EPIC™ RESEARCH DIAGNOSTICS	Risk Management Report and Summary for EPIC ClearView™ System

ORIGINATOR:

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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 results for the EPIC ClearView™ system.

2. Scope

2.1. This document covers the risk management and analysis for the EPIC ClearView™ system and includes the products listed in the table below. The risk analysis was performed according to the current status of the product as reflected in this document and the EPIC ClearView™ Technical File/DMR).

Name	Reorder Number
EPIC ClearView™	TBD

3. Definitions

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

4. Qualitative and Quantitative Characteristics (that could affect safety) – from Annex C of ISO 14971:

Intended use	The EPIC ClearView ™ is a Galvanic Skin Response (GSR) measurement tool for the evaluation of the human systems to help direct the physician when choosing further standard of care testing.
Contact with patient or other persons?	The health care professional will utilize a computer to capture calibration and patient images. The health care professional will contact the calibration probe and all other components on the outside of the ClearView during set up for image capture. Set up exposure will be temporary (less than 10 minutes). Image capture can take 10 to 15 minutes per patient during which time the health care professional will primarily operate the equipment through the computer/software interface. Patient will insert the fingers onto the glass charge cover through the finger shroud in order to properly place the finger on the glass lens. The finger will come in contact with the glass surface of the dielectric plate (glass lens). Each finger will contact the glass surface of the dielectric plate (glass lens) for less than 1 minute. Patient could potentially contact any outer surface of the ClearView

	including the plastic housing, the charge glass cover, finger shroud, and the plastic filter. Image capture can take 10 to 15 minutes per patient. The entire process is non-invasive.
Materials and/or components used	Per the Device Master Record
Energy delivered to and/or extracted from the patient?	The ClearView creates a potential on a glass lens suspended over a camera. When a finger is placed on this lens and an image is initiated, a micropulse potential is applied to the bottom of the lens, this generates a very localized electromagnetic field around the finger tip. Under the influence of this field, the combination of the subject and the field if energetically strong enough will produce a burst of light via ionization of the air around the finger in the visual and ultraviolet range which is captured by the camera below. The electrical current created at the moment of light emission is very low (on the order of <3.5 microAmp). Most people will not experience any sensation when exposing their fingertip to the glass lens. The applied electric field is pulsed on and off every 10 microseconds, and the fingertip is exposed for only 0.5 seconds. The light emitted from the electro-emission process is detected directly by a charge-coupled detector that initiates image capture by a camera.
Substances delivered to and/or extracted from the patient?	N/A, the EPIC ClearView does not extract substances from the patient.
Biological materials processed by the device for subsequent re-use?	N/A, the EPIC ClearView does not process the biological material.
Supplied sterile or intended to be sterilized by the user?	No sterility requirement since the patient contact is always external to the body.
Intended to be routinely cleaned and disinfected by the user?	Device housing and patient contact surfaces must be cleaned between patient use with a 70% Isopropyl Alcohol

	wipe.
Intended to modify the patient environment?	N/A, the EPIC ClearView does not modify the patient's environment.
Measurements?	The ClearView measures the galvanic skin response (i.e., bioimpedance at skin surface). This measurement is taken when the light emitted from the finger is detected directly by a charge-coupled detector. The signal from the charge-coupled detector is sent directly to a computer and software calculates a variety of parameters that characterize the pattern of light emitted, including brightness, total area, form, area, fractality, and density. These measurements are not used for diagnostic purposes.
Is the device interpretative?	The software can provide a severity index which alerts trained professionals of potential areas of concern, but it is not used for diagnostic or interpretive purposes. . The EPIC ClearView ™ is a Galvanic Skin Response (GSR) measurement tool for the evaluation of the human systems to help direct the physician when choosing further standard of care testing
Intended for use in conjunction with medicines or other medical technologies?	N/A The EPIC ClearView is not intended to interact with any other device or drug.
Unwanted outputs of energy or substances?	The EPIC ClearView is not intended to produce any unwanted outputs of energy; the device has been tested to meet electrical requirements.
Is the device susceptible to environmental influences?	No, there are no environmental influences.
Essential consumables or accessories associated with the device?	N/A: there are no accessories or consumables that are associated with the EPIC ClearView device.
Routine maintenance and/or calibration?	The unit must be calibrated prior to use each day or after the unit sits idle for four

