FIELD OF SCIENCE: ENGINEERING AND TECHNOLOGY

SCIENTIFIC DISCIPLINE: AUTOMATION, ELECTRONIC, ELECTRICAL ENGINEERING AND SPACE TECHNOLOGIES

SELF REPORT OF DOCTORAL THESIS

Powering Medical Internet of Things Systems in a Steam Sterilisation Environment

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Research Aims

The main research objective of the study was to answer the following questions related to the topic of powering the medical Internet of Things in the context of sterilisable medical containers and surgical instruments. The main research question was:

Is it possible to provide a reliable power source for sensors in smart surgical tools during steam sterilisation?

This research question was divided into the following subquestions that have been formulated in the process of developing possible solutions:

RQ1: What are the possibilities of powering low-power electronics in the steam sterilization environment?

RQ2: Is it possible to design a maintenance-free power solution for sterilizable medical tools using energy harvesting solutions, what are the design constraints?

RQ3: What is the energy balance of the proposed design, what are the main constraints and possibilities for size optimization?

RQ4: What are the limitations in terms of sensor design related to power consumption?

In addition, as the PhD thesis have been developed within the industrial cooperation with the company B.Braun Aesculap AG a set of industrial constraints had to be taken under consideration:

IC1: Applicability in mass production,

IC2: Robustness of the design,

IC3: Maintenance-free nature of the target solution,

IC4: Compatibility with the concept of the Internet of Medical Things (IoMT) system.

1. Introduction

The concept of hospitals equipped with sensor networks, able to track assets, surgical tools and devices (so called smart hospital) has been in focus for many years. The idea itself promises a lot of benefits including cost reduction, data-driven predictive maintenance, and better, more accurate, automated documentation tracking. From the medical industry point of view, it opens one more opportunity which is especially in the spot - the possibility of creating new business models based on usage statistics.

However, there are still very few attempts to develop this technology and put it into the mass market. One of the key limitation factors is the problem of powering the sensors and tracking electronics embedded in the surgical container. Each surgical container, visible in Fig. 1, needs to undergo sterilization before being used in the operation room. The most popular sterilization method is steam sterilization, where surgical products placed in the autoclave are exposed to an environment with temperature up to 140°C and pressures from -1 to 2 bars for at least 15 minutes. This excludes using regular batteries as a power source for the electronic sensor and the market research performed by the author resulted in very few possible candidates with limitations related to usability and performance (The only available high-temperature rechargeable battery on the market - Tadiran TLI-1550HT).

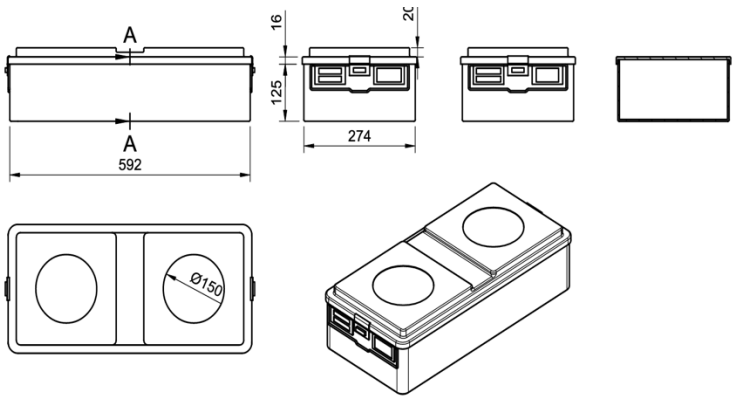


Fig. 1. Example of surgical container which is vastly used in hospitals; container sizes might vary, however, the general design principle is similar among different manufacturers.

2. Energy harvesting device idea and research concept

In thermal energy harvesting, the device of choice is the thermoelectric generator presented in figure 2. It is a solid-state device that produces electrical energy from the thermal gradient across the device. TEGs are usually built from TE elements. The TE element is composed of a pair of p-type and n-type semiconductors connected in series with a copper connector, while being placed between two ceramic plates in a form of a sandwich. This structure forms the so-called TE pair which is connected electrically in series and thermally in parallel. The fundamental principle of TEGs is based on thermoelectric effect that can be described as direct conversion of temperature differences to electric voltage and vice versa via a thermocouple. To generate power, thermoelectric generators require a thermal gradient across, so one side of the TEG can be referred to as a cold side and the other side as a hot side. However, in case of steam sterilization, it is necessary to design a special container for the TEG to force the creation of thermal gradients across the TEG.

