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Liane Koker*, Ulrich Gengenbach, and Georg Bretthauer

Reflection on boon and bane of Water Absorbing Components in Active Implants during Package Testing and Operation

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Abstract: For package testing of active implants internal humidity measurements are performed. Thereby, the water absorbency of the measurement components can affect the measurement result, leading to an erroneously prolonged predicted lifetime. Here, the influence of internal components is discussed using an exemplary setup. It is described how to model and consider the components' absorbencies for lifetime estimation and how beneficial they are during implant operation.

Keywords: Humidity measurement, accelerated aging, lifetime, packaging, implant, hermeticity.

1 Introduction

Contact of mechanical and electronic components and interconnections with humidity and water can lead to corrosion and system failure [1]. Since active implants are often complex systems surrounded by body fluids, one main focus of implant development lies on packaging [2], [3]. The internal relative humidity rh of implant cavities shall be kept as low as possible during operation. Thus, water intrusion resulting from production and operation must be minimized. Measures are hermetic package sealing under protective atmosphere and baking of components to remove absorbed water before assembly to prevent outgasing [1], [4]. Additionally, getter materials can be integrated to absorb intruding water [5], [6].

The reverse process to outgasing is the absorption of intruding water by internal components. They function as reversible getters and decrease the resulting rh in the cavity. This effect is beneficial during operation, but it can lead to an erroneously prolonged predicted lifetime during package testing. Its influence can only be neglected, if the water absorbency of the measurement component is insignificant or if the component is included in the final system as well, prolonging not only the predicted but also the effective lifetime. In this paper, the influence of internal components on the resulting internal rh is discussed by an example implant during testing and operation.

2 Methods

The process of diffusion in isotropic substances is described by the Fickian law [7]. Fick already emphasized that the laws describing the influence of molecular forces on diffusion of dissolved material are analogous to the spreading of warmth in a conductor described by Fourier and applied to electricity by Ohm [8]. Thus, to visualize the processes of water permeation and absorption, the analogy to the voltage charge curve of an electric RC element is used (cp. [9], [10]). The capacitor voltage corresponds to the internal partial pressure of water vapor p_{in} which is described as the product of internal rh and saturated vapor pressure E_w at the respective temperature [11]. The value of p_{in} depends on the external partial pressure p_{ex}, that equals E_W for packages immersed to fluids (cp. [12]), the permeation resistance R_P of the package and the water absorption capacities of the internal components K_W

$$p_{in} = p_{ex}\left(1 - e^{-\frac{t}{R_P \cdot K_W}}\right). \tag{1}$$

The permeation resistance R_P at constant temperature T depends on material and geometry of the package. In analogy to the electric capacity, defined as amount of electric charge q_{el} stored at the applied voltage U, the water absorption capacity K_W is described at constant temperature as the amount of water Q_i absorbed at p_{in}, with the maximum Q_0 at E_W. Q_i can be described as the product of water vapor saturation concentration C_i and respective component volume V_S (cp. [12])

$$K_W = \frac{Q_i}{p_{in}} = \frac{Q_0}{E_W} = \frac{C_i \cdot V_S}{p_{in}}. \tag{2}$$

In material datasheets, the maximum water vapor saturation Q_0 is generally given in percent by weight at room temperature. The water absorption capacity of gases $K_{W\,gas}$ can be derived as

$$K_{W\,gas} = \frac{V_{gas}}{T \cdot R_{S\,water}} \tag{3}$$

using the ideal gas law [11] and the gas volume V_{gas}, temperature T and specific gas constant of water vapour $R_{S\,water} = 461.4 J/(kgK)$ [11]. The applicability of this simplified analogous model was shown in [9] and [13]. While the latter is focusing on the absorption capacity of the package, the focus hereafter lies upon the absorption capacities of the internal components.

***Corresponding author: Liane Koker,** Institute for Automation and Applied Informatics (IAI), Karlsruhe Institute of Technology (KIT), Karlsruhe, Germany, liane.koker@kit.edu
Ulrich Gengenbach, Georg Bretthauer, IAI, KIT, Karlsruhe, Germany

