

*Alternative Sensors for Retort Applications Workshop*  
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EMI Concerns and  
Validation for  
Equipment Used to  
Measure Critical Fluids

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# EMI Environmental Influences

- EMI Influences Can Cause Equipment to read Inaccurately or Fail
- Closed Loop Temperature Controls may Control Inaccurately in a high EMI environment
- EMI Labs May Run Tests to Force Readings to be Inaccurate so that Design Changes may be applied to Prevent Inaccuracy
- Correcting Inaccuracy due to EMI during prototyping new equipment is inexpensive in the lab compared to fixing problems in the field and it is the Law in Europe.

# EMI Standards

- In the U.S. the FCC enforces emissions but not immunity. Europe enforces both emissions and immunity through legislation called "CE Mark".
- Medical Equipment must meet both emissions and immunity by international law. EN 60601-1 governs safety and EN 60601-1-2 governs Environmental Effects.

# EMI Requirements of EN 60601-1-2

- EN 61000-4-2 ESD



ESD stands for Electrostatic Discharge. It is caused by rapid depolarization of oppositely charged masses. It is also an effect that readily causes electronics to fail if not appropriately protected. A person may readily feel discharges from ESD when walking on a carpet.



# EMI Requirements of EN 60601-1-2

- EN 61000-4-3  
Radiated Immunity
- Immunity against high electric fields causing inaccuracies and failures in electronic equipment
- Most important test performed by an EMI Lab for its Sponsors
- Different Levels of Protection – 1, 3, 10 or 20 Volts/Meter



# EMI Requirements of EN 60601-1-2

- EN 61000-4-4 & EN 61000-4-5, EFT & Surge



EFT applies Low Energy but High Intensity Pulses to the Device being tested. The rapid nature of the pulses may greatly disturb electronic digital devices.

Surge applies High Energy and High Intensity Lightning Like Pulses to the Device being tested. The high Joule rating can destroy power supplies. High voltage disturbances are common on power lines.

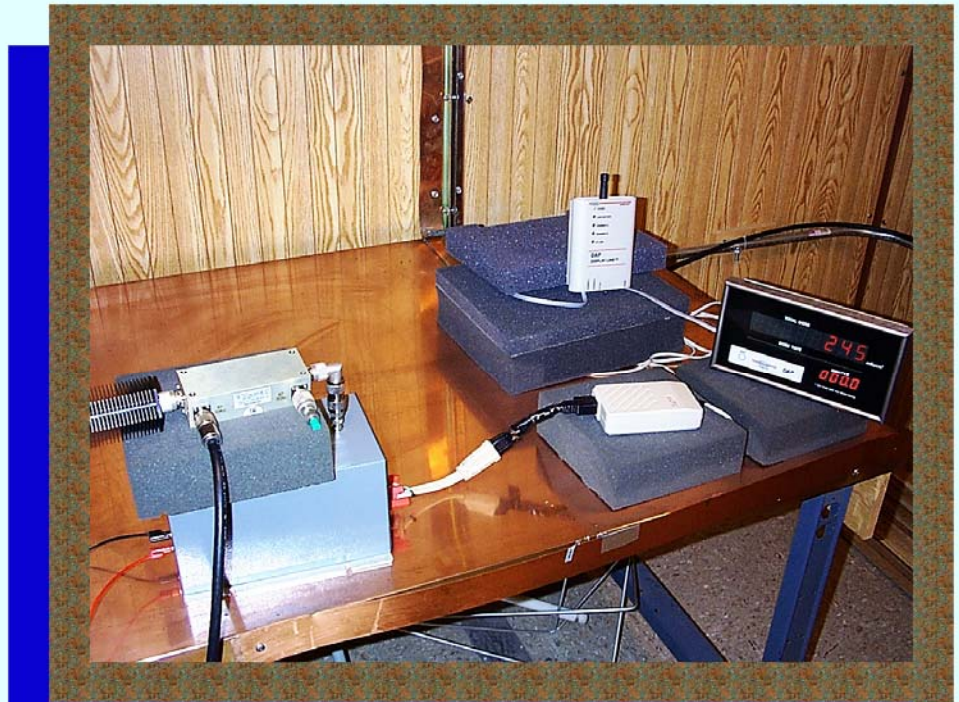


# EMI Requirements of EN 60601-1-2

- EN 61000-4-6 Conducted Immunity

The Conducted Immunity setup permits RF immunity waves to travel through the power mains.

The RF level applied is constant over frequency and finds resonances in internal circuitry that can disable the power supply cause malfunctions in the machine. RF does exist on power mains from sources such as TV and FM transmitters.



# EMI Requirements of EN 60601-1-2

- EN 61000-3-2, -3-3 and EN 61000-4-11  
Harmonics, Flicker and Voltage Fluctuations



These tests examine the system for producing too much energy at harmonics of the power frequency that can lead to failure of the building's neutral, whether the device has the potential to create epileptic seizures by causing flickering in lighting and how the system will react to power blackouts and brownouts.



