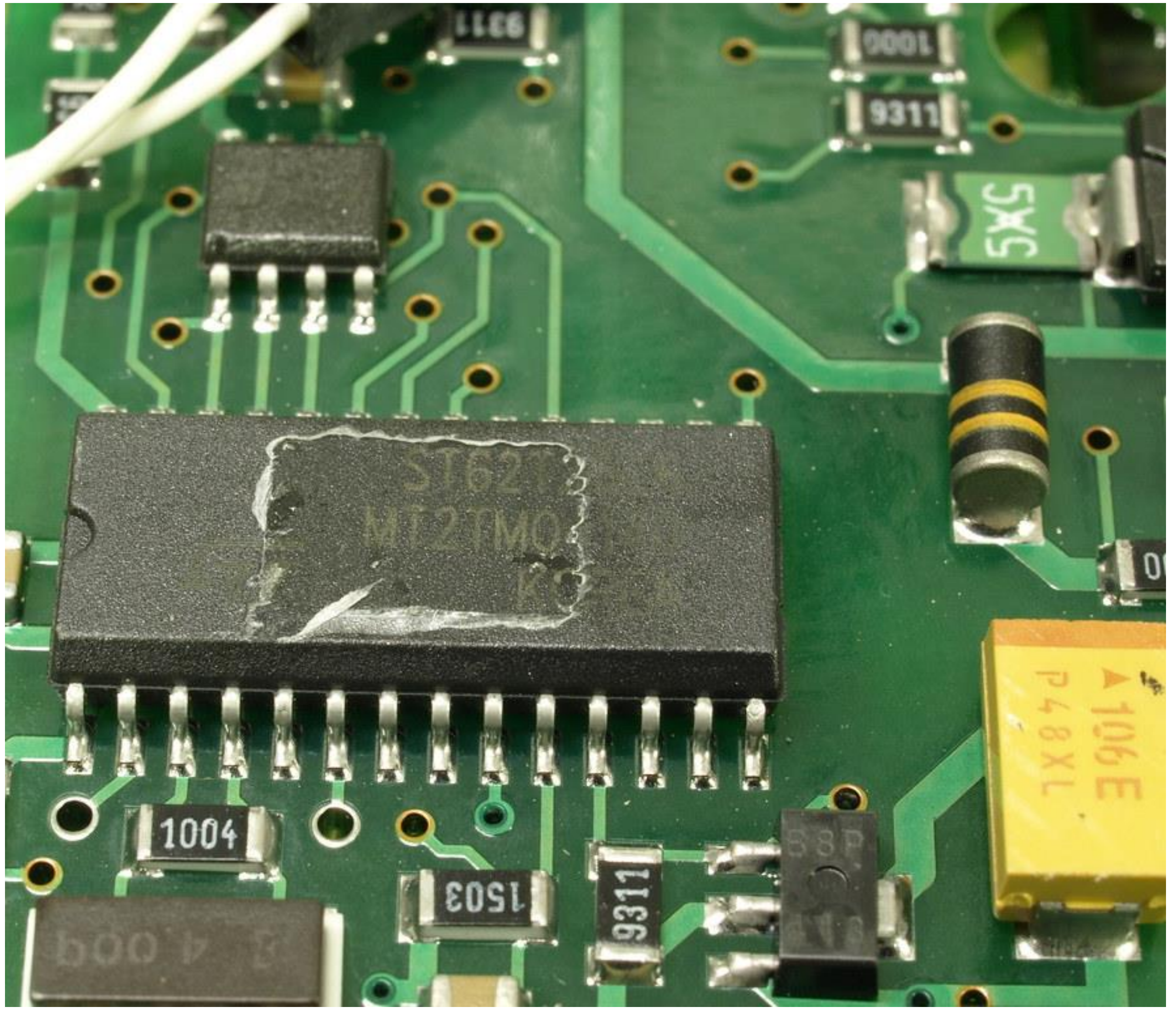
Qualification of the reliability of electronic components for implantable medical devices, case study: chip resistors



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AIMDs

- Growth in the market for Active Implantable Medical Devices (AIMDs).
- Trend towards embedded electronics in AIMDs vs. gaps in reliability assessment of electro-medical devices.
- **Objective**: define a methodology for qualification electronic components relevant to the environment of AIMDs.

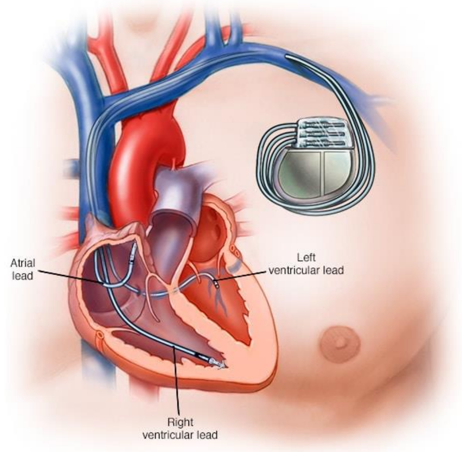

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Figure 1 : Example of AIMD: pacemaker.

