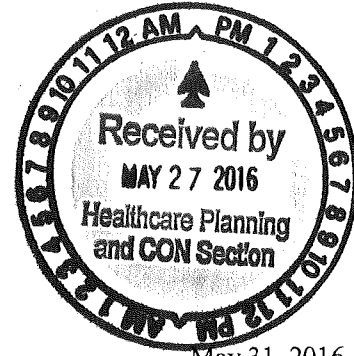


DELIVERED VIA EMAIL 5/27/2016



May 31, 2016

Raleigh Radiology, LLC  
150 Parkway Office Court, Suite 100  
Cary, NC 27518

Ms. Martha Frisone, Assistant Section Chief  
Ms. Gloria Hale, Project Analyst  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
2704 Mail Service Center  
Raleigh, North Carolina 27699

**Re: Comments on Competing Applications for a Certificate of Need for acquisition of one fixed Magnetic Resonance Imaging scanner in Wake County, HSA IV; CON Project ID Numbers:**

**J-011167-16, Duke University Health System  
J-011172-16, Wake Radiology, LLC  
J-011159-16, Raleigh Radiology, Cary**

Dear Ms. Frisone and Ms. Hale:

On behalf of Raleigh Radiology, LLC, Project ID# J-011159-16, thank you for the opportunity to comment on the above-referenced applications for development of a new fixed Magnetic Resonance Imaging (MRI) scanner in Wake County.

## CONTEXT

Three applicants submitted for the need identified in the *2016 State Medical Facilities Plan* for one fixed MRI scanner in Wake County. Since the Plan and statute permits only one award, the decision will have a significant influence on county health service access. Competitive impact, timeliness of availability, location, cost of services, program accessibility, and equipment proposed are critical selection elements. The need identified in the Plan was in response to a petition from Raleigh Radiology that documented: high demand for its services, access and quality limitations, high costs and lack of staff control associated with its present MRI lease from a third party vendor. Raleigh Radiology is the only major radiology group in Wake County that does not own an MRI. We believe that the applications submitted confirm and support Raleigh Radiology as the most qualified applicant to address the identified need.

---

## WHY APPROVE RALEIGH RADIOLOGY, LLC

### Competitive Overview

Competitively, Raleigh Radiology proposes the most cost effective and highest value MRI. The table below and comments that follow support this fact. It is the only applicant to propose replacement of an expensive third party vendor lease, and the only applicant who proposes to bring 3T MRI capability to Wake County. Raleigh Radiology offers the best value to both payers and people whose health insurance plans involve significant out of pocket costs for MRI services. Raleigh Radiology also proposes to bring this value to Wake County soonest, and proposes to offer with more capabilities than any other MRI in Wake County.

It is telling that only one of the applicants, Raleigh Radiology, has an agreement with WakeMed Key Community Care, an Accountable Care Organization that includes the largest network of primary care physicians in the Triangle. WakeMed Key consistently scores high on quality and total cost per Medicare beneficiary. For example, in 2014, according to CMS, the per beneficiary cost in Duke Connected Care, a Medicare MSSP ACO, was \$8,644: WakeMed / Key IPA cost was \$7,606.<sup>1</sup> In the same vein, applicant, DUHS, is not included in the BCBSNC lower cost Blue Value plan, and applicant, Wake Radiology, consistently lists second only to DUHS on costs on the BCBSNC Treatment Cost Estimator for MRI.<sup>2,3</sup>

In the past, the Agency has considered percent of service to Medicare and Medicaid beneficiaries as a measure of access by medically underserved individuals. It is important to note that the wording in statutory criterion 131E-183(13) lists Medicare and Medicaid recipients as categories of persons to whom the project should be accessible. All applicants propose to serve these beneficiaries. The distinguishing feature among applicants in this batch is the proposed service to underinsured individuals. Though the legislation did not single them out, persons who cannot afford high out of pocket costs are an underserved group. According to a recent NY Times article by Aaron Carroll, “over 13 percent of people age 19-64 had a deductible that was 5 percent of their income or more.....and 29 percent of adults with a deductible large enough to render them underinsured skipped a test.”<sup>4</sup> This group is as important as Medicaid and Medicare. Moreover North Carolina Medicaid pays more than Medicare for many MRI procedures, for example, MRI of the Brain (CPT 70551), MRI of the Cervical Spine (CPT 72141), and MRI of the Lumbar Spine (CPT 72148).<sup>5</sup>