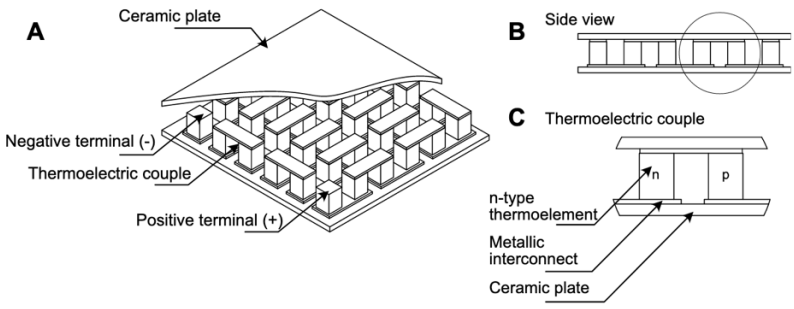


Fig. 2. Schematic overview of the design of the thermoelectric generator.

The main idea, shown in the figure 4, was to use a thermally isolated heat storage unit made of steel and attach it to one side of the TEG, whereas the other side has been attached to the metal casing of the prototype. Such a design ensured the heat flow from outside, through the TEG into the HSU. During this flow, part of the thermal energy is converted into electrical energy. The same mechanism works after the whole sterilization procedure, when the whole module is taken outside of the steam sterilization, but the heat flow is in the opposite direction, from inside to outside, again causing electrical energy production.

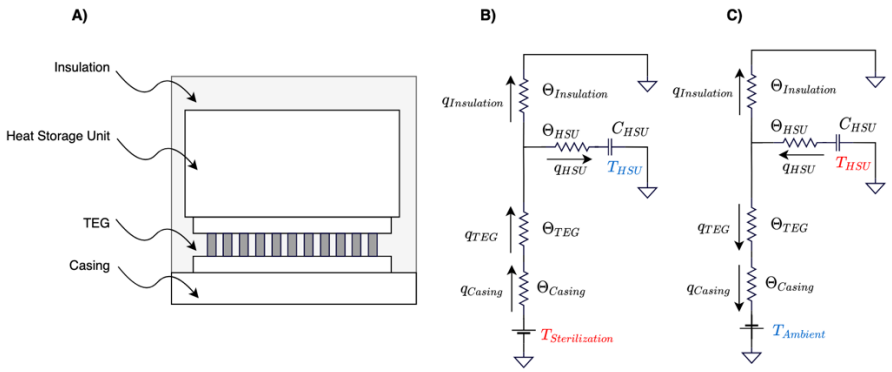


Fig. 4. The general idea of the energy harvesting module and its representation as a SPICE model, where the current represents the heat flow and the voltage represents the temperature of given construction elements. A) - schematic drawing of the prototype construction, B) heat transfer while steam sterilization (heat transfers toward HSU), C) heat transfer after the steam sterilization (heat transfers from the HSU to outside of the prototype)

The whole research had four phases:

1. Initial design, construction of the physical model, and parametrization of the material of the digital model of the device
2. Development of the SPICE model of the TEG and it's validation
3. Optimization of the energy consumption of the sensor module
4. Adjustment of the virtual model to optimize its size
5. Perform a set of simulations to achieve minimal size that meets the power requirements of the sensor module.

3. Physical Model of the Device

A physical model of the device was created and its schematics is shown in the Figure 3. It was assembled from aluminium casing (resistant to high pressure, but still with great heat conductivity and relatively low weight. Inside the casing a TEG Ferrotec Nord TEG-127-0.6-1.6 has been placed and glued to the casing with thermal grease. On the other side of the TEG a steel HSU has been attached. The remaining space has been filled with Active Aerogel foam to provide mechanical stability with good thermal insulation.

