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Test and Measurement Coalition

Policy Recommendations

November 2022

I. **Test & Measurement Coalition & experience with RoHS**

II. Policy & regulatory context

III. Policy recommendations

Introduction to the Test & Measurement Coalition

- The Test & Measurement Coalition **created in 2005**
- Represents roughly **60% of the global production of industrial test & measurement products** and other Category 9 industrial equipment including **chemical analysers**
- **Members**: Agilent Technologies, Fluke Corporation, Keithley Instruments, Keysight Technologies, National Instruments, Tektronix and Thermo Fisher Scientific

- Our products are sophisticated EEE, designed for **professional & industrial use**, with **high reliability and serviceability**; having a typically active life of **ten years**
- **Sustainable-by-design** products are the **norm** in the sector
- **The industrial Test & Measurement sector is enabler of innovation**

What is industrial Test & Measurement equipment? Examples of T&M products & applications

Gas Analyzers

FTIR Spectrometer

Environmental & chemical testing systems (e.g., spectrometers, imagining systems, analysers) used for **measuring microplastics**, toxic substances in soil, impurities in hydrogen, biofuels, battery composition, etc.):

- Critical to **advancing the understanding of how microplastics affect humans and the environment**.
- T&M analyzers and testing methods play an **important role in the transition to alternative energy sources**.

Wireless Network Emulation

Airbag Test Systems

Automotive / Autonomous driving solutions (e.g., Radar Signal Analysis, e-mobility test solutions) & 5G Solutions & 6G Innovations (e.g., testbeds, waveform generators, oscilloscopes):

- Help drive **innovation in the automotive industry and its fusion with the clean energy ecosystem.**
- **Innovation enablers in the communications industry** (R&D, testing, performance optimisation).

What is industrial Test & Measurement equipment? Examples of T&M products & applications

Krios Microscope

Tecnai Microscope

Instruments (electron microscopes & sequencing instruments) used for providing a 3D model of the COVID virus. This allowed the development of COVID rapid tests used around the globe, and facilitated vaccine development.

- T&M products played **a role in the EU coronavirus response, incl. in increasing vaccine manufacturing capacities and speeding up development, authorization and availability of vaccines**.

- Electron Microscopes, sequencing instruments and analysers are also **used in cancer research, including cancer genomics, cancer biomarker research, and cancer cell analysis.**

Semiconductor Switching Systems

Semiconductor test systems needed to source, measure, connect, control or communicate direct current or pulsed electrical signals in the area of semiconductor device development and fabrication.

- T&M instruments are also **vital for providing/developing batteries needed to achieve the electrification of transport sector** (phase out of combustion engine in new cars as of 2035).

Key applications of our equipment:

Sophisticated EEE used in critical & strategic applications	
Calibration & National standards	Government and security
Cellular Communications	Digital Design and Interconnect
Wireless Connectivity	RF & Microwave
Aerospace and Defence	Optical & Photonic
Component and Device-Specific	Petrochemicals
Forensics	Education
Automotive and Energy	Air & soil
Food & Beverage	
Pharmaceutical	

