Medical Device Integration of Neurodiagnostic Equipment with Hospital EMR/HIS at UMass Memorial Medical Center, MA

Pratyusha Mattegunta
University of Connecticut, Department of Biomedical Engineering
260 Glenbrook Road U-2247, Storrs, CT 06269-2247

I. Introduction:

In the United States, one of the most pressing forces behind the integration of CE and IT is integration, the major effort to integrate medical devices with electronic health records [EHRs; also referred to as electronic medical records (EMRs)]. This effort has been in the planning stages for years, and we have started implementing it at UMass Memorial Medical Center. In January 2009, President-Barack Obama announced the goal of having all medical health records digitized within five years. At the time, only about 8% of the nation's 5,000 hospitals and 17% of its 800,000 physicians were using computerized recordkeeping systems. The goal was ambitious, to say the least. Within a year, health-care IT reform had been officially mandated as part of the stimulus package (the American Recovery and Reinvestment Act of 2009). Under the reform, known as the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, eligible health-care professionals and hospitals can qualify for Medicare and Medicaid incentive payments when they adopt certified EHR technology and use it to achieve specified objectives. There had always been practical and commonsense reasons to integrate devices to the EHR; now, there are significant financial incentives from the federal government to do so as well. The challenges to achieving integration with the EHR by 2015 are considerable, and clinical engineers are at the center of the process, playing a crucial role. CE leaders all agree that advancing device interoperability is one of the field's biggest challenges now and this paper talks about the process of integration.

II. Scope:

The main scope of the project was to replace obsolete EEG and EMG hardware in Neurodiagnostic Center at UMass Memorial Medical Center, which would address antiquated methods to manipulate and store patient information acquired from studies by integrating the EEG & EMG Machines into Electronic Medical Records. The idea was to create a consolidated approach to data acquisition, storage, and retrieval by automating EMR interfaces, eliminating manual process whenever possible, addressing long-term data accessibility, security and storage needs. It also addresses other issues like standardization of the machines across the hospital and establishing Standards of Care using new procedures/methods to optimize patient care (change in practice and workflow).

III. Background and significance:

An Electroencephalograph (EEG) is an instrument for recording electrical activity of brain, which generates in the individual neuron of the brain. It is an effective method for diagnosing many neurological illness and diseases such as epilepsy, tumor, sleeping patterns, mental disorders, etc. Electrodes are placed around the head (scalp or cerebral cortex) measure and record activity of the brain. Transform ionic currents from cerebral tissue into electrical currents used in EEG Preamplifiers.

Similarly, Electromyography (EMG) is a technique for evaluating and recording the electrical activity produced by skeletal muscles. EMG is performed using an instrument called an

Pratyusha Mattegunta
University of Connecticut, Department of Biomedical Engineering
260 Glenbrook Road U-2247, Storrs, CT 06269-2247

Electromyograph, to produce a record called an electromyogram. An Electromyograph detects the electrical potential generated by muscle cells when these cells are electrically or neurologically activated. The signals can be analyzed to detect medical abnormalities, activation level, and recruitment order or to analyze the biomechanics of human or animal movement.

The EEG and EMG machines used in the Neurodiagnostics Department (hereby referred to as NDC Dept.) at UMass Memorial Medical Center were about 20 years old (some of the dated back to 1984 and 1999) and obsolete, which means they were no longer supported by the Manufacturer, the parts were unavailable; they were also from different vendors and different models, which means we had to use different software to read the test data on different machines. The process of entering patient information into the systems was cumbersome as it was manual, which in turn increased the chances of increasing error in entering the patient details. Thus, a request was put to the Administration to upgrade the old equipment, which would deal with and resolve most of the before mentioned issues.

Thus, in order to choose the right equipment for the NDC Department, we did a Technology evaluation of the Electroencephalographs and Electromyographs available in the market. Owing to the main purpose of the project, which was to network these machines into the hospital system, the main comparison was made between the networking capabilities of each of these machines.

The first step is to study the current workflow of the NDC Department when using the EEG and EMG Equipment. A copy of the Workflow Diagram is shown in Figure 5(See Appendix). This helped me understand the requirements of the Department and deduce what functionality will be needed in the new machines to improve the workflow and provide more efficient patient care.