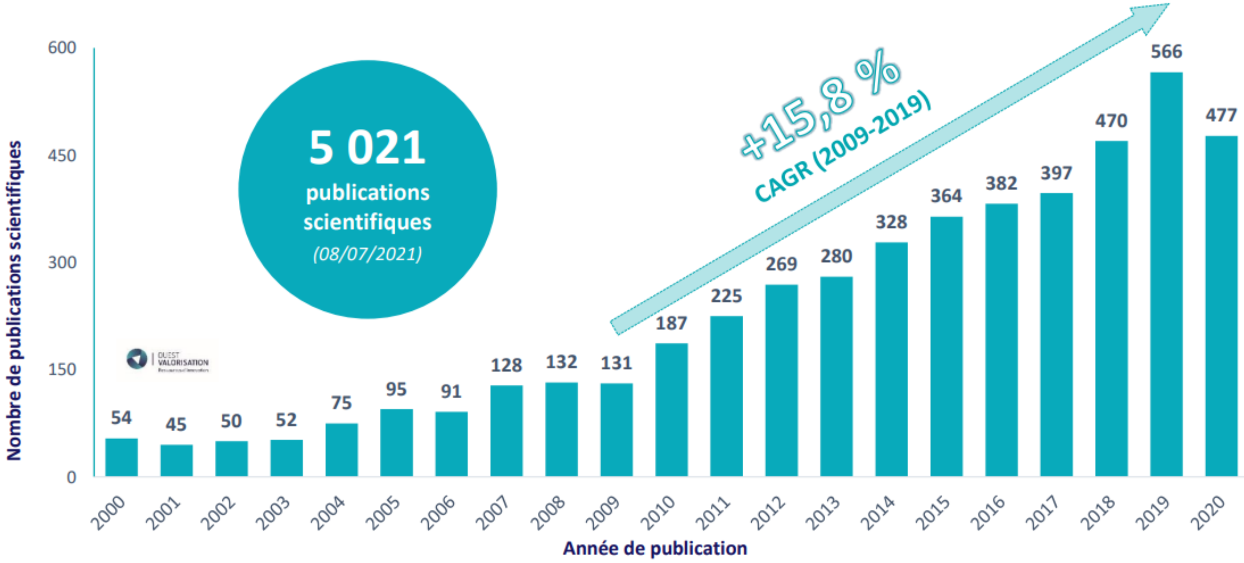


Figure 2: Annual trend in scientific publications worldwide since 2000 on active implantable medical devices (AIMDs) incorporating electronics.

FMMEA

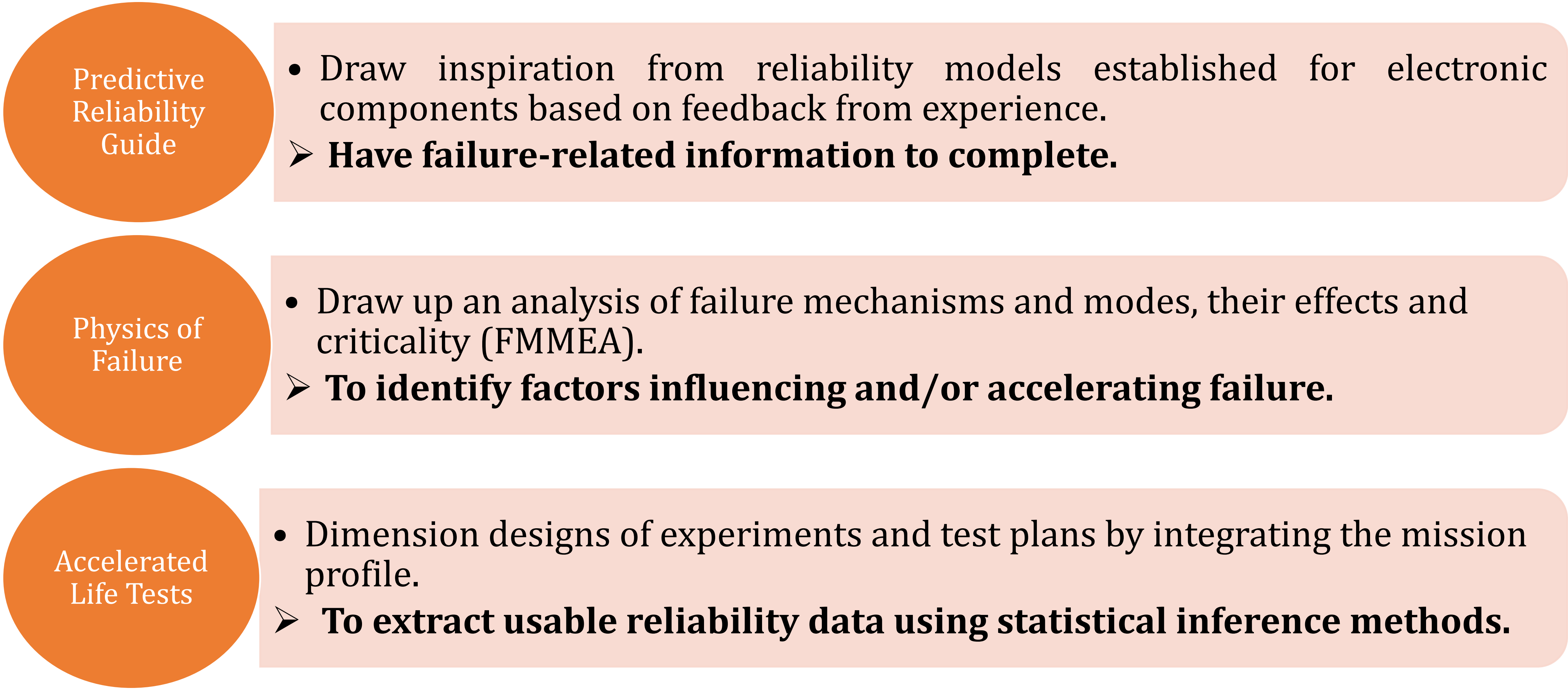
- <u>Relevant technological characteristics</u>:
  1. Film material: thin or thick,
  2. Size (01005 – 1206),
  3. Resistance value (0,01Ω – 100kΩ) ,
  4. Manufacturer.

