PRECISION DEVICES knowles

Components for Medical

MEDISCHE ELEKTRONICA
Ontwikkelingen, normen en toepassingen

7 februari 2023 | FHI Leusden

History
Medical

Definition:
- Device surgically placed inside the body and stays in after surgery for a long period of time

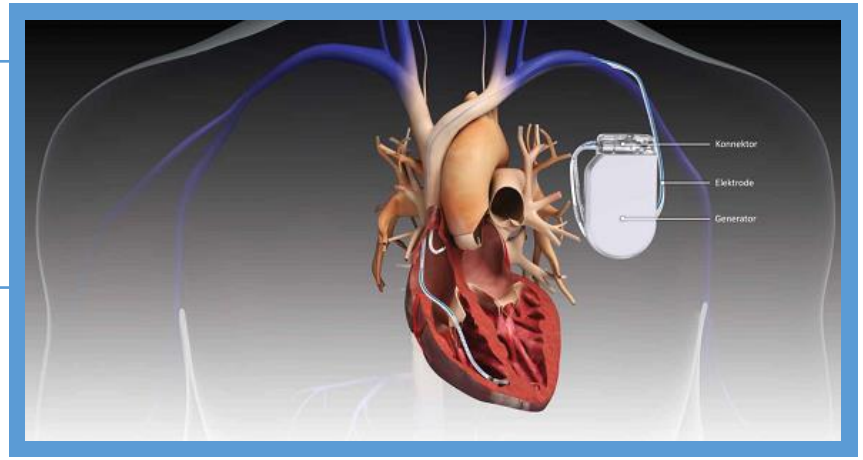
Examples:
- Pacemakers
- Defibrillators
- Insulin Pumps
- Cochlear Devices
- Bladder Stimulator

Clinical Benefits:
- Rebuild or rehabilitate body function
- Obtain better quality of life
- Increase longevity of the human body

1952
- First electrical pulse stimulation treatment of the heart
- Paul Maurice Zoll
- External stimulation successful for 52 hours

1958
- Wilson Greatbatch collaborated with a surgeon, William Chardack to invent the first implantable pacemaker

2010
- Fast forward to 2010 and the first commercialized wireless blood pressure measurement system was introduced



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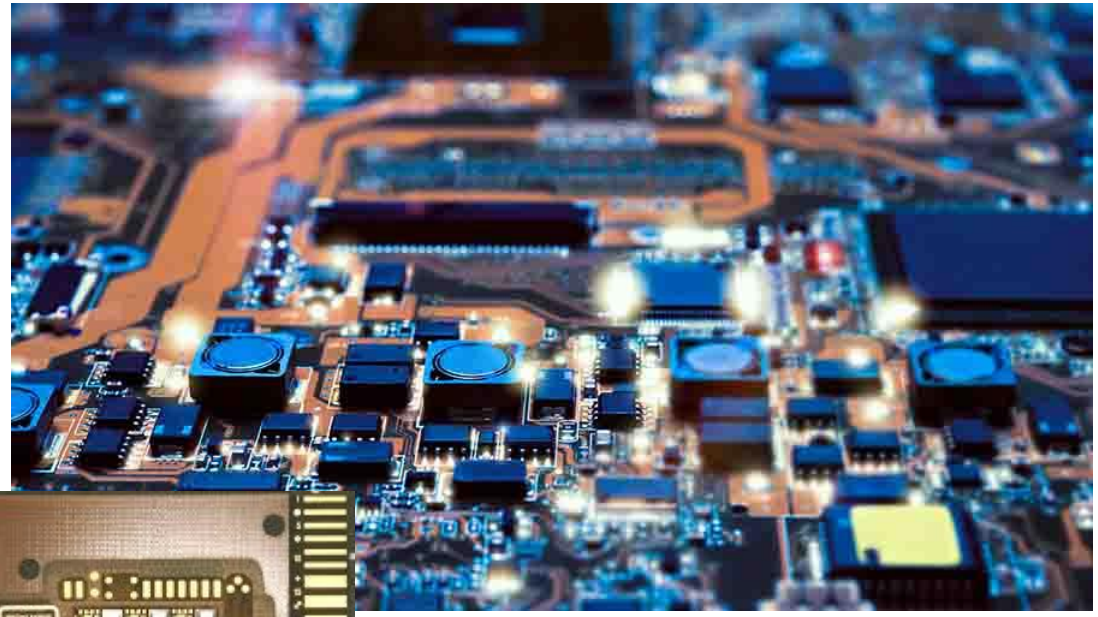
Market Demand
Medical

