cdot \begin{pmatrix}
\sigma_{11} \\
\sigma_{22} \\
\sigma_{33} \\
\sigma_{12} \\
\sigma_{13} \\
\sigma_{23}
\end{pmatrix}
\]

(2.4)

The piezoresistive coefficients \(\pi_{11}, \pi_{12}, \pi_{44}\) are depending on the type and amount of doping as well as the temperature and the crystal

Table 2.2: Typical values of piezoresistive coefficients for several dopings at room temperature [18, 19]

<table>
<thead>
<tr>
<th></th>
<th>(\rho) ((\Omega \text{cm}))</th>
<th>(\pi_{11}) ((10^{-11} \text{m}^2\text{N}^{-1}))</th>
<th>(\pi_{12}) ((10^{-11} \text{m}^2\text{N}^{-1}))</th>
<th>(\pi_{44}) ((10^{-11} \text{m}^2\text{N}^{-1}))</th>
</tr>
</thead>
<tbody>
<tr>
<td>p-Si</td>
<td>7,8</td>
<td>6,6</td>
<td>-1,14</td>
<td>+138,1</td>
</tr>
<tr>
<td>n-Si</td>
<td>11,7</td>
<td>-102,2</td>
<td>53,4</td>
<td>-13,6</td>
</tr>
</tbody>
</table>
State of the art

orientation. Sample coefficients as typical values for p-doping and n-doping are shown in table 2.2.

In pressure measurements stress only occurs in the top plane along the membrane of the pressure sensor. The change in resistance can now be explained with the longitudinal and the transversal piezoresistive effect with their coefficients $\pi_{lo}$ and $\pi_{tr}$. A resistor with a current flow in longitudinal direction is thus defined as:

$$\frac{\Delta \rho}{\rho} = \pi_{lo} \cdot \sigma_{lo} + \pi_{tr} \cdot \sigma_{tr}$$

(2.5)

Crucial for the specification of the piezoresistive effect is the combination of doping and placement of the resistors. The data for longitudinal and transversal coefficients as a linear combination of the piezoresistive coefficients is presented in table 2.3. For a sensor layout changes in the resistors are maximized by combining p-doping and a placement of the membrane in the (100)-layer.

In order to use this effect, four strain gauges are implanted close to the border of the membrane in a manner that two at a time are elongated in transversal and longitudinal direction. Those four strain gauges are wired as a Wheatstone bridge. Using the fact of $\pi_{44}$ being the dominating factor, the resulting change in resistance is negative for tension in transversal direction and positive for tension in longitudinal direction. Thus the values of resistance are maximized, or respectively minimized, resulting in a maximized bridge voltage. The total value of the resistance is described as $R = \rho_0 \frac{l_0}{w_0 \times h_0}$ where $l_0$, $w_0$ and $h_0$ represent the length, the width and the hight of the resistor. In

Table 2.3: Longitudinal and transversal piezoresistive coefficients for varying layers in dependency of the piezoresistive coefficients $\pi_{11}, \pi_{12}, \pi_{44}$ [18]

<table>
<thead>
<tr>
<th>layer</th>
<th>direction of current flow</th>
<th>$\rho_{lo}$</th>
<th>Transversal</th>
<th>$\rho_{tr}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>(100)</td>
<td>[110]</td>
<td>$\frac{1}{2}(\pi_{11} + \pi_{12} + \pi_{44})$</td>
<td>[110]</td>
<td>$\frac{1}{2}(\pi_{11} + \pi_{12} - \pi_{44})$</td>
</tr>
<tr>
<td>(110)</td>
<td>[001]</td>
<td>$\pi_{11}$</td>
<td>[110]</td>
<td>$\pi_{12}$</td>
</tr>
<tr>
<td>(110)</td>
<td>[111]</td>
<td>$\frac{1}{2}(\pi_{11} + 2\pi_{12} + \pi_{44})$</td>
<td>[112]</td>
<td>$\frac{1}{2}(\pi_{11} + 2\pi_{12} - \pi_{44})$</td>
</tr>
<tr>
<td>(111)</td>
<td>[110]</td>
<td>$\frac{1}{2}(\pi_{11} + \pi_{12} + \pi_{44})$</td>
<td>[112]</td>
<td>$\frac{1}{2}(\pi_{11} + 5\pi_{12} - \pi_{44})$</td>
</tr>
</tbody>
</table>
addition to the piezoresistive effect the change in dimension leads to an additional term when calculating the total differential:

\[
\frac{\partial R}{R} = \frac{\partial R}{\partial \rho_0} \Delta \rho + \frac{\partial R}{\partial l_0} \Delta l_0 + \frac{\partial R}{\partial w_0} \Delta w_0 + \frac{\partial R}{\partial h_0} \Delta h_0 \tag{2.6}
\]

\[
\frac{\Delta R}{R} = \frac{\Delta \rho}{\rho_0} + \frac{\Delta l_0}{l_0} - \frac{\Delta w_0}{w_0} - \frac{\Delta h_0}{h_0} \tag{2.7}
\]

Typically the change in geometry can be neglected because the resulting changes are by factor 50 to 100 smaller than the ones of the piezoresistive effect. Thus the change of the total resistance can be determined as the sum of the transversal and the longitudinal piezoresistive effect. As the implanted areas are arranged in a way with either the longitudinal or transversal component predominating, the bridge resistors can be simplified to:

\[
R_{1,3} = R_0 + \Delta R_{1,3} = R_0(1 + \pi_{lo} \cdot \sigma_x) \tag{2.8}
\]

\[
R_{2,4} = R_0 + \Delta R_{2,4} = R_0(1 + \pi_{tr} \cdot \sigma_y) \tag{2.9}
\]

Inserting this in the formula of a Wheatstone bridge (formula 2.10) the following correlation can be formulated:

\[
\frac{U}{U_0} = \frac{\frac{R_2 R_4 - R_1 R_3}{(R_1 + R_2)(R_3 + R_4)}}{(2 + \pi_{lo} \cdot \sigma_{x R1} + \pi_{tr} \cdot \sigma_{y R2})(2 + \pi_{lo} \cdot \sigma_{x R3} + \pi_{tr} \cdot \sigma_{y R4})} \tag{2.11}
\]

For a symmetrical sensor it can be assumed that the strains at the opposing gauges are equal: \( \sigma_{x R1} = \sigma_{x R3} =: \sigma_x \) and \( \sigma_{y R2} = \sigma_{y R4} =: \sigma_y \). Thus the resulting formula 2.11 can even be reduced to:

\[
\frac{U}{U_0} = \frac{\pi_{tr} \sigma_y - \pi_{lo} \sigma_x}{\pi_{tr} \sigma_y + \pi_{lo} \sigma_x + 2} \tag{2.12}
\]

### 2.1.2 Capacitive pressure sensors

The major advantage of capacitive pressure sensors over piezoresistive sensor is that they can be fabricated on-chip in a CMOS process more
Figure 2.2: Schematics of a capacitive pressure sensor

Figure 2.3: SEM micrograph of a capacitive pressure sensor [20]
2.1 Pressure sensor technology

easily. Thus generally a higher integration and a smaller system design can be achieved. The measuring principle of capacitive pressure sensors is based on the change of the gap between the two capacitor plates and the thereby caused change of capacity. A basic schematics is shown in figure 2.2 and a detailed SEM micrograph in figure 2.3. The silicon membrane represents the top electrode of the capacitor, the bottom electrode is in the silicon bulk. External stress deforms the top electrode, lowing the distance between the two electrodes. The resulting capacity can be detected with a readout circuit or in simulation it is derived from the area integral of the two plates. The transformation of the capacitance to an output voltage is commonly realized in a two–stage switched–capacitor circuit. The first stage compares the sensor capacity with a passivated reference capacitance. By this comparison the measurement is less dependant on manufacturing variability. The second stage is an amplification of the signal. For the measurement of absolute pressure, reference capacitors are created by passivating the surface membrane inhibiting movement almost completely. Thus process-related differences can be neglected. An array of sensor and reference capacitors is implemented on a chip in varying numbers to match the needs of the application.

To determine the capacity and that way the applied pressure, the area integral of the two electrodes has to be calculated. At first the bending of the upper electrode is of importance. The modelling of the circular plate is performed on the basis of this differential equation [21]:

$$\Delta \Delta w = \frac{1}{D} (p + p_{el})$$

where

$$D = \frac{E}{1 - \nu^2} \frac{t_p^3}{12} \quad (2.13)$$

with the double Laplace-operator $\Delta$ of the vertical deflection $w$, the flexural rigidity of the plate $D$, the external pressure $p$ and electrostatic pressure $p_{el}$. The rigidity is defined by the Young’s modulus $E$, the Poisson’s ratio $\nu$ and the thickness of the plate $t_p$. The electrostatic pressure is caused by the the applied read-out voltage and supports the ongoing deflection by electrostatic attraction. It is defined by the radius $r$, the distance of the electrode plates $d$, the applied voltage $V$, \[ \text{and the thickness of the plate } t_p. \]
the dielectric constant $\epsilon$ and the deflection $w(r)$ [21]:

$$p_{el}(r) = \frac{1}{2} \epsilon \left( \frac{V}{d - w(r)} \right)$$  \hspace{2cm} (2.14)

This dependency of the electrostatic pressure to the deflection does not allow the solution of equation 2.13 by simply solving the forth integral. For an approximation of the solution, the electrostatic pressure $p_{el}$ is approximated [21]:

$$p_{el}(r) \approx \sum_{i=0}^{n} a_i r^i$$  \hspace{2cm} (2.15)

Now the integral in equation 2.13 can be solved:

$$w = \frac{1}{64} \frac{p}{D} r^4 + \frac{C_1 r^2}{4} \left( \ln \frac{r}{R_0} - 1 \right) + \frac{C_2 r^2}{4} + C_3 \ln \frac{r}{R_0} + C_4 + \sum_{i=0}^{n} \frac{A_i r^{i+4}}{(i+2)(i+4)^2}$$  \hspace{2cm} (2.16)

This integration results in a dependency of the radius $R_0$ of the circular upper electrode and the integration constants $C_1$ to $C_4$. By narrowing the boundary conditions, this integral can be constraint and solved further. The most obvious restriction would be assumption that the electrodes do not touch each other:

$$w = \frac{1}{64} \frac{p}{D} (R_0^2 - r^2)^2 + \frac{(R_0^2 - r^2)}{2D} + \sum_{i=0}^{n} \frac{A_i R_0^{i+2}}{(i+2)(i+4)^2}$$  \hspace{2cm} (2.17)

$$- \frac{1}{D} \sum_{i=0}^{n} \frac{A_i (R_0^{i+4} - r^{i+4})}{(i+2)^2(i+4)^2}$$

Other boundary conditions could be the fixation of the electrode or the dynamic of the plate movement. Also the case of a touchdown of the upper electrode is of further interest. In the case of an electrical contact between the two electrodes, the capacitance would break down.
But assuming the upper electrode touches an isolation layer, the capacitance is still measurable and by increasing the applied pressure the contact area and thus the capacitance rise. Figure 2.4 shows the curve of a capacitive pressure sensor [21]. At the applied pressure of approx. 2600 mbar a break can be clearly seen. At this point the upper electrode touches the isolation on top of the lower electrode. After this break the linear dependency of the sensor continues straight proportional. Figure 2.5 shows the calibration curve of a capacitive pressure sensor from the project Hyper-IMS (see also chapter 4). Because the capacitances are integrated on-chip and the readings are digitalized directly, the precision of the whole working range is affected by the described non-linearities. The limited number of quantization steps are evenly distributed to the whole range of capacity. Thus the precision of the pressure measurement rises with steeper slopes. Thus the geometry should be adjusted to the expected pressure range to avoid contact between the electrodes. Figure 2.5 shows a sensor calibration from the beginning of the project, in the course of the project, the geometry was
adjusted so that the touchdown now takes place beyond 1400 mbar. For further information about the project Hyper-IMS see chapter 4.

### 2.2 Silicones

Silicones are synthetic compounds that are used in many different areas. The wide variety of individually adjustable parameters can be used to trim the silicone to the wanted use. Typically heat-resistant, nonstick, and rubber-like, they are commonly used in cookware, medical applications, sealants, adhesives, lubricants, insulation, and breast implants. In glass construction silicones are used as adhesives because of their similar mechanical behaviour to organic adhesives, and various unwanted characteristics like weathering are not as strong as in these compounds. Furthermore the temperature range is greater because at high temperatures silicones nearly don’t melt or oxidate and at low temperatures they stay soft and smooth due to missing crystallization effects. Typically silicones show a constancy of properties over a wide
temperature range of about $-100$ to $250\, ^\circ C$.

For the encapsulation of pressure sensors silicones are used because of their incompressibility, biocompatibility, electrical isolation and their good handling properties.

### 2.2.1 Chemistry of silicones

The wide range of adjustable properties of silicones originates in the nearly infinite number of possible chemical composition. This chapter shall give an overview of fabrication and classification of silicone to help understand the chemistry of silicones. \[22\]

Organic chemistry is based on chain-, ring- or mesh-like compositions of the element carbon. As an element of the fourth main group carbon is able to form strong linkages to elements with a high or a low electronegativity. \[23\] Furthermore covalent bindings of carbon are very strong giving the possibility of forming very long chains. Elements of the same main group often show similar properties. Silicon is able to form stable covalent bindings although these are not as strong as carbon bindings. Due to the higher ordinal number and thereby bigger size causing greater distance between the individual atoms, the bond energy is smaller. This results in a limitation of possible chainlength of silicon atoms. After failed experiments to exchange carbon with silicon in organic compounds, compounds of carbon and silicon were investigated.

### Synthesis

In 1901 Kippling established the the name silicone for silicon-carbon-based compounds. Thereby the term silicone denominates chain-, ring- and meshstructures composed of silicon and oxygen with organic groups at free silicon-bindings. The alternating silicon and oxygen atoms provide a strong binding and that way a stable compound. The name silicone apparently is a misunderstanding of Kippling’s. He assumed silicone-synthesis was similar to the synthesis of acetone by
separating water of two hydroxyl-groups in an intramolecular reaction.

\[
\text{CH}_3\text{C} = \text{CH}_3 \quad \rightarrow \quad \text{CH}_3\text{C} - \text{CH}_3 + \text{H}_2\text{O} \quad (2.18)
\]

Actual synthesis takes place in an intermolecular reaction by condensing two hydroxyl-groups. This direct synthesis used in industrial fabrication was proposed by Müller and Rochow. [23] With the catalytic influence of copper and other promoters at temperatures of \(250^\circ C - 300^\circ C\) silicon reacts with alkyl- and arylchlorides. The resulting mixture of alkyl- and aryl-chloride-silanes is hydrolysed to silanols with seperated hydrogen chloride:

\[
\text{R}_i\text{SiCl}_{(4-i)} + (4 - i)\text{H}_2\text{O} \rightarrow (4 - i)\text{HCl} + \text{R}_i\text{Si(OH)}_{(4-i)} \quad (2.19)
\]

In a final condensation these silanoles form the \(Si - O - Si\) -bindings (siloxane-bindings). Exemplary the reaction to disiloxane is presented:

\[
\text{CH}_3\text{Si}<\text{OH} \quad + \quad \text{HO}<\text{Si}<\text{CH}_3 \quad \rightarrow \quad \text{CH}_3\text{Si}<\text{O}<\text{Si}<\text{CH}_3 + \text{H}_2\text{O} \quad (2.20)
\]

Depending on the number of hydroxil-groups bound to the siliconatoms, the resulting structures of this reaction varies from rather simple silicone molecules to complex three-dimensional meshes. [23, 24] The molecular structure predominates the physical characteristics of the silicone. Thus chain or ring structures stay fairly liquid forming the group of silicone oils. Threedimensional meshes can result in solid formations and are classified as silicone lacquers or resins. Different
mixtures, hybrid forms or intermediate stages are possible offering almost all kinds of hardness degrees. Long chain structures with a few intermolecular connections for example are classified as silicone elastomers. This stable but highly flexible compound can provide elongations of over 250%, like found in organic rubber. This classification is based on the appearance and thus intuitive. Further differentiation results mainly in the synthesis of the silicone.

The temperature during fabrication is the crucial factor for inner stress. Depending on the curing temperature, silicones are classified in two groups: High temperature cure and cold or room temperature cure. Furthermore silicones are classified as one or two component systems. In addition to the presented condensating silicones generating a by-product like water, there are two-component silicones cross-linking sideproduct-free. In this addition curing, the chains typically don’t link at the siloxane groups, but at the carbon bindings of the organic groups.

$$\begin{align*}
\cdots O-Si-O-Si-O-CH=CH_2 + H-Si-CH_3 & \rightarrow \cdots O-Si-O-Si-O-CH=CH_2 \cdots CH_2-CH_2-Si-CH_3
\end{align*}$$

(2.21)

Formula 2.21 shows the vulcanizing reaction of the most commonly used base polymer vinyl-blocked polydimethylsiloxane with platinum catalyst and polymethylsiloxane. For such a reaction, the ratio of the base polymer and the curing agent are the crucial factor for the cross-linking and thus the stiffness of the product. By varying the mixing ratio, so that less functional Si-H-groups than reactive polymers are available, not all base polymers are able to react, leaving behind open ends of polymers chains. These uncured polymers chains are kept inside the structure due to osmotic pressure, resulting in a silicone gel with
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less hardness than the regularly and thus completely cured silicone. Furthermore the shortened and uncured polymers result in physical adhesion and stickiness at the surface. None the less, an inherently stable gel with a elongation at break of 1000% can be achieved. By adding other organic groups or substances silicone oil or pigments, properties of the resulting silicone can be diversified. In addition to active components added, some kinds of silicones are blended with non-functional additives to add volume and save costs. In the following, the most important parameters shall be discussed.

2.2.2 Physical properties of silicones

Due to the enormous number of commercially available silicones, it is impossible to provide a complete listing of silicones and properties. The most important parameters for this work shall be introduced and discussed with regard to the specific silicones used in experiment.

