

Risk Management Compliance Report

IEC 60601-1:2005

Medical electrical equipment

Part 1: General requirements for basic safety and essential performance

Report Reference No	200807
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Approved by (+ signature)	
Date of issue	
Verification laboratory	System Safety, Inc.
Address	10165 Pinecastle Street San Diego, CA 92131-2291
Verification location	
Applicant	
Address	
Standard	Risk related items in IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
Test Report Form No	03092008
Test procedure	Audit / Review
Procedure deviation	None
Non-standard test method	None
Type of end product	
End product Trademark	
End product Model and/or type reference	
End product Manufacturer	
End product Address	See above
End product Rating(s)	

PEMS/PESS Configuration Information:	No special hardware configuration necessary.
Software Designer (if different than end Product manufacturer).	NA
Address	NA
	NA
Method of Identification of Software:	Revision
Particular Risks Addressed by Software:	As contained in hazard analyses

GENERAL INFORMATION

Possible verification case verdicts

Verification case does not apply to the verification item ----- : **N**(ot)/**A**(pplicable)
 Verification item is available ----- : **N**(oted)
 Verification item does meet the requirement ----- : **P**(ass)
 Verification item does meet the requirement under the limited scope of this assessment ----- : **P**(ass) **L**(imited Scope)
 Verification item does not meet the requirement ----- : **F**(ail)
 Verification item does not meet the requirement under the limited scope of this assessment -- : **F**(ail) **L**(imited Scope)

Minor non-compliances are noted in regular case and font
 Major non-compliances are note in **ALL CAPS** and / or **BOLD**

General remarks

"(See enclosure #)" refers to an enclosure appended to this report.
 "(See appended table)" refers to a table appended to the report.
 Throughout this report a period is used as the decimal separator.
 The verification results presented in this report relate only to the item being verified.
 This verification report shall not be reproduced except in full without the written approval of the verification laboratory.

SUMMARY OF CONTENTS:

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Acronyms and Abbreviations:

COTS	Commercial of the shelf software
DFU	Directions for Use
H&RA	Hazard and Risk Analysis
MDD	European Medical Device Directive
PEMS	Programmable Electronic Medical Devices
RMP	Risk Management Plan
SOP	Standard Operating Procedure
V&V	Verification and Validation



Results and Conclusions:

If further risk evaluation is necessary then "applicable" is answered with yes (Y), otherwise a rationale has to be given, why the requirement needs no further risk evaluation.

Clause	Requirement (clause title)	Applicable [Y/N]	Rationale if N or Remarks	Section, line #
4.2	RISK MANAGEMENT PROCESS			
4.3	ESSENTIAL PERFORMANCE			
4.4	EXPECTED SERVICE LIFE			
4.5	Equivalent safety			
4.6	Parts that contact the PATIENT			
4.7	SINGLE FAULT CONDITIONS			
4.8	Components of me equipment			
4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS			
5.1	Type tests			
5.4.a	Other conditions			
5.7	Humidity preconditioning treatment			
5.9.2.3	Actuating mechanisms regarded as ACCESSIBLE PARTS			
7.1.1	USABILITY of the identification, marking and documents			
7.9.1	ACCOMPANYING DOCUMENTS provided electronically			
8.1.b	Fundamental rule of protection against electric shock			
8.3.d	Classification of applied parts			
8.4.2.c	ACCESSIBLE PARTS including APPLIED PARTS			
8.5.2.2	Type B applied parts			
8.5.2.3	Patient leads			
8.6.3	Protective earthing of moving parts			
8.8.4.1	Mechanical strength and resistance to heat			
8.10.1	Fixing of components			
8.10.2	Fixing of wiring			
8.10.5	Mechanical protection of wiring			
8.11.5	Mains fuses and OVER-CURRENT RELEASES			
9.2.1	Hazards associated with moving parts - General			
9.2.2.4.3	Movable GUARDS			
9.2.2.4.4	Protective measures			
9.2.2.5.c	Continuous activation			
9.2.2.6	Speed of movement(s)			
9.2.3.2	Over-travel			
9.2.4	Emergency stopping devices			
9.2.5	Release of PATIENT			
9.3	HAZARD associated with surfaces, corners and edges			
9.4.2.4.3	Movement over a threshold			
9.5.1	Expelled parts - Protective means			
9.6.1	Acoustic energy - General			
9.6.2.2	Infrasound and ultrasound energy			
9.7.2	Pneumatic and hydraulic parts			
9.7.4	Pressure rating of ME EQUIPMENT parts			
9.7.6	Pressure-control device			
9.7.7	Pressure-relief device			
9.8.1	HAZARDS associated with support systems - General			
9.8.2	TENSILE SAFETY FACTOR			
9.8.3.1	Strength of PATIENT or OPERATOR support or suspension systems - General			

Clause	Requirement (clause title)	Applicable [Y/N]	Rationale if N or Remarks	Section, line #
9.8.3.2.a&b	Static forces due to loading from persons			
9.8.4.1	Systems with MECHANICAL PROTECTIVE DEVICES - General			
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended for single activation			
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES			
10.1.2	ME EQUIPMENT Intended to produce diagnostic or therapeutic X-radiation			
10.2	Alpha, beta, gamma, neutron and other particle radiation			
10.3	Microwave radiation			
10.5	Other visible electromagnetic radiation			
10.6	Infrared radiation			
10.7	Ultraviolet radiation			
11.1.1 -tab 23 -tab 24	Excessive temperatures in ME EQUIPMENT - Maximum temperature during NORMAL USE			
11.1.2.1	APPLIED PARTS intended to supply heat to a PATIENT			
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT			
11.1.3	Measurements (rationale in case of no test!)			
11.1.3.e	Measurement			
11.2.2.1 a & b	RISK of fire in an OXYGEN RICH ENVIRONMENT			
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT			
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents			
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM			
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS			
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS			
11.6.8	Compatibility with substances used with the ME EQUIPMENT			
12.1	Accuracy of controls and instruments			
12.3	Alarm systems			
12.4.1	Protection against hazardous output - Intentional exceeding of safety limits			
12.4.2	Indication of parameters relevant to safety			
12.4.3	Accidental selection of excessive output values			
12.4.4	Incorrect output			
12.4.5.2	Diagnostic X-ray equipment			
12.4.5.3	Radiotherapy equipment			
12.4.5.4	Other ME EQUIPMENT producing diagnostic or therapeutic radiation			
12.4.6	Diagnostic or therapeutic acoustic pressure			
13.2.6	Leakage of liquid			
14.1	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)			
14.2	Documentation			
14.3	RM plan			
14.4	PEMS DEVELOPMENT LIFE-CYCLE			
14.6.1	Identification of known and foreseeable hazards			
14.6.2	RISK CONTROL			
14.7	Requirement specification			

Clause	Requirement (clause title)	Applicable [Y/N]	Rationale if N or Remarks	Section, line #
14.8	Architecture			
14.9	Design and implementation			
14.10	VERIFICATION			
14.11	PEMS VALIDATION			
15.1	Construction of ME EQUIPMENT - Arrangements of controls and indicators of ME EQUIPMENT			
15.3.2	Push test			
15.3.3	Impact test			
15.3.4.2	PORTABLE ME EQUIPMENT			
15.3.5	Rough handling test			
15.4.1	Construction of connectors			
15.4.2.1.a, b,c,d,h.	Temperature and overload control devices - Application			
15.4.3.1	Batteries - Housing			
15.4.3.5	Excessive current and voltage protection			
15.4.5	Pre-set controls			
15.4.7.3.b	Entry of liquids			
16.1	General requirements for ME SYSTEMS			
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS			