Analysis Function Requirements

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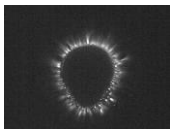
1.0 Purpose

The purpose of this document is to describe the requirements for the image analysis process.

2.0 Scope

The scope of this document consists of the Analysis Function processes as a whole, no other systems requirements are defined in this document. The initial release of this document addresses only the requirements for the core system; this will be augmented as new requirements are introduced.

3.0 Definitions

Background Noise Level	This is the pixel intensity (a value between 0 and 255) that represents the point at which we will consider the pixel 'on'. This is used to remove extraneous noise from the image.
Bitmap	A graphic format used by the system. All images captured by the system are stored in this format. The images are all 320 pixels by 240 pixels in size.
Calibration Image	An image captured using a probe rather than a human finger. This is used as a baseline in performing some image calculations.
Coefficients	Numerical calculations that describe specific attributes of the image.
Encryption	Modifying human readable text into a format that is not readable without performing a conversion.
Energized Image	The image captured by the scanner showing the release of energy. This image is captured and stored as a bitmap having a width of 320 pixels and a height of 240 pixels and 24 bit color depth. An example of an energized image is show below: 

EPIC Image Analysis Engine (EIAE)	A library of code that processes data contained in an image and produces a set of measurements from the data (coefficients).
EPIC Scoring Engine (ESE)	A library of code that is responsible for processing the coefficients to obtain a response scale value. The response scale value is the value that is reported to the end user.
Filtered Image	An energized image obtained by placing a specially designed filter between the subject's finger and the scanner lens.
Finger Image	The raw image of the finger captured before the voltage is applied to the plate.
Finger Sector	A portion of the finger that image that is analyzed for the calculating the various coefficients. All of the fingers have between 6 and 9 sectors for calculation purposes. The sectors are represented as 'pie slices' emanating from the calculated center of the image.
Fractal	A geometrical or physical structure having an irregular or fragmented shape. In an energized image, the fractal coefficient identifies the presence of a repeated pattern in the image.
License Key	File containing a value or string that represents the capabilities of the software. This string is always encrypted.
Pixel	A graphical component that has the ability to turn on and off and display color and intensity.
Scan	The process of collecting the energized images from the fingers of a subject. A complete scan will consist of 10 filtered and 10 unfiltered images.
Sector Quadrant	One of four equal in radius sections of a sector. This can be thought of like a piece of pie segmented into 4 sections starting at the inner radius of the sector out in four equal radii measurements.
Unfiltered Image	An energized image obtained by placing the subject's finger directly on the scanner lens.

4.0 System Requirements

4.1 Image analysis must take place immediately upon request by the user after all of the images are captured.

4.2 Analysis requires a set of 10 filtered and 10 unfiltered images.

4.3 A valid calibration set must be current and available before analysis can begin.

4.4 The general data flow will be as follows:

Collect images → Perform coefficients calculations → Store raw data (coefficient calculations) → Run raw data through analysis algorithm → Result in Response Scale Measurement (GSR measurements), NB score and LR score→ store analyzed data → produce a report.

4.5 The system must calculate a noise value which will be referred to as the background noise level. This level should be the pixel intensity below which will be considered 0 or no intensity at all. This process is documented in the SR-203-01.

4.6 Energized finger images are to be divided for analysis into sectors; these sectors are to be unique for each finger and will be known as finger sectors. All calculations will be done based on the area within the specified sector.

4.7 The number of pixels within a sector that are above the noise level should be measured, this coefficient will be known as the sector area.

4.8 The area respective to the size of the sector must be calculated, this coefficient will be known as the normalized area.

4.9 The average intensity of all pixels in a sector must be determined; this coefficient will be known as average intensity.

4.10 The measurement of disorganization in a sector should be measured; this coefficient will be known as the entropy.

4.11 Measure the level of continuity along the radii of the sectors, this coefficient will be known as form. The form coefficient will encompass approximately 2/3 of the depth of the sector, a separate coefficient called Form2 will look at the outer 1/3 of the sector.

4.12 Breaks or lines in a sector will be known as Break Coefficient

4.13 A measurement of the fractal dimension in a sector must be calculated, this coefficient will be known as fractal.

4.14 A measurement of the difference between a calibration image and the captured energized image per sector must be reported, this coefficient will be known as NS.

4.15 A measurement of form in the first quadrant of the sector must be reported, this coefficient will be known as Form1_1.

4.16 A measurement of form in the first quadrant of the sector must be reported, this coefficient will be known as Form1_2.

4.17 A measurement of form in the first quadrant of the sector must be reported, this coefficient will be known as Form1_3.

4.18 A measurement of form in the first quadrant of the sector must be reported, this coefficient will be known as Form1_4.

4.19 A measurement of the average intensity in the first quadrant of the sector must be reported, this coefficient will be known as AI1.

4.20 A measurement of the average intensity in the first quadrant of the sector must be reported, this coefficient will be known as AI2.

4.21 A measurement of the average intensity in the first quadrant of the sector must be reported, this coefficient will be known as AI3.

4.22 A measurement of the average intensity in the first quadrant of the sector must be reported, this coefficient will be known as AI4.

4.23 A measurement of the number of pixels along radii that are within a specific intensity of each other must be calculated. In some cases this value may be zero. This coefficient will be known as Ring Thickness.

4.24 A measurement of the number of the average intensity in the area that makes up the value for Ring Thickness must be reported, this will be known as Ring Intensity.