---

<sup>1</sup> Data.CMS.gov, data for July 2015 <https://data.cms.gov/dataset/Medicare-Shared-Savings-Program-Accountable-Care-O/teru-84gk#column-menu> accessed May 9, 2016

<sup>2</sup> BCBSNC was able to lower costs for the Blue Value plan by collaborating with UNC Health Care, REX Healthcare, WakeMed Health and Hospitals and Key Physicians, a medical home network of independent primary care practices, to reduce the price of coverage by as much as 15 percent\*. This smaller, more streamlined network of providers helps consumers control their costs without sacrificing benefits. Initially, Blue Value will be sold across the state, except in the Charlotte region. <http://www.keymedicalhome.com/bluevalue/> accessed May 9, 2016.

<sup>3</sup> <http://www.bcbsnc.com/content/providersearch/treatments/index.htm#/>

<sup>4</sup> Carroll, Aaron E. Underinsurance Remains Big Problem Under Obama Health Law, The New York Times, Dec1, 2014, on line [http://www.nytimes.com/2014/12/02/upshot/underinsurance-remains-big-problem-under-obama-health-law.html?\\_r=0](http://www.nytimes.com/2014/12/02/upshot/underinsurance-remains-big-problem-under-obama-health-law.html?_r=0)

<sup>5</sup> Raleigh Radiology data from DMA / CMS payment history.

Thus, to compare how applicants serve medically underserved individuals, metrics that reflect collected revenue, for example, Percent-Uncompensated Care (charity) and Net Revenue Per Procedure reflect access better than measuring the percent of procedures provided to Medicare and Medicaid beneficiaries. These other measures have the added value of reflecting impact on both patients and payers. Similarly, how soon the equipment will be available and whether it will replace a high-priced lease affect community access.

All applicants propose wide-bore equipment. Only one, Raleigh Radiology, proposes higher resolution 3T equipment that increases the value of the scan, without changing the price. Raleigh Radiology's application describes the clinical advantages of the 3T. Material in Attachments C and D to this letter also shed light on the difference between a 3.0 Tesla and a 1.5 Tesla magnet. The 3T supports prostate imaging without an endorectal coil; its reduced signal to noise ratio improves accuracy of breast interpretations; and it provides superior resolution for musculoskeletal and neurological imaging. These advantages improve both patient comfort and MRI's power as a diagnostic tool. Wake is the only major urban area in the state without a 3T, and with 21 fixed equivalent scanners, it should have one 3T option.

The most recent competitive MRI review completed by DHSR CON Section was the 2015 New Hanover County MRI applications. In that competitive review, the Agency considered six metrics:

- Geographic Accessibility
- Access to Underserved Groups
- Ownership of Fixed MRI Scanner in the County
- Gross Revenue per Procedure
- Net Revenue per Procedure
- Cost per Procedure

With the exception of Gross Revenue per Procedure, we believe that all of these are reasonable for evaluating the 2016 Wake MRI applications. However, we believe that the Agency should consider additional metrics that represent the spirit and intent of the SMFP regarding value, quality, and accessibility. We believe that the following summary presents a strong and reasonable comparison of the three applicants with regard to value elements. It ranks applicants highest to lowest; and scores ties highest or lowest, as appropriate.

