CE MARKING

Of Electrical & Electronic Products

Chetan Kathalay

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By
Chetan Kathalay
B.E. (Electronics)

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Electromagnetic Compatibility – Without Equations.

A Compliance Guide To Electrical Safety – For CE Marking

(Available on www.amazon.in and www.flipkart.com)

To my wife Madhuri and daughter Aditi

And

To my parents who always encouraged me to learn

Declaration

The views expressed by the author are his own and not that of the government

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PREFACE

CE marking has become *the* most sought after marking for manufacturers since it not only introduces them to new avenues for expanding their business to the European Union (EU) but also enhances product acceptance in their domestic market. Although the CE marking simply means that the product complies with applicable European laws, such has been its impact that many have started considering it as an ultimate symbol of quality (which it isn't) and that gives a big boost to product sales and gives them universal acceptability.

As compared to other conformity assessment processes, CE marking remains by far the simplest since it allows *self-declaration* on part of the manufacturer.

People who are new to the CE marking process and who have gone through a rather painful process of other product and system certifications, the concept of self-declaration is out of this world. In fact, the process for majority of the products (which are in the *low risk* category) is so simple that many find it hard to believe. The plight of these people is like an Australian who is visiting Africa for the first time and is shown a Giraffe. The Australian exclaims that *such an animal does not exist* although the animal is right there in front of him! The reason why people don't believe in the simplicity of the process is because they try to draw parallels between CE marking and other product certifications (like UL, FCC, SABS, C-tick etc) or even between system certifications like ISO 9000. This is the reason that misconception, misinformation and confusion rule the roost and that there is no clarity. The confusion is also partly created because many CE marking consultants also happen to be ISO 9000 consultants and who fail to drive home the point that CE marking is a product certification as opposed to ISO 9000 which is a system certification. Also, these consultants in an attempt to play safe, rely on over-compliance insisting on certain steps which may be unwarranted and which, often than not, become the norm that is then followed blindly.

It should be noted that although the CE marking process is simple, it requires compliance of the product with certain technical requirements. It is here that the real challenge lies especially to those manufacturers who are new to the process. This book, while providing a step-by-step approach to CE marking of electrical and electronic equipment also seeks to provide insights into product design and test methodologies so that the product meets the technical requirements. It also seeks to clarify the many doubts and misconceptions about CE marking. Contrary to other certification processes, CE marking has a two-pronged approach with the conformity process being split into two –the *legal* process and the *technical* process which is one of its unique features. The legal process requires that the manufacturer himself/herself declare conformity to certain *essential* requirements given by a legal document called as the *directive*. The basis of this declaration could be a simple technical justification or a laboratory test report that demonstrates conformity to a *standard* (which translates the essential requirements into technical tests). This standard is prepared by a standardisation body that has been authorised by the very legal entity that makes the directive, so that the process comes a full circle.

The book begins with a chapter that introduces the reader to the nuances of the CE marking process, the ways or methods to approach conformity and to compile supporting documents that illustrate the process. The book is restricted to five directives which more or less cover a majority of the electronic and electrical equipment range viz. low voltage directive (LVD), electromagnetic compatibility (EMC) directive, medical devices directive (MDD), radio equipment directive (RED) and the directive on restriction of use of certain hazardous substances (RoHS). Although the directives are five, they essentially contain EMC and electrical safety requirements (barring RoHS) and as such, EMC and safety requirements are dealt with in detail. The chapter on safety describes the principles of safety as found in the international IEC and European harmonized standards. It provides ways and means to improve product design so as to ensure reasonable compliance when a product is subject to safety evaluation by a test laboratory. The information is generally applicable to most product types such as information technology equipment (ITE), test and measurement devices, appliances, machinery, and other similar equipment. The design tips concentrate on problematic areas that manufacturers most often encounter during their first safety assessment. Then there are two chapters dedicated to EMC. One explains the fundamentals, standards and the test methodology while the other deals with EMC design. The design chapter contains ways and means to incorporate EMC measures at the design stage so that the product can comply with the EMC tests with a minimum of iterations. The design means discussed are very practical in nature and are given in such a way that the design engineer can immediately incorporate them without worrying too much about theory. As is the case with a majority of international and European standards, one of the newest requirements of all the directives is the emphasis on risk analysis and risk reduction. All the directives now-a-days require a detailed risk assessment to be carried out in addition to testing as per standards. Thereafter the risk assessment needs to be documented so as to demonstrate how the risks have been reduced/eliminated. The book deals with this aspect in detail for all the directives under consideration.

And last but not the least, the CE marking procedure is not complete unless the entire process is documented through the so-called *technical file* or *technical documentation*. This document resides inside the European Union and is kept with the manufacturer (if European) or the importer/representative (if the manufacturer is non-European) to be produced if demanded by the European surveillance authorities. The chapter on technical documentation explains how this documentation is to be compiled as required by the directives.

It is important to note that a book of this nature can, at best, only draw out the meaning, significance and practical consequences of the directives to which it refers. It can give a simpler explanation of the legal text but cannot replace it or change what the law-making agencies have decided. Hence it is always prudent on behalf of the reader to refer to the actual text of the directive or the standard wherever he/she thinks a conflict exists. Needless to say, the contents of the actual directive or standard take precedence over the contents of this book.

As is known that after Brexit, the UK has replaced the CE marking with its own mark i.e. the UKCA mark, which is the acronym of United Kingdom Conformity Assessed. The procedure for UKCA marking is similar to CE marking and hence for the benefit of readers, this book also includes an Annexure on UKCA marking. This Annexure explains the UKCA procedure, tells about the timelines for transition and explains the related documentation.

It is sincerely hoped that the book will prove to be an invaluable aid towards understanding and simplifying the process of CE marking and that the manufacturer can approach it with professionalism, zeal and confidence.

Chetan Kathalay
Pune, 2020.

1

CE MARKING

1.1 INTRODUCTION

CE is the French acronym of "Conformite` Europe`ene". In English it stands for European Conformity i.e. conformity of a product to European laws. It is a mandatory compliance marking printed on all products intended to be placed in the European Union (EU) or more precisely the European Economic Area (EEA) which consists of 27 nations of EU (at the time of writing this book) plus Iceland, Liechtenstein and Norway. The EEA is also referred to as "community market". It should be mentioned here that Turkey is presently not a part of the EU but has implemented all EU laws and as such CE marking is applicable here as well. Again, Switzerland is not a member of the EU, but for some products it accepts the CE marking based on mutual recognition agreement (MRA) (see section 1.6). In addition, the CE marking is applicable over Northern Ireland and some overseas colonies of the EU member countries like Guadeloupe, French Guyana, Martinique, Réunion, Saint-Barthélemy, Saint-Martin, the Azores, Madeira and the Canary Islands. The CE marking consists of the label "CE" placed on the product (or its nameplate) as a visible proof indicating that the product meets all essential requirements (concerning health and safety) as prescribed by the applicable EU *directives* (laws). Once a product bears the CE marking, it is free to enter the EU and to move freely within the EU and hence many people consider CE marking as a *passport* to the EU.

1.2 BACKGROUND OF THE EUROPEAN UNION

The second world war had caused enormous damage to life and property and had resulted in large scale destruction of most of Europe. After the war, the idea of a unified Europe began to develop, in order to maintain peace and tranquillity in the region and to avoid future wars. Furthermore, the US and the USSR had become superpowers both militarily and economically. There was also a thought that the European nations, if united, could more effectively face economic challenges posed by these superpowers. The seeds of the EU were sown when six countries namely Belgium, France, Italy, Luxemburg, Netherlands and West Germany met in Rome and signed the European Economic Community (EEC) treaty in 1957. Customs duty between these countries was abolished and common policies in trade and agriculture were put into place.

Further in 1960, four countries namely Iceland, Liechtenstein, Switzerland and Norway formed the European Free Trade Agreement (EFTA) to promote free trade and economic cooperation between these countries. Denmark, Ireland and the United Kingdom joined the EEC on 1st January 1973, raising the number of member states to nine. By 1986, Greece, Spain and Portugal also joined the EEC taking the membership to twelve and the single European act was signed in the same year. This treaty provided the basis for a six-year programme allowing free flow of goods across EU borders and the concept of *single market* was conceived. In a major upheaval, the

Berlin wall was pulled down on 9 November 1989, and the border between East and West Germany was opened for the first time in 28 years. This led to the reunification of Germany. Finally, in December 1991, the European Union treaty or the Maastricht treaty was signed between twelve nations and the EU finally came into being on 1st November 1993. In 1994, the EU along-with three EFTA members namely Iceland, Liechtenstein and Norway formed the European Economic Area (EEA). In 1995, Austria, Finland and Sweden joined the EU taking the membership to fifteen. In 2004, in one of its biggest expansions, as many as thirteen nations joined the EU. However, in 2020, the unification process received a major setback when the UK decided to leave the EU. Presently the EU consists of 27 nations namely Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovenia, Slovakia, Spain and Sweden.

