

Certification Exhibit

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Manufacturer: Proventix Systems, Inc. Model: CU3000

Manual

Proventix[™]

Eliminate the spread of infectious disease in healthcare and hospitals.

enGage. Implementation Guide

Proventix. Systems, Inc.

4518 Valleydale Rd. Suite 201 • Birmingham Alabama • 35242

(205) 383 -1156

www.proventix.com

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About nGage

Our lead healthcare product, nGage[™], is a point of care system that motivates workers to seek out hand hygiene opportunities. The person, while engaged in washing their hands, is rewarded with important professional, performance and user-defined content through an active communication display unit. RFID tags are used to monitor compliance and create data for hospital executives and managers. nGage is an expandable communications and device infrastructure that will improve compliance and create opportunities for efficiencies.

About Proventix Systems, Inc.

Proventix[™] is a technology company whose mission is to eliminate the unnecessary human and economic costs of infectious diseases in the healthcare and hospitality industries. We provide tools and services for quality compliance monitoring, active point of care communication, and successful behavior modification.



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Purpose

This document describes implementation of the nGage system. The document focuses on approach, scope, and explanation of concepts pertaining to the system. Each installation is defined by a specific, individualized plan of action and such plan of action may refer to the items described in this guide.

The document includes:

- Technical Specifications
- Outline of Implementation
- Implementation Plan
- Infrastructure
- Site Planning
- Coding and Validation
- Standard Operating Procedures
- Support Procedures



TYPICAL DEPLOYMENT

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Implementation

The goal of the implementation process is to build a network of the individual sensors and tags and to connect it to the server software. The major phases outlined below are discussed in further detail later in the document.

Outline of Implementation

Technical Specifications

This outlines devices and hardware.

Site Planning

This creates a depiction of the physical environment (floor plan) with the positions of the individual units depicted and named.

Infrastructure

This is the outline of what is needed to support the installation of the nGage system.

Coding and Validation

This describes the process of coding the positions, tags, staff, and other configurations of the nGage system. The validation of the system implementation is outlined.

Client Data Extraction

HL7 – ADT and HIS Census data feeds to Proventix server.

Standard Operating Procedures

This describes the standard operating procedures for operating the nGage system. It only includes activities that may be done by the key operator at the client site. All other activities will be performed under the support category.

Support Procedures

This describes the support procedures.

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The implementation of the nGage system will determine the utility of the product within the hospital environment. The system gathers information from multiple Radio Frequency (RF) devices and stores data in a useful form inside the server database. The reporting database is accessible to authorized users via SSL-encrypted Internet connection. The validity of the installation depends on establishing and keeping all referential information correct.

Terminology

In order to understand the implementation, one must have a good understanding of the individual elements of the nGage network.



The picture above shows the basic outline of the **nGage system**. It consists of a network of various devices that communicate with a **Server**. The number and disposition of individual elements will vary with each installation, but following are the basic elements:

	The second
	Central server consists of software with database and a physical server computer. Typically,
Server	one server runs on each site and performs all communication functions. The server contains all
	the configuration data as well as history of all events from the network. The server may be
	connected to one or more BR units.
BR	Bridge is a unit that performs the translation of data between Ethernet and SNAP [®] network, a
	mesh network over which all the wireless devices communicate.
	Control Units are adjacent to the dispenser stations and perform two functions: wake up when
CU	a TAG is nearby and issue CU transmission to the BR. Each CU configuration is location specific
	within the hospital.
TAG	Tag is an RF device worn by an individual. The CU monitors when a person enters the room,
	engages the alcohol or soap dispenser, and exits the room.

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Implementation Plan

Establishing and following an implementation plan is essential to the project success. The plan serves as a primary communication venue between the Proventix and its Client. A detailed Implementation Plan and checklist is included in the Appendix.

Technical Specifications

FCC/IC Statements

PLEASE NOTE

Electrical equipment should be installed, operated, serviced, and maintained

only by qualified personnel. No responsibility is assumed by Proventix Systems for any consequences arising out of the use of this material.

