Washington Laboratories, Ltd.

Global Product Safety

Designing for Compliance

Berri Remenick

NARTE Certified Product Safety Engineer
Product Safety Manager

Washington Laboratories, Ltd.
Laboratory Workshop
September 24, 2004
Gaithersburg, MD

Overview

- North American Requirements
- European Requirements
- Product Safety Hazards
- Product Safety Design Guidelines for 60950-1 and 61010-1

North American Safety Requirements

- Product Liability
  - Threat of Product Liability Lawsuits
- Customer demands
  - Contractual Requirements
- Legal requirements
  - Occupational Safety and Health Agency (OSHA) (CFR 1910.399) for workplace safety
  - National Electric Code: NEC requires listing of products connected to telephone lines
  - Local Laws. Enforced by local authorities
  - Canadian Provincial Laws
  - Mexican Product Safety Requirements

North American Safety Requirements

Routes to Conformance

USA

- Underwriters Laboratories, Inc. (UL)
- NRTL: Nationally Recognized Testing Laboratories accredited by OHSA (such as TUV)

Canada

- CSA
- c-UL
- c-NRTL (such as cTUV)

Mexico

- NOM

UL Standards (a short list)

UL 60950-1: Information Technology Equipment

(formerly UL1950)

UL 60065: Audio-Video Products and Accessories

(formerly UL1492, UL1409, and UL6500)

UL 60601-1: Medical Electrical Equipment

(former UL 2601-1)

UL 508: Industrial Control Equipment

UL61010-1: Lab equipment

(formerly UL3101-1, UL61010A-1)

European Safety Requirements

- New Approach Directives
  - Self-Certification
  - Technical Construction File
- Evidence of conformity to essential requirements
  - EMC and Safety
- Intended for Market Inspectors
- Documentation to support the use of the CE Marking is required.
- Manufacturer Affixes CE Mark
- Notified Body Required for some products

European Safety Requirements

Routes to Conformance

- Self declare by using CE Mark
- Use CE Mark with a competent body review
- Obtain TUV, VDE, or other European safety approval mark in addition to CE Mark

Member States

- Austria
- Luxembourg
- The Netherlands
- Portugal
- Spain
- Sweden
- United Kingdom
- Ireland
- Italy
- Belgium
- Denmark
- Finland
- France
- Germany
- Greece

New members coming…..

- Norway
- Iceland
- Lichenstein
- Czech Republic
- Cyprus
- Estonia
- Latvia
- Hungary
- Lithuania
- Malta
- Poland
- Slovakia
- Slovenia

Low Voltage Directive

- Has been around since 1973 - recently amended (1993) to include the use of the CE Marking.
- For products intended for connection to Mains voltages between 50 and 1000V~.
- Generally for household products, office or laboratory equipment - NOT for machinery or medical products.
- For products where hazards are primarily electrical in nature.
- Documented internal QUALITY ASSURANCE required.

Low Voltage Directive Common Standards

- Information Technology Equipment EN60950-1
- Laboratory Equipment EN61010-1
- Audio Video Equipment EN60065
- Household Appliances EN60335

Other Common Directives

- RTTE Directive: For products connecting to the telephone network or containing radio transmitters. Requirements for the Low Voltage Directive apply without minimum voltage limitations.
- General Product Safety Directive: "Catch all" directive stating that all products must be safe.
- Machinery Directive: For devices with hazards primarily mechanical in nature.
- Medical Devices Directive: For Medical Devices.

NEW APPROACH DIRECTIVES

- Low Voltage (73/23/EEC) Amended by 93/68/EEC
-Simple Pressure Vessels (87/404/EEC) Amended by 90/488/EEC
-Toy Safety (88/378/EEC) Amended by 93/68/EEC
-Construction Products (89/106/EEC) Amended by 93/68/EEC
-EMC (89/336/EEC) Amended by 93/68/EEC
-Machinery (98/37/EEC)
-Personal Protective Equipment (89/686/EEC)
-Non-Automatic Weighing Instruments (90/384/EEC) Amended by 93/68/EEC
-Appliances burning gaseous fuels (90/396/EEC) Amended by 93/68/EEC
-Radio Equip & Telecom Terminal Equipment (91/263/EEC)
-Hot Water Boilers (92/42/EEC) Amended by 93/68/EEC
-Medical Devices (93/42/EEC)
-Recreational Craft (94/25/EEC)
-Active-implantable medical devices (90/385/EEC) Amended by 93/42/EEC
-Explosives for civil uses (93/15/EEC)
-Equipment explosive Atmospheres – ATEX (94/9/EC)
-Packaging and Packaging Waste (94/62/EEC)
-Lifts (95/16/EC)
-Pressure Equipment (97/23/EC)
-In-vitro diagnostic medical devices (98/79/EC)
-Cableway installations designed to carry persons (2000/9/EC)

