

Medical Device EMC Test Preparation Checklist

Use this checklist before sending medical electrical equipment or systems for EMC testing. It helps your team prepare the information, samples and monitoring arrangements needed to agree the laboratory test plan.

Product / model: _____

Technical contact: _____

Target markets / specification: _____

Planned test date: _____

1. Define the device and requirements

- ☐ Provide the product name, model, variants, intended use and target markets.
- ☐ Identify the intended electromagnetic environment: professional healthcare, home healthcare or a special environment.
- ☐ Specify the required IEC 60601-1-2 edition and applicable collateral or particular requirements. For IVD equipment, identify the applicable IEC 61326 requirements.
- ☐ List requested emissions, immunity and proximity-field evaluations; agree method availability and accreditation coverage with the laboratory.

2. Define performance and acceptance criteria

- ☐ Supply the manufacturer's essential-performance statement and the relevant device-specific risk information.
- ☐ Provide observable, measurable immunity pass/fail criteria, including limits and any permitted recovery behaviour.
- ☐ Identify the operating modes and functions to monitor, including outputs, alarms, measurements, control and communications as applicable.
- ☐ Provide a monitoring procedure and suitable simulators or loads; agree how results will be recorded without disturbing the EMC measurement.

3. Prepare a representative configuration

- ☐ Provide production-representative samples and identify hardware, software and firmware versions.
- ☐ List accessories, applied parts, sensors, power supplies, chargers, batteries, cables and interconnected equipment needed for the tested system.
- ☐ Document cable types, lengths, routing and port functions; explain proposed representative or worst-case configurations.
- ☐ Explain model-family differences and identify the configurations proposed for testing.

4. Make the sample ready to operate

- ☐ Include setup instructions, safe handling information, operating procedures and the tools or access needed to run the sample.
- ☐ Provide agreed non-clinical test loads, simulators and consumables; establish how any patient-related functions will be simulated.
- ☐ Confirm supply voltage, frequency, current, battery endurance and charging arrangements.
- ☐ Describe wireless functions, antennas and simultaneous-transmission modes; provide existing module approvals where relevant.

5. Agree logistics and documentation

- ☐ Send sample dimensions, mass, handling requirements and a photo or configuration drawing.
- ☐ Confirm sample quantities, spares, accessories, shipping arrangements and the requested schedule.
- ☐ Provide the technical contact who can resolve setup questions and any required remote-support arrangements.
- ☐ Agree report identifiers, tested configurations, requested documentation and treatment of deviations before formal testing.

Before you book

Stancer's A2LA scope (certificate 7352.01) lists IEC 60601-1-2, BS EN/EN 60601-1-2, CISPR 11 and relevant IEC 61000 methods. It also lists IEC 61326-2-6. Required editions, additional methods and the final test matrix are confirmed for each project.

The manufacturer remains responsible for intended use, risk evaluation and essential-performance definitions. This is a preparation aid, not a complete compliance matrix or evidence of medical-device approval.

Send the completed checklist and product information to [Stancer's technical team](#).

Notes for the laboratory