At first glance, silicones provide similar properties to equally structured organic polymers. For instance, silicones are typically hydrophobic due to their low surface tension. But in contrast to most other materials, silicones have a high permeability to water vapour and similar gasous materials. The dissolving power of water is also remarkably higher. Despite this, electrical isolation and protection against corrosion is given, as long as the protective layer is free of air entrapments at electrical contacts. Another important difference to organics is that silicones have a lot stronger chemical binding between the siloxane groups. Typically silicones show a constancy of properties over a wide temperature range of about $-100$ to $250 \, ^\circ \text{C}$ and a high resistance to ultraviolet light, oxygen and ozone. [24, 25]

However the most important aspect for encapsulating pressure sensors are the mechanical properties of the silicone. These are predominantly defined by the filler materials. As described in section 2.2.1 silicone elastomeres are of a meshlike structure. Every chain segment stays fairly elastic and agile between the links thus providing the typical elasticity. Relatively small forces lead to big but reversible deformations.
The entropy in a statistically unsorted, highly interlooped system is the highest. Caused by the agility of the chains and the free volume in the molecules, transpositions occur striving for the construction with the highest entropy. Thereby the almost free rotability of the siliconoxide links has a great effect. The resulting clews however cause a reduced agility of the chains as soon as interloops between the molecule chains are formed.

This effect is the contrast to the agility reduction caused by crystallisation, where the molecule chain form parallel oriented areas. In addition to typical crystallisation depending on temperature, there is the elongation crystallisation, where the formation of the chains is caused by external force. The entropic elasticity results from the Brownian molecular motion. In an unstretched system all segments can move freely, whereas with increasing deformation chains are stretched lowering the entropy. Forces caused by thermal motion counteracts this deformation. Thus unfilled elastomers stiffen at higher temperatures.

**Viscoelasticity**

In section 2.2.2 the elongation is described as a reversible process. Due to the high mobility of the chain segments, even small forces lead to great deformations. However the stress-strain curve is non-linear, as shown in figure 2.6. The elongation is not ideally elastic, because inner- and intramolecular friction converts the kinetic energy into thermal

![Figure 2.6: Stress-strain behaviour of elastomers](image-url)
energy. This dissipated energy is reflected in figure 2.6 as the area of the hysteresis. This viscoelastic behaviour is depending on the applied frequency. Whereas at a quasi-static load the molecular displacement is only of minor interest, higher frequencies lead to an increase of the effect. For example rubber brackets tend to stiffen at high frequencies.

The viscoelasticity of elastomers shows effect in two other areas. While applying longterm static forces, the strain releases over time. This behaviour is called relaxation. The other effect is the viscoelastic creep, where after a long duration of stress, the deformation increases.

**The influence of filler materials**

The behaviour of an elastomere is highly influenced by the filler materials. For example the agility of the chains can be reduced, because stiff fillers cause the elastomere to be stretched further, thus resulting in higher reset forces at the equivalent level of elongation. This change in viscoelasticity is called hydrodynamic enhancement. By linking the filler to the elastomere chains, the average free chainlength decreases, causing the elastomere to stiffen. From a specified amount of filler, cluttering occurs, amplifying this effect even more.

The stress-strain curve depends on the maximum loading previously applied to the silicone. This is caused by an inner reconstruction of the material, like tearing the shorter chains or the filler. The phenomenon, named Mullins effect for the British rubber scientist Leonard Mullins, can be idealized for many purposes as an instantaneous and irreversible softening of the stress-strain curve that occurs whenever the load increases beyond its prior all-time maximum value. At times when the load is less than a prior maximum, non-linear elastic behaviour prevails. If an elastomer like silicone is loaded to a particular strain level followed by complete unloading to zero stress several times, the change in structural properties from cycle to cycle as measured by the stress strain function will diminish. When the stress strain function no longer changes significantly, the material may be considered to be stable for strain levels below that particular strain maximum. If the elastomer is then taken to a new higher strain maximum, the structural
properties will again change significantly. An example is shown in figure 2.7 where a thermoplastic elastomer is strained to 20% strain for ten repetitions (red curves) followed by straining to 50% for ten repetitions (blue curves). [26, 27] This effect leads to the conclusion, that every silicone has to be conditioned to its final pressure range, before any viable measurement with an encapsulated sensor can be made.

The viscoelasticity of elastomers is also influenced by the filler materials. The incline of a straight line through the reversal points of the hysteresis loops of the stiffness is called dynamic stiffness. This effect is decreasing with rising amplitudes and can be observed in figure 2.8. [28]

**Influence of temperature**

As explained above, silicone properties depend on temperature, with a special attention on the state of aggregation. All previously described properties are only valid in the range between glass transition temperature (approx. \(-127 ^\circ C\)) and decomposition temperature (>250 \(^\circ C\)). [29, 30] Due to the Brownian molecular motion, the stiffness of unfilled elastomers increases with rising temperature. This correlation is not valid for all filled elastomers, there are some available, where stiffness decreases with rising temperature. Also the viscoelastic behaviour is temperature dependant. A higher agility of the polymer chains at higher temperatures causes faster relaxation and creep.

Below the glass transition temperature silicone predominately forms an amorphous body with local areas of crystallisation. Due to the random linking during the cure, a complete crystallisation of the whole body would demand an enormous amount of energy for reconstruction. Thus instead of striving for the state of absolute minimal energy, the system stays in a local minimum. The slower the cooling takes place, the lower the energy minimum and the bigger the crystallized areas can be, because the system has more time to reorganize by thermal movement. On the other hand it can be noted, that the inner stress is higher with rising cool-down speed, which can be important for
(a) Schematics: a) initial load cycle; b)(b) Measurement of multiple strain cycles [27] stabilized hysteresis pressure 1; c) first load of pressure 2; d) stabilized hysteresis pressure 2

Figure 2.7: Conditioning elastomer to two different maximum strain levels

Figure 2.8: Dynamic stiffness: Straight line through the reversal points of the hysteresis loops. This effect is decreasing with rising amplitudes
the encapsulation of sensors [31]. No thermal transition takes place instantly, but within a certain transition zone. The Brownian molecular motion is reduced until almost no more movement is possible causing a change from entropy elasticity to energy elasticity. In spite of the higher stiffness elastomeres keep a certain amount of elasticity, in contrast to other crystal materials. Additionally the whole crystallisation process is reversible.

2.3 Simulation and modelling

Simulation is the imitation of operations of a real-world process or system over time. The act of simulating something requires a model to be developed at first; this model represents the key characteristics in behaviours or functions of the selected physical or abstract system or process. The model represents the system itself, whereas the simulation represents the operation of the system over time. By changing variables in the simulation, predictions can be made about the behaviour of the system. It is a tool to virtually investigate the behaviour of the system under study. [32, 33] Traditionally, the formal modelling of systems has been via a mathematical model, which attempts to find analytical solutions enabling the prediction of the behaviour of the system from a set of parameters and initial conditions. Computer simulation is often used as an adjunct to, or substitution for, modelling systems for which simple closed form analytic solutions are not possible. There are many different types of computer simulation, the common feature they all share is the attempt to generate a sample of representative scenarios for a model in which a complete enumeration of all possible states would be prohibitive or impossible.

2.3.1 Finite Element method

FEM is a numerical technique for finding approximate solutions to boundary value problems. It uses variational methods (the Calculus of variations) to minimize an error function and produce a stable solution. Analogous to the idea that connecting many tiny straight lines can
approximate a larger circle, FEM encompasses all the methods for connecting many simple element equations over many small subdomains, named finite elements, to approximate a more complex equation over a larger domain. The subdivision of a whole domain into simpler parts has several advantages: [34]

- Accurate representation of complex geometry
- Inclusion of dissimilar material properties
- Easy representation of the total solution
- Capture of local effects

A typical work out of the method involves

1. dividing the domain of the problem into a collection of subdomains, with each subdomain represented by a set of element equations to the original problem, followed by

2. systematically recombining all sets of element equations into a global system of equations for the final calculation.

The global system of equations has known solution techniques, and can be calculated from the initial values of the original problem to obtain a numerical answer. A feature of FEM is that it is numerically stable, meaning that errors in the input and intermediate calculations do not accumulate and cause the resulting output to be meaningless. In the first step above, the element equations are simple equations that locally approximates the original complex equations to be studied, where the original equations are often partial differential equations (PDE). To explain the approximation in this process, FEM is commonly introduced as a special case of Galerkin method. The process, in mathematics language, is to construct an integral of the inner product of the residual and the weight functions and set the integral to zero. In simple terms, it is a procedure that minimizes the error of approximation by fitting trial functions into the PDE. The residual is the error caused by the
trial functions, and the weight functions are polynomial approximation functions that project the residual. The process eliminates all the spatial derivatives from the PDE, thus approximating the PDE locally with a set of algebraic equations for steady state problems or a set of ordinary differential equations for transient problems. [35] These equation sets are the element equations. They are linear if the underlying PDE is linear, and vice versa. Algebraic equation sets that arise in the steady state problems are solved using numerical linear algebra methods, while ordinary differential equation sets that arise in the transient problems are solved by numerically integration using standard techniques such as Euler’s method or the Runge-Kutta method. In the second step above, a global system of equations is generated from the element equations through a transformation of coordinates from the subdomains’ local nodes to the domain’s global nodes. This spatial transformation includes appropriate orientation adjustments as applied in relation to the reference coordinate system. The process is often carried out by FEM software using coordinates data generated from the subdomains. FEM is best understood from its practical application, known as finite element analysis (FEA). FEA as applied in engineering is a computational tool for performing engineering analysis. It includes the use of mesh generation techniques (called model meshing) for dividing a complex problem into small elements, as well as the use of software program coded with FEM algorithm. In applying FEA, the complex problem is usually a physical system with the underlying physics such as the Euler-Bernoulli beam equation, the heat equation, or the Navier-Stokes equations expressed in either PDE or integral equations, while the divided small elements of the complex problem represent different areas in the physical system. [35] FEA is a good choice for analyzing problems over complicated domains (like cars and oil pipelines), when the domain changes (as during a solid state reaction with a moving boundary), when the desired precision varies over the entire domain, or when the solution lacks smoothness. For instance, in a frontal crash simulation it is possible to increase prediction accuracy in ”important” areas like the front of the car and reduce it in its rear (thus reducing cost of the simulation). Another
example would be in numerical weather prediction, where it is more important to have accurate predictions over developing highly non-linear phenomena (such as tropical cyclones in the atmosphere, or eddies in the ocean) rather than relatively calm areas. [35]

2.3.2 Material modelling of silicones

Although experimental results can be explained with the molecular structure and behaviour presented in section 2.2, deviating a prediction of deformation or stress of the material is not possible. During construction or development the knowledge about the mechanical behaviour could help saving time and money, because prototyping could be reduced to a minimum after system behaviour prediction. But the molecular examination is not viable for such a prediction because the exact atomic structure is depending on many factors during processing. Thus a prediction of the behaviour would only be possible after exact analysis of a single workpart.

As long as the arrangement of the polymer chains is a statistic distribution the behaviour of the material can be determined with a model using the mean free chain length. To get valid results with this model the average of enough free variables has to be taken into account. In this case that means, that the model can only be applied to bodies with dimensions a good deal bigger than the average free chain length of the polymer. For such a body an isotropic and homogeneous behaviour can be assumed, that is nearly independent from the actual structure of the vulcanisate. To achieve a physical adequate model with reproducible outcomes, it is inevitable to follow certain principles. Thus a stress state can only be influenced by deformations in direct range and the stress states in the immediate past or presence. The model also has to be invariant to coordinate transformation. Because silicones show a nearly perfect incompressibility, the model can be postulated as incompressible [28]. In the next sections different material models for simulation of silicones will be presented.
Elastic behaviour with Hooke’s Law

As a linear description of stress and strain, Hooke’s Law represents small deformations of most materials pretty good. The stress state of an infinite element can be described by the Cauchy stress tensor \( \sigma \):

\[
\begin{pmatrix}
\sigma_{11} & \sigma_{12} & \sigma_{13} \\
\sigma_{22} & \sigma_{22} & \sigma_{23} \\
\sigma_{33} & \sigma_{32} & \sigma_{33}
\end{pmatrix}
= 
\begin{pmatrix}
\sigma_1 & \tau_{12} & \tau_{13} \\
\tau_{22} & \sigma_2 & \tau_{23} \\
\tau_{33} & \tau_{32} & \sigma_3
\end{pmatrix}
\tag{2.22}
\]

Every component \( \sigma_{ij} \) stands for the stress of the surface of an infinite cube vertical to the \( i \)-axis bearing \( j \). Thus the tensor can be described by normal stress \( \sigma_i \) and shear stress \( \tau_{ij} \). The symmetry of the shear stresses \( \tau_{ij} = \tau_{ji} \) limits the linearly independent coefficients to six, as given in the Voigt notation \( \vec{\sigma} = (\sigma_1, \sigma_2, \sigma_3, \tau_{12}, \tau_{13}, \tau_{23})^{Tr} \). The state of strain \( \varepsilon \) can analogical be described with the help the strain components \( \varepsilon_{ij} \):

\[
\begin{pmatrix}
\varepsilon_{11} & \varepsilon_{12} & \varepsilon_{13} \\
\varepsilon_{22} & \varepsilon_{22} & \varepsilon_{23} \\
\varepsilon_{33} & \varepsilon_{32} & \varepsilon_{33}
\end{pmatrix}
= 
\begin{pmatrix}
\varepsilon_1 & \gamma_{12} & \gamma_{13} \\
\gamma_{22} & \varepsilon_2 & \gamma_{23} \\
\gamma_{33} & \gamma_{32} & \varepsilon_3
\end{pmatrix}
\tag{2.23}
\]

Similar to the stress, the coefficients are differentiated by strain in normal direction \( \varepsilon_i \) and vertical slippage \( \gamma_{ij} \). As rotations of rigid bodies have no influence on the state of strain, again the symmetry \( \gamma_{ij} = \gamma_{ji} \) leads to the Voigt notation \( \vec{\varepsilon} = (\varepsilon_1, \varepsilon_2, \varepsilon_3, \gamma_{12}, \gamma_{13}, \gamma_{23})^{Tr} \).

The interrelation between stress and strain is given by the elasticity tensor \( \overrightarrow{E} \). In the context of Hooke’s Law \( \overrightarrow{E} \) is only dependant on the Lamé constants \( \lambda \) and \( \mu \) or Young’s modulus \( E \) and Poisson’s ratio \( \nu \) [36, 37]:

\[
\begin{pmatrix}
\sigma_1 \\
\sigma_2 \\
\sigma_3 \\
\tau_{12} \\
\tau_{13} \\
\tau_{23}
\end{pmatrix}
= 
\begin{pmatrix}
\lambda + 2\mu & \lambda & \lambda & 0 & 0 & 0 \\
\lambda & \lambda + 2\mu & \lambda & 0 & 0 & 0 \\
\lambda & \lambda & \lambda + 2\mu & 0 & 0 & 0 \\
0 & 0 & 0 & \mu & 0 & 0 \\
0 & 0 & 0 & 0 & \mu & 0 \\
0 & 0 & 0 & 0 & 0 & \mu
\end{pmatrix}
\begin{pmatrix}
\varepsilon_1 \\
\varepsilon_2 \\
\varepsilon_3 \\
\gamma_{12} \\
\gamma_{13} \\
\gamma_{23}
\end{pmatrix}
\tag{2.24}
\]
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with

\[ \lambda = \frac{E\nu}{(1 + \nu)(1 - 2\nu)} \quad \text{and} \quad \mu = \frac{E}{2(1 + \nu)} \]

respectively

\[ \nu = \frac{\lambda}{2(\lambda + \mu)} \quad \text{and} \quad E = \frac{\mu(3\lambda + 2\mu)}{\lambda + \mu} \]

Young’s modulus and Poisson’s ratio are descriptive physical values, that can directly be measured with a uniaxial pulling test. In this case Young’s modulus is the linear factor linking stress \( \sigma \) and strain \( \epsilon \):

\[ \sigma = E \cdot \epsilon \quad (2.25) \]

whereas Poisson’s ratio \( \nu \) describes the relative volume change \( \Delta V/V \) depending on the relative change in length \( \Delta l/l \):

\[ \frac{\Delta V}{V} = (1 - 2\nu) \frac{\Delta l}{l} \quad (2.26) \]

The greatest advantage of this linear elastic material model is the independence of Young’s modulus from the real deformation and the kind of stress. Thus elastic behaviour can be predicted with in the range of small deformations with the help of parameters, that can be determined in a relatively simple experiment. Due to their structure silicones can experience deformations way above 100%. As shown in figure 2.7 the range of linearity is depleted quickly at higher deformations. To be able to simulate deformations in all ranges, hyperelastic models have to be used.

**Hyperelastic modelling**

In hyperelastic modelling Young’s modulus \( E(\epsilon) \) and Poisson’s ratio \( \nu(\epsilon) \) are dependent on the state of strain \( \epsilon \). For a complete explanation kinematics have to be described in more detail. First of all the reaction of a body to external force can be described by the deformation gradient
2.3 Simulation and modelling

$F(t)$ in dependency of time $t$ [38]. Taking the basic principles of system modulation into account a formula for the Cauchy strain tensor $\sigma(t)$ can be derived, depending on the momentarily deformation and its’ progress over time [28]:

$$\sigma(t) = -p(t) \cdot I + f(C(t)) + F_{s=0}[G(s), C(t)] \quad (2.27)$$

Instead of the deformation gradient $F(t)$ the Cauchy-Green deformation tensor $C(t) = F(t)^T F(t)$ is used because it is invariant to movements of rigid bodies [38]. Furthermore the strain is dependent on hydrostatic pressure $p(t)$, which is effectively only added to normal strain due to the multiplication to the unit tensor $I$. The actual material model is represented in the function $f$ and the functional $F$. This functional is composed of the Cauchy-Green deformation tensor $C(t)$ and its’ deformation history $G(s)$, that again represents a backward timeline in its’ variable $s(s = 0 : t = t; s \rightarrow \infty : t \rightarrow -\infty)$ [28].