The second step in this process was to create a comparison chart for each of the vendors using some of the criteria listed below. A Screenshot of the EEG Technology Evaluation for five vendors of EEG machines is attached as Figure 2 in the Appendix.

- Required Network Speed; Hardwired/ Wireless? Both?
- Storage Type
- Number of servers required
- Digital Video - Live Playback option, Size of Video files , Compression format, Synchronization
- IP Addressable Camera - Zoom level
- Data sent to server real-time / after study
- Client software needs to be installed on all computers that need access?
- Number of Reader Stations required
- Hardware Requirements? Web-based application to log in?
- Accessible remotely from Physicians home?
- Remote User account Hierarchy - View, modify, delete files?
- Report generation, saving format HTML, Word? Size? Downloadable on any PC?
- Software Upgrade options? Frequency? Covered during warranty period and after warranty?

After carefully reviewing the networking capabilities for each of these machines, the right vendor was chosen that would meet the requirements of the NDC Department.

Pratyusha Mattegunta
University of Connecticut, Department of Biomedical Engineering
260 Glenbrook Road U-2247, Storrs, CT 06269-2247

IV. Procedure

Interoperability means the capability of two systems to cooperate using exchanged information to allow for a seamless flow of information between many disparate devices over a network and to/from intended recipient. The following explains the steps taken to integrate the EEG/EMG machines into the Hospital EMR:

PHASE – I Project Initiation:

Needs Assessment:
The first step in this project is to make a list of all EMG and EEG equipment in the Department and identify equipment in need of upgrade Vs. Equipment that needs replacement. For each of the machines, identify needs – if they require Data Storage, their Storage Time and need for Remote viewing options. Based on the needs, identify Data Jacks and Power Receptacles in each of the Exam Rooms for existing equipment.

Current Workflow and Dataflow:
The most important step of integration is to study current workflow of the department. This will help us indentify areas of improvement and design an automated process that would ensure a smooth flow of information between the users and an uninterrupted workflow in and between departments. It was observed that it was a completely manual process – where the Technologist manually enters patient information on a piece of paper, and does an EMG study, prints the study and takes it over to the Physician sitting in the Reading Room, who then reviews it, and goes back to do a Needle EMG Test. The Physicians notes the muscle names and readings on a paper and then the Technologist types it out and prints it. Two copies of these test results are made and sent over to Medical Records and Referring Physicians in a folder at the end of the day.

Proposed Workflow and Dataflow:
Based on the observations, the next step is to develop Flow Chart for Proposed Workflow of Physicians/Technologists for EMG Equipment. This draft of the Proposed Workflow is revised with Department Manager, Physicians and Technologists at NDC. On the other hand, a Flow Chart is developed for Proposed Dataflow for EEG/EMG Equipment separately. It is very important to review the proposed workflow and requirements with the Vendor and work out possibility of implementation of **each of those components separately**. There need to be some brain storming sessions between the vendors, Clinical Engineers and the IT Department to discuss the best methods of implementation. One of the ideas that came up during the discussions was to integrate the Speech-to -Text Recognition Software that would make reporting easier for the Physicians and reduce the amount of typing that needs to be done.

Hardware finalization and quotes:
Once the workflow and dataflow are finalized and the number of Acquisition Stations and Reader Stations are identified, identify physical hardware and software configurations for Acquisition

Pratyusha Mattegunta
University of Connecticut, Department of Biomedical Engineering
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stations and Reader Stations. Also, identify the configurations of the Server - multiple servers for database and SQL (Application). Determine the pros and cons of Virtualization of the server vs. Physical server hardware. Once the decision about Physical vs. Virtual server is made, obtain server specifications from the vendor. If the vendor does not use proprietary hardware, if you have the right infrastructure in-house, building the servers in-house might prove to be more advantageous in terms of cost, support and maintenance. It would also provide more security to the ePHI stored in the database server. Confirm number of Acquisition machines for purchase, Obtain quotes for (four) Reader station desktops, review & approve requirements. Also, identify Data jack requirements, Power Receptacles, UPS, etc. in each of the rooms (incl. exam rooms and reading room).

