EPIC ClearView
Product Requirements Trace Matrix - User

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

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User (UR)							
Ref. #	**Requirement**	**Source of Requirement**	**Design Inputs (Specification)**	**Verification Methodology**	**Design Outputs (Verification Results)**	**Validation Results**	**Status**
UR-1	Intended use statement for FDA application: The EPIC ClearView™ is a Galvanic Skin Response (GSR) measurement tool for the evaluation of the human cardiovascular system to help direct the physician when choosing to do further standard of care testing. Intended use statement for ISO certification: The EPIC ClearView™ is a Galvanic Skin Response (GSR) measurement tool for the evaluation of the human body's primary organ systems (cardiovascular, renal, pulmonary, gastrointestinal, and liver) to help direct the physician when choosing further standard of care testing.	Defined intended use	IFU	Documentation System Policy, QA-005 ClearView vs. Asyra Comparison Bench Testing Report Algorithm Development Documentation Algorithm Verification and Validation Reports	EPIC ClearView IFU, CS-100		
UR-2	Device is intended to be used by qualified professionals only.	Defined use conditions	IFU	Device Labeling Development, MKT-001 Documentation System Policy, QA-005	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		
UR-3	Device is intended to be used in a clinical environment and is not intended for home use.						
UR-4	Easy to use by trained individuals including logical progression of use.						
UR-5	Acceptable risk of use is no more than slight tingling at the fingertip during scanning.	Acceptable risk in field	IFU Product Specifications	Documentation System Policy, QA-005 IEC 60601-1 Certification IEC 60601-1-2 Certification	EPIC ClearView IFU, CS-100 EPIC ClearView Device BOM, 06690 EPIC ClearView IEC 60601-1-2:2007 Final Test Report, ENG-002 TUV Report		
UR-6	Device must be able to be thoroughly cleaned prior to and between patient use.	Established cleaning requirements	Product Specifications IFU	Device Design Verification Documentation System Policy, QA-005	Cleaning Cloth, 1282-1500 70% Isopropyl Alcohol Swabs, 1282-		

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					1504 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		
UR-7	Patients will not exhibit any of the contraindications for use.	Internal design requirement by company founder	IFU	Documentation System Policy, QA-005	EPIC ClearView IFU, CS-100		
UR-8	User is able to properly orient the energized image using the image axes and lit image.		Product Specifications IFU	Device Design Verification Documentation System Policy, QA-005	EPIC ClearView Device BOM, 06690 • PCBA Flood LED, 06602 • Cable Flood LED, 06673 Software Requirements: SR-001, SR-202, SR-203, SR-204, SR-205 Software Specifications: SS-001, SS-202, SS-203, SS-204, SS-205 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		

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					• DV-001 Clinical Trial, ENG-019 • DV-002 Clinical Trial, ENG-020 • EPIC-003 Clinical Trial, ENG-021		
UR-9	Caution users not to image themselves.	Product Safety	IFU	EPIC ClearView UL Safety Testing, ENG-XXX Documentation System Policy, QA-005	EPIC ClearView IFU, CS-100 TUV Report		
UR-10	It is contraindicated to measure anyone who has any electrical object implanted in their body (i.e. pacemakers).	Contraindications	Product Specifications IFU	Device Design Verification Documentation System Policy, QA-005	EPIC ClearView Device BOM, 06690 Software Requirements: SR-001, SR-202, SR-203, SR-204, SR-205 Software Specifications: SS-001, SS-202, SS-203, SS-204, SS-205 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		
UR-11	It is advisable to avoid measuring subjects who have lacerations or burns on the pad of any of their fingers, as these alterations to the skin may affect results.						
UR-12	It is recommended to avoid measuring subjects who have dirt, debris, or lotion on any of their fingers, or have long fingernails including acrylic nails. Subjects should avoid washing their hands within 20 minutes prior to scanning.						
UR-13	Instructions for proper removal of surface contaminants that could create artifacts in the image.	Cleaning Instructions	Product Specifications IFU	Device Design Verification Documentation System Policy, QA-005	EPIC ClearView IFU, CS-100 Receiving Inspection Record, QAF-012 Calibration Testing Reports, ENG-006 & ENG-007 Cleaning Cloth, 1282-1500 70% Isopropyl Alcohol Swabs, 1282-1504 Calibration Probe, 06680		
UR-14	Proper cleaning of calibration probe.						

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					Calibration Probe Cable, 06683 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		
UR-15	Proper placement of calibration probe during calibration process.	Imaging Instructions	IFU EPIC ClearView Product Specifications	Verification to Product Specifications	EPIC ClearView IFU, CS-100 EPIC ClearView Software Solution Calibration Testing Report, ENG-006 EPIC ClearView Software Solution Calibration Testing Modification Report, ENG-007		
UR-16	Proper data entry, data storage, and data modification of patient demographic information into ClearView database.				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		
UR-17	Instructions for confirming proper power cord and/or USB shielded cable connection.	Troubleshooting	Product Specifications IFU	Documentation System Policy, QA-005 Device Design Verification	Panel Mount USB Connector, 1282-0057 USB External Cable, 68806-0004 Power Entry Module, 1282-0044 Wire Assembly from Power Board to Ground to Earth, 1282-0047 Power Cord, 312007 EPIC ClearView IFU, CS-100 EPIC ClearView System Performance Reports: • GBMC Clinical Trial, ENG-018 • DV-001 Clinical Trial, ENG-019		
UR-18	Instructions on improper environments (i.e., device use near other electrical field generating equipment).						
UR-19	Instructions for why user is not able to capture image.						

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					• DV-002 Clinical Trial, ENG-020 • EPIC-003 Clinical Trial, ENG-021		
UR-20	Instructions for proper installation.	Instructions Content	Product Specifications IFU	Documentation System Policy, QA-005 Device Design Verification	Cleaning Cloth, 1282-1500 70% Isopropyl Alcohol Swabs, 1282-1504 Capacitive Barrier, 1282-1025 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		
UR-21	Proper image capture procedures.						
UR-22	Explanation of Response Scale Report and meaning of values.						
UR-23	Instructions provided to user prior to use.						
UR-24	Instructions for user to follow if patient experiences any discomfort throughout the procedure.						
UR-25	Device should be lightweight enough for portability by the average professionally trained installer.	Device weight requirements	Product Specifications IFU	Documentation System Policy, QA-005 Device Design Verification	EPIC ClearView Device BOM, 06690 • Assembly Top Cover, 1282-1014 • Enclosure Bottom, 1282-1015 • Charged Glass Assembly, 1282-1019 • Charged Glass Support Ring, 1282-1008 • Conductive Glass, 1282-1016 Capacitive Barrier, 1282-1025 Finger Shroud, 1282-1005 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		
UR-26	Device should look and be comfortable, not imposing and place the patient and user at ease. Device should project a sophisticated, clean appearance.	Aesthetics					
UR-27	Patient will access the glass electrode via a light delimiting cover one finger at a time in order to capture images with and without a filter.	Patient use configuration					
UR-28	Simple device set up including powering on and off, cleaning, connectivity, and calibration of the device.	Ease of patient/user setup					
UR-29	System will be portable and capable of moving from one location to another.	Ease of portability					