For a straight hyperelastic behaviour the viscoelastic properties are disregarded:

$$\sigma(t) = -p(t) \cdot I + f(C(t)) \quad (2.28)$$

Without further knowledge of the function $f(C(t))$ this representation does not provide any insightful winning. To determine this function, usually the strain energy density function $W$ is taken into account. Physically $W$ does not have a direct representation but is used as a scalar isotropic tensor function relating to the sum $S = f(C) + pf(I)$. Thus the so called determined strain $S$ can be specified to:

$$S = 2C \frac{dW(C)}{C} = f(C) \quad (2.29)$$

Materials with an existing strain energy density function $W$ can be described as hyperelastic. But the pure existence of this function is not sufficient for the development of an adequate model. Additionally $W$ has to be put in relation with the deformation. Usually the deformation gradient is expressed uniquely in terms of the principal stretches
\( \lambda_1, \lambda_2, \lambda_3 \) or the invariants of the Cauchy-Green deformation tensor \( I_1, I_2, I_3 \) \[28\]. Again all shear stresses \( \tau_{ij} \) can be neglected for the principal coordinate system:

\[
\sigma = \begin{pmatrix}
\lambda_1^2 & 0 & 0 \\
0 & \lambda_2^2 & 0 \\
0 & 0 & \lambda_3^2
\end{pmatrix}
\]  \hspace{1cm} (2.30)

Thus the three invariants \( I_1, I_2, I_3 \) can be defined as:

\[
I_1 = \text{trace}(\sigma) = \lambda_1^2 + \lambda_2^2 + \lambda_3^2 \]  \hspace{1cm} (2.31)

\[
I_2 = \lambda_1^2 \lambda_2^2 + \lambda_2^2 \lambda_3^2 + \lambda_1^2 \lambda_3^2 \]  \hspace{1cm} (2.32)

\[
I_3 = \text{det}(\sigma) = \lambda_1^2 \cdot \lambda_2^2 \cdot \lambda_3^2 \]  \hspace{1cm} (2.33)

The invariants do not change with a transformation between coordinate systems. The physical representation in a infinite cube for the first invariant \( I_1 \) would be changes in length of the body diagonal. The second invariant \( I_2 \) represents changes of surface and the third \( I_3 \) changes in volume. As silicone is defined as incompressible, the third invariant applies to \( I_3 = 0 \) \[39\].

Several approaches exist for the explicit formulation of the strain energy density function \( W \). The most comprehensive derivation of \( W \) would be from the molecular structure. But a detailed knowledge of the behaviour of the free polymer chains and their distribution in length would be needed. Another possibility is the phenomenological approach. In this case, given experiments and similar load situations are projected pretty well, whereas other applications can lead to big deviations. With both procedures hyperelastic models could be derived describing the actual quasi-static behaviour of many elastomers. As even different mix ratios of the basis polymer to the curing agent can influence the behaviour a lot, it is a common way to measure some parameters and decide on the best fitting model afterwards. An often used model for incompressible elastomers was formulated by Mooney and Rivlin \[40, 41\], which expresses the strain energy density function
2.3 Simulation and modelling

$W$ as a polynom:

$$W = \sum_{i+j=1}^{N} C_{ij}(I_1 - 3)^i(I_2 - 3)^j \quad (2.34)$$

Depending on the requirements and the given material parameters $C_{ij}$, the model is restricted to two, three, five or nine terms [28].

Although hyperelastic models represent the silicone behaviour quite accurately for quasi-static cases, they have to be extended by time dependency for a full description.

**Modelling linear viscoelasticity**

To incorporate the dependency of the deformation history, represented in formula 2.27 by the functional $\mathcal{F}$, various viscoelastic models are provided. For the coupling of the elastic and the viscous behaviour, mechanical models are used for explanation. In these models the elastic part is represented by a spring, as this reflects the behaviour of a uniaxial pulling test by Hooke’s Law. The viscous part is illustrated as a damper, for which the strain $\sigma$ is presumed as the product of viscosity $\eta$ and the changes in time of stress $d\varepsilon/dt$:

$$\sigma = \eta \frac{d\varepsilon}{dt} \quad (2.35)$$

With these mass-free elements rheological models are build [42]. Firstly exemplary calculation with linear spring elements are presented, that can directly be transferred to hyperelastic models. The basic models are the Maxwell model and the Kelvin-Voigt model, shown in figure 2.9, consisting of a single spring and damper combination. In the Maxwell model they are connected in series and in the Kelvin-Voigt model in parallel. Thus in the Maxwell model the time change of the deformation $d\varepsilon/dt$ is composed of the direct reaction to stress changes $d\sigma/dt$ and a linear part representing the viscoelasticity [42, 43]:

$$\frac{d\varepsilon}{dt} = \frac{1}{E} \frac{d\sigma}{dt} + \frac{\sigma}{\eta} \quad (2.36)$$
State of the art

Figure 2.9: Basic hyperelastic models

The deformation $\epsilon$ is depending on the strain history, but does not show complete elastic behaviour anymore:

$$\epsilon_{\text{Maxwell}}(t) = E \cdot \sigma(t) + \int_{s=0}^{t} \frac{\sigma(s)}{\eta} ds$$  \hspace{1cm} (2.37)

In the Kelvin-Voigt model the plastic flow is established better, because the deformation approximates exponentially to the maximum deflection $\sigma(t)/E$:

$$\epsilon_{\text{Kelvin-Voigt}}(t) = \frac{\sigma(t)}{E} - e^{-\frac{E}{\eta} t}$$  \hspace{1cm} (2.38)

Although these two basic models are fairly adequate for a first estimate, a closer look on the results, especially of step functions of strain or deformation, uncovers their weaknesses. The viscous part in the Maxwell model leads to a malleable deformation rising linearly with strain, as shown in figure 2.10. Thus the elastic behaviour can only unsufficiently be represented by the Maxwell model. The same effect also occurs during relaxation. As presented in section 2.2.2 strain decreases over time due to intermolecular processes, but the strain of the polymer chains keeps up enough energy to rebuild the form. The Kelvin-Voigt model shows the exact opposite reaction to forced deformation. As time dependency is only indirectly given by deformation, strain will stay constant after achieving maximum deformation.
2.3 Simulation and modelling

Figure 2.10: Illustration of relaxation and viscoelastic creeping behaviour of different models [44]
without developing any relaxation. The creeping in the Kelvin-Voigt model forms an exponential approximation of the deformation, but the excursive distortion after step in strain is not taken into account.

**Standard linear solid model** An improvement to these inadequacies is provided by the standard linear solid model as presented in figure 2.9(c). It combines the Maxwell model with a Hookean spring in parallel. The governing consecutive relation for this model is [42]:

$$ \frac{d\varepsilon}{dt} = \frac{E_2}{\eta} \left( \frac{\eta}{E_2} \frac{d\sigma}{dt} + \sigma - E_1 \varepsilon \right) \frac{E_1}{E_1 + E_2} $$

(2.39)

Under a constant stress, the polymer will instantaneously deform to some strain, which is the elastic portion of the strain, and after that it will continue to deform and asymptotically approach a steady-state strain. This last portion is the viscous part of the strain. Although the Standard Linear Solid Model is more accurate than the Maxwell and Kelvin-Voigt models in predicting material responses, mathematically it returns inaccurate results for strain under specific loading conditions [45].

**Generalized Maxwell model** The Generalized Maxwell model, or Maxwell-Wiechert model, is the most general form of modelling hyperelasticity. It takes into account that relaxation does not occur at a single time, but at a distribution of times. In this model a spring is connected in parallel to as many Maxwell model as needed for accuracy. A mathematical description is Prony’s method, allowing adjustment of the time dependency of Young’s Modulus for different materials:

$$ E(t) = E_0 \left( 1 - \sum_{i=1}^{N} a_i \left( 1 - e^{-\frac{t}{b_i}} \right) \right) $$

(2.40)

### 2.3.3 Determination of material parameters

It is almost impossible to approximate the atomic structure of an elastomer. Even though the durometer, that is always supplied by
the silicone producer, and the Young’s Modulus correlate with some non-linear function [46], it is best to conduct tests for better values. Usually pulling tests are conducted. In this section experiments will be described with a special focus on the problems of elastomers.

### Uniaxial traction tests

The density, Young’s Modulus and Poisson’s ratio are needed to set up a linear material model. All three can be determined with the help of the uniaxial traction test. For this experiment an elongate specimen is stretched along its’ axis. Young’s Modulus $E$ and Poisson’s ratio $\nu$ can thus be evaluated from the relative changes in length $\frac{\Delta l}{l}$ and width $\frac{\Delta b}{b}$ against the applied stress $\sigma$ (see also figure 2.11):

\[
E = \frac{\sigma}{\epsilon_{tech}} = \frac{\sigma}{\frac{\Delta l}{l}} \quad (2.41)
\]

\[
\nu = -\frac{\frac{\Delta b}{b}}{\frac{\Delta l}{l}} \quad (2.42)
\]

### Extended time invariant traction tests

A better adoption to the real material behaviour for big deformations can be realized by using hyperelastic models. For these models more parameters are needed where not only unidirectional loads are considered. Thus the experiments should be extended by the pure shear and biaxial traction tests, as presented in figure 2.11. Almost all load cases can be taken into account as a combination of the these three idealized loads considering the shown equivalent compression tests. For incompressible materials the third invariant of the Cauchy stress tensor $I_3 = 1$ does not change. Thus the following correlations for Lamé constants $\lambda_1, \lambda_2, \lambda_3$ result from the three traction tests:

\[
\begin{align*}
\text{uniaxial:} & \quad \lambda_1 = \lambda, \quad \lambda_2 = \frac{1}{\sqrt{\lambda}} \quad \lambda_3 = \frac{1}{\sqrt{\lambda}} \\
\text{pure shear:} & \quad \lambda_1 = \lambda, \quad \lambda_2 = 1, \quad \lambda_3 = \frac{1}{\lambda} \\
\text{biaxial:} & \quad \lambda_1 = \lambda, \quad \lambda_2 = \lambda, \quad \lambda_3 = \frac{1}{\lambda^2}
\end{align*}
\]

(2.43)
Figure 2.11: Illustration of the different types of traction tests and their equivalent compression tests
These correlations help fitting experimental results to the strain energy density function $W$. Thus quasi-static loads can be used to predict the behaviour of elastomers towards external loads. Dynamic behaviour can still differ from the prediction, when the viscous behaviour is not considered.

**Dynamic mechanical analysis**

For the consideration of the viscous behaviour Young’s modulus $E$ and the shear modulus $G$ are specified as complex values. Determination of these complex moduli is realized by applying a sinusoidal load $\sigma(\omega) = \sigma_0 \cos(\omega t)$ with the frequency $\omega$. From the resulting sinusoidal deformation $\epsilon(\omega) = \epsilon_0 \cos(\omega t + \phi)$ the complex Young’s modulus $E(\omega)$ can be determined for the linear elastic case:

$$E(\omega) = \frac{\sigma(\omega)}{\epsilon(\omega)} = |E(\omega)| e^{i\phi} = E'(\omega) + iE''(\omega) = E'(\omega)(1 + id(\omega))$$

(2.44)

The time delay of the deformation $\epsilon(\omega)$ caused by the viscosity of the material, shifts the phase of the Young’s modulus $E(\omega)$ making it complex. For the angle $\phi = 0^\circ$ sole elastic behaviour is existent. In this case the real part $E'(\omega)$ is equivalent to the non-complex Young’s modulus $E$. In contrast to this case, an angle of $\phi = 90^\circ$ represents the sole viscoelastic behaviour where all inserted energy is transferred into heat. For viscoelastic behaviour $0^\circ < \phi < 90^\circ$ the imaginary part $E''(\omega)$, also called loss modulus, represents the dissipated energy. Usually only the relative energy loss, given as the quotient $d = \frac{E''(\omega)}{E'(\omega)}$, is of interest. With the knowledge of the complex Young’s modulus Prony’s method can be adjusted. [47]

**2.3.4 Equivalent Circuits**

In electrical engineering and science, an equivalent circuit refers to a theoretical circuit that retains all of the electrical characteristics of a given circuit. Often, an equivalent circuit simplifies calculation, and
more broadly, that is a simplest form of a more complex circuit in order to aid analysis. [48] In its most common form, an equivalent circuit is made up of linear, passive elements. However, more complex equivalent circuits are used that approximate the non-linear behaviour of the original circuit as well. These more complex circuits often are called macromodels of the original circuit.

Equivalent circuits can also be used to electrically describe and model either a) continuous materials or biological systems in which current does not actually flow in defined circuits, or, b) distributed reactances, such as found in electrical lines or windings, that do not rep actual discrete components.

**Linear time-invariant systems**

Linear time-invariant (LTI) system theory comes from applied mathematics and has direct applications in many technical areas. It investigates the response of a linear and time-invariant system to an arbitrary input signal. Linearity means that any linear combination of input signals $x_i(t) (i = 1, 2, 3, ...)$ leads to the corresponding linear combination of output signals $y_i(t)$. Thus for any real scalar variable $a_i$ the superposition is fulfilled:

$$\sum_i a_i * x_i(t) = \sum_i a_i * y_i(t) \quad (2.45)$$

Time invariance means for any time shift $t_0$:

$$x(t - t_0) = y(t - t_0) \quad (2.46)$$

or in other words whether an input is applied to the system now or the point in time $t_0$, the output will be identical except for a time delay. Hence, the system is time invariant because the output does not depend on the particular time the input is applied. A good example of LTI-systems are electrical circuits that can be made up of resistors, capacitors and inductors. [49]
Low pass filter

A low-pass filter is an LTI-system that passes low frequency signals but reduces the amplitude of higher frequency signals. The most important characteristic is the cut-off frequency $f_c$, at which the amplitude reduction starts. The most simple electrical circuit representing a low-pass filter consists of a resistor and a capacitor wired in series, as shown in figure 2.12(a). This filter is also called Butterworth-Filter first order and its’ transfer function (as shown in figure 2.12(b)) is calculated to

$$H = \frac{V_{out}(t)}{V_{in}(t)} = \frac{1}{1 + j\omega CR} \tag{2.47}$$

with a cut-off frequency of

$$f_c = \frac{1}{2\pi RC} \tag{2.48}$$

By the coupling of more low-pass filters, higher orders can be achieved resulting in higher attenuations. [49]

Mechanical equivalent circuits

The elements of a passive linear electrical network consist of inductors, capacitors and resistors which have the properties of inductance, elas-
Table 2.4: Mechanical elements and their electrical counterparts

<table>
<thead>
<tr>
<th>Mechanical element</th>
<th>Formula</th>
<th>Mechanical impedance</th>
<th>Electrical counterpart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stiffness, $S$</td>
<td>$S = \frac{F}{x}$</td>
<td>$Z = \frac{S}{j\omega}$</td>
<td>Elastance, $\frac{1}{C}$</td>
</tr>
<tr>
<td>Mass, $M$</td>
<td>$M = \frac{F}{a}$</td>
<td>$Z = j\omega M$</td>
<td>Inductance, $L$</td>
</tr>
<tr>
<td>Damping, $D$</td>
<td>$D = \frac{F}{v}$</td>
<td>$Z = D$</td>
<td>Resistance, $R$</td>
</tr>
</tbody>
</table>

tance (inverse capacitance) and resistance, respectively. The mechanical counterparts of these properties are, respectively, mass, stiffness and damping. The mechanical counterparts of voltage and electric current in this type of analysis are, respectively, force ($F$) and velocity ($v$) and represent the signal waveforms. From this, a mechanical impedance can be defined in terms of the imaginary angular frequency, $j\omega$, which entirely follows the electrical analogy. The scheme presented in table 2.4 is known as the impedance analogy. Circuit diagrams produced using this analogy match the electrical impedance of the mechanical system seen by the electrical circuit, making it intuitive from an electrical engineering standpoint. [50, 51, 52, 53, 20]

Transferring the basic models as described in chapter 2.3.2 into their electrical equivalents leads to low-pass filters. The Kelvin-Voigt model is transferred to the simplest RC-low-pass-filter as shown in figure 2.12. The more elements are added to the generalized Maxwell model the higher the order of the filter of the equivalent model.

2.3.5 Limits of analogies

Mechanical equivalent circuits as analogies to the real system have their limitation. All factorize the elements in linear correlations, but this circumstance can not always be assured. For example the viscous friction is linearly dependent on the viscosity and can thus be represented as a resistor. In the Coulomb-friction on the contrary static and dynamic friction with different coefficients of friction have to be differentiated.

44
2.4 Blood pressure

The blood pressure is the pressure of a pulse wave of the circulating blood upon the vessel walls. It is driven by the heart and usually stated as the ratio between the systolic blood pressure (maximum value during heart ejection) and diastolic blood pressure (minimum value during heart refilling) at heart level. The mean blood pressure decreases as the circulating blood moves away from the heart through arteries. The term blood pressure usually refers to the arterial pressure measured at or in a person’s big arteries. It is typically measured on the inside of an elbow at the brachial artery, which is the upper arm’s major blood vessel that carries blood away from the heart. Physically speaking the blood pressure is subject to Ohm’s Law for liquids and equals to the product of cardiac output and the vascular resistance. Although the SI-unit for pressure is is Pascal (1 Pa = 1 kg/m s\(^2\)) or bar (1 bar = 10\(^6\) Pa), traditionally the unit millimeter of mercury (mmHg) is used for blood pressure:

\[
1 \text{ mmHg} = 133.333 \text{ Pa}
\]

At rest systolic blood pressure typically varies between 100 – 130 mmHg (133 – 173 mbar) and the diastolic value between 60 – 85 mmHg (80 – 113 mbar). [54, 55, 56] Various factors influence a person’s average blood pressure and variations. Factors such as age [57] and gender [58] influence average values. Also, an individual’s blood pres-
sure varies with exercise, emotional reactions, sleep, digestion and time of day. While standing, the blood pressure is higher in the lower body half than while laying due to gravity, whereas above the hydrostatic indifference level it is lower than the value while laying. In addition to the systolic and diastolic blood pressure, the mean arterial pressure and the pulse pressure are of medical relevance. The mean arterial pressure (MAP) is the average over a cardiac cycle and is determined by the cardiac output (CO), systemic vascular resistance (SVR), and central venous pressure (CVP): [54]

\[ \text{MAP} = (CO \times SVR) + CVP \]  

(2.49)

The mean arterial pressure can be approximately determined from measurements of the systolic pressure \( P_{sys} \) and the diastolic pressure \( P_{dias} \) while there is a normal resting heart rate: [54]

\[ \text{MAP} \approx P_{dias} + \frac{1}{3}(P_{sys} - P_{dias}) \]  

(2.50)

The pulse pressure is determined by the interaction of the stroke volume of the heart, compliance (ability to expand) of the aorta, and the resistance to flow in the arterial tree. The pulse pressure can be simply calculated from the difference of the measured systolic and diastolic pressures: [54]

\[ P_{pulse} = P_{sys} - P_{dias} \]  

(2.51)

2.4.1 Pathophysiology

Pathological blood pressure, either high blood pressure (hypertension) or low blood pressure (hypotension), can have various causes and should be treated in the long run, as it can cause severe damage to the human body. As this subject can fill own books, only a brief overview is given in this paragraph, for further information please refer to adequate literature (e. g. [54, 55, 56]).
2.4 Blood pressure

Hypertension
Due to a definition of the World Health Organisation (WHO) hypertension starts above a systolic pressure of 140 mmHg and a diastolic pressure of 90 mmHg, not caused by immediate diseases, medication or pregnancy. [59, 60] In industrialized countries up to 50% of the population suffer from hypertension. [61] Hypertension does not necessarily cause direct or characteristic symptoms. Possible symptoms include headache, dizziness, nausea, epistaxis, weariness and insomnia. In progression it can lead to arteriosclerosis, lipometabolic disorder, strokes, heart attacks, heart failure, arterial aneurysms and persistent hypertension is the leading cause of chronic renal failure. Even moderate elevation of arterial pressure leads to shortened life expectancy. Hypertension is treated not only medicamentous but mainly with a major change in the lifestyle of the patient. Various factors have a verifiable influence on hypertensive blood pressure: Smoking, consumption of alcohol, weight reduction, physical activity, reduction of salt consumption and a controlled diet of fruit, vegetables and fish with less saturated fats. [56, 54]

Hypotension
Hypotension is generally considered systolic blood pressure less than 90 mmHg and diastolic less than 60 mmHg [54]. The similarity in pronunciation with hypertension can cause confusion. Hypotension is a medical concern only if it causes signs or symptoms, such as dizziness, fainting, or in extreme cases, shock. When arterial pressure and blood flow decrease beyond a certain point, the perfusion of the brain becomes critically decreased (i.e., the blood supply is not sufficient), causing lightheadedness, dizziness, weakness or fainting. Sometimes the arterial pressure drops significantly when a patient stands up from sitting. This is known as orthostatic hypotension (postural hypotension); gravity reduces the rate of blood return from the body veins below the heart back to the heart, thus reducing stroke volume and cardiac output. Other causes of low arterial pressure include sepsis, hemorrhage (blood loss), toxins including toxic doses of blood pressure
medicine, hormonal abnormalities such as Addison’s disease and eating disorders (particularly anorexia nervosa and bulimia). [54]

2.4.2 Blood pressure measurement

Arterial blood pressure measurements are either made indirectly (non-invasive blood pressure (NIBP)) with a cuff on an extremity or directly (invasive blood pressure (IBP)) with the help of a pressure detector inside a blood vessel. Both types of measurement are influenced by various factors. [62] Not only a incorrectly calibrated system or inadequate equipment like wrongly dimensioned cuffs lead to incorrect readings. A misinterpretation or wrong handling of manually operated equipment, the situation of the measurement and the physiological circumstances all have considerable influence on the outcome. Nervousness due to the consultation, strangury, speaking or caffeine are only a few factors that can rise the acute blood pressure.