Accelerated aging is performed to predict long-term processes like slow diffusion through the package and aging that cannot be determined by leakage tests. The implant packages are placed into water or body fluid equivalents and the intruding water is monitored. To accelerate aging, the increase of reaction rate k at elevated temperature T is used, that is described by the Arrhenius equation (cp. [15])

$$k = A_F \cdot e^{-\frac{E_A}{R \cdot T}}, \tag{4}$$

depending on factor A_F, activation energy E_A and universal gas constant R. Since there are two unknown parameters E_A and k depending on material and production process of the package, accelerated aging has to be performed at two different elevated temperatures T_1 and T_2 to derive k_{op} at operation temperature T_{op} (cp. [16]). A commonly used method to determine the lifetime of the package regarding hermeticity is to define a failure criterion and measure the mean time to failure (MTTF) [2], [17]. This MTTF is used as constant of the reaction rate. With the described procedure, the measurement is event-based. The experiment is finished as soon as the criterion of failure is fulfilled. The lifetime can be determined only for the packaged system used during measurements. Hereafter, based upon the RC model, the permeation resistance R_P of the package is applied as constant of the reaction rate. It can be described as the reciprocal of the rate of water ingress (cp. [13]). Thus, not only the influence of water absorbing measurement components and their effect on the measured relative humidity of the system are taken into account. Additionally, the determination of R_P at operation temperature enables the determination of lifetime for the final system by replacing the water absorption capacities of the measurement components by the final implant components.

Depending on the setup, the consideration of the internal water absorption capacities K_W can significantly increase the accuracy of the predicted lifetime. Still, the exact determination of K_W is challenging. The most precise quantification can be implemented for gases using eq. (3). Here, the accuracy of K_W is only affected by manufacturing tolerances and inaccuracies in temperature measurements. For internal sensor components, on the contrary, often only an estimation of K_W is possible. The reasons for that is the lack of information regarding volume, material and water absorption of the material, e.g., for commercially available sensors or printed circuit boards (PCB) comprising components with plastic packages or globtop material. This issue is further aggravated for elevated temperatures, since the respective water vapor saturation concentration of a polymer $C_0(T)$ raises with temperature comparably to the reaction rate of the Arrhenius equation [12]. Thus, mostly either only estimations are possible or own water absorption measurement have to be performed.

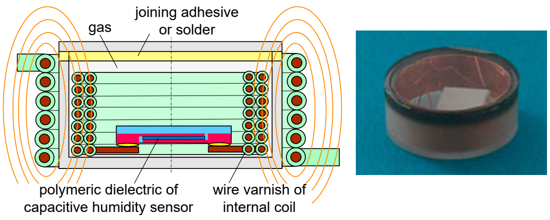

Fig. 1: Measurement setup for package testing. Schematic representation (left) and realization (right).

3 Practical application

To demonstrate the previously discussed influences of components on the internal relative humidity, an example implant is used. The Artificial Accommodation System [18], an active lens implant that shall restore the accommodation ability of the human eye, is packaged by a glass housing. There are different approaches to join the package without applying thermal stress to the internal components, either by locally heated glass or metal solder [19] or adhesive bonding sputtered with a sealing titanium layer on the adhesive area [20]. Since the latter is a multilayer joint, the application of the Arrhenius model for vapor permeation can only give an orientation due to additional failure mechanisms [13]. The adhesive can absorb water. Its absorption capacity K_{W_a} is determined by the joint width of max. 450 µm and height of max. 50 µm. Since C_0 of the adhesive [21] is unknown, a maximum of <3 % is adopted from a UV-curing epoxy adhesive described in [22].

3.1 Measurement setup

With respect to the influence of internal components on the measurement result, the objective of the sensor setup design was to keep the water absorption capacities of the measurement components as small as possible. Thus, comparably large sensors and an internal PCB were avoided. Since the package of the investigated implant has no feedthroughs, a wireless sensor system was chosen to monitor the internal humidity: a capacitive sensor forming a resonant circuit in combination with a transducer coil. A change of rh leads to a change of the dielectric constant of the sensor polymer. The resulting changes of the internal resonance frequency are acquired by measuring the current within an external supply coil. In Fig. 1, the measurement setup is presented indicating the comprised water absorbing elements in schematic representation (left) and in realization (right). The measurement components had to be commercially available, very small, with good signal transmission and as low water absorption capacity as possible. The sensor of choice was the KFS140-MSMD sensor [23]. The air-cored coils were manufactured using metal wires coated with two layers of varnish. For the coil placed inside the package, the smallest possible increment of wire diameter was used according to IEC 60317-0-1, leading to a thickness of 10 µm for the inner insulating polyurethane and 7 µm for the outer thermosetting polyvinylbutyral. At worst case, each thickness has an additional increment of 1 µm due to manufacturing tolerance and a water absorption of <2 % for the thermosetting polymer [24]. For polyurethane, a water absorption of <0.5 % is presumed (cp. [25]). The coil has 55 windings with a wire diameter of 100 µm and coil diameter of 8.4 mm. Detailed information about the electrical characteristics of the setup are given in [26]. In Tab. 1, the water absorption capacities of the different components and the maximum amount of water absorbed by the components at 20 °C (E_W=2335 Pa) are given. The determination of the wire varnish K_W is based upon a worst case estimation, resulting from the maximum water absorption and the maximum volume of the varnish. Aging effects on K_W and surface adsorption are not taken into account.