- <u>Standards & guides</u>:
  - FIDES
  - CECC EN 140401-801 & CECC EN 140401-802
  - MIL-STD-883 Method 1031
  - IEC 60115-1

Table 1: A summary table of the FMMEA for chip film resistors based on state-of-the-art analysis.

Environmental factor	Failure mechanism	Failure mode
Thermal stress	**Solder crack**	Drift; Open circuit
	Electrode separation	Drift; Open circuit
Power overload	**ESD**	Drift; Open circuit
	Damage to resistive element	Drift; Open circuit
	Deterioration of resistive element	Drift
Humidity + Current	**Corrosion**	Drift; Open circuit
	ECM	Drift; Short circuit
Humidity + Current + Sulfuric components	**Sulfurization**	Drift; Open circuit
Mechanical stress	**Electrode separation**	Drift; Open circuit

Overview of methodology



Predictive Reliability Guide

- Draw inspiration from reliability models established for electronic components based on feedback from experience.

➢ **Have failure-related information to complete.**

Physics of Failure

- Draw up an analysis of failure mechanisms and modes, their effects and criticality (FMMEA).

➢ **To identify factors influencing and/or accelerating failure.**

Accelerated Life Tests

- Dimension designs of experiments and test plans by integrating the mission profile.

➢ **To extract usable reliability data using statistical inference methods.**

Qualification test plan

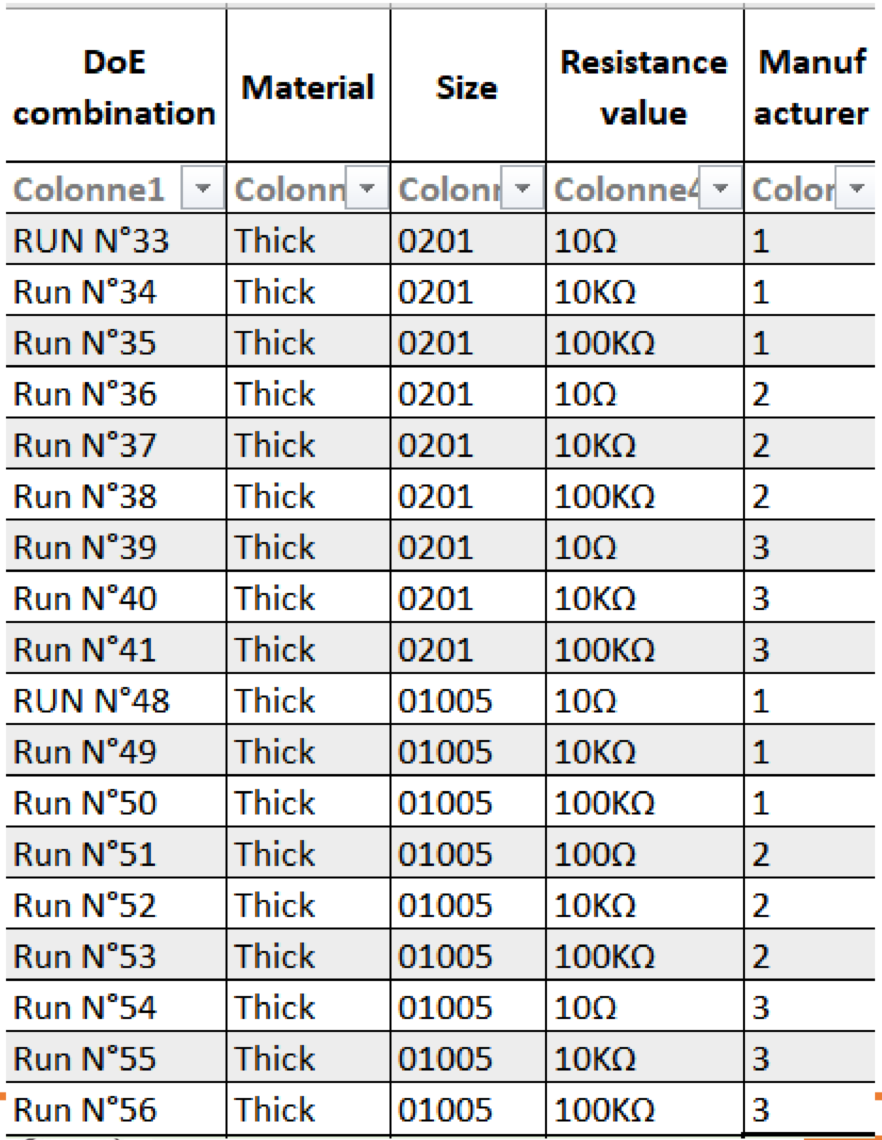
1. Extract and detail the **mission profile** of AIMDs.
2. Through an **FMMEA**, determine the **critical failure mechanisms** of concern for chip resistors within the context of AIMDs' mission profile.