1.3 OBJECTIVES OF THE EU

The main objective of the EU is the creation of a common internal market without trade boundaries which allows free movement of goods, personnel, services and capital. These are sometimes referred to as the *four freedoms*. It is commonly observed that varying national legislations cause barriers in trade restricting free movement of goods. Hence it was essential to ensure that the same law is applicable over the entire EU. This process is called as *harmonisation* (i.e. one law applicable over the entire EU) and it is one of the basic features of the EU.

The other objective, which is not immediately obvious, is to bring about cost savings to manufacturers. Before harmonization, if a manufacturer desired to export his product to one country, he had to comply with the laws of that country. If, at a later stage, he had orders from another European country, then the process had to be repeated for that country as well. This not only involved additional cost and time delays but also resulted in unnecessary hassles for the manufacturers located both within the European region and outside of it. In the present scenario, the manufacturer has to comply with only one law and after that he is free to export his goods to any EU member state. This avoids duplication of efforts thus saving both time and money. Another objective is to ensure/enhance product safety. Since

2

THE LOW VOLTAGE DIRECTIVE

2.1 INTRODUCTION

The directive on *electrical equipment designed for use within certain voltage limits* popularly known as the *low voltage directive* (or LVD in short) is perhaps the oldest directive and has been in force since 1973. It would not be an exaggeration if someone refers to it as the mother of all directives –which it is. The directive has been revised many times, the latest revision being the 2016 version of the directive codified as 2014/35/EC published on 26th February 2014 and replaces the old directive 2006/95/EC. The new directive is a recast of the older version which means that all major provisions of the older version remain as they are. The new continued compliance i.e. ensures that all samples of the same model subsequently coming out of the production line are identical to the sample that was tested. This can be done by having an internal quality system or a quality system based on ISO 9000 where in appropriate procedures to that affect have been defined.

2.2 CONTENTS OF THE LOW VOLTAGE DIRECTIVE

As with any other directive, the LVD being a legal document starts with the so-called *recitals* typically beginning with the word *whereas*. It is then followed by *articles* which give information regarding a particular aspect of electrical safety. The directive ends with various annexures giving details of procedures to be followed for documentation, CE marking, risk analysis etc. Let us take a look at the various articles one by one.

2.3 ARTICLE 1 : SCOPE

This article deals with the subject matter and scope of the directive and calls for providing high level of protection to persons, animals and property and is applicable to all electrical equipment operating between 50-1000 V ac and 75-1500 V dc. Products that are outside the scope are given in Annexure II. Accordingly, the directive is not applicable to electrical equipment covered by other specific directives like those used in an explosive atmosphere (covered by ATEX directive), electrical equipment for radiology and medical purposes (covered by medical devices directive), electrical parts for goods and passenger lifts (covered by the lifts directive), electricity meters plugs and socket outlets for domestic use, electric fence controllers, radio transmitters and amateur radio equipment (covered by RED), specialised electrical equipment for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which the member states participate.

2.4 ARTICLE 2 : DEFINITIONS

This article provides definitions of important terms used in the directive. Of importance to Indian manufacturers is the definition of importer who, as we have seen, is any natural or legal person established within the EU (i.e. who is a citizen of one of the European member states) who places electrical equipment from a third country on the European market. In simpler terms, manufacturers outside the EU can make their product available in the EU market through the importer who being a citizen of one of the member states of the EU is liable to pay for damages, in case the product is found to be unsafe.

2.5 ARTICLE 3 : MAKING AVAILABLE IN THE MARKET AND SAFETY OBJECTIVES.

As we have seen, making available in the market means supply of any equipment for distribution, consumption or use in the EU i.e. any transfer of a product between economic operators. The article identifies *essential requirement* of the directive and states that any equipment made available in the EU, when properly installed and maintained, should be constructed using good engineering practices and should not endanger health and safety of persons, domestic animals and property.

The hazards against which that the directive seeks protection are listed in annexure I of the directive. The hazards arising from the equipment (when used in applications for which it was made) include harm or injury caused by direct or indirect contact with the equipment (shock hazard), temperature, arcs, radiation and non-electrical dangers (like chemical contamination). The directive also states that the insulation should be suitable for the purpose for which the equipment is being used. The directive also seeks to reduce the hazards due to external influences on the equipment like conditions of overload. The equipment should also not pose mechanical hazards.

2.6 ARTICLE 4 : FREE MOVEMENT

This article ensures one of the *four freedoms* i.e. freedom of movement of goods within the European Union. It states that if equipment meets the requirements

3

DESIGN FOR SAFETY

3.1 INTRODUCTION.

The low voltage directive is the primary directive for safety compliance of electrical equipment. Some people assume that the term low voltage means safe voltage, but as we have seen the LVD applies to products that operate at typical line (mains) voltages (e.g., 230/400 volts) that present shock and fire hazards. Safe voltages are those less than 42.4 V ac (peak voltage) or 60 V dc, depending on the standard or term applied and are referred to as extra-low voltage or safety extra-low voltage (ELV/SELV). The LVD applies to all safety aspects of electrical equipment, including protection from mechanical and other hazards.

In this chapter we will take a look at the basics of electrical safety of equipment. Proper application of the guidelines in this chapter and chapters that follow, along with the standards, will ensure that the product complies with European standards. Let us get familiarised with some important terms that we would be frequently referring to in this section.

Safety means *freedom from unacceptable risk*. Equipment is sometimes referred to as product and includes machinery also. The term *appliance* is generally applied to household and similar products and includes commercial appliances. *Operator* is an authorized person designated to operate a machine as intended, except service personnel. Safety requirements assume that operators do not mean to create a hazardous situation and are not aware of electrical and other hazards. One also must assume that the operator does not normally possess tools reserved for service and maintenance purposes. Sometimes the terms *user* and *consumer* are also used instead of operator and hence are equivalent terms. Apart from this, equipment must protect janitors and casual visitors too. An *operator access area* is any area that, under normal operating conditions, allows access without the aid of a tool, for example, by a person's hand or fingers alone. Opening a hinged door by hand, without a tool, makes the area behind the door an operator access area and all hazards should be adequately guarded or the door interlocked to remove hazards before access.

Service personnel are those that have training and experience and are considered be aware of potential hazards while performing a task and can take measures to minimize the danger to themselves and others. Service personnel have access to maintenance areas and have to be reasonably careful in dealing with the obvious hazards. A *tool* is reserved for service personnel and defined as *any object that can be used to operate a screw, latch, or similar fixing means*. The *service access area* is an area, other than the operator access area, that service personnel can access even with the equipment in power ON condition.

As a designer one should first give careful consideration to the selection of components and construction requirements, which minimizes the risk that the product will fail its first test, thus, causing costly product redesign. One should not - rely on test results to be the stimulus for the safe design of the product rather safety should be considered at the design stage, before addressing other design elements. A product's conformity to the European safety standards relies on the use of proper component and construction principles. Testing should be performed only after a sound design is in place.

3.2 THE SINGLE FAULT CONCEPT.

The European safety standards stress an important principle called the *single fault* concept that is at the core of safety philosophy. This principle states that even under a single fault (i.e. a wire coming loose/neutral open/component failure/ short/open circuit/insulation failure etc.) at least one level of protection (LOP) or insulation must be maintained (after the first fault) to ensure adequate protection of the user. This concept is sometimes referred to as *double improbability* which relies on the fact that the failure of one LOP is high but the failure of the second LOP (after the first) is extremely low and that there is always a second means of protection or insulation should the first one fail. This means that two levels of protection should be provided such as by insulation, grounding, shielding or safety interlocks.

This will be clear by taking the example of insulation which is one of the methods to isolate circuits carrying hazardous voltages from user accessible parts (like switches or enclosures). If only one layer of insulation is used, it provides protection under single fault conditions. To take care of second failure as a consequence of a first failure, safety standards demand a redundant system with at least two levels of protection. Thus, in case of accessible components/parts, they must be insulated from hazardous voltages by a double-level system. One method is single insulation plus protective earthing of a conductive enclosure. Here if the insulation between hazardous voltage and enclosure fails, the earthing provides a second level of protection. Another method is to use two layers of insulation (double insulation) so that in the event of failure of one layer of insulation, there is still another layer for protection.