The industrial Test & Measurement sector is enabler of innovation

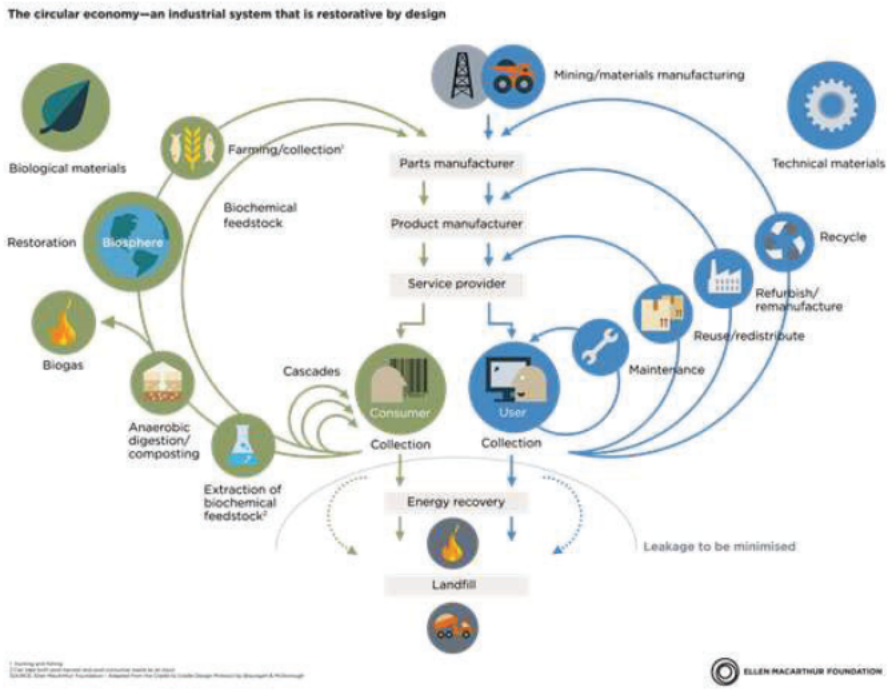
Specificity of industrial T&M equipment

- **High-mix, low volume portfolio**, typically having **2~3000 active products** *plus their options* currently being made available on the market at any time
- All equipment is **highly complex**; requiring a vast supply chain involving **thousands of suppliers & parts**
  - Handheld oscilloscope
    - **1,900 parts**
  - A member of Performance Network Analyzer family
    - **30,000 parts**
  - Mass spectrometry
    - **40,000 parts**
  - Pulse function arbitrary noise generator
    - **16,000 parts**




- Equipment is designed for **high reliability and serviceability**; having a typically active life of **ten years, with a use phase of to 40 years**
- We estimate Category 9 Industrial product to be **0.2%** by mass of all EEE placed on the EU market, and 0.1% of e-waste (Eurostat WEEE Data, 2017).

Circular Economy model for Test & Measurement instruments:
A strong focus on maximizing the use phase



- **MAINTAINING:** expectation of repeatable and accurate results throughout product lifetime (typical first use 10 years, up to 40 years total)
- **REPAIRING:** repair services typically provided for min 5 years after market withdrawal.
- **REFURBISHING:** substantial trade-in discounts, steady supply chain of equipment for refurbishment. Significant secondary markets (refurbishment and resale).
- **RECYCLING:** Collected exclusively through B2B schemes. Represents 0.2% by mass of all EEE placed on the EU market, and 0.1% of e-waste (Eurostat WEEE Data, 2017)

Impact on entry of Cat. 9 industrial into RoHS scope

Impacts on Category 9 industrial products:

- The redesign started in 2005 and took over 12y
- **60% of the products had to be redesigned**
- Cost of compliance – **10% of product turnover**
- **7.5% of the products had to be withdrawn** from the EU market, affecting **7% of companies' turnover**
- Managing compliance within complex supply chains is an ongoing challenge

Input provided T&M to COM & Ecorys based on robust SEA on impact of RoHS on sector

- **Initial investment costs** for RoHS compliance: **10% of product turnover!**
  12 y to redesign 60% of the products portfolio, 7.5% of products prematurely withdrawn
- **Annual cost** for maintaining RoHS compliance: 4,185,000 EUR
- **RoHS substances** used annually: 89 kg (total aggregated figure)

Measure of cost - effectiveness: 46,780 EUR/kg!

Impact on the Competitiveness of the EU's engineering industries and digitalisation

- Input to the Study on the **Competitiveness** of the EU's **engineering industries** & the impact of **digitalisation** (CSES)
- Industrial T&M is an **enabler of innovation** and **digitalisation** in all other sectors
- **Restriction of essential substances** would impact the ability of **European engineering companies** to **innovate** and compete against non-EU technologies
- RoHS 2 restriction resulted in **early market withdrawal of key equipment** for EU engineering sector, when still available for non-EU competitors
- **Customer response:** moving activities using cat.9 industrial outside EEA. Increased admin burden for providing equipment to industries exempted from RoHS. Where possible, provide alternative equipment

The conclusions of this study should be considered for the Impact assessment of RoHS!