Identify SAN Space & Costs:
In order to calculate the amount of space required on the network, conduct EEG/EMG Prerequisite Analysis to verify data (SAN) requirements for each of the machines in the Department (EEG/EMG/EP/Botox/LTM etc.). This should include the existing equipment in the Department (that are not being replaced), and should be calculated per year – based on approximate number of studies on each machine per week, and amount of data storage required for each machine for each test. It is advisable to have a 15% contingency in these calculations and buying storage space upfront than to request for more space later.

Software requirements finalization and Costs:
The next step is to Spec out the Software to be installed on each of the machines – Acquisition software, Reader Software, number of licenses, cost of licenses, etc. Obtain Server OS license quotes, Obtain SQL license quotes for the server.

Data Distribution and Permissions:
The next step is to work on the data distribution part of the system – the flow of data to Network storage, HIS, outside providers and Referring Physicians. For this, we need to identify interface requirements. Clearly identify the protocols followed by the Scheduling Software to send Patient Appointment information into each of the Acquisition machines, which is usually HL7 (Health Level 7). HL7 provides a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. It is an important standard used in the integration of these machines and the main component that aids the equipment and the software in "talking" to each other.

Identify the number of users and types of logins required for each of them, keeping in mind the security required for each of these accounts (based on user account hierarchy – users and administrators). Create and submit Rack & Power Change Control to get approval and permissions to the Network Share where the studies will be initially sent, from where they would go to the HIS.

PHASE - II Project Implementation:

System Build:
Start working on the System Build - Complete OS build, SQL build, prepare SAN (Shared Area Network) space on the Hospital network and the Application Build - execute vendor installation of

Pratyusha Mattegunta
University of Connecticut, Department of Biomedical Engineering
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the EEG and EMG Acquisition and Reader software, verify Video Assessment (remote video, standard)

Interface Build:
The most important step in implementation is the Interface Build and conducting User Acceptance Testing. As seen in the Figure 4 (EMG Dataflow) in the Appendix, at UMass, we had three different software for different purposes –

- Scheduling software – to import patient information and appointment order into the EEG/EMG machines on the Acquisition stations before starting the study
- After the study, when the study report was ready to be exported, it had to be converted into a PDF in order to be sent to our EMR. This conversion needs to done by software that will be referred to as "Word-to-PDF Conversion Software" in this report.
- This PDF File is stored in a folder on the Network Share, and then send to EMR using an automated script, which will be referred to as "Automated Script" in this paper.

This, Interface build would consist building Test Interfaces at the Scheduling software, Word-to-PDF conversion software, and the automated script to build a "Smart Route" from the storage to EMR.

Interface Testing:
Testing of these interfaces and the interaction of these machines with each other and the Reader Stations is done by setting up one Acquisition station, one Reader Station, one Test Database Server and one SQL Server and activating all the Interfaces in production environment. Begin using Acquisition & Readers stations as in a regular clinical environment, including reviewing the test results, study data and summary dictation. In addition, testing also includes evaluating an EEG/EMG unit running in the ICU environment on wireless for long durations. Also, test remote desktop connection, which would provide the Physicians access to the Reader Stations from their home computers. Coming to the interface, confirm the HL-7 interface pulling ADT for both Inpatient and outpatients (different scheduling software for inpatients and outpatients) are working. Trace and follow the path of the report from the Acquisition stations to the reader stations to the Word-to-PDF Conversion software to network storage and finally to EMR.

PHASE –III Project Execution

Once all the testing is done and the problems or issues of implementing the project are ironed out and fixes are identified, create and finalize Implementation Activation Plan for the project.

*Logistics:*Based on the Equipment order date and shipping and delivery dates, coordinate the logistics to arrange storage area availability for equipment, and schedule incoming inspection with the Biomed Technician.

Pratyusha Mattegunta
University of Connecticut, Department of Biomedical Engineering
260 Glenbrook Road U-2247, Storrs, CT 06269-2247

Equipment Setup:
Once the equipment is on-site, work with the Biomed Technician to set up the Equipment – hardware assembled; Software installed on all servers, acquisition stations, reader stations; Equipment setup and configured; and entering the new equipment into the Asset Management Database.

Training:
Schedule Training for Physicians, Technologists, and Biomed Technician. Make sure you have pre-training, on-site Training on day of install and follow-up training. Coordinate availability of the Physicians, Technologists and Vendor Support along with conference rooms. Make sure there are super-users in the group who can train and support the other technologists as needed.

