

EMC Test Plan (per EN60601-1-2)**QMF 17q Issue 02****RN Electronics Ltd**

Arnolds Court, Arnolds Farm Lane, Mountnessing, Brentwood, Essex, CM13 1UT

Registered in England No 3051259 Registered Office Arnolds Court, Arnolds Farm Lane, Mountnessing, Brentwood Essex, CM13 1UT

Tel: +44 1277352219 Fax: +44 1277352968 E-mail: sales@RNelectronics.com www.RNelectronics.com

Please Fax or E-mail back to R.N. to agree the plan before commencement of test

- Please complete clearly for each item to be tested, the answers will be used within your report after testing.
- Equipment under test (EUT) should be representative of a production model.
- Please copy for each additional piece of equipment to be tested.

Test Date

RN Job No

Our Quotation is based on the information supplied to us. Incorrect information may lead to extra charges if insufficient time has been allocated to you.

A : Configuration of EUT during testing**1 Description**

to realistically simulate EMC conditions, the equipment assembly will represent a typical installation as specified by the manufacturer.

2 Composition of EUT

list of all devices, racks, modules, boards, etc. significant to EMC.

3 Assembly of EUT(s) tested

rationale for selection of configurations tested (all modules must be tested).

4 I/O Ports

Under Test:

Not Under

Test:

5 Auxiliary Equipment

all patient physiological, accessory and sub-systems provided for use with EUT or simulated:

6 Cabling and earthing (grounding)

cables and earth to be connected during tests.

7 Patient Coupling

Description of any patient-coupled cable termination used / simulated patient physiological signals required for normal operation.

B : Operation conditions of EUT during testing

8 Environmental conditions

temperature	humidity	pressure	voltage	(ac) frequency
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

9 Emissions

Classification (see annex CCC)

Group: <input type="text" value="1 / 2"/>	CISPR 14 simple electrical component only	<input type="text" value="Y / N"/>
Class: <input type="text" value="A / B"/>	CISPR 15 lighting equipment	<input type="text" value="Y / N"/>
	CISPR 22 ITE equipment	<input type="text" value="Y / N"/>
	shielded location use only	<input type="text" value="Y / N"/>
	radio equipment	<input type="text" value="Y / N"/>

10 Immunity

Classification (see section 2 terminology and definitions)

Life-supporting equipment or system	<input type="text" value="Y / N"/>	RF receiver(s) in equipment / system	<input type="text" value="Y / N"/>
Internally powered equipment that cannot be used during charging.	<input type="text" value="Y / N"/>		

11 Essential performance (definition of functions for immunity testing).

If a risk analysis exists for the equipment or system, please attach. If not, all functions must be tested to 36.202.

12 Modes (definition of modes for each function).

During immunity testing, each function that is associated with essential performance is to be tested in the mode that is most critical from a patient outcome perspective. If no risk analysis exists, all modes are to be tested.

13 Compliance Criteria

Details of the compliance criteria required to confirm essential performance. Special software or hardware may be required to enable performance of non-observable functions to be monitored. Degradation of performance that does not affect essential performance or safety may be exhibited.

14 Immunity Testing Levels

(see annex DDD & EEE)
 Immunity levels are based upon a typical health care environment. If environment characteristics justify higher levels; or physical, technological or physiological limitations justify lower levels, describe levels and their justification.

15 Fail safe

Definition of what is 'safe'. Due to interruptions in power supply, equipment without battery back-up will not be able to perform as normal, however it must remain safe, experience no component failures and be restorable to its previous state.

16 "ON" Time

List of all modes and whether rated for continuous duty or not

Mode	Continuous	Max time in mode
<input type="text"/>	<input type="text" value="Y/N"/>	<input type="text"/>
<input type="text"/>	<input type="text" value="Y/N"/>	<input type="text"/>
<input type="text"/>	<input type="text" value="Y/N"/>	<input type="text"/>
If the equipment or system is not rated for continuous duty, the operating mode may instead be selected such that reliable operation is obtained for the applicable test	<input type="text" value="Y/N"/>	<input type="text"/>
<input type="text"/>	<input type="text" value="Y/N"/>	<input type="text"/>

17 Variable Gain

Description of any variable gain control incorporated in the equipment or system
 Equipment or system is to be tested at the highest gain setting that allows proper operation. A special test mode may be required.

18 EUT software during test version details

as required to simulate different modes for test

19 Tests to be applied

Any additional information needed for the practical implementation of the tests given in EN 60601-1-2