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Policy & Regulatory context

REACH:
Restriction of PFAS
Lead & Annex XIV

REACH/CLP review:
Generic approach to risk management
New hazard classes Evaluation of mixtures

Chemical Strategy for Sustainability:
Essential use
One Substance One Assessment

Industrial Test & Measurement equipment

RoHS Directive
Revision & exemption evaluation
Non EU RoHS

Ecodesign:
Sustainable Product Policy initiative

End of life management:
Waste framework directive
SCIP database
WEEE Directive revision

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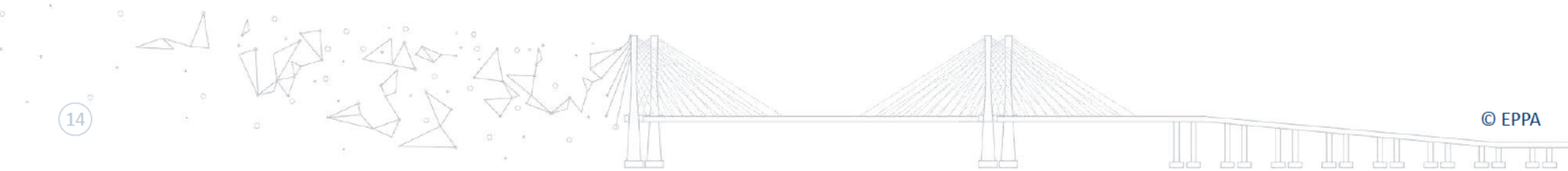
REACH & RoHS: policy & regulatory coherence

- **Define the priorities regarding substance bans:**
  - RoHS should not address risks arising during manufacture of electronics
  - RoHS should focus on substances of relevance in the end of life phase
  - Precautionary principle need to be interpreted coherently between REACH & RoHS
  - Substances suspected of hazardous properties: RoHS should not create a separate stream of assessment

- **Exclude from the scope of REACH uses of substances in EEE regulated under RoHS**
  - Memorandum of understanding REACH & RoHS
  - Efficient use of REACH art 58 (2)



Prioritisation of lead for inclusion in Annex XIV

- Lead has a **critical function** in industrial monitoring & control equipment
- Exemptions granted under RoHS, but substantial **reduction of quantities** since 2004
- The risk of workers or environmental exposure is properly managed at all life cycle stages
- The largest use is in aluminium, steel and copper alloys for which there is **no suitable alternatives.**
- **Recommendation: exclude use of lead in electronics from REACH authorisation**

Industrial Test & Measurement EEE placed on the EEA market			Lead			
2004 Quantities	Total Units Sold	Total Product Weight	Solder on printed circuit boards	Ball Grid Arrays	Radiation Shields	Other uses
	840,319	1,358,875	15,726	32	2010	91
2019 Reduction estimate			100%	100%	99.4%*	15%**

Estimated weights (in kg) of products and RoHS-restricted substances sold in the EU in 2004 and in 2019. Source: Survey of the Test & Measurement Coalition, 2019.

Example of negative socio-economic impacts from RoHS restriction of lead:

VXI mainframes & modules used in aerospace were retired early from the EU market due to use of lead in solders.

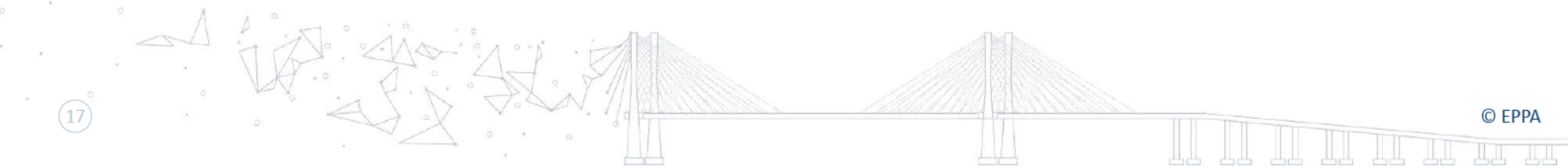
EU Aerospace customers were not able to build new test systems using the VXI standard or extend their current VXI systems with additional modules.