Other Directives based on New Approach

- -Interoperability of trans-European high speed rail system (96/48/EC)
- -Energy Efficiency requirements (96/57/EC)
- -Marine Equipment (96/98/EC) Amended by 98/85/EC
- -Interoperability of trans-European conventional rail system (2001/16/EC)
- -Transportable pressure equipment (1999/36/EC)
- -Noise emission in the environment by equipment for use outdoors(2000/14/EC)
- -Energy efficiency requirements for ballasts for fluorescent lighting (2000/55/EC)

What is a TF ?

- A Technical File (TF) brings together all required elements to show compliance with applied standards and incorporates the items outlined in the directive.
  - The TF is a neat, organized, professionally prepared report which will be accepted by any authority in Europe
  - The TF should make the product as understandable as possible to a third-party not familiar with the product

The TF includes…

A Test Report

- A clause-by-clause description of how the product complies with the requirements
- Or why a particular requirement does not apply.

The TF includes…

A Critical Component List (CCL)

- CCL identifies all components related to product safety
- Lists the manufacturer, part number, approvals, and ratings
- Must be a link to agency certificates(TUV,VDE, UL), manufacturer's declarations of conformity, or test data to back up the claims of compliance.
- NOTE: There MUST be a Specifications and Certification/Declaration or Test Data for every component in the CCL.

The TF includes…

- Drawings, schematics, and parts list
  - All items relevant to Product Safety should be available
  - Must be clear and legible and correspond with the sample identification
  - Block Diagram is very useful to quickly illustrate a product's electrical interconnections.

The TF includes…

- Specifications
  - Provide design and performance criteria- may not indicate the safety related limits or ratings
  - Should be available for every component listed in the CCL
    - Used to verify proper application of the relevant parts only when the information does not appear on an official document (agency certificate, mDOC).

Spec Sheet Example

AXIAL LEAD AND CARTRIDGE FUSES

Littelfuse

DESIGNED TO IEC STANDARD

5 x 20 mm Time Lag Fuse (Slo-Blo® Type Fuse)

- Designed to International (IEC) Standards for use globally.
- Meets the IEC 60127-2, Sheet 3 specification for Time Lag Fuses.
- Available in Cartridge and Axial Lead Form.
- Available in ratings of 0.032 to 10 amperes.

ELECTRICAL CHARACTERISTICS:

% of Ampere Rating	Ampere Rating	Opening Time
150%	.032–.100	60 minutes, Minimum
	.125–6.3	60 minutes, Minimum
210%	.032–.100	2 minutes, Maximum
	.125–6.3	2 minutes, Maximum
275%	.032–.100	0.2 sec., Min.; 10 sec. Max.
	.125–6.3	0.6 sec., Min.; 10 sec. Max.
400%	.032–.100	.04 sec., Min.; 3 sec. Max.
	.125–6.3	.15 sec., Min.; 3 sec. Max.
1000%	.032–.100	.01 sec., Min.; 0.3 sec. Max.
	.125–6.3	0.02 sec., Min.; 0.3 sec. Max.

AGENCY APPROVALS: Sheet III IEC 60127-2:* SEMKO, VDE approved thru 6.3 amps. BSI approved 0.08-6.3 amps. Recognized under the Components Program of Underwriters Laboratories and recognized by CSA. 0213 series MITI approved 1-5A.

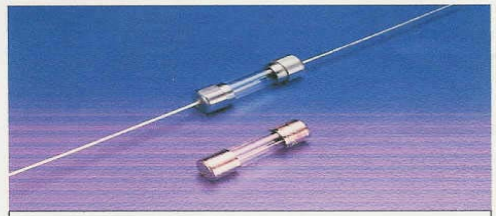
VOLTAGE RATING: 250 VAC

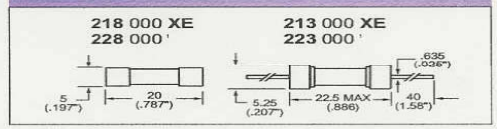
INTERRUPTING RATINGS: 35 amperes or 10 x rated current; whichever is greater.