**Table 1 – Relative Score on Critical Value Measures  
(High Score is Best)**

Measure	Wake Radiology	Duke University Health System	Raleigh Radiology, Cary
Geographic Accessibility	1	2	3
Percent Charity Care Procedures	1	1	3
Percent Medicare plus Medicaid Procedures	3	2	1
Least number of owned fixed MRIs in the County	1	2	3
Technical gross revenue per procedure (charge)	1	3	2
Technical net revenue per procedure	1	2*	3
Cost per procedure	1	2	3
Direct care as percent of total expense	1	2	3
Magnet Strength	1	1	3
Hours available per week	2	1	3
Date available	2	1	3
Replaces a high-cost lease	1	1	3
<b>Total Score</b>	<b>16</b>	<b>20</b>	<b>33</b>

\* DUHS understates Medicaid revenue, thus may score lower.

## Comparison Notes

Table 2 lists the specific metrics for each score in Table 1. Additional comments regarding each measure are included in notes below the table and in the discussion of each applicant in the attachments to this letter.

**Table 2 – Metrics Associated with Data Scores**

	Measure	Source in Application	Wake Radiology	Duke University Health System	Raleigh Radiology, Cary
a	Geographic Accessibility	III.2	Wake Forest	Holly Springs	Cary
	Percent Charity Care	VI.15	1.9%	1.9%	5.8%
	Percent Medicare plus Medicaid Procedures	VI.15	44.5%	32.6%	32.5%
	Least number of owned fixed MRIs in the County	II.8	4	2	0
b	Technical gross revenue per procedure (charge)	Pro forma Forms Cand D	\$2,185	\$1,052	\$1,177
c	Technical net revenue per procedure Year 03	Pro forma Forms Cand E	\$849	\$534	\$373
	Cost per procedure Year 03	Pro forma Forms C	\$597	\$400	\$146
	Direct care as percent of total expense	Pro forma Form C	26%	41%	77%
	Magnet strength	II.1	1.5 T	1.5T	3T
	Hours available per week	VI.5(b)	78	70	92
	Date available	XI.1	10/1/2017	7/1/2018	5/1/2017
d	Replaces a high-cost lease	II.1	No: replace own mobile	No: new site	Yes

*Notes:*

- a. When compared to southern Wake County, northern Wake County has an abundance of fixed MRIs; therefore, Wake Radiology's location is not preferable. As demonstrated in our supplemental comments on the DUHS application, Holly Springs is not a preferable location to Cary. As noted in the Raleigh Radiology application, page 67ff, the proposed Cary location can serve far more people in southern Wake County, including Holly Springs, than a location in Holly Springs. A Holly Springs location isolates the MRI in a less populated area in far southern Wake County.

- b. The Agency has historically ranked average Gross Charges in competitive reviews, the metric does not accurately reflect cost or access, because few if any patients pay that amount; hence it is not a good comparison metric. Moreover, the application submitted by DUHS proposes an arbitrary average Gross Charge that is not supported by any evidence in the application, and that application's Average Net Revenue per Procedure (what patients actually pay) are higher than proposed by either of the other applicants.
- c. These comparisons, exclude professional fees to assure comparability. Note in detailed analysis of DUHS Criterion 5, DUHS understates Medicaid revenue. This metric may be understated.
- d. The replacement comparison is not common in competitive reviews. However, if Raleigh Radiology is not approved and Raleigh Radiology cannot reach an agreement on price with the third party vendor that has the grandfathered MRI, then Raleigh Radiology Cary, a provider with lower costs to patients would disappear and demand for MRI service would be forced to either go out of county or seek higher priced in-county providers. Thus, in this review, replacement is an important metric.

### **Gross Revenue per Procedure Does Not Provide a Valid Comparison**

Gross Revenue per Procedure is an arbitrary measure. Two applicants based it on history. One provided an unsupported number. For further explanation of the arbitrary nature of the measure, please see attached comments on DUHS, Criterion 5.