3. Calculate the **acceleration factors** corresponding to significant environmental stressors based on available literature on the physics of failure of chip resistors as well as the **FIDES models' parameters**.
4. Subsequently, determine the **reliability test metrics** such as stress duration and sample size depending on the mission profile and calculated acceleration factors.

Design of Experiments

- Taguchi factorial design: 4 factors with different levels.

- Analysis:
  - Signal / Noise ratio.
  - Case where the optimum is a minimum, minimize the loss function: $L = K.Y^2$.

Table 2: Extract of Taguchi design of experiments.



DoE combination	Material	Size	Resistance value	Manuf acturer
Colonne1	Colonn	Colonn	Colonne4	Color
RUN N°33	Thick	0201	10Ω	1
Run N°34	Thick	0201	10KΩ	1
Run N°35	Thick	0201	100KΩ	1
Run N°36	Thick	0201	10Ω	2
Run N°37	Thick	0201	10KΩ	2
Run N°38	Thick	0201	100KΩ	2
Run N°39	Thick	0201	10Ω	3
Run N°40	Thick	0201	10KΩ	3
Run N°41	Thick	0201	100KΩ	3
RUN N°48	Thick	01005	10Ω	1
Run N°49	Thick	01005	10KΩ	1
Run N°50	Thick	01005	100KΩ	1
Run N°51	Thick	01005	100Ω	2
Run N°52	Thick	01005	10KΩ	2
Run N°53	Thick	01005	100KΩ	2
Run N°54	Thick	01005	10Ω	3
Run N°55	Thick	01005	10KΩ	3
Run N°56	Thick	01005	100KΩ	3

Tests implementation

- Types of ALTs:
  1. Thermal Cycling (TC).
  2. Single Pulse Load (SPL).
  3. Electrical Overload (EO).
- Failure criteria: Drift of resistance (% depends on component).

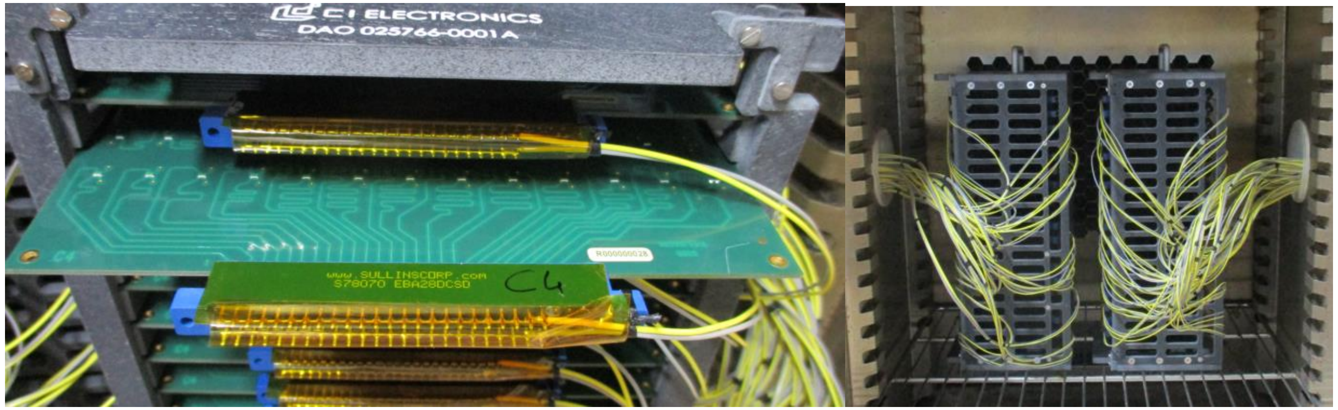


Figure 3 : Accelerated life tests of SMD resistors – Thermal Cycling.