Non-invasive measurement

The noninvasive measurements are simpler and quicker than invasive measurements, require less expertise, have virtually no complications, are less unpleasant and less painful for the patient. However, noninvasive methods may yield somewhat lower accuracy and small systematic differences in numerical results. Noninvasive measurement methods are more commonly used for routine examinations and monitoring. Most commonly NIBP is measured via a sphygmomanometer, where an inflatable (Riva-Rocci) cuff is placed around the upper arm at roughly the same vertical height as the heart. Historically the height of a column of mercury was used to reflect the circulating pressure [63, 64] but today usually it is used with a stethoscope as the auscultatory method (from the Latin word for "listening"). The mercury manometer, considered the gold standard, measures the height of a column of mercury, giving an absolute result without need for calibration and, consequently, not subject to the errors and drift of calibration which affect other methods. A cuff of appropriate size is fitted smoothly and snugly, then inflated until the artery is completely occluded. Listening
with the stethoscope to the brachial artery at the elbow, the examiner slowly releases the pressure in the cuff. When blood just starts to flow in the artery, the turbulent flow creates a ”whooshing” or pounding (first Korotkoff sound). The pressure at which this sound is first heard is the systolic blood pressure. The cuff pressure is further released until no sound can be heard (fifth Korotkoff sound), at the diastolic arterial pressure. [64] The auscultatory method is the predominant method of clinical measurement. [57]

The oscillometric method was first demonstrated in 1876 and involves the observation of oscillations in the sphygmomanometer cuff pressure caused by the pulse. [57] The electronic version of this method is sometimes used in long-term measurements and general practice. The cuff is inflated to a pressure initially in excess of the systolic arterial pressure and then reduced to below diastolic pressure over a period of about 30 seconds. When blood flow is nil (cuff pressure exceeding systolic pressure) or unimpeded (cuff pressure below diastolic pressure), cuff pressure will be essentially constant. When blood flow is present, but restricted, the cuff pressure, which is monitored by a pressure sensor, will vary periodically in synchrony with the cyclic expansion and contraction of the brachial artery. The values of systolic and diastolic pressure are computed, not actually measured from the raw data, using an algorithm. Ambulatory blood pressure devices can take readings every half hour throughout the day and night. Except for sleep, home monitoring could be used for these purposes instead of ambulatory blood pressure monitoring. [65] But this method is generally considered uncomfortable for the patient, because of the repentantly inflated cuff but is generally used to evaluate high blood pressure.

**Invasive measurement**

For the direct, invasive blood pressure measurement (IBP) a blood vessel, usually a peripheral artery like radial, femoral, dorsalis pedis or brachial, is punctured and a sensing device is inserted. This system can constantly monitor pressure beat-by-beat, and a waveform (a
graph of pressure against time) can be displayed. The measurement is very accurate and allows a continuous surveillance. Because the invasive technique carries the risk of bleedings, infections or nerve injuries it is only used in human and veterinary intensive care medicine, anesthesiology, and for research purposes. An IBP can also measure the venous blood pressure by punctuating a venous vessel. Thus the central venous pressure or the pulmonary artery pressure (in the lung artery) especially during right hearted catheter examination can be observed.

2.5 Medical implants

Medical implants can be classified as either active, e.g. containing electrical circuitry, or passive e.g. artificial joints. In the course of this work only active implants will be discussed. Due to the ever-rising number of implants, only a short overview of active implants is included in this thesis. The interested reader can find further listings at [20, 66, 67, 68, 64, 69, 70, 71], especially the phd thesis of Schlierf [72] gave valuable stimulus to this chapter.

2.5.1 Intra ocular pressure

Glaucoma is one of the most common diseases of the visual nerve, untreated resulting in irreversible loss of vision. It is correlated with an increase in pressure of the aqueous fluid. An early diagnosis is crucial for effective treatment. For this reason even home tonometry is proposed [73]. Medicamentous therapy can regulate the pressure of the aqueous fluid efficiently. For this therapy the pressure has to be determined, at best continuously for several hours for it can vary a lot over time [74]. Usually examination of the IOP is conducted with a tonometer of any kind, which all are not applicable for long time measurement. First efforts to develop an active system with an miniaturized pressure sensor was presented in 1967 [75]. Over the years several groups independently developed active implants [76]. A first system embedded in an artificial lens was presented in 1990 [77].
This idea was taken up and brought to marketability by Mokwa et al. [78, 79, 80] by implementing the whole unit including sensor and transponder into a soft lens. This approach allows an easy implantation by using the standardized minimally invasive procedure for artificial lenses.

As up to date no implant is available at the market, efforts are undertaken to develop a system integrated in a contact lens. Thus a higher acceptance could be reached due to the easier handling without operational procedures. [81, 82, 83]

### 2.5.2 Intracranial pressure

Increased intra cranial pressure is usually caused by accidents (more than 1.5 billion/year in the USA), chronic diseases (like chronic hydrocephalus: > 50000/year in the USA) or a tumor (more than 15000/year in the USA). [84, 85]

Treatment is inevitable otherwise irreversible damage to the brain can be caused. Up to date, catheter-based systems are used for measurement. For regulation passive brain shunts can be implanted. Technically shunts fulfil the function of a valve draining cranial fluid in case of high pressure. First telemetric systems with integrated pressure sensors were presented in 1979 and 1981 [86, 87]. A first digital system was presented in 1995 by Zacheja [88, 89]. This system separated the pressure sensing unit from the telemetric unit. The same concept was driven further by Kroin in 2000 and tested successfully in long-term animal studies [90]. More recent developments are the integration of the sensor unit into active shunt control, like presented in 2008 by Jetzki [91].

### 2.5.3 Urodynamics

The standard procedure for urodynamic testing is performed with a two-catheter system. The procedure involves force-filling the bladder with water and measuring pressure changes as the patient empties it. This ambulant treatment is fairly uncomfortable for the patient
leading to uncertain results. An implantable system could provide measurements in the patient’s natural environment during everyday activity. It would also be possible to integrate a regulator circuit to stimulate the bladder function [92].

A first implant with an integrated pressure sensor and active telemetric unit was presented in 1984. Embedded in a ceramic housing, the battery would last three to four days. [93] A similar battery-driven system was presented in 2002 [94]. Latest developments are typically equipped with a passive telemetric unit. Thus continuous measurement and regulatory function can be implemented. All presented systems unite resistive pressure sensors and processing units in cylindrical capsules, either on a rigid carrier [95] or on flexible substrates [96, 97].

2.5.4 Cardiovascular pressure

There are multiple diseases of the cardiovascular system each with a different requirements on the indication and the measurements. Most of the pressure sensing systems are set up as a catheter-based system for temporary use during surgery or intensive care. Such systems operate with optical [98], piezoresistive [99] or capacitive pressure sensors [100].

Blood flow

Atherosclerosis causes luminal narrowing by deposition of fatty material like cholesterol. Generally this concludes in reduced blood flow and supply and can ultimately lead to infarctions. As a treatment meshed tubes (stents) are implanted to widen the affected artery to ensure unhindered blood flow. The success of this implant can be controlled with flow measurement, that can be realized for example with two pressure sensors integrated at both ends of the stent [101].

Pacemakers

Pressure sensors are also used for the adaptive regulation of pacemakers. In 1992 Bennett et al. [102] presented a modified pacemaker electrode to detect the right ventricular pressure. This system was realized with
a capacitive pressure sensor and integrated inside a pacemaker for telemetric read-out. Measuring the left ventricular pressure would offer more therapeutic possibilities but is mostly avoided due the risk of abruption of a thrombus arisen on the surface of the implant. Such a thrombus provides a high stroke risk coming from the left ventricle. To avoid this problem Walton and Krum [103] presented a system with integrated pressure sensor and inductive telemetric unit for energy and data transfer, that measures through the artery vessel wall.

In 2010 an implantable system for telemonitoring the intravascular pressure in the pulmonary artery was presented. A catheter-bound pressure and temperature sensor is placed in the pulmonary artery. This catheter can in the long run be connected to a pacemaker to monitor the pulmonary artery pressure and the cardiac output and thus hopefully avoid hospitalization of patients suffering from heart insufficiency by early changes in therapy. [104]

**Chronic heart failure**
The disease pattern of chronic heart failure (CHF) developed to a relevant medical and economical problem. No disease increased more dramatically in the last years, approximately 10 million patients suffer from heart-insufficiency. [105] A minimally invasive implantable system could help in therapy by long-term surveillance of relevant haemodynamic parameters. In 2007 an implant was presented [106, 100, 107] to detect and transmit the pulmocapillary wedge pressure (PCWP), which can otherwise only be detected in intensive care with a catheter-based system. Another approach was presented by Mahnken et al. [108] with a modification of a Swan-Ganz catheter that shows excellent performance and was equipped with an expandable balloon an a telemetric unit.

**Abdominal aorta aneurysm**
For the treatment of abdominal aorta aneurysms a foldable stent is inserted by minimal invasive surgery [109, 110]. These stents provide the risk of leakage which lead to inner exsanguination if not treated in
time. Different approaches were presented to ensure early detection of leakages. CardioMEMS, Inc. brought a system to the market based on a micromechanical pressure sensor. An interesting aspect of this system is, that the pressure is measured by capacity variations changing the resonant frequency of a LC-resonant circuit. [111] Another system with digital data transfer was presented in 2005 by Schlierf et al. [72, 112, 113]. The major advantage of this capsule is that it can be integrated into the stent making a separate surgical intervention obsolete.

**Hypertension and arrhythmia**

Hypertension is the major cause of death all over the world [114] and represents a major risk factor for myocardial infarction and the most important risk factor for stroke. Two thirds of strokes and half of myocardial infarctions arise from a systolic blood pressure > 115 mmHg. Hypertension is considered the leading risk factor of preventable deaths worldwide. [115] Yet it is not detected at all or treated correctly in the major part of the affected patients. [116, 117]

In diagnosis and therapy of hypertension or irregular heartbeat, a permanent supervision of the intravascular blood pressure can be very profitable. In 1998 an implantable cuff with integrated micromechanical pressure sensor was presented [118]. By using a measurement system outside the vessel, the risk of thrombi is minimized, but an unknown risk of traumatizing the vessel by the applied outer pressure and the necessity of dissecting the vessel completely, oppose the benefit. Other systems were presented by Chatzandroulis [119] in 2000 and Chau [120] presented a catheter driven idea in 1988. Implants for IBP can generally be divided in two basic approaches. In the first the whole system is integrated monolithically, in the second approach the point of measurement and the main electronics like data processing and the telemetric unit are spatial divided.

A monolithically integrated system was patented in 2000 by Schmitz-Rode et al. [121]. The system is based on a pressure sensor application-specific integrated circuit (ASIC) with integrated inductive telemetry
for energy and data transfer [122, 123, 124]. The whole system is encapsulated in silicone and formed as a capsule of 2 mm outer diameter and 30 mm length. For anchorage at a vascular diversion the system is equipped with three poles, which unfold after the system is brought to its’ destination by catheter.

A modified version of the ICP-measurement-system presented above [88] was used for blood pressure measurement [125]. In 2007 a modular system with a higher measurement rate was presented allowing an enhanced analysis of haemodynamics [113]. This project is the predecessor of the project presented in chapter 4 where the ideas were optimized in a smaller and faster system [126, 127, 128].
3 Encapsulation techniques

The goal of the studies in this thesis is the determination of the influence of the encapsulation on the signal of the pressure sensor. Selected silicones will be studied in detail. As a basic model a column of silicone is examined with various factors of influence like height, width or the opening of the pressure inlet. As a parameter for system performance the damping of the pressure amplitude as the reaction to a square pressure pulse is chosen, in analogy to the square pulse in signal theory.

To study the influence of the encapsulation on piezoresistive pressure sensors, sensors of the type MS767 [129] from the company Intersema, Inc. are used in experiments (chapter 3.3), their mechanical and electrical parameters were used in simulations (chapter 3.1). This special sensor die was chosen because of its’ size and availability of the die. With a piezoresistive sensor die experiments can be performed without signal conditioning on chip, as it would be necessary with a capacitive silicon sensor.

3.1 Simulations

3.1.1 The piezoresistive pressure sensor

The sensor MS767 from Intersema, Inc. was measured under microscope to get precise data for simulation, as the most relevant data is not available. A photo with dimensions is given in figure 3.1 and the resulting data in table 3.1. As the membrane thickness could not be determined in detail, it was estimated to 20 μm. An adequate simulation model can be build up with these data. To keep simulation fast and fairly easy, the following approximations can be assumed...
3.1 Simulations

(a) Relative position of the piezoresistive elements

(b) Size of the piezoresistive elements

Figure 3.1: Topographical survey of the piezoresistive pressure sensor MS767 (Intersema, Inc.) [130]
Table 3.1: Dimensions of the used pressure sensor MS767 from Intersema, Inc.

<table>
<thead>
<tr>
<th></th>
<th>length in mm</th>
<th>width in mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon chip</td>
<td>1,605</td>
<td>1,465</td>
</tr>
<tr>
<td>Pyrex glas body</td>
<td>1,705</td>
<td>1,565</td>
</tr>
<tr>
<td>Membrane</td>
<td>0,540</td>
<td>0,545</td>
</tr>
<tr>
<td>Resistors</td>
<td>0,125</td>
<td>0,019</td>
</tr>
</tbody>
</table>

without losing accuracy:

- The resistors take the whole height of the membrane. Only this way an adequate accuracy for the thin resistors inside the membrane can be achieved with a high enough number of knots.

- Underlying PCB material or the surrounding guiding walls are assumed as rigid bodies and thus the most elementary material model for steel is chosen.

- Silicon and pyrex glas body are simulated with the help of a linear material model.

Assuming the isotropic model an error can be expected, as crystal silicon is a material with anisotropic behaviour. This divergence can be approximated to 2% [131]. But real deviation resulting from this statistical error on the amplitude reduction of the system can be anticipated to be even smaller. Thus the simplification of the model overweights the expected systematic deviation.

To compute the voltage output of the sensor, changes in length $\Delta l$ and width $\Delta w$ are determined for each resistor element in the membrane. These are embedded as discrete objects to achieve high linking and thus minimizing the statistical error. Because the linear material model is used the strain $\sigma$ can be computed from the stress $\epsilon$, respectively from the change in length $\Delta l$ and Young’s modulus $E = \frac{\partial \sigma}{\partial \epsilon}$.
3.1 Simulations

\(\sigma = E \cdot \epsilon = E \cdot \frac{\Delta l}{l_0}\). Thus this correlation results from formula 2.11:

\[
\frac{U}{U_0} = \left( \frac{1}{E} + \pi_{tr} \cdot \frac{l_{R2}}{l_0} \right) \left( \frac{1}{E} + \pi_{lo} \cdot \frac{b_{R1}}{b_0} \right) - \left( \frac{1}{E} + \pi_{lo} \cdot \frac{b_{R1}}{b_0} \right) \left( \frac{1}{E} + \pi_{tr} \cdot \frac{l_{R4}}{l_0} \right)
\]

\[\left( \frac{2}{E} + \pi_{lo} \cdot \frac{b_{R1}}{b_0} + \pi_{tr} \cdot \frac{l_{R2}}{l_0} \right) \left( \frac{2}{E} + \pi_{lo} \cdot \frac{b_{R3}}{b_0} + \pi_{tr} \cdot \frac{l_{R4}}{l_0} \right)\]

(3.1)

For symmetrical sensors formula 2.12 can analogically be applied:

\[
\frac{U}{U_0} = \frac{\pi_{tr} \frac{l_y}{l_0} - \pi_{lo} \frac{b_x}{b_0}}{\pi_{tr} \frac{l_y}{l_0} + \pi_{lo} \frac{b_x}{b_0} + \frac{2}{E}}
\]

(3.2)

Figure 3.2 shows the membrane deflection of an exemplary simulation. The deflection is exaggerated to visualize the movement of the membrane, because the few micrometers would not show in comparison to the overall dimensions.

