Environmental impact on medical devices’ safety
An overview of the failure mechanism, impacts, and solutions

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Abstract

Environmental impact on medical devices’ safety

Medical devices are always exposed to and affected by numerous environmental factors, like temperature, vibration, humidity, dust, electromagnetic interference, and air pressure. These factors can potentially lead to a broad range of failures causing functional problems or safety related risks to the patients.

To construct a robust design is very important to understand the impact of these environmental factors allowing for safe and reliable operation within the specified environmental conditions expected throughout the service life of the device. Before completing the actual design, it is always recommended to establish design requirements from a risk-based approach, which can help to identify potential hazard or adverse effects during device usage. The aim of this article is to give the reader an overview of the importance and impacts of each environmental factor and offer advice on implementation of general design principles.

Major environmental contributors to medical device failures:
- Excessive temperature
- Humidity
- Dust
- Change in air pressure
- Shock and vibration
Failure mechanisms in medical devices caused by environment

Medical devices, like other electronics, always face a number of environmental stress factors such as temperature, vibration, humidity and dust depending on the use environment (Fig. 1). These stress factors can trigger various failure mechanisms, which in turn, depending on the device design and application, can render the medical device useless, unable to provide the treatment as intended, or in other way compromise the safety of the user.

Nowadays, a growing number of medical devices are intended for use in home healthcare and outdoor applications, where the environmental impact is particularly likely to compromise the reliability, safety or efficiency of poorly designed devices. Similarly, other factors such as electromagnetic compatibility (EMC), excessive or low air pressure also pose a threat to medical devices. Thus, the failure mechanism and ways to design and verify robustness towards these are discussed below.

Impact of vibration and shock

If we magnify the mechanical environment a given medical device is subjected to, we see quite a noisy picture, with potentially strong impact over the lifetime of the device. The noise can be divided into vibration, which is a continuous “noise” phenomenon with a long-term impact, and shock, which is a transient short-term “noise” phenomenon with immediate impact.

The failures caused by vibration and shock are mainly mechanical such as components breaking off, intermittent connectors, or physical damage to the components. Vibration and shock phenomena are amplified by resonances within the device, which over time, further stresses the construction to the point of breaking.

Impact of temperature

Temperature related failure causes account for 55% of all electronics failures and therefore play a pivotal role over the lifetime of the device (Fig. 1). The operating temperature is composed of the ambient temperature to which the device is subjected, and power loss driven self-heating of the device. The mean time between failures (MTBF) of any electronic component or device is directly related to its operating temperature. In practice, such dependency means that lowering the operating...
Temperature by 10 °C potentially doubles the reliability of the product; and vice versa; increasing temperature by 10 °C halves the lifetime [2, 3].

Temperature and its variation alter the physical and chemical properties of the materials used leading to degradation. Excessive difference in coefficients of thermal expansion (CTE) between the components and the printed circuit board (PCB) causes stress followed by fatigue failure mode on solder joints and embedded copper structures [4]. On a less visible scale, high temperature may result in failure of wire-bonds, breaking of encapsulation and packaging, and semiconductor die attachment whereas electrolytic capacitors can suffer from deterioration and degradation of dielectric [5].

Magnetic components and semiconductor components are particularly sensitive to high operating temperature. Increased temperature influences functional properties, such as saturation flux density, of the magnetic components [6,7]. Likewise, high operating temperature causes degradation of semiconductor devices in terms of reduction of breakdown voltage and increase in leakage currents [5,8]. The result is often increased power losses, functional failures, or breakdown.

Size restrictions and comfort requirements push modern electronics into a high degree of miniaturization resulting in reduced cooling surface area [9-11]. Reduced surface cooling challenges the ability for the device to dissipate heat, which in turn leads to further increased operating temperature. High power density design and small footprint of electronics are mostly achieved through higher switching frequencies, which further increase switching power losses [9,10,12]. Hence, presently, controlling the temperature is a main limitation for a higher degree of miniaturization and as a result, thermal design management has become more of a central issue and a challenging task in present electronics engineering.
Impact of humidity

Deployment of medical devices in humid environment can lead to a range of moisture related failure mechanisms: Acceleration of corrosion, leakage currents, alternation of material properties, short or open circuits caused by electrochemical metal migration, formation of electrically conductive aqueous paths on surfaces and interfaces as well as substrate resistance degradation below the tolerance of attached components [13-23]. These failure mechanisms are the most important issues found in electronics applications, e.g. implants, pacemakers, medical devices used in ground and air ambulances and home health care. Similar to temperature issues, moisture problems pose an increasing challenge due to the continuous miniaturization and cost reduction of electronic devices, requiring lower power consumption to keep temperature low, however, thereby limiting the ability for the device to evaporate the moist efficiently.

