# FAQ on Device Safety Standards Compliance of the LX4000 and LX5000 Data Acquisition Systems

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1. **Who publishes, regulates, or enforces compliance with device standards pertaining to the LX4000 and LX5000 devices?**

There is no governing body or organization that is empowered to regulate or enforce standards pertaining to the LX4000, LX5000, or other polygraph devices. However, there are organizations such as the AAPP (American Association of Police Polygraphists) and APA (American Polygraph Association) that publish and enforce standards for basic instrumentation, code of conduct, training, quality control, best practices, etc. There are also published ASTM (American Society for Testing and Materials) standards that codify many of the same issues and topics. Psychophysiologists have also published recommendations for data acquisition and signal processing. Instrument manufacturers strive to produce equipment that meets or exceeds published standards and examiners' expectations. Enforcement of these standards is largely driven by the polygraph community itself. There is no mandated third party oversight for polygraph manufacturers, but equipment that fails to meet established standards would not be widely adopted into the market.

One area where standards do carry the force of law is in the area of Electromagnetic Compliance (EMC). In this case, polygraph equipment is regulated simply because it is electronic. Some countries, those in the European Union in particular, require electronic equipment to be certified for EMC. Many other countries are starting to implement similar laws, while compliance in the United States is not yet mandatory for all electronic equipment. The standards for EMC compliance are typically maintained by the International Electrotechnical Commission (IEC). Individual countries may have their own standards such as the UL and FCC in the United States or the British Standards Institute in the United Kingdom. There is typically very little difference between the regional standards and the IEC international standards, and certifying to an IEC standard will often be accepted in other countries.

2. **Is the polygraph a medical device and does it require medical grade connectors?**

No. Polygraph devices, including the LX4000 and LX5000 devices, are not medical devices. According to the United States Food and Drug Administration (FDA) a medical device is an instrument "intended for the use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals". Other medical device regulations from around the world including the European Union Medical Device Directive and Canada's Food and Drug Act, use concepts and language similar to that of the FDA. Polygraph devices are not intended for the

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diagnosis, treatment or management of disease and are not designed to meet medical device standards.

According to IEC 60601-1, medical devices are designed with stringent standards due to the inherent risk to medical patients. These risk factors sometimes occur because the patient is unable to detect and respond to hazards due to being unconscious or anesthetized. Hazards may include breaks in the skin which compromise its resistance to electric currents, simultaneous connection to multiple devices, and the application of electrical circuits directly to the patient, some of which may be high power, or provide artificial support for vital processes which cause a risk to the patient if interrupted. Polygraph test subjects do not face the same life support and health risk factors as patients in a medical setting. Medical grade connectors and instrumentation can be used for polygraph devices but are not required to ensure the safety of the subject.

There are several features which qualify connectors to be rated as medical grade. Among these are biocompatibility with exposed or compromised skin, ability to be sterilized, latching mechanisms so as to prevent disconnection which could cause a potential health hazard, keying or notching to prevent misconnection into an unintended socket, shrouding so that a patient cannot inadvertently touch or be connected to an electrical power source, and rating for high mating/un-mating cycles to ensure high reliability of the connections. So, while medical grade connectors are suitable for polygraph devices, there is nothing about the LX4000 or LX5000 devices that expressly requires them. There are a large number of connector choices that offer the same robust, reliable performance as medical grade connectors, though they may not be specifically rated for medical use. There is no basis to suggest that a connector is inferior for polygraph devices simply because it is not medically rated.

