ASSESSMENT and QUALIFICATION of the RELIABILITY of ELECTRONIC ASSEMBLY COMPONENTS and PROCESSES FOR MEDICAL APPLICATIONS

Host laboratory: LARIS Laborotory – Dependability and decision support team (Polytech'Angers - University of Angers)

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Keywords: Electronics, Microelectronics, Medical Devices, Reliability, Qualification, Reliability testing.

Industrial context

TRONICO designs, industrializes and manufactures complex products with a predominantly electronic component that can be found in all fields, particularly in the health sector. As a result, new medical systems implemented in development must demonstrate a high level of reliability in a specific (humidity...) and constrained environment [1]. The use of electronics is regulated by numerous documents that deal with electro-medical devices, often called Medical Devices (MD). Currently, this regulation is largely based on the 60601 standard and its numerous derivatives or equivalent standards at the international IEC, European EN or national NF level ([2], [3] and [4]). In these documents, the reliability of electronic components is not explicitly addressed. Nevertheless, there are some indications, for example [2]:

- **Component with high reliability characteristics**: component that, due to its characteristics, cannot present a defect compromising the safety of MDs.
- **First fault condition**: the MD is in a first fault condition when an anomaly occurs (typically a technical failure). The first defect conditions of the means put in place to reduce the risks will be carefully examined.
- **Lifetime**: the period of use defined by the manufacturer.

Currently, there is no standardized process for qualifying electronic components for medical applications. Product designers often look for components that have been qualified for other fields such as the automotive, military or aeronautical industries, where the tests carried out have verified their robustness or safety level (ASIL, SIL) in relation to their manufacturing process [5].

Some component manufacturers offer a medical range. This often involves selecting components from the commercial, automotive or military range and keeping only those components that meet the more stringent criteria after more severe tests.

The testing of "medical" electronic boards is a major challenge to reconcile different aspects: Technical, Cost, Reliability and Safety ([6] and [7]). These tests must therefore be addressed and designed from the first phases of the design of electronic boards.

Objective/Research topic

Within the framework of the regional project RECOME (Reliability of Electronic COmponents for MEdical devices), the purpose of this research work is to define a methodology to qualify an electronic component to respect a level of safety of MD. It will be a question of defining the tests to be carried out according to the type of components and the medical application.

This study will be based on the various standards for the qualification of components and/or their manufacturing process, on the requirements for the safe operation of medical devices, and on the ageing models for electronic components. It will have to evaluate, if necessary, processes of implementation of these components allowing to increase their reliability in application (underfill, coating...) with technological locks and in particular the miniaturization and the impossibility of carrying out traditional tests (functional tests, tests in situ).

The methodology will have to be integrated in a global process of electronic boards' assembly with elements of reception control and supplier audit. The results of feedback from different fields (Aeronautics, Automotive, etc...) and those of reliability tests can be combined to validate the methodological approach on Medical Devices.

Several scientific barriers will be removed in the context of this work. The qualification process of a component from accelerated testing needs to be formalized with respect to the monitoring of manufacturing processes using quality tools ([8] and [9]) and/or Bayesian networks [10] but also the optimization of these processes using a design of experiments approach. ([11] and [9]. Moreover, the impact of the implementation processes (underfill, coating) on the reliability of a product is not yet quantified ([12], [13]). Finally, small components as well as the use of wired chips do not have to date a predictive reliability model listed in databases such as [14] or [15].

In order to achieve this objective, the principle envisaged is (by mission profile and by component technology):

- To identify the weaknesses of the component and the failure modes by feedback or by research analysis,
- To define qualification and validation processes for components,
- Define reliability demonstration methods based on accelerated life tests ([16], [17], [18] and [19]).

In a first step, it will be necessary to develop a list of tests for "classical" components (passives of size 0402 or higher, BGA and QFN at 500µm pitch). In a second time, to follow the path of miniaturization of components, this work should be continued for smaller components (size 01005 for passives, BGA and QFH with a pitch of 300µm) by focusing particularly on new constraints, especially during the transfer of these components, induced by the decrease in their size. Finally, in a context of increasing integration, the use of wired chips (conventional or MEMs) on substrate will have to be evaluated according to their technologies and processes of transfer and robustification of assemblies.

The research carried out will bring an innovation on the recent processes of manufacture and integration of electronic embedded systems of miniaturization. It will allow on these evolutions to improve the implementation of a component in a product to optimize its reliability.

It will allow to establish predictive models of the physics of failure associated to guarantee the reliability of a couple product / process. This research will lead to a gain in competitiveness by limiting the costs of qualification and testing of components by precisely defining the "right need".

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Planned actions/work type

- Modeling of mission profiles encountered by medical equipment
- Study of component failure models according to their mission profiles (bibliography and characterization)
- Realization of reliability tests
- Establishment of a methodological guide, in connection with the acceptance control or/and supplier audit, determining the qualification and validation tests of components
- Valuation of scientific works and writing of the thesis

Evaluation of the breakdown of activities

Bibliography (15%), Modeling (25%), Simulations (20%), Experiments (25%), Thesis and Articles (15%)

Training/skills required:

Electronics and microelectronics,
Reliability tests,
Reliability testing, operational safety,
Optimization and statistical control of processes.

Location of the thesis:

The candidate will be geographically located on the site of Polytech'Angers/University of Angers in Angers and regular travel will be required on the site of TRONICO in Nantes / St-Philbert-de-Bouaine.

Candidate profile:

The candidate will have to manage a balance between research in academia and research and development as well as laboratory testing in academia and industry. He/she must have a research or professional master's degree. Holders of an engineering degree may also apply.

The qualities sought in candidates are self-motivation, perseverance, intellectual curiosity, critical thinking, creativity and a taste for problem-oriented applied research.

A thorough knowledge of reliability and numerical programming is essential. Fluency in reading and writing scientific English is also essential.
Knowledge of electronics is a plus.

Application deadline: 30 May 2021

Presentation of the recruiting institution:

The Laboratoire Angevin de Recherche en Ingénierie des Systèmes (LARIS) is a host team EA7315 of the University of Angers, composed of 3 interconnected teams:

- Dynamic Systems and Optimization (SDO)
- Information, Signal, Image and Life Sciences (ISISV)
- Dependability and Decision Support (SFD)

The current staff is:

- 54 teacher-researchers including 24 HDR
- 3 research engineers and 1 project engineer
- 1 administrative and financial manager
- 30 PhD students
- 1 post-doctoral student, 1 temporary teaching and research assistant

LARIS brings together researchers from four components of the University of Angers (Polytech'Angers, IUT, UFR Sciences, ESTHUA), the CHU, the UCO and the ESAIP. It is a stakeholder in the Pôle Math-STIC of the University of Angers.