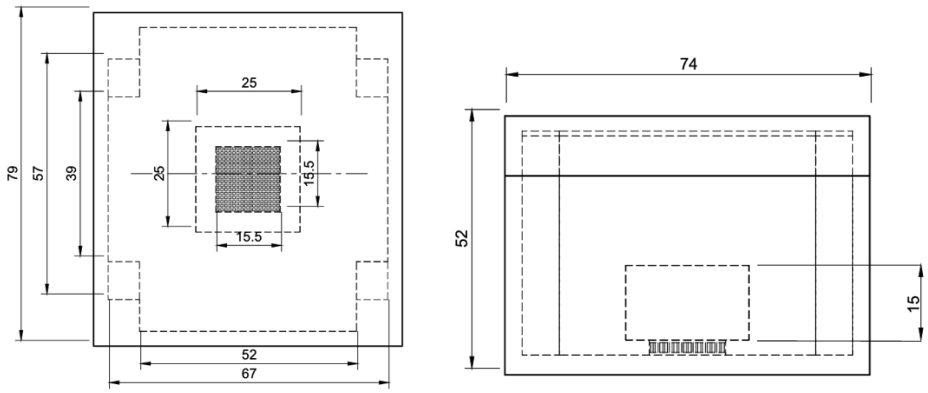


Fig. 3 Schematics of the physical model of the device constructed for the initial proof of concept and the parameterization of materials needed for further simulations and optimizations.

4. Virtual Model of the Device

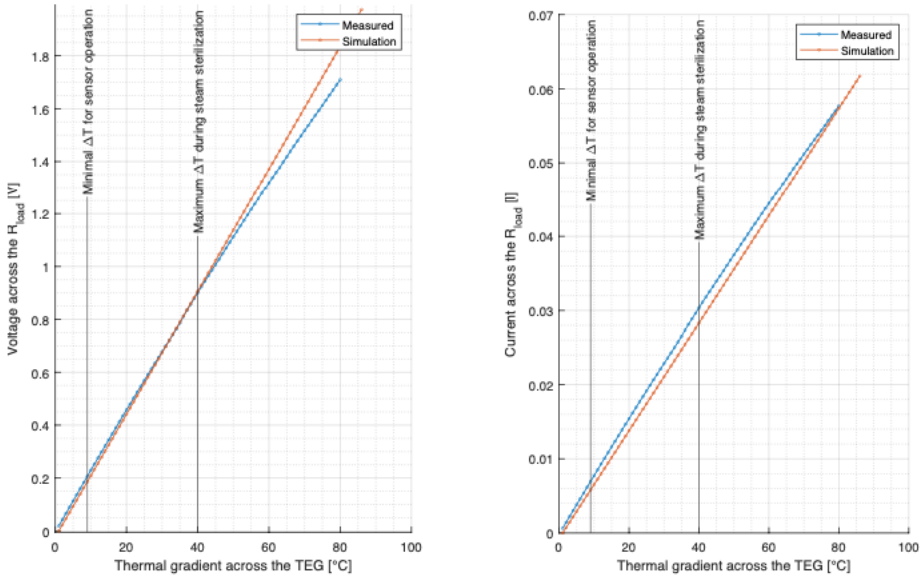
Based on the physical model, a virtual model of the device has been created using CAD software. The CAD model then was then parametrized using material parameters listed in the table below.

This was done using pre-selected tabular values of material parameters and validating the heat distribution in comparison to the physical device by measuring its thermal step response and comparing it with the simulations performed in FEM software SimScale. The accuracy of the simulation with an error being within measurement error of physical prototype response.

The power generated by the TEG initially varied throughout the steam sterilization cycle. It exceeded the initial design requirements of constant generated power for sensor electronics. However, the size of the physical model and the power efficiency of the sensor itself were not satisfactory, and in both cases there was space for improvements and optimization.