### **VALUE AND ACCESS**

Raleigh Radiology has demonstrated long-term commitment to Wake County; and it took the lead in making MRI imaging affordable to patients by introducing a low pricing schedule and a generous discount policy. Raleigh Radiology recently increased its outreach to groups that traditionally serve low-income persons, making specific commitment to accept referrals from these groups (see correspondence in Exhibit 29 of the Raleigh Radiology application). Although DUHS presented a slightly lower average proposed charge, the DUHS application provides no support to back up the proposed charge, and the application consistently claims the charge "may" be lower than hospital prices.

### **NON-CONFORMING APPLICATIONS**

Comparisons aside, the other applications do not conform to all required statutory criteria. The Wake Radiology application is non-conforming GS 131E-183(b) with regard to the Special Rules. Specifically, Wake Radiology fails to comply with requirements of performance standard: 10A NCAC 14C.2703(b)(2). On page 29, the application indicates that the applicant's mobile MRI scanner will reach 2,124, not the required 3,328 weighted scans by year 03. We believe that same applicant should be found non-conforming to GS 131E-183(a) criteria 3, 4, 5, 6, 13(a), and 14.

The other application from DUHS appears to be non-conforming to GS 131E-183(a) criteria 3,4,5,6,7, 12, and 18a. Among other things, it relies on construction of a building that does not yet exist and for which it provides no evidence of intent to build, or of a building schedule that would support the proposed MRI timeline. No data in Section VIII, or Exhibit 2, the site narrative, indicate investment capacity or intent of Durham Realty, Inc. to build the proposed facility.

Detailed discussions in the attachments to this letter elaborate on reasons why the other applications should not be approved.

## CONCLUSION

Raleigh Radiology Cary's application is clearly the most cost effective, with the highest value among the three. It is the only one that fully conforms to the statutory review criteria; therefore, Raleigh Radiology's application should be approved and the others denied.

Thank you for your time and consideration. Please do not hesitate to call me if you have any questions.

Sincerely,



Satish Mathan, MD  
President, Raleigh Radiology Associates

Attachment(s)

**ATTACHMENTS**

Competitive Review of Duke University Health System, Application for Fixed MRI,  
Project ID# J-11167-16 ..... A

Competitive Review of Wake Radiology, LLC, Application for Fixed MRI,  
Project ID# J-11172-16 ..... B

Article: 3T versus 1.5T Siemens Magnetom MRI ..... C

Article: 3T Tool for Maximum Business and Clinical Productivity ..... D

Data: Treatment Cost Estimator Results – Duke University Health System,  
Wake Radiology, LLC, and Raleigh Radiology, LLC .....E

Correspondence: Request for Copy of Duke University Health System Exemption Request for  
Medical Office Building.....F

Excerpt: Novant Health Franklin Medical Center, 2015 Hospital License Renewal Application,  
MRI Services Patient Origin ..... G



# ***Attachment A***

---

Competitive Review of Duke University Health System,  
Application for Fixed MRI, Project ID# J-11167-16

*Competitive Review of –  
Duke University Health System, Application for Fixed MRI  
Project ID# J-11167-16*

---

**OVERVIEW**

This application to develop space in a proposed medical office building and install a fixed 1.5 tesla GE Optima MR450w in Holly Springs is non-conforming with statutory review criteria: 3, 4, 5, 6, 7, 12, and 18a.

**CON REVIEW CRITERIA**

**According to GS 131E-183(a)... an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.**

- 3. The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.**

The applicant proposes to serve southwest Wake County, Durham County and other counties in the state. It proposes less than 70 percent of its use will be from Wake County residents. However, the applications need analysis overlooks the need of patients in southeast Wake County, which has no MRI scanner and is the lower income sector of the county. It also fails to connect the proposed service to Durham County to the excess supply of DUHS scanners in Durham County.

The applicant has 17 official fixed scanners of which two are in Wake County (Section I.12) and 15 are in Durham County. It leases an Alliance mobile scanner for its facility in Cary, Wake County; and DUHS has four other MRI scanners “used solely for research in its Durham facility.” According to the application, DUHS received CON approval for another MRI scanner, J-8030-07, almost ten years ago, which it has not yet put in service. According to the Duke University Hospital Licensure Renewal application for 2016, DUHS also has one intra-operative MRI.