Warning: Changes or modifications to this device not expressly approved by Proventix Systems could void the user's authority to operate the equipment.

FCC NOTICE

"NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the

receiver is connected.

• Consult the dealer or an experienced radio/TV technician for help."

Control Unit RF Exposure Statement

"This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter."

Tag RF Exposure Statement

Not applicable

IC NOTICE

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Ce dispositif observe l'Industrie de Canada la norme(s) RSS exempte de licence. L'opération est soumise aux deux conditions suivantes : (1) ce dispositif ne peut pas causer l'interférence et (2) ce dispositif doit accepter n'importe quelle interférence, y compris l'interférence qui peut causer l'opération peu désirée du dispositif.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

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Hardware

nGage Client Server

- Provide power and Ethernet
- Static IP address
- Needs remote access
- Run MySQL Server database
- Needs Internet Access
- Runs Proventix HL7 Listener

SNAP[®] network

- IEEE protocol 802.15.4
- 16 selectable channels in a frequency range of 2400-2480 MHz
- Uses two channels: one for the tag and a second for the control unit

Control Units (CU)

- 120Vac 0.1A or 8-16Vdc 0.2A
- Installed adjacent to soap and hand sanitizer dispensers in each room or hallway

Bridge Unit

- Provide power and Ethernet
- 120Vac 0.2A
- Installed in local area to communicate with the CU units
 - Typically 1 per floor depending on configuration and layout of hospital

System Architecture

The system architecture accessing the databases consists of the database server and the application server. The purpose of this section is to outline the architectural infrastructure of the system.

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nGage Client Server Application

- The application collects the data from the SNAP[®] network of detection devices and constructs a comprehensive history of events.
- The configuration component of the application maintains locations, tags, persons, messaging and full application management detail.
- The application is designed to operate without intervention and, at the same time, allow immediate actions by the operator.

Technology

- The application is written in Microsoft .NET framework.
- The secure SSL infrastructure supports user authentication with user specific capabilitys set. User type determines what features can be accessed.
- Database server is MySQL Server. The server is accessed using MySQLClient drivers for .NET.

Network

- The nGage system consists of the detection units that capture the information, connectivity software and hardware, and the server that receives all data, computes the information database, and provides both configuration and analysis access to the information.
- The CU Units gather information about dispensing and entry/exit of the control areas. This information is sent to a server using SNAP^{*} network via Bridge unit. The Bridge unit translates the SNAP^{*} to Ethernet and provides data buffering.
- Trial The Client Server Application runs the nGage Server application and MySQL Database server behind the firewall. This provides access for operation and configuration messaging.
- Long-Term To be discussed with facility.

nGage Web Server

The server software manages the data gathering, interpreting, and presenting. Major parts of the system are depicted below:

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Infrastructure

The nGage system consists of multiple components. The components should be organized to ensure highest quality of resulting data. The hardware components, connectivity software, and server software represent the infrastructure of the installation.

Procure & Prepare

- All requisite equipment procured and prepared for installation.
- Prepare all requisite items and order any parts to ensure availability of complete list.

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• Prepare all units and perform testing, prepare for installation and procure all equipment.

nGage Client Server

Install the server and establish the network configuration. See **nGage Client Server** definitions in this document for more details.

- Prepare the server system and load all system software.
- Load the nGage client server software, database, and verify function.

Connect to Internet

Establish Internet connectivity to the network (using BR units) and from the server to the external access (SSL, firewall, etc.) See **nGage Client Server** definitions in this document for more details.

- Install the server hardware and BR hardware at client's site and configure for remote access.
- Validate the connection to the Bridge unit and configure the IP addresses and port numbers.

Install Components

Install all CU and BR units as defined in the site plan and verify all are properly identified by the SNAP® Network.

- Install the CU units in their respective locations.
- Verify that SNAP[®] connectivity is acquired for each CU.
- Resolve any issues.

Client Data Extraction for Tracking and Reporting

- <u>HL7</u>
 - o ADT
- HIS Census
 - \circ $\;$ Identify a HIS inpatient census report that contains the data elements below.
 - Send a sample report to Proventix for content and structure confirmation.
 - Schedule report 4 times daily (e.g. 4am, 10am, 4pm, & 10pm) and send to d:\nGage_data on the Proventix nGage server.