4.1 Virtual model of the TEG

A review of the TEG modelling has been done and a SPICE-based modelling technique has been selected. To perform this a several different SPICE models of thermoelectric generators have been reviewed and the Kubov model has been selected. This was due to it's simplicity and the fact that it can be easily populated with the data taken from the TEG manufacturers which has a significant importance in the industrial context. The model have been parametrized and was evaluated with the parameters from the evaluation of a real device. The evaluation of the real device has been performed on the heating-cooling test stand to induce appropriate thermal gradients across the TEG. The model validation results are shown in the Fig. 6. The validation procedure involved applying the resistive load equal to the TEG internal resistance.



(a) Output voltage V_{out} of the TEG as a function of thermal gradient

(b) Output current I_{out} of the TEG as a function of thermal gradient

Fig. 6: The validation results of the Kubov TEG model used in creation of TEG virtual model.

5. Optimizations

Although the power requirements in the first embodiment of the device have been fulfilled, it was necessary to reduce its size and weight as much as possible due to the functional requirements of the industrial partner. The problem was addressed from two different perspectives, from one side the power consumption of the sensor had to be limited. On the other hand, the dimensions of the device had to be reduced.

5.1. Power Consumption Optimizations

The optimizations of power consumption involved software optimizations of the RF430FRL152H chip. For the need of the power optimizations an initial requirement has been set to reduce the data acquisition intervals, further optimizations involved using low power modes of the chip. In the second step of the optimizations, special attention has been paid to the IC peripherals – all peripherals that had no direct involvement with the temperature measurement had been turned off or turned into deep sleep mode. Finally, the program was optimized using Texas Instruments Ultra-Low Power Advisor technology. All measurements have been made using TI EnergyTrace technology and direct measurements using the Agilent 34410A laboratory multimeter and have been validated with the precise current measurement tool CurrentRanger. As a result of the optimizations, the average energy consumption of the module dropped from 1.674 mW to 0.353 mW Having established minimal power requirements for a given sensor module, it was possible to move to the second step – optimize the module size so the minimal power requirements are met.

5.2. Module Design Optimizations

Module design optimizations had been performed using a virtual simulation environment in SimScale software. The optimization process has been performed as follows:

1. A set of 3D CAD models had been developed in PTC Creo software.
2. CAD models had been prepared for FEM simulations by applying the CAD cleaning procedure.
3. The appropriate mesh type had been selected.
4. Preliminary mesh creation had been performed.
5. Mesh underwent an evaluation procedure.
6. Critical areas of the model (sharp edges, small parts) had been adjusted by increasing the mesh density.

In general, a set of different mechanical models had been analyzed that differed in the size of the HSU and the thickness of the thermal insulation - the two most space-consuming elements of the prototype. Mesh adjustation had been performed by reducing the global and local element size, mesh adjustment, and local mesh refinement. After the mesh was set up, a numerical setup and simulation run setup had been performed to ensure a proper simulation process. As a boundary condition, a steam sterilization temperature curve has been set. The initial assumption has been made that the temperature on the surface of the instruments inside the autoclave chamber needs to be equal to the standard EN-285+A1:2021. The results evaluation procedure involved temperature readout on each element of the module. Then a gradient across the TEG was calculated during the whole simulated steam sterilization cycle. As a result of thermal simulation, a thermal gradient curve has been acquired. This thermal gradient has been provided as an input to the TEG virtual model to simulate the power generation during the steam sterilization procedure. The load attached to the TEG model was equal to the TEG internal resistance. This procedure has been repeated for different sizes of insulation and heat storage unit. After obtaining power generated by the TEG the simulation of sensor energy consumption could be performed. This simulation involved a sensor working without so called “low power mode” enabled (active mode simulation) and with “low power mode” enabled (passive simulation). The simulations involved also a scenario with energy storage system (like supercapacitor) and without energy storage system – when the sensor was powered directly from the TEG module.

6. Results

The examples of the results are shown in the Fig. 8 and Fig. 9. Figure 8 presents a scenario with low power mode and without the energy storage system attached, while Fig. 9 presents the scenario without the low power modes and with energy storage system.