The application based need calculations on the population of Holly Springs / Apex, but the facility will be located in Holly Springs very close to Cary. In fact, the location is only 9.2 miles, and 12 minutes, from the Raleigh Radiology Cary site. Also, the town center of Apex is closer to the proposed Raleigh Radiology Cary site than to the proposed site for Duke Radiology Holly Springs. The application does not mention the population of Holly Springs. According to the US Census Quick Facts, the 2014 population was 30,157. According to the same source, the population of Cary was 155,227 in 2014 and the population of Apex was 43,907 in 2014.

To produce the volumes necessary to meet performance standards, the application relies on creative growth rates and “Project Shift,” market shifts from other Duke University Health System (DUHS) facilities. The application notes that Duke Raleigh Hospital (DRAH) facilities are operating at the administrative rule standard of 4,805 procedures and that desired time slots are not “easily scheduled” (page 60). However, the application relies on convenience, not need, to support the shift. Even by this argument, Raleigh Radiology is more convenient for many of the patients the DUHS application suggests will shift to the proposed Holly Springs scanner. DUHS projected that the majority of MRI patients from Apex who are currently getting scans at Duke Raleigh, Duke University Hospitals, and Duke Imaging Center Cary Parkway will shift to the new Holly Springs scanner. Apex is closer to Raleigh Radiology Cary. If the choice were simply based on convenience, these patients would select Raleigh Radiology Cary.

The project does not start until 2019, thus the application relies on population growth by 2021 to justify the utilization. Moreover, the CAGR for historical data at DRAH are overstated. The applicant’s arithmetic to get the 5.7 percent CAGR for outpatient and the 1.7 percent CAGR for inpatient appears to be flawed. None of the various forms of growth rates for the procedure categories presented by DUHS (Page 99) produce growth rates equal to those cited in the application. The table below shows the actual CAGRs using the DUHS’s own data from page 99 of its application.

**Table 1 - Calculation of CAGR for DRAH MRI Procedures FY 2013 to FY 2015**

Type of Procedure	FY 2013	FY 2014	FY 2015	FY 2016	FY 2013 - FY 2015 CAGR	CAGR/4
Inpatient w/Contrast	549	562	564	744	1.4%	0.3%
Inpatient w/o Contrast	434	455	453	476	2.2%	0.5%
Outpatient w/ Contrast	2,630	3,063	3,641	3,939	17.7%	4.4%
Outpatient w/o Contrast	2,580	3,050	3,967	4,130	24.0%	6.0%
All Inpatient	983	1,017	1,017	1,220	1.7%	0.4%
All Outpatient	5,210	6113	7,608	8,069	20.8%	5.2%
Procedures	6,193	7,130	8,625	9,288	18.0%	4.5%
Weighted	7,858	8,987	10,714	11,649	16.8%	4.2%

*CAGR Formula:  $(FV/PV)^{(1/n)} - 1$ , where n is the number of years.*

Dividing the true FY 2013 to FY 2016 CAGR by four would produce a forecast increase of only 3.6 percent a year.

This application appears to be designed more to preserve DUHS market share of existing MRI procedures and prevent other market entry than to serve an unserved population. On page 22, the application notes "Holly Springs residents currently travel approximately 21 miles to reach DRAH, or 31 miles to DUH and pass competitor facilities along the way. The heat map on page 42 suggests that patients from Holly Springs and southern Wake need a DUHS site in Holly Springs. However, the map measures only distance to other DUHS facilities. It ignores other, lower cost facilities in the same vicinity.

By failing to consider the need of the entire population of the service area, rather than the needs of DUHS to retain patients in its network, the application fails to demonstrate the need of the population to be served for an additional DUHS 1.5 tesla magnet. Thus, the application is non-conforming to this criterion.