4.25 The raw coefficients should be persisted in their original state in a table in the ClearView database.

4.26 Z-scores will be calculated for each instance of all coefficients as described in the SR-203-01.

4.27 A base score will be calculated for each finger sector, this score is a product of the weighting factor (which is unique to each coefficient), the calculated coefficient and the coefficient z-score as described in the SR-203-01.

4.28 Specific combinations of high scoring coefficients will be worth more than others. Rules will be put in place to enforce this. The rules are identified in the document SR-203-01.

4.29 A scale will then be applied to the score that was created; the scale will reduce the results to a number between 0 and 25. The EPIC score scaling mechanism is documented in the SR-203-01.

4.30 A new scoring process (Naive Bayse) will be added to the scoring calculation. This will be calculated completely independent of the EPIC scoring process.

4.31 The Naive Bayse (NB) score will be displayed in a new section in the ClearView report separated from the standard scoring section. This will be treated as an overall score.

4.32 The Logistic Regression score will be calculated. The method of converting the EPIC score value to the final score for the report will be modified to use the process outlined in SR-203-01 to take population data into consideration.

4.33 The method of converting the Logistic Regression score value to the final score for the report based on the process outlined in SR-203-01. This calculation will take the population data into consideration.

4.34 A process for selecting which of the two scores for each measurement to select (EPIC or Logistic Regression) will be implemented into the score development algorithm.

4.35 The ability to export data related to a scan must be implemented. Where applicable, the data must be exported in CSV format and files names will include finger and hand references (e.g., 1R) to the calibration images that are exported. The export functionality should only be available to the administrator user.

4.36 The following data should be exported:

- The raw coefficients as well as the center point and angle of the images
- The raw report data (data that would display in the report)
- Calibration images
- Energized images
- Finger Images (if applicable)
- Calibration data (the number of pixels that failed validation)

4.37 Calibration images must be saved with the raw data.

4.38 The final report data must be saved to the ClearView database.

4.39 The raw Logistic Regression and EPIC scores and ranks must be able to be exported.

4.40 An electronic record audit trail will be collected at the data collection points within the software. The audit trail will consist of who initiated the processing of the data (the current user ID) as well as the time and date stamp for the insertion of. The data collection points are:

- Patient Data Demographics (defined in the Patient Demographics Functions, Requirements document)
- Calibration images Patient images, raw data and results of the final algorithm
- A unique value will be created and used to delineate historical data that did not capture the name of the user ID that collected the data.

~~4.41~~ The user will have the ability to print a report of the Response Scale measurements.

4.41 System should be able to graphically display the score results for organ systems, showing Physical and Autonomic scores and right and left values where appropriate.

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4.42 The user will have the ability to view a graphical representation of the NS coefficient.

4.43 The user will have the ability to view the energized image sectors in relation to a visual representation of the body known as the Biofield.

~~4.44 The Biofield page allow the user to easily toggle between organ systems as displayed.~~

~~4.45~~4.44 The magnification algorithm used ~~on the Biofield page will be enhanced to facilitate a~~should implement a smooth scaling routine.

~~4.46~~4.45 A report viewer will be used to allow the user to print and (based on user ID access) export the final ClearView Report.

~~4.47~~4.46 The ClearView report will be modified to have these sections in the "Full" license mode:

- The patient's treatment date, age at time of scan and gender
- An overview section containing the indications for use, NB scores for all five organ systems.
- The supporting organ system GSR readings
- A definitions section containing text definitions

The word 'Normal' should not be used in the report

~~4.48~~4.47 The ClearView report will be modified to have these areas in the "CV" license mode:

- The patient's treatment date, age at time of scan and gender
- An overview section containing the indications for use and NB scores for all five organ systems
- The supporting organ system GSR readings
- A definitions section containing text definitions
  Note: The word 'Normal' should not be used in the report

~~4.49~~4.48 The ClearView report for the "Basic" licensed product will display only one section that contains Hand/Finger/Measurement # and the appropriate scores.

~~4.50~~4.49 The version of the firmware used in the device that was used to capture the patent images should be captured and stored with the treatment record.

~~4.51~~4.50 The version of device firmware as well as the version of ClearView software should be displayed ~~on the worksheet tab of the analysis output~~ when the results of a scan are viewed.

~~4.52~~4.51 The Id of the user that performed a calibration must be captured as well as the time and date of the calibration.

5.0 Reference Documents

SR-203-01, Algorithm Requirements
SR-001, Patient Demographics Functions- Requirements

EPIC™ RESEARCH DIAGNOSTICS	**Analysis Function Requirements**

Document Revision History

Version Number:	Description of Change:	Date:	Updated by:
000	Introduction	5/24/11	A. Mason
001	Update to include new raw coefficients, the logistic regression scoring mechanism, and the Naïve Baise scoring mechanism in order to implement a new look to the ClearView Report. Remove the requirement for an organ system sub-tab in the Biofield Report Tab, include requirement to use Crystal Reports for generating the ClearView Report, and implement the license requirements in order to offer two different sets of reports based on the user requirements. Alphabetically ordered the Definitions.	10/20/11	A. Mason
002	Update to modify the order in which some requirements are listed and add requirements for data displayed in the CV and Full versions of the ClearView Report. Added requirement for division of energized finger images into sectors which was previously in the specification, but not in these requirements. Added formatting, verified that requirements matched the latest engineering documentation. Added user and date time auditing requirement for the saving of raw data and report data. Added the requirement to collect device firmware version number each time a scan is performed.	3/5/12	A. Mason
003	Update to the reports. Removed any reference to Odds Ratios. In addition, change the headings of the organ systems to match the clinical trial report.	3/15/12	A. Mason
004	Removed reference to sortable organ system display page this page is no longer needed.	7/18/12	A. Mason