

Risk Management File

Exhibit A: EN60601-1 PEMS Structure Trace

PEMS Structure, PEMS Development Life-Cycle and Documentation				
60601-1 Ref*		60601-1 Requirement	Policies and Procedures	Records and/or Documentation
52.201 52.207	H.1	Example for PEMS/PESS Structure	SOP-09-00022 Design Control Procedure 01-00016 Quality Process Overview	CD-10-00029 Theory of Operation – the truFreeze System is a simple PEMS structure with the system comprised of a mechanical cart, electronics (panel PC and cDAQ), and software.
52.203	H.2	PEMS Development Life-Cycle Model – requires a PEMS development life-cycle be specified and then followed.	SOP-09-00057 CryoSpray Software (SW) Planning – includes process for software design control from design input through post-market surveillance. Procedure is based on EN-62304:2006 standard (Medical device software- software life cycle processes). 01-00015 Quality Manual 01-00016 Quality Process Overview - Includes slides of product development process, requirements traceability, development V-model, software file structure, drawing control.	DP-09-0001 truFreeze Development Plan DP-09-0002 truFreeze Development Checklist CD-10-00029 Theory of Operation DP-09-00005 truFreeze Risk Management Plan DP-11-00004 truFreeze Risk Management Report DP-11-00005 truFreeze Risk Management File
52.203	H.3	Software Processes	---	---
52.203	H.3.1	PEMS Development Life-Cycle	SOP-09-00057 CryoSpray SW Planning	DP-09-0001 truFreeze Development Plan DP-09-0002 truFreeze Development Checklist
52.206	H.3.2	Requirements Specification	SOP-09-00057 CryoSpray SW Planning SOP-09-00022 Design Control Procedure	02-00023 truFreeze Product Requirements Document 02-00031 truFreeze Console Software PPS 02-00025 truFreeze Console Hardware PPS 03-00016 truFreeze System DFMEA DP-09-0001 truFreeze Development Plan DP-09-0002 truFreeze Development Checklist
N/A	H.3.3	Third-Party Off-the-Shelf Software	SOP-09-00057 CryoSpray SW Planning	02-00031 truFreeze Console Software PPS
52.208	H.3.4	Integration	SOP-09-00057 CryoSpray SW Planning SOP-09-00022 Design Control Procedure SOP-09-00030 Test Documentation 01-00016 Quality Process Overview	19-00036 truFreeze Verification and Validation Plan/Summary 19-00026 truFreeze Console PPS Trace 19-00030 truFreeze Spray Kit PPS Trace 19-00031 truFreeze Console Software PPS Trace
52.203	H.3.5	Configuration Management	SOP-09-00057 CryoSpray SW Planning SOP-09-00001 Document Control SOP-09-00002 Control of Records SOP-09-00024 Drawing Control 01-00016 Quality Process Overview	Document Change Orders 13-series software drawings

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PEMS Structure, PEMS Development Life-Cycle and Documentation

60601-1 Ref*		60601-1 Requirement	Policies and Procedures	Records and/or Documentation
52.212	H.3.6	Modification/Change Control	SOP-09-00057 CryoSpray SW Planning SOP-09-00001 Document Control SOP-09-00024 Drawing Control SOP-09-00030 Test Documentation	13-00008 truFreeze Software Load Package 13-series software drawings/documents (e.g., ini files, application and source code) Document Change Orders Test Reports
52.208	H.4	Design and Implementation	SOP-09-00057 CryoSpray SW Planning SOP-09-00022 Design Control Procedure	02-00023 truFreeze Product Requirements Document 02-00031 truFreeze Console Software PPS 02-00025 truFreeze Console Hardware PPS 02-00030 truFreeze Spray Kit Product PPS
52.201	H.5	Documentation	SOP-09-00057 CryoSpray SW Planning SOP-09-00022 Design Control Procedure SOP-090028 Risk Management Procedure	DP-09-0005 truFreeze Risk Management Plan DP-11-0004 truFreeze Risk Management Report DP-11-0005 truFreeze Risk Management File
N/A	H.6	Network/Data Coupling	---	---
6.8	H.6.1	General	SOP-09-00057 CryoSpray SW Planning	Not applicable - not a networked system
N/A	H.7	Design Considerations for Network/Data Coupling	SOP-09-00057 CryoSpray SW Planning	Not applicable – not a networked system

* 6 and 52 series numbers refer to 60601-1-4:1996 + A1:1999 collateral standard. H series numbers refer to Annex H of 60601-1:2005.