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 \circ $\;$ The census report is used with ADT to build an accurate facility census and patient

movement model. ADT alone does not allow us to do this.

- HIS Census File Specification
 - The HIS census file contains the roster of the hospital patients at a particular date and time.
 - Each row describes one patient
 - All fields should be pipe '|' delimited

Field	Description	Required
Site	Client or hospital site ID. This identifies an individual hospital	Yes
Census date	Format: MM/DD/YYYY [09/03/2004]	Yes
Census time	HH:MM:SS Military time	Yes
Report date	Date that the report was generated. Format: MM/DD/YYYY [09/03/2004]	Yes
MR number	Medical record number	Yes
Account number	Unique number for this patient's current admission	No
Admission date	Format: MM/DD/YYYY [09/03/2004]	Yes
Location	Nursing station or ward [4W]	Yes
Room – Bed	Room number –Bed Number	Yes
Patient name	Last name, first name or last name, first name, middle initial	Yes
Patient DOB	Date of birth	Yes
Patient age	[60 or 6M]	No
Diagnosis		Yes
MD	Attending physician name	Yes

Example: (this example shows a patient record without Account number and Patient age – both are optional fields)

HOSPA|1/22/2004|0:00:00|1/22/2004|000123456||1/21/2004|4W|8-A|Doe, John, M | |5/22/1938||INCONTINENCE|Cure, All, MD|

• Catalogs (if available)

• Facility location catalog

HL7 Specifications

Our protocol follows the default HL7 standard. We listen, on the configured port, for HL7 (2.2 or 2.3) messages, with the following standard HL7 wrapper:

<0x0B>data<0x1C><0x0D>

Where "data" is a stream of HL7 data, typically ADT messages. The data content, including the format of the HL7 messages, is not validated by the listener.

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When we receive data in this wrapper, we immediately send back an acknowledgment in the following format:

0b 4d 53 48 7c 5e 7e 5c 26 7c 7c 7c 7c 7c 7c 7c 7c .MSH|^ ~\&|||||| 41 43 4b 7c 47 7c 47 7c 32 2e 33 0d 4d 53 41 7c ACK|G| G|2.3.MSA| 41 41 7c 46 0d 1c 0d AA|F...

No other wrapper / ACK / NAK is expected.

Below is our preferred HL7 file layout (v2.3). Versions 2.1 and 2.2 layouts are available upon request. If your default HL7 file layout differs from this, please let us know. We can accept data in many different formats, as long as the required fields are sent. (minimum desired ADT trigger events are listed in FAQ section at the end of this document).

