



EPIC ClearView Product Requirements Trace Matrix - Accessories

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REVISION HISTORY

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



EPIC ClearView

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This section of the Product Requirements Trace Matrix covers all accessories to the ClearView device including the Computer System (1282-1511), USB Hardware Key (1282-1515), Printer (1282-1513), Uninterruptible Power Supply (1282-1514), Capacitive Barrier (1282-1025), 70 % Isopropyl Alcohol Swabs (1282-1504), Cleaning Cloth (1282-1500), and the Workstation on Wheels (WOW-100).

Accessories (AR)							
Ref. #	Requirement	Source of Requirement	Design Inputs (Specification)	Verification Methodology	Design Outputs (Verification Results)	Validation Results	Status
AR-1	Computer system includes monitor, keyboard and mouse.				ClearView System Installation and Operational Verification, IT-004		
AR-2	The computer has an operating system with these minimum requirements:				ClearView System Installation and Operational Qualification		
	<ul style="list-style-type: none"> Microsoft Windows XP Professional, Service Pack 3 Intel® Core™ Duo CPU or better 3.00 GB of Ram 250 GB of hard drive Internet ready 				Receiving Inspection Record, QAF-012		
AR-3	Accessories such as keyboard and mouse are hardwired to the computer not wireless or Bluetooth technology.	Computer System, 1282-1511 USB Hardware Key, 1282-1515	Documentation System Policy, QA-005 Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	Application Functions Validation Report, ENG-009 Camera Functions Validation Report, ENG-010 Capture Functions Validation Report, ENG-011 Patient Demographics Functions Validation Report, ENG-012 Users Functions Validation Report, ENG-013	EPIC ClearView System Performance Reports: <ul style="list-style-type: none"> GBMC Clinical Trial, ENG-018 DV-001 Clinical Trial, ENG-019 DV-002 Clinical Trial, ENG-020 EPIC-003 Clinical Trial, ENG-021 		
AR-4	Computer system has sufficient USB connections to accommodate all accessories such as the ClearView device, keyboard, mouse, printer and USB hardware key.						
AR-5	Computer system does not have a DVD drive.						
AR-6	Equipped with a USB hardware key to prevent unauthorized use by untrained personnel.						
AR-7	Monitor has a minimum display of 20", 16 x 9 format with 1920 x						



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AR-8	Capable of connecting to the computer.			Documentation System Policy, QA-005	ClearView System Installation and Operational Verification, IT-004	EPIC ClearView System Performance Reports: <ul style="list-style-type: none">• GBMC Clinical Trial, ENG-018• DV-001 Clinical Trial, ENG-019• DV-002 Clinical Trial, ENG-020• EPIC-003 Clinical Trial, ENG-021	
AR-9	Prints 8 1/2" x 11" paper reports in color from EPIC ClearView software.	Printer	Printer, 1282-1513	Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	ClearView System Installation and Operational Qualification and Receiving Inspection Record, QAF-012		
AR-10	Provides medical-grade UPS protection for device and computer system.	Uninterruptable Power Source (UPS)	Uninterruptable Power Source (UPS), 1282-1514	Documentation System Policy, QA-005	ClearView System Installation and Operational Verification, IT-004	EPIC ClearView System Performance Reports: <ul style="list-style-type: none">• GBMC Clinical Trial, ENG-018• DV-001 Clinical Trial, ENG-019• DV-002 Clinical Trial, ENG-020• EPIC-003 Clinical Trial, ENG-021	
AR-11	Capable of moving to different locations within a building while maintaining power to ClearView device.			Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	Receiving Inspection Record, QAF-012	EPIC ClearView System Performance Reports: <ul style="list-style-type: none">• GBMC Clinical Trial, ENG-018• DV-001 Clinical Trial, ENG-019• DV-002 Clinical Trial, ENG-020• EPIC-003 Clinical Trial, ENG-021	
AR-12	Capable of mounting computer, monitor, keyboard, mouse, printer, power supply, cleaning supplies, filters, and EPIC ClearView device.	Workstation	ClearView Workstation, WOW-100	UL Safety Testing Workstation Inspection Record	TUV Report		
AR-13	Allows user access to the computer, monitor, keyboard and mouse while standing.						