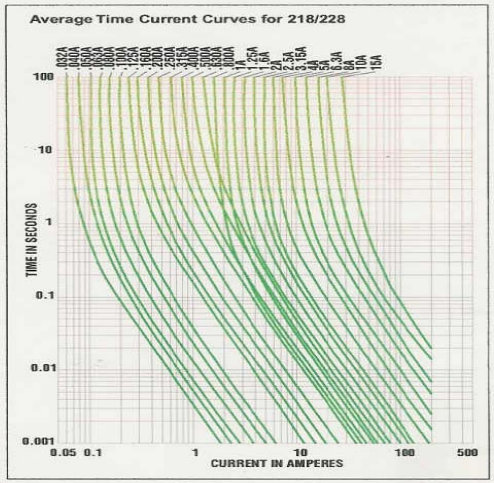
ORDERING INFORMATION:
For axial leaded change 218 to 228 and 213 to 223.

	218/228			213/223 Surge Withstand		
Ampere Rating	Cartridge Catalog Number	Nominal Resistance Cold Ohms	Nominal Melting I²t A²Sec.	Cartridge Catalog Number	Nominal Resistance Cold Ohms	Nominal Melting I²t A²Sec.
.032	218.032	58.45	0.00305	–	–	–
.040	218.040	35.70	0.0055	–	–	–
.050	218.050	23.30	0.0071	–	–	–
.063	218.063	18.1	0.012	–	–	–
.080	218.080	12.6	0.0265	–	–	–
.100	218.100	8.95	0.0495	–	–	–
.125	218.125	4.41	0.150	–	–	–
.160	218.160	2.44	0.225	–	–	–
.200	218.200	1.60	0.350	0213.200	1.60	0.350
.250	218.250	1.05	0.555	0213.250	1.05	0.555
.315	218.315	0.848	1.14	0213.315	0.848	1.14
.400	218.400	0.535	1.35	0213.400	0.535	1.35
.500	218.500	0.370	2.90	0213.500	0.370	2.90
.630	218.630	0.275	4.80	0213.630	0.275	4.80
.800	218.800	0.073	1.99	0213.800	0.165	9.42
1	218 001	0.055	3.33	0213 001.	0.117	19.20
1.25	218 1.25	0.042	5.80	0213 1.25	0.081	27.15
1.6	218 01.6	0.032	10.61	0213 01.6	0.055	44.2
2	218 002	0.029	14.80	0213 002.	0.044	92.7
2.5	218 02.5	0.022	23.85	0213 02.5	0.030	138.0
3.15	218 3.15	0.017	39.20	0213 3.15	0.022	226.5
4	218 004	0.013	70.95	0213 004.	0.017	202
5	218 005	0.010	114.0	0213 005.	0.011	314
6.3	218 06.3	0.0075	204.0	0213 06.3	0.08	600
8	218 008	0.0059	350.5	–	–	–
10	218 010	0.0045	583.0	–	–	–
15	218 015	0.0030	1441.0			

* IEC Standards for 5 x 20 fuses do not include ratings above 6.3A, but are under consideration.







Please contact Littelfuse for Average Time Current Curve for 213/223 surge withstand.

' 228 and 223 Series are used for North American ordering.

The TF includes…

Declarations and Certifications

- Are required for verifying compliance of components used in the systems
- mDOCs should be properly formatted and contain the correct part number (traceable back to the specification and CCL listing)
- Certifications should have the correct part number (traceable back to the specification and CCL listing) and the standards applied

Certificate Example

Certificate

No: B 01 09 24238 250

TÜV PRODUCT SERVICE

Power-One, Inc.

740 Calle Plano
Camarillo, CA 93012-8593
USA

with production faclity(ies)
24238 24258 24260 36080

is authorized to label the following products with the
certification mark E20
as shown in the certification mark list. See also notes overleaf.

Product: **Netzgeräte**
AC / DC Switching Power Supply

Model: **MAP40-1005**
MAP55 Series

Parameters:		
	Rated Input Voltage:	100 - 240 V AC
	Rated Frequency:	50 / 60 Hz
	Rated Input Current:	2 A
	Rated Output Voltage:	See Attachment
	Rated Output Current:	See Attachment
	Protection Class:	I (at end-use)
	Degree of Protection	IPXO

Remarks: When installing the equipment, all requirements of the below mentioned standard must be met.
See attachment 1 for additional information.

The product meets the relevant safety requirements and was tested according to (report no.: SI105313-107)

EN 60950:2000
IEC 60950:1999

Released with the above certificate number by TÜV PRODUCT SERVICE, the Product Certification Body of TÜV AMERICA INC.

R - (B 97 01 24238 091)

Department: SDGMIC/HP Date: 09/20/01

TÜV PRODUCT SERVICE, INC · Danvers · MA · **www.tuvglobal.com**

RTIFIKAT ◆ CERTIFICATE ◆ 認証証書 СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERT ICAT

The TF also includes…

- Installation/User/Service Instructions
- Photographs
- Copy of the Declaration of Conformity

Declaration of Conformity

Application of Council Directive (s):

89/336/EEC, 72/23/EEC

Standard(s) to which Conformity is Declared:
EN55022, EN60950

Manufacture's Name:	COMPANY NAME
Manufacture's Address:	ADDRESS
Importer's Name:	(EU Representative's Name)
Importer's Address:	(EU Representative's Address)
Type of Equipment:	EQUIPMENT DESCRIPTION
Model Number:	MODEL NUMBER
Year of Manufacturer:	(Year of Manufacture)

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s).