Go-Live Checklist:
Prepare a checklist before Go-Live to make sure that all of the steps are followed to ensure a smooth transition of change in workflow and data flow in the department.

Make sure that all the acquisition stations and Reader stations have the software installed on them with the correct licenses and permissions based on the user accounts. By now, each user should have their own login and permissions should be given to them based on their privileges as either an Administrator or user. Wireless NIC Cards should be installed on all the Acquisition Machines in order to have the capability of running them in a non-wired location and to help copy the data to the SAN while the machine is being transferred between patients. Confirm the mapping the old DVD Archive on the SAN and back up old data from the machines that are being replaced or upgraded. Schedule patient rooms and Reading rooms for Go-Live. Communicate Go-Live plan with the physicians and Technologists and coordinate patients scheduling accordingly.

It is also important to create a downtime procedure during day of install to ensure that there is no disruption to the workflow and no interference with the Technologists' care giving. Also, create a Disaster Recovery Management Plan for times when the network is down.

During Go-Live, coordination between various departments is absolutely essential – the IT Department, Clinical/Biomedical Engineering Department, Neurodiagnostics Department, etc. At the end of the phased out swap out of the old machines with the new system, ensure that all the components are working, and the main aspect – that the users are happy!

V. Conclusion:

Integration of the Neurodiagnostics Equipment into the hospital EMR is a unique and interesting process. It is also a team-effort, and includes the absolute coordination of all the teams that fulfill their respective functions in various stages of the project. The most important lessons learnt during this process were during the testing phase. During this phase, we had an opportunity to work on various glitches in implementing the action plan that was on paper all this while. We worked with the end users – the Physicians and Technologists and modified the process to make it make user friendly

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University of Connecticut, Department of Biomedical Engineering
260 Glenbrook Road U-2247, Storrs, CT 06269-2247

and this was very important in making the users happy. Having a checklist of all the items that needed to be done during each phase proved to be quite helpful. It is very important to maintain a Project Plan that would log the action items, time lines, person/group/department responsible, status of each item and overall progress of the project. We tried to stick to the timelines and follow up regularly and communicate often to make sure that the schedule was on track. In the end, we found that there is no straightforward procedure to integrate these systems – innovative problem solving skills are required to initialize and devise a plan, and we needed to continually modify it to overcome roadblocks and come up with an optimal solution. Lastly, not everything might go as planned – it is good to be prepared and expect the unexpected.

Pratyusha Mattegunta
University of Connecticut, Department of Biomedical Engineering
260 Glenbrook Road U-2247, Storrs, CT 06269-2247

Appendix

List of Figures:

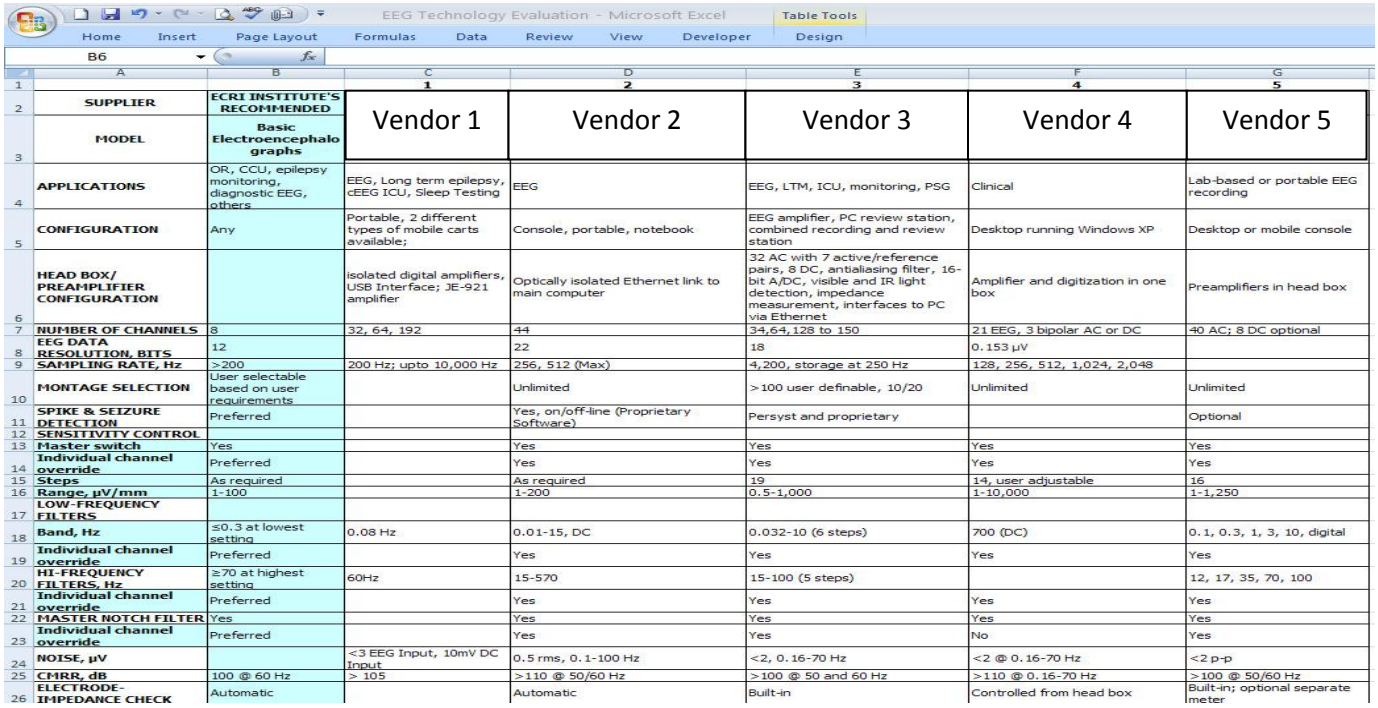
Pratyusha Mattegunta
University of Connecticut, Department of Biomedical Engineering
260 Glenbrook Road U-2247, Storrs, CT 06269-2247

Figure 1: Screenshot of list of equipment for Obsolete Equipment Replacement Planning

