EPIC RESEARCH DIAGNOSTICS	EPIC ClearView Clinical Build Summary – SN0987

ORIGINATOR:

Name	Job Title	Signature	Date
Scott Pletzer	Quality & Program Management Director		22MAY12

APPROVALS:

Name	Job Title	Signature	Date
Nancy Rizzo	Founder and CEO		5/22/12
Tom Blondi	President		5/22/12
Mike Stowell	Chief Financial Officer		5/22/12
Andrew Mason	Chief Technology Officer		5/22/12
Don Pegg	Senior Electrical Engineer (PADT)		

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	22May12	Initial Release	Scott Pletzer

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1.0 Purpose

This report summarizes the assembly and testing performed to ensure that EPIC ClearView device SN0987 functions properly and is safe to release only for clinical trials or internal purposes at EPIC Research & Diagnostics, Inc. (EPIC). This EPIC ClearView system will not be sold or distributed.

2.0 Scope

This summary only addresses EPIC ClearView device SN0987 as part of the requirements of Design and Development Plan DDP-003, Revision 001. Other devices manufactured under that plan will be summarized under separate summary reports.

3.0 Executive Summary

This EPIC ClearView system consists of this ClearView device SN0987 loaded with pre-release EPIC ClearView Firmware version 4.0.0 (part 06690 Rev. A), a computer system (1282-1511 rev. 001) loaded with the EPIC ClearView Software (designated ClearView version 1.1.1.3) and all relevant accessories. The device has met performance requirements and functions as intended in order to recommend it be released for clinical use.

4.0 Build Summary and Results

Prior to the completion of manufacturing by MJS Designs, Inc. (MJS) this device had been partially assembled by MJS and a previous contract manufacturer that went out of business (Ditron, Inc.). Full component traceability is not known, so the results of the design verification and validation testing have ensured the device performs as intended.

Device SN0987 was originally released by MJS March 21, 2012 to EPIC for verification and validation testing. Due to poor image quality it was decided that the device be reworked under EPIC NCMR #1011 to replace the electrode assembly and camera. The rework was performed by MJS and released to EPIC on May 11, 2012. During device evaluation it was observed that the glass ITO coating within the electrode assembly was failing, necessitating a second rework. The second rework was performed by MJS and released to EPIC on May 18th, 2012.

Device history records (DHRs) for the original build and both rework builds of this device are held by EPIC and this device has completed verification and validation testing under ENG-017, Revision 001. Specific project requirements under DDP-003, Revision 001 are listed below, followed by a response in ***bold italics.***

4.1 The necessary work instructions, inspection/test procedures, and forms will be approved and released in MJS Designs' quality system prior to continuing device builds under this DDP. Draft documentation will be included in the final summary report for any con-critical work instructions and/or controlled documents will be referenced. – ***Not all of the work instructions, inspection/test procedures, and forms were not approved and released in MJS' quality system prior to building this device. At this time EPIC, MJS, and PADT are still finalizing these items. Attachment A details the status of these documents and serves as the current DMR. Based on the enhanced testing described below in section 4.3, the incomplete documents do not pose a risk to the performance of this device.***

4.2 A complete Device Master Record (DMR) will be created to document the approved procedures used in the assembly of the IDE devices. A summary of the known assembly deviations will be generated and included in the review and approval of the Clinical Build DMR. – ***A complete DMR does not exist at this time as EPIC, MJS, and PADT are still finalizing the DMR items. Attachment A details the status of these items and serves as the current DMR. Based on the enhanced testing described below in section 4.3, the incomplete DMR does not pose a risk to the performance of this device.***

4.3 Design verification testing of one (1) device will be performed by PADT under a pre-approved test protocol. All requirements of that test protocol will need to be met or accepted with appropriate justification and supporting rational prior to release of ClearView Systems for use in IDE investigations. – ***Although a pre-approved test protocol was not used, PADT conducted extensive development testing of this device. This device was not designed from scratch, but was based on a commercialized plan of a design from a previous contract design firm (i.e., Suntron) units. Four (4) units from this other design firm were tested and evaluated by PADT to fully characterize the performance requirements required for this device. This device design is intended to meet to the performance characteristics of those original units. Based on (1) acceptance testing by MJS, (2) firmware testing and release by EPIC, (3) independent safety testing by TUV, and (4) verification and validation testing by EPIC it was determined that other development testing by PADT was verified. The status and references to this testing are detailed in Attachment B.***

