LIFETIME MANAGEMENT SYSTEMS FOR MEDICAL DEVICES Specific Methods for Life Extension of Equipment and Systems in Medical Devices

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This position paper describes research activities in the scope of targeted lifetime extension of components Abstract: which are used in medical devices and high energy physics. The considered medical areas are in the diagnostics and the therapy field. The focus of the analysis of medical machines and systems with highpower tubes is on the x-ray-radiation or rf-power performance. On this occasion, the operational behaviour of such tubes is of special interest. In this paper a methodology will be presented to examine the specific influence of service life-determining parameters. For the implementation of the methodology a discrete event simulation is constructed using the realtime design tool MLDesigner from MLDesign Technologies, Inc. With the help of different example tubes in the form of workable specifications the mean physical behaviour is copied. The base specification is extended by additional functions for special types of tubes. Therefore, studies can be carried out with regard to the tube service life in different components. The simulation shows that the targeted specific influence on the service life-determining parameters can prolong useful service life of a high power tube.

INTRODUCTION 1

As part of research work at the Computer Architecture Group of the Technical University (Technische-Universität-Ilmenau) Ilmenau the default behavior of high-power tubes used in medical equipment is investigated. The focus of this research work aims to develop new business and application models for service life extension of equipment in medical technology. To develop appropriate additional sensors and condition monitoring concepts, it is especially necessary to provide a detailed look at the life-defining parameters. With the help of modeling a realtime discrete theoretical event simulation. the assumptions of the research work, meaning that by means of a targeted control of service lifedetermining the parameters, the whole useful service life of high power tubes can be extended essentially, will be investigated. The expected outcome of this investigation is the consolidation of the theoretical assumptions by means of an appropriate physical experiment with the implementation of all required

information about the tube specific life-defining parameters.

Functions in a medical system (eg radiotherapy equipment, particle therapy, computed tomography, mammography and angiography equipment) use for diagnosis or treatment high-power tubes such as klystrons, magnetrons, thyratrons, x-ray tubes, and linear accelerators. The flow of diagnostic and therapeutic applications is to be modeled and investigated by means of a simulation. An investigation of the relationship between the loadprofile of a system and the service life of a tube used in that system is possible.

Partial of models for hardware and software of the control system as well as of the electronic and electromechanical components are necessary. Exemplary models of high tubes are established and inserted into the simulation system. Partial models are to be interchangeable for use in simulations for different application fields.

It is necessary to establish a basic tube model for the simulation tool MLDesigner (MLDesign Technologies, Inc. 2007), as well as the implementation of predefined algorithms and

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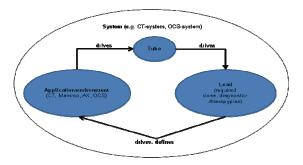


Figure 1: MLDesigner simulation structure overview.

methods for evaluation of the tube-data (Heuermann, 2006).

The structure of the model is done in several phases. The first priority is the development of a basic tube, complying with a typical x-ray tube, just the way it is used in most cases in practice. Based on these results of the modeled tube, an optimized design is created, in which the predetermined factors affecting service life-determining parameters are changed selectively. By a direct comparison of the two models, with and without optimization, a very accurate statement on the expected life of such a tube is possible (Wippler, 2007, Krestel, 1988).

2 BACKGROUND

The life of vacuum tubes, used to produce radiation (reception, screening, treatment and therapy) in the medical technology, is determined to a large extent by the emission of the cathode. In all type of tubes, directly as well as indirectly heated cathodes, and "cold" emitting cathodes, during the period of usability a reduction of the electron emitting material can be noticed (eg filament evaporation rate and barium evaporation rate). Some of the service life-determining parameters for the vacuum tubes used in medical technology are as follows:

x-ray/carbon nano tubes:

• anode roughening, anode heat capacity, filament evaporation rate, scan-seconds load (load profile), temperature, timing, arcing

They have a finite, but not in all applications reliably predictable service life and must be replaced by the facility to ensure availability.