_____
(Full Name, Title)

_____
(Signature)

_____
(Date)

Anatomy of a Technical File

- Cover Page
- EMC Report
- Safety Report
- Test Equip. List
- Parts List
- Photos
- Schem-atics
- Ratings Label
- User's Manual
- Theory Of Operat'n
- Specs
- Certs

OPTIONAL

- Test Plan
- EMC Design
- Quality System
- Risk Assess.

Product Safety Hazards addressed in 60950-1 and 61010-1

- Electric Shock
- Energy
- Fire
- Mechanical
- Radiation
- Thermal
- **Your Product must be safe in NORMAL and SINGLE FAULT conditions**

Electric Shock Hazards:

- High voltage at low frequency can travel through the heart and cause ventricular fibrillation.
- Higher frequencies can cause burns.
- Voltages above 30Vrms or 60Vdc considered hazardous.

Energy Hazards:

- High current at low voltage can cause insulation or other parts to ignite and start a fire.
- Excessive current can cause metal parts to fragment, creating a physical hazard from shrapnel.

Fire Hazards:

- Excessive temperatures can ignite materials inside the equipment or in close proximity to external surfaces.
- Beside the danger of the fire itself, the release of toxic gases is a concern.

Mechanical Hazards:

- Moving parts.
- Expelled parts.
- Motor overspeed.
- Locked rotors or motor shafts.
- Sharp edges.

Radiation Hazards:

- Ultraviolet.
- Laser.
- Sonic (audible noise)
- Ionizing.
- Damage to the components in the equipment must be considered in addition to hazards to the operator or service personnel.

Thermal Hazards:

- Excessive external temperatures may cause burns.

- High temperatures may start a fire or degrade insulation.

Product Safety Design Guidelines for 60950-1 and 61010-1

- Design and Construction Requirements
- Labeling and Markings
- Instructions Manuals
- Language
- Wiring and Connection to the supply
- Resistance to Fire and control of spread of fire
- Connection to Telecommunications Network

Design Requirements

Protection against electric shock and energy hazards:

The OPERATOR can not touch bare or inadequately insulated parts at hazardous voltage or energy levels.

Hazardous Voltage Level is typically >30Vrms, 42.4Vpeak, or 60VDC.

Hazardous energy is typically >240VA or 8A

Protection may provided via insulation, guarding or interlocking.

What is Insulation?

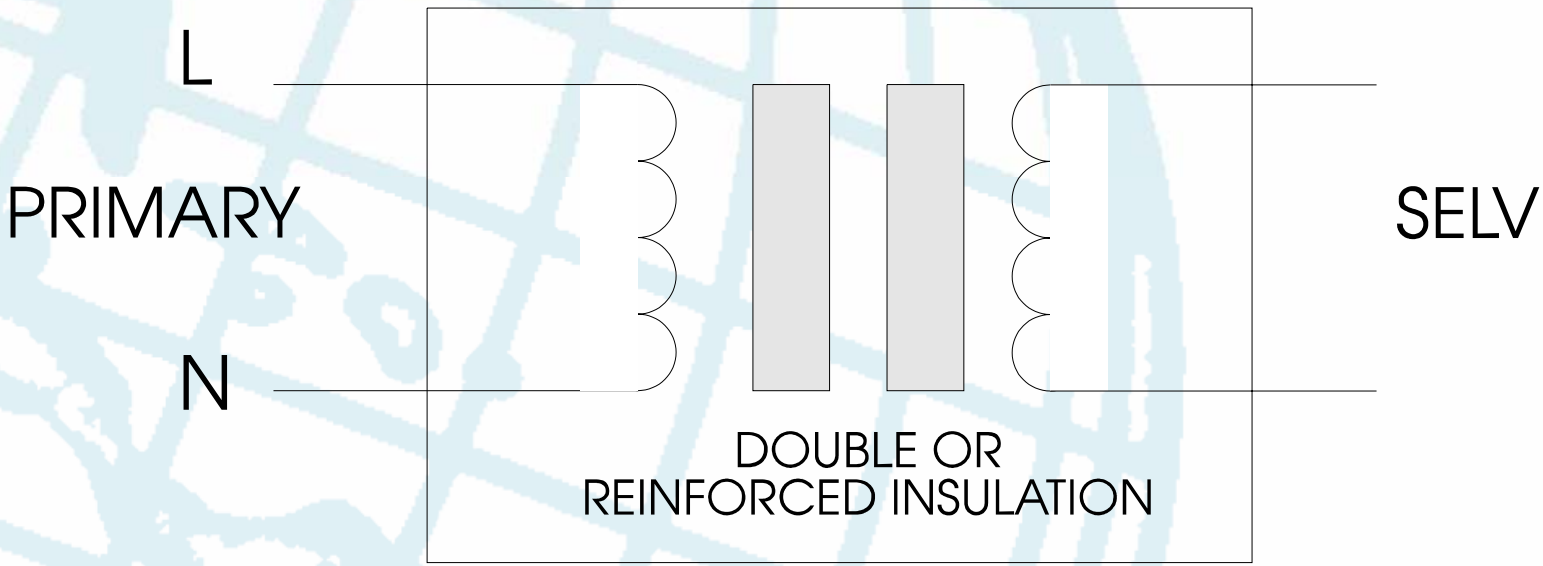
- Physical barrier between two parts (tape, plastic shield, wire insulation, enclosure, etc)

