EPIC ClearView Device
Design Control Statement

ORIGINATOR:

Name	Job Title	Signature	Date
Andrea Miller	Quality Assurance Manager	Andrea Miller	8/8/12

APPROVALS:

Name	Job Title	Signature	Date
Nancy Rizzo	Founder, Chief Executive Officer	N Rizzo	8/8/12.
Michael Stowell	Chief Financial Officer	M. Stowell	8/8/12
Tom Blondi	President	T L D Blondi	8/8/12
Scott Pletzer	Quality & Program Management Director		08AUG12
Patsy Folio	Clinical Programs Director	Patsy Folio	8/8/12
Daniel Miller	Manufacturing Engineer	Daniel R Miller	8/8/12
Andrew Mason	Chief Technology Officer		8/8/12
Don Pegg	Senior Electrical Engineer	See attached SP 10 Sep 12	

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	08Aug12	Initial Release	A. Miller

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1.0 PURPOSE

1.1 To document the design control history for the ClearView Device development. This document is intended to summarize the design controls utilized during early development of the ClearView Device.

1.2 To define the design controls being completed for each phase and activity. This statement will ensure that all necessary activities executed by EPIC and/or contract consultants are addressed including the method in which they will be conducted and all responsible parties involved therein.

2.0 SCOPE

2.1 The objective of this design statement is to outline the activities to be performed in order to develop and manufacture the ClearView Device. Included in this document are the roles and responsibilities of individuals that are required to perform these activities.

2.2 The scope of this project is to develop a galvanic skin response measurement tool, the ClearView device. The ClearView software has been developed under a separate Design History File.

2.3 Aspects of the design process required for this Design Control Statement are planning, design, verification, validation, design transfer, and premarket submission (i.e., 510k) to the FDA.

3.0 REFERENCE DOCUMENTS

FDA 21 CFR 820, Quality System Regulations (QSRs)

3.1 06500, PADT ClearView Design Plan

3.2 DDP-004, ClearView Device Firmware

3.3 DD-005, Risk Management Plan for EPIC ClearView System

3.4 EG-001, Design Control Procedure

3.5 Regulatory Documentation:

- FDA 21 CFR 820, Quality System Regulations (QSRs)
- ISO 13485:2003 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

4.0 DEVICE DESCRIPTION

4.1 The ClearView device is intended to be used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the pads of the fingers. The system measures the electrical resistance of a finger in contact with a glass electrode. A series of painless electrical impulses are applied to the glass electrode generating a localized electromagnetic field around the finger. Under the influence of this field, and depending on the resistance of the skin of the finger, a very small high frequency current is created within the air molecules resulting in a surrounding small burst of light (in the visible and ultraviolet range). This light image is captured by an automated digital camera.

4.2 The images captured by the digital camera are then analyzed by the ClearView software. The analysis of the light patterns and intensities of all ten fingers provides the inputs for the galvanic skin response measurement. A report summarizing the galvanic skin response measurements is generated and may be used by a licensed physician. It provides data points that may assist a physician in choosing further standard of care testing.

5.0 DESIGN CONTROL HISTORY

EPIC Research & Diagnostics, Inc. contracted with Suntron Corporation, a design engineering provider, to provide the necessary skill and expertise for design and development of the ClearView device. The design documentation generated during this early development is located in several CDs. Reference the Memo to File dated 6/27/12 placing the following CDs in the Design History File (DHF):

- One CD labeled Technology Transfer 9/26/2009
- Two CDs labeled Technology Transfer 12/14/2009 (i.e., Part 1 of 2 and Part 2 of 2)
- One CD labeled Suntron Technology Transfer (via PADT) 1/25/10

Much of the information contained on these CDs is duplicated, but information represents the development work done by Suntron to develop a working prototype and represent three distinct transfers of design information. An initial Design Review approving the project was not conducted as EPIC did not have a functioning quality system at the time of project initiation.

The component specifications are included on the CDs. Suntron procured the components for an initial prototype build and were used to assemble the first several units (which included device serial numbers SN0001, SN0007, SN0009, and SN0025). Suntron developed early assembly procedures and verification testing. The early assembly procedure, EPIC Camera (ClearView) Rev. B, included a Board Level Test, Unit Level Assembly, and Unit Level Test. These early assembly and verification test procedures were not controlled through EPIC's quality system and, therefore, do not meet EPIC's current documentation system requirements. A copy of the assembly procedure and the verification testing is located in the Build folder of the Technology Transfer CD labeled "12/14/2009 1 of 2". Additionally, the design verification document EPIC Camera Design Verification is located in the Documents folder under the sub-folder Compliance of the Technology Transfer CD labeled "12/14/2009 1 of 2".

