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Heat Resistant Electronic Modules for Intelligent Medical Sterile Containers

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Abstract

The digitalisation gets more and more important in our daily life. Also in medical technology instruments and devices need to become intelligent and be able to both collect and provide additional data. This research is about the development of an electronic sensor system for sterilisable medical containers. Hereby just a few concepts exist to equip the containers with sensor modules but the high temperature of 135 °C during the sterilisation is still a big challenge.

The objective for this research is to find a heat resistant insulation for an electronic system with a power supply, sensors for both sterilisation and transport and a low power communication module. Furthermore, the thermal energy of the sterilisation shall be used for powering up the system.

In a first step an epoxy resin was used to insulate the electronics and a high temperature battery. By using the temperature sensor of a Bluetooth module the module temperature could be measured during multiple steam sterilisations. Following, a partly insulated thermoelectric generator shall be used to get energy by the achieved temperature difference.

First results show that the used epoxy resin limits the temperature to 81 °C. However, the resin was damaged after 21 sterilisation cycles due to its high mass and entrapped air. Therefore, the insulation needs to be minimized and the electronic components need to be able withstanding higher temperatures. Additionally, insulations with not yet considered materials will be tested. Also the possibility of insulating just heat-sensitive parts like the power elements will be investigated.

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1 Introduction

Over the last few years the digitalisation became more and more a part of our daily life. For industry and consumer market the communication between different devices and machines is already well established. However, in medical technology this change is still in its infancy. But especially in hospitals a communication between the internal infrastructure and the medical devices would be able to decrease the costs and increase the efficiency (Hanada, Ohira, Hayashi, Sawa, 2015).

Beside medical devices like instruments also medical sterile containers can be equipped with electronic components to store data. Hereby it would be possible to get additional information about the container inventory without opening it. Furthermore, a tracking of the position can increase the efficiency and ease the asset management in a hospital (Hanada, Hayashi, Ohira, 2015). Beside the possibility of tracking, the new generation of intelligent medical containers could be equipped with different sensors to get data from sterilisation cycles and control the transport between hospitals and central sterile service departments.

However, for implementing identification labels or sensor modules, the electronics need to withstand multiple steam sterilisations with maximum 135 °C and 3 bar of steam pressure. Especially for the use of batteries a thermal insulation is necessary to prevent a significant capacity loss (Feng et al., 2014) or in the special case of lithium-ion to avoid the danger of causing a fire (Wang et al., 2012). To test the insulation a high number of sterilisation cycles need to be performed (George, Compagno, Waldron, Barrett, 2012). The objective of this research is to find a thermal insulation for a sensor system with a primary battery and a communication module.

2 Materials and Methods

One approach for the tracking and identification of medical sterile containers is the use of radio-frequency identification (RFID) labels. These labels can withstand multiple sterilisation cycles and are also able to store additional data. The system range can be from contact to several meters. To measure sterilisation parameters like temperature, pressure and time, different sensors are needed.

For controlling the transport of the containers, it is important to capture drops, shocks or rollovers with low power sensors. The captured data has to be stored and transmitted to an external device. For the development of such a sterilisable sensor module several problems need to be solved. During the steam sterilisation in an autoclave a maximum temperature of 135 °C is reached, which is difficult to handle for most electronic components. Additionally, electronic circuits must be protected from the steam during the procedure. Furthermore, the module needs to withstand multiple sterilisation cycles over a couple months. Therefore, the chosen insulation should have a long durability to prevent system failures.

To get a battery life as long as possible a thermoelectric generator (TEG) shall be implemented to power the sensor system during the sterilisation procedure. These generators are able to convert a temperature difference into usable electric energy by the so called Seebeck effect. To get this temperature difference the TEG needs to be partly insulated.

The first approach was to test a custom mixed epoxy resin with an amine-adduct hardener for high temperatures. To measure the temperature inside the thermal insulation the Bluetooth module “cB-OLP425i-16” by u-blox with an on-board temperature sensor was used. This module is able to withstand a storage temperature of 125 °C and an operation temperature of 85 °C. For providing the needed power, the Lithium Thionyl Chloride battery “SL-560” by Tadiran, able to withstand up to 130 °C, was used. The Bluetooth module and the battery were connected by a simple circuit board.

First tests were made with the maximum possible insulation volume of approximately 375 cm3 in the container. For comparing the inner temperature with the environmental conditions during the sterilisation, a temperature- and pressure data logger of the EBI 10 series by ebro was placed in an open medical sterile container with the insulated test module.

3 Results

After the first sterilisation cycles the results seemed to be quite promising, because the maximum temperature captured by the insulated sensor did not exceed 81 °C. Furthermore, a temperature difference up to 95 °C was detected. Results were shown in Figure 1.

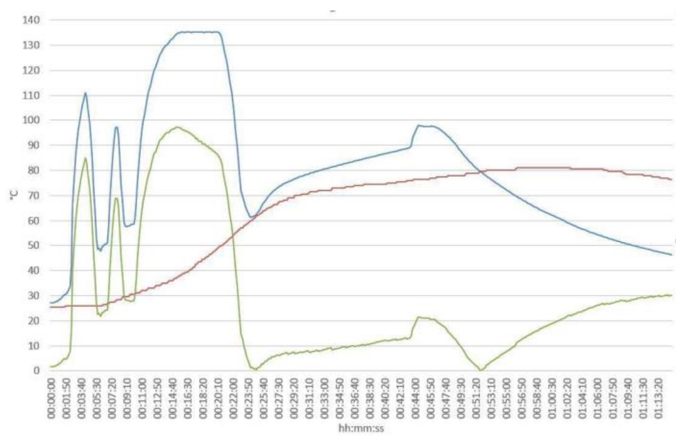

Figure 1: Temperature measurement (blue: container sensor; red: insulated sensor; green: difference).

Although the results of the temperature measurement would fit the requirements the resin was damaged after 21 sterilisation cycles. A comparison of the module before and after sterilisation is shown in Figure 2.

Figure 2: Insulated module before use (left); Damaged epoxy resin after 21 sterilisation cycles (right).

This damage was caused on the one hand by entrapped air during the socketing procedure and on the other hand by the high mass of the resin block. The different expansion coefficient caused a significant internal pressure, leading to the shown damage.

4 Discussion

The results show that the used insulation is able to significantly reduce the inner temperature for the electronic systems. However, it needs to be investigated if the damage of the epoxy resin can be prevented for example by reducing the insulation thickness. For further development, high temperature sensors and microcontroller need to be chosen and tested. Additionally, different insulation materials will be tested.

To reduce the size and cost of the sensor module it also needs to be investigated if just the heat-sensitive components like the power elements need to be insulated. For this several tests in different setups will follow in the sterilisation test laboratory.

For collecting data from sterilisation processes with wireless sensor modules some approaches were already tested (Sisinni, Depari, Flammini, 2016). Also, systems implementable into medical sterile container were designed (Childers et al., 2015). However, these approaches do not consider the possibility of using thermoelectric power generators for supplying the module.

Additionally, important data about the transport conditions cannot be captured. The research of the efficiency and usability of different insulation materials needs to be investigated to develop a sensor module for the first generation of intelligent medical containers.

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