The Medical electronics industry is continually tasked with:

- **Reducing Size**
- **Increasing Reliability**
- **Improving Materials / Design**

Components requiring high reliability:

- **Capacitors**
- Resistors
- Batteries
- Inductors
- Transistors



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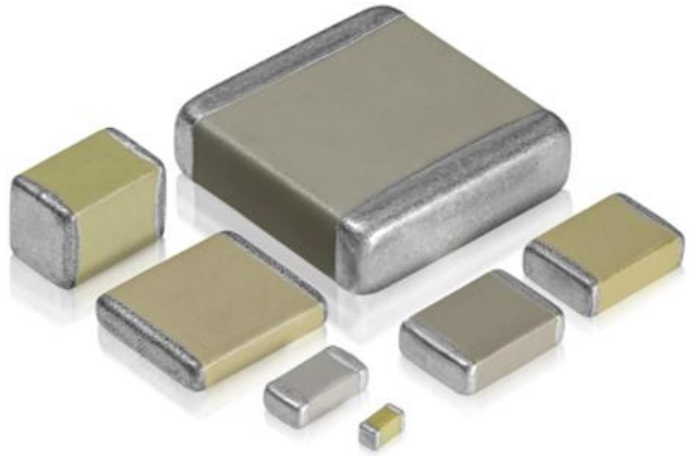
MLCC Considerations

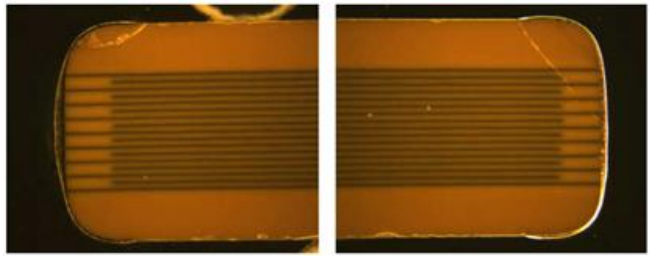
Ceramic Capacitor

Capacitor - Passive electronic component that can store electric charge in an electric field



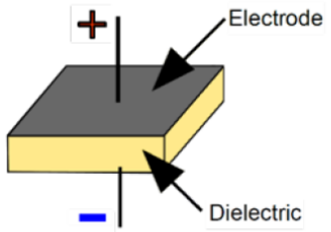
Battery vs Capacitor

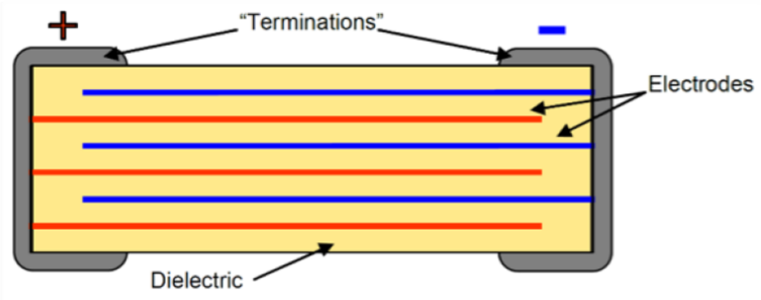
- Batteries: Stores energy and then gradually releases it
- Capacitors: Can be discharged in an instant



