

Design Considerations for Maximum Allowable Temperature

as per Safety Standards IEC 60601-1, IEC 60950-1 and IEC 61010-1
AN-G012





PURPOSE

To review considerations in assessing potential hazards and risks posed by excessive temperatures and other hazards during a normal use of equipment within the scope of the following standards:

IEC 61010: Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements

IEC 60950: Information technology equipment - Safety, Part 1: General requirements

IEC 60601: Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance

This application note is intended as a guide and not a standard. Consult the appropriate regulatory standard(s) for your product to determine the actual requirements.

DESCRIPTION

Safety standards dictate the requirements for products to remain safe during the normal operating condition of the product as well as during an abnormal single fault condition. Standards also require products to operate safely within a minimum set of environmental conditions, such as an ambient temperature range and supply voltage fluctuations.

Temperature tests are performed at the specified temperature range, and at least the minimum range, specified in the relevant standard, to limit the risk of burn injuries or fires. Abnormal tests are performed to verify that the product will remain safe even when there is a fault condition, such as blocked cooling vents or a component short.

ENCLOSURE ALLOWABLE MAXIMUM TEMPERATURES

A product enclosure or part that has excessive surface temperatures can injure or cause discomfort to a user. Additionally, if a component or material gets too hot it can cause burns to a person.

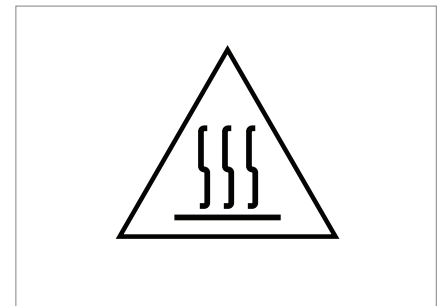
Information Technology Equipment Safety IEC 60950-1 and Test Equipment Safety IEC 61010-1 standards define maximum allowed temperature limits for operator access areas where the conditions of contact are divided into two main categories:

- Surfaces and parts used to hold the equipment or control the functions. Listed examples of such parts are handles, knobs, grips and similar. Touching these parts is necessary for normal equipment use.
- Every other internal or external surfaces of the equipment like enclosure, cables or components that may be touched accidentally.

The scope of Medical Safety Standard IEC 60601-1 however is to provide safety requirements of equipment from operator and patient contact perspective therefore the limits are categorized into:

- Medical electrical equipment which includes those accessories that are necessary to enable the normal use of it.
- Applied part, which per definition is part of medical electrical equipment that in normal use necessarily comes into physical contact with the patient to perform its function.

IEC 60950-1 and IEC61010-1 standards provide rules if exceeding maximum allowed temperature is required for functionality. In such cases for example the equipment must be marked with standardized IEC 60417-5041 (2002-10) symbol:





Exceeding maximum allowed temperature per IEC 60601-1 must be documented in Risk Management File.

All three standards classify limits of the touchable surface temperature according to surface material and are listed in tables 23/24 of standard IEC 60601-1 3rd Ed., table 4C of standard IEC 60950-1 2nd Ed. and table 19 of standard IEC 61010-1 as shown here as a guide. Check the actual standard for the current requirements.

	Part	Metal	Vitreous Material (glass, ceramics etc.)	Plastic, Rubber	Coated Metal (non metallic paint)
IEC 60950-1	Handles, knobs, grips, etc. continuously in normal use	55°C	65°C	75°C	-
	Handles, knobs, grips, etc. Held or touched for short periods	60°C	70°C	85°C	-
	External surfaces or parts inside the equipment that may be touched	70°C	80°C	95°C	-
IEC 61010-1	Handles and knobs held or touched in normal use	55°C	65°C	70°C	70°C
	Outer surface of enclosure touched unintentionally	65°C	80°C	85°C	80°C

Notes:

- IEC 61010-1: small areas (<2 cm²) that are not likely to be touched in normal use: 100°C

IEC 61010-1:2010 Table 19 and IEC 60950-1:2005 Table 4C – Touch/surface temperature limits



	Part	Contact Duration for a time "t"	Metal and Liquids	Glass, Porcelain, Vitreous Material	Plastic, Rubber, Wood, Molded Material
IEC 60601-1	Medical electrical equipment	$t < 1 \text{ s}$	74°C	80°C	86°C
		$1 \text{ s} \leq t < 10 \text{ s}$	56°C	66°C	71°C
		$10 \text{ s} \leq t < 1 \text{ min}$	51°C	56°C	60°C
		$1 \text{ min} \leq t$	48°C	48°C	48°C
	Applied part having contact with patient	$t < 1 \text{ min}$	51°C	56°C	60°C
		$1 \text{ min} \leq t < 10 \text{ min}$	48°C	48°C	48°C
		$10 \text{ min} \leq t$	43°C	43°C	43°C

IEC 60601-1:2005 Table 23 and Table 24 – Allowable maximum temperatures

While IEC 60601-1 clearly specify maximum allowed temperature limits based on touch duration of the surface for each material for healthy skin of adults, IEC 60950-1 rate only short period touch vs. continuously held in normal use. In the standard IEC 61010-1: 2010 edition the surface temperature limits have been modified to conform to the limits of EN 563 which provide information about the effect of the duration of contact.