3.1.2 Experimental determination of material parameters

To set up accurate simulations, it is inevitable to determine material parameters. In the course of this work an uniaxial traction test could be performed for three silicone rubbers and a silicone gel. The Institute of Bio- and Nanosystems at the Research Centre Jülich was so kind to perform the experiments with me in their test chamber optimized for tensile tests on elastomers. For the experiments cylindrical test pieces were prepared using channels in agarose. A metal cylinder of 10 cm in length was placed vertically on a Teflon plate and filled with a 2%
Encapsulation techniques

(a) Membrane deflection, whole sensor

(b) Membrane deflection, membrane closeup

Figure 3.2: Membrane deflection to compute voltage output of sensor, exaggerated deflection shown to visualize the small movement
Figure 3.3: Sample evaluation of experiments to determine Young’s Modulus
solution of molten agarose to a height of 1 cm. After agarose gelation, glass capillaries with a diameter of 1.4 mm were stuck vertically into the agarose layer. Subsequently, the metal cylinder was filled to the top with molten agarose. After agarose hardening, the glass capillaries were removed. To prevent sample defects residual water in the channels was dried out by argon flushing. The dry channels were carefully filled with premixed, yet still uncross-linked silicone using a syringe. The whole assembly was covered with parafilm to prevent agarose drying and baked at 60 °C over-night. Cross-linked silicone cylinders were removed by melting the agarose block in boiling water. Afterwards the silicone cylinders were washed three times in boiling water to remove residual agarose. For calibration experiments, samples were mounted vertically between a precision scale and a micromanipulator. Accurate alignment of the samples was imperative to prevent shear forces and to minimize focus changes upon stretching. The samples were observed using a stereo-microscope connected to a camera. Scale readings, i.e., the acting forces, were automatically recorded every 0.25 s. Elastomer rods were stretched in five successive steps, each resulting in a relative elongation of approximately 1%, followed by a subsequent equilibration period of about 45 min. Camera images were captured by software, so all stretching steps and the complete, stepwise release of the samples were recorded. Deformations were measured at the middle of the samples to avoid errors due to possible waist formation. As markers for sample deformation, chalk dust was applied to the surface of the rods. The focus was set to the edges of the sample, at the median plane, in order to allow accurate measurement of the sample diameter. Evaluation of the measurements was performed using routines developed with the software MATLAB. A sample evaluation can be reviewed in figure 3.3.

The complete test results are given in table 3.2. In this test, two values are determined, one for the elongation process and one for relaxation process. Even though the experiment averages about 30 measurements for each material, the deviation is still so high, that these results can only be used for simulating varying stress states with caution.
3.1 Simulations

3.1.3 Solver settings

Some basic settings are valid for all presented simulations of silicones. In this section those will be presented.

Material parameters

As presented in section 2.3.2 the behaviour of silicone can be described by various material models. For the choice of the right model, different factors have to be taken into account. On the one hand the behaviour should be represented as accurate as possible but on the other hand computing time, system performance and the gain of scientific knowledge have to be considered. Furthermore available material parameters and their complexity of acquisition might be relevant. This consideration has to be undergone for every new problem as one change can lead to differing boundary conditions and thus resulting in a different choice of parameter sets. Only by defining boundary conditions and the problem, a specific and efficient study can be made.

The goal of this work is the study of the influence of encapsulation on the behaviour of pressure sensors during measurement. This behaviour can be reduced to the mechanical influence due to its predominance over any other influence. As a special focus is the use of the pressure sensors in medical systems, other assumptions can be taken:

1. The temperature is nearly constant at about 37 °C and thus explicitly higher than glass transition temperature of silicone (ref. to chapter 2.2.2)
2. The dimensions of the sensor are all only several millimetres
3. The stability of encapsulation is commonly given by a stable housing filled with silicone
4. Changes in pressure are in the range from normal pressure to a maximum of 350 mbar
5. As changes in physiology are rather slow, relevant pressure changes can be estimated to 100x-maximum pressure, resulting in the assumption of a change rate below 40 bar/s
Encapsulation techniques

By defining the boundary conditions precisely crucial simplifications can be made. Thus the model can be reduced by some parameters in favour of precision and computing time. A valid simplification with the given assumptions with major impact is considering the quasi-static behaviour instead of the dynamic. Thus viscoelastic creeping does not have a relevant influence on the accuracy of measurement. This again legitimises the reduction to quasi-static analysis for simulation.

This consideration allows simulations with linear-elastic and hyperelastic models. Using a linear-elastic model provides various advantages. On the one hand this simplification of the modelling leads to a reduction of the computing time for equivalent models. On the other hand the acquisition of the relevant material parameters for the hyperelastic model is by far more complex and expensive. The actual behaviour of the silicones differs more and more with rising deformation. But the hydrostatic pressure of the incompressible silicone can hardly lead to big deformations. This is even more effective when the silicone is surrounded by a solid housing.

**Coupling between silicone and surroundings**

A solid housing filled with silicone provides protection and high stability for the system. This dimensional stability and the coupling between silicone and cover has great influence on the amplitude reduction as will be shown by simulation and experiment. Simulations without a coupling of the silicone to the housing walls showed almost no amplitude reduction. Although the silicone could delaminate, it is not reasonable to make this assumption, as the protective functionality would be lost to the system. Thus all simulations are made with a fixated coupling between the housing and the included encapsulation material.

**Pressure application**

The simulations are conducted as quasi-static analyses. Various loads from 1000 mbar to 3000 mbar are applied to the system to evaluate the dependency of the amplitude reduction to the applied pressure. As low pressure changes are closer the environment of medical applications,
the first steps are smaller to evaluate this pressure range in more detail, as shown in table 3.3. To avoid rigid body motion, the knots opposing all pressure inlets have to be fixated.

**Meshing**

The meshing of the models is conducted with the help of the integrated physical meshing tool. The interesting areas are refined manually to improve precision and keep computing time in a reasonable manner as small as possible.

### 3.2 Parameter evaluation

Different models are taken into account to derive various parameters of dependencies of the amplitude reduction due to encapsulation. The following sections evaluate different parameters and their influence on the amplitude reduction. [133, 130]

At first (chapter 3.2.1) a general model is presented to evaluate the plausibility of the modelling and general simulation parameters like the influence of different solver settings. This general geometry as a pillar of silicone on top of the sensor die with the impact force coming straight from the top. The second model, as described in chapter 3.2.2, evaluates the influence of a size reduction of the pressure inlet. In order to provide more protection of the electronics, a system can be placed inside a rigid hull with discrete pressure inlets in which case this model would apply. The next case study (chapter 3.2.3) describes the influence of lateral force impact on the pressure die. The possibility of protecting the pressure die in a countersink is evaluated in chapter 3.2.4. A common problem during assembly of pressure sensor systems is air entrapments in the silicone, their impact on the

<table>
<thead>
<tr>
<th>Table 3.3: Pressure application for simulation and experiment</th>
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</thead>
<tbody>
<tr>
<td>Simulation time step</td>
</tr>
<tr>
<td>Pressure in mbar</td>
</tr>
</tbody>
</table>
Encapsulation techniques

pressure sensor signal is described in chapter 3.2.5. The last presented system shows the possibility of varying the geometry and evaluates a non symmetric footprint in simulation and experiment (chapter 3.2.6).

The height and the width of the silicone placed on top of the sensor element are the crucial parameters for the amplitude reduction of the signal detected by the sensor underneath. It can be expected, that the higher the silicone the more amplitude reduction will be observed and the closer to the sensing element the borders of surrounding structures are, the more they take influence on the signal. This is the reason why in the following chapters the aspect ratio of height $h$ to width $w$ of the silicone $a = \frac{h}{w}$ was chosen as the comparative value between the different consideration of influence factors.

3.2.1 Influence of height and width

With this first and rather general model the plausibility of the modelling and general simulation parameters like the influence of different solver settings is evaluated. In this model a sensor die is centrally placed underneath a pillar of silicone surrounded by a hard shell, with the impact force coming straight from the top, as shown in figure 3.4. The system has two reflection symmetry planes, one in the x-z-plane and the other in the y-z-plane, thus the modelling can be reduced to a quarter of the system, as presented in figure 3.4.

In this series of simulations various parameters were picked for evaluation. Beside the silicone height $h$ and width $w$, two different silicones were observed. The silicone Med-6015 was derived with a linear model and the silicone Med-4950 with a hyperelastic model. Both silicones have a durometer of 50A [135, 136], providing the option of a direct comparison of both simulation methods (see chapter 2.3.3). As the sticking to the bordering walls is crucial two different geometries were chosen, one with a circular footprint (see figure 3.4(a)) and the other with a square footprint (see figure 3.4(b)).

Simulation results

With the deformation of the silicone shown in figure 3.5, the dis-
Figure 3.4: Simulation models to determine the influence of height and width of silicone pillar

Figure 3.5: Deformation of silicone as a result of simulation to determine the influence of height and width of silicone pillar
Encapsulation techniques

Distribuition of the pressure can be demonstrated. The surface deforms downwards in a concave manner. In this case the integral over the displacement of the surface equals the compression of the system, which, as expected, is very low due to the incompressibility of the silicone. The concave shape is dominated by the contact constrains. While a loose contact results in an evenly distributed surface shift, the fixed coupling does not allow movement resulting in the concave displacement. With bigger surfaces of the wall in relation to the pressure inlet, the coupling is capable of taking up more of the applied load, resulting in relatively smaller displacements. This uneven distribution of the force concludes in a non-linear damping behaviour.

A first set of simulations shall point out the dependency of the amplitude reduction in relation to the height $h$ and width $w$ of the silicone pillar above the sensor. Figure 3.6 shows the amplitude reduction over the aspect ratio $a = \frac{h}{w}$ of a test setup with a square footprint. In this case simulations of silicone with a linear model in three different widths ($b_1 = 1 \text{ mm}, b_2 = 2 \text{ mm}, b_3 = 4 \text{ mm}$) and a silicone with a hyperelastic model are compared. It can be clearly seen that the geometric parameters height $h$ and width $w$ are correlated in their influence on the quasi-static amplitude reduction.

The correlation shows the characteristic of a low pass filter, as explained in chapters 2.3.2 and 2.3.4. The shown fitting is calculated as second order low-pass filter with the resistor being dependent on the aspect ratio of the silicone pillar and arbitrary values for the capacitors.

Furthermore the simulations with the hyperelastic model of the silicone verify the chosen linearelastic model. No significant divergence between the two different approaches can be determined, due to the relatively small displacements in the silicone body. Thus all further simulation were undertaken with the linearelastic model.

Similarly to the first test series, a second series was set up with circular footprint. Figure 3.7 shows the result of the simulations varying in height and width of the silicone pillar. Again the shown fitting in figure 3.7 is calculated as a second order low-pass filter. This time the attenuation is slightly higher than for the circular footprint. Due to the smaller area covered by the circular footprint the damping
3.2 Parameter evaluation

![Graph showing amplitude reduction vs. aspect ratio with different silicone pillars.](image)

Figure 3.6: Influence of height and width of silicone pillar on the amplitude reduction, square footprint, silicone Med6015 is used for linear modelling, silicone Med4950 is used for hyperelastic modelling.

![Graph showing amplitude reduction vs. aspect ratio with different aspect ratios.](image)

Figure 3.7: Influence of height and width of silicone pillar on the amplitude reduction, circular footprint.
Encapsulation techniques

of the silicone and thus the equivalent resistance is higher leading to a higher amplitude reduction.

The observed bend of the simulation at the aspect ratio of approximately five seems to be an imperfection of the meshing resulting in a slight variation of the results. A similar bend with less impact can be observed at the aspect ratios of approx. 0.5 and 8. In the system with the square footprint a small irregularity can be observed at the aspect ratio of 5.

Both test series with either footprint show a drastic increase of the amplitude reduction at aspect ratios over two. To avoid a damping of over 50 % it can be generally postulated that the aspect ratio of five should not be passed.

Another interesting aspect that emerged in these simulation series was the small dependency of the applied pressure on the amplitude reduction. Figure 3.8 shows the dependency of the amplitude reduction to the applied maximum pressure. In this case all simulations with a circular footprint were taken to the mean and plotted against the applied maximum pressure. All simulations were conducted as a pressure lift from 1 bar to the according maximum pressure. A difference of 0.45 % of the amplitude reduction between the lowest (1 bar – 1.1 bar) and the highest (1 bar – 3 bar) pressure lift can be noted.

This non-linearity is based on the geometry of the system and will never occur in an uniaxial traction test. The incompressible material silicone is fixed to the stiff wall and the relative maximum deflection decreases with rising pressure. Because a linear behaviour is presumed for the silicone, the reset force and thus the amplitude reduction decreases with a smaller deflection.

3.2.2 Reduced size of the pressure inlet

The elastic material in the opening of the pressure inlet is more susceptible to mechanical damage than a stiff hull. For some applications a closed hull with a minimized pressure inlet is of high interest to protect the electrical system in the best manner. To evaluate the influence of such an opening, the simulations presented in section 3.2.1
3.2 Parameter evaluation

Figure 3.8: Influence of applied pressure on the amplitude reduction

were extended with a lid as shown in figure 3.9(a). In this model the pressure inlet is minimized to a circular opening with the diameter $b$ in the lid. This opening is filled with silicone because in medical systems a surface with no sharp edges is inevitable for biocompatibility [4].

In addition to the diameter $b$ of the opening, the height $h$ of silicone and the footprint of system are modified for evaluation. As in section 3.2.1 a circular and a square footprint examined. The opening in the lid is adjusted accordingly.

**Simulation results**

Figure 3.9(b) qualitatively shows the pressure distribution in the system with the help of the deformation of the silicone. In the area of the opening the silicone deflects similarly to the pillars described in section 3.2.1. Due to the fixation to the lid the deformation propagates almost spherical.

As long as the thickness of the lid stays moderately small, the significant factors for the calculated amplitude reduction $\alpha$ are the width of the opening $w$ and the distance $h$ between the opening and the sensor surface. Figure 3.10 demonstrates the amplitude reduction $\alpha$ to
Figure 3.9: Simulation to determine the influence of a reduced size of the pressure inlet
3.2 Parameter evaluation

Amplitude reduction

Aspect ratio of hole

Figure 3.10: Influence of the aspect ratio and the height of the hole on the amplitude reduction
the aspect ratio \( a = \frac{h}{w} \) of the hole in the lid with a height of 0.1 mm. The varying height between the lid and the sensor die is coded in the colours of the measuring points.

As described in chapter 3.2.1 the fitting is calculated as a low-pass filter, in this case of forth order. The two resistors in the equivalent circuit represent the two stages of the silicone, one in the hole and the other the pillar between the lid and the sensor. As the lid is very small in size, the amplitude reduction is comparatively higher than in the models without the lid.

### 3.2.3 Lateral pressure inlet

In contrast to the first systems, the third evaluated system has a lateral pressure inlet. An idealized model used in the simulations is shown in figure 3.11(a). All labelled dimensions are varied. Only the displacement of the sensor out of the center axis was left out. This symmetry axis is used to split the model in half and thus reduce the computing time.

#### Simulation results

An exemplary deformation of the system is shown in figure 3.11(c). The volume just behind the pressure inlet deforms similarly to the deformation described in chapter 3.2.1. The pressure sensor forms a barricade reducing the deformable volume of silicone. The sensor body itself is slightly deformed by the lateral pressure impact as shown in figure 3.11(b). Evaluation however shows, that this deformation can be neglected compared to the deformation of the membrane. Such a small deformation has no relevant influence on the sensor signal.

In conformity with the earlier simulations, the amplitude reduction is compared to the aspect ratio of the distance \( h \) between pressure inlet and sensor and the width \( w \) of the silicone. As this model is not based on a square or circular footprint, the smaller width of the opening \( w_{\text{min}} \) is used as the corresponding size in the plot. The resulting graph is shown in figure 3.12. For comparison with a vertical pressure inlet, the fitted low-pass function as determined in section 3.2.1 is plotted.
3.2 Parameter evaluation

(a) Simulation model

(b) Simulation of chip deformation

(c) Simulation of silicone deformation

Figure 3.11: Simulation to determine the influence of a lateral pressure inlet
Figure 3.12: Influence of the aspect ratio of the silicone on the amplitude reduction at lateral pressure impact
3.2 Parameter evaluation

within. The results of geometries with height of less than 1 mm are shown in a different colour. Their amplitude reduction is considerably higher compared to the bigger gaps. This can be explained by the increasing shear resistance due to the silicone sticking to the upper wall. All in all the results can be compared with the previous ones due to the same low-pass behaviour as in the system with the vertical pressure inlet.

3.2.4 Countersinking the pressure sensor

A countersink for the pressure sensor could be helpful in the assembly process to reduce the size of the bond wires and would mechanically protect the sensor die. Even though the handicaps described in chapter 3.3.3 rule this set up out in the end, simulations where undertaken to understand the failure mechanisms. The model presented in section 3.2.1 is extended with a countersink for the pressure sensor as shown in figure 3.13. The diameter of the sink with its 2.4 mm is kept at a minimum to hold the sensor. As described in section 3.1.1, the sensor MS 767 has a diagonal of 2.31 mm.

Simulation results

Figure 3.14(a) shows the resulting deformation of the silicone at a pressure of 300 mbar. A heavy deformation of the silicone in the cavity of the sink can be identified. A comparable system without a countersink is shown in figure 3.14(b). Due to the higher volume of silicone in this model, the deformation at the pressure inlet is higher in its absolute value. Regardless of this higher deformation, both systems have an approximately equal amplitude reduction when the given height of the silicone pillar is the same.

A displacement out of the center of the countersink or an incomplete filling of the sink with silicone (see also chapter 3.2.5) result in nearly complete loss of the sensor signal. The amplification of the deformation at one or two sides of the sensor body lead to a deformation of the rigid silicon structures of the element causing a pre-stress on the membrane
which again does not allow any valid sensor reading. For these cases no reasonable simulations could be completed.

### 3.2.5 Air entrapments in the silicone

In the course of assembly it should be avoided under all circumstances to generate air entrapments inside the silicone. Anyhow due to several factors such air entrapments can occur. For example when in cavities the buoyant force of entrapped air is not high enough to overpower the inertia and the reset force of the surface tension of the silicone to leave the cavity, an air pocket is left behind in the cured material. To understand this phenomenon and make firm propositions whether an air entrapment could be responsible for imprecise sensor readings, simulations were undertaken. For all simulations it is assumed the silicone is cured in normal pressure leaving a pressure of 1100 mbar inside. During the simulations the bubble turned out not to change shape in larger scales. Due to the fairly small deformation of the bubble in comparison to the enclosed gas the pressure inside can be assumed as constant.
3.2 Parameter evaluation

(a) Silicone deformation

(b) Model without countersink for reference

Figure 3.14: Silicone deformation of a model with countersink

Figure 3.15(a) shows the closeup of an air bubble that occurred accidentally during assembly. With the help of a microscope the size and location was identified. The diameter of the nearly round bubble is determined to \( d = 0.55 \text{ mm} \). As the setup can only be observed from the top, the thickness \( t = 3 \text{ mm} \) and distance between the sensor die and the bottom of the bubble \( h = 3 \text{ mm} \) can only be estimated by the focus heights of the microscope. Figure 3.15(b) shows the resulting simulation model. The sensor used in this assembly is the SM5108 lowered in a countersink under a silicone pillar with the height \( h_{\text{silicone}} = 5 \text{ mm} \) and the diameter \( d_{\text{silicone}} = 3.6 \text{ mm} \). As displayed the bubble is estimated as a cylindrical body with rounded edges that is slightly displaced out of the center axis.