### 3. What safety measures are taken on the LX4000 and LX5000?

Although the LX4000 and LX5000 are not medical devices, they do share something in common with medical devices in that they provide an electrical connection directly to the human body. This direct connection comes through the EDA sensor. Other channels such as the cardiograph, pneumograph, and pulse plethysmograph attach to the body but do not provide a direct electrical connection. Under normal circumstances, the direct connection would not pose any danger to the subject since the polygraph is powered from the USB connector which is very low voltage. International safety standards do not consider low voltages to be an inherent risk. However, the direct connection presents two potential hazards to the subject if a fault condition occurs. One, an electrical surge on the computer power system could make its way through the attached polygraph and energize the test subject. Two, the subject could touch a high voltage source and the energy could travel through them to ground. This second scenario is very unlikely as there are not typically high voltage sources in the polygraph environment. If the computer has a power supply that has been safety rated, and most are, then these risks are mitigated to a large degree just from the power supply. The polygraph hardware then adds another layer of protection by electrically isolating the EDA circuit. This further ensures that electrical energy cannot make its way either from the power supply to the subject or from the subject to ground. There is no set or published standard for this additional isolation on the EDA channel, and will vary by manufacturer and by model number, but is typically between 2000 volts and 5000 volts of additional isolation. Current production versions of the LX4000 and LX5000 devices are compliant with a 5000 volt isolation level. The safety-rating of the computer power supply along with the additional electrical isolation on the EDA channel, also combined with the absence of high voltages in

the polygraph environment, all make the polygraph instrument a very safe system for both the subject and examiner.

## 4. What is Electromagnetic Compliance, and how does it affect the design of the LX4000 and LX5000?

Electromagnetic Compliance (EMC) is a term that describes how an electronic device interacts with other electronic devices in its environment. It does not necessarily certify overall product quality or guarantee that a device will perform its intended function as expected. It merely is a measure of the level of interference caused by and inflicted upon other devices. There are two main parts to EMC: immunity and emissions.

Immunity deals with how well a device resists the effects of energy or interference from outside sources. These sources can be anything from power surges, power spikes, power interruptions, voltage dips, radio frequency interference conducted through the power lines, power frequency magnetic fields, radio frequency electromagnetic fields, and electrostatic discharges. In some electronic devices, the immunity performance can have a significant effect on the safety of the device. However, this is not the case for a polygraph device.

There is no immunity or EMC issue that will result in an unsafe operation of the LX4000 or LX5000 devices. In the worst case for polygraph, the test chart could be interrupted or rendered unusable due to "noise" on the traces, or the polygraph hardware could become damaged and cease working altogether. During immunity testing, the LX4000 and LX5000 devices are exposed to different forms of radiated and conducted energy. The device is graded based on the level of interruption or damage that occurs when exposed to each of the prescribed energy types. This grading is known as performance criteria, and it is broken down into four categories depending on whether or not any effects were observed and the action needed to maintain or resume normal operation. Most devices will exhibit no effect or will require no user intervention to maintain or resume normal operation. A device that is damaged during testing would fail and would not be certified under any published standard. The LX4000 and LX5000 have been shown to withstand immunity tests while maintaining normal operation with no additional user intervention.

Emissions testing deals with the degree to which an electronic device emits electromagnetic energy that could interfere with other electronic devices in the immediate environment. Emissions can take the form of radio frequency interference coming from the device, radio frequency interference being conducted through the power lines to other devices, or harmful power frequency magnetic fields being generated by the device. Standards making entities determine what level of emissions is acceptable for each category and publish those levels for compliance. During testing, antennas or other measurement equipment are used to measure the field strengths being emitted by the device under test. If the device is emitting above the compliance level, design changes are implemented to shield the device or otherwise block the unwanted energy from emitting from the device.

As with immunity issues, emissions problems do not have any bearing on the safety of the LX4000 and LX5000 devices. If a polygraph did not meet emissions requirements, a worst case scenario would be that a cell phone, computer, or other electronic device in very close proximity to the polygraph could have its performance degraded due to the interference being emitted. Because both the LX4000 and

LX5000 are under the specified limits, there are no electrical emissions issues when using these devices.

## 5. How are the LX4000 and LX5000 designed to handle Electrostatic Discharge (ESD)?

Electrostatic discharge occurs when a person or object becomes charged with static electricity. When a person comes into contact with another person or object, the electricity can move or discharge to that other person or object. A classic example of ESD occurs when a person walks on carpet and then touches a doorknob or light switch. A small electric spark jumps from the person into the object that they are touching. These static discharges can reach into the thousands of volts of electricity. If the object that is being touched is electronic, then the static discharge may cause intermittent failures and even permanent damage to the device. Therefore, ESD protection is integral to an electronic device and is part of compliance testing for EMC immunity.