In fact, most humidity related failures are caused by condensed water forming layers on critical surfaces of PCBAs and components. However, based on Perkins, Licari, and Buckelew studies, pure uncontaminated water does not cause the aforementioned failures or corrosion inside electronics [21]. In fact, the entry of hygroscopic contaminations (substances absorbing water vapor or water from its surrounding) in the water causes the problems, by reducing the critical relative humidity/surface energy levels allowing for water layer formation [24-30].

Impact of dust

Dust always exists in the air and plays an important role in the reliability of electronics dependent on operating conditions. Dust has a complex nature and normally includes inorganic minerals, water soluble salts, organic materials and a small amount of water [31-33].

Studies show that dust may cause electrical leakage and shorting and opening of PCBs under different conditions [34,35]. A conductive electrolyte film degrading the surface insulation resistance
between conductors can be formed in the presence of dust. Dust particles may lead to increased friction on contacting surfaces, which in turn changes the contact resistance of connectors [32]. Moreover, dust particles act as dielectric materials causing signal interference in the contaminated signal connectors and lines [31].

Dust, like mechanical impacts and humidity, also poses an increasing challenge towards the reliability of electronics due to miniaturization of technology [33]. Miniaturization of technology reduces the trace-to-trace spacing on PCB and reduces lead-to-lead spacing on the component level both increasing the risk of short circuit [31]. Dust accumulation behaves as an insulating layer on the heat sink, power connectors, and active components and therefore can be a cause for overheating of components further challenging thermal design management.

The effect of dust can be particularly significant for medical devices when exposed to outdoor environment, emergency medical service vehicles, i.e. ambulances, or when intended for use in mobile home healthcare settings.

Impact of electromagnetic compatibility

The ever-increasing numbers of electrical devices everywhere pose an increasing risk to the safe operation of medical devices. All electronic products are subjected to interference from other products and responsible for emitting electromagnetic disturbances, both intentionally, as required for wireless communication and unintentionally, because of the nature of flow of currents within the products. It is not only a question of protecting your device against the surroundings, as much as it is a question of protecting the surroundings against your device. Emissions are invisible and the level of immunity for the device is difficult to predict and thus electromagnetic compatibility must be controlled by design and the performance verified to meet specifications. Patients are often depending on treatment and lack of treatment or failed treatment may therefore pose an unacceptable risk to the patient. In many cases patients do not have skills, health, or ability to actively compensate for failure of the medical device to operate as intended, and consequently medical devices are subjected to more severe regulation in this field than most other electronics. From January 1st, 2019 all medical electrical devices must comply with the new edition of the EMC standard IEC 60601-1-21. This topic was discussed in a previous FORCE Technology article, which deals specifically with this subject [36].

Impact of air pressure

According to the standard IEC 60601-1, general requirements for basic safety and essential performance of electrical medical devices, pressure or variations of pressure are designated as some of the environmental effects with a potential safety impact to medical devices causing functional failures or inaccuracy in measurements. Many medical devices i.e. spirometer, cooling mechanisms, autoclaves, sterilizers, artificial lung ventilation equipment, and instruments used for narcosis, may experience functional problems or failure if the air pressure changes. Generally, these devices rely on mechanical ventilation, which uses compressed gas to deliver or monitor a required volume to/from the patient [37-39]. As an example, variation of pressure might cause invalid measurements of volume air going in and out of a lung through a spirometer in turn leading to incorrect diagnosis of a lung disease. Moreover, air pressure changes can alter the concentrations of oxygen, air, nitrous oxide and volatile agents delivered to patients being treated with anesthetic equipment [40]. It is emphasized that

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1 IEC 60601-1-2 ed. 4.0: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
the mechanical ventilation can be very challenging during air medical transport, especially due to the impact of varying atmospheric pressure when altitude changes [37]. Usually, flight altitudes in air medical transports can reach up to 14,800 ft/4,500 m [37]. Although helicopters rarely go to altitudes that require the body to adapt, alterations related to the changes of ambient pressure can have a significant impact on the volumes delivered by the ventilator posing a safety risk to the patient [37,41].

Risk management

Risk management is an integral part of medical device development. Resources with adequate competence should be included in the risk management team to identify risks caused by environmental stress as described above, specify relevant design requirements, and further ensure that such risks are controlled, and that the efficiency of the risk control measures is verified (ISO 14971).