To illustrate the effect that an internal PCB would have had, additionally K_W and Q_0 are listed for a blank disc of PCB material FR4, water absorbency 0.1 % [27], of 9 mm diameter and a standard thickness of 1 mm. Alternative polymer substrates made of PI [28] or PET [29] have similar or higher magnitudes of K_W. Their significantly smaller thicknesses are compensated by comparably high water absorbencies; and, additionally, PET becomes fragile in high humidity tests [30].

Tab. 1: Water absorption capacity K_W and absorbed water at 20 °C of internal gas, adhesive and measurement components as worst-case estimations. For comparison, additionally the K_W of a blank FR4 PCB is listed.

	K_W **in g/Pa**	Q_0 **in g**
Gas	**$1.5{\cdot}10^{-9}$**	**$3.6{\cdot}10^{-6}$**
Adhesive	**$1.1{\cdot}10^{-8}$**	**$2.5{\cdot}10^{-5}$**
Sensor KFS-140	**$7{,}9{\cdot}10^{-12}$**	**$1{,}8{\cdot}10^{-8}$**
Wire varnish	**$2.3{\cdot}10^{-8}$**	**$5.4{\cdot}10^{-5}$**
Blank FR4 disc	***$5.0{\cdot}10^{-8}$***	***$1.2{\cdot}10^{-4}$***

For the described setup, only K_W of the sensor can be neglected. The neglection of the wire varnish or a PCB would lead to a significant error of the lifetime prediction, since, in analogy to the electrical domain, the time constant τ is determined by $\tau = K_W R_P$. This still applies, even if K_W of the varnish actually amounts to only 50 % of this worst case estimation. In Fig. 2, the resulting p_{in} over time is visualized for the above application. The left diagram shows the package joined by adhesive, the right the soldered package, both integrating either only gas, varnished wires or an FR4 disc. The influence of the package joint adhesive is also significant. Still, this K_W is also present in the final operation setup, so that the only source of error when neglecting this component during the measurement is the temperature-depending difference between measurement and operation. During accelerated aging, τ is determined for each elevated temperature by regression of the measurement curves of internal relative humidity. Now, K_W is used to calculate the two respective permeation resistances R_P. Using eq. (4), R_P at operation temperature T_{op} is calculated. Subsequently, the failure criterion can be defined with respect to the sensitivity of the final implant components to rh (cp. [13]). It is independent of the measurement itself.

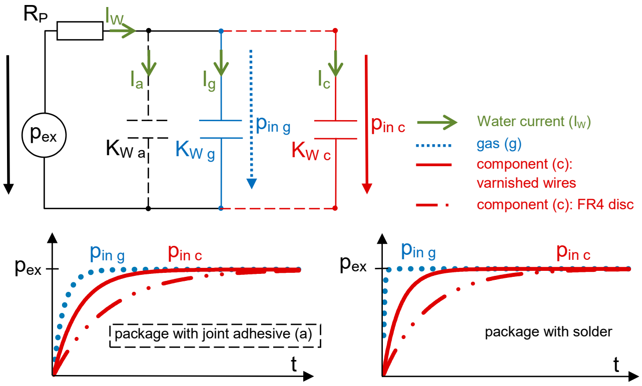

Fig. 2: Vizualisation of influence of K_W of package adhesive K_{W_a}, internal gas K_{W_g} and components K_{W_c} like wire varnish or FR4 PCB on resulting measured partial pressure of water p_{in} over time using an RC-model in analogy to the electrical domain.