- Separation between two parts (creepage or clearance distance)

Insulation Types

- Functional / Operational Insulation (DC input to ground)
- Basic Insulation (Primary to Ground, TNV to Ground, TNV to SELV)
- Reinforced Insulation (Primary to Secondary)

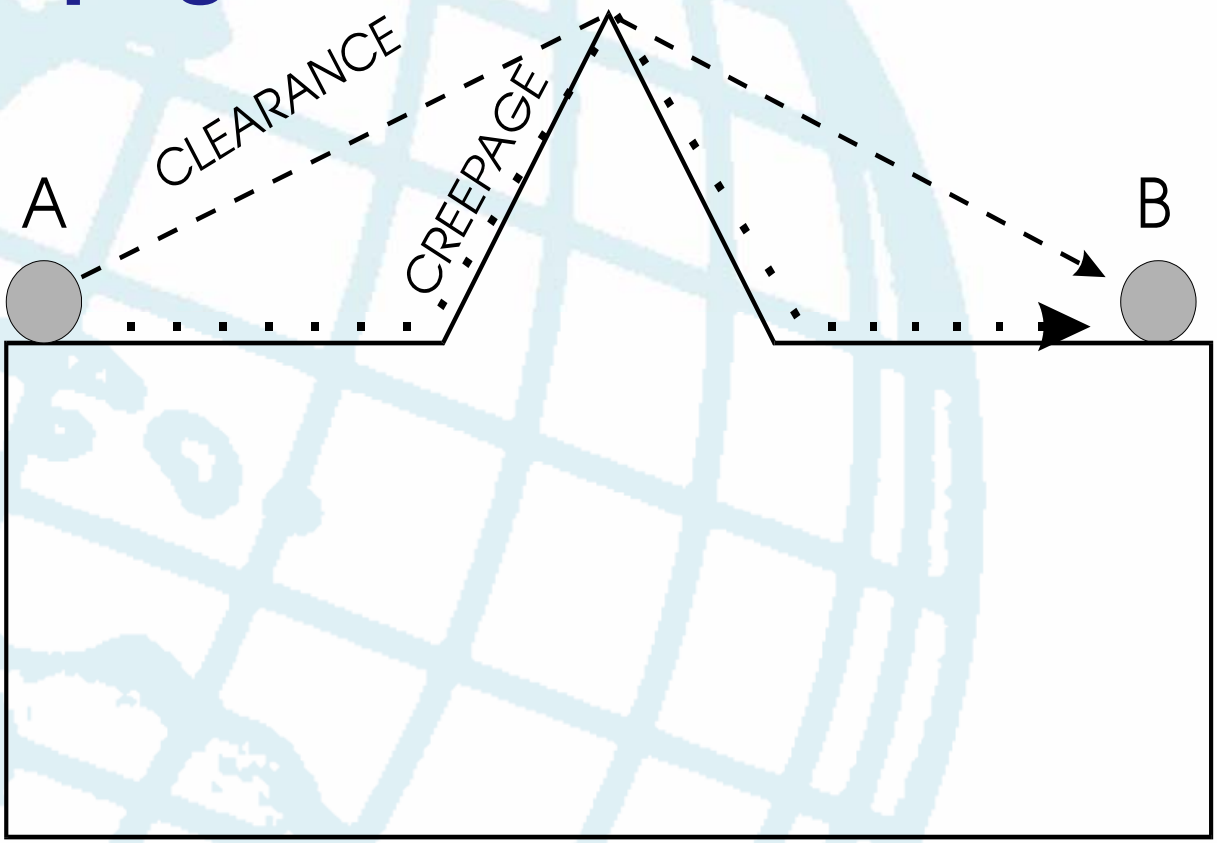
Reinforced Insulation Example



Spacings

- Determine insulation required for your circuit.
- Determine maximum working voltage for your circuit.
- Go to tables in standard and determine required creepage and clearance distances.
- Maintain these distances in your design.