At the beginning of 2010, EPIC engaged PADT, Inc. (PADT), a design engineering provider, to perform design development of the ClearView device. PADT was originally engaged to provide all required design controls; therefore a document called the ClearView Design Plan, PADT document number 06500 revision X1, was approved on 2/9/2010. This design control plan provided a design control plan for the ongoing development of the ClearView Device and was originally created to provide design controls compliant with the quality system regulations (21 CFR 820). Subsequent to this original release, the ClearView Design Plan was revised on two occasions; on 4/6/2010 the document was updated to change responsibility for Requirements and Risk Analysis from PADT to EPIC and again on

11/30/2010 to update the tasks and responsibilities for Project 6 to release the CV1 (**C**ommerical **V**ersion 1) product. Ultimately, version CV1 of the ClearView product was issued as a Rev. F design to the 06690 product drawing.

During the early development work by PADT, four of the original prototypes (device serial numbers SN0001, SN0007, SN0009, and SN0025) were reworked in order to implement multiple improvements in the design to meet the existing requirements. PADT generated a rework procedure within their quality system and executed the rework, creating new device history records to be added to the original Suntron documentation. The original Suntron Device History Records (DHRs) for these devices were reviewed during the 9/24/10 design review of the ClearView Software version 1.0.0. This review is documented in the Design Review Meeting Minutes form dated 9/24/10 which is filed in the ClearView Software Design History File (DHF) and contain the original DHR records.

The original rework records generated by PADT are currently being controlled through PADT's quality system and will be a part of the final design transfer at the end of this phase of development. Copies of these records are being held by QA as a quality system record.

A design review was held on 9/24/10 to review design history records to that point. These records summarize the following:

- Design and Development Planning
- Preliminary Input/output Matrices
- Preliminary Risk Analysis Documentation Form and a preliminary FMEA
- Original Design Verification Reports, and
- Original Software Design Documentation.

The record of this design review is documented on a Design Approval Form dated 9/24/10 filed in the ClearView Device Design History File (DHF).

The design development process has proceeded under the ClearView Design Plan controlled through PADT's quality system. All design control requirements (other than product requirements and risk analysis as specified in the revision X2 version of the ClearView Design Plan, 06500), were documented using PADT's quality system.

A separate Design & Development Plan, DDP-004, was issued to document the design controls process for a rewrite of the ClearView device firmware. The ClearView device firmware runs on a microcontroller that is a part of the control board. The firmware accepts serial commands from a host computer and controls the electrical pulses applied to the ClearView Device glass electrode. The firmware design utilizes the hardware peripherals included in the microcontroller to control system timing, communications, boost voltage, PWM0 pulse width frequency and duration and to monitor the boost voltage level. The design history of the ClearView Firmware is considered to be a part of the

ClearView Device DHF, though the documentation was approved and controlled through the separate Design & Development Plan, DDP-004.

6.0 PROJECT REQUIREMENTS

6.1 Since PADT has controlled the development of significant portions of the design control process, a design review will be held to ensure that all EPIC design control elements required by EPIC's Design Control Procedure, EG-001, will be executed and/or a justification and rationale will be documented.

6.2 Specifications are being developed and derived from top level requirements, working prototypes and early clinical trial results. The specifications are not yet complete, but have been summarized in a preliminary Input/output Matrix.

6.3 Although multiple versions of design verification and validation testing have been conducted, final verification testing will still need to be conducted against the released specifications.

6.4 Preliminary acceptance testing have been developed and used during clinical device build. The adequacy and completeness of this acceptance testing requires further evaluation.

6.5 The Design & Development Plan (DDP) ClearView Device (DDP-006) has been developed to ensure compliance with EPIC's Design Control Procedure (EG-001).

7.0 RESPONSIBILITIES

EPIC has contracted with a design engineering firm to provide design development support for the ClearView device development. Additionally, EPIC has contracted with a contract manufacturer to develop the manufacturing procedures and processes for the assembly, test and release of the ClearView device. The design and development plan, DDP-006, has been developed to establish specific responsibilities.

8.0 ORGANIZATION, INTERFACES, RESPONSIBILITES, AND APPROVAL AUTHORITY

8.1 Documentation generated by PADT to satisfy requirements of the ClearView Design Plan, 06500, will follow the approval authority specified in the ClearView Design Plan.

8.2 All pertinent steps and documents generated outside of PADT's ClearView Design Plan will follow the approval authority of the design and development plan (DDP-006).

9.0 RISK ANALYSIS

A Risk Management Plan for EPIC ClearView System, DD-005, was initially approved on 4/3/12. This plan outlines the risk management approach and activities. All current and future risk management activities will be managed through this plan.

10.0 DESIGN HISTORY FILE (DHF)

The DHF contents will be summarized in a Table of Contents and will satisfy EPIC's Design Control Procedure, EG-001.