Programmable Electrical Medical System (PEMS)

60601-1 Ref*		60601-1 Requirement	Policies and Procedures	Records and/or Documentation
52.202	14.6.1	Identification of Known and Foreseeable Hazards	SOP-09-00057 CryoSpray SW Planning SOP-090028 Risk Management Procedure SOP-09-00039 FMEA Procedure	03-00016 truFreeze System DFMEA
52.204	14.6.2	Risk control	SOP-09-00057 CryoSpray SW Planning SOP-09-00022 Design Control Procedure SOP-090028 Risk Management Procedure SOP-09-00030 Test Documentation	03-00016 truFreeze System DFMEA 19-00036 truFreeze Verification and Validation Plan/Summary 19-00026 truFreeze Console PPS Trace 19-00030 truFreeze Spray Kit PPS Trace 19-00031 truFreeze Console Software PPS Trace DP-09-0005 truFreeze Risk Management Plan DP-11-0004 truFreeze Risk Management Report DP-11-0005 truFreeze Risk Management File
52.205 52.206	14.7	Requirement Specification	SOP-09-00057 CryoSpray SW Planning SOP-09-00022 Design Control Procedure	DP-09-0001 truFreeze Development Plan DP-09-0002 truFreeze Development Checklist 02-00023 truFreeze Product Requirements Document 02-00031 truFreeze Console Software PPS 02-00025 truFreeze Console Hardware PPS 02-00030 truFreeze Spray Kit Product PPS

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Programmable Electrical Medical System (PEMS)				
60601-1 Ref*		60601-1 Requirement	Policies and Procedures	Records and/or Documentation
52.207	14.8	Architecture	SOP-09-00057 CryoSpray SW Planning SOP-09-00022 Design Control Procedure	DP-09-0001 truFreeze Development Plan DP-09-0002 truFreeze Development Checklist Software Concept Documents CD-10-00029 Theory of Operation 02-00031 truFreeze Console Software PPS
52.208	14.9	Design and Implementation	SOP-09-00057 CryoSpray SW Planning SOP-09-00022 Design Control Procedure	02-00023 truFreeze Product Requirements Document 02-00031 truFreeze Console Software PPS 02-00025 truFreeze Console Hardware PPS 02-00030 truFreeze Spray Kit Product PPS
52.209	14.10	Verification	SOP-09-00057 CryoSpray SW Planning SOP-09-00022 Design Control Procedure SOP-09-00030 Test Documentation	19-00036 truFreeze Verification and Validation Plan/Summary 19-00031 truFreeze Console Software PPS Trace 02-00031 truFreeze Console Software PPS Technical Characterization Reports
52.210	14.11	PEMS Validation	SOP-09-00057 CryoSpray SW Planning SOP-09-00022 Design Control Procedure SOP-09-00030 Test Documentation	19-00036 truFreeze Verification and Validation Plan /Summary 19-00031 truFreeze Console Software PPS Trace 17-Series Protocols and Reports
52.211 52.212	14.12	Modification	SOP-09-00057 CryoSpray SW Planning SOP-09-00001 Document Control SOP-09-00024 Drawing Control SOP-09-00030 Test Documentation	13-series software drawings/documents (e.g., ini files, application and source code) Document Change Orders Test Reports – Regression Testing
N/A	14.13	Connection of PEMS by Network/Data Coupling to Other Equipment	SOP-09-00057 CryoSpray SW Planning	Not applicable – not a networked system

* 52-series numbers refer to 60601-1-4:1996 + A1:1999 collateral standard. 14-series numbers refer to Clause 14 of 60601-1:2005.