LX4000 and LX5000 devices are tested for ESD compliance in the same manner as other electronic devices: static discharges are systematically applied to the device. The charges are applied by direct contact wherever a person could potentially touch any conductive part of the device and by air discharge on any non-conductive part of the device. The charge severity is specified by the standard being applied and is rated in four different levels for direct contact and air discharge:

- Level 1: 2,000V contact discharge, 2,000V air discharge
- Level 2: 4,000V contact discharge, 4,000V air discharge
- Level 3: 6,000V contact discharge, 8,000V air discharge
- Level 4: 8,000V contact discharge, 15,000V air discharge

The reaction to the ESD pulse is rated in the same way as all of the other immunity tests: Performance Criteria A with no response to Performance Criteria D where the device is permanently damaged. If the device does not pass the prescribed discharge level with the prescribed performance criteria, then steps are taken to protect the device from ESD energy. Generally, these steps try to prevent ESD energy from entering the device or try to route the energy away from sensitive parts of the circuit and into ground connections. LX4000 and LX5000 devices have been tested and shown to be immune to ESD up to 4000 volts contact discharge and 8000 volts air discharge according to the IEC 61326 standard. The devices are additionally tested at even higher levels to ensure that no permanent damage occurs even at level 4 discharge voltages.

## 6. What is actually being certified to on a Declaration of Conformity?

There are up to three tiers of regulation that can affect the compliance of a device. These are directives, standards, and test procedures. Directives are very broad “umbrella” type documents. They declare that devices should be compliant, give some criteria for what types of equipment are covered by the directive, and list some basic essential requirements. Electronic products are covered under the EMC directive, which simply means that electronic products cannot cause excessive interference nor be overly susceptible to interference from other electronic devices. To get to specific requirements for a device, standards are used. A standard designates detailed criteria for device performance and is also very specific as to what devices and applications are covered. For example, there are separate standards for information technology equipment, lab equipment, and medical

equipment. There are also separate standards for EMC compliance and device safety. A single device can easily be required to meet more than one standard to achieve full compliance. A standard will usually "call out" or designate not only the required test levels for a device, but also the test procedures used to carry out the evaluation. If each device is to be evaluated equally, then a standard method of performing each test must be established. This is where test procedures come in. A test procedure establishes the equipment, methods, and test setups used to perform the tests required by the standard. There is typically a separate written test procedure for each test that is specified. There can therefore be multiple test procedures for each standard. So, then, when a Declaration of Conformity is issued, the manufacturer will typically list the directive that is being addressed, the standard that is being met, and the specific tests that were carried out to evaluate the compliance to the standard. Declarations of Conformity for LX4000 and LX5000 devices are available from Lafayette Instrument Company.

## 7. What specific Directives, Standards, and Test procedures may appear on a Declaration of Conformity for various electronic devices?

A Declaration of Conformity will usually state that a device meets the essential requirements of one or more directives:

- Electromagnetic Compliance Directive: Designates how electronic devices interact with each other
- Low Voltage Directive: A very broad safety directive for electric and electronic devices
- Medical Device Directive: This is a common directive to reference, but does not apply directly to the polygraph because a polygraph is not a medical device.
- WEEE directive: Directive that covers recycling of electronic equipment
- ROHS directive: Restriction of hazardous substances, disallows certain materials in electronic devices

There is no single standard that specifically covers the LX4000 or LX5000 devices, but there are several common standards that cover similar type equipment which are applicable to the polygraph hardware.