With the single-fault concept we can determine the protection or insulation needed to satisfy the electrical safety standards. In addition, it is through single-fault

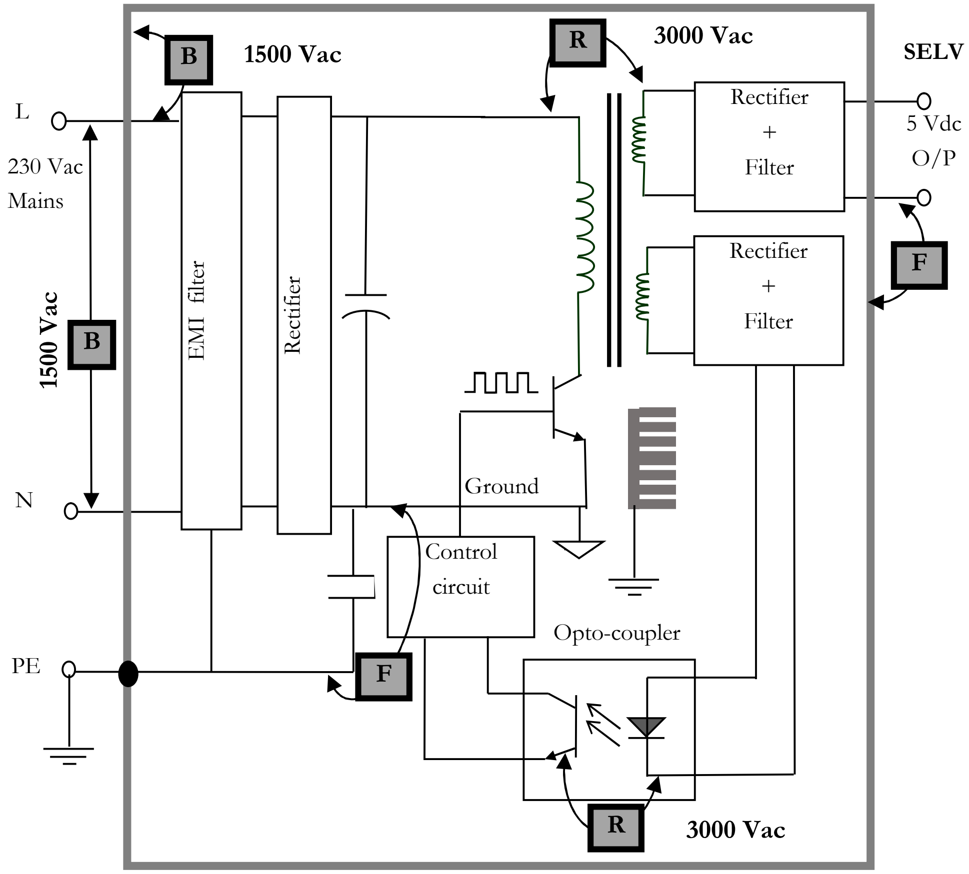


Fig. 3.14: HV Test Levels For I.T. SMPS

3.10.6 Properties Of Insulating Material

Insulating material is characterized by electric strength, thermal strength, mechanical strength, dimensions and other properties. The choice and application of insulating material should take into account the needs for electrical, thermal and mechanical strength, frequency of the working voltage and working environment (temperature, pressure, humidity and pollution). For solid insulation (see 3.10.8.3) only non-hygroscopic, flame resistant materials should be used. In case of wiring insulation, some material compounds may contain plasticizers (for imparting flexibility) but with a side effect of increased flammability. Semiconductor devices

3.10.8.1 Creepage

As shown in Fig. 3.15, creepage is the shortest distance along the surface of an insulation material between two conducting parts (such as PCB tracks or component leads). It is associated with tracking. For a component, this shortest distance may be either over the package or under the package or side of the package. To visualize creepage, one can imagine an ant *creeping* (i.e. crawling) on a surface. The ant will move along the surface always hugging all the undulations. Creepage is a slow phenomenon determined by dc or rms voltage rather than peak events and is heavily influenced by the surface conditioning of the insulating material. Inadequate creepage distance may take days or even months before the insulation fails.

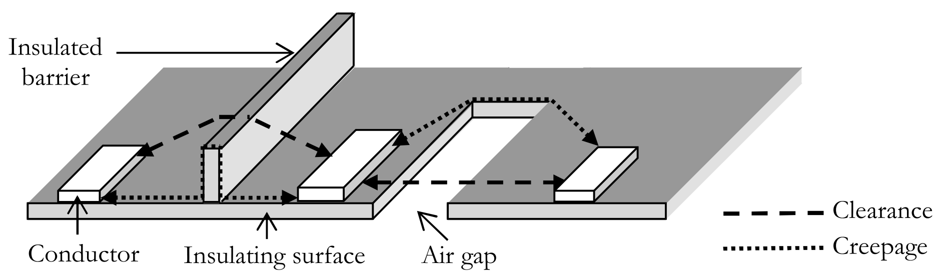


Fig. 3.15: Creepage And Clearance

3.10.8.2 Clearance

Clearance (see Fig. 3.15) is defined as the shortest distance through air between two conducting parts. A very good analogy is a flying insect which will go from one point to the other directly through the air. For component leads, clearance distance can be visualised as the *line-of-sight* distance. Clearance is heavily influenced by the quality of the air. Normally 1 mm of air gap will breakdown at 3 kV at sea level. At such a high voltage, electrons are stripped of their atoms and become free, causing air to become conductive. The presence of humidity, moisture, conductive particles can cause the breakdown to happen at lower voltages as there are already some free electrons to start with. Another important factor is the altitude. Now this comes as a surprise as one may think what does altitude have to do with insulation breakdown? Well as the altitude increases, the air density decreases and the dielectric

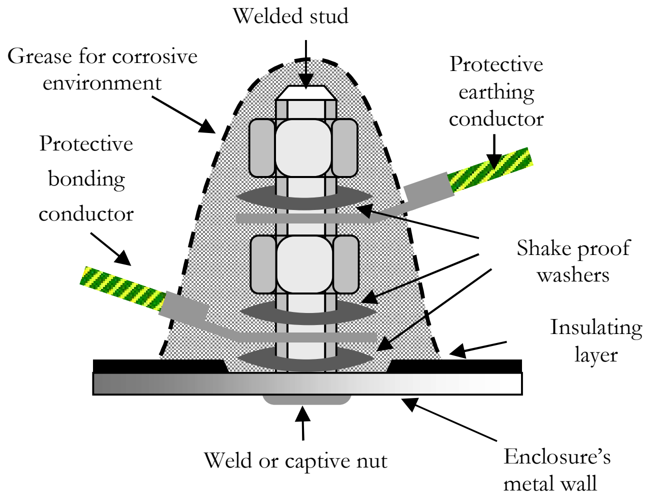


Fig. 3.29: Bonding Of Earth Wire

As per EN 60950, if they are of dissimilar metals, then they should be such that the electrochemical potential they develop should be less than 0.6 V. The choice of metal is given in Annex J of the standard.

3.11.8 General Considerations

Following are some general considerations as regards to earthing in an equipment:

– Fixing of the PE conductor should be such that it cannot be disconnected during the servicing operation to replace any parts. This means that the grounding stud or screw should not be used to hold any other replaceable part in place.
– In a system of interconnected equipment, the protective earthing connection should be ensured for all equipment requiring such a connection.
– Protective earthing conductors and protective bonding conductors should not contain switches or overcurrent protective devices.
– Protective earthing connections should be such that disconnection of a protective earth at one point in a unit or a system does not break the protective earthing connection to other parts or units in a system.

- fter-glow time “t3” (time for which glowing combustion persists after both removal of the flame and flaming of sample) in seconds.
- Whether there are any molten drips of the sample.
- Whether these molten drips ignite the cotton pad.
- Whether the test specimen burned completely up to the clamp.

The vertical burning is then classified as per the table 3.20:

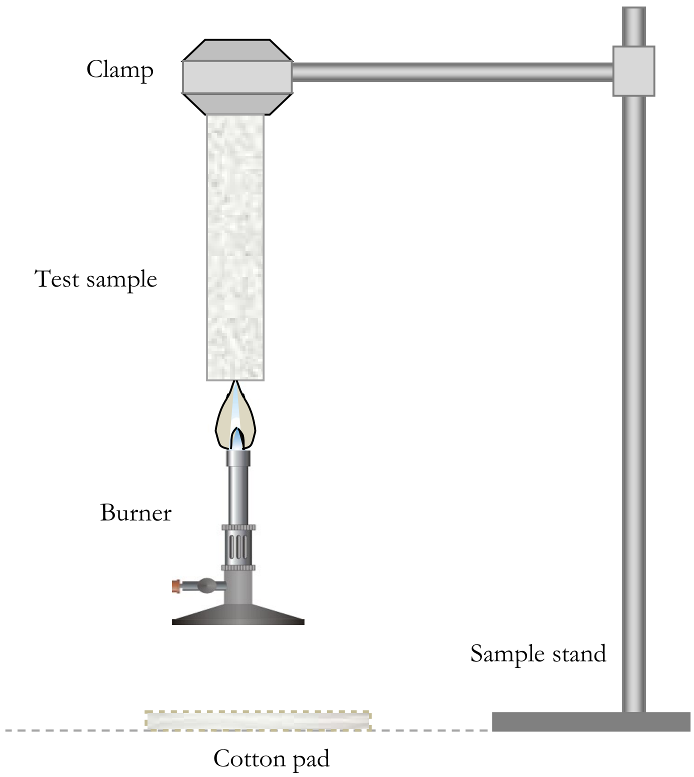


Fig. 3.32: Vertical Burning Test Set-up

Table 3.20: Vertical Burning Classification

Criterion	Classification		
	V-0	V-1	V-2
Individual test specimen after-flame times (*t*1, *t*2)	≤ 10s	≤ 30s	≤ 30s

– If an equipment has a microwave source then the power density of the radiation should not exceed 10 W/m2 (EN 61010) in frequency range of 1 GHz to 100 GHz at a point 50 mm from the equipment under normal and single fault condition.