Two main building blocks of a multi-layer capacitor

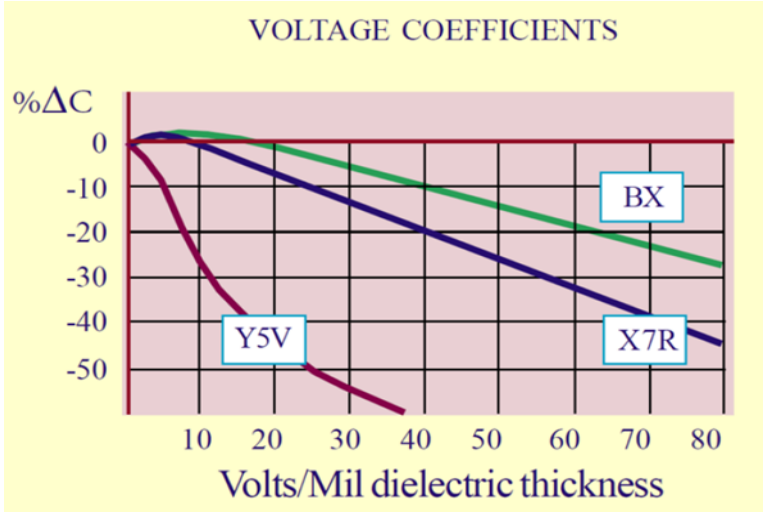
- Dielectric – Made with ceramic type materials, paraelectric or ferroelectric
- Electrodes – Materials with good conduction
  - Aluminum
  - Copper
  - Nickel
  - Palladium
  - Silver

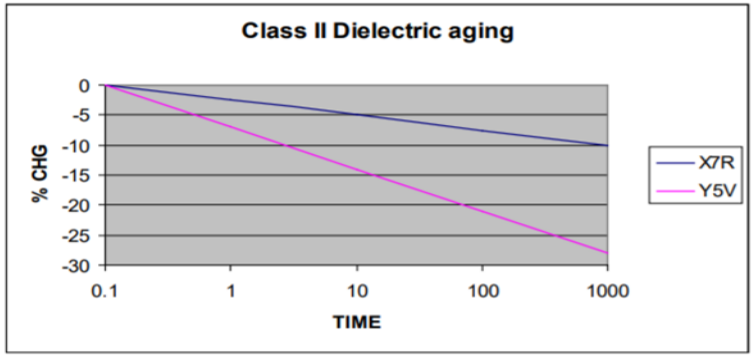




MLCC Considerations
Basic

Class 1 NP0/C0G, X8G	Class 2 X5R, X7R	Class 3 Z5U, Y5V
+ Accurate temperature-compensating + Offer the most stable voltage temperature, and frequency + Lowest losses out of the three + No aging	+ High permittivity (better volumetric efficiency) + Offers higher capacitance than Class 1	+ Even higher permittivity than Class 2
- Low volumetric efficiency	- Lower accuracy and stability - Value changes depending on applied voltage - Aging 1% to 3,5%	- Worse electrical characteristics - Not part of industry standard - Aging up to 10%





Medical Market

Why Reliability?

Patient safety is paramount and priority

High reliability screening lessens the possibility of malfunctions, recalls and replacement surgeries

Economic impact of recalls is important to note because of:

- Reputational and monetary risks
- Lowered market share
- Cost for replacements
- Potential legal repercussions and ramifications

The demand for new medical products drives ongoing improvement and innovation from all over the industry

Capacitors Reliability

Medical

Class I (low risk),
Class IIa (medium risk),
Class IIb (medium/high risk)
Class **III (high risk)**