**4. Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.**

The applicant's pro formas for year 03 show that only 41 percent of its total project expense will be for direct care. This reflects the high cost of the space in the proposed new building and the high administrative costs associated with DUHS operations. These costs also produce no improvement in technical MRI capability in the county. The proposed scanner strength is only 1.5 tesla and the service will be available only 70 hours a week, and those hours will not be available until the year 2020.

Lower cost alternatives are available in this competitive batch. Thus, the application is non-conforming to this criterion.

**5. Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs, as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.**

The DHUS application contains several financial assumptions that are unreasonable. In the third year of operation, Duke Radiology Holly Springs MRI proposes to serve 231 Medicaid beneficiaries. According to FORM E in its application, DUHS expects to collect no revenue for these patients. Medicaid covers MRI procedures provided they are medically necessary. As a result, DUHS understated its average net revenue per procedure. When evaluating net revenue per procedure, the CON reviewer should adjust for the fact that the DUHS average net revenue per procedure has been clearly understated.

The DUHS application also makes no allowance for normal delays associated with establishing a freestanding unit that does not bill Medicare on the basis of an existing hospital outpatient department. It presumes that DUHS will begin billing Medicare and Medicaid on the first day of service, a difficult feat for a provider that must procure a new Medicare and Medicaid provider number. Those can take months. If DUHS intends to bill under its existing provider number, then the proposed charges are likely understated. DUHS has good reason to maintain consistently high charges across all facilities that are tied to the hospital provider numbers. Medicare pays the lower of cost or charges. Medicare would look to the lowest DUHS charge and reduce all other DRAH MRI payments accordingly.

This application broadly references the new Medicare site-neutral payment provision, which for reference is in Section 603 of the Bipartisan Budget Act of 2015.<sup>1</sup> The application is not clear about the organization of the proposed imaging service. Is it a freestanding diagnostic center? If so, it will need new provider numbers. Is it a hospital outpatient department? If so, it will presumably use the Duke Raleigh Hospital provider numbers and the Duke Raleigh Hospital charge structure. Either way, the application is unclear and fails to demonstrate reasonable projections of charges.

Even if the proposed DUHS site will be considered a freestanding imaging center, DUHS suggested charges seem questionable. As noted in Raleigh Radiology's application, Duke Raleigh is consistently the most expensive provider of MRI services in Wake County. Using information publicly available from Blue Cross Blue Shield of North Carolina and calls made to Duke's Cary Parkway Imaging facility, Raleigh Radiology estimated a reasonable charge assumption for Duke Radiology Holly Springs.

Tables 2 and 3 below compare the charges for selected outpatient MRI procedures in the DUHS and Raleigh Radiology applications to those posted on the NC Blue Cross Blue Shield Treatment Cost Estimator for both applicants. The data show that for both organizations BCBSNC "allowable" rates are about 50 percent of gross charges.

---

<sup>1</sup> New Law Excludes New Provider-Based Off-Campus Outpatient Hospital Locations from OPSS  
<http://www.klgates.com/new-law-excludes-new-provider-based-off-campus-outpatient-hospital-locations-from-ops-12-08-2015/>

---

**Table 2 – DUHS Wake County Outpatient MRI Charges Compared to BCBSNC Cost Estimator Values**

Procedure	Duke Imaging Cary Parkway		
	Charge <sup>a</sup>	BCBS Report <sup>b</sup>	BCBS % of Charge <sup>c</sup>
Breast MRI Bilateral w and wo	\$ 4,456	\$ 2,039	45.8%
MRI Lower Extremity wo contrast	\$ 3,482	\$ 1,741	50.0%
MRI Brain w and wo contrast	\$ 4,814	\$ 2,349	48.8%
Average			48.2%

Notes: a: Obtained from calling Duke Imaging Cary Parkway  
b: Obtained from the BCBSNC Treatment Cost Estimator Tool  
c: b / a

