ORIGINATOR:

Name	Job Title	Signature	Date
Scott Pletzer	Director of Quality & Program Management		03APR12

APPROVALS:

Name	Job Title	Signature	Date
Nancy Rizzo	Founder and CEO		4/3/12
Andrew Mason	Chief Technology Officer		4/3/12

REVISION HISTORY

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

1. Purpose
   1.1. The purpose of this document is to document the risk management requirements and activities for the EPIC ClearView™ system.
2. Scope
   2.1. Device - EPIC ClearView™ is a non-invasive galvanic skin response (GSR) measurement system. The EPIC ClearView system consists of the EPIC ClearView device attached to a computer/software system. 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 further standard of care testing. The system measures the electrical resistance of a fingertip in contact with a glass electrode. A series of painless electrical impulses are applied to the underside of the glass electrode generating a localized electromagnetic field at the top surface of the glass electrode surrounding the fingertip. Under the influence of this field, and depending on the resistance of the skin of the fingertip, a very small high frequency current will be created via ionization of 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. A software 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, this may be used by a licensed physician to help direct the physician when choosing further standard of care testing.
   2.2. Life Cycle - Life cycle of this device is from 'development through obsolescence'. Risk Analysis will be performed in accordance with the EG-001, EG-010, and EG-012 during the development process and transfer to manufacturing. Post-production monitoring will be performed and documented in the Risk Management File. Annual audits will be performed and documented on the Risk Management File.
   2.3. Risk Management File Documents - The Risk Management File will include but is not limited to the following documents:
      - DD-005 Risk Management Plan
      - DD-006 EPIC ClearView Risk Management Report and Summary
      - DD-009 EPIC ClearView System/Clinical FMEA
      - DD-010 EPIC ClearView Software FMEA
      - DD-011 EPIC ClearView Design FMEA
      - Risk Ranking Table
      - Post Production monitoring documents or reference to those documents
      - Revisions to:
        - Risk Management Plan
        - Risk Management Report & Summary and/or
        - FMEAs
      - Annual reviews, including any changes to the Risk Management Documents
3. Definitions

The definitions of ISO 14971:2007 apply to the risk management requirements and activities of the EPIC ClearView™ system.

4. Allocation of Responsibility

Person	Responsibility
Scott Pletzer (EPIC: Director of Quality & Program Management)	Project Leader, Risk Management Plan/Report & FMEA Approval
Nancy Rizzo (EPIC: CEO & Founder)	FMEA Team Member, Risk Management Plan/Report & FMEA Approval
Andrew Mason (EPIC: CTO)	FMEA Team Member, Risk Management Plan/Report & FMEA Approval
Andrea Miller (EPIC: Quality Assurance Manager)	Post Market Surveillance

5. Criteria for Acceptability of Risk
   - 5.1. Risks will be evaluated in accordance with EG-012 Risk Management procedure for Effects of Failure, Severity, Probability of Occurrence, Probability of Detection, and Risk Priority Number (RPN)
   - 5.2. Acceptable Risk per RPN for EPIC ClearView™ is *216*.
   - 5.3. Any RPNs above this value or any severity or detection ratings above six (6) require additional mitigation to reduce their rating.
6. Requirements for Review of Risk Management Activities
   - 6.1. A Failure Mode and Effects Analysis Report will be initiated during product design and updated as necessary.
     - Device characteristics that could impact on safety (reference Annex C in ISO 14971) will be identified in the on the EPIC ClearView Risk Management Report and Summary or via other means.
     - The EPIC ClearView FMEA report contains product and use hazards.
     - FMEAs will be completed from a system/clinical, software, and design perspectives. Data on the FMEA Table includes:
       - Process/Item Function Process/Function Description
       - Potential Failure Modes (Identification of Hazards)
       - Potential Effect(s) of Failure & Estimation of Risk
       - Potential Causes(s) Mechanism(s) of Failure & Estimation of Risk
       - Current Controls & Estimation of Detection
       - RPN value (Risk Evaluation)
       - Recommended Action(s) if RPN exceeds acceptable limits – including Responsibility & Target Completion Date; Action Taken; Severity, Occurrence & Detection values and revised RPN.

       Note: If RPN still exceeds acceptable limits, further action will be required.

6.2. FMEA table will identify whether or not a new risk has been created. If so, this risk will be added to the FMEA table.