ADT

	•	
2.3	MSH_MessageControlld	MSH/MessageControlID
2.3	MSH MessageDateTime Day	MSH/DateTimeOfMessage/Time/Day
2.3	MSH_MessageDateTime_Hours	MSH/DateTimeOfMessage/Time/Hours
2.3	MSH MessageDateTime Minutes	MSH/DateTimeOfMessage/Time/Minutes
2.3	MSH MessageDateTime Month	MSH/DateTimeOfMessage/Time/Month
2.3	MSH MessageDateTime Year	MSH/DateTimeOfMessage/Time/Year
2.3	MSH SendingApplication	MSH/SendingApplication/NamespaceID
2.3	MSH Sending Facility	MSH/SendingFacility/NamespaceID
2.3	AccountNumber	PID/PatientAccountNumber/IDNumber
2.3	AdmissionDateTime Day	PV1/AdmitDateTime/Time/Day
2.3	AdmissionDateTime Hours	PV1/AdmitDateTime/Time/Hours
2.3	AdmissionDateTime Minutes	PV1/AdmitDateTime/Time/Minutes
2.3	AdmissionDateTime Month	PV1/AdmitDateTime/Time/Month
2.3	AdmissionDateTime	PV1/AdmitDateTime/Time/Year
2.3	AdmittingDiagnosisCode	DG1[0]/DiagnosisCodingMethod
2.3	AdmittingDiagnosisDescription	DG1[0]/DiagnosisDescription
2.3	AssigningFacility	PID/InternalPatientID/AssigningFacility
2.3	AttendingDoctor FirstName	PV1/AttendingDoctor[0]/GivenName
2.3	AttendingDoctor LastName	PV1/AttendingDoctor[0]/FamilyName
2.3	BirthDate Day	PID/DateTimeOfBirth/Time/Day
2.3	BirthDate_Month	PID/DateTimeOfBirth/Time/Month
2.3	BirthDate_Year	PID/DateTimeOfBirth/Time/Year
2.3	PatientAddress_Address1	PID/PatientAddress[0]/StreetAddress
2.3	PatientAddress_Address2	PID/PatientAddress[0]/OtherDesignation
2.3	PatientAddress City	PID/PatientAddress[0]/City
2.3	PatientAddress_State	PID/PatientAddress[0]/StateOrProvince
2.3	PatientAddress_ZipCode	PID/PatientAddress[0]/ZipOrPostalCode
2.3	PatientBed	PV1/AssignedPatientLocation/Bed
2.3	PatientClass	PV1/PatientClass
2.3	PatientFirstName	PID/PatientName[0]/GivenName
2.3	PatientHomePhone	PID/HomePhoneNumber[0]/PhoneNumberString
2.3	PatientId (Medical Record Number)	PID/PatientIdentifierList[0]/IDNumber
2.3	PatientLastName	PID/PatientName[0]/FamilyName
2.3	PatientLocation	PV1/AssignedPatientLocation/PointOfCare
2.3	PatientRoom	PV1/AssignedPatientLocation/Room
2.3	PatientType	PV1/PatientType

Site Planning

The nGage system monitors the location of a person at a given time. The CU (Control Unit) detects a person's position. A specific Tag associated with each individual detects who is near the CU range. Mapping of all the devices must be clearly understood and accurate.

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Floor Plan

Obtain the floor plan and walk through the facility recording the location of units (CU and BR). Note the power and Internet connection availability.



The example above shows the sample coding of the locations. Note that the floor plan does not have to be to scale as long as components and their locations are properly labeled.

Assign Locations

Finalize the plan of locations, prepare list of any electrical or mechanical work needed to prepare the site. As indicated above, each location must establish type of location, name of location, power supply needs and placement of the unit.

- Determine whether any special wiring is needed.
- Determine where the BR unit will be positioned to ensure connectivity and appropriate location.
- Determine the range limits of the CU units.

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Approvals

The proposed setup will be reviewed to ensure the unit position provides a functional environment. Compliance with hospital and regulatory policies will also be reviewed. Any discrepancies will be corrected.

Coding and Validation

The results of site planning will be coded into the Server software to allow correct recording of person's to a location. This section focuses on coding of devices to associate them with locations and persons.

Code Configuration

- Prepare configuration on the Server.
- Code the Site, Region, and Departments as needed.
- Using Site Plan, code all locations and assign to the proper Building, Floor, Room, and individual locations.
- Code all CU units and associate with the individual locations.
- Code the Tags into the tag master, code staff into the person master, and associate the persons with the Tags.
- Verify all BR units in the connection list with proper IP addresses.

Validate Configuration

Validate the proper coding by separate audit. This requires independent review of information and all against discrepancy.

Perform Proventix Test Run

Perform several test runs, record results, and compare with the system recorded information. The test run requires that the sample tags go through the motions at all locations and the information recorded at the Server is validated.

Perform Client Data Extraction Test Run

HL7 – ADT and HIS Census

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Standard Operating Procedures (SOPs)

The nGage system is designed to function for the most part automatically. During its operation, the server periodically polls the devices, stores the data, and generates information. The purpose of this section is to develop SOPs to support its operation.

Changing Tags

This procedure describes the steps to assign or un-assign a person's tag. This also involves training the staff.

Moving CUs

This process will be performed when the unit is replaced or moved. This also involves training the appropriate staff.

Monitoring Operation

This describes periodic monitoring. Note: Proventix support monitors the system and will notify the Client's staff of any specific events. This includes steps to take when to restart or stop the system for any reason.