After this verification exemplary failure mechanisms were set up as shown in figure 3.16(a): At first a model to evaluate the influence of entrapments next to the sensor in countersinks (see also chapter 3.2.4). In systems with a reduced pressure inlet (see also chapter 3.2.2), it is possible that the ascending gases accumulate at the bottom of the top panel. A system with two entrapped bubbles is shown in figure 3.17(a).
Encapsulation techniques

Figure 3.15: Modelling of a sensor system with an air entrapment
Simulation results
Due to the entrapped air, the compressibility of the whole system is highly increased. Depending on the position of the entrapment there are various consequences. An entrapment between the pressure inlet and the sensor and thus in the direct incidence of the pressure reduces the pressure propagation significantly. As demonstrated in figure 3.15(c) the deformation of the silicone above the bubble is fairly high compared to a system without an entrapment (see also figure 3.5). Below the bubble though, the deformation is reduced to a minimum, affecting the deflection of the sensor membrane. The resulting amplitude reduction of 77% is significantly higher of a system without the entrapment with 23%.

A divergence this high can not be observed in systems with entrapments next to the sensor. As presented in figure 3.16(b) the deformations of the silicone above the bubbles is significantly high, but the deformations propagating towards the membrane are rather unaffected. The determined amplitude reduction of approx. 4% suits the equivalent system without a bubble. In case of two opposing bubbles the sensor is forged towards the bubbles due to the higher resulting pressure from the silicone-filled cavities. In this case the elongation of the resistances due to the applied pre-stress cause an amplitude reduction of about 10%.

Air entrapments close to the covering lid lead to an additional deformation of the silicone right beneath the lid, as presented in figure 3.17(b). This setup leads to an amplitude reduction of 52% and is significantly higher than a system without a bubble.

With the given examples of systems with air entrapments it can be concluded, that the size of the bubble is not the main factor responsible for the enlarged amplitude reduction. Rather the final position is of major importance for the pressure propagation. Generally entrapments in the path of the pressure leads to the highest damping. This again stresses the importance of appropriate evacuation and a proper choice of the material. Resinous materials can hardly be evacuated properly and even very small entrapments not directly visible can have an unwanted impact on the whole system.
Encapsulation techniques

Figure 3.16: Modelling of a sensor system with an air entrapment in the sensor cavity

Figure 3.17: Modelling of a sensor system with an air entrapment not in the direct way of pressure propagation
3.3 Experiments

3.2.6 Non-symmetric footprint

For a better reproducible assembly a non-symmetric footprint was chosen, as presented in figure 3.18(a). For this setup a DIL-package is used to hold two sensor dies symmetrically, which again is covered with silicone of defined height inside a housing identifying the external dimensions.

Simulation results

The qualitative pressure propagation is presented in figure 3.18(b). As this setup is supplied with a full-scale inlet, the results are comparable to the findings of the system presented in figure 3.5. The variations can be explained with the longish geometry and the resulting displacement of the sensor die out of the center. The resulting dependency of the amplitude reduction of the height of the covering silicone is plotted in figure 3.19. Herein two different silicones are considered varying only in their Young’s Modulus. On the one hand the Young’s Modulus of 3.11 MPa as determined earlier in chapter 3.1.2 and on the other hand a slightly lowered Young’s Modulus of 2 MPa to consider variation in manufacturing. This shows that small variations, which can easily occur in manufacturing, do not pose difficulties.

3.3 Experiments

For the verification of the simulation models and the caused amplitude reductions, various assemblies were built and tested. This also provided an opportunity to study the effects of long-term storage on encapsulated sensors.

3.3.1 Sensor assemblies

In all assemblies silicone pillars formed by housings are placed on top of the sensor dies. For verification purposes, the models were designed according to the idealized simulation models described in section 3.2.1. In any case, the sensor die is fixed to a PCB with an adhesive. The
Encapsulation techniques

Figure 3.18: Modelling of a sensor system with a non regular footprint

Figure 3.19: Influence of the height of the silicone on the amplitude reduction in dependency of Young’s Modulus

(a) Model

(b) Silicone deformation

Young’s Modulus 2 MPa

Young’s Modulus 3.11 MPa
shape of the encapsulation is formed by a solid mould attached to the PCB and filled with silicone.

**PCB material and electronic assembly**

The right choice of the PCB material turned out to be a crucial factor for the assembly. At first benefits and drawbacks of countersinking the sensor in the PCB as described in section 3.2.4 have to be weighed. The benefits are given by the mechanical protection of the sensor die and the planar closing of the sensor with the pads of the PCB allowing short bond wires. Shorter bond wires provide a higher stability. But many drawbacks arise during assembly and as described in section 3.2.4 in the final behaviour of the system are noted. Due to the small diameter of the sink, the fixation of the die is highly fault-prone. For example the bottom of the sensor die has to be fixed with a small but just right amount of adhesive, so that the sensor is placed exactly in the center and no adhesive pastes over the side wall of the sensor. This would lead to a fixation of the die to the side wall of the sink and the uneven distribution could distort the die during the curing process leaving pre-stress on the sensor that will influence the performance in an unforeseeable manner. Furthermore during encapsulation air can be entrapped in the small cavities. Due to the small width the buoyant force of the gas is not high enough to separate from the cavity and drift to the top of the silicone and thus leave the encapsulating material. Thus air entrapments tend to stay behind causing severe problems as described in section 3.2.5. Even if a bubble-free filling can be realized, problems caused by uneven stress to the sensor die can cause improper readings due to not exactly centred or crooked placement of the sensor leading to unwanted shear stress.

As the drawbacks of the countersink outbalance the advantages especially during manual assembly and first systems showed sensor readings differing heavily from the expected values, a setup without countersink was chosen. The sensor die is fixed to the PCB in the center of the milling groove separating the four connection pads, as presented in figures 3.20(a) - 3.20(c). Thus the bond wires have to
bear down the height of the sensor, enlarging the mechanical fragility of the system, but usually the used gold bond wire of 25 µm thickness is stable enough. The pin layout at the backside of both setups is identical. All pins are inserted with minimal overhang on the top side of the PCB, soldered to the pad and fixed with the structural adhesive Delo Duopox AD1895 from Delo [137]. The sensor die is glued to the PCB with liquid adhesive EPO-TEK 302 from Polytec Inc. [138] and connected to the PCB via ball-wedge bonding.

Another series of sensors was realized in DIL-packages, as shown in figure 3.20(d). Two sensor dies were glued in the package and the bond wires could be connected to the given elevated pads for minimum length of the bond wires. Problems as described earlier concerning countersinks do not apply in this case due to larger dimensions.

### Encapsulation of the sensors

All setups are encapsulated fairly similar. At first a housing is attached to the electrically tested assembly with the structural adhesive Delo Duopox AD1895 from Delo. These housings are either made of plastic reinforced with glass fibers (Stanyl®TE250F8) for the PCB mounted sensors or aluminum for the DIL-packages. All housings can be supplied in various heights.

The encapsulation itself is accomplished by backfilling the housings. The dual-component, byproduct-free and medically compliant silicone rubbers MED-6015 and MED-4210 as well as the silicone gel MED-6340 from NuSil Technology are used in all test series. The components are mixed according to the manufacturer instruction [135, 139, 140] and stirred under vacuum for ten minutes to ensure proper dilution and the minimization of air inclusion. After dispensing the silicone in the housing from bottom to top with a appropriate needle, the whole assembly is evacuated again to withdraw potential air entrapments. If needed this procedure is repeated after refilling the housing several times. When the system is visually free from defects and filled over the top of the housing, they are cured as recommended. In order to minimize internal tensions temperatures during curing time are kept as
3.3 Experiments

(a) PCB assembly
(b) PCB assembly with housing
(c) PCB assembly closeup
(d) DIL package

Figure 3.20: Assemblies for the experiments [130]
Encapsulation techniques

low as possible and systems are kept at room temperature afterwards for longer time to let the stress in the silicone relieve appropriately.

### 3.3.2 Measuring system

All assemblies are fully tested before and after encapsulation to compensate the individual variance of every sensor die in a specially designed test setup [141, 130]. This test setup will be described in the following paragraphs.

The key component of the test equipment is a pressure chamber supplied with tapped holes on three sides to take up two pressure sources and a reference sensor. A small volume of approx. 2.3 cm$^3$ is provided to facilitate a pressure change as quick as possible. The reference sensor is a 19C050PA7 from Honeywell Inc. [142]. It is a stainless steel transducer with a high media compatible membrane and a 1/4-BSPP mount. The sensing element is calibrated to 50 psi (approx. 3.5 bar) and an amplification and temperature compensation circuit are integrated in the housing.

A connector for the device under test (DUT) is supplied at the bottom side of the test chamber’s lid, thus for the slightly different assemblies either with PCB or in the DIL-package, only different lids are used in the same pressure chamber. The volume of the chamber is minimized to keep the dead volume as small as possible and allow high pressure slew rates.

Figure 3.22 shows the pneumatic equivalent network of the test equipment. The pressure in the test chamber is controlled by two 2/2-way-valves from Festo, each connecting a storage tank to the chamber. The pressure in the storage tanks is separately controlled by pressurestats and a pressure reducer from the central air supply. Due to the limited volume of the storage tanks switching the valves induces a divergence from the adjusted pressure by in- or out-streaming air. The bigger the volume of the test chamber in comparison to the storage tanks is, the longer the transient effect lasts until the adjusted pressure is regulated in the chamber.

For precision and verification purposes, the pressure in the storage
3.3 Experiments

(a) Construction drawing [142]

(b) Foto of build-up in test chamber [44]

Figure 3.21: Reference sensor Honeywell 19C050PA7

Figure 3.22: Pneumatic equivalent network of the test equipment
Encapsulation techniques

tanks can individually be counterchecked with pressure measuring equipment, as the pressurestats do not allow very precise readings. The valves could theoretically switch at a rate of 380 Hz. They are supplied with a laboratory-power-supply of 24 V and connected via interfaceboard and USB port to the controlling computer.

The complete test equipment is shown in figure 3.23. The connected computer can not only control the valves but also record the data of the DUT and the reference sensor. For that purpose two circuits with instrumentation amplifiers INA125 [143] were set up. In order to avoid the superposition of the 50 Hz line frequency, these circuits are not supplied with laboratory power-supplies but two lead accumulators. Two amplification circuits are realized to have separate channels for the reference sensor and the DUT and both are set to an amplification factor of 50. Both signals are fed via BNC-cables in data acquisition (DAQ) module NI USB-6251 from National Instruments, which has 16 16-bit-A/D-converters with sum sampling rate of 1 MS/s. All incoming data is buffered and transferred to the computer via USB. [144] The whole unit is controlled with a self written LabView-program, that can start and stop the measurements, control all parameters, plot the recorded data and save every measurement.

Limits of the measurement equipment

The resolution of 16 bit results in a theoretically resolvable 0.3 mV of an input signal of 20 V. The output of the amplifier circuit at the set amplification of 50 is 2.4 mV mbar, resulting in the theoretical minimal resolution of the AD-converter is 1.27 * 10^{-4} mbar. Thus the real limitation lies within the circuitry and cables, as a random noise of about 20 mV can be detected at the output of the amplification circuit, leading to a detectable minimum of 8 − 9 mbar.

An ideal pressure step has a rectangular shape with a change in pressure without delay. A realizable pressure step though is limited by the volume and geometry of the test chamber, the size of the valves and the storage volumes. For the perfect pressure step, the following conditions would have to be fulfilled:
3.3 Experiments

Figure 3.23: Test equipment [130]

- The valves have to open and close absolutely simultaneously and completely

- The storage volumes have to be infinite to avoid any pressure loss

- The test chamber and the feeding lines have to be infinitely small

- The geometry should have no influence on the flow during the exchange

As these ideal requirements cannot be fulfilled, they have to be matched as good as possible. The feeding lines and the test chamber are chosen small in comparison to the fairly large storage compartments. Figure 3.24(b) shows the reference measurement of a pressure step of 500 mbar at a switching frequency of 1 Hz. A small overshoot can be observed during the application of the 500 mbar. This behaviour is caused by the limits of the whole system. At the pressure step of 250 mbar (see figure 3.24(a)) a slower linear gradient just before reaching the upper pressure value can be observed. This has to be a geometrical problem of the setup, as at no other pressure step this
Encapsulation techniques

(a) Pressure step of 250 mbar

(b) Pressure step of 500 mbar

Figure 3.24: Reference measurements to observe the behaviour of the pressure chamber

phenomenon can be observed to this extend. For the measurements determining the influence of the encapsulation the reference curves always have to be taken into account.

A change in pressure stabilizes to its’ new constant value after approximately 10 ms. Thus the theoretical limitation of frequency by the setup is 50 Hz. In all experiments a maximum frequency of 1 Hz is used, any pressure changes occurring in the human body should be sufficiently simulated. The most interesting pressure change for the focus project Hyper-IMS (see chapter 4) is caused by the human heart with a frequency range of 50-100 beats per minute at rest.

Measurement procedure

For the characterization of a sensor, five test series are recorded after every relevant process step. The reaction of the assembled system to a square-pulse with a frequency of 1 Hz and pressure steps from respectively 1000 mbar to 1100 mbar, 1250 mbar, 1500 mbar, 2000 mbar and 3000 mbar is inspected. For this purpose the sensor is inserted in the test chamber, which is closed pressure-sealed. Before the first measurement the maximum pressure step is applied to the DUT to pre-condition the system (see also section 2.2.2) for a minute. After these 60 load cycles no further material-caused changes of the sensor readings due to the Mullins-effect (see also section 2.2.2) are expected.
3.3 Experiments

One measurement lasts three seconds or respectively three load cycles and is recorded at a sampling rate of 100 kHz.

**Variation of the measurement procedure under wet conditions**

Even though silicone can generally be regarded as hydrophobic, it takes up water in small amounts which again leads to swelling. For that reason, the system behaviour is tested under wet environment. As a main focus of this work is the behaviour of an implant, Locke-Ringer’s solution is used, to simulate the mineral composition of human blood. The devices are stored in Locke-Ringer’s solution for up to 67 days and measured afterwards. The given measurement equipment is used with a slightly changed pressure chamber. The chamber is deeper and the residual volume is filled with with Locke-Ringer’s solution so that the DUT is kept wet, except for the electronics, which have to be protected with a rubber inlay. The measurements are taken as described above with the exception of the 3000 mbar step which caused too much splashing.

3.3.3 Results of the measurements

In this section the experimental results are presented. Two major aspects are considered: The experiments for the verification of the simulation models and the longterm stability trails under humid conditions.

**Processing of the data**

All data gained in the experiments is processed and evaluated in a self-written MatLab program. The underlying routines and algorithms will be explained in the following section. Exemplary processed data is shown in figure 3.25. As the used reference sensor is also a piezoresistive absolute pressure sensor it can be simultaneously be processed with the same routines as the DUT. Due to the high sampling frequency of 100 kHz a comparatively strong thermal noise can be observed. Smoothing of the signal is realized with a local regression method (in figure 3.25: DUT / reference signal smoothing). The locally weighted
Figure 3.25: Display of the data processing with all auxiliaries
3.3 Experiments

scatterplot smoothing (LOWESS) method can efficiently be used in this case due to the densely sampled data sets given from the measurements.

For the determination of the amplitude reduction factor, partial regression lines are computed of the upper and the lower plateau (in figure 3.25: Upper / lower signal value) before and after the encapsulation. The gradients of these regression lines correspond to the drift caused by temperature or other irregularities and should be zero. A high drift of the system can point to problems in the assembly or encapsulation process of this device under the fairly stable conditions of the measurements. Slight drifts in the signal can be adjusted with the help of lines with averaged inverted gradients.

Conversion from the measured output voltage is done with the regression lines and the known preset of the pressure. The pressure set for the measurement is given to the program that relates the corresponding voltage the pressure. These pairs of values define the parameters of the linear correlation of pressure and output voltage. Pressure sensors have a fairly linear correlation in a defined range, allowing a simple conversion from output voltage to pressure. For an unencapsulated absolute pressure sensor the underlying line crosses the origin. Encapsulation can dislocate the signal as shown later in this section. This displacement equals the axis intercept of this line. For the determination of the amplitude reduction the slope is of major interest. To eliminate inaccuracies like slightly different adjusted pressure values in the chamber, every measurement is regarded in relation to the reference sensor. From these relative gradients the amplitude reduction is finally computed.

Comparison of these relative gradients of an unencapsulated sensor for the different pressure steps exhibits a variation in all sensors, given in table 3.4. This variation is caused by the slight non-linearities of the two sensors – the assembled sensor MS767 from Intersema, Inc. and the reference sensor 19C050PA7 from Honeywell, Inc. – that do not totally coincide causing this offset.
Table 3.4: Variation of the relative amplitude ratio of the sensor MS767 and the reference sensor as a percentage of the maximum pressure

<table>
<thead>
<tr>
<th>Pressure step in mbar</th>
<th>Percental variation of maximum pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000-1100</td>
<td>1,36%</td>
</tr>
<tr>
<td>1000-1250</td>
<td>1,06%</td>
</tr>
<tr>
<td>1000-1500</td>
<td>0,98%</td>
</tr>
<tr>
<td>1000-2000</td>
<td>0,65%</td>
</tr>
<tr>
<td>1000-3000</td>
<td>0,00%</td>
</tr>
</tbody>
</table>

Influence of height and width

As in the simulations presented in chapter 3.2.1 data for various aspect ratios was collected and plotted with a fitting that equals a low pass filter, as shown in figure 3.26. The most important aspect of this data is that it proves the simulation parameters right. The only factor where the simulation is fairly inaccurate is in the range of very low aspect ratios. There the influence of a sticking to the housing wall seams to be slightly greater then simulated (see also following paragraphs). During assembly of the system various other aspects turned out to have a more or less important influence on the pressure signal. Thus the following paragraphs evaluate various aspects of influence.