EMC Standards:

- IEC 61326-1: EMC standard for measurement, control and laboratory electrical equipment
- IEC60601-1-2: EMC Standard for medical equipment
- CISPR11: EMC RF Emissions standard for industrial, scientific and medical RF equipment
- EN 55011: EMC RF emissions standard for industrial, scientific and medical RF equipment
- CISPR22: EMC RF Emissions standard for information technology equipment
- EN 55022: EMC RF Emissions standard for information technology equipment
- EN 55024: EMC Immunity standard for information technology equipment

Safety Standards:

- IEC 60601-1: Safety standard for medical equipment
- IEC 60950: Safety standard for information technology and electrical business equipment
- IEC 61010-1: Safety standard for measurement, control and laboratory electrical equipment

Test Standards

- IEC/EN 61000-4-2: ESD immunity test standard
- IEC/EN 61000-4-3: Radiated Immunity test standard
- IEC/EN 61000-4-4: Electrical fast transient/Burst immunity test standard
- IEC/EN 61000-4-5: Surge immunity test standard
- IEC/EN 61000-4-6: Conducted RF immunity test standard
- IEC/EN 61000-4-8: Power magnetic field immunity test standard
- IEC/EN 61000-4-11: Voltage dips, interruptions, and variations immunity test standard

## 8. What standards are the LX4000 and LX5000 certified to?

The LX5000 and LX4000 are certified to meet the essential requirements of the EMC directive. They are also certified to IEC 61326 which is the EMC standard for measurement, control, and laboratory electrical equipment. This standard calls out many other standards and test procedures. The LX4000 and LX5000 devices, by virtue of being compliant to this standard, are also compliant to EN 55011 (CISPR11) for emissions and uses test procedures IEC61000-4-2, -3, -4, -5, -6, and -11 to evaluate the immunity compliance.

A large part of the published safety standards apply to devices that plug directly into the wall/mains voltage. Since the polygraph plugs into a computer for its operation and not directly into the wall, the computer safety becomes the key factor in the system safety. Any computer purchased on the consumer market or supplied by a reputable manufacturer will be certified to the IEC60950 standard, making the polygraph as safe as or safer than anything rated to this standard. So, while the LX4000 and LX5000 devices do not carry this rating of themselves, they can be said to inherit the safety rating of the computer, and then add an additional layer of protection with isolation on the EDA connection.

## 9. Besides Electrical Safety and EMC are there any other ratings or certifications that apply to the LX4000 and LX5000 devices?

The LX4000 and LX5000 carry safety ratings on the plastic used for the device enclosure. The ratings describe the flammability of the material and the test procedures used to define its mechanical properties. The flammability rating is UL 94V-0 which means that after being exposed to an ignition source (open flame) the material will stop burning within 10 seconds and will not drip any flaming particles. The mechanical properties of the material are tested according to ASTM (American Society for Testing and Materials) standard procedures. The tests ensure the quality and consistency of the material and allow properties such as density, tensile strength, impact strength and hardness to be measured and defined.

## 10. What are the standards for EDA measurement circuits and do the LX4000 and LX5000 meet those standards?

There is no official standard for the design or performance of EDA measurement circuits. However, there is consensus among researchers who study EDA that the current density to the subject should be limited. The recommended maximum level is 10 microamps (Boucsein, 2012, Edelberg in Brown eds., 1967) per square centimeter (10uA/cm2). EDA can be measured as either resistance or conductance and there is an exact mathematical relationship between the two. Psychophysiologists

have published a standardization proposal in favor of constant voltage recording. Boucsein (2012) provided a comprehensive discussion of the advantages and disadvantages of the two methods (p. 247-251), and noted that resistance recording systems remains in use. For a resistance measurement, a constant current source is used, and it is relatively easy to limit the current source to below 10 uA while also ensuring the electrode area is at least one square centimeter. The constant current source on the LX4000 is set to 6.7 uA and the current on the LX5000 is set to 4 uA for resistance measurement (EDR). The LX5000 is also capable of conductance measurements (EDC), for which the LX5000 circuit uses a constant voltage that is automatically ranged for each subject when the EDA circuit is closed, ensuring that the maximum current is less that 10μA for all test subjects. The advantage of the auto-ranging design is to optimize EDA response sensitivity across a wide range of subject resistance levels while remaining within the proposed current density specification.

For more information, please email info@lafayetteinstrument.com or call 1 (765) 423-1505.