EPIC™ RESEARCH DIAGNOSTICS

EPIC ClearView
Product Requirements Trace Matrix - Device

ORIGINATOR:

Name	Job Title	Signature	Date
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APPROVALS:

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REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	03Apr12	Initial Release	S. Pletzer

Device (DR)							
Ref. #	**Requirement**	**Source of Requirement**	**Design Inputs (Specification)**	**Verification Methodology**	**Design Outputs (Verification Results)**	**Validation Results**	**Status**
DR-1	Camera and lens assembly capable of capturing an energized image.	Lens assembly	Phillips Camera (SPC900NC/27) ClearView BOM, 06690 CCD Camera and Collar, 1282-1003 Westech Lens, 1282-1004	Documentation System Policy, QA-005 Device Design Verification and Validation	Device Design Verification (PADT), #07612 Device Design Validation, ENG-017		
DR-2	Camera capable of image capture at a minimum of 15 pictures/10 sec exposure	Established by electrophotography techniques	Phillips Camera (SPC900NC/27) ClearView BOM, 06690	Documentation System Policy, QA-005 Device Design Verification and Validation	Device Design Verification (PADT), #07612 Device Design Validation, ENG-017		
DR-3	Camera must be able to be controlled through the software for all available settings pertaining to image quality.	Established by electrophotography techniques	Phillips Camera (SPC900NC/27) ClearView BOM, 06690	Documentation System Policy, QA-005 Device Design Verification and Validation	Device Design Verification (PADT), #07612 Device Design Validation, ENG-017 Camera Functions Validation Report, ENG-010 Application Functions Validation Report, ENG-009		
DR-4	A transparent electrode which can be configured for receiving a fingertip of a subject, such as on a top surface thereof. A transparent electrode able to withstand high voltages in excess of 25k volts at high frequencies. Able to generate a localized electromagnetic field around the finger.	Established by electrophotography techniques	Electrode Assembly, 06617 PCBA, Control Board, 06596	Documentation System Policy, QA-005 Device Design Verification and Validation	Device Design Verification (PADT), #07612 Device Design Validation, ENG-017 Capture Functions Validation Report, ENG-011		

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DR-5	IEC 60601-1 compliant	Regulatory requirements	ClearView BOM, 06690	IEC Certification Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016 Device Design Verification and Validation	IEC 60601-1 Report, ENG-002 Device Design Verification (PADT), #07612 Device Design Validation, ENG-017 Receiving Inspection Record, QAF-012 EPIC ClearView IEC 60601-1-2:2007 Final Test Report, ENG-002 EPIC ClearView FCC Rule Part(s) 15, Subpart B Final Test Report, ENG-003 EPIC ClearView FCC Rule Part(s) 15.20, 15.209 Final Test Report, ENG-004		
DR-6	IEC 60601-1-2 compliant						
DR-7	FCC, Part 15 compliant						
DR-8	Device is designed to ensure proper grounding of electrical current to prevent patient and operator exposure to electrical currents.	Safety features identified					
DR-9	Per IEC 60601-1, device materials, manufacture and use do not present a flammability risk.	Flammability risks					
DR-10	Device operation is repeatable and reliable against IFU stated conditions.	User preference	ClearView BOM, 06690	Documentation System Policy, QA-005 Device Design Verification and Validation	Device Design Verification (PADT), #07612 Device Design Validation, ENG-017 DV-002 Clinical Study Report		
DR-11	Device has an EPIC branded logo on the top surface.	EPIC marketing requirement	Housing Cover, Finished, 06646	Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	Receiving Inspection Records, QAF-012		

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DR-12	Device is usable by patients regardless of variability in size and position (e.g., ambidexterity, prone, etc.) and moveable to accommodate patient access without special modifications.	Patient anthropometric requirements and patient comfort	ClearView BOM, 06690	Documentation System Policy, QA-005 Device Design Verification and Validation Clinical Trial Performance Monitoring	Device Design Validation, ENG-017 EPIC ClearView IFU, CS-100 EPIC ClearView System Performance Reports: • GBMC Clinical Trial, ENG-018 • DV-001 Clinical Trial, ENG-019 • DV-002 Clinical Trial, ENG-020 • EPIC-003 Clinical Trial, ENG-021		
DR-13	Device can be shown to capture images that accurately represents the subject's galvanic skin response	Reliability requirements	ClearView BOM, 06690	Documentation System Policy, QA-005 Device Design Verification and Validation	Device Design Validation, ENG-017 EPIC ClearView IFU, CS-100 EPIC ClearView Clinical Trial Reports: • GBMC Clinical Trial Report • EPIC ClearView Algorithm Development Report • EPIC-003 Clinical Trial Report		
DR-14	PER IPX0 rating, device must resist the ingress of liquids, and be operated under standard room conditions, similar to other solid state electronic devices.	Device use, care, and storage requirements	ClearView BOM, 06690	IEC Certification Clinical Trial Performance Monitoring	IEC 60601-1 Report, ENG-002 EPIC ClearView IFU, CS-100 EPIC ClearView System Performance Reports: • GBMC Clinical Trial, ENG-018 • DV-001 Clinical Trial, ENG-019 • DV-002 Clinical Trial, ENG-020 • EPIC-003 Clinical Trial, ENG-021		