Fig. 3.35: Laser Warning Label

– For equipment incorporating lasers greater than class1, then access without tool is not permitted and the equipment should carry warning label as given in section 3.35 for laser radiation. Class 3A laser products should also bear an explanatory label as per EN 60825-1 as shown in Fig 3.35. The label may also be depicted in the equipment manual.

– For equipment containing UV source, which is not for external illumination, the enclosure should not allow escape of the UV radiation. It is advised that equipment bears appropriate explanatory label, as shown in the Fig 3.36.

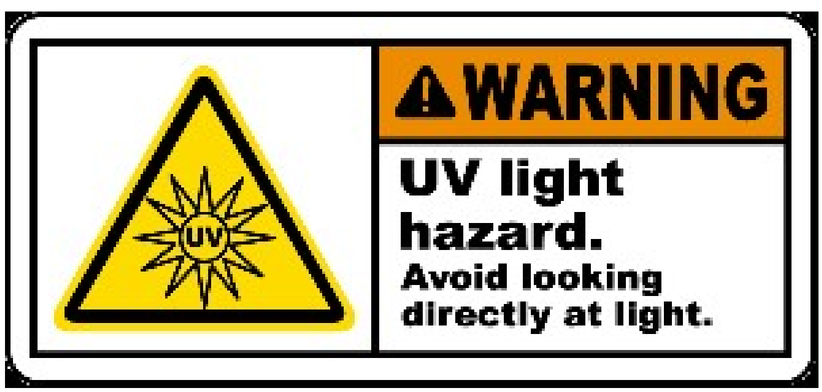


Fig. 3.36: UV Warning Label

3.35 WARNINGS AND INSTRUCTIONS

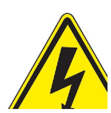
In order to avoid hazards when operating, installing, maintaining, transporting or storing equipment, safety information should be provided by the manufacturer in the form of *warning symbols* on the product, along with *instructions* in the product documentation. Maintenance instructions are normally made available only to service personnel. For pluggable equipment intended for user installation, operating and installation instructions should be made available to the user. Further, the instructions should be in a language acceptable to the country in which the equipment is to be installed and used. Warnings are required for all hazards on any enclosure panel or door that does not clearly show that it contains a hazard in order to notify the operator/user. The service persons must also be warned of any possible hazards such as high voltage or energy, moving parts, high temperature or laser radiation before they access a compartment. Additional warning symbols may be required on internal covers and adjacent to hazards within the compartments to protect against accidental or inadvertent contact.

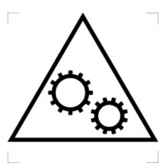
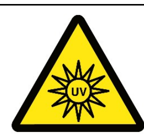
In some cases, a warning may be considered adequate if it is not possible to make hazardous moving parts directly involved in the process completely inaccessible and where the associated hazard is obvious to the operator. In such a case where fingers, jewellery, clothing, etc. can be drawn into the moving parts, a warning should be provided in a visible and prominent position (see table 13.1). An example of where it may not be possible to guard the hazard is the visible moving parts of a paper cutter where hand-feeding is required. Warnings are only permitted when no other means are possible and should not take the place of a safe design. For example, a moving parts warning is allowed only when the hazard is directly involved in the production process and there are no other possible options i.e., guards, interlocks, stop-switch, sensors etc. Therefore, if a guard or other protection means is possible, it must be employed.

3.35.1 Common Warnings And Cautions

Some of the common warnings and caution instructions are discussed in this section and should be a part of instructions or manual supplied along with the equipment is to be installed (ref; EN 60950, EN 61010-1, 73/23/EEC, 89/392/EEC, others). Warning symbols must discourage operator access to compartments containing hazards and must warn service personnel of potential hazards when the hazard is not evident. Safety warnings should be unequivocal by colour, shape, and size and located as close to the hazard as possible. The warning symbols' size and colours are described in the relevant product safety and other supportive standards (ref; EN 60417, EN 60204-1, IEC 1310-1/-2, ISO 3461-1/3864/4196/7000, others). Caution symbols are normally within rectangular box. The preferred method is to use black and yellow warning symbols, without text or signal words (as for as possible), so that the safety warning is unambiguous and negates the need to translate text. A black triangle and pictogram on a yellow background, in accordance with the standards, should be used for warning symbols. The triangle outline and the symbol are black while yellow colour fills the triangle. Other colours may be acceptable depending on the product-specific standard. If signal words and text are used, they should be translated into the appropriate languages. The user instruction or manual must clearly explain the meaning of the various warning symbols that are used on the product or alternatively such information should be marked on the equipment. Some of the more common warning symbols are given in table 3.27:

Table 3.27: Hazard Warning Symbols

	Hazardous voltage
	Hot surface
	Laser Radiation

	Battery Acid
	RF Radiation (Non ionizing)
	Ionizing radiation
	Neutral Fusing
	Stability Hazard
	Cutting hazard due to sharp edges
	Cutting hazard due to moving objects
	UV light

Except for general warnings, words and text are not required when symbols are present. The warning symbol should be placed as close as possible to the hazard to warn the operator and/or service person before the hazard is accessed.

circuits. As we have seen, the test levels depend upon the type of insulation i.e. functional, basic /supplementary and reinforced. It is also required between secondary and body if only functional insulation separates the two. A typical set up for hi-pot test for 2-wire device under test (DUT) is as shown in the Fig. 3.45.

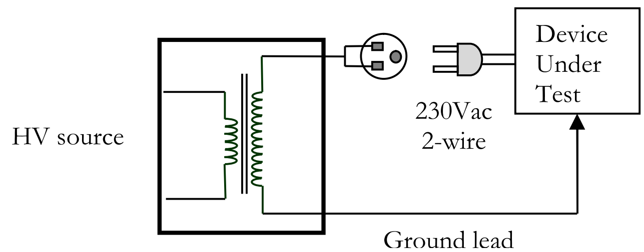


Fig. 3.45: HV Test For 2-Wire DUT

High voltage (HV) generated by a HV source (AC or DC) is applied between live-neutral shorted and DUT body. In case of 2-wire supply, the body of the DUT is normally of non-conductive material. In such a case a metal foil is kept in contact with the insulating body surface. Although care is to be taken that no flashover occurs at the edges of the insulation (especially if the test is done on internal insulating surfaces). The best way is to use adhesive metal foil, with the condition that the adhesive should be conducting. The Fig. 3.46 shows a typical set up for hi-pot test for 3-wire DUT. Here, the HV is applied between live-neutral shorted and earth. The DUT complies if there is no insulation breakdown during the test. Insulation breakdown is considered to have occurred when the current (which flows as a result of the application of the test voltage) rapidly increases in an uncontrolled manner, i.e. insulation does not restrict the flow of the current.

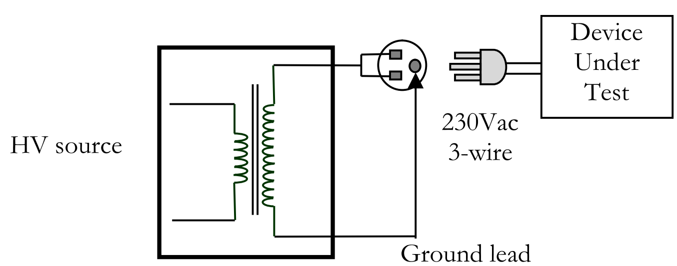


Fig. 3.46: HV Test For Three Wire DUT

operator as a part of its normal use. As per EN 60950, the equipment is dropped three times from positions likely to cause the most adverse effects onto a wooden floor (consisting of 13 mm thick hard wood mounted on two layers of plywood each 18 mm thick). Hand-held and direct plug-in equipment is dropped from a height of 1 m, while desktop equipment is dropped from a height of 750 mm. After this test, the product can suffer mechanical damage but it should not be damaged in any way that would cause a hazard. In particular, hazardous parts must not become accessible or clearances should not be reduced below specified values.

3.36.12.4 Impact Test

Equipment other than those mentioned in drop tests, is subjected to the ball impact test (Fig 3.53), wherein a steel ball of diameter 50 mm and weight 500 g is dropped from a height of 1300 mm on to the enclosure of the product.