RF-components:

 cathode roughening, barium evaporation rate, beam-seconds load (load profile), temperature, gascomposition/vacuum quality, ion back-bombardement, timing, arcing They have a finite, but unpredictable service life and must be replaced at short notice by the facility to ensure availability (Heuermann, 2010).

In the field of x-ray tubes, there are procedures for lifetime prediction known, e.g. used in high resolution CT-systems. The analysis of input vectors, taking into account disturbance vectors, generates output vectors. These output vectors do reliably produce predictable lifetime calculations with high confidence. In prior art solutions mostly the condition monitoring is restricted to the view from the "outside" on the physical behaviour of the tube (Heuermann, 2006, 2007).



Figure 2: TubeGuard@CT structure overview.

In the field of high power tubes, usually the resistance of the heater coil is measured. With the knowledge of the used materials and the dimensions, a thermal model can be created and the cathode surface temperature of the direct heated tungsten filament can be calculated. The emitter deterioration is based on sensor data of tube current and filament current (Siemens Guardian Programm, 2007).

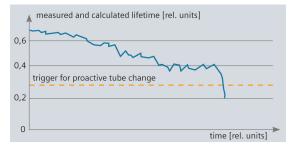


Figure 3: Measurement of emitter deterioration.

This procedure is the calculation of the cathode surface, from which the evaporation rate is dependent, but not sufficiently accurate. Many disturbance vectors, such as tube-stray distribution, time dependant varying parameters of the tube itself, and different ambient temperatures of the object to be considered, alter the thermal balance of the system, which is used for the calculation. As a result, a heating scheme materializes that does not match the actual existing surface temperature. For example figure 4 shows a thermal investigation done on an e-gun. The simulation was performed by the manufacturer of the e-gun with a COSMOS/M model. Cathode is 40°C, other points 20°C higher in the specific tube model. This results in a shorter predicted service life. On the other hand, if the model does not reflect the real thermal balance the cathode temperature could be much higher. As an example for the given dimensions of the used e-gun back-heating as a cause of ion-back-bombardement (beam but no RF: 50°C, beam and RF: 110°C) adds 60°C to the cathode surface.

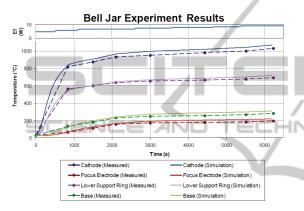


Figure 4: Mismatch between simulated and measured temperatures in an e-gun assembly.

As an example of the importance of accurate surface temperature estimation the effects in a klystron will be explained as follows:

For a nominal surface temperature given with 890° C, production of only 50° C more temperature on the surface results in twice as high barium evaporation. The same is true for all types of high-power tubes (klystron, magnetron, thyratron, accelerator), which use barium enriched materials as an electron emitter in the gun because of the low work function. This released barium is deposited on the cold spots in the tube and provides over time a reduction of dielectric strength in the tube. The result is a high voltage low impedance breakthrough (so called arcing) (Heuermann, 2007, 2010).

Researchers working on that topic also published solutions like continuously measuring the μ P (micro perveance) and keep the cathode current to 98% of the nominal value (Wright, Oiessen, 2000). Another solution is to implement thermo-couples in the cathode surface structure (Noguchi, 1996).

These solutions represent the state of the art in the field of condition monitoring for electron tubes.

The usual practice today is that tubes, depending

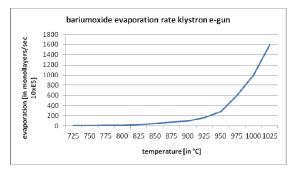


Figure 5: Example of evaporation rate vs. temperature.

on the type (x-ray, klystron, magnetron, linac, thyratron), are assigned to according maintenance contracts, which stipulate an exchange at a certain time.

It is the top priority of the equipment manufacturers, to avoid tube-failures of this manner from the very beginning. However, there is no possibility to ensure a complete avoidance of incidents. This is why, in so called unavoidable circumstances, one would like to have at least a big enough lead time, to ensure the exchange can be made before there is a downtime of a system.