It should be considered if temperature, humidity, dust, mechanical stress or other environmental impacts on the design may cause safety or treatment related hazards. Safety hazards are always of crucial importance towards any medical device, and risks related hereto must, according to the medical device regulation, be controlled and mitigated. Meanwhile, it is highly recommended to also consider risk of the device not performing treatment according to its intended use. The European standards do generally not consider failure to perform treatment as a harm, unless lack or degrading of treatment constitutes an unacceptable risk to the patient, in which case the design has essential performance, which must be maintained. However, the FDA, which regulates products placed on the US market, considers failure to perform treatment as harm, and hence to be fully compliant internationally, risks for both safety hazards and failure to perform treatment should be considered in the risk management process.

To ensure an efficient risk management process, leading to a safer and better design, it is crucial to start the risk management process early. Starting late often leads to delayed product launch or inefficient risk control measures, while starting early allows for designing safety control measures directly into the design.

Design for medical device safety

Any medical device must be able to perform its intended purpose, which is shown through clinical evaluation or clinical investigation of a final product. However, while doing so the medical device must also be safe for the patient and coexist with other devices when exposed into the intended use environment. Thus, the design must be constructed while considering all possible environmental conditions and use scenarios to operate reliably within the defined service life. The challenge is to identify all critical environments to which the device will be exposed throughout its service life. To this end, it is important to consider both transport and storage, as well as the continuous operation environment, and shelf life time. While EN/IEC 60601-1 primarily covers the professional healthcare environment, i.e. hospital, there are a number of collateral standards serving to establish requirements focused on other use environments, i.e. EN/IEC 60601-1-11 for home healthcare medical devices and EN/IEC 60601-1-12 for medical devices intended for use in emergency service vehicles.

Once the intended use environment has been identified and the requirements have been established, the standards help predicting the environmental impacts, offer design guidelines, and provide test guidance for verifying the robustness against the requirements. The following presents some general principles to observe.
Principles for effective temperature management are discussed in literature [42-44]:

- To avoid keeping the device in restricted surroundings, temperatures between -40 °C and +70 °C, and possibly even more should be considered over the entire product life time.
- Maximize top and bottom surface areas and keep uniform temperature distribution across surfaces to achieve effective natural convection.
- Maintain all components at optimal operating temperatures to minimize power losses.
- Use thermal vias, preferably connected to layers of the PCB, to control thermal spreading.
- Consider geometrical integration of components to enclose air as little as possible for optimal air flow.
- Choose component packaging to make components fit to each other to achieve better thermal conduction and enable temperature sharing between components. However, be careful as doing so increases thermal proximity, which in turn presents new thermal challenges because the operating temperature of each individual component becomes dependent on its neighbors.

Principles for humidity control inside electronic enclosures [28] [45-46]:

- Absolute humidity control method (AHCM) where absolute humidity is kept to a minimum e.g. by using desiccant (a drying agent).
- Relative humidity control method (RHCM), where the moisture is controlled by maintaining the temperature higher than the dew point temperature.
- Potting or coating of electronic boards, thereby creating a barrier for the moist ingress to the surface.
- Metallic encapsulation.
- Constructing tightly sealed enclosures to keep moist out or design enclosures large enough to allow for airflow to keep the inside temperatures evenly distributed to reduce the risk of condensation.
- Prevent condensation by keeping the relative humidity below 60 % and avoid sudden temperature variations.
- Keep the surface temperature at least 8-10 °C higher than the dew point to avoid condensation.

For dust control, the entry of particulate contamination into an enclosure can be controlled to a high degree using appropriate encapsulation, use of appropriate gaskets and air-filter systems [30].

Verification

For market access any medical device needs to be safe for the user, i.e. patient/operator/distributor/ etc. Unfortunate experiences have forced authorities worldwide to establish requirements which must be fulfilled before placing the device on the market in the specific countries. As the requirements differ on a global scale it is quite complicated to gain world-wide market access. However, international organizations like ISO\(^2\) and IEC\(^3\) help to set common safety, performance, and risk-based requirements, with world-wide acceptance.

Independent and continuously audited test houses, like FORCE Technology, are placed round the world. Many of these are offering accredited tests according to harmonized standards, and

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\(^2\) ISO - International Organization for Standardization

\(^3\) IEC - International Electrotechnical Commission
certification services under the CB scheme\textsuperscript{4} system providing testing for medical product safety and electromagnetic compatibility to allow for unhindered market access world-wide.

\textsuperscript{4} Operated by the IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE), the IECEE CB Scheme is an international system for mutual acceptance of test reports and certificates dealing with the safety of electrical and electronic components, equipment and products.
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