Restriction of MCCP under REACH

- MCCPs are known to be used both as a **plasticiser** and a **flame retardant** over a very large number of formulations are in use for a wide range of **industrial applications**
- To date, **no known suitable alternative exists** which can perform all functions of MCCPs:
  - **No direct substitution** that can be consistently applied,
  - **Different solutions** will need to be **specifically tailored** in each applicable use.
  - **Extended time needed** to determine if the **reliability of substitutes** is assured for our sector
  - Each potential **alternative** to flame retardant applications will be **subject to product safety third-party certifications**
- Category 9 industrial producers will be **forced to redesign, test and requalify the entire portfolio.**
- **Severe negative impact** anticipated on the **product availability and innovation** not only on Category 9 **industrial producers but also on our customers**.

Assessment of 7 substances under RoHS

- **Active participation of T&M in the consultations and workshop:**
  - **TBBP-A:**
    - *No drop-in replacement available, failure to identify adequate substitutes*
    - *Cost of substitution: premature design cycling of entire portfolio, risk of forced market withdrawal*
    - *Challenges on screening and analytical methods – concrete feasibility challenges in detection / enforcement*
  - **MCCP:**
    - *Challenges on screening and analytical methods – concrete feasibility challenges in detection / enforcement*
    - *No known alternatives can perform all functions of MCCPs*
  - **ATO:**
    - *Suitability of alternatives (i.e. halogenated flame retardants) with larger negative env impact*
- **There is no cost-benefit justification to the inclusion to RoHS Annex II of MCCP, ATO and TBBP-A for cat.9 industrial**
- **Should cat.9 industrial be in the scope of the new substance restriction, a differentiated timeline is necessary and additional time granted of 12 y minimum!**



Possible REACH – RoHS model

- **RoHS substance restrictions:**

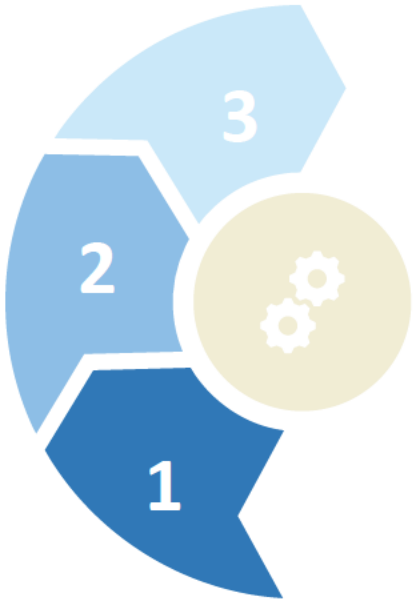
- **RoHS exemption process:**

- **Advantages:**
  - Benefit from SEAC experience on SEA
  - Timeline is generally respected
  - Use of adequate data generated under REACH
  - In line with OSOA principle

- **Challenges:**
  - Less familiar with RoHS and waste issues
  - Can ECHA manage increasing workload?

Introducing “Essential use” concept in RoHS

Allow use of hazardous substances when the use is considered essential!



1. **The risk is controlled**
   → Cat 9 professional & industrial use
2. **Lack of suitable alternatives**
   → Specific technical performance, high reliability, long product lifetime
3. **Necessary for health, safety or critical for functioning of society**
   → Critical function of the substance in the application + uses in critical sectors (Security, pharma, food etc.)

Consideration for cat 9.derogation based on the “essential use” concept!

