Electro-Medical Devices: Preparation for launching safety tests in accordance with Standard IEC 60601-1

Practical Advice

Complementary documentation to “Guide to defining a test strategy”
April 2015
In accordance with its guiding principle of helping manufacturers of medical devices define a testing strategy, the LNE has published a new series of practical tips to help medical devices manufacturers prepare themselves for the electrical safety tests related to Standard IEC 60601-1.

This complex standard requires manufacturers to submit a variety of information on their devices. It is therefore necessary to be well prepared in order to avoid unnecessary wastes of time and additional expenses.

The goal of this series of practical tips is to help manufacturers anticipate errors in how the standard is interpreted, avoid the most common pitfalls, and understand the traceability requirements for properly preparing their test programmes.

The most critical requirements: clarification and recommendations from LNE

In order to help manufacturers understand the most critical requirements, the LNE has selected the articles for which advance preparation is essential.

The following items will be explained with recommendations from the LNE, since transmitting them beforehand is a sine qua non condition for starting and planning any testing programme.

- **Article 4.2 - The risk analysis must be accompanied by a risk management plan. The risks identified in Standard IEC 60601-1 must be included in the risk analysis.**

  The risk analysis should consist of at least:

  - a risk management plan ensuring compliance with Standard ISO 14971
  - an analysis identifying the risks and dangerous phenomena to be listed, for example, in a spreadsheet.

  Guide OD2044 issued by the LNE will help you determine the minimum risks you will need to identify in your risk analysis.

- **Article 4.3 - The essential performances should be included in the risk management file. The standard requires verification of compliance with the essential performances during testing. These performances should therefore be defined by the manufacturer as early as possible so that the LNE can conduct the tests.**

  The specific standards usually specify which performances are essential. If there are no essential performances defined in the specific standards, then it will be necessary to follow the definition indicated in Standard IEC 60601, Amendment 1: «An essential performance refers to the performance of a clinical function as opposed to a function that is related to basic safety, such that a loss or degradation of it beyond the limits specified by the manufacturer would create an
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unacceptable risk.»

The standard recommends using the clinical functions as a basis and reporting the associated essential performance list in the risk management file.

Example: essential performance of an operating table:
- the clinical function is: «To ensure the expected kinematics of the table in the operating theatre»
- the associated essential performance would then be: «An absence of inadvertent movements in the event of an initial fault and in all combined fault conditions».

• Article 4.4 - The lifespan of the medical equipment should be included in the risk management report. Correctly define which components are critical.

The lifespan should be quantified in years in the risk management report.

A critical component is any component that would cause an unacceptable risk by failing. For example: risk of fire, electrical risk (in the case of network components: power cables, fuses, power supplies, transformers, opto-isolators [e.g., for ensuring isolation]), loss of essential performance...

The certificates of conformity indicate the testing standards applied for the components and the technical features that must be communicated to the LNE as soon as possible.

In the case of tests performed as part of a national exception, the network cables and components of the countries in question need to be communicated to the LNE with their certificates of conformity and their technical data sheets. The components must comply with a standard applicable in the countries in question.

• Articles 5.9.1 / 7.9.2.5 - Defining applied parts.

The first step for electrical safety tests is to prepare an isolation schematic. To do this, the list of applied parts (to the patient) must be known from the outset. Otherwise, the conformity results of the dielectric and current leakage tests may be brought in to question and the tests will need to be taken again.

• Article 7 - Verification of the user manual.

The user manual must include the signs present on the medical device. Each sign should be explained.

• Article 7.1.1 - Usability guide.

The LNE will send you a usability guide when the device is launched. This guide will need to be filled out to ensure compliance with Standards EN 62366 and IEC 60601-1-6.
• **Article 7.2.3 - Verification of markings.**

The following icon must be placed in colour on the device if the risk management report specifies that the guide must be read in order to reduce a risk specified in the report:

![Verification of markings](image)

• **Verification of markings on accessories :**

a. **Article 7.2.2** - « THE ELECTRO-MEDICAL DEVICE and its removable components must be marked with the name or trademark of the MANUFACTURER, and an indication of its MODEL OR TYPE. »

b. **Article 7.2.4** - « ACCESSORIES must be marked with the name or trademark of their MANUFACTURER or their supplier, and an indication of their MODEL OR TYPE». Where marking accessories is not practical, the markings may be affixed to the individual packaging. 

Each removable component and accessory (i.e., that can be removed without tools) must be specifically marked.

• **Articles 7.8 / 15.4.4 - Verification of the colour of warning lights.**

Follow the requirements of the standard.

See the table below:

<table>
<thead>
<tr>
<th>Colour</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red</td>
<td>Warning - an immediate response is required from the OPERATOR</td>
</tr>
<tr>
<td>Yellow</td>
<td>Caution - a quick response is required from the OPERATOR</td>
</tr>
<tr>
<td>Green</td>
<td>Ready to use</td>
</tr>
<tr>
<td>Any other colour</td>
<td>In accordance with the manufacturer's specifications</td>
</tr>
</tbody>
</table>

• **Article 7.9.1 - If the guide comes in an electronic format (CD-ROM, website...), the risk management report must list the information that needs to be provided in hard copy format.**

This information must be submitted to the LNE

• **Article 8.7.3 - Verification of leakage current tests.**

For the leakage current tests, external voltage must be applied to the devices’ input/outputs
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(e.g.: USB ports). If the signal specifications are not indicated in the documents, the level to be applied should be the network voltage, which can be destructive.

• Article 8.11.5 - Protective devices must have enough breaking capacity to cut off the maximum potential fault current (including the short circuit current).

The data sheets for the fuses must be submitted to the LNE.

• Verification of the clauses.
  a. Article 9.8.1: dangers associated with support systems.
  b. Article 15.3.7: Environmental influences.

The articles cited here must be addressed by the manufacturer in the risk management report.

• Article 11.1.3 - Mandatory requirements for temperature tests.

In order to be declared to have passed the heat tests, the following items must be submitted to the LNE:
  - the maximum usage temperature of the device
  - the datasheets for the critical components

For each accessible part, the estimated contact times for the patient and the operator (see the tables in Article 11).

• Article 11.6.6 - Verification of cleaning products to provide during testing.

The claimed cleaning products must be communicated to the LNE when the device is launched so that the leak current test can be conducted and the markings verified.

• Article 11.7 - Verification of the biocompatibility certificate.

The biocompatibility of any parts liable to come into contact with patients must be demonstrated. The LNE will expect to receive a test report in accordance with Standard ISO 10993 for the parts in question.

For medical devices parts that are not subject to biocompatibility requirements:
  - Indicate in the risk management report the reason why they are exempt from biocompatibility tests (see Appendix B of Standard ISO 10993-1)
  - Provide the rationale for using the materials in the device and/or the post-production functional analysis.
• **Article 14** - The case of medical devices that include software (computer software or internal software in a component).

There are two possible cases:
- If the risk analysis shows that a software failure would entail an unacceptable risk, the LNE will analyse the software’s development process, applying the requirements of Articles 14.3 to 14.4 of Standard IEC 60601-1.
- If the risk analysis shows that a software failure would not entail an unacceptable risk, then Article 14 should be marked as «does not apply» in the test report.

### Conclusion

Based on the LNE’s experience, this guide will evolve. New versions will be published on a regular basis. Please do not hesitate to send any questions to info@lne.fr, especially since they may improve this guide.