Figure 4 : Thermal cycling profile 2 for 0201 to 01005 film resistors.

Figure 5 :

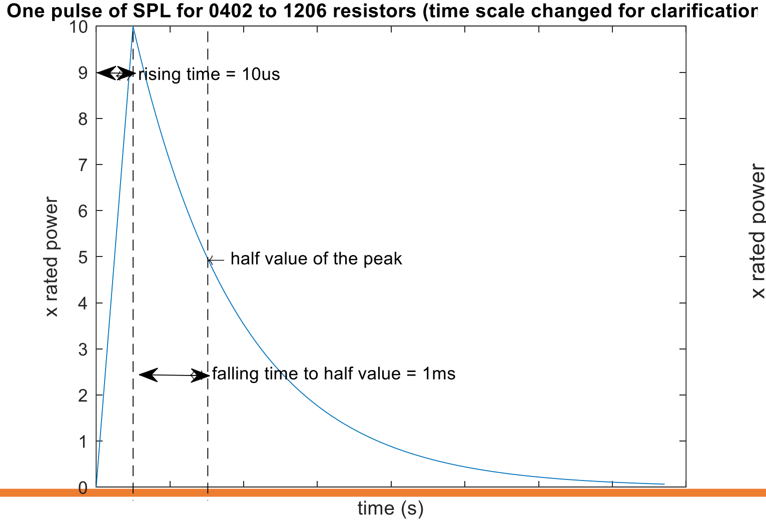
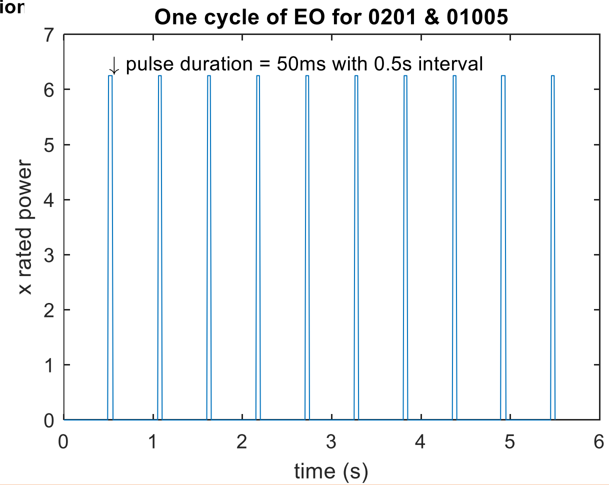


Figure 6 :



Tests implementation

Figure 4 : Thermal cycling profile 2 for 0201 to 01005 film resistors.

Tests implementation

Figure 5 :