Creepage / Clearance



Creepage

- Creepage = distance between two points along the surface
- Creepage is measured on 1:1 artwork or on a blank board
- Locations of circuits determined by reviewing schematics

Clearance

- Clearance = distance between two points through the air
- Clearance is measured on a populated sample

Abnormal Operation

"None of the following conditions shall create a hazard within the meaning of the Standard:"

- Fan Fail
- Transformer Overload
- Component Short- and Open-circuits
- Failure of unapproved Thermal Limiting device.
- Locked Rotor.
- and others, depending upon equipment.

Labeling and Marking

- Rated voltage, current or power, frequency
- Manufacturer's name or registered trademark.
- Model or type number.
- Fuse replacement info (if applicable).
- IEC symbols wherever possible.
- Warnings and Cautions appropriate for the particular equipment.

KINGSPAO
SWITCHING POWER SUPPLY
INPUT: 115V/230V~ 5A/3A. 47-63Hz
OUTPUT: DC230W
+5V 23A
-5V 0.5A
+12V 8.8A
-12V 0.5A
MODEL: KU-230P
E141295
LR80190
LEVEL 3
BY
CAUTION!
Do not remove this cover.
Check input voltage before plug in.
Air opening should not be covered.
ACHTUNG!
Gehäuse nicht öffnen.
Vor Anschluß Eingangs-spannung überprüfen.
Lüftungsöffnung nicht abdecken.

DELL™
www.dell.com
FOR USE WITH ADAPTER MODEL PA-6.
Model No: PP01L
Input: 20V ⎓ 3.5A
Inspiron 4000
Tested to comply with FCC Standards.
FOR HOME OR OFFICE USE
Ref Number: 99123
IC Class: B ICES-003
Apparatus Claims of U.S. Patent Nos. 4,631,603, 4,577,216, 4,819,098 and 4,907,883 licensed for limited viewing uses only.
Dell LBL P/N: 436DM A00
HI

User Instructions

- Installation Instructions - information regarding mounting, connection to the supply, ventilation, input ratings, etc.
- All information regarding use, cleaning, maintenance (if necessary).
- All safety warnings and cautions.
- Restricted Access Location statement if applicable.
- Rack Mount instructions.
- Instructions for Racks.

Language

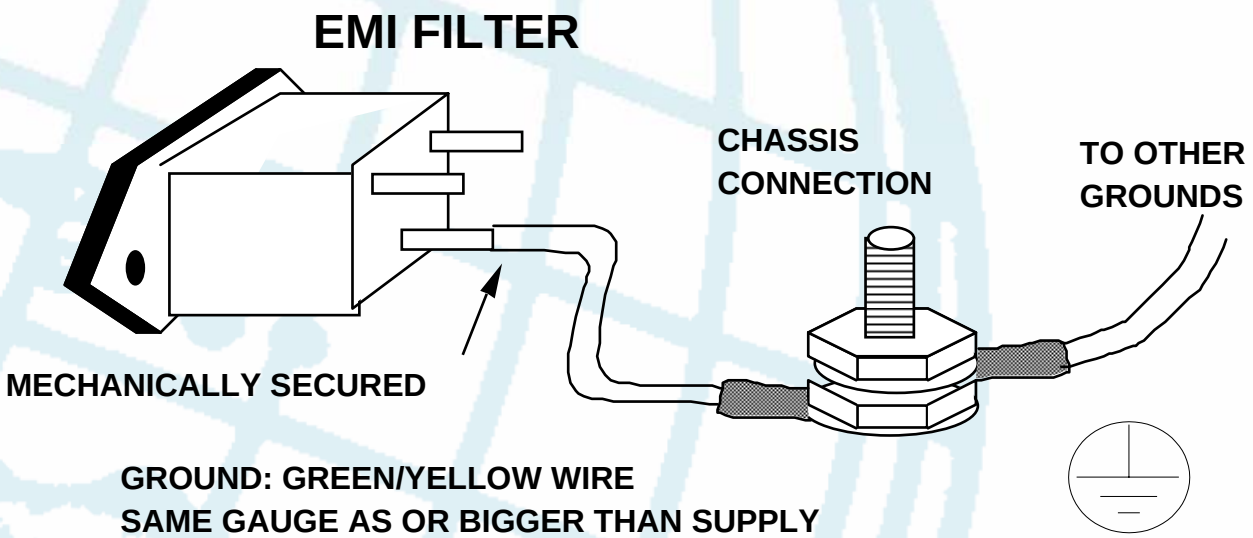
- ‘Safety-related’ information to be in appropriate language.
- Service Instructions may be in English.
- Many times, the entire User Manual must be translated (for specific market areas, dependent on intended end-user, etc).

