



ClearView Synchronization Service Risk Analysis Documentation Form

APPROVALS:

Name	Job Title	Signature	Date
Scott Pletzer	Director of Quality & Program Management		28Jun12
Andrew Mason	Chief Technology Officer		6/28/12

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	28Jun12	Initial Release	S. Pletzer



ClearView Synchronization Service Risk Analysis Documentation Form

1.0 General

- 1.1 Device or Accessory Name: ClearView Synchronization Service
- 1.2 Complete Description of the Device or Accessory: The ClearView Synchronization Service (SSS) is a windows based service that is responsible for reporting and maintaining state between the ClearView system and EPIC Central. [EPIC Central is a Software as a Service (SaaS) based application that monitors and maintains the usage and performance of the ClearView systems in the field.] The SSS is designed to be running and reporting any time the computer system that houses ClearView is on. It was deemed necessary to create this as a standalone application rather than part of the ClearView product to ensure as much consistent connectivity as possible with EPIC Central, as per HIPPA requirements, the ClearView system will automatically close after 15 minutes of no user activity.

2.0 Identification of Qualitative and Quantitative Characteristics

- 2.1 Intended Use: The ClearView Synchronization Service is intended to be used to perform synchronization tasks between the ClearView software and EPIC Central.
 - 2.1.1 Indication for Use: A data synchronization service.
 - 2.1.2 Intended User: N/A, the ClearView system interacts with this service, not the ClearView operator.
 - 2.1.3 Required Skill and Training of the User: N/A.
 - 2.1.4 Environment of Use: In a ClearView installation.
 - 2.1.5 Potential Influence(s) of Patient on Device Use: None, as the patient has no direct access to it.
- 2.2 Intended Contact
 - 2.2.1 User Contact (doctor, nurse, etc.): N/A, the operator does not use the synchronizer.
 - 2.2.2 Patient Contact (non-invasive, invasive, etc.): N/A, the patient has no contact or access to the synchronizer.
 - 2.2.3 Anatomical Surface(s) contact (blood, tissue, skin, etc.): N/A.
 - 2.2.4 Duration of Patient Contact (transient, short-term, long-term): N/A.
 - 2.2.5 Frequency of Patient Contact: N/A.

2.3 Materials and/or Components:

N/A, the ClearView Synchronizer Service is simply a software component of the ClearView system.



ClearView Synchronization Service Risk Analysis Documentation Form

- 2.4 Energy Delivered or Extracted: None.
- 2.5 Substances Delivered or Extracted: None.
- 2.6 Biological Materials Processed for Subsequent Reuse: None.
- 2.7 Sterility Considerations: N/A.
- 2.8 Patient Environment Modification: N/A.
- 2.9 Measurements Made: None.
- 2.10 Interpretations Made: None.
- 2.11 Control of or Interactions with Other Devices: The ClearView Synchronization Service interacts with the ClearView software on one end and EPIC Central on the other.
- 2.12 Unwanted Outputs of Energy or Substances: None, there is no energy or substances produced by the ClearView Synchronizer Service.
- 2.13 Environmental Influences:
- 2.13.1 Operation: None
 - 2.13.2 Transport and Storage: N/A.
- 2.14 Essential Consumables or Accessories: None.
- 2.15 Routine Maintenance and/or Calibration: None.
- 2.16 Software: The ClearView Synchronizer Service is a standalone product that requires no other software other than the host operating system.
- 2.16.1 Device Functions Controlled by Software: The ClearView Synchronization Service does not directly control any aspect of the device. It does provide a data point to the ClearView system which either allows or denies the ClearView application to use the device.
 - 2.16.2 Software Feature Functions
 - Acts as the conduit between the ClearView application and EPIC Central.
 - Provides authorization status as to whether or not a device can be used by the client.
 - Provides data backup and synchronization between the EPIC Application and EPIC Central.
 - Updates EPIC Central with the activity of the ClearView system.



ClearView Synchronization Service

Risk Analysis Documentation Form

- 2.17 Shelf-life Restrictions: From a software perspective, the application has no predefined shelf-life, as it will be updated on a yet to be defined frequency basis with new and/or modified code.

2.18 Delayed and/or Long-term Use Effects: N/A.

2.19 Mechanical Forces: N/A, No mechanical forces are being delivered or received.

2.20 Lifetime of the Device: The software that drives the system will be updated on a yet to be determined frequency, thereby extending its lifetime indefinitely.

2.21 Single Use or Reuse: The ClearView Synchronization Service is intended for reuse.

3.0 Identification of Possible Hazards:

Normal Conditions

Fault Conditions

Synchronization Service will not start.

Service cannot connect to EPIC Central.

Service stops unexpectedly