Device (DR)							
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DR-15	Device/system compatible with IEC 60601-1, IEC 60601-2, and FCC Part 15 requirements	User expectation	ClearView BOM, 06690	IEC Certification Clinical Trial Performance Monitoring	EPIC ClearView IFU, CS-100 Final Test Reports: • EPIC ClearView IEC 60601-1-2:2007 Final Test Report, ENG-002 • EPIC ClearView FCC Rule Part(s) 15, Subpart B Final Test Report, ENG-003 • EPIC ClearView FCC Rule Part(s) 15.20, 15.209 Final Test Report, ENG-004 EPIC ClearView System Performance Reports: • GBMC Clinical Trial, ENG-018 • DV-001 Clinical Trial, ENG-019 • DV-002 Clinical Trial, ENG-020 • EPIC-003 Clinical Trial, ENG-021		
DR-16	Maintain certifications and regulatory requirements: 21 CFR 801.415 - Maximum Acceptable Level of Ozone. Device cannot be released for use without these in place.	Applicable safety standards	ClearView BOM, 06690	Ozone emissions testing Risk Analysis Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	EPIC ClearView Ozone Emissions Verification, ENG-005 EPIC Scanner Risk Analysis Documentation Form, DHD-101 EPIC ClearView Failure Modes and Effects Analysis, DHD-102 Receiving Inspection Record, QAF-012		
DR-17	Device materials must be non-toxic wherever skin contacts the device.	Toxicity risks	ClearView BOM, 06690	Inspection and Release of Incoming,	Electrode Assembly, 06617		

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DR-18	Device materials are biocompatible with user and/or patient.	Biocompatibility		In-process and Finished Devices and Other Materials, QA-016 Regulatory Review	Housing Base, Painted, 06647 Housing Cover, Finished, 06646 FDA 510k Submission		
DR-19	Device glass electrode surface needs to be cleanable with 70% IPA and not damaged between patient uses.	Product life and maintenance requirements	Cleaning Cloth, 1282-1500 70% Isopropyl Alcohol Swabs, 1282-1504 Calibration Probe, 06680 Calibration Probe Cable, 06683 EPIC ClearView IFU, CS-100	Device Design Verification and Validation Documentation System Policy, QA-005 Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016 Clinical Trial Performance Monitoring	Device Design Verification (PADT, #07612) Device Design Validation, ENG-017 EPIC ClearView IFU, CS-100 Receiving Inspection Record, QAF-012 Calibration Testing Reports, ENG-006 & ENG-007 EPIC ClearView System Performance Reports: • GBMC Clinical Trial, ENG-018 • DV-001 Clinical Trial, ENG-019 • DV-002 Clinical Trial, ENG-020 • EPIC-003 Clinical Trial, ENG-021		
DR-20	Device needs to be calibratable per instructions for proper performance.						
DR-21	Device has a power on switch accessible by the user which clearly indicates the device is powered on.	Access control	ClearView Device, Packaged BOM, EPC-100 Power Entry Module	Documentation System Policy, QA-005 Device Design	Device Design Verification, XXX-XXX Device Design Validation, XXX-XXX		

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DR-22	Device housing must be secured in such a way that tampering will not occur without tools.		Assembly, 06686 Rear Panel LED Cable, 06670 EPIC ClearView System Description, SD-003 EPIC ClearView Software Description, SD-001 USB Hardware Key, 1282-1515 EPIC ClearView IFU, CS-100	Verification and Validation Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	EPIC ClearView IFU, CS-100 Receiving Inspection Record, QAF-012		
DR-23	Device capable of communicating with a computer.			Documentation System Policy, QA-005 Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016 EPIC ClearView Software Validation	EPIC ClearView IFU, CS-100 Receiving Inspection Record, QAF-012 Validation Reports: • Camera Functions Validation Report, ENG-010 • Capture Functions Validation Report, ENG-011 • Patient Demographics Validation Report, ENG-012 • Users Functions Validation Report, ENG013 • Report Functions Validation Report, ENG-014		
DR-24	Device complies with applicable international and national standards and requirements.	• 21 CFR Part 820 • 21 CFR Part 11 • ISO 13485 • MDD	EPIC Quality System	Documentation System Policy, QA-005 Internal and External Audits	Internal Audit Reports, QAF-008 FDA 510k Submission ISO 13485/MDD External Audit		