Support Procedures

The support procedures ensure effective communication between Proventix and the Client. The Proventix technical and client support is critical part of the system operation.

Time of Operations

Proventix office hours are Monday-Friday 8am -5pm Central.

Contact Numbers

Proventix main office number is (205) 383-1156. Clinical support is (205) 332-1750 or (205) 588-5523. Technical support is (205) 383-3654 or (205) 332-1725.

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nGage Client Server

The server hardware and software contains all configuration data, all processes that assemble and interpret information, and all communication within the nGage network and outside Internet.

Requisite Functions

The server performs the following services:

- nGage server software is a windows application designed to manage all data management and collection functions of the system. The application operates on the windows .net framework.
- nGage server hardware needs to be accessible for technical support using Remote Desktop with the appropriate VPN access security.
- nGage server needs to be connected to all BR (Bridge Units) via HTTP port 8080.

Server Hardware

The requirements for hardware are current expectations only and will evolve through testing and client experience. A Virtual Server is preferred with Windows 2008 R2 and 40GB of Disk Space.

	A CONTRACT OF A
Processor	2 - 4GHz, dual core or faster
Memory	4GB minimum
Disk Space	40GB optimally (only one week of data is retained on server)
Network Adapter	10/100 or faster
Optical Drive	For example: 16x DVD+/-RW Drive (not necessary)
Chassis Type	Recommend virtual PC but 1U or Desktop PC can be utilized

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Server Software

OS	Preferred Windows Server 2008 R2 Standard (License provided by Proventix) Other OS must be approved by Proventix
Server	Requires static IP address and configuration of the internal network to allow access. Also needs internet access.
VPN / Remote Desktop	To provide access in configuring and managing the software.
nGage Server Software	Proventix will install

The requirements for software are described below.

Network Diagram

The image below shows the layout of the network.



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The actual configuration will wary depending on the physical layout.

- There is one Site Server per location (hospital/facility).
- The Site Server handles one or more Bridge units. The Bridge translates information between SNAP[®] units and Site Server.
- The Bridge handles a SNAP[®] network consisting of Tags, Control Units (for detection of hand washing and of room entry and exit).

Network Elements

The requirements for the individual nGage-specific devices are in the table below:

lcon	Description	Size/Weight	Power
	Control Unit: located near the dispenser, it detects a person operating the dispenser as well as entry and exit into room.	4" x 4" x 1.5" (approximate) Weight 5.6 oz	8-16VDC at 0.2A OR 110VAC at 0.1A
Tools	Dispenser: The nGage system works with any dispenser. The Control Unit must be mounted within 4" of the place where the hands are rubbed.	NA	NA
	 Bridge Unit: located within range (200' or more* of the nearest other unit. * the range may be affected by other objects and will vary. 	4" x 4" x 1.5" (approximate) Weight 5.6 oz	120VAC at 0.2A
Proventa	Tag: assigned to the person and is worn by the person for proper detection.	1.75" x 3.5" x .4" (approximate) Weight 1.1 oz	Battery CR2450 3VDC

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Appendix

	Implementation Checklist			
Step	Description	Person Completed	Date Completed	Completion Notes
1	Project Staffing			
1.1	Prepare Contact Sheet for the project. This includes staff from Proventix and the Client required for carrying out the tasks.			
1.2	Obtain approval from Proventix and Client.			
2	Initial Project Meeting			
2.1	Present the Implementation Plan to the staff involved in the project and ensure that everyone understands.			
2.2	Prepare a preliminary schedule by assigning the responsibilities and dates.			
2.3	Discuss the communication methodology and the types of documents available.			
3	Site Planning			
3.1	Obtain the floor plan and walk through the facility recording the location of units (CU) and Note the power and internet connection availability.			
3.2	Identify Ethernet connection for bridge unit (BU)			
3.3	Finalize the plan of locations, prepare list of any electrical or mechanical work needed to prepare the site.			
3.4	Procure approvals			
4	Infrastructure			
4.1	Prepare all units and perform testing, prepare for installation and procure all equipment.			
4.2	Install the server hardware and make it available to establish the configuration.			
4.3	Establish internet connectivity to the network (using BR units) and from the server to the			