6.3. Risk Management Report and Summary Risk or via other applicable documents will identify / summarized whether or not the RPN numbers meet the values in the Risk Management Plan and will include a statement that all known hazards will be identified.

7. Verification Activities

7.1. If applicable, verification and validation testing in EG-001 Design Control Policy will be cross referenced in the Current Controls and/or the Actions Taken columns of the FMEA table.

8. Approvals

8.1. Approvals of this plan are required by:

Scott Pletzer (EPIC: Director of Quality & Program Management) **OR** Andrea Miller (EPIC: Quality Assurance Manager)
Nancy Rizzo (EPIC: CEO & Founder)
Andrew Mason (EPIC: CTO)

8.2. The Risk Management Report and Summary will be reviewed and approved to ensure completeness and conformance to EG-012 Risk Management procedure and this Risk Management Plan. Approvals are required by:

Scott Pletzer (EPIC: Director of Quality & Program Management) **OR** Andrea Miller (EPIC: Quality Assurance Manager)
Nancy Rizzo (EPIC: CEO & Founder)
Andrew Mason (EPIC: CTO)

9. Location of Risk Management Files

9.1. The Risk Management Files are a part of the product design history file and are located in the EPIC document control. These files are kept for the life of the product.

9.2. Reviews and updates to the Risk Management Files will be done on an annual basis through the internal audit procedure and project review meetings.

9.3. Reviews and updates will be documented and approved and included with the applicable Risk Management File.

10. Reference Documents

10.1. DD-006 Risk Management Report and Summary

10.2. DD-009 EPIC ClearView System/Clinical FMEA

10.3. DD-010 EPIC ClearView Software FMEA
10.4. DD-011 EPIC ClearView Design FMEA
10.5. EG-001 Design Control Policy
10.6. EG-010 Software Development
10.7. EG-012 Risk Management
10.8. ISO 14971:2007 Medical devices – Application of risk management to medical devices

11. Attachments
    11.1. Attachment 1 – Ranking System for Failure Mode Effects Analysis

Attachment 1 – Ranking System for Failure Mode Effects Analysis

SEV - Effects of failure (Severity)

Ranking	Degree of Severity
1, 2	The failure is a cosmetic defect only. The failure will not have any perceptible effect on the performance of the product. The user will probably not notice the failure.
3, 4	The user is only minimally affected. The user will probably notice only a minor deficiency in the product or system.
5	The failure causes dissatisfaction on the part of the one affected. The user will notice decreased product or system performance. The product is operable at reduced performance level. The use of the device may be prolonged and the patient interface with the device may be elongated.
6	The failure necessitates medical or surgical intervention by a health care professional.
7	The failure necessitates medical or surgical intervention by a health care professional to preclude permanent damage to body function or permanent damage to the body structure.
8	The failure results in permanent impairment of the body function or permanent damage to a body structure.
9	The failure results in a complication that is life threatening.
10	The failure results in a complication that would lead to death.

OCC - Probability of Occurrence

Ranking	Occurrence Rating
1	Remote, failure unlikely
2, 3	Low, relatively few failures
4, 5, 6	Moderate, occasional
7, 8	High, repeated failures
9, 10	Extreme, almost inevitable failure

DET - Probability of detection

Ranking	Effectively of Detection
1, 2	Controls will almost certainly detect or enable the user to detect a potential cause and subsequent failure mode. Current control(s) will almost certainly detect the failure mode. Reliable detection controls are known in similar process.
3, 4	Very likely that controls will detect a potential cause and subsequent failure mode prior to release to inventory. Very high likelihood that current controls will detect failure mode and/or control will enable user to detect a potential cause and subsequent failure mode.
5, 6	Moderate to low likelihood that controls will detect or enable the user to detect a potential cause and subsequent failure or that current controls will detect the failure mode.
7, 8	Remote chance that controls will detect or enable the user to detect a potential cause remote likelihood that current controls will detect failure.
9, 10	Undetectable until failure occurs in the field or no control available to detect the failure mode.

Determination of acceptable risk:

Risk Priority Number (RPN)

RPN = Effects of failure (severity) X Probability of Occurrence X Probability of detection

Risk Index

The RPN will be a number between 1 and 1000. The guideline for the maximum acceptable RPN value is 216 (RPN = 6 x 6 x 6 = 216). Regardless of the RPN value, severity or detection ratings above six (6) require additional mitigation to reduce their rating.