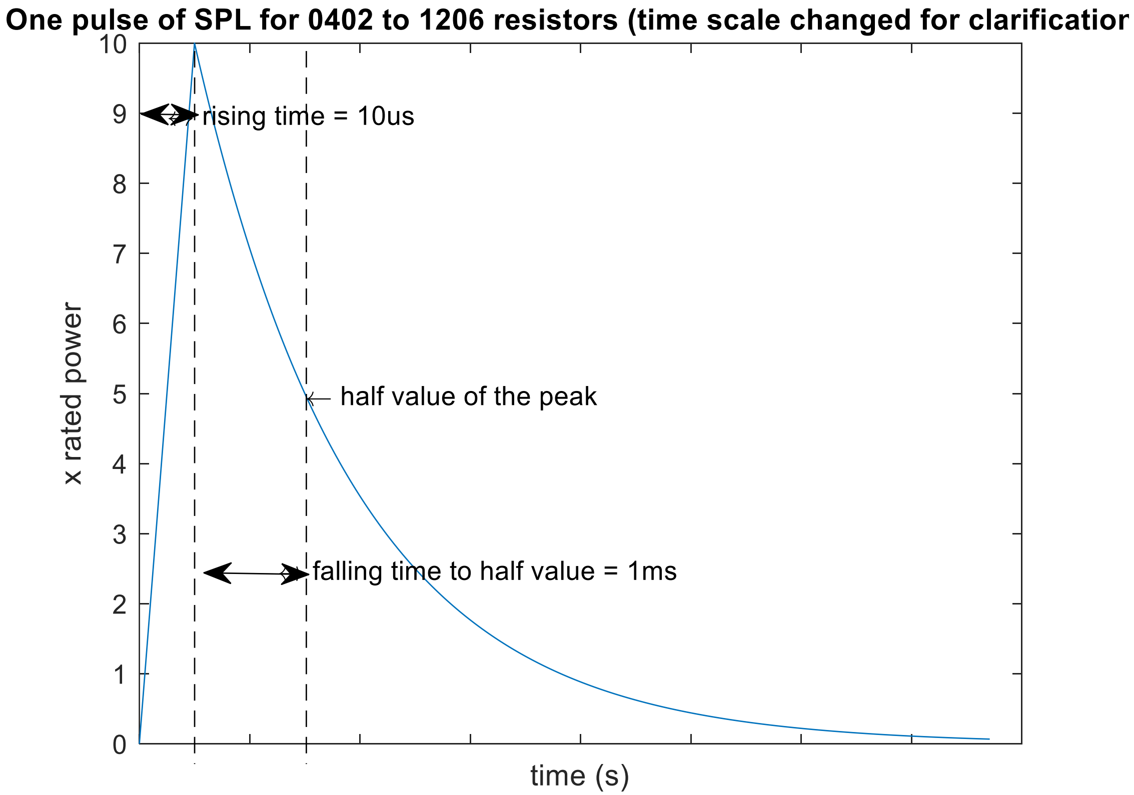
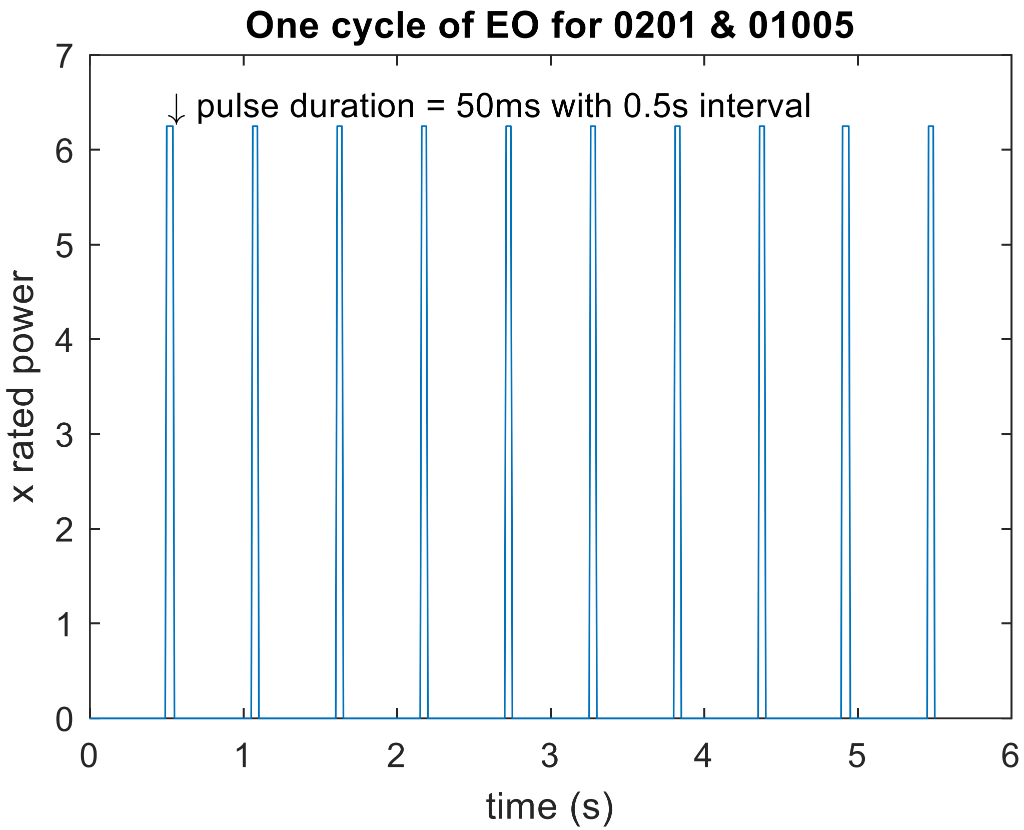


Figure 6 :



Results for miniature components

Main questions:

- Which combinations of controllable factors display the highest robustness against ALTs?
- Which ALT type yields the greatest effectiveness in identifying potential failures?