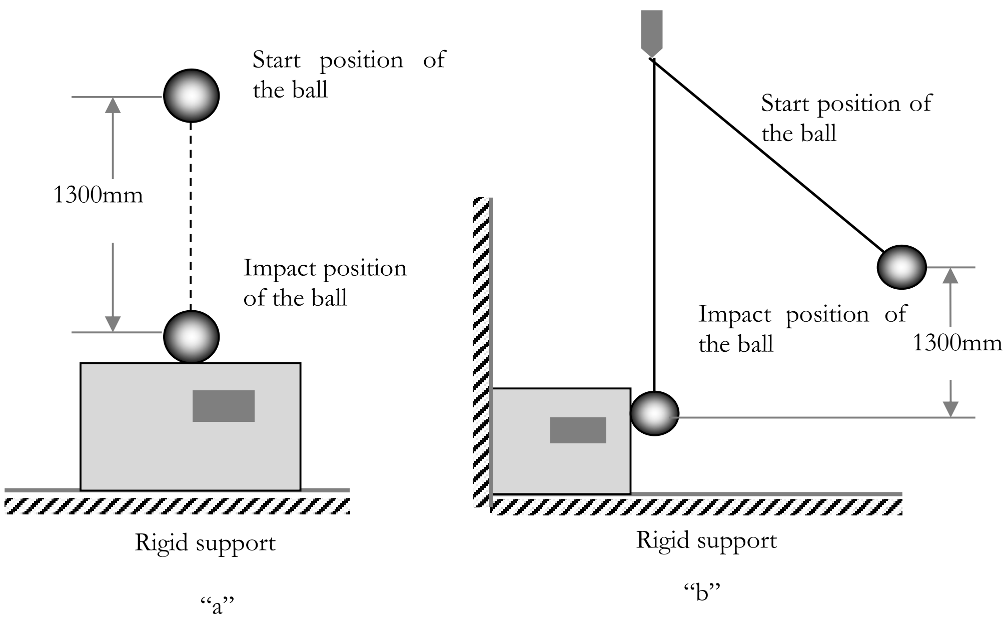
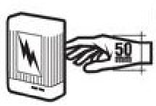
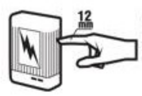
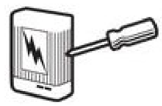
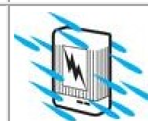
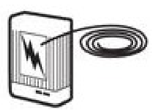
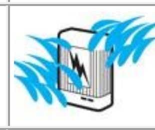
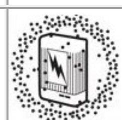
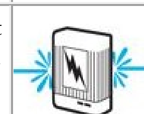
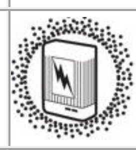
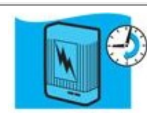
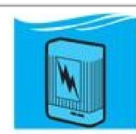


Fig 3.53: Impact test

A horizontal side is subjected to this test either by rotating the product 90° from its normal position. Vertical surfaces are tested by suspending the steel ball

Table 3.29: Ingress Protection (IP) Levels per IEC/ EN 60529

IP.	First digit: Ingress of solid objects		Second digit: Ingress of liquids	
0	No protection		No protection	
1		Protected against solid objects over 50mm e.g. hands, large tools.		Protected against vertically falling drops of water or condensation.
2		Protected against solid objects over 12.5mm e.g. fingers, tools.		Protected against falling drops of water, if the enclosure is tilted up to 15 from vertical.
3		Protected against solid objects over 2.5mm e.g. wire, small tools.		Protected against sprays of water from any direction, if the enclosure is tilted up to 60 from vertical.
4		Protected against solid objects over 1.0mm e.g. wires.		Protected against splash water from any direction.
5		Limited protection against dust ingress. (no harmful deposit)		Protected against low pressure water jets from any direction.
6		Totally protected against dust ingress.		Protected against high pressure water jets from any direction
7	N/A			Protected against short periods of immersion in water between 15cm and 1m for 30 minutes.
8	N/A			Protected against long, durable periods of immersion in water.

Example is IP X4, which addresses splashing water resistance only. EN 60529 does not specify sealing effectiveness against risk of explosions, certain types of moisture conditions, e.g., those that are produced by condensation, corrosive vapours, fungus

Description of the safeguards, interacting functions and interlocking of guards for hazardous movements and

- Description of safeguarding means and methods where the safeguards are suspended.

3.38 RISK ASSESSMENT

Electrical equipment, during its normal operation and use, will always pose a certain amount of risk. The manufacturer of the electrical equipment should endeavour to reduce the risk to such an extent that the residual risk (i.e. the risk remaining after all possible protective measures have been taken) is tolerable (i.e. which is accepted in a given context based on current values of society). The best way the manufacturer can do this is to get his product evaluated to the relevant electrical safety standard. The standardization committee, while preparing the standard, normally takes into consideration almost all the risks that can be posed by the equipment. There are certain documents (like the CENELEC guide 32) that guide the standard making committee regarding risk assessment. In other words, risk assessment is ingrained in the basic structure of the standard and compliance to the standard means that the residual risk posed by the equipment is tolerable. Thus, compliance to a relevant safety standard will give the *manufacturer presumption of conformity* with the essential requirements of the LVD.

Well, at-least that is what we thought up till now! Then comes the new LVD which makes risk assessment compulsory even if the equipment complies with all the requirements of the relevant product standards. This has left manufacturers confused and often than not there has been a query as to why a separate risk assessment is required when the standards itself are created on the basis of risk assessment and compliance with the standard means that all the possible risks have been addressed and complied with. Not that the risk assessment is new to manufacturers, especially those making measurement, control and laboratory use equipment where the product standard EN 61326-1 has a clause on risk assessment (Clause 17). However, in many a report this clause has simply been addressed (or should we say dismissed?) by such statement as *complied with all previous clauses and the equipment possesses no risk in addition to these clauses*.

outs, limit switches to limit movement, proximity switches, warning lamps, guards, fire enclosures, access control devices etc.

3.38.6.3. Risk reduction by instructions and warnings.

The risks that cannot be reduced even after implementing all possible design and technical measures are called residual risks. For example, for our LCD projector we cannot reduce the light intensity below a certain level since the device will become useless or for a drilling machine or a grinding machine, one cannot possibly cover the entire drilling head or grinding tool. These risks can be reduced by providing adequate information the user through appropriate instructions in the product literature and by using relevant warning signs. Instruction to the user should clearly indicate residual risks and the measures to be taken by the user to take care of these risks, about shortcomings of the protective devices, whether specialized training is required and specify appropriate personnel protective equipment.

Warning signs can be effectively used to warn the user about eminent danger. These can be located on the equipment and placed strategically so as to be easily seen. The signs can also accompany safety instructions in equipment literature. At the end of the risk reduction procedure, it should be checked that all operating conditions and all intervention procedures have been taken into account. The protective devices or the safety measures are compatible to each other and themselves do not generate new hazards and that the user's working conditions and the usability of the equipment are not jeopardized by the protective measures taken. The users are sufficiently informed and warned about the residual risks and sufficient consideration has been given to the consequences that can arise from the use of equipment designed for professional / industrial use when it is used in a non-professional / non-industrial context.

The section that follows provides a format of documentation of the risk reduction that has to be included in the technical documentation as per the requirements of the new LVD.

4

THE EMC DIRECTIVE

4.1 INTRODUCTION

The Electromagnetic Compatibility (EMC) directive 2014/30/EU was published on 26th February 2014. There was a transition period of almost two years and the directive came into force on 20th April 2016 i.e. it is legally binding for products falling under the scope of this directive and placed into market (or put into use) on or after this date to meet the requirements of this directive. The directive aims to ensure EMC in community market by ensuring that an equipment does not emit electromagnetic disturbance (see section 4.4) above a certain limit (as prescribed by EMC standards) and at the same time is not affected (i.e. its operation is not disturbed) by the electromagnetic disturbance generated by equipment in its vicinity or by any electromagnetic phenomenon for that matter. We will now take a look at the various provisions of the directive which are given in the form of articles.

4.2 ARTICLE 1: SUBJECT MATTER

This directive aims at regulating electromagnetic compatibility (see section 4.4). Its basic goal is to ensure functioning of the EU market by requiring an equipment to comply with *adequate level* of electromagnetic compatibility. The directive has used the words *adequate level* since it is practically impossible to ensure that the emission of electromagnetic disturbance is zero or that it should tolerate infinite level of electromagnetic disturbance. Thus, only *reasonable* electromagnetic compatibility is expected out of the equipment depending on its operational environment.

4.3 ARTICLE 2: SCOPE

Within the scope of this directive are only those electrical/electronic equipment capable of generating EMI and/or the performance of which is liable to be affected by such disturbance. Equipment excluded from scope are as follows:

4.3.1 Equipment which do not contain electrical and/or electronic parts, since these will not generate electromagnetic disturbances and its normal operation and will not be affected by such disturbances.

