GE Healthcare

Revolution CT, Revolution CT ES, Revolution Apex

Technical File Documentation

Document Number: DOC1520191

This technical file follows the NB-MED recommendation NB-MED/2.5.1/Rec5 “Technical Documentation”

Review and Approvals (Minimum functional area required signatures.)

Name	Function	Role	Signature/Date
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Confidentiality Statement

GE Healthcare

2.6. Summary of Design Verification / Validation

2.6.1. Bench Testing

2.6.1.1. Safety of Medical Electrical Equipment

Safety of medical electrical equipment testing of the device was performed in accordance with the standards listed in Section 1.5. Refer to table B1 in the MDD Essential Requirement Conformance Form DOC1520168 for a list test report document numbers and location.

2.6.1.2. Electromagnetic Compatibility

Electrical compatibility testing of the device was performed in accordance with IEC 60601-1-2: Electromagnetic Compatibility. Refer to table B1 in the MDD Essential Requirement Conformance Form DOC1520168 for a list test report document numbers and location.

2.6.1.3. Software

Software testing of the device was performed in accordance with technical standards applied. Refer to the following protocols and reports.

Document Title	Document Number
IEC60601-1 Report	Table B.1 of DOC1520168
IEC62304 SDLC EC (1.0, 1.5 programs)	Table B.1 of DOC1520168
IEC62304 SDLC EC (2.X programs)	Table B.1 of DOC1520168

2.6.1.4. Biological Safety

The device did not require biological safety testing to demonstrate compliance with the essential requirements because the device and its components do not contain or incorporate animal or human tissue or its derivatives.

2.6.1.5. Human Factors/Usability

The device was evaluated against IEC60601-1-6, General requirements for basic safety and essential performance – Collateral Standard: Usability. Refer to the following reports for the scenarios tested.

Document Title	Document Number
IEC60601-1-6 Checklist	Table B.1 of DOC1520168
IEC 62336 Checklist	Table B.1 of DOC1520168
Usability Impact Analysis	DOC1978774
Revolution 2.2C Usability Impact Analysis	DOC2431881

Use Error was also evaluated as part of Risk Management (Refer to section 2.3).

2.6.1.6. Pre-clinical Animal Testing

The device did not require pre-clinical animal testing to demonstrate compliance with the essential requirements.

2.6.1.7 Verification & Validation of Electronic IFU