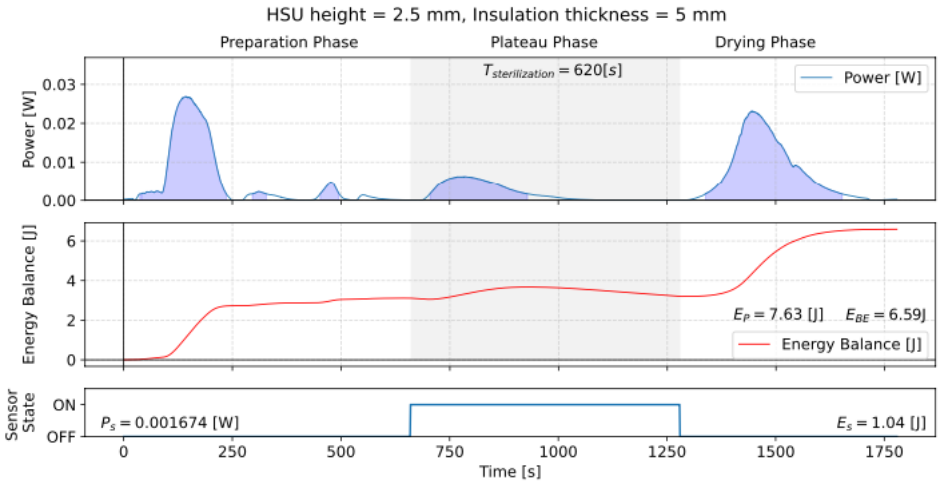


Fig. 8: Generated power and energy balance during the preparation phase, plateau phase and drying phase of the steam sterilization procedure for a HSU of height 2.5 mm and insulation thickness of 5 mm. The sensor is turned on for the surveillance of sterilization phase, while remaining inactive in the preparation and drying phase.

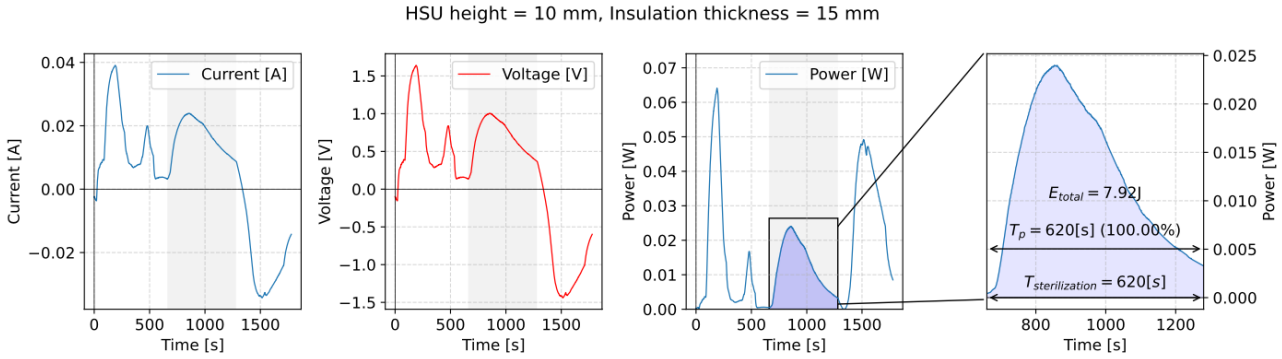


Fig. 9: Current, voltage, and power generated through the steam sterilization procedure assuming no energy storage system connected. The power generated through the plateau phase which exceeds the minimum level for sensor operation is marked in blue.

7. Summary

As a result of this PhD thesis, following research questions (RQ) stated have been addressed and answered (RA):

RQ1: What are the possibilities of powering the low power electronics in the steam sterilization chamber using energy storage devices?

RA1: The options for powering medical IoT devices that are subject to steam sterilisation are limited. Three groups of solutions can be distinguished. The first is based on primary high-temperature cells. However, it is characterised by a relatively high cell unit price and the need for regular battery replacement, which is unacceptable for maintenance-free IoMT devices. The second solution can be the use of secondary electrochemical energy storage - lithium-ion batteries, supercapacitors, and hybrid capacitors. In this case, however, the need for regular recharging of the ESS must be considered. In addition, there are serious limitations to the use of ESS devices due to their thermal behaviour at elevated temperatures. These include accelerated ageing, increased internal resistance, increased degradation of the separator layer in secondary batteries and electrolyte degradation. In particular cases, this can lead to the exothermic chain reaction known as thermal runaway, which in the case of lithium-ion secondary cells can cause massive heat generation and explosion.