Study Type	Description	Control #	Description	Manufacturer	Model#	Serial#	Status	User Needs
EEG, AMBULATORY	ELECTROENCEPHALOGRAPHS, AMBULATORY	125999	ELECTROENCEPHALOGRAPHS, AMBULATORY	BIO-LOGIC SYSTEMS	CEEGRAPH VISION	UR061642	New (2008)	User just needs network storage for exams
EEG, LTM	ELECTROENCEPHALOGRAPHS, LTM	126999	ELECTROENCEPHALOGRAPHS, LTM	GRASS	BHHN	08D0377G	New (2008)	User just needs network storage for exams
EEG, LTM	ELECTROENCEPHALOGRAPHS, LTM	126636	ELECTROENCEPHALOGRAPHS, LTM	GRASS	BHHN-LTM64	08D0456G	New (2008)	User just needs network storage for exams
EEG, LTM	ELECTROENCEPHALOGRAPHS, LTM	107423	ELECTROENCEPHALOGRAPHS, LTM	BIO-LOGIC SYSTEMS	CEEGRAPH IV	CG499K0185	not being replaced	
EEG, LTM	ELECTROENCEPHALOGRAPHS, LTM	117599	ELECTROENCEPHALOGRAPHS, LTM	BIO-LOGIC SYSTEMS	CEEGRAPH IV	CG499K0183	Obsolete	User just needs network storage for exams
EEG, ROUTINE	ELECTROENCEPHALOGRAPHS, ROUTINE	101560	ELECTROENCEPHALOGRAPHS, ROUTINE	BIO-LOGIC SYSTEMS	CEEGRAPH IV	CG499K0184	Obsolete	User just needs network storage for exams
EEG, ROUTINE	ELECTROENCEPHALOGRAPHS, ROUTINE	106351	ELECTROENCEPHALOGRAPHS, ROUTINE	BIO-LOGIC SYSTEMS	CEEGRAPH IV	CSE97K0300	Obsolete	User just needs network storage for exams
EEG, ROUTINE	ELECTROENCEPHALOGRAPHS, ROUTINE	116404	ELECTROENCEPHALOGRAPHS, ROUTINE	BIO-LOGIC SYSTEMS	CEEGRAPH VISION	CGVO4IO039	New (2004)	User just needs network storage for exams
EEG, ROUTINE	ELECTROENCEPHALOGRAPHS, ROUTINE	117626	ELECTROENCEPHALOGRAPHS, ROUTINE	BIO-LOGIC SYSTEMS	CEEGRAPH VISION	CGV05L0289	New (2005)	User just needs network storage for exams
EEG, ROUTINE	ELECTROENCEPHALOGRAPHS, ROUTINE	H026468	ELECTROENCEPHALOGRAPHS, ROUTINE	BIO-LOGIC SYSTEMS	SE	CSE97K0300	Obsolete	User just needs network storage for exams
EEG, ROUTINE	ELECTROENCEPHALOGRAPHS, ROUTINE	129227	ELECTROENCEPHALOGRAPHS, ROUTINE	BIO-LOGIC SYSTEMS	CEEGRAPH VISION	2UA74314B2	New (2008)	User just needs network storage for exams
EMG, ROUTINE	ELECTROMYOGRAPHS, GENERAL	108615	ELECTROMYOGRAPHS, GENERAL	TECA	TD20	96090	Obsolete	Integration with EMR needed for documentation
EMG, ROUTINE	ELECTROMYOGRAPHS, GENERAL	101798	ELECTROMYOGRAPHS, GENERAL	VIASYS	VIKING 2P	K1990169	Obsolete	Integration with EMR needed for documentation
EMG, ROUTINE	ELECTROMYOGRAPHS, GENERAL	107428	ELECTROMYOGRAPHS, GENERAL	NICOLET BIOMED	VIKING 2P	K1990164	Obsolete	Integration with EMR needed for documentation
EMG, ROUTINE	ELECTROMYOGRAPHS, GENERAL	M009701	ELECTROMYOGRAPHS, GENERAL	VIASYS	VIKING 4P	H0990367	Obsolete	Integration with EMR needed for documentation
EVOKED POTENTIAL (EP)	ELECTROMYOGRAPHS, GENERAL	117558	ELECTROMYOGRAPHS, GENERAL	VIASYS	VIKING SELECT	OE050413	New (2005)	EP Machine
SURGERY SUPPORT	ELECTROMYOGRAPHS, GENERAL	119872	ELECTROMYOGRAPHS, GENERAL	VIASYS	VIKING SELECT	PA050128	New (2005)	OR Machine
EMG, ROUTINE	ELECTROMYOGRAPHS, GENERAL	104670	ELECTROMYOGRAPHS, GENERAL	VIASYS	VIKING SELECT	NK030189	New (2003)	No discussion with Memorial EMG Physician group.

Pratyusha Mattegunta
University of Connecticut, Department of Biomedical Engineering
260 Glenbrook Road U-2247, Storrs, CT 06269-2247