4.3.2 Equipment which are inherently *benign* in terms of EMI. Such equipment are those whose inherent physical characteristics are such that they are incapable of generating or contributing to electromagnetic emissions and which will operate without unacceptable degradation in the presence of the electromagnetic disturbance. Examples of such equipment are:

- Cables and cabling, cables accessories, considered separately.
- Equipment containing only resistive loads without any automatic switching device; e.g. simple domestic heaters with no controls, thermostat, or fan.
- Batteries and accumulators (without active electronic circuits).
- Headphones, loudspeakers without amplification.
- Pocket lamps without active electronic circuits.

5

EMC FUNDAMENTALS, STANDARDS AND TESTING

5.1 INTRODUCTION TO EMI

Pollution is the bane of modern society. It is the undesirable by–product of mankind's scientific and technological progress. Air pollution, for example, is the introduction of certain undesirable gasses like sulphur–dioxide or carbon–mono oxide, to name a few, which otherwise are not part of the standard atmosphere and which can have adverse effect on human health. The most recent form of pollution is electromagnetic pollution (if we can call it that) i.e. the generation of electromagnetic energy that can have an adverse effect on the *health* of an electrical/electronic equipment. We have already seen electromagnetic disturbance and the definition of EMI. Electromagnetic disturbance can occur across the entire range of the electromagnetic spectrum and some of it may fall within the radio frequency range of 3kHz to 300GHz (which is normally used for radio communication) in which case it is referred to as radio frequency disturbance. We can then define RFI or radio frequency interference as *the degradation in reception of a wanted signal caused by radio frequency disturbance*. In simpler terms, EMI/RFI is an electromagnetic pollution caused by the generation of electromagnetic energy that is unwanted or unwarranted. This can interfere with the normal operation of an electronic equipment resulting in the degradation of its health. The electromagnetic phenomenon is the source of EMI, which travels through the intervening medium and affects the operation of nearby electronic equipment that receives the EMI and becomes a victim.

5.2 THE PROBLEM OF EMI

In recent years the market has been flooded with a myriad of electronic gadgets that are potential generators of electromagnetic energy. It is not their business to generate such energy, but because of the very nature of circuitry and technology they do so inadvertently or *unintentionally* and interfere with radio communication and other electronic gadgets. The problems have compounded with the advent of digital devices with high clock rates and low rise-times, which pour electromagnetic energy over entire range of the radio spectrum. The situation is worsened by the use of switching power supplies, thyristor converters and similar equipment that switch voltages at high rates causing unwanted emission of electromagnetic noise.

5.3 NEED FOR EMC

We have already seen the definition of electromagnetic compatibility in the previous chapter. Now, if we have a group of equipment, each emitting EMI below a certain level and each having sufficient immunity to this EMI, then we can say that each equipment is *electro–magnetically compatible* with other equipment and hence the name electromagnetic compatibility. EMC/EMI is used many-a-times as a combined term since we are trying to achieve EMC by limiting EMI. EMI is what we are trying to avoid and if we succeed in doing so, we achieve EMC.

input first passes through an input attenuator and then via a pre-selector to the RF amplifier. The pre-selector is a bandpass filter which allows only a small band around the tuned frequency to pass through. This is essential to reduce measurement errors since the receiver usually measures pulsed EMI which has a large number of frequency components. Exposing the front end to such a large band will cause overloading the RF amplifier generating spurious responses leading to measurement errors.

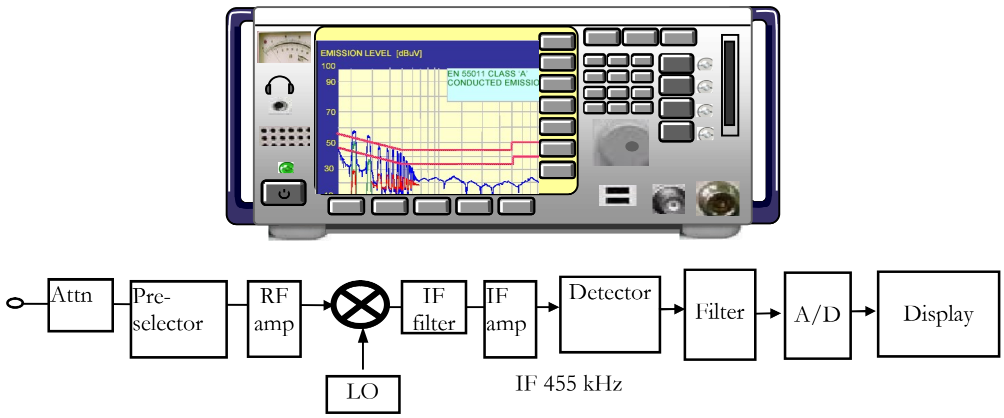


Fig. 5.8: EMI Receiver

The mixer stage which follows the RF amplifier, mixes or heterodynes the incoming signal with signal generated by the local oscillator (LO) to generate an intermediate frequency (IF). The bandwidth of the IF filter, which follows the mixer is called resolution bandwidth. The final IF is fed to the detector stage the output of which is displayed on a screen or printed by a printer/plotter. Three types of detectors are prescribed by EN standards viz. peak, quasi-peak (QP) and average.

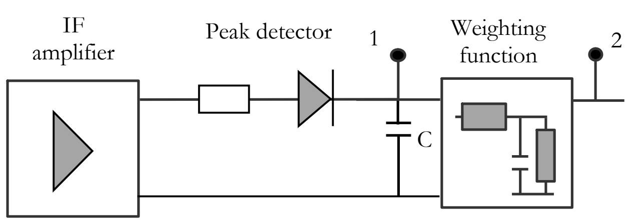


Fig. 5.9: Basic Detector

5.30.1 EFT/B Pulse Shape

The wave–shape as specified by EN 61000–4–4 is as shown in the Fig. 5.21. The Fig. 5.21a shows repetitive bursts, each burst is a *packet* of pulses of 15 ms burst width (or duration) and burst separation (or period) is 300 ms. The individual burst is shown in Fig. 5.21b, the frequency at which the pulses occur (the PRF) is 5 kHz. The individual pulse, shown in the Fig. 5.21c, has a rise time of 5ηs and pulse width of 50 ηs. EN 61000–4–4 also specifies an optional 100 kHz PRF in which case, the burst duration is 0.75 ms.

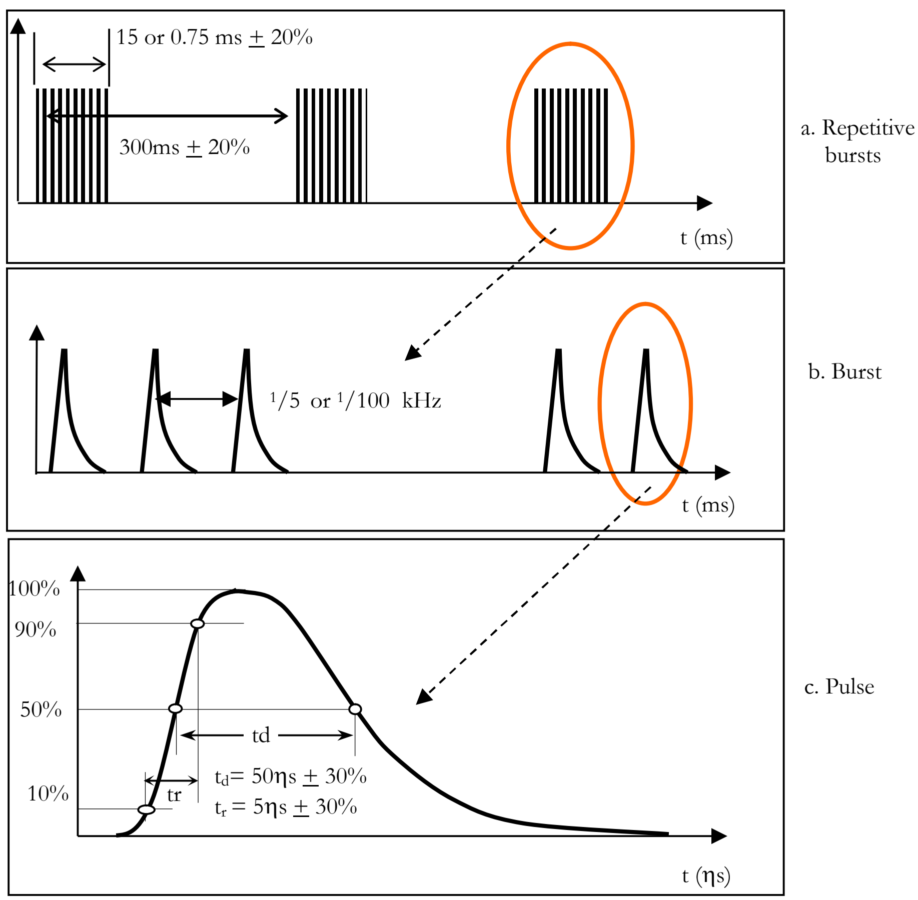


Fig. 5.21: EFT/B Pulse And Burst Characteristics

This typical burst is only a representative of real-life situation and is the best that can be achieved by a test generator. The source impedance of the generator is 50 Ω and the output is unbalanced. The generator generates specified amplitude calibrated to 50 Ω load but the actual voltage impressed on the EUT depends upon the EUT source impedance. The transients generated are coupled in non–symmetrical mode on to the power supply port of EUT using coupling/decoupling network (CDN) through a 33 ηF capacitor. For coupling EFT/B to input/output (I/O), control or communications cables of the EUT, a non-contact method using a capacitive coupling clamp is specified.