Another factor that negatively affects the use of this solution is the very low availability of high temperature ESS solutions, which comes at a high price. There are individual technologies on the market that are designed for elevated temperatures, but the cost of such devices is significantly high, the certification process can be challenging, and the design process is highly dependent on the manufacturer, which can lead to supply chain issues.

RQ2: Is it possible to design a maintenance-free power solution for sterilizable medical tools using energy harvesting solutions, what are the constraints of the design?

RA2: The use of energy harvesting and the recovery of electricity from the heat of the steam sterilisation process seems particularly desirable for low-power electronic devices. The energy harvesting system can thus directly power the device during sterilisation or charge a high temperature ESS. The disadvantage is certainly the relatively high initial cost of such solutions, but in the long run this solution can be economical due to its simplicity, reliability and maintenance-free operation. However, there are limitations to the design of such a solution. Firstly, it is necessary to create a thermal gradient across the TEG using a thermally insulated heat storage device. The dimensions and thermal capacity of this device must be matched to the desired working environment. Secondly, the selection of the TEG itself can be challenging as it needs to combine high energy efficiency with appropriate thermal conductivity and low hysteresis.

RQ3 What is the energy balance of the proposed design, what are the main constraints and possibilities for size optimization?

RA3: The proposed design is composed of the TMG-128-1.6-0.4 thermoelectric generator, which can produce up to 11 mW of power on average in the design with 20 mm high HSU and 20 mm insulation. The power consumption of the RF430FRL152H chip varies from 0.353 mW to 1.674 mW including safety margins and considering the low power efficiency of the boost converter circuit. As can be seen, the power produced by the energy harvesting module exceeds the chip's requirements by many times. However, it is worth considering the use of other technologies such as Bluetooth low energy, which has much higher power requirements. However, there are some limitations in the design. The main constraint is the steam sterilisation process itself and the temperature variability inside the autoclave. The whole design must be adapted to the need to create a thermal gradient across the TEG. Using the TMG-128-1.6-0.4 TEG and the RF430 chip, it was possible to limit the size of the HSU to 7.5 mm in height and the thickness of the aerogel insulation to 5 mm and to provide sufficient power to the chip for over 95 % of the steam sterilisation plateau phase time.

RQ4 What are the limitations in terms of sensor design related to power consumption?

RA4: In the case of sensor design constraints, the lowest possible power consumption and a flexible supply voltage range are of primary importance. In the case of the steam sterilisation process, the sensor should be able to operate continuously without the use of additional energy storage. This means that its power requirement should not exceed 0.353 mW. These types of sensors are systems with passive data transmission via the NFC protocol, where the energy required to read the information is taken from the reader. In the case of sensors with active data transmission - for example, devices based on the Bluetooth Low Energy protocol - despite the very low energy consumption for the transmission of data packets, a relatively rapid consumption of the energy generated during sterilisation should be expected.

8. Original Input

The following objectives were achieved within the scope of the work which are original achievements of the author:

1. The feasibility of powering medical internet of things sensors in a steam sterilisation environment was analysed,

2. Defined the requirements for sensors operating in a steam sterilisation environment and performed a market review of available solutions, then selected the optimal sensor model and optimised its power consumption for energy harvesting from the temperature prevailing in the autoclave during sterilisation,

3. The concept of an energy harvesting module using aerogel insulation to power the sensor was developed and then its physical model was constructed,

4. The physical model of the energy harvesting module was parameterised and its digital twin was built for simulation purposes,

5. A simulation methodology was proposed using FEM and the SPICE environment,

6. The selected thermo-generator module was parameterised and simulated in a steam sterilisation environment,

7. Potential scenarios for powering the IoMT sensor in a steam sterilisation environment are defined,

8. Optimisation of the size of the energy harvesting module in terms of size, while maintaining the mini- mum required power generation was carried out,

9. Filing of a number of patent applications related to thesubject matter addressed, in particular application WO2021148450A1 relating directly to the thesis.