3.2 Implant setup during operation

Now, the water absorption capacities K_W of the final components at T_{op} are estimated and used to determine the system's lifetime. In contrast to the measurement, high absorption capacities are desirable here, since they function as getter and extend the system lifetime. As a prerequisite, of course, the components have to be properly pre-dried before being assembled. Exemplarily, a lifetime estimation is performed for the Artificial Accommodation System at three different scenarios: firstly, an empty gas-filled package; secondly, with an integrated PMMA AH-lens system (cp. Fig. 3 and [31]) of 3.4 mm thickness, a mass of 50.3 mg and a weight related water absorbency of 2 % [32]. The third scenario is the idealized best case regarding water absorbency, a complete polymer casting of the cylindrical ring around the optical element without com-

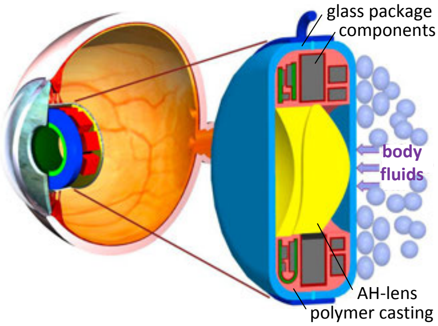

Fig. 3: Schematic drawing of the Artificial Accommodation System placed within the human eye and comprising internal components.

ponents. For the latter, a weight related water absorbency of 3 % is applied. There are casting materials with higher absorbency available, but the resulting swelling would introduce too high mechanical strain in the system. In Tab. 2 the K_W of the considered implant components are listed. The lifetime is estimated using two different failure criteria. Firstly, the prevention of liquid water during operation. This is achieved by keeping rh below 70 % rh at T_{op} of 35 °C, which complies with 100 % rh at minimum implant temperature in the eye at -20 °C outdoor temperature [9]. The second is the commonly used criterion of 5000 ppm in the gas to prevent the formation of liquid water at any temperature [1]. The results in Tab. 2 are based upon the mean R_p of $2.96 \cdot 10^{11}$ hrs·Pa/g at T_{op} determined for the package joined with coated adhesive.

Tab. 2: Estimated lifetime t_{lt} based upon mean measured R_P and $K_{W\,C}$ of components comprised in final system at T_{op} 35 ℃

	Gas	**AH-lens**	**Casting**
$K_{W\,a}$ **in g/Pa**	**$8.8 \cdot 10^{-9}$**		
$K_{W\,c}$ **in g/Pa**	**$1.58 \cdot 10^{-9}$**	**$1.75 \cdot 10^{-7}$**	**$8.3 \cdot 10^{-7}$**
t_{lt} **in yrs, 70 % rh, 35 ℃**	**0.2**	**7**	**34**
t_{lt} **in yrs, 5000 ppm**	**0.04**	**0.7**	**3**

4 Conclusion

It was demonstrated that the water absorbency of internal components of a miniature package, like used for active implants, have a significant influence on the internal relative humidity. This phenomenon can be used to prolong the lifetime during operation. For package testing, on the other hand, these influences are rather undesirable. Their neglection can lead to erroneously prolonged predicted lifetimes. By means of an exemplary implant and measurement setup, it was illustrated that even small volumes of polymer like wire varnish have a considerable influence. Even though this effect on lifetime can mostly be compensated by the water absorption of the final implant components, the influence must be considered to keep measurement results comparable. Based upon the knowledge of the absorption capacities of measurement components and final implant components and the use of the permeation resistance to characterize the package hermeticity in accelerated aging tests, a more exact estimation of the final implant lifetime is possible. The limitation, so far, is the inaccuracy of the knowledge of the water absorption capacities of measurement components. Thus, volumetric parts with unknown material parameters should be avoided as far as possible.