Figure 2: EEG Technology Evaluation



EEG Technology Evaluation - Microsoft Excel

	A	B	C	D	E	F	G
1			1	2	3	4	5
2	**SUPPLIER**	**ECRI INSTITUTE'S RECOMMENDED**	Vendor 1	Vendor 2	Vendor 3	Vendor 4	Vendor 5
3	**MODEL**	**Basic Electroencephalographs**					
4	**APPLICATIONS**	OR, CCU, epilepsy monitoring, diagnostic EEG, others	EEG, Long term epilepsy, cEEG ICU, Sleep Testing	EEG	EEG, LTM, ICU, monitoring, PSG	Clinical	Lab-based or portable EEG recording
5	**CONFIGURATION**	Any	Portable, 2 different types of mobile carts available;	Console, portable, notebook	EEG amplifier, PC review station, combined recording and review station	Desktop running Windows XP	Desktop or mobile console
6	**HEAD BOX/ PREAMPLIFIER CONFIGURATION**		isolated digital amplifiers, USB Interface; JE-921 amplifier	Optically isolated Ethernet link to main computer	32 AC with 7 active/reference pairs, 8 DC, antialiasing filter, 16-bit A/DC, visible and IR light detection, impedance measurement, interfaces to PC via Ethernet	Amplifier and digitization in one box	Preamplifiers in head box
7	**NUMBER OF CHANNELS**	8	32, 64, 192	44	34,64,128 to 150	21 EEG, 3 bipolar AC or DC	40 AC; 8 DC optional
8	**EEG DATA RESOLUTION, BITS**	12		22	18	0.153 µV	
9	**SAMPLING RATE, Hz**	>200	200 Hz; upto 10,000 Hz	256, 512 (Max)	4,200, storage at 250 Hz	128, 256, 512, 1,024, 2,048	
10	**MONTAGE SELECTION**	User selectable based on user requirements		Unlimited	>100 user definable, 10/20	Unlimited	Unlimited
11	**SPIKE & SEIZURE DETECTION**	Preferred		Yes, on/off-line (Proprietary Software)	Persyst and proprietary		Optional
12	**SENSITIVITY CONTROL**						
13	**Master switch**	Yes		Yes	Yes	Yes	Yes
14	**Individual channel override**	Preferred		Yes	Yes	Yes	Yes
15	**Steps**	As required		As required	19	14, user adjustable	16
16	**Range, µV/mm**	1-100		1-200	0.5-1,000	1-10,000	1-1,250
17	**LOW-FREQUENCY FILTERS**						
18	**Band, Hz**	≤0.3 at lowest setting	0.08 Hz	0.01-15, DC	0.032-10 (6 steps)	700 (DC)	0.1, 0.3, 1, 3, 10, digital
19	**Individual channel override**	Preferred		Yes	Yes	Yes	Yes
20	**HI-FREQUENCY FILTERS, Hz**	≥70 at highest setting	60Hz	15-570	15-100 (5 steps)		12, 17, 35, 70, 100
21	**Individual channel override**	Preferred		Yes	Yes	Yes	Yes
22	**MASTER NOTCH FILTER**	Yes		Yes	Yes	Yes	Yes
23	**Individual channel override**	Preferred		Yes	Yes	No	Yes
24	**NOISE, µV**		<3 EEG Input, 10mV DC Input	0.5 rms, 0.1-100 Hz	<2, 0.16-70 Hz	<2 @ 0.16-70 Hz	<2 p-p
25	**CMRR, dB**	100 @ 60 Hz	> 105	>110 @ 50/60 Hz	>100 @ 50 and 60 Hz	>110 @ 0.16-70 Hz	>100 @ 50/60 Hz
26	**ELECTRODE-IMPEDANCE CHECK**	Automatic		Automatic	Built-in	Controlled from head box	Built-in; optional separate meter

Pratyusha Mattegunta
University of Connecticut, Department of Biomedical Engineering
260 Glenbrook Road U-2247, Storrs, CT 06269-2247

Figure 3: NDC Storage Requirements

NDC Storage requirements - No cost.xls [Compatibility Mode] - Microsoft Excel

	A	B	C	D	E
1		**EEG Routine**	**EEG Ambulatory**	**EEG LTM**	**EMG**
2					
3	**Without Video**				
4	Size of each file(GB)	0.20	1.00	0.02	0.02
5	Avg. no. of tests per day	10.00	2.00	4.00	10.00
6	Avg. no. of tests per week	70.00	8.00	20.00	70.00
7	Avg. no. of tests per year	3100.00	170.00	1040.00	3640.00
8	Space required per day (GB)	2.00	2.00	0.08	0.20
9	Space required per week (GB)	14.00	8.00	0.40	1.40
10	**Space required per year (GB)**	**620.00**	**416.00**	**20.80**	**72.80**
11					
12	**With Video**				
13	Size of Video File per day (GB)	12.00	0.00	9.50	0.00
14	Avg. no. of tests with video per year per machine			55.00	
15	Avg. no. of tests with video per year	200.00	0.00	220.00	0.00
16	**Space required per year (GB)**	**2400.00**	**0.00**	**2090.00**	**0.00**
17	**Total Storage/Year (with and without Video) (GB)**	**3020.00**	**416.00**	**2110.80**	**72.80**
18					
19					
20	**Storage required for other machines (ENG, etc.)**	**??**			
21					
22	Total Estimated Test Data Storage per Year (GB)	5619.60	5.49 TB		
23					
24	**ARCHIVING OPTIONS**				
25	No. of old studies in DVD Formats	300.00			
26	Avg File Size of each DVD (GB)	9.40			
27	Storage Space required (GB)	2820.00	2.75 TB		
28					
29					
30	Storage Requirement per year (TB)	5.49			
31					
32	Total Yearly Storage Requirements (TB)	8.24			
33	+15% storage contingency (TB)	9.48			
34					