2.1 Simulation

The hospital-specific diagnostic and treatment requirements are implemented into the simulation environment. The daily routine of a clinic is considered in the simulation as well as a statistically spread patient number, the load profile given by logging files recorded over months will give all necessary operating points.

Particularly interesting is the implementation of the "optimization". The calculation of residual life is based on the fact that all calculated life-critical values are afflicted with an error reflected from practise of about + -15%. This is due to manufacturing tolerances of the tube and its The thermal environmental factors. balance calculated with the knowledge of the geometries and materials does not show the correct value for the surface temperature of the anode plate or the cathode surface. The "optimization" deals with the simulation exactly as before, but with a smaller error: + -2%. This error is the assumed total residual error of the measurement chain (pyrometer, operational amplifiers, AD-converter) to measure the surface temperature.

A solid basis for creating a discrete event simulation, which is extended and detailed, and with the load profiles of hospitals, enables reliable investigations. The work has shown that MLDesigner (MLDesign Technologies, Inc. 2007) is the right tool for the reconstruction of the technically physical processes within a medical facility.

During observation it soon becomes clear that this is a classic optimization problem. It is a balancing act between maximized service life (carry out the exchange as late as possible), and realizing the avoidance of potential downtime. A statement of this quality on the life of a high-performance tube can not be given to this day in a satisfactory manner.

The existing studies and investigations are only estimates and approaches. The complex relationships and calculations within such a tube are seen analyzed and evaluated from the outside of the tube (Wippler, 2009, Heuermann, 2006).

The underlying research work pursues a fundamentally new approach. This means a direct view on the processes within the tube, instead of just estimating. This allows examining the condition of the tube much more in detail, with the result that the statements on the processes are significantly more related to reality.

A simple example is the surface temperature of the cathode. So far, the temperature is calculated according to complex procedures. Despite all precision and complexity of observation, the result is still estimation. The idea of the research works however is just to measure the surface temperature of the cathode. Thus, it is possible to respond to changes almost immediately. The model to be developed will shed light on whether it is precisely this optimization, that will be prove decisive for the substantial extension of the economic life of a high power tube.

The realization of this comparison is carried out by two simulation models. The basic model corresponds to the current usage of high power tubes, ie without any optimizations. Based on that first developed basic model, a model extension is designed. This serves a direct comparison between the basic and extended model. These extensions include the optimizations as discussed. Thereafter, the data of the two simulation runs can be compared. With the optimization, a service life extension should be observed under normal circumstances.

The simulation run for a klystron (Figure 6) and a x-ray tube (Figure 7) shows patient count per hour, statistically spread over one day, machine load profile, actual condition of the gun and the anode. The optimization option was off. Within the optimization option two specific calculations will be used. Once the exact cathode surface temperature and second the gas pressure inside of the tube. Both parameters will give the control system the most significant service life-determining parameters. The rate of change of μP and ion-back-bombardement will indicate how fast the cathode is loosing emission (Heuermann, 2007, 2009, 2010).

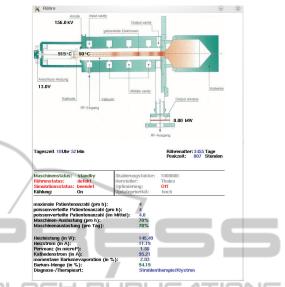


Figure 6: Simulation run example for a klystron.

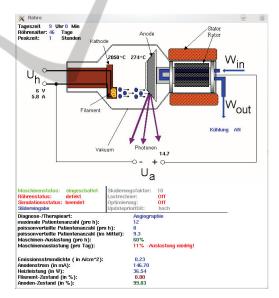


Figure 7: Simulation run example for a x-ray tube.