MAXIMUM ALLOWABLE TEMPERATURES FOR EMBEDDED POWER SUPPLIES POWER SUPPLY MOUNTING – TRADE-OFFS

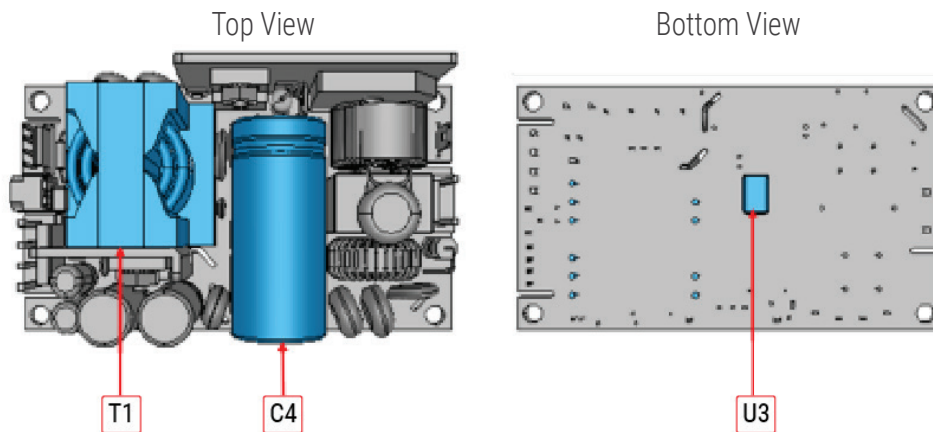
Proper layout in applications with internal power supplies consists of appropriate thermal design where generated heat by power components is checked and dissipated in best available way. Generally, safety agency CB test reports of the mentioned standards list critical components with maximum rated temperature values which are to consider for enclosure construction. Derating curves in most datasheets show maximum power ratings versus ambient temperature of the power supply. These measurements are made in climate chambers on power supplies in unobstructed air conditions which may not be the actual case in the application. Integration of power supply unit into the system creates heat barriers hence the temperature of the components may rise. For example, enclosing the power supply with covers or mounting it close to walls or other elements creates heat traps in the system and so decrease heat dissipation effectiveness of the unit.

Contact your local field applications team to help to identify components of power supply with maximum rated temperatures.



IDENTIFYING TEMPERATURE CRITICAL COMPONENTS – EXAMPLE

A power supply from SL Power Electronics TB65S Family can be taken as example while determining heat critical components. The 3D picture shows three components with critical temperatures that were identified based on the safety CB test report and must be monitored:



- Bulk capacitor C4 is electrolytic capacitor and is significantly affected by temperature. AC ripple currents in these capacitors create additional heat. The higher the long-term temperature of the electrolytic capacitors, the shorter the life of the component. It is strongly recommended to keep its temperature 5°C – 10°C below the max allowed value of 105°C under worst case condition especially without active air flow.
- Main Transformer Winding T1 is the main power element allowing maximum temperature up to 130°C. While selecting other system elements near this transformer designer should keep in mind the high temperature that these closely mounted system elements must withstand.
- Located on bottom of printed circuit board Opto-Coupler Body U3 is rated to maximum 115°C therefore need to have enough spacing between the power supply unit and system enclosure. Mounting TB65S on >5mm standoffs ensures proper heat dissipation.

TEMPERATURE TEST REQUIREMENTS – MEASUREMENT GUIDELINE INFORMATION TECHNOLOGY EQUIPMENT – IEC 60950-1

Maximum operating temperatures apply to components/materials including those that carry, support, or contain hazardous voltage or current. As an example, a plastic enclosure has two temperature ratings, maximum surface temperature and its own maximum operating ambient air temperature. Used materials shall be selected so that under normal load, the temperature limits will not be exceeded.

Designer should consider effective shielding of components working at higher temperature to avoid overheating of other systems parts in the application. Helpful information sources beside thermal measurements are material data sheets.