5.30.2 Laboratory Test Setup

The Fig. 5.22 shows how an equipment is tested for EFT/B in a laboratory. The equipment under test (be it table–top or floor standing) is placed above a ground reference plane (GRP) (a flat metal sheet whose potential is used as a common reference) and insulated from it by 0.1m thickness insulating support.

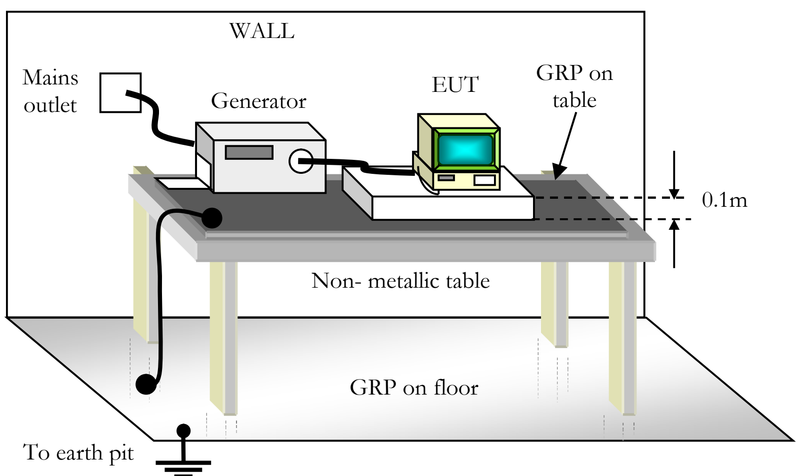


Fig. 5.22: EFT/B lab set–up for table–top equipment

The EFT/B generator is placed directly on the GRP and firmly bonded to it by a low inductance bond (i.e. a metal strap). The standard gives a test set–up

6

EMC DESIGN METHODOLOGIES

6.1 INTRODUCTION

In this chapter, we are going to discuss various EMC design methodologies like filtering, shielding, grounding/bonding and cable routing which are required to make a product compliant to EMC norms. It is important to understand that these measures should ideally be incorporated at the design stage. It can be shown that the cost of product modification at the end of product development cycle can be many times more than the cost incurred at design stage. In addition, the time required for product modification at fag end of product development cycle can also be very high. Considering the scorching pace at which technology is evolving, product lifetimes have become very short. It could therefore, be possible that by the time the product is launched, there may be no market for the product. Hence, design stage EMC measures are indispensable so that product cost is low and it is introduced in time.

6.2 FILTERING

Filtering is a method of attenuating conducted EMI that is entering or leaving an equipment through the power, signal and control lines by introducing line filters and other suppression components so that the equipment can comply with conducted emission and immunity tests as prescribed by EMC standards.

6.2.1 Power Line Filters

Power line filters typically have a configuration as shown in Fig. 6.1. Since they have to deal with both common mode and differential mode EMI currents present on a power line, they need to employ certain components that suppress common mode and others that suppress the differential mode current. Capacitors and inductors both can be used to attenuate common and differential mode currents, it is just a question of how they are connected.

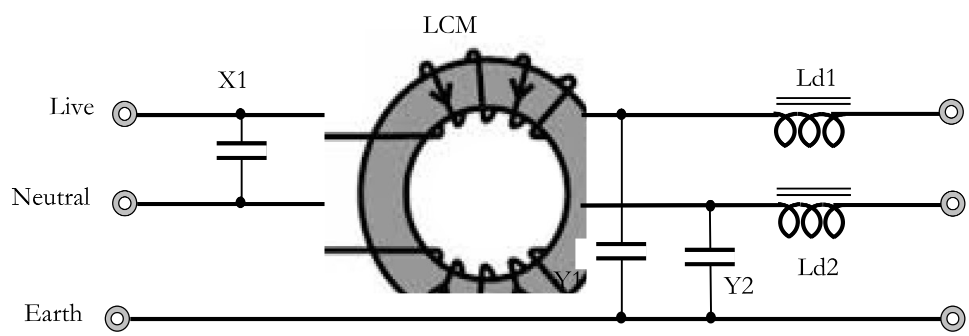


Fig. 6.1: Power Line Filter

In order to attenuate differential mode EMI currents, capacitors need to be connected across the live and neutral wires and hence these are referred to a 'X' capacitors (like the capacitor X1 in the Fig. 6.1) while inductors (that attenuate differential mode) need to be in series with the live and neutral wires ('Ld1' and 'Ld2' in Fig. 6.1). On the other hand, capacitors that attenuate the common mode currents need to be connected across the live & earth and neutral & earth. These are called as 'Y' capacitors (like Y1 and Y2 in the Fig. 6.1). Inductors that attenuate the common mode EMI have a characteristic construction where two coils, one in series with the output cable via stray capacitance that is formed if the wires are near to each other or via the mutual inductance between the wires. This coupling bypasses the EMI rendering the filter ineffective.

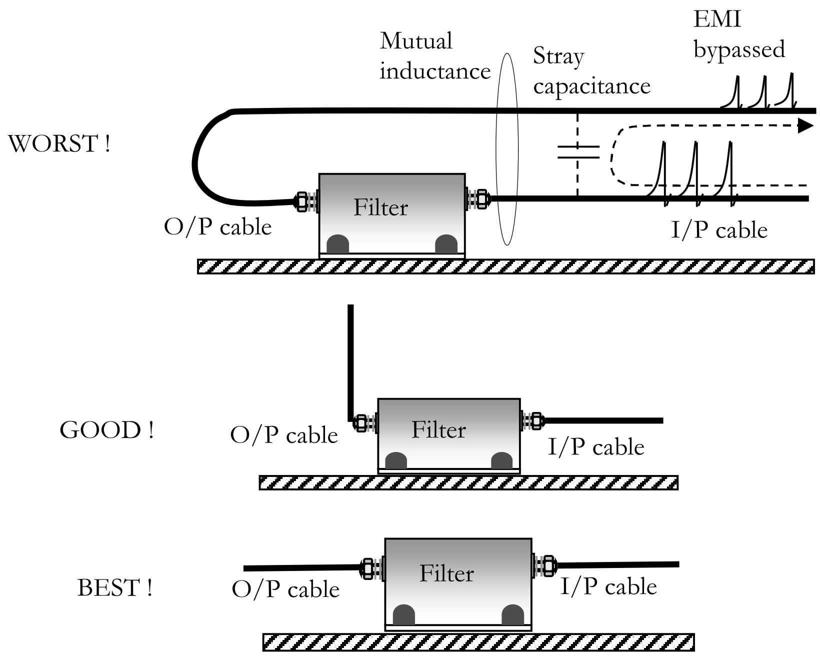


Fig. 6.11: Filter I/P And O/P Cables

6.6 SHIELDING

Shielding is a method of reducing radiated EMI entering or leaving a component, equipment or system. A typical shield works either way i.e. it reduces radiated emissions from an equipment and at the same time increases immunity by attenuating radiated EMI entering the equipment. Shielding works partly by reflection, which is the result of mismatch between impedance of the wave and the impedance of the shielding material and partly by absorption suffered by the wave as it travels through the shield material. Metals are the best option for shielding material not only because they provide the sudden impedance discontinuity for a wave travelling through space or air. Although metals are good for providing shielding, one cannot just use any metal just for the sake of it. The choice must be judiciously made depending on the type of wave –viz. electric, magnetic or electro-magnetic, the

6.9 GROUNDING

Most of the EMI suppression methods, in one way or the other, use two basic techniques –filtering for conducted EMI and shielding against radiated EMI. Also, ESD and its associated transient noise is reduced by bonding and earthing equipment frames. A low resistance connection to earth is required if any of the interference suppression methods are to work properly. Grounding can be defined as *a connection, whether intentional or accidental, between an electrical circuit or equipment and the earth or to some conducting body that serves in place of the earth*.

On the other hand, bonding is defined as *a permanent joining of metallic parts to form an electrically conductive path that not only ensures electrical continuity but also has the capacity to conduct safely any current imposed on the joint*. Thus, bonding is that means which serves to give a *low resistance connection to earth* which is an essential part of a good ground.