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Author Statement

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References

[1] Greenhouse H, Lowry R, Romenesko B. Water in Sealed Packages. In: Hermeticity of Electronic Packages, Elsevier; 2012:243-288.
[2] Ko W, Wang P, Lachhman S. System integration and packaging. In: Bhunia S, Majerus S, Sawan M. Implantable Biomedical Microsystems. Elsevier; 2015: 113-36
[3] Jiang G, Zhou DD. Technology Advances and Challenges in Hermetic Packaging for Implantable Medical Devices. Biol Med Phys Biomed Eng–Impl Neur Prosth 2010; 2: 27-61.
[4] Schuettler M, Schatz A, Ordonez JS, Stieglitz T. Ensuring minimal humidity levels in hermetic implant housings. IEMBS 2011: 2296-9.
[5] Vacca P. Functional chemicals for advanced packaging in printed electronics. LOPEC 2018.
[6] Sparks D, Massoud-Ansari S, Najafi N. Reliable vacuum packaging using NanoGetters and glass frit bonding. Proc. SPIE 5343, Reliab, Testing, Charact MEMS/MOEMS III 2003.
[7] Crank J. The Mathematics of Diffusion. Oxford Univ. Press; 1975.
[8] Fick A. Ueber Diffusion. Ann Phys Chem 1855; 94: 59-86.
[9] Rheinschmitt L. Erstmaliger Gesamtentwurf und Realisierung der Systemintegration für das Künstliche Akkommodationssystem. PhD thesis KIT scientifc publishing; 2012.
[10] Dahan N, Vanhoestenberghe A, Donaldson N. Moisture ingress into packages with walls of varying thickness and/or properties: A simple calculation method. IEEE Trans. Comp., Pack. Manuf Techn 2012; 11: 1796-1801.
[11] Dammel F, Ochterbeck JM, Stephan, P. Thermodynamics. In: Grote KH, Antonsson EK ed. Handb of Mech Eng, Springer; 2009: 223-293.
[12] Jouwersma C. Die Diffusion von Wasser in Kunststoff. Chem–Ing–Techn. 1959; 10.
[13] Vanhoestenberghe A, Donaldson N. Corrosion of silicon integrated circuits and lifetime predictions in implantable electronic devices. J Neural Eng 2013; 10(3): 1:13. Jun;. doi: 10.1088/1741-2560/10/3/031002. Epub 2013 May 20.
[14] Kumar AH, Ozmat B, ed. Tummala RR, Rymaszewski EJ. Microelectronics Packaging Handbook. Van Nostrand Reinhold; 1989.
[15] Arrhenius S. Quantitative laws in biological chemistry. G. Bell; 1915.
[16] Herrlich S, Schuettler M, Wilde J, Stieglitz T. A Miniaturized Hermetic Package for Neuroprosthetic Implants. BMT. 2007.
[17] Harpster TJ, Nikles SA, Dokmeci MR, Najafi K. Long–Term Hermeticity and Biological Performance of Anodically Bonded Glass-Silicon Implantable Packages. IEEE Trans. Device Mater. Rel 2005; 5(3).
[18] Bretthauer G, Gengenbach U, Nagel JA, Beck C, Fliedner J, Koker L, et al. Current progress of the Artificial Accommodation System. KliMo Augenh 2014; 231(12): 1174-82.
[19] Rheinschmitt L, Burkhardt T, Nagel JA, Beckert E, Gengenbach U, Bretthauer G. Investigation of the use of Solderjet Bumping for joining the thin-walled glass package of a complex mechatronic lens implant. BMT 2012; Suppl 1: 863-866.
[20] Rheinschmitt L, Hahn L, Leiste H, Gengenbach U, Bretthauer G. Low temperature production process for hermetic transparent implant packages. BMT 2012; 57 Suppl 1: 180.
[21] Epoxy Technologies. Custom Formulation Data Sheet 354–T. Nr. 23 Rev. A.
[22] Eyerer P, Elsner P, Hirth T, ed. Domininghaus H. Kunststoffe u. ihre Eigenschaften. Springer 2005.
[23] Hygrosens Instruments GmbH. Capac. SMD humidity sensor KFS140-MSMD 2007; datasheet.
[24] Heermann GmbH. Backlackdraehte 0,03 – 0,90 mm 2007. datasheet.
[25] Amsler and Frey AG. Polyurethan 2003. datasheet, ed. 7.6.1.
[26] Koker L, Nagel J, Ritter F, Schulz B, Vollmannshauser S, Gengenbach U et al. Automation of the Test Procedure for Accelerated Aging of Implant Packages. at 2016; 64(10).
[27] Farnell. FR4 datasheet. https://www.farnell.com/datasheets/1644697.pdf. downl 23.03.2018.
[28] Pahl B, Loeher T, Burkard H, Link J, Petersen A, Aschenbrenner R. Flex Technology for Foldable Medical Flip Chip Devices. IMAPS Conf Dev Pack. 2008.
[29] Gengenbach U, Ungerer M, Aytac E, Koker L, Reichert KM et al. An Integrated Workflow to Automatically Fabricate Flexible Electronics by Functional Printing and SMT Component Mounting. IEEE CASE 2018, *accepted*.
[30] Lahokallio S, Saarinen K, Frisk L. Changes in water absorption and modulus of elasticity of flexible printed circuit board materials in high humidity testing. Europ Microel Pack Conf 2011: 1-6.
[31] Rheinschmitt L, Sieber I, Gengenbach U, Bretthauer G. Comparison of different approaches for the packaging of the Artificial Accommodation System. Smart Systems Integr 2009: 504-507.
[32] Kern GmbH, Technische Kunststoffteile. Datasheet PMMA. downl 22.02.2018.