➢ Statistical analysis:

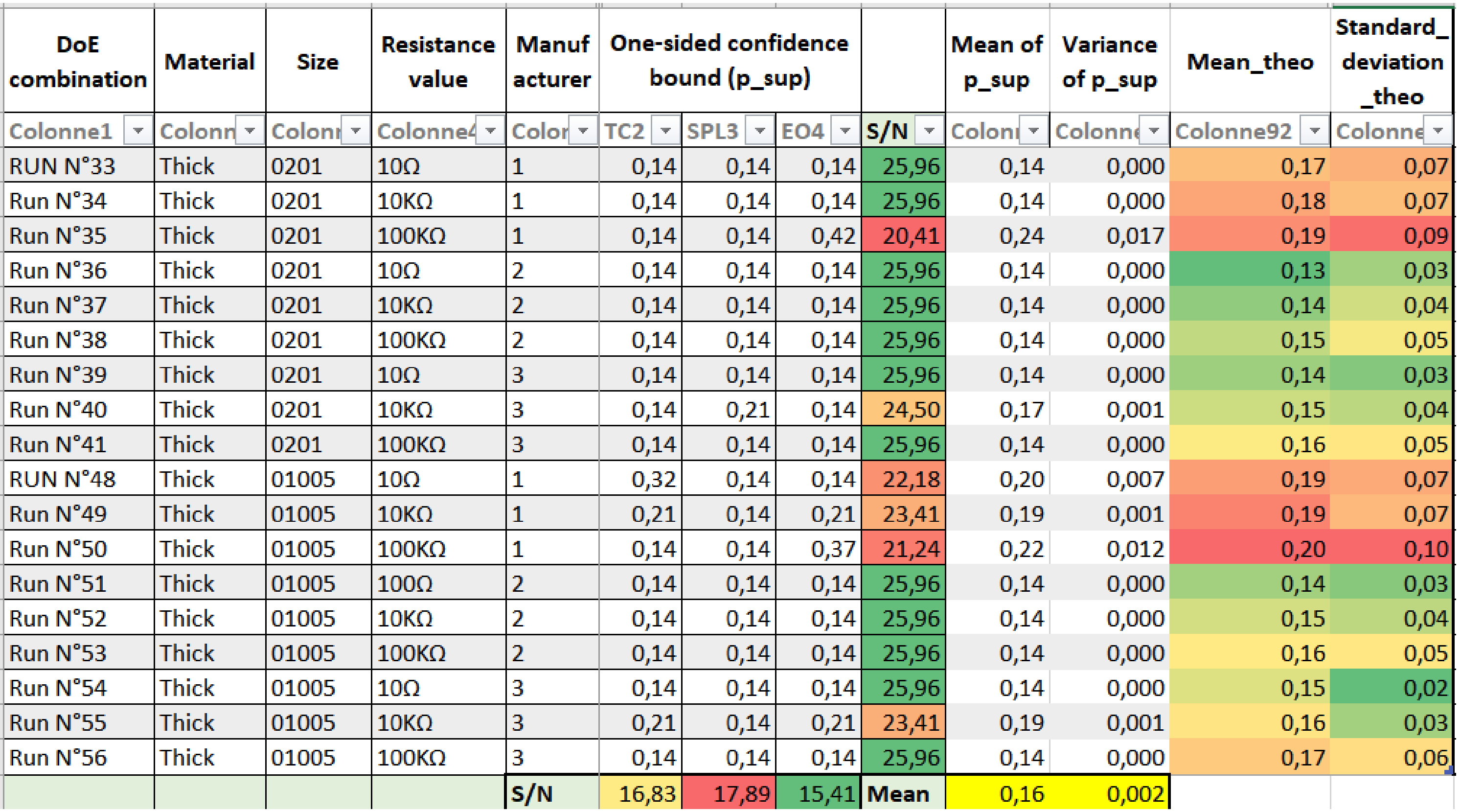
1. Calculate the signal-to-noise ratio.
2. Analyse the effect of each factor on the mean. Calculate the theoretical mean for each combination to determine location effects.
3. Repeat the previous step using the variance to identify dispersion effects.

Table 3: Factors are A) Film material, B) Size, C) Resistance value, D) Manufacturer; ALTs are: TC - Thermal Cycling, SPL - Single Pulse Load, EO - Electrical Overload.

DOE COMBINATION	**A**	**B**	**C**	**D**	**NUMBER OF FAILURES**		
					TC	SPL	EO
RUN N°33	Thick	0201	10Ω	1	0	0	0
RUN N°34	Thick	0201	10KΩ	1	0	0	0
RUN N°35	Thick	0201	100KΩ	1	0	0	5
RUN N°36	Thick	0201	10Ω	2	0	0	0
RUN N°37	Thick	0201	10KΩ	2	0	0	0
RUN N°38	Thick	0201	100KΩ	2	0	0	0
RUN N°39	Thick	0201	10Ω	3	0	0	0
RUN N°40	Thick	0201	10KΩ	3	0	1	0
RUN N°41	Thick	0201	100KΩ	3	0	0	0
RUN N°42	Thin	0201	100Ω/22Ω	4	0	0	0
RUN N°43	Thin	0201	10KΩ	4	0	0	0
RUN N°44	Thin	0201	100KΩ	4	0	0	0
RUN N°45	Thin	0201	100Ω	3	0	1	1
RUN N°46	Thin	0201	10KΩ	3	0	0	0
RUN N°47	Thin	0201	100KΩ	3	0	0	0
RUN N°48	Thick	01005	10Ω	1	3	0	0
RUN N°49	Thick	01005	10KΩ	1	1	0	1
RUN N°50	Thick	01005	100KΩ	1	0	0	4
RUN N°51	Thick	01005	100Ω	2	0	0	0
RUN N°52	Thick	01005	10KΩ	2	0	0	0
RUN N°53	Thick	01005	100KΩ	2	0	0	0
RUN N°54	Thick	01005	10Ω	3	0	0	0
RUN N°55	Thick	01005	10KΩ	3	1	0	1
RUN N°56	Thick	01005	100KΩ	3	0	0	0