Influence of the bonding of the housing

As described earlier, the form of the encapsulating silicone is given by a housing bonded on top of the sensor assembly. In the process of bonding it is crucial that no adhesive reaches the sensor die. In some of the first specimen this goal was not utterly reached and the adhesive crept to the sensor die, touching it or even covering it completely. The consequences are exemplified with the data of one sensor where the adhesive covered about 30 % of the sensor membrane.

Figure 3.27 shows a processed measurement of the exemplary sensor before and after the bonding of the membrane at a pressure step from 1000 mbar to 3000 mbar. The amplitude reduction of the voltage
3.3 Experiments

Amplitude reduction

<table>
<thead>
<tr>
<th>Aspect ratio</th>
<th>0,00 %</th>
<th>25,00 %</th>
<th>50,00 %</th>
<th>75,00 %</th>
<th>100,00 %</th>
</tr>
</thead>
</table>

Figure 3.26: Influence of height and width of silicone pillar on the amplitude reduction in sensor assemblies

Figure 3.27: Measurement of a pressure before and after stressing the membrane with adhesive
Encapsulation techniques can be clearly seen. The damping for this sensor is 65% and is induced by the stiffening of the membrane by the adhesive. Furthermore the signal has a offset of $-0.40 \text{ V}$ caused by the pre-stress which is generated by the volume reduction of the adhesive during curing.

**Influences on the dynamic behaviour**

The modification of the dynamic response of the sensor and the linearity of the signal caused by the adhesion can only be estimated. Figure 3.28 shows the recorded pressure of the reference sensor in relation to the sensor signal at the pressure step from 1000 mbar to 3000 mbar. The two averaged curves are nearly congruent. The flanks of the curves indicate the pace of the detected pressure change in the chamber. As the maximum change rate in air is equal to 80 bar/s it can be assumed that this is the actual change rate in the chamber. Vital for this assumption is the reaction rate of the reference sensor which is much higher. Thus the influence on the dynamic reaction of the sensor can only be stated to a minimum of 80 bar/s.

Likewise the linearity of the signal can only be approximated. The values of the amplitude reduction and their development, as shown in table 3.5, indicate a small influence on the linearity of about 3 %.

<table>
<thead>
<tr>
<th>pressure step in mbar</th>
<th>Amplitude reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000-1100</td>
<td>67,69%</td>
</tr>
<tr>
<td>1000-1250</td>
<td>67,49%</td>
</tr>
<tr>
<td>1000-1500</td>
<td>67,31%</td>
</tr>
<tr>
<td>1000-2000</td>
<td>64,80%</td>
</tr>
<tr>
<td>1000-3000</td>
<td>65,60%</td>
</tr>
</tbody>
</table>

In conclusion it can be stated that a sensor covered partially by adhesives is not necessarily unqualified for further measurements. This is dependent on the implied pre-stress. In the exemplary case of this sensor the offset was $-0.40 \text{ V}$. A higher offset could cause the signal
3.3 Experiments

Figure 3.28: Measurement of a pressure step from 1000 mbar to 3000 mbar to show the congruence between the DUT and the reference sensor to exceed the available measurement range. In order to process such a signal, the amplification circuits would have to be modified causing additional work which is often not legitimate in the process of assembly. Furthermore the amplitude reduction caused by the adhesive is not tolerable when it exceeds a certain value defined in preposition. Thus a contact of an adhesive with the membrane of the sensor or an unwanted distribution along the die should be avoided under all circumstances.

**Influences of storage in Ringer’s solution**

Even though no quantitative statement can be made about the induced amplitude reduction, qualitative statements about the different ways of measurement, encapsulation and storage can be provided. The fairly small influence of the changes in the pressure conducting media can be exemplified with the data of an exemplary sensor as follows: Figure 3.29 shows the measurements of the encapsulated sensor before and after the storage in Locke-Ringer’s solution for 30 days, the applied pressure load is 1000 mbar to 2000 mbar, the
Figure 3.29: Measurement of sensor in dry air and after 30-day-storage in Ringer’s solution
temperature is $21 \pm 2 \, ^\circ\text{C}$. The second measurement was conducted in Locke-Ringer’s solution, as described earlier. Between the two measurements, a shift in the offset can be observed, but the amplitude is not affected. The quality of the signal is also in comparable limits, whereat the thermal noise has increased by a factor of 2-3. This fact can be balanced by an adequate curve fit, so that in the smoothed data and all following data processing no difference can be determined. Thus the storage and calibration in Locke-Ringer’s solution of systems meant for invasive applications is considered reasonable and can be recommended.

This way the actual behaviour of the system after moisture swelling can be judged. Even after the storage over a period of 56 days in Locke-Ringer’s solution, the sensor signal differs only insignificantly from the signal of the reference sensor. Figure 3.30 shows the dynamic behaviour of two exemplary sensors: One after a storage in Locke-Ringer’s solution for 30 days at $21 \pm 2 \, ^\circ\text{C}$, followed by a dry out period of 26 days at $36 \, ^\circ\text{C}$, the other with a sole storage of 56 days at $21 \pm 2 \, ^\circ\text{C}$ in Locke-Ringer’s solution. Both sensors show no significant deflection in their response characteristic, but the sensor without the dry out period shows a small offset in the pressure output. This comparison shows that influences of penetration water is reversible, but has no influence on the dynamic behaviour itself. As both sensors show only slight differences in their output signal, it can clearly be stated that this kind of encapsulation is appropriate for such an environment.

**Assemblies with non-symetric footprint**

All following conclusions were drawn from the experiments with the non-symetric footprint assemblies, as described in sections 3.2.6 and 3.3.1. In these assemblies, two sensor dies are attached in one DIL-housing. This way the extraction of influence factors is made a little more easy, because faulty sensor signals due to bad assemblage or broken sensor elements can be eliminated allowing direct conclusions on the influence of the encapsulation. Table 3.6 shows the average amplitude reduction of all measurements of this series. The following subsections
Encapsulation techniques

(a) Measurement after 56 days of storage in Ringer’s solution
(b) Measurement after 28 days of storage in Ringer’s solution and drying of 26 days in dry air of 36 °C

Figure 3.30: Dynamic behaviour of pressure sensors after storage in Ringer’s solution and drying afterwards

Influence of the encapsulation layers on the signal amplitude

All sensors were measured after every relevant step of assemblage. Due to the more generous geometry, the housings could be fixed to the assembly without influencing the sensor signal from the start. This can be observed in the comparatively small amplitude reduction of all systems. The marginal deviation in the offset of about 0.26% of the not encapsulated sensors can be explained by temperature changes in the lab of ±1 °C max. influencing the uncompensated sensor die. After encapsulation with silicone-filled aluminium fixtures of different heights, the signal reductions of the various sensors are compared. As expected, the measurements of the different series were comparable and the results are presented in table 3.6 as mean values of the various applied pressure steps. The amplitude reduction is lower than expected by the simulations. The reason for that could be found in the curing
3.3 Experiments

Table 3.6: Amplitude reduction of assemblies and simulations with non-symmetric footprints

<table>
<thead>
<tr>
<th>Silicone height</th>
<th>5mm</th>
<th>10mm</th>
<th>15mm</th>
<th>20mm</th>
<th>25mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assemblies (averaged)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1: S1-S5</td>
<td>1,50%</td>
<td>55,81%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2: S6-S10</td>
<td>53,48%</td>
<td>76,41%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 3: S11-S15</td>
<td>30,43%</td>
<td>69,06%</td>
<td>78,03%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simulations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MED-6015 (3.11 MPa)</td>
<td>38,49%</td>
<td>79,72%</td>
<td>94,48%</td>
<td>98,43%</td>
<td></td>
</tr>
<tr>
<td>MED-6015 (2 MPa)</td>
<td>30,97%</td>
<td>78,66%</td>
<td>94,02%</td>
<td>99,08%</td>
<td>99,53%</td>
</tr>
</tbody>
</table>

Process of these samples: For minimal thermal tension they were cured at room temperature unlike the other samples which were cured at an elevated temperature of 50 °C. Even though the datasheet supplied by the manufacturer [135] stated the possibility, curing at room temperature led to a wet, sticky and softer silicone. This fact was tested in extra samples, where the softness could be felt by hand, but the silicone was too soft to determine the Young’s Modulus. Simulations showed that the Young’s Modulus of this silicone had to be around 0.9 MPa. A stacking of a second aluminium fixture could be realized with some assemblies, but the samples had to be cured at room temperature, as temperatures of 65 °C led to tension inside the silicone. This tension caused the silicone to expand so heavily, that the bonding of the two fixtures broke apart. So again, no harder silicones could be measured. The stacked silicone layers caused a different amplitude reduction leading to the conclusion that the two layers did not bond homogeneously, forming a multilayer encapsulation system. These multilayer systems should be investigated in detail in further studies, as they were not part of this thesis.
Influence of the contact force between silicone and housing wall

As stated in the simulation section 3.1.3, lost coupling between the housing and the encapsulation material can be seen as an frictionless contact causing no amplitude reduction from the encapsulation material. This phenomenon could be observed in the course of this experimental series. Two systems showed no mentionable amplitude reduction and the delamination of the silicone could be examined in a visual inspection. A second processing with silicone obviously filled the gap and led to comparable amplitude reduction as observed in the other systems.

3.4 Conclusions

In general, silicones show a hyperelastic behaviour, that can be described with different material models. With the help of the finite elements method different geometries were simulated. It could be shown that due to the high incompressibility and the consequential low deformation, a linear material model is sufficient in most cases. Although creeping and relaxation behaviour are neglected, no difference from a hyperelastic model could be detected in the simulations.

For several medical-grade silicones the Young’s Modulus was measured in an uniaxial pull test. The Young’s Modulus of 3.11 MPa was used for the following simulations of various geometries, as a silicone of this grade turned out to be very good to process in a series of experiments, performed in addition to the simulations. Based on a simple pillar of silicone surrounded by a rigid body, variations of the pressure inlet were investigated on their influence. A holohedral inlet was taken as basic geometry, that was reduced in size by adding a lip. In another series the sensor die was tilted over 90° applying the pressure to the die from the side.

For the simulations the model of a piezoresistive pressure sensor was build allowing to investigate the incoming pressure signal by evaluating the deformation of the piezoresistive elements in the membrane. Analog
to a real sensor element the deformation leads to a change of resistance. Taking resistors at all four edges into consideration, the change of the bridge voltage of the Wheatstone bridge can be evaluated. In the model of an encapsulated system the change of the bridge voltage due to the encapsulation can be determined as a rate for the signal reduction. For all presented models, the correlation between the amplitude reduction and the aspect ratio of the silicone height to the silicone width was determined. It could be shown that all damping due to the silicone has the characteristic of a low pass filter. A transformation of the mechanical viscoelastic model into the electrical realm explains this behaviour very elegantly. As it turnes out, the height of the silicone pillar equals the size of the resistance in the equivalent circuit. A variation in diameter, for example caused by the added lid, adds another order to the filter.

In order to verify the results of the simulations, systems with the pressure sensors MS767 from Intersema Inc. were assembled and encapsulated according to the simulation models. A test bench was build for the application of pressure square wave signal. Verification experiments showed that a pressure from one bar absolute to three bars absolute can be applied with an slew rate of up to $80 \text{ bar} / \text{sec}$.

Some assembly guidelines were sustained with simulation and experiment: Air entrapments behave like sinks in the path of the pressure. It should be avouided under all circumstances to obtain such entrapments during assembly. A borehole to ease assembly and protect the pressure die can cause unforeseeable problems mainly by shearing and prestressing the membrane. It is recemended not to work with assemblies containing such countersinks.

The behavior of the sensors was evaluated before and after encapsulation in order to determine the amplitude reduction of the signal. With the system setup, the influence of the encapsulation could be analyzed in dynamic behavior. The high change rate in pressure up to $80 \text{ bar} / \text{sec}$ shows that in these systems the viscoelastic behavior of silicones poses no relevant influence in the resolution.

A storage of up to 56 days in Ringer’s solution could prove no influence on the sensor system. The signal is slightly influenced caused
Encapsulation techniques

by the variation of mechanical parameters of the encapsulating silicone, but the effect is completely reversible by drying processes. Furthermore the influence of the mechanical adhesion between the silicone and a surrounding body could be demonstrated. Some systems lost the adhesion and no more amplitude reduction could be detected. In medical application this phenomenon is of no relevance, because the encapsulation is meant to protect electronics and patients from each other.
4 Project Hyper-IMS

4.1 Motivation

Approximately ten million people suffer from hypertension (high blood pressure) in Germany [61]. About 10% of these patients can hardly be stabilized on drugs and for another 10% of this group a long term monitoring is advisable. Up to now conventional extracorporeal systems like blood pressure cuffs for long-term monitoring with individual measurements are used which tend to be a handicap for patients due to inflating and deflating painfully, especially at night. Furthermore those cuffs do not allow continuous measurements. For invasive blood pressure monitoring catheters are available for short-term use during surgery. Those are restricted to clinical use due to the required permanent access to the body posing a permanent and clinically relevant origin of infection. Dislocation of the catheter or the upper-arm cuff cause measuring errors making both methods fault-prone. Furthermore the patient is restricted in his mobility by catheter-or cable-systems that can even induce injuries by unwanted jams.

In the following chapter an implantable system for long term blood pressure monitoring is presented. This system is an image-guided minimal-invasive implantable and removable telemetric pressure measurement system, primarily developed for hypertensive patients that are difficult to regulate by drugs. The main advantage for the patient will be the highly increased quality of as the system, once implanted, is not noticeable in contrast to external measuring system like automatic blood cuffs.

The whole system is based on experiences gained in former developments [80, 113, 145, 146]. The implant consists of a newly designed sensor chip integrated at the head of a catheter (Ø 1.1 mm) and a
telemetric unit. The sensor tip is placed into the femoral artery while the telemetric unit is implanted into the subcutaneous tissue. Thus the disturbance inside the blood vessel and the distance for wireless communication are kept as small as possible to obtain optimal parameters. The implant is supplied with energy wirelessly via inductive coupling from the external reader station. Data is readout from the external station with approx. 30 Hz and an overall accuracy of ±2 mbar. The system was developed to realize a comfortable 24/7 monitoring for these patients without the drawbacks of the extracorporeal systems.

4.2 System setup

In the project a newly monitoring system was developed allowing a continuous observation of blood pressure, pulse rate and body temperature of hypertensive patients. In order to minimize the risk of thrombus building, the implant inserted into the femoral artery (*arteria femoralis*, see figure 4.1) is buildup as small as possible and supplied with an adequate coating. Thus a division of the main functions is specified. One ASIC is designed to take up all measurements of blood pressure and temperature recording the pressure at a rate of 30 Hz. This chip is supplied with pressure and temperature sensors and a first amplification circuit and is assembled in a 3-F-medical catheter. The tip is electrically connected to the transponder unit containing the second ASIC. This ASIC is supplied with a second amplification unit and transponder circuits. With the help of a planar coil the implant can be inductively coupled to an external read-out
station where energy is brought into the system and via amplitude modification the data is transferred out. Figure 4.2 shows the schematic working principle of the whole system.

### 4.2.1 The implant

In the following section the fabrication of the implant is described in detail.

#### Chipsets

The core piece of the implant is a pair of ASICS specially designed and fabricated by the Fraunhofer Institute for Microelectronic Circuits and Systems (Fraunhofer-IMS). In order to maintain the stated available space, especially in terms of the tip inserted in the artery, a single chip could not be realized. The pair consists of a pressure and temperature measurement chip placed directly at the metering point and a telemetric chip placed subcutaneously. Both chips are connected electrically and only work in conjunction. This local disunion was a complete new development for the Fraunhofer-IMS.

For the pressure sensor ASIC four different designed were developed to minimize design risks. To determine the needed number of capacitive load cells, all designs were realized with 36, 48 and 60 load cells resulting in 12 combinations to be tested during the specification phase of the project. The telemetric chip however was design to universally work with any specified design. After pre-tests a version with 48 load cells and five outgoing electrical lines. All chips were fabricated at Fraunhofer-IMS in their 8”-CMOS clean rooms and supplied as thinned chips with an overall hight of about 400 µm. The realized sizes of the two chips are given table 4.1 and a processed pressure sensor chip is shown in figure 4.3. With this chipset an overall accuracy of ±2 mbar could be realised.

#### Plastic carrier for the tip sensor

In order to provide a reproducible integration of the mechanically susceptible pressure sensor chip, a chip carrier was engineered and
Figure 4.2: Schematic principle of the system

Table 4.1: Realized sizes of the two ASICs

<table>
<thead>
<tr>
<th>parameter</th>
<th>sensor chip size in mm</th>
<th>telemetric chip size in mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>min</td>
<td>typical</td>
</tr>
<tr>
<td>chip length</td>
<td>–</td>
<td>5.45</td>
</tr>
<tr>
<td>chip width</td>
<td>–</td>
<td>0.67</td>
</tr>
<tr>
<td>chip height</td>
<td>0.32</td>
<td>0.35</td>
</tr>
</tbody>
</table>
4.2 System setup

Figure 4.3: Sensor chip in size comparison placed on a finger tip [127]

Figure 4.4: Chip carriers in size comparison with a match head [127]
manufactured in micro injection moulding technology. Figure 4.5 shows the injection moulding tool with a maximum of eight cavities. Whereas figure 4.6(a) shows a dimensioned illustration of the chip carrier, figure 4.6(b) demonstrates the highly precise placement of the sensor chip in the carrier. To achieve innate stability in spite of the low wall thickness smaller than 100 µm and an overall length of 9 mm, a liquid crystalline polymer (LCP) with glass fibre reinforcement was used. The carefully chosen injection geometry allows for perfect fibre alignment. Figure 4.4 shows a detached chip carrier for size comparison next to a match head.

**Steel housing of the implant tip**
For mechanical protection the sensor chip is housed in a steel tube with pressure inlets, as shown in figure 4.7(a). The tube has an outer diameter of 0.95 mm, an inner diameter of 1.05 mm and an overall length of 12 mm. The openings for the pressure inlets are cut with a Nd-YAG laser. For the closure at the top of the tip, a steel cap is produced in CNC-turning (see figure 4.7(a)) and laser-welded to the steel tube. Figure 4.7(b) shows the unpolished welding seam.

**Flextape as platform for tip assembly**
For the connection of the elements in catheter tip, a miniaturized flextape is produced consisting of polyimide and to layers of gold lines.

For the production (see figure 4.8) a polyimide-layer of 5 µm is deposited in liquid phase on a 4”-wafer with a sacrificial layer and structured with lithography. A undercoating of chrome-gold is vapour-deposited with a height of 300 nm. This layer is electroplated with gold and structured in lithography. For the second layer of electrical lines, this procedure is repeated. A top layer of polyimide with openings for the connection pads serves as a protection against shunt faults. The flextapes are individualized by wet-etching of the sacrificial layer.