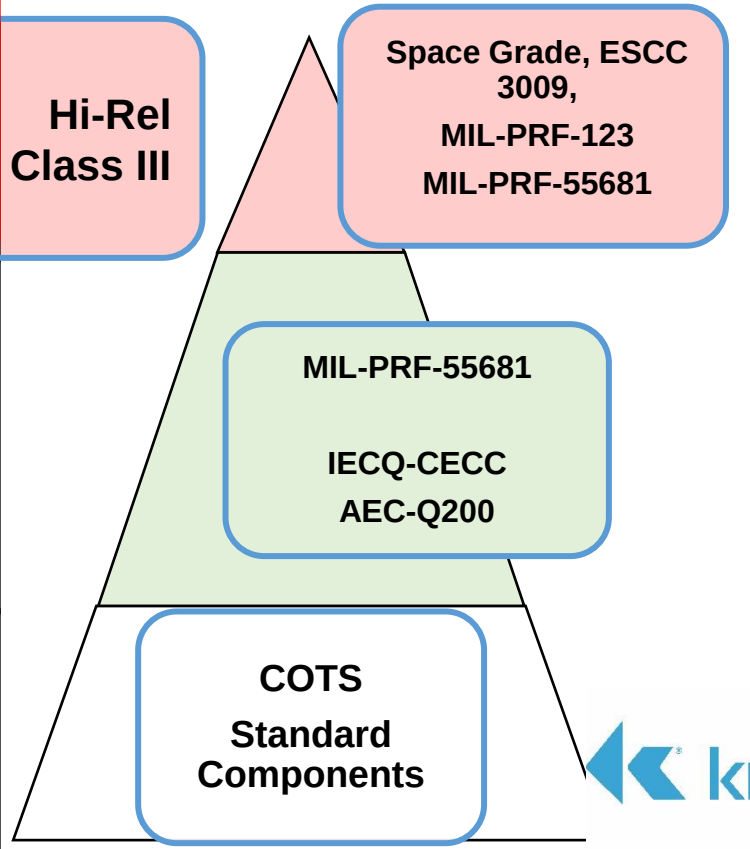
Higher

Reliability

		High Performance
• Glucose Monitoring • Insulin Delivery • Ultrasound	• Electrophysiology • Hearing Implants • Neuro modulation	• CRM • Cardiac Assist • Ophthalmic Lasers • Heart pump
• Diagnostic / Measurement • C-Arms • Mammography • Nuclear Imaging • Endoscopy • Robotic Surgery • Renal Dialysis • Interventional Neuro radiology	• Respiratory Devices • Dental Imaging • Bone Densitometers • X-Ray Systems • Neurological Diagnostic • Hearing aid	• MRI Systems • Surgical Energy Devices • Dental Lasers • Angio Suites
• Speech Aid Devices • Wearable	• Wearable • Emergency remote control	

Hi-Rel Class III

Lower — Technical Performance — Higher



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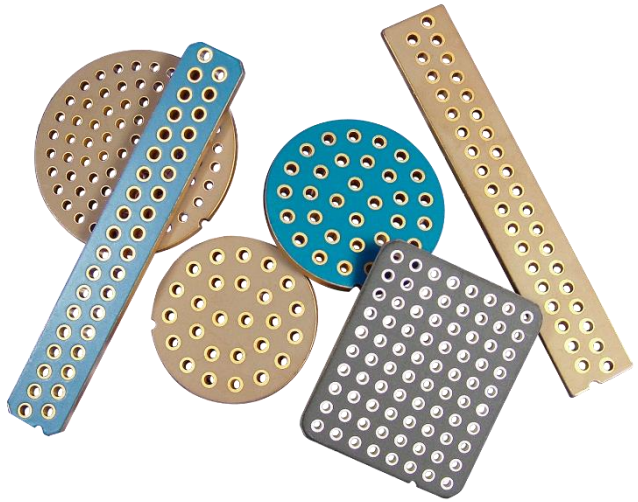
Design Stage – Quality / Reliability



Some data to take into account

Assembly Process

- Mounting: Soldering / bounding / sticking
- Terminations: Sn, SnPb, Ag, Au…etc.
- Terminations: Flexible, non-magnetics…etc.
- Thermal: 160°C, 220°C, 260°C to >400°C
- Mechanical: Avoid board stress areas for MLCs

Quality / Reliability

- Wearable or implantable
- Life support or not
- Repairability

Mission Critical

- Mechanical: Stress (Vibration, shock…etc.)
- Thermal shock: Board expansion coef Vs MLC
- Over Voltage: Battery change, recharge
- Therapy: X-Ray, MRI…etc.
- Aging: Vs dielectric