6.10 TYPES OF GROUNDING

6.10.1 Single Point Grounding

Here each subsystem/module has its own ground. These individual grounds are finally connected by shortest route back to a single system ground point by simple wires (Fig. 6.14, left). Such system is advantageous for low frequency and analogue circuits because no common impedances (that cause common mode coupling) exist. At high frequencies (above 1MHz) however, the grounding wires start to exhibit high inductance and consequently start offering high impedance to ground currents. At the same time the capacitive reactance of stray capacitance between the modules starts reducing. The ground currents no longer follow the high impedance path offered by the ground wires to ground, but are rather invited to follow the low impedance offered by the parasitic capacitance to other modules. This causes common mode coupling and can be reduced by reducing the inductive reactance of the ground wires. This is achieved by multipoint grounding.

fforts should be directed towards reducing ground impedance which in turn can be reduced first by reducing the inductance i.e. replacing the wires by a metal sheet (a mounting plate) and then to reduce the value of ground resistance by proper grounding and bonding practices. Also interconnecting cables should be shielded so that the common mode EMI currents now flow (see Fig. 10.5d) on the outside of the shield reducing common mode coupling.

6.12 CABLE SELECTION AND ROUTING

It is frequently observed that the overall system often fails to pass EMC tests (particularly emissions) because one crucial aspect of EMC design that of cable routing and selection has not been given proper attention. To complete the EMC design process therefore, one has to select the correct cable type i.e. shielded or unshielded, armoured or un-protected, balance or unbalanced, single core or multi-core, twisted or un-twisted etc depending upon the frequency of operation, voltage and current levels, type of loads and length of cable runs. After identifying the cable type, attention has to be given to the grouping or segregation of cables to avoid interference between various type of circuits. Thirdly, various cables and cable groups have to be properly routed so as to minimize cable-to-cable and cable-to-component coupling.

6.13 CABLE CLASSES

In order to properly segregate cables, they can be split into six classes as per EN 61000-5-2 depending upon their application, voltage or current levels, the frequency of signals they carry, the type of signal they carry (like analogue or digital), the components they connect to etc. These classes are as follows:

6.13.1 Class 1

These are cables that carry highly sensitive signals like low level analog signal (in mV) from transducers, instrument lines, radio receiver antenna cables and cables carrying high frequency digital signals such as ethernet. Such cables are highly susceptible to noise and interference and can be further classified as class 1A that carry analogue signals and class1B that carry digital signals. Class 1A and 1B cannot be bundled or twisted together, although they can run parallel to each other.

7

OTHER DIRECTIVES

7.1 INTRODUCTION

In this chapter we are going to discuss three more directives generally applicable to electrical/electronic products namely the medical devices directive, the RoHS directive and the radio equipment directive. Only unique requirements will be discussed and common requirements regarding placing in the market, free movement, roles of manufacturers/importers/distributors, presumption of conformity, declaration of conformity, affixing rules for CE marking, market surveillance, action on non- compliances, safeguard procedure, penalties, transposition and transitional provisions will not be discussed to avoid duplication. Clauses not related to electrical/electronic equipment are also not discussed.

7.2 MEDICAL DEVICES DIRECTIVE (MDD) (93/42/EU)

This directive applies to medical devices and their accessories and gives essential requirements that manufacturers and importers must meet to sell their devices in the EU. The objective is to provide, maintain or improve level of protection of medical devices to patients, users or third party. Since the MDD covers many types of devices, the specific requirements depend on the risk classification and intended use of the device. Contrary to the LVD and EMC directives, the use of an EU notified body (NB) is required to assess compliance with this directive in most of the cases. Although MDD covers a wide variety of devices, we are going to concentrate only on electrical devices in this chapter.

7.2.1 Scope

The definition of a medical device falling under the scope of the directive is given in article 1. Medical device falling under the scope of the directive is *any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of:*

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

The medical device also includes software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application.

Accessory means *an article which whilst not being a device is intended specifically by its manufacturer to be used together with the medical device.* This accessory enables the use of the medical device as intended by its manufacturer.

What are not considered as medical devices are products which achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means. For example, medications and pharmaceutical preparations, which treat medical conditions through chemical action or by being metabolised by the body, are not considered medical devices, and are subject to different regulations and requirements. Hence medical devices should not be confused with such classes of products.

7.3 THE RoHS DIRECTIVE (2015/683/EU)

RoHS stands for Restriction on the use of Hazardous Substances. The original directive 2002/95/EC was published in 2002. The directive laid down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (hereafter referred to as EEE) with a view to contributing to the protection of human health and the environment. It sought to restrict the use of more than the permitted levels of six substances namely lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants. It included eight product categories out of ten of the Waste Electrical and Electronic Equipment (WEEE) directive. At that time, it was not a CE directive. The directive was recast in 2011 as 2011/65/EC as a CE marking directive and included all ten WEEE product categories. In 2015, four additional substances called *phthalates* were added to the list taking the number of banned substances to ten. The directive was re-designated as 2015/683/ EC and as such is identical to 2011/65/EC except for the annexure 2 which adds the four new substances.

7.3.1 Scope

Article 2 gives the scope of the directive. Accordingly, the directive applies to all EEE with a voltage rating not exceeding 1000 Vac and 1500 Vdc. The product categories to which the directive applies in given in annex I of the directive and includes:

- **Large household appliances**
  Examples are refrigerators, washing machines, dish washing machines, electric stoves/ hotplates, microwaves, electric fans, air conditioners etc.
- **Small household appliances**
  These include vacuum cleaners, irons, toasters, grinders and the like.
- **IT and telecommunications equipment**.
  PCs, laptops, printers, fax, telephones, cell phones etc.
- **Consumer equipment**.
  TVs, radios, cameras, audio amplifiers, music systems etc.
- **Lighting equipment.**

7.4 THE RADIO EQUIPMENT DIRECTIVE (RED) (2014/53/EU)

This directive concerns the placement of radio devices where radio frequency (RF) energy is intentionally generated. It not only ensures electrical safety and electromagnetic compatibility of a radio device within its scope but also ensures an efficient use of radio spectrum to avoid harmful interference (especially due to out of band emissions). Although radio receivers themselves may not cause interference, reception capabilities are also a part of efficient use of the spectrum and as such the directive seeks to ensure that receivers should operate as intended and should be protected from harmful interference.

7.4.1 Scope

Article 1 gives the scope of the directive. Radio equipment under the scope of the directive is defined (as per article 2) as:

An electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radio determination, OR

An electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radio determination

Now the term radio communication is communication using radio waves (i.e. waves below 3000GHz propagating in free space as electromagnetic waves). The term 'radio determination' is the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves. Rather than giving a list of radio equipment within scope, the annexure I of the directive gives a list of equipment outside the scope. The equipment ***outside the scope*** include:

- Radio equipment *exclusively* used for activities concerning public security, defence, state security and the activities of the state in the area of criminal law.
- Radio equipment used by radio amateurs like radio kits for assembly and use by radio amateurs, radio equipment modified by and for the use of radio amateurs and equipment constructed by individual radio amateurs for experimental and scientific purposes are excluded.

8

TECHNICAL DOCUMENTATION

8.1 INTRODUCTION

Technical documentation is an important part of the CE marking process as it documents the entire conformity assessment process. As we have seen in chapter 1, the technical documentation may be demanded anytime by surveillance authorities and as such should unambiguously describe the equipment and the conformity process. It is important to note that in the event of any safety incident involving the equipment, the technical documentation will come to the rescue of the manufacturer/importer as it proves due diligence on the part of the manufacturer and can be a part of legal defence (if required). Each directive specifies the contents of the documentation which are more or less similar barring certain additional requirements considering specific application of a particular directive. The documentation can also be in soft copy form. The documentation should include the following:

8.2 DECLARATION OF CONFORMITY

This is usually the first page of the documentation. The Fig. 8.1 shows suggested DOC format for SMPS considered in section 1.13 for which EMC, LVD and RoHS directives are applicable. The DOC format for a high frequency surgical equipment considered in section 1.13 is as shown in Fig 8.2. Since this DOC is for medical device, it should also identify the class and rule according to which the classification was done (see section 7.2.3.1). Again, most of the medical devices refer to conformity assessment module that requires the assessment to be done by a NB. In that case the DOC should also mention the name, identification number of the NB, the EC type examination certificate number and date. The DOC format for a radio device is as given in Fig. 8.3. It should be noted that the above contents of D.O.C are the bare minimum. The manufacturer may include additional information if deemed necessary.

8.3 PROFILE OF MANUFACTURER AND IMPORTER

This section should provide detailed information of the manufacturing company like brief company history, type of products being manufactured, quality policy, etc. It should also include detailed address of the manufacturer and importer (if the manufacturer is non-European) along with contact details.

8.4 EQUIPMENT DESCRIPTION

This section should provide in detail a general description of the electrical equipment so as to enable EU surveillance authorities to clearly understand the equipment and its intended use. This detailed information will protect the manufacturer (or his representative) in event of a hazard as a result from wrong use.