	(4) hours or more.
Software?	A dedicated computer workstation supplied as part of the device package houses the software applications and provides the user interface for the device. The application analyzes the scan data to provide a Tree-View Severity Index which acts as a weighing mechanism to alert an end user to identify body systems that may need further evaluation. The primary application running on the Device workstation is the Client User Interface (CUI). The CUI is installed by EPIC prior to patient receipt and installation of the device. Therefore, the end user is not provided information regarding installation of the software.
Restricted "shelf-life"?	N/A there is no shelf-life for the EPIC ClearView device.
Possible delayed and/or long term use effects?	Given the transient nature of the patient/device interaction, no known delayed and/or long-term effects of use.
Is the device subject to mechanical forces?	No mechanical forces are being delivered or received as the unit is stationary during use.
What determines the lifetime of the device?	At this time, it is anticipated that the device will have lifetime of approximately 10 years. Future testing will support this determination.
Is the device intended for single use?	No, the EPIC ClearView is intended for reuse.
Is safe disposal of the medical device necessary?	N/A the EPIC ClearView device is equipment and not a disposable device.
Is installation or special training required?	Yes, The EPIC ClearView™ system will be installed by trained personnel using documented procedures.
Will new manufacturing processes be established or	No, standard printed circuit board

introduced?	manufacturing process and equipment will be used in accordance with assembly instructions for the device. Manufacturing will be performed in accordance with documented procedures, using trained personnel, and applicable records will be documented.
Is device critically dependent on human factors such as user interface?	Yes, the EPIC ClearView device requires interaction by a trained professional using a computer and software system.
Does device have connecting parts or accessories?	The EPIC ClearView™ system consists of the device, calibration accessories, glass electrode cover and finder shroud, USB hardware key, monitor, keyboard, mouse, and computer tower and is delivered as a system to the customer.
Does device have control interface?	Yes, the EPIC ClearView device has control interfaces as part of the software system.
Does device display information?	Yes, the EPIC ClearView device displays information for the trained health professional to direct the patient or review as part of the assessment.
Is device controlled by menu?	Yes, the EPIC ClearView device is controlled using a software system that has a menu to provide the healthcare professional options for different tasks.
Is device intended to be mobile or portable?	No, the EPIC ClearView device is not intended to be mobile.

5. Risk Priority Number (RPN) Ranking

5.1. RPN Ranking scale used is as follows based on Risk Management Procedure EG-012.

5.2. Criteria for acceptability

- 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.

6. Failure Mode and Effects Analysis (FMEA)
   - 6.1. DD-009 contains the EPIC ClearView™ System/Clinical FMEA
   - 6.2. DD-010 contains the EPIC ClearView™ Software FMEA
   - 6.3. DD-011 contains the EPIC ClearView™ Design FMEA
7. Generation of Other Hazards
   - 7.1. Recommendations and actions taken to reduce risks were determined not to introduce any new hazards at this time.
   - 7.2. The highest Risk Priority Numbers (RPN) for each FMEA is as follows:
     - DD-009 System/Clinical FMEA – RPN of 125
     - DD-010 Software FMEA – RPN of 30
     - DD-011 Design FMEA – RPN of 75
8. Evaluation of All Identified Hazards
   - 8.1. To the best of our knowledge we have identified all know hazards at this time. Based on the Risk Management Procedure EG-012, no mitigation is required at this time.
9. Adequacy of Device Safety
   - 9.1. A review of the risks associated with the use of the EPIC ClearView™ System and its intended purpose and application documents the result of this analysis. With respect to perceivable conditions in which the product would be subjected to a worst-case environment or human error scenario, the outcomes of these risks are considered **acceptable**. The ranking of each potential risk, after any recommended action taken, did not exceed 216, or any severity or detection ranking greater than 6, which is considered to be an acceptable risk (as indicated in the RPN ranking above).
   - 9.2. EPIC will continue to monitor the risks associated with the use of the device through its implementation procedures, including manufacturing, inspection and testing, complaint handling, non-conformances reports, customer (inquires) queries, post market surveillance, product changes and Management Reviews.
   - 9.3. The Risk Analysis will be reviewed at a minimum on annually during one of the Management Review Meetings. This Risk Management and Analysis documents will be updated, if applicable. The review will be documented and added to the Risk Management file.
10. Reference Documents

10.1.	CS-100	EPIC ClearView™ User Manual/Instructions for Use
10.2.	DD-005	Risk Management Plan
10.3.	EG-012	Risk Management
10.4.	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.