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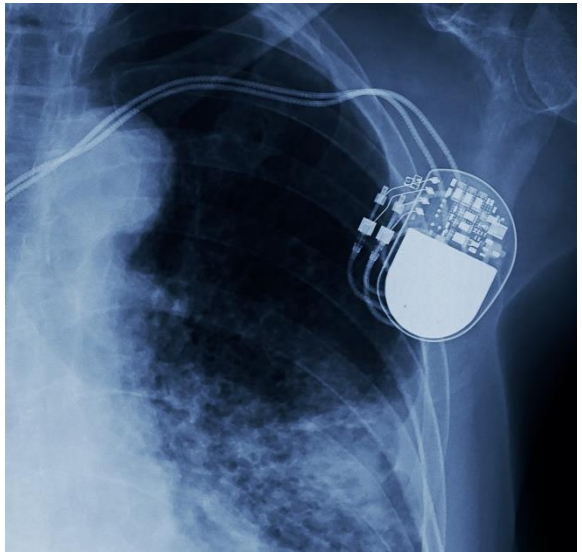
Quality / Reliability

The strong integration of medical equipment, and more particularly when it is implantable, does not allow the number of redundancies to be multiplied sufficiently to ensure the reliability of the system.

The reliability of the components themselves then becomes paramount in determining the reliability of the device

To date, there is no standard that electronic components must meet to be used in medical devices.

As there is no standard, the best is to start from the needs of the device and the descriptions of the various constraints that it must be able to undergo and to deduce the resulting constraints for the components.



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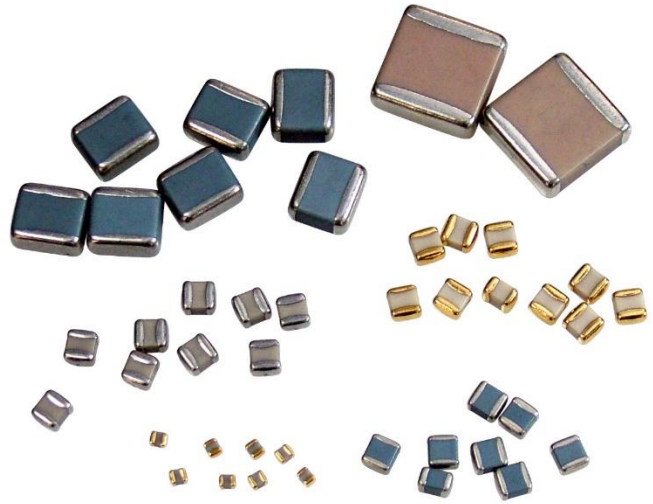
Most Common Applicable SCDs

Strict guidelines place more weight on reliability grade, size, and durability over other important parameters



Few Source Control Drawings (SCD's) most widely used for capacitor in medical applications

- AECQ-200 Process Qualification
- IECQ-CECC Process Qualification
- MIL-PRF-55681 100% burn-in
- MIL-PRF-123 100% burn-in

Capacitors covered by these specifications may be used in:

- Aerospace, airborne, medical, and various military applications

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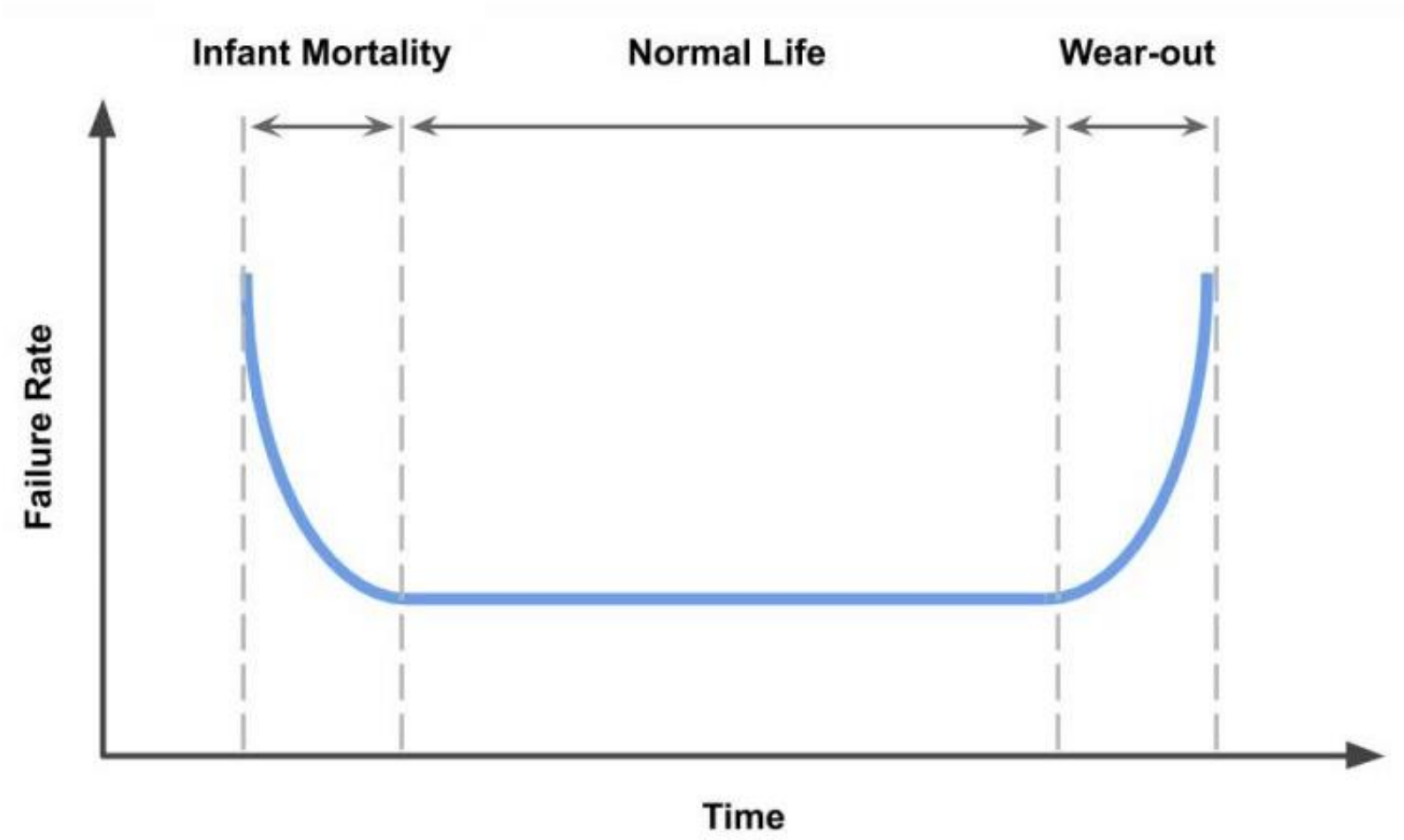
MIL-PRF-55681

- Voltage Conditioning:
  - 100 Hrs
  - 2x Rated Voltage
  - Max temperature 125°C
- Dielectric Withstanding Voltage (DWV):
  - Temperature: Max operating temperature, 125°C
  - Time: 5 seconds
  - Insulation Resistance (IR), Capacitance, Dissipation Factor (DF)
- Solderability: 10 Samples
- Visual & Mech. Inspection Sample (AQL Sample Plan)
- Percent Defective Allowable PDA: 8% Max

MIL-PRF-123

- Thermal Shock, 20 Cycles:
  - Minimum operating temp to max operating temp.
- Voltage Conditioning:
  - 168/264 Hrs
  - 2x Rated Voltage
  - Max temperature 125°C
- Dielectric Withstanding Voltage (DWV):
  - Temperature: Max operating temperature, 125°C
  - Time: 5 seconds
  - Insulation Resistance (IR), Capacitance, Dissipation Factor (DF)
- Visual & Mech. Inspection Sample (20)
- Destructive Physical Analysis (DPA): 1
- Percent Defective Allowable PDA: 3% (0.1%), 5% (0.2%) Max(2)

Why Burn-in?



