EPIC™ RESEARCH DIAGNOSTICS	Document Name: **Design & Development Plan (DDP) for Camera Replacement**

ORIGINATOR:

Name	Job Title	Signature	Date
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APPROVALS:

Name	Job Title	Signature	Date
Nancy Rizzo	Founder and CEO		4/5/12.
~~Michael Stowell~~	~~Chief Financial Officer~~	4/4/12	
Andrew Mason	Chief Technology Officer		4/4/12
Scott Pletzer	Quality and Project Implementation Director		04APR12
Don Pegg	Senior Electrical Engineer		4/4/12
Andrea Miller	Quality Assurance Manager	Andrea Miller	4/4/12

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	4/4/12	Initial Release	Michael Stowell

1.0 PURPOSE

1.1 The purpose is to define the Design & Development Plan (DDP) for replacing the camera in the EPIC ClearView device. A new camera must be sourced and engineered into the device because the camera that is currently used is no longer manufactured. This DDP will provide a comprehensive view of the project to assist the design team in successful completion of each phase and activity.

1.2 This will ensure that all necessary activities 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 DDP is to outline the activities to be performed in order to identify, develop, and implement a replacement camera for the Philips SPC 900NC camera currently used in the ClearView device. Included in this document are the roles and responsibilities of individuals that are required to perform these activities.

2.2 Aspects of the design process included within this DDP are planning, design, verification, validation, and design transfer. Included in the plan are all individuals, resources, and facilities involved.

3.0 REFERENCE DOCUMENTS

3.1 Regulatory Documentation:

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

3.2 GEOST ClearView Replacement Camera Report

4.0 PROJECT REQUIREMENTS

4.1 Camera and lens assembly capable of capturing an energized image.

4.2 Camera capable of image capture at a minimum of 15 pictures/10 second exposure.

4.3 Camera must be able to be controlled through the software for all settings pertaining to image quality.

4.4 Camera parameters to match the existing Philips SPC 900NC camera as close as possible. Current specifications for the SPC 900NC were identified in the GEOST ClearView Replacement Camera Report and are listed in Attachment 1. The GEOST report is contained in Attachment 2

4.5 Implement replacement camera based on recommendations in the GEOST ClearView Replacement Camera Report.

5.0 RESPONSIBILITIES

5.1 Quality and Project Management Director – oversight of camera selection, subsequent design controls, and implementation.

5.2 Chief Financial Officer – oversight of project financial considerations.

5.3 Quality Assurance Manager – management of quality system requirements.

5.4 Chief Technology Officer – development of CV software interface.

5.5 Engineering Department – development of design specifications, implementation into manufacturing, and verification of performance standards with ClearView system. Note: Currently Engineering efforts are outsourced to Phoenix Analysis and Design Technologies, Inc. (PADT)

6.0 ORGANIZATION, INTERFACES, RESPONSIBILITES, AND APPROVAL AUTHORITY

6.1 All pertinent steps and documents, such as design control documents, design review, verification, and validation, must be approved by the following departments:

- Executive Management
- Operations
- Information Technology
- Quality Assurance
- Engineering

6.2 All Engineering Studies must have the signature of the following departments:

- Quality Assurance
- Engineering
- Information Technology (as applicable)

7.0 MAJOR TASKS (MILESTONES) & SCHEDULE

7.1 Camera replacement options are sourced for the Philips SPC 900NC based on current camera parameters and financial considerations. (December, 2011)

7.2 Review and approval of DDP by Executive Management.

7.3 Acceptable replacement camera identified and rationale for selection developed.

7.4 Project team updates plan.

7.5 Design review of formalized plan.

7.6 Design inputs and outputs are documented and approved.

7.7 Design developed resulting in design outputs documentation.

7.8 Periodic design reviews as appropriate.

7.9 Design verification and validation.

7.10 Final design review and approval.

7.11 Design release for manufacturing.

8.0 DESIGN VERIFICATION & VALIDATION APPROACH

8.1 Design verification and validation will include at a minimum an assessment of calibration images to ensure they meet existing standards, and an assessment of human subject images to existing standards. Additional testing may be necessary and will be implemented based on project plan.

9.0 RISK ANALYSIS

9.1 Plan will incorporate the change into the current risk analysis to evaluate any impact.

10.0 PROJECT CONSTRAINTS

10.1 The project has a business need to identify and implement a camera replacement prior to manufacturing additional devices. Any additional constraints will be noted in a further revision of this plan.

11.0 DESIGN HISTORY FILE (DHF)

11.1 The outputs of this effort will be added to the current DHF.

Attachment 1

	Current Camera Specifications - Philips SPC 900NC	
1	**Mechanical**	
1.1	Board Size	Approximatly 1"x 1"
1.2	Form Factor (single/double stack)	Double stack for 1"x 1", ~ 0.5"
1.3	Camera Board Depth/Thickness	TBD
1.4	Lens mounting (board or standalone)	Board Mount, reference EPIC DRW#06694, PEAU Productions - M12x0.5 w/ hole spacing 18mm
1.5	Camera Mounting Interface/Housing	Reference EPIC DRW#06623 - 1.02" MAX camera stack up
1.6	Connector Interface	Molex PN: 87439-0600 1.5mm pitch, 6 pos, single row
2	**Electrical**	
2.1	Supply Voltage	+5VDC
2.1	Supply Current	N/A
2.2	Video type/Interface	USB 1.1 or greater
2.3	Shutter/Trigger	yes
2.4	CCD Array size	SONY ICX445AQA, 1.23 MP, 1280 x 960
2.5	CCD Pixel Size	3.75µm (H) x 3.75µm (V)
2.6	Binning	4x4
2.7	Sensitivity	TBD
2.8	Frame rate	10 Hz min
2.9	Color Depth	Bayer Filters: 400 - 700 nm
2.1	Gain Control	yes, AGC
3	**Optical**	
3.1	F/#	F/2.5, Westech Optical Corp. MDL: 1122NR
3.2	Enterance Pupil Diameter	Ø1.515mm
3.3	Exit Pupil Diameter	Ø19.743mm
3.4	Lens Focal Length	2.2mm, BFL 5.49mm, 1/4" format
3.5	Field of View (FOV)	120° (D), 97° (H) x 72° (V)
3.6	Instantaneous FOV (IFOV)	0.075°
3.7	Spectral Range	TBD
3.8	Filter	N/A
3.9	Assembly Length	18.27mm
4	**Software**	
4.1	Operating Platform	Windows XP 32 bit, update to Windows 7 planned
4.2	Drivers/API	DirectX and DirectShow
4.3	SDK (Software Development Kit)	N/A
5	**Environmental**	N/A

Attachment 2

GEOST ClearView Replacement Camera Report