Coda cx1 EMI/EMC Test Procedure

CDL 1-TP07-0400:0209
MIT Ref. 85-01050.03

Revision 1.0

28th March 2002
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1. Introduction

1.1 Activity Description

This document is intended to specify the requirements for Electromagnetic Interference (EMI) and Electromagnetic Compatibility (EMC) testing. The tests are to be performed on the Coda cx1 sensor unit, 8-marker drive boxes and markers to demonstrate EMC compliance in accordance with the collateral standard for Medical Electrical Equipment EN60601-1-2.

EMC is concerned with the protection of the radio spectrum and requires that electrical and electronic products made or sold in the United Kingdom be constructed so that they do not cause excessive electromagnetic interference and are not unduly affected by electromagnetic interference.

On completion of an EC Declaration of Conformity under the EMC Regulations that states that the apparatus conforms with the protection requirements of the EMC Directive (89/336/EEC), the apparatus may carry CE marking.

2. Requirements

2.1 Context

This procedure supports the activities contained in the Short Form Functional Test Procedure (CDL 1-TP07-0100:0208) and the Long Form Functional Test Procedure (CDL 1-TP07-0500:0211).

2.2 List of Hardware Under Test

Coda cx1 sensor unit
5 externally powered 8-marker drive boxes
32 markers
1 internally powered 8-marker drive box complete with 2 markers

2.3 List of Support Hardware Items

Mini hub adapted for current monitoring
Host PC with RS-422 serial card
Power supply for marker drive boxes
Coda interface cable
Serial cable
Digital multi-meter

2.4 List of Software Requirements

Coda Motion Analysis Software V6.xx
Coda cx1 calibration files
Coda cx1 configuration file
SHARC DSP system file Vxxxx
2.5 List of Additional Documentation

2 Copies of the Coda cx1 Short Form Functional Test Procedure (CDL 1-TP07-0100:0208)
2 Copies of the Coda cx1 Long Form Functional Test Procedure (CDL 1-TP07-0500:0211)
3. Configuration

3.1 General Constraints

Electrostatic discharge (ESD) protection procedures per MIT 99-01003 shall be observed.

Connector mating/demating procedures per MIT 99-03002 shall be observed. Except that a mate/demate log will not be required.

3.2 Test Configuration

The tests are to be conducted with items configured as described in CDL 1-TM07-0300:0211.

3.3 Test Specification

The Coda cx1 system is to be tested in accordance with the collateral standard for Medical Electrical Equipment EN60601-1-2. This standard covers both emissions and immunity and includes the following:

- Electrostatic Discharge – EN61000-4-2
- Radiated RF Fields – EN61000-4-3
- Electrical Fast Transients/Bursts – EN61000-4-4
- Voltage Surges – EN61000-4-5
- Conducted RF Fields – EN61000-4-6
- Radiated Magnetic Fields – EN61000-4-8
- Power Frequency Magnetic Fields – EN61000-4-8
- Voltage Dips and Interruptions – EN61000-4-11
- Mains Voltage Harmonics – EN61000-3-2
- Mains Fluctuations and Flicker – EN61000-3-3
- Conducted and Radiated Emissions – EN55011
4. Procedures

Administrative information for this test is to be recorded in the space provided in Section 4.1. In addition, the test conductor may annotate the procedures to more accurately document the course of the test whether routine or anomalous. The following pages, plus test data generated by the host PC, will be attached to the test report which is completed every time this test is conducted. The test conductor is assumed to have reasonable familiarity and competence in navigating through software applications which observe standard Windows conventions.

4.1 Identification of Equipment and Personnel

Coda cx1 sensor unit

32 Coda markers

5 Coda externally powered 8-marker drive boxes

Test Conductor

Test Date

Test Location

QA Representative

Other individuals
4.2 Long Form Functional Test (Pre-EMI/EMC)

Perform the Coda cx1 Long Form Functional Test (CDL 1-TP07-0500:0211), and attach the completed document to this report.

<table>
<thead>
<tr>
<th>Pass</th>
<th>Fail</th>
<th>Time</th>
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4.3 EMI/EMC Tests

4.3.1 Test Configuration and System Set-up

Configure the test hardware as shown in CDL 1-TM07-0300:0211. Attach a single marker to the marker 1 socket of an internally powered 8-marker drive box and secure to the marker disc. Launch and configure the software as described in Section 4.3.4 of the Short Form Functional Test Procedure (CDL 1-TP07-0100:0208) but on this occasion select the setup file:

*EMC.stp*

From the Coda menu select **Display Marker Positions**. A dialog box will appear showing the position of marker 1. Ensure the Coda system remains in this state while the Medical Electrical Equipment (EN60601-1-2) tests are being conducted.

4.3.2 Medical Electrical Equipment (EN60601-1-2) Tests

Conduct the following tests covered by the EN60601-1-2 standard and attach performance plots for each case to this report.

Electrostatic Discharge – EN61000-4-2

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Radiated RF Fields – EN61000-4-3

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Electrical Fast Transients/Bursts – EN61000-4-4

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Voltage Surges – EN61000-4-5

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Conducted RF Fields – EN61000-4-6

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Radiated Magnetic Fields – EN61000-4-8

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Power Frequency Magnetic Fields – EN61000-4-8

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Voltage Dips and Interruptions – EN61000-4-11

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Mains Voltage Harmonics – EN61000-3-2

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Mains Fluctuations and Flicker – EN61000-3-3

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Conducted and Radiated Emissions – EN55011

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4.4 Long Form Functional Test (Post-EMI/EMC)

Perform the Coda cx1 Long Form Functional Test (CDL 1-TP07-0500:0211), and attach the completed document to this report.

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5. Test Operator Information

5.1 In the Event of Test Failure

Problems are covered in a similar section of the Short Form Test Procedure so are not repeated here.