Wiring and connection to the supply

– Protective Earth -

- PE conductor must be green/yellow or bare insulation conductor
- PE connections must be double secured so that both the wire and insulation are crimped
- IEC PE symbol shall be marked adjacent to PE stud
- PE conductor shall connect to chassis directly from input (inlet, terminal block, etc).
- PE conductor must be secured with washer and locknut.
- Additional PE conductors can be secured to PE stud with a second washer and locknut.

PE Stud Example



Wiring and connection to the supply – Primary Wiring -

- All AC wires shall be double secured. Double securement can be met by:
  - Double crimp connector or
  - Single crimp connector and cable tie or
  - Single crimp connector and shrink sleeving.
- AC wiring shall be rated for the maximum working voltage and current.
- AC wiring shall be isolated from low voltage wiring or low voltage parts, this can be accomplished by:
  - Shrink sleeving the AC conductors or
  - By routing the AC conductors away from low voltage wires and securing with cable ties or
  - By using UL1015 Reinforced Insulation wire.

Resistance to fire and control of fire spreading

- Flammability of enclosure, internal, and external parts
- Flammability ratings
  - 5VA
  - 5VB
  - V0
  - V1
  - V2
  - HB40
  - HB75

Resistance to fire and control of spread of fire

- 60950-1
- Fire enclosure openings shall be:
- Top and side openings shall be:
  - less than 5mm in any dimension or
  - less than 1mm in width regardless of length or
  - meet the 5° projection rule.
- There shall be no bottom openings (some exceptions allowed but difficult to meet)

Methods for Meeting Fire Requirements in 61010-1

- Requirement: There shall be no spread of fire outside the equipment in Normal or Single Fault Conditions.

- Methods of Compliance:
- A: Testing in single fault conditions
- B: Reducing sources of ignition within the equipment
- C: Containing fire within the equipment should it occur

Electrical Enclosure

60950-1

Even if fire enclosure is not required an electrical enclosure is required for hazardous parts.

Electrical enclosure openings shall:

- be less than 5mm in any dimension or
- be less than 1mm in width regardless of length or
- meet the 5° projection rule or
- not allow access to hazardous parts via the test finger or test pin.

Electrical Enclosure

- 61010-1
- Not allow access to hazardous parts via the test finger or test pin.
- Test pin 4mm diameter and 100mm long shall not contact hazardous parts when suspended vertically.