4.4 Design validation testing of the four (4) devices will be performed by EPIC Research & Diagnostics, Inc. under a pre-approved test protocol. All requirements

of that test protocol will need to be met or accepted with appropriate justification and supporting rational prior to release of ClearView Systems for use in IDE investigations. – ***Successful verification and validation of device SN0987 was completed by EPIC from March 21st, 2012 – March 22nd, 2012 under ENG-017, Revision 001.***

4.5 Prior to releasing the device for use in IDE investigations, EPIC Research & Diagnostics will generate a report summarizing the build activities and results, with a recommendation to use the devices as described. – ***This report serves as that summary and will be reviewed and approved as part of an EPIC design review.***

4.6 Upon completion of the ClearView Device Master Record (DMR), the final ClearView System DMR will be compared to the Clinical Trial DMR generated as part of this project plan. The comparison will be made to ensure that the devices assembled using the Clinical Trial DMR are significantly equivalent to the final ClearView System DMR requirements. Any deviations/discrepancies will be identified and resolved prior to the completion of any IDE investigations with the Clinical Trial ClearView Systems assembled under this Design and Development Plan. – ***This has not been performed as the ClearView DMR is not complete. Based on the enhanced testing described above in section 4.3, the incomplete DMR does not pose a risk to the performance of this device.***

5.0 Conclusions

EPIC ClearView device SN0987 has met performance requirements and functions as intended, therefore it is recommended to be released for clinical use. Incomplete items under DDP-003 will be tracked and completed prior to commercialization of EPIC ClearView Systems.

6.0 Attachments

6.1 Attachment A **DMR Summary**

6.2 Attachment B **Device Evaluation and Testing Summary**

Attachment A - DMR Summary

Document #	Document Name	Location	Status
XEPC01_1	Cover Assy WI	MJS	Released
XEPC01_2	Base Assy WI	MJS	Released
XEPC01_3	Final Assy and Acceptance Testing WI	MJS/EPIC	Draft, NCMR #1011 contains current WKI for final assembly and testing and serves as the document used to support release of this device.
XEPC02	Electrode Assy WI	MJS	Released
XEPC03	Electrode Board WI	MJS	Released
XEPC06	Power Entry Module WI	Draft	Released
XEPC07	Camera Cable WI	MJS/EPIC	Draft
XEPC09	DC Power Cable WI	MJS/EPIC	Draft
XEPC10	AC Power Cable WI	MJS/EPIC	Draft
XEPC11	Flood LED Cable WI	MJS/EPIC	Draft
XEPC12	Rear Panel LED WI	MJS/EPIC	Draft
XEPC13	Shield to Ground Cable WI	MJS/EPIC	Draft
XEPC14	USB Panel Mount Cable WI	MJS/EPIC	Draft

Attachment B - Device Evaluation and Testing Summary

Document Number	Document Description	Location
SN0987 DHR	Device History Record for original build of device 0987 released 21Mar12	EPIC/MJS
SN0987 DHR – Rework #1	Device History Record for first rework of device 0987 released 11May12	EPIC/MJS
SN0987 DHR – Rework #2	Device History Record for first rework of device 0987 released 11May12	EPIC/MJS
Notebook Testing	Evaluation of Suntron units 0001, 0007, 0009, and 0025	PADT
Notebook Testing	Evaluation and development testing of EPIC device 0987	PADT
ENG-009, 010, and 011	ClearView Software Verification and Validation Reports – Version 1.1.1.3	EPIC
ENG-029	Firmware Verification Report – Version 4.0.0	EPIC
ENG-030	ClearView Shell Verification and Validation Report – Version 1.1	EPIC
N/A	IEC 60601-1 Safety Testing by TUV	EPIC