# European EMI Classification System

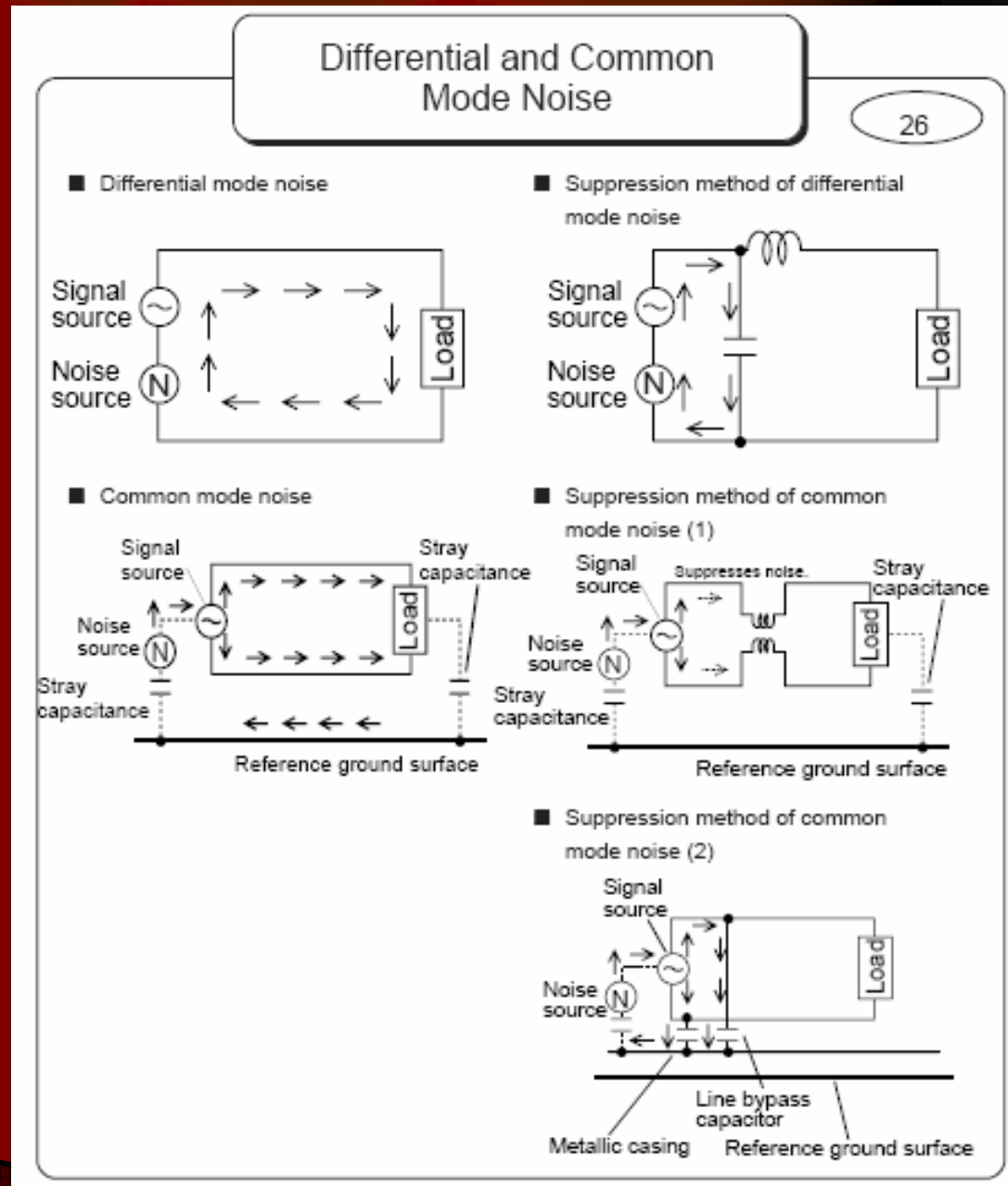
- EN 61000-6-1 Light Industrial Immunity
  - EN 61000-6-2 Heavy Industrial Immunity
  - EN 61000-6-3 Residential Emissions Std
  - EN 61000-6-4 Industrial Emissions Std
  - Particular Standards/Special/Medical
- These environmental electrical standards establish the levels of compliance required for classes of equipment as well as the allowable emissions that systems can radiate or conduct into the environment. As such they form the backbone of what EMI engineers commonly call the "CE MARK"

# Real Life Anecdotal Case Studies

- Tools in the Lab Environment
- Ohio Hospital Field Environment
- EKG / Urine Meter Case
- EKG / Ventilator Case
- Electrosurgical Unit Case
- Air Sensor Case

# Common & Differential Mode

The Concepts of Common and Differential Mode are essential to explain unexpected EMI related phenomenon found in the medical environment. In the following examples attempt to identify the coupling effects that are altering the readings of correct medical measurement.





# Retort Safety

- Previous cases show even safest machines are susceptible to EMI Fields
- Sensitive readings may change due to common mode interference of EMI Fields
- Closed Loop Control can Backfire and Ruin Batches of Fluids such as Milk
- FDA suggests two methods should be used to “trust but verify” closed loop controls
- New Method of Safely Cross Checking Retorts is Introduced

# Camera Surveillance System

- Common Cameras have been found to be resistive to EMI Effects
- Camera with VCR or DVD Recorder can perform Surveillance and Save Proof of Quality for Inspection Purposes
- Wired Systems best against EMI Effects
- Anaconda Surveillance System from X10

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