Reliability Testing

Electric Testing

Capacitance	MIL-STD-202, Method 305
Insulation Resistance	MIL-STD-202, Method 302
Dielectric Withstanding Voltage	MIL-STD-202, Method 301
Quality Factor	MIL-STD-202, Method 306
DC Resistance	MIL-STD-202, Method 303A

Mechanical Testing

Constant Acceleration	MIL-STD-883, Method 2001
Mechanical Shock	MIL-STD-883, Method 2002
Solderability	MIL-STD-883, Method 2003
Visual	MIL-STD-883, Method 2008
External Visual	MIL-STD-883, Method 2009
Bond Strength	MIL-STD-883, Method 2011
Die Shear	MIL-STD-883, Method 2019
Ball Shear	ASTM 1269
Tape Test	ASTM 3339

Physical Testing

Vibration	MIL-STD-202, Method 201
Resistance to Soldering Heat	MIL-STD-202, Method 210
Acceleration	MIL-STD-202, Method 212
DPA	EIA-469

Environmental Testing

Humidity	MIL-STD-202, Method 103
Immersion	MIL-STD-202, Method 104
Moisture Resistance	MIL-STD-202, Method 106
Thermal Shock	MIL-STD-202, Method 107
Temperature Cycling	MIL-STD-883, Method 1010
Burn-In	MIL-STD-883, Method 1010

- C, DF, IR, DWV
- TCC, TVC
- ESR
- Power
- Hot IR
- Cross Section
- Visual Appearance
- Scanning Acoustic Imaging
- Plating Thickness
- Terminal Strength
- Resistance to Soldering Heat
- Life
- Shock & Vibration
- Pulse
- Group B & C

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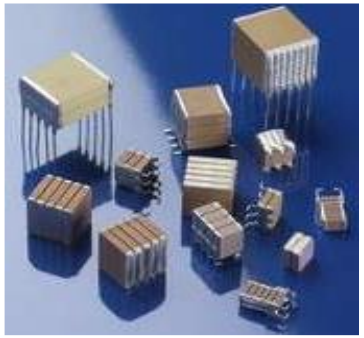
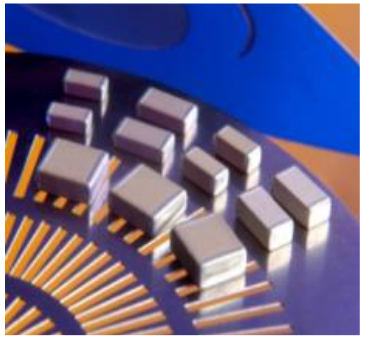
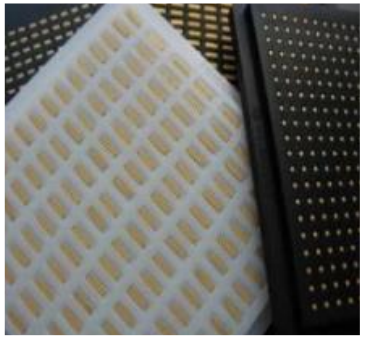
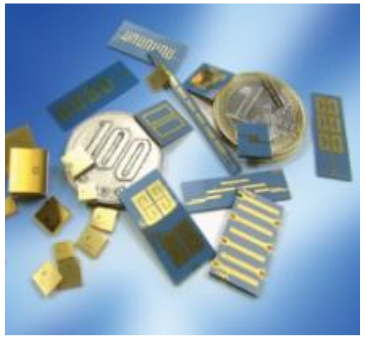
Portfolio
Medical

Brands	NOVACAP	SYFER	DIELECTRIC LABORATORIES, COMPEX	Voltronics, Johanson	ITF, DIELECTRIC LABORATORIES, INTEGRATED MICROWAVE
Products	**High Reliability Capacitors**	**Multi-Layer Capacitors (MLC)**	**Single Layer Capacitors (SLC)**	**Trimmer Capacitors**	**Thin Film Components**
					
Applications	**High Reliability, Zero Failure (Implantables)**	**High Q, High Temp, High Voltage**	**Optical Networking Microwave**	**Variable Capacitance, Test & Meas. Non-Mag (MRI)**	**RF Filtering, Electronic Warfare, 5G, Built to print services**
Markets	**Medical Devices, Military, Space**	**Industrial, Telecom, Automotive, Medical**	**Military, Telecom**	**Medical Devices, Telecom**	**Military, Telecom, Medical**

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Why Choose Knowles?

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