RoHS exemptions: key challenges & concerns

- **Key challenges:**
  - **Lack of predictability on the timing of submission of exemption requests**
  - Consequences **of early exemption renewal requests** not fully considered
  - Keep **consistency of exemption structure:** wording, numbering, timelines
  - Challenges related to the transposition of the Delegated Directives in the EU Member States
- **Case Study: Mercury in lamps**
  - Exemption application submitted in 2015 for cat 1-7 & 10 COM and evaluated by Oeko Institut
  - In July 2021 COM published Delegated Dir, with expiry dates for **all categories**

  → **Issue: no data, lack of evaluation, lack of transparency of COM re evaluation scope extension**
- **COM's position:**
  - COM evaluation not limited to the scope of the application
  - Expiry dates are not legally binding → exemptions can be evaluated any time for all categories

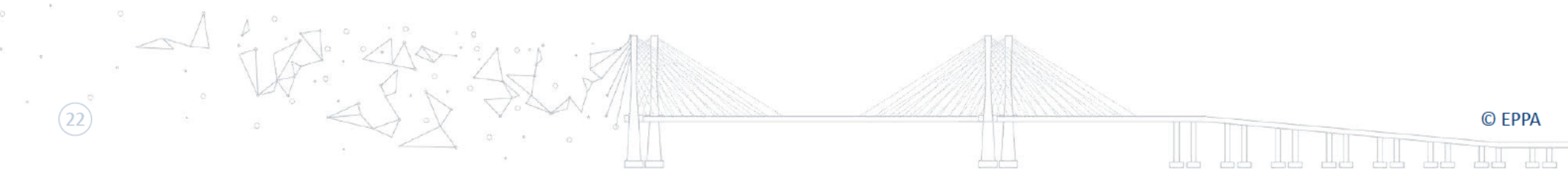
  → Precedent under RoHS!

RoHS exemptions – suggested improvements

- Current process takes far **too long**
- **Exemption methodology** needs to be **coherent with substance methodology**
- **Synchronize the validity timeline** for all exemptions across all categories: 6 & 12y?
- Set **review windows for submission** of new & renewed exemptions
- Advantages to combine Annex III and IV and enforce **consistent numbering scheme**
- Need to consider **resources to address increasing exemption needs** related to new substances & obligations
- **Integration of RoHS exemption methodology in the text of RoHS to ensure legal certainty!**
- **Make RoHS 3 a Regulation:** would eliminate the need for transposition and ensure better clarity of scope and implementation timing; reduce administrative burden for Member States

Key recommendations for the revision of RoHS

- General support of the RoHS model, RoHS shall not be merged with other legislation
- Transform RoHS into Regulation to ensure better clarity of scope and implementation timing
- Improvement of RoHS substance identification and exemption processes is needed
- Using ECHA's resources and experience would optimise the process in a cost-effective way
- Consider implementing "essential use concept" in RoHS
- Given the policy context of the Circular Economy and the cost-effectiveness ratio for Cat.9 industrial, we recommend a thorough analysis of the relevance of adding Cat.9 industrial in the scope of future restrictions and introduction of simplified exemption procedure



Thank you!

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Overview of Exemptions which need to be continued

Annex III

- 6(a): Lead as an alloying element in steel containing up to 0,35% lead by weight
- 6(b): Lead as an alloying element in aluminum containing up to 0,4% lead by weight
- 7(a): Lead in high melting temperature type solders (i.e. lead-based alloys containing 85% by weight or more lead)
- 7(c)-I: Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound
- 8(b): Cadmium and its compounds in electrical contacts
- 13(a): Lead in white glasses used for optical applications
- 13(b): Cadmium and lead in filter glasses and glasses used for reflectance standards
- 15: Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit Flip Chip packages
- 34: Lead in cermet-based trimmer potentiometer elements