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	external access (SSL, firewall, etc.)			
	Install all CU and BR units as defined in the site			
4.3	plan and verify all are properly identified by			
	the SNAP [®] Network.			
5	Coding and Validation			
51	Code all locations, tags, and persons. Associate			
5.1	the persons with tags and CU with locations.			
5.2	Validate the proper coding by separate audit.		h.	
	Perform several test runs, record results, and		2	
5.3	compare with the system recorded			
	information.	P =		
6	Standard Operating Procedures			
6.1	Prepare SOP's and approve with Client.			
7	Startup			
71	Reset the system for startup and initiate		-	
/.1	startup monitoring.			

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Frequently Asked Questions

Where will the application software reside (locally on a site server or, instead, remotely on a

Proventix server)?

The nGage Server will reside on the client's machine. The nGage Web application will reside on a remote Proventix server.

The nGage Server (Client-Side)

- Monitor Bridge Units.
- Get Unit transactions from Bridge Units.
- Store Person and Control Unit Messages and Names.
- Send messages to Control Units.
- Send Unit transactions and server messages to remote Proventix server.
- Receive Person and Control Unit messages and Name updates from Proventix server.

The Proventix Server (Remote)

- Uploads unit transactions and server messages into Database server.
- Provide Web interface for reporting, monitoring, and inventory.
- Sends message and name updates to individual client nGage servers.

Where will the database software reside (it appears this will be local)?

The main database will reside on a remote Proventix server. The raw archive database that resides on the client server only retains one week of data

Are the application software and the database software, in fact, separate programs?

Yes, the application software is written in Microsoft .NET and the database software is written in MySQL database.

Virtual Server requirements:

• OS: Windows Server 2008 R2 Standard – license can be provided by Proventix.

<u>Disk Space Usage</u>
(8M)
(55M)
Phython Windows 32 bit.
(138M)
(38M)
(47M)
ication (29M)
(9M)

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Proventix HIS Census Processer	(1M)
Proventix Client Data Server	(1M)
Proventix Total :	(326M)
	(240)

Database growth essentially non-existent. As only a weeks' worth of data is archived on the client server machine. 40G of disk space is desired which would include the OS.

Desired ADT trigger events needed:

A01, A02, A03, A04, A06, A07, A08, A09, A10, A11, A12, A13, A23, A32, A33, A34

ADT Trigger Events desired

ALUE	DESCRIPTION	REQUIRE	<u>p</u>
A01	Admit a patient	Yes	
<mark>A02</mark>	Transfer a patient	Yes	
A03	Discharge a patient	Yes	
A04	Register a patient	Yes	
A05	Preadmit a patient	No	
A06	Transfer an outpatient to inpatient	Yes	
A07	Transfer an inpatient to outpatient	Yes	
A08	Update patient information	Yes	
A09	Patient departing	Yes	
A10	Patient arriving	Yes	
A11	Cancel admit	Yes	
A12	Cancel transfer	Yes	
A13	Cancel discharge	Yes	
A14	Pending admit	No	
A15	Pending transfer	No	
A16	Pending discharge	No	
A17	Swap patients	No	
A18	Merge patient info - NO LONGER USED	No	
A19	Patient guery	No	
A21	Patient goes on a "leave of absence"	No	
A22	Patient returns from a "leave of absence"	No	
A23	Delete a patient record	Yes	
A24	Link Patient Information	No	
A25	Cancel pending discharge	No	
A26	Cancel pending transfer	No	
A27	Cancel pending admit	No	
A28	Add person information	No	
A29	Delete person information	No	
A30	Merge person information	No	
A31	Update person information	No	
A32	Cancel patient arriving	Yes	
A33	Cancel patient departing	Yes	
A34	Merge patient information -patient ID only	Yes	
A35	Merge patient information - account number only	/ No	
A36	Merge patient information - patient ID & account	# No	
A37	Unlink patient information	No	

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