Figure 4.9(a) shows a production wafer before the separation of the flextapes, figure 4.9(b) a size comparison with a one-Euro-cent of a single foil and figure 4.9(c) a detailed close-up. For the different
Figure 4.5: Injection moulding tool for production of the chip carriers

(a) Illustration of the chip carrier  (b) Foto of the placement of a chip in the carrier

Figure 4.6: The chip carrier
designs supplied by the Fraunhofer-IMS, ten different foil-designs in two generations were produced.

Assembly of the sensor tip
The flextape described before serves as a platform for the tip assembly. The manufacturing process is illustrated in figure 4.10. At first, the connecting cable is electro-welded to one end of the foil. A SMD-capacitor in a 0201-housing serving as line decoupling is soldered on the appropriate pads in a reflow oven. The sensor chip is mounted by ultrasound induced flip-chip-welding.

The different variants of the foils were fabricated to optimize the placement of the assembly in the chip carrier. The flextape has to be wider than the inlay of the carrier to hold the cable appropriately. Thus the foil has to be folded or bend and the variation mainly differed in trenches to alleviate this process. Tests turned out, that all variants are usable equally good. The trenches helped to fold the foil in the adequate region, but due to the inalienable greater width the foil straightens up again more easily and emerges the border of the chip carrier. In the course of the project, all three designs were used without
Figure 4.8: Production process of the polyimide flextape
Figure 4.9: The polyimide flextape

Figure 4.10: Assembly of the sensor tip
noticeable problems.

This stage of assembly can be mounted in the chip carrier, as shown in figure 4.11 and figure 4.12. After inserting the system into the carrier, it is fixated with an underfill-adhesive.

**Encapsulation of the tip**
The mounted chip carrier is finally fixated in the steel tube. The cable is inserted in a polyurethane catheter. After bonding the tube and catheter, the system is filled with silicone from the backside, where later the telemetric unit is mounted. At this procedure air entrapments have to be avoided under all circumstances not only to avoid unwanted effects on the sensor signal (compare section 3.2.5) but also could moisture condensate. These condensates could possibly shorten the implant’s life expectancy due to local electrochemical effects. Final sensor tips with full encapsulation are shown in figure 4.13.

**Telemetric unit**
The telemetric units were also fabricated manually according to the specifications of the Fraunhofer-IMS. The whole process is documented in figure 4.14. On the milled printed circuit boards(PCBs) the passive components are soldered in a reflow oven. Afterwards the telemetric chip is adhered and electrically connected with wedge-wedge-bonding. For protection of the chip and the wedges, they are encapsulated in epoxy resin. As the last step, the planar coils is mounted to the backside of the PCB and soldered to the circuit through vias.

After an electrical test, the unit can be connected to a assembled tip. For a shape forming cast, the telemetric unit and the end of the catheter are encapsulated with a dead-mould casting. The geometry

Figure 4.11: Mounted sensor ASIC in carrier
Figure 4.12: Size comparison of complete assembly with a paper clip

(a) Size comparison [147]  (b) Closeup of two tips

Figure 4.13: Encapsulated sensor tip

Figure 4.14: Fabrication steps of the telemetric unit [148]
is equipped with three steel loops to facilitate proper fixation in the tissue during implantation, as shown in figure 4.15. The final moulding or the units was performed at our industrial partners’.

**Calibration of the sensor unit**

The measurement range of the system is 900 mbar (675 mmHg) to 1400 mbar (1050 mmHg) which comprises realistically achievable body pressures. Within a temperature range from 30°C to 45°C, the calibrated accuracy is less than ±0.66%FSS which corresponds less than ±3.3 mbar (±2.5 mmHg). A calibration plot of a readily assembled and encapsulated sensor unit is given in figure 4.16. As the system is compensated and amplified with the second ASIC the calibration curves look very much alike before and after encapsulation.

**4.2.2 Readout station**

The Fraunhofer-IMS developed an external readout station for telemetric use of the implant, as shown in figure 4.2. Via inductive coupling energy is transferred to the unit from the external reader station. Data transfer from the implant to the reader station is realized by amplitude modulation of the supplied energy carrier wave. The base frequency of transmission is set to 133 kHz. By using the free industrial, scientific and medical radio bands (ISM band) at 133 kHz, it is possible to achieve the highest penetration depth in the human tissue.

![Encapsulated telemetric unit](image)
Figure 4.16: Calibration plot of a sensor unit after encapsulation
4.2 System setup

[112, 149, 150]. All data is recorded and can be transferred to a PC for further evaluation. As a final system, the readout station should be minimized, thus the potential patient could take the station home for autarkic long term monitoring but for the evaluation of the implant, the supplied system was sufficient.

4.2.3 Implantation procedure

The application system has been developed by the medical partners at Helmholtz-Institute for Biomedical Engineering in Aachen (HIA) and are only described in short to give a full picture of the application. The requirements on an application system are a secure and uncomplicated positioning of the implant in the artery, as well as a secure closure of the vessel penetration after pulling back the application system. The principle of the vascular sealing is demonstrated in figure 4.17. The occurring circular gap between the sensor catheter of the implant and the vessel wall is plugged up by a absorbable collagen sponge. The collagen swells when coming in contact with blood and activates the blood coagulation cascade, assuring an effective closure.

The dimensions of the application instrument is dictated by the dimensions of the implant. The inner diameter has to ingest the implant’s catheter of 1.05 mm. In order to realize a safe vessel aditus the instrument has to be fairly stable and guarantee a frictionless insertion of the implant. Furthermore the system has to be realized as

Figure 4.17: Principle of vascular sealing (adapted from [147])
a peel-away application because the shape of the implant does not allow a simple pull over. Thus the application instrument is constructed as a catheter made of polytetrafluoroethylene (PTFE) with a wall thickness of 100 µm.

Figure 4.18 shows the developed and patented application system peel-away sheath introducer set (PASIS) allowing a vessel aditus of 1.49 mm (about five French (5F)). The system consists of three catheter sheaths placed coaxial with individual functions during the implantation process. The inner sheath working as the insertion sheath is equipped with a specially constructed peel-away valve. The outer sheath holds the collagen sponge as described earlier and a pusher sheath to put the collagen into place during the procedure. The collagen cuff (10 mm in length) is applied to seal the annular gap remaining around the indwelling catheter after removal of the insertion sheath. The collagen cuff is made from absorbable gelatin sponge that resorbs within 3-5 weeks.

### 4.3 Simulations

Based on the results of the proven simulations of chapter 3, the geometry of the sensor capsule was reconstructed for simulation, as shown in figure 4.19(a). As the sensor chip from the Fraunhofer-IMS is build up with capacitive pressure sensing elements, these should have been rebuild in the simulation. But it turned out, that no valuable signal determination from this membrane could be derived in the simulation software, because of the special geometry of the capacitors. As described in chapter 2.1.2 the gap between the membrane and the silicon bulk material is only a couple micrometers. Thus the mesh of the bulk material in the simulation has a greater impact on the membrane, than it would be expected in reality, when the chip is deformed in any way. At a pressure impact of 40 mbar the membrane can not be differentiated from the bulk. Thus only qualitative conclusions for the tip design can be derived from these simulations.

The simulation (figure 4.19(b)) shows the pressure propagation lead-
Figure 4.18: Design of the PASIS (peel-away sheath introducer set) [128]

...ing to a deformation of the sensor chip due to the pressure distribution around the front of the chip. Therefore the pressure cells experience pre-stress again leading to a loss of accuracy of the sensor signal. The grade of deformation is depending on the chosen design of the covering hull and the exact position of the sensor. Thus an exact positioning of the chip is inalienable. But the simulation also shows an adequate distribution and propagation of the sensor signal inside the capsule, which results in an appropriate sensor signal.

A smaller pressure inlet at the backside of the sensor could help to reduce the deformation and further improve the signal quality. Unfortunately this setup could not be realized in the actual assemblies.

4.4 Experiments

The following experiments have been undertaken in close collaboration with the HIA. All examinations were performed after approval from the local committee on animal affairs.
Figure 4.19: Simulation of the Hyper-IMS blood pressure implant capsule [134]
4.4 Experiments

4.4.1 In-vitro experiments

In order to evaluate the desired direction of implantation dummy models of the implant were inserted in a circulation model with and against the blood flow. This circulation model is constructed from a three dimensional CT-model and made of silicone, as shown in figure 4.20(a). During these tests no remarkable differences could be noted. Thus the implantation for a system presented here, the implantation against the blood flow is preferred for experimenting in-vivo because this insertion procedure is equivalent to the standard heart catheter procedure performed as daily routine in every cardiological clinic. A punctuation with the blood flow is slightly more complicated and especially for obese patients afflicted with higher complication risks.

A first evaluation of the implant was performed in the same model. The fully equipped test stand is presented in figure 4.20(b). For reference the system was controlled with a reference sensor system of clinical standard: A piezoresistive pressure sensor system produced by the Mammendorfer Institute for Physics and Medicine. The system works with a sampling rate of 125 Hz and an accuracy of ±3 mmHg. The quantitative curve progression of the two systems matches very good, as presented in figure 4.20(c). The absolute values do not match, because the preliminary processed implant was not yet calibrated to absolute values.

4.4.2 In-vivo experiments

The in-vivo experiments were conducted with Rhön sheep (female, weight 60 – 80 kg) in an overall of 16 experiments. As before, a piezoresistive pressure sensor produced by the Mammendorfer Institute for Physics and Medicine served as reference. All procedures were performed under general anaesthesia and with ECG-monitoring.

The follow-up period after vascular puncture and sealing was about 4 hours, 1 month and 3 months. The objective in acute animals was to test device handling, to evaluate if local bleeding occurs after
Figure 4.20: In-vitro measurement

(c) Measured data set shows very good match of reference signal and demonstrator implant
4.4 Experiments

sealing the annular gap around the indwelling catheter, and to evaluate implant functionality. In this setting the same reference sensor as in the in-vitro experiments rate was placed contra lateral for simultaneous pressure measurement. The purpose of longterm animal testing was to evaluate the implantation procedure (vascular complications), the stability of sensor-tip location in the vessel, and the hemocompatibility of the implant.

All procedures were performed in the supine position via femoral arterial approach. In all animals, the femoral artery was punctured against blood flow. All implantation procedures were performed under fluoroscopic guidance. For handling of the PASIS, the Seldinger-technique is used. After puncture of the femoral artery by means of Doppler ultrasound, the needle was withdrawn and a guide wire was inserted through the catheter tube of the needle into the vessel. The catheter tube was replaced by the PASIS via guide wire. The guide wire was then replaced by the HYPER-IMS system. After positioning the sensor-tip of HYPER-IMS in the artery, the insertion sheath with hemostasis valve was peeled off. Thereafter, the collagen cuff was positioned and pressed against the arterial wall by using the pusher. Subsequently, the empty outer sheath and pusher were peeled off. For subcutaneous implantation of the telemetry, a medial skin incision of about 20 mm was realized. Thus the telemetry was fixed on the muscle fascia by three loops via non-absorbable suture material. The skin incision was also sutured with non-absorbable suture material.

After the implantation procedure, X-ray images for positioning control of the HYPER-IMS system and an angiogram from the contra lateral femoral arterial access were performed to ensure artery patency and exclude bleeding complications. The follow up setting included B-mode ultrasound (weekly in the first month, then monthly) and an angiography (midterm) for vessel patency, haematoma control and sensor-tip positioning.

In all interventions the implantation procedure of HYPER-IMS with the use of PASIS worked without any problems. In each animal, arterial access was successfully achieved as well as a secure seal around the indwelling polyurethane tube without bleeding. There were no prob-
lems during the positioning of the collagen cuff. In acute experiments, neither secondary bleeding around the catheter, nor subcutaneous bruising was observed after positioning the collagen seal using PASIS.

Figure 4.21: Telemetrically recorded blood pressure in the femoral artery of an anesthetized sheep in comparison with the reference measurement

Moreover data could be read out telemetrically, as illustrated in Figure 4.21, over a distance of 80 mm which is a realistic distance when wearing the telemetric reader station close to the body. The pressure curve demonstrates good qualitative agreement with the reference curve. The offset can be explained by the contra lateral position of the sensors and by calibration inaccuracies. The rather low levels in blood pressure are suspected to be related to the anesthetized state of the sheep.

The puncture site follow-up of the longterm implantations showed no swelling, signs of bruising, local reactions or infections. B-mode
Figure 4.22: Series of x-ray images of the femoral artery with indwelling Hyper-IMS system marked in yellow.
ultrasound showed no haematoma. Angiography revealed vessel patency immediately, as well as one and three months after the procedure. There were no complications related to the collagen plug, particularly no embolization. Figure 4.22 presents x-ray images of the femoral artery with indwelling sensor-tip post-surgery and after one month. Figure 4.22(c) shows a contrast-enhanced angiogram 35 days post-surgery. The system displacement observed in figure 4.22(b) did not occur in later experiments due to an improved implantation technique. Figure 4.23 demonstrates stable placement after three months.

4.5 Conclusion

Hypertension is an important risk factor for vascular diseases (arteriosclerosis), renal and heart insufficiency. In Germany, approximately 10 million people suffer from hypertension. 10% of the people affected are difficult to medicate. Furthermore, 10% of this group are candidates for long term monitoring. Therefore a fully implantable and
telemetrically controlled blood pressure system is presented to realize a comfortable long term monitoring for these patients. The developed implant consists of a newly designed sensor chip integrated at the tip of a polyurethane tube and a telemetric unit. The dimensions of the system permit a minimal invasive procedure, following the steps of Seldinger-technique with a specially designed collagen based peel-away sheath introducer set (PASIS). The telemetry and the sensor are connected via micro-cable. The sensor-tip is placed into the femoral artery while the telemetric unit is implanted into the subcutaneous tissue. Thus the disturbance inside the blood vessel and the distance for wireless communication are kept as small as possible to obtain optimal parameters. The implant is supplied with energy wirelessly via inductive coupling from the external reader station. Data is readout from the external station with approx. 30 Hz and an overall accuracy of ±2 mbar.

Within in vivo experiments with sheep, first implantation experiences of the fully implantable blood pressure system HYPER-IMS have been presented. Successive extraction of the sensor-tip, observed in longterm experiments, is most probably due to muscle activation of the hind limb. With regard to the implantation procedure an additional extravasal fixation of the polyurethane tube, close to its vessel entrance point, might improve intravasal stability of the sensor-tip. Furthermore, spaced x-ray markers have to be attached on the HYPER-IMS system for better x-ray visibility and therefore optimized and reproducible positioning. Telemetric measurements in acute experiments could be successfully conducted. The long term stability of the Hyper-IMS system is matter of ongoing evaluation. The system is aimed for implantation of a maximum of thirty days. Assuming an average heart rate of 75 beats per minute and approx. 43,000 minutes per month, the implant will encounter roughly 3.2 million load changes. Further long term in vivo experiments up to 6 months, as well as a systematic and detailed histological analysis, are the next steps to estimate tissue and thrombus apposition and its influence to data transfer.
5 Summary and Outlook

5.1 Summary

Medical technology has been developing at a rapid pace, using new microsystem technologies to develop implantable monitoring devices. A key issue is the need for biocompatible materials which serve as protection both for the human body and the vulnerable electric components. Given the great relevance of hypertension in cardiovascular medicine, a reliable way to monitor blood pressure over long periods of time via an implantable pressure sensor could be beneficial to the treatment of many patients. The aims of this thesis were to investigate the influence of a protective silicone covering on the signal received by the pressure sensor and to apply the findings to the development of an implant for long-term monitoring of arterial blood pressure.

As a first step, the influence of the encapsulation’s shape and material parameters on pressure propagation was examined. Due to little or no available literature on this topic, preliminary tests using each component were conducted. Consequently, mathematical models predicting silicone influence on pressure propagation were developed. The calculated results were verified by empirical testing.

For all models used, the correlation between the amplitude reduction and the aspect ratio of the silicone height to the silicone width was determined, showing that all damping due to the silicone has the characteristic of a low pass filter.

A mathematical model was then used to simulate the effects of various system designs for the implantable blood pressure sensing unit of the Hyper-IMS system. The Hyper-IMS has shown promising results regarding pressure and temperature monitoring in a vascular model as well as first in-vivo experiments with sheep, but further testing and
5.2 Outlook

The simulations presented in this thesis provide a good basis to predict the behavior of encapsulation systems. In order to be able to cover a wider range of systems it would be necessary to evaluate some more silicones in their physical properties. Softer silicone gels and silicone oils might be of interest to simulate, as the variation in the Young’s Modulus probably influences the behavior significantly. Another interesting aspect to consider in the simulations might be the consideration of dynamic responses of the silicones. Especially high pressure change rates are limited in the current modeling to $80 \text{ bar}$. The adoption of the simulation to fluid modeling and an enclosed liquid could provide the interface to silicone gels and oils. The combination of different materials as layering systems could be very interesting, as this way of assembly would provide more possibilities. Not only silicones can be included in this material models, but also parylene or polyurethane would be interesting to include in the simulations, as these materials can be used as conform cover and outer layer for medical implants. This way further suggestions for optimal encapsulations of medical systems and implants could be made.

The presented implant system HYPER-IMS could be assembled in a small series and implantation in sheep showed first good results. With regard to the implantation procedure, an additional extravasal fixation of the polyurethane tube, close to its vessel entrance point, might improve intravasal stability of the sensor-tip. Furthermore, spaced x-ray markers have to be attached on the HYPER-IMS system for better x-ray visibility and therefore optimized and reproducible positioning.

The long term stability of the Hyper-IMS system is matter of ongoing evaluation. Further long term in vivo experiments up to 6 months, as well as a systematic and detailed histological analysis, are the next steps to estimate tissue and thrombus apposition and its influence to
data transfer. All necessary experiments have been conducted and have been published by Cleven et al. [147]. Currently studies in humans are under way.

The achieved degree of miniaturization allows for a multitude of possible applications. The digital data transfer allows a wireless transmission and recording of a variety of body pressures without the interferences and noise known from analogue data transmission. Other realizations with even smaller dimensions of the sensor tip and increased length of the cable are under development to be implanted in deeper and smaller anatomical structures. Due to the galvanic isolation of the sensor from any electrical source, the presented sensor tip represents an interesting alternative even in the field of catheters and endoscopes. Furthermore, the wireless transmission of transient pressure conditions with a miniaturized system offers new diagnostics and therapies in fields like cranial or gastro-intestinal pressure monitoring.
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