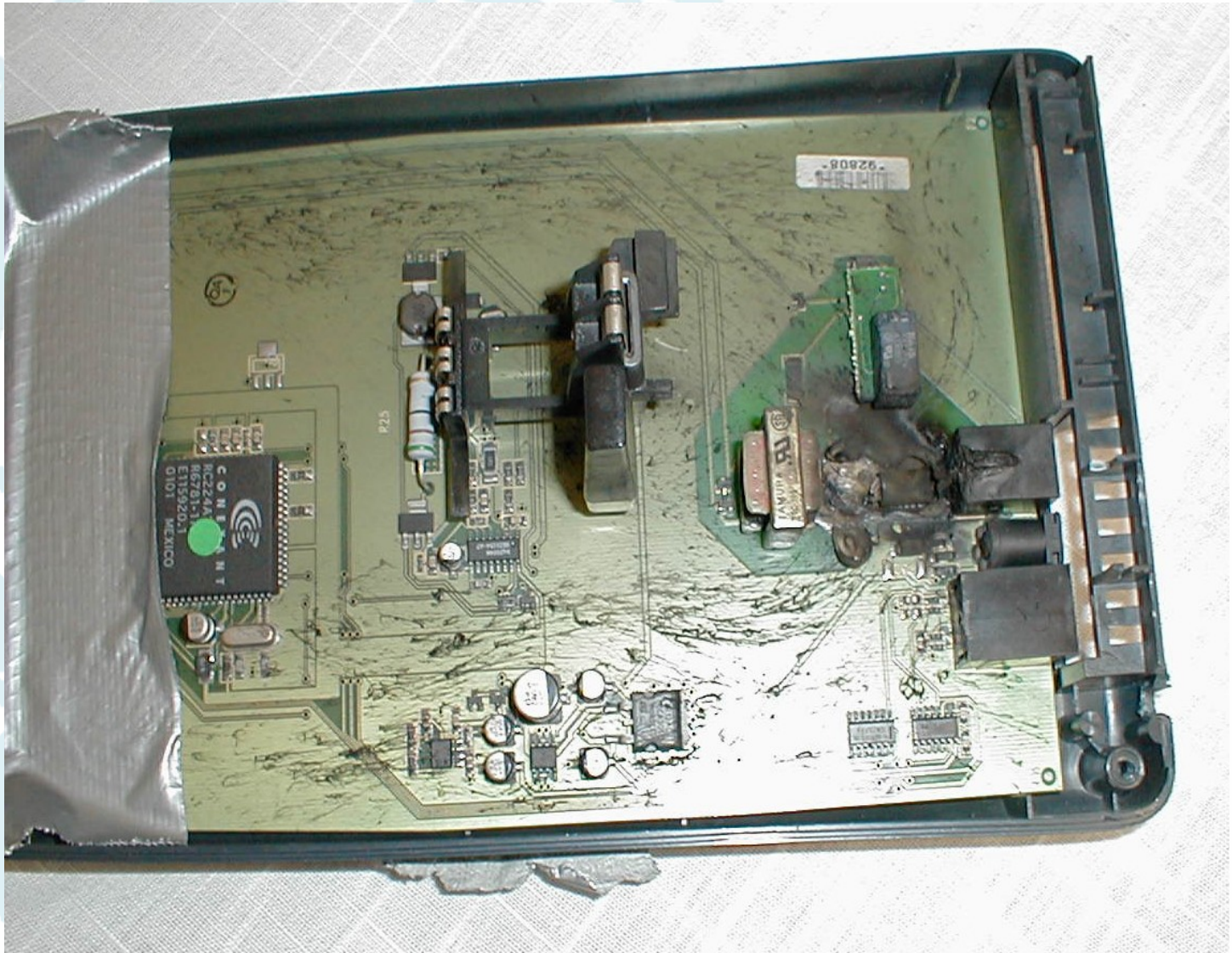
Connection to Telecommunications Networks (60950-1)

- TNV-1: Within SELV limits, but subject to overvoltages (goes outside the building). T1, T3, DS1, DS3, etc.
- TNV-2: Exceeds SELV voltages, but not subject to overvoltages (does not leave the building). Unit which generates a ringing signal to connect to a local phone.
- TNV-3: Exceeds SELV limits and is subject to overvoltages (goes outside the building). Port that connects to the PSTN.

Overvoltage Tests – see flowchart in UL60950-1

- 600V 40A 1.5s - Not required if 26AWG cord is specified
- 600V 7A - 5s
- 600V 2.2A - 30 minutes
- 600V 135% fuse rating - 30 minutes (if fuse blows during 2.2A test, the fuse is bypassed and repeated at this level)
- __V at 2.2A or 135% fuse rating - 30 minutes (if MOV rated to conduct at >285V, test is repeated at voltage just below conduction voltage)
- All overvoltage tests are conducted in Metallic (tip to ring) and Longitudinal (Tip and Ring to ground) modes. If unit does not have a ground connection, then only metallic mode is performed.
- All overvoltage tests are conducted in both On-hook and Off-hook modes (therefore unit must be able to stay off-hook for 30 minutes)

Overvoltage Test Example



Overvoltage Test Example

Common Non-compliances Discovered During Safety Evaluations

- Not using European approved components (requires additional testing)
- CE marked components meet EMC requirements only, not safety (requires additional testing).
- Inadequate Labeling (Warning labels don't use IEC symbols, no voltage ratings, no Protective Earth labels, etc.)
- Overcurrent protection not provided (Fuses, circuit breakers, etc.)

Common Non-Compliances Continued

- Improper Primary Wire Connection Methods
- Improper Protective Earth Connection Methods
- Not providing adequate documentation (schematics, wiring diagrams, manuals, parts lists, etc.)
- Not considering Creepage / Clearance requirements (Requires re-designing circuit boards)

Washington Laboratories, Ltd.

- Evaluate your product to the appropriate Safety Standard and offer solutions for non-compliances.
- Provide product design assistance.
- Provide pre-compliance reviews and testing
- Assist in obtaining UL or NRTL, c-UL or c-NRTL, GS Mark, and other approvals.
- WLL is approved under the UL CAP Program for UL60950-1 and UL6500.
- WLL is a Partner Test Lab for TUV Rheinland of North America for UL/EN60950-1, UL/EN61010-1, and UL/EN60065

Washington Laboratories, Ltd.

Give us a call or send us info about your product - we're here to help!

Berri Remenick
Product Safety Manager
Phone: 301-473-1255
Fax: 301-473-1257
E-mail: berri@wll.com