Unit under temperature test should be operated under normal load conditions in accordance to supply voltage with respect to worst case condition until the temperature has stabilized. Common power supplies support wide input voltage range to cover worldwide AC mains networks. The standard defines the supply voltage tolerance to be +6% and -10%, unless wider tolerance is declared by supplier.



The IEC 60950-1 standard permits to test components or parts as a standalone unit as long as the test conditions are similar to those in complete systems where the unit under test should be installed into.

MEDICAL EQUIPMENT IEC 60601-1

IEC 60601-1 Safety Standard defines additional setup conditions to test medical electrical equipment hence power supply.

Positioning:

The ME Power Supply Adapter is placed in a test corner which consists of two walls right angles, a floor and, if necessary, a ceiling, all of dull black painted plywood of 20mm thickness. The linear dimensions of the test corner are at least 115% of the linear dimensions of the ME Power Supply Adapter under test. The ME Power Supply Adapter is positioned in the test corner as follows:

- ME Power Supply Adapter normally used on a floor or a table is placed as near to the walls as is likely to occur in normal use.
- ME Power Supply Adapter normally attached to a wall is mounted on one of the walls, as near to the other wall and to the floor or ceiling as is likely to occur in normal use.
- ME Power Supply Adapter normally attached to a ceiling is mounted on the ceiling as near to the walls as is likely to occur in normal use.

Thermal Stabilization:

- ME Power Supply Adapter intended for non-continuous operation:
After operating in standby/quiescent mode until thermal stability is reached, the ME Power Supply Adapter is operated in normal use over consecutive cycles until thermal stability is again achieved, or for 7h, whichever is shorter. The "on" and "off" periods for each cycle are the rated "on" and "off" periods.
- ME Power Supply Adapter for continuous operation:
The Power Supply Adapter is operated until thermal stability is reached.

EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE IEC 61010-1

The temperature tests are made similar to general safety requirements as per IEC 60950-1 in normal condition use. IEC 61010-1 standard allows to determine the maximum temperature levels by measuring the temperature rise under reference test conditions and adding this rise to 40°C or to the maximum rated ambient temperature if higher.

For equipment intended to produce heat for functional purposes IEC 61010-1 also require correct positioning in test corner, a power supply considered here as a part of the equipment and obviously built in internally. Applying this test to external power supplies should be justified:

The equipment with power supply is placed in a test corner which consists of two walls right angles, a floor and, if necessary, a ceiling, all of dull black painted plywood of 20mm thickness. The linear dimensions of the test corner are at least 115% of the linear dimensions of the equipment under test. Equipment is positioned at the distances from the walls, ceiling, or floor specified by the manufacturer. If no distances are specified then:

- Equipment with power supply normally used on a floor or a table is placed as near to the walls as is likely to occur in normal use.
- Equipment with power supply normally attached to a wall is mounted on one of the walls, as near to the other wall and to the floor or ceiling as is likely to occur in normal use.
- Equipment with power supply normally attached to a ceiling is mounted on the ceiling as near to the walls as is likely to occur in normal use.

If equipment intended for installation in a cabinet or a wall it is built in as specified in the installation instructions, using walls of plywood painted matt black, approximately 10mm thick when representing the walls of a cabinet, approximately 20mm thick when representing the walls of a building.



THERMAL TEST SETUP

1. For best worst-case thermal verification, use the lowest rated line input voltage with the highest rated load. Place thermocouples on the listed components on a non-conductive area to measure excessive temperatures and to determine correct thermal design.
2. Analyze accessible enclosure surfaces and critical components to identify the hottest locations on touchable surfaces and critical components/materials, including internal components and materials.
3. Attach thermocouples (TCs) for measurements:
 - Affix TCs to several locations on the enclosure for surface measurements, such as on the hottest metal and plastic surfaces including enclosure top, sides, bottom, and air openings.
 - Affix TCs to the hottest plastic materials and internal components, and where temperature rise could exceed the materials/components maximum operating temperature.
4. Perform the temperature test:
 - Make and record measurements at +10% and -10% of the product's voltage rating.
 - Temperature chambers may be used, especially when the temperature rating of the product exceeds 40°C. Cooling due to chamber air circulation should be minimized. Otherwise this can significantly influence the results.
 - Monitor and record temperature until they stabilize for a minimum of an hour (thermal stabilization for medical equipment explained above).
5. The stabilized temperature result measurements of the touch surfaces must not exceed the temperature limits in tables as specified in corresponding standard.

Caution! In internal power supplies the components with critical temperature are often located on primary side of AC-DC power supply! Use appropriate safety measures as these components are at hazardous voltage levels. Only qualified personnel should attempt to make these measurements.



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