Pratyusha Mattegunta
University of Connecticut, Department of Biomedical Engineering
260 Glenbrook Road U-2247, Storrs, CT 06269-2247

Figure 4: EMG Dataflow

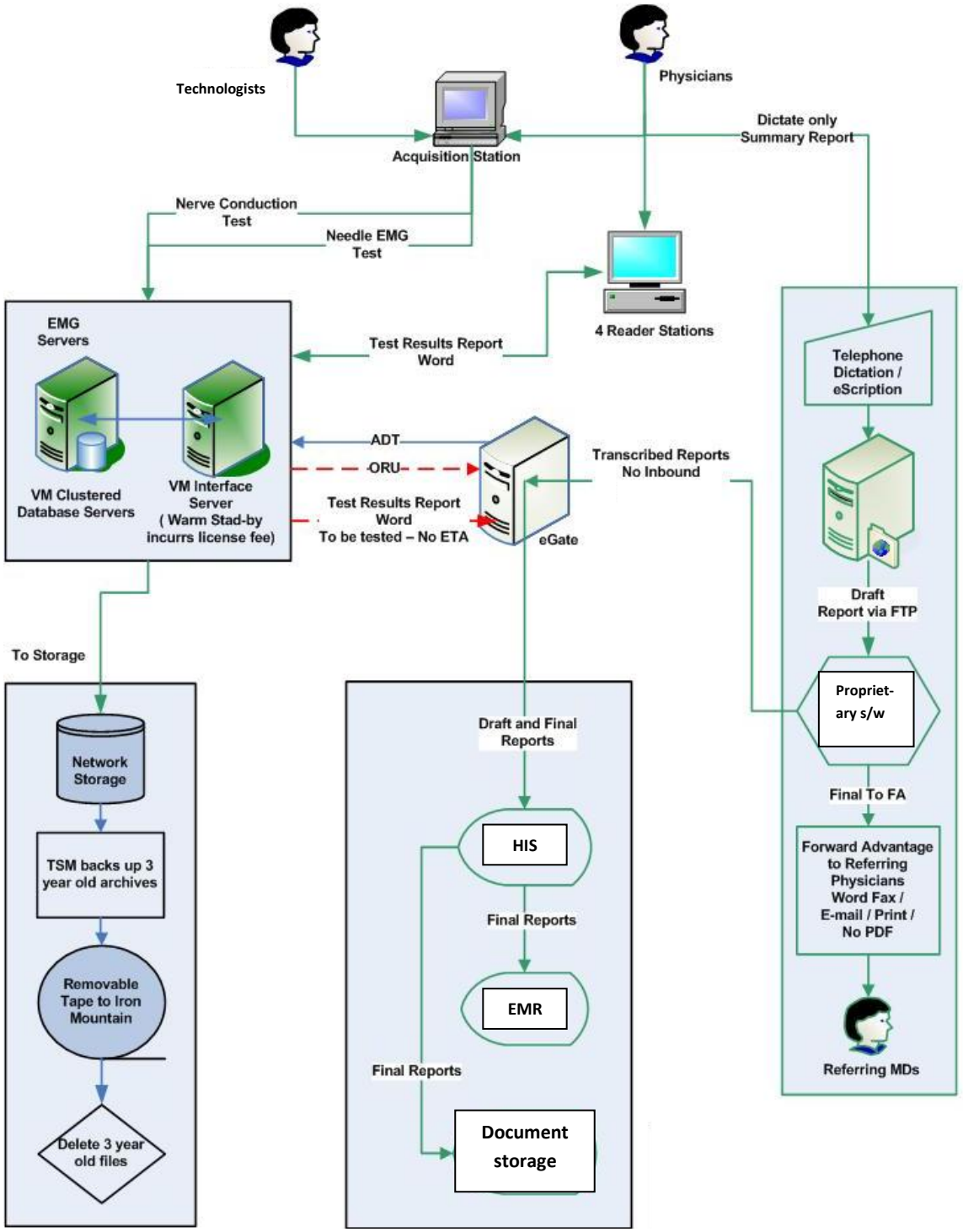


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Figure 5: Physician Workflow - EMG