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AR-14	Adjusts device position to accommodate subjects while sitting, standing or lying down.						
AR-15	Capable of storing a limited amount of cleaning supplies and filters.						
AR-16	Appropriate cord management to ensure containment of accessory cords within the workstation.						
AR-17	Electrostatic discharge (ESD) protection for equipment and device.						
AR-18	Plastic film placed on the glass electrode is intended to act as a barrier between moisture on subject's fingertips and the glass electrode.	Capacitive Barrier	Capacitive Barrier, 1282-1025	Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	Receiving Inspection Record, QAF-012	EPIC ClearView System Performance Reports: <ul style="list-style-type: none">• GBMC Clinical Trial, ENG-018• DV-001 Clinical Trial, ENG-019• DV-002 Clinical Trial, ENG-020• EPIC-003 Clinical Trial, ENG-021 Clinical Trial Results Summary	
AR-19	Capacitive barrier thickness is minimized to ensure accurate energized image capture.						
AR-20	Provides a streak-free surface for image capture.			Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	Receiving Inspection Record, QAF-012	EPIC ClearView System Performance Reports: <ul style="list-style-type: none">• GBMC Clinical Trial, ENG-018• DV-001 Clinical Trial, ENG-019• DV-002 Clinical Trial, ENG-020• EPIC-003 Clinical Trial,	
AR-21	Doesn't leave residue on glass.	Cleaning Liquid	70% Isopropyl Alcohol Swabs, 1282-1504	Calibration Reports, ENG-006, ENG-007			
AR-22	Prevents cross-over contamination.						



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AR-23	Disposable cloth.					ENG-021	Clinical Trial Results Summary
AR-24	Works with cleaning liquid to provide a streak-free surface for image capture.					EPIC ClearView System Performance Reports:	
AR-25	Does not scratch or create other physical damage resulting in artifacts in the image.	Cleaning Cloth	Cleaning Cloth, 1282-1500	Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	Receiving Inspection Record, QAF-012	<ul style="list-style-type: none"> • DV-001 Clinical Trial, ENG-018 • GBMC Clinical Trial, ENG-019 • DV-002 Clinical Trial, ENG-020 • EPIC-003 Clinical Trial, ENG-021 	Clinical Trial Results Summary
AR-26	Device damage prevention.	Packaging Requirements	ClearView Shipping Container, 1282-1512	Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	Receiving Inspection Record, QAF-012	EPIC ClearView 510k Submission	
AR-27	Accessories are labeled to comply with appropriate FDA regulations and any certification marks as applicable. (i.e. FCC, TUV, FDA, etc.)	Labeling	Investigational Device Label, 1282-1600 EPIC ClearView Device Label, 1282-1502 EPIC ClearView Tamper Prevention Label, 1282-1503 ClearView Serial Number Label, 1282-1501	Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	Receiving Inspection Record, QAF-012	EPIC ClearView 510k Submission	Label Integrity Testing and/or Certification



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Ref. #	Requirement	Source of Requirement	Design Inputs (Specification)	Verification Methodology	Design Outputs (Verification Results)	
AR-28	Capacitive barrier and alcohol swab accessories have unique lot code and alcohol swab has expiration label.		Capacitive Barrier, 1282-1025 70% Isopropyl Alcohol Swabs, 1282-1504	Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	Receiving Inspection Record, QAF-012	
AR-29	User is unable to modify the accessories in any manner.	IP Security Requirements	Computer System, 1282-1511 USB Hardware Key, 1282-1515 Printer, 1282-1513 Uninterruptable Power Source (UPS), 1282-1514 Capacitive Barrier, 1282-1025 70% Isopropyl Alcohol Swabs, 1282-1504 Cleaning Cloth, 1282-1500 ClearView Workstation, WOW-100	Inspection and Release of Incoming, In-process and Finished Devices and Other Materials, QA-016	Receiving Inspection Record, QAF-012	<p>EPIC ClearView System Performance Reports:</p> <ul style="list-style-type: none"> • GBMC Clinical Trial, ENG-018 • DV-001 Clinical Trial, ENG-019 • DV-002 Clinical Trial, ENG-020 • EPIC-003 Clinical Trial, ENG-021