2.2 Temperature Measurement

The in section 2 mentioned problem with electron emitting cathode material and the evaporation of cathode material in vacuum tubes is solved by using an integrated optical measuring equipment for continuous cathode or anode surface temperature measurement (in x-ray tubes the anode temperature is of special interest too) for calculating the evaporation rate in vacuum tubes of medical technology. By a direct measurement of the actual surface temperature an effectively working control of the heating system can be realized. Therefor a photo semiconductor is integrated in the tube.

Temperatures from about 700° C can be measured pyrometrically with photo diode in the visible spectral range. Pyrometers (sensor incl. evaluation system), also called radiation thermometers, are used for contactless temperature measurement. Mostly the reception wavelength range of high-temperature pyrometers is determined by the photo detector: The lowest reception wavelength of silicon photodiodes is, for example, about 1.1 microns. A body with a temperature of 3000 K has its maximum radiation, but temperatures from about 700° C can already be measured. The surface temperatures in klystrons, magnetrons, thyratrons and accelerators range from 890° C to 1050° C (depending on the type of cathode, ie oxide or impregnated). The surface temperature of the tungsten filament wire in x-ray tubes is about 2000° C.

emitting material of the cathode on the cold surface of the photo sensor (in klystron, magnetron, thyratron and accelerator), a central lock (a so-called shutter) is used. The shutter consists of a number of curved steel plates, which will be steered out of the measurement beam. Such shutters are well known in the camera technology and are available in high volumes at low prices. The shutter protects the sensor optics in phases, in which no measure is taken. To measure the surface temperature, the shutter, which is located in a vacuum, is activated and opened electromagnetically from the outside through a media gap (barrier of glass or ceramic between the vacuum of the tube and the ambient pressure). After measurement, the shutter is closed again. The measurement itself takes place cyclically, in time intervals still to be defined in detail. Also usable as a shutter is a disc with an opening which rotates when activated and releases the beam path to the sensor.

The advantages for the use of standard integrated optical measuring equipment for continuous cathode or anode surface temperature measurement in vacuum tubes are the reliable service life prediction and the targeted life extension. With the help of the exact measurement of surface temperature, the state (electron emission at currently supplied heating power) of the cathode can be detected and be used to determine a precise heating control. The result of an exact sequence for a heating system is the significant extension of the life of a tube. Here the following advantages of the invention compared to a contact temperature measurement appear:

Very fast measurement (<1 ms to 10 ms depending on construction). Very long, continuous ranges possible (eg, 350 ... 3500° C), no wear (excl. shutter mechanics), no temperature influence on the measurement object or errors by poor thermal contact. Possibility of measurement at high voltages, electromagnetic fields, or corrosive materials.

The proposed novel approach allows continuing an ongoing monitoring of the condition of the tube. Slowly impending loss (reducing the temperature at constant heating power supply) can be detected, an integration of evaluation into the overall control of the entire system allows sending of service messages before the system fails (predictive maintenance). With the known evaporation rate and the available quantity of barium in the cathode from the beginning, an arcing probability can be calculated (Heuermann, 2009, 2010).

To prevent deposition of evaporated electron 3 CONCLUSIONS

In the field of high-power tubes there is a large development potential regarding service life management and condition monitoring services to be found.

A targeted control of the service life-determining parameters extends the life of high-power tubes. As proof of a life extension a simulation model is used, which provides information about the behavior of service life-critical parameters. Results produced by the simulation model are transferable to reality and can be used in a practical implementation. The simulation shows that a targeted control of service life-determining parameters influences the overall lifetime of a tube. In a next step, real load profiles recorded at customer sites will drive the tube model. These reflect the daily routine in a hospital with the individual patient distribution and their diagnostic and therapy schedules and, as a result, the real tube load. This novel approach will improve the uptime of medical systems. First results from single x-raytube systems (CT, Angiography, Fluoroscopy, Mammography) show that in case of direct heated cathodes the predictive maintenance works well. In case of multiple tube systems like radiation therapy machines, at least three high power tubes are used in one system, the proposed specific methods for life extension of equipment and systems in medical devices will increase the uptime dramatically.

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