Statistical analysis

Table 4: Results of statistical calculations on the reduced Taguchi design (one-sided confidence bound of the true failed proportion at the 95% confidence level).



DoE combination	Material	Size	Resistance value	Manufacturer	One-sided confidence bound (p_sup)				Mean of p_sup	Variance of p_sup	Mean_theo	Standard_deviation_theo
Colonne1	Colonn	Coloni	Colonne4	Color	TC2	SPL3	EO4	S/N	Coloni	Colonne	Colonne92	Colonne
RUN N°33	Thick	0201	10Ω	1	0,14	0,14	0,14	25,96	0,14	0,000	0,17	0,07
Run N°34	Thick	0201	10KΩ	1	0,14	0,14	0,14	25,96	0,14	0,000	0,18	0,07
Run N°35	Thick	0201	100KΩ	1	0,14	0,14	0,42	20,41	0,24	0,017	0,19	0,09
Run N°36	Thick	0201	10Ω	2	0,14	0,14	0,14	25,96	0,14	0,000	0,13	0,03
Run N°37	Thick	0201	10KΩ	2	0,14	0,14	0,14	25,96	0,14	0,000	0,14	0,04
Run N°38	Thick	0201	100KΩ	2	0,14	0,14	0,14	25,96	0,14	0,000	0,15	0,05
Run N°39	Thick	0201	10Ω	3	0,14	0,14	0,14	25,96	0,14	0,000	0,14	0,03
Run N°40	Thick	0201	10KΩ	3	0,14	0,21	0,14	24,50	0,17	0,001	0,15	0,04
Run N°41	Thick	0201	100KΩ	3	0,14	0,14	0,14	25,96	0,14	0,000	0,16	0,05
RUN N°48	Thick	01005	10Ω	1	0,32	0,14	0,14	22,18	0,20	0,007	0,19	0,07
Run N°49	Thick	01005	10KΩ	1	0,21	0,14	0,21	23,41	0,19	0,001	0,19	0,07
Run N°50	Thick	01005	100KΩ	1	0,14	0,14	0,37	21,24	0,22	0,012	0,20	0,10
Run N°51	Thick	01005	10Ω	2	0,14	0,14	0,14	25,96	0,14	0,000	0,14	0,03
Run N°52	Thick	01005	10KΩ	2	0,14	0,14	0,14	25,96	0,14	0,000	0,15	0,04
Run N°53	Thick	01005	100KΩ	2	0,14	0,14	0,14	25,96	0,14	0,000	0,16	0,05
Run N°54	Thick	01005	10Ω	3	0,14	0,14	0,14	25,96	0,14	0,000	0,15	0,02
Run N°55	Thick	01005	10KΩ	3	0,21	0,14	0,21	23,41	0,19	0,001	0,16	0,03
Run N°56	Thick	01005	100KΩ	3	0,14	0,14	0,14	25,96	0,14	0,000	0,17	0,06
				S/N	16,83	17,89	15,41	Mean	0,16	0,002		

- Upper bound of confidence interval of probability of failure

Given

$$\sum_{k=0}^{N_d} \binom{n}{k} p_U^k (1-p_U)^{n-k} = \alpha$$

- n: sample size,
- p_U: the upper 100(1-α)% limit,
- N_d: number of defects recorded.

Conclusions:

- ➢ Chip resistors with the lowest resistance value seem to exhibit higher robustness to the relevant environmental factors.
- ➢ Electrical overload ALT appears to enhance the identification of failure.

Takeaways

- Definition of accelerated life test should be based on the unique mission profile of AIMDs.
- A detailed test protocol aligned with test objectives must be established: detecting defects for chip resistors.
- Identification of defects or ageing is linked to the quantity of thermal cycles the components undergo.
- Definition of test metrics is based on the physics of failure of chip resistors.
- Application of design of experiments for accelerated testing (input on quantities to be observed and interpretation).

RECOME

Reliability of Electronic COmponents for MEdical devices

Thank you for your attention !