Annex IV

- 4: Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons

Annexes

Environmental Monitoring

XRF Analyzers

(ICP-MS) Inductively coupled plasma mass spectrometry

Gas Analyzers

Radiation Detectors

Gamma Density Gauges

Gas Chromatographs

(AAS) Atomic Absorption Spectrometry

PHS/ORP/ Conductivity Meters

Handheld Raman Spectrometer

Flow Monitors

Liquid Chromatograph

(ICP-OES) Inductively coupled plasma optical emission spectromtry

FTIR Spectrometer

Elemental Analyzers

Photometric & Electro-chemcial Analyzers

[The test methods identified in BS EN 62321 for testing of chemicals in articles for RoHS]

Communications

Wireless Network Emulation

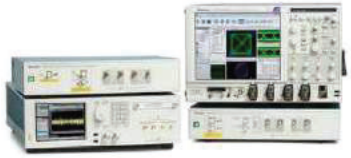
Waveform Generators

Telecom Test Sets

Signal Generators

Enterprise Network test, emulation and security

Vector Signal Generators



Optical Modulation Analyzers

Network Cable testers

Wireless Channel Emulators

Network Analyzers

Bit Error Rate Tester

Function Generators

Network Health Analyzers

Wireless Test Solutions

Bit Error Rate Test Solutions

Spectrum Analyzer

Vector Network Analyzer

Spectrum Analyzer

Noise Figure Analysis

In-circuit test solutions

Medical Device, Diagnostic, and Pharmaceutical Testing

Pharmaceutical Analytics PCR system

Pharmaceutical Metal Detector

K6460S Clinical TQ LC/MS System

Automated Microbial Detection System

Blood Bank Centrifuge

IVF Incubator

Magnis Next Generation Sequencing

Capillary electrophoresis

Blood bank refrigerators

Automotive and Energy

Airbag Test Systems

Battery Simulators

Power Meters and Sensors

Parametric Curve Tracers

Parametric Test System

Automotive Energy emulation and test

Parametric Test Solutions

E8718A Radar Target Simulator

Device Current Waveform Analyzers

COVID-19 Response

Krios Microscope

Showed the first 3-dimensional structure of COVID-19

Tecnai Microscope

QuantStudio

Instruments used to diagnose / sequence the virus

SeqStudio

PCR Testing Instruments

Rapid testing and vaccine manufacturing

Bioreactors

Hospitals & Clinics

Centrifuge

Chromatographs

C02 Incubators

Real-Time Cell Analyzers

Capillary Electrophoresis

Thermocyclers

Cold Storage/ Freezers

Biosafety Cabinets

IVD Instruments

Semiconductor Testing

Semiconductor Switching Systems

ICP-MS (ICP-QQQ) for measuring trace & ultra-trace level contaminants in Silicon substrate

GC/MS to detect organic impurities in air during µ-Processor manufacturer

Scanning Electron Microscope for localization of transistor and metallization faults

Atomic force probe based nanoprober for electrical fault localization in transistors and interconnects

Static optical fault isolation for identifying process, design or integration issues

Industrial and Utilities

Power Suppliers

Digital Multimeters

Insulation Testers

Power Analyzers

Multi-phase Power Quality Standards

Data Acquisition DMM

Compact RIO Programmable Automation Controller

Power Quality Monitors / Analyzers

Parameter Analyzers

Compact Vision systems

Electronic Loads

Current Sources

Academics (Research) / Forensic

Rapid Hit ID System

Forensic DNA Extraction System

X-Ray Inspection Systems

Visual & Fluorescent microscopes

Mass Spectrometers

Ion & Liquid Chromatographs

Particle Monitoring

Flow Cytometers

Scanning & Transmission Electron Microscopes

Neuron Flux Monitors

UV-Vis Spectrophotometers

Clean Energy

ICP-OES Impurity Testing of Raw Materials used in Production of Li-ion Batteries

LC to characterize fuel composition for Biofuel

Gas Chromatographs for the ASTM D6584 analysis of biodiesel

Cary 630 FTIR Spectrometer for fuel quality & purity

1260 Infinity II SFC System to determine olefins in denatured ethanol to ASTM D7347-07

990 Micro GC system for rapid analysis of high-purity hydrogen