**Table 3 – Raleigh Radiology Wake County Outpatient MRI Charges Compared to BCBSNC Cost Estimator Values**

Procedure	Raleigh Radiology		
	Charge <sup>a</sup>	BCBS Report <sup>b</sup>	BCBS % of Charge <sup>c</sup>
Breast MRI Bilateral w and wo	\$2,720	\$1,473	54.2%
MRI Lower Extremity wo contrast	\$1,470	\$725	49.3%
MRI Brain w and wo contrast	\$2,896	\$1,563	54.0%
Average			52.5%

Notes: a: Obtained from Raleigh Radiology internal charge data  
b: Obtained from the BCBSNC Treatment Cost Estimator Tool  
c: b / a

Assuming that each organization's percent of charge would be consistent with the averages shown in Tables 2 and 3, we believe that, in Year 03, based on the Commercial rates listed on Form D, Duke Radiology Holly Springs would have average charges of \$1,374 for its proposed MRI services, \$320 higher than what it lists in the application's pro formas. By the same logic, Raleigh Radiology would have charges of \$1,168, nine dollars less than what it included in the application. Table 4 shows these calculations.

**Table 4 – Expected Charges for Proposed MRI Based on Historical Percent of BCBSNC Charge Data**

Provider	Commercial Reimbursement <sup>a</sup>	Expected Charge <sup>b</sup>	Actual Charge in CON <sup>c</sup>
Duke Radiology Holly Springs	\$662	\$1,374	\$1,053
Raleigh Radiology Cary	\$613	\$1,168	\$1,177

Notes: a: CON FORM E  
b: a / Percent of charge calculated in Tables 3 / 4  
c: CON FORM D

As a result, it appears that DUHS’s charge assumptions are not reasonable.

In Section IX, the application shows only three months of working capital and \$80,000 required in the start-up period. Yet, the payor mix in the proforma assumptions show 32.6 percent Medicare and Medicaid and 57.6 percent Managed Care in the first year of operations. A new provider can take three to six months to get a new provider number and at least a few months to negotiate new rates with managed care companies. The application provides no detail to explain how the \$50,000 in working capital was calculated, or how the high first year Medicare and Medicaid revenue is achievable on a cash basis. DUHS’s charge, revenue, and working capital assumptions are not reasonable and therefore the application does not confirm with criterion 5.

**6. The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.**

The 2016 SMFP permits approval of only one additional fixed MRI scanner in Wake County.

The applicant has 17 official fixed scanners of which two are in Wake County (Section I.12). It also leases an Alliance mobile scanner for its facility in Cary and has other MRI scanners “used solely for research.” It received CON approval for another MRI scanner (J-8030-07), almost ten years ago, and has not yet put it in service. The applicant shows the proposed MRI Holly Springs project would become operational in July 1, 2018. However, the building in which it would be located is not yet under construction. The application contains no plans for the building, suggesting that plans are not even in preliminary design. Zoning for the site does not permit the proposed use (Section XI.1 (d)). The applicant’s history of delay in development of approved MRI CON, J-8030-07, suggests that the Holly Springs application is an attempt to prevent competition and to delay the time at which more MRI capacity would be available in Wake County. If DUHS were to receive the award and keep the MRI undeveloped, DUHS would continue to be the highest charge MRI provider in Wake County.

As demonstrated in Raleigh Radiology's application, Duke Raleigh's BCBSNC MRI reimbursement, which does not include professional radiologist fees, can be over 200 percent higher than Raleigh Radiology. The differential is even higher because the Raleigh Radiology fees include the professional radiology component. This means that the cost of a Duke MRI may be more than 200 percent higher than the cost of an MRI at Raleigh Radiology.

As noted in the discussion with regard to Criterion 3, the application relies on market shift of procedure volumes from existing DUHS MRI facilities, not a response to need of the population to be served. The justification for duplicating existing DUHS capacity is that the service will be "more convenient...for patients now using DRAH or Durham DUHS facilities." As noted earlier, Raleigh Radiology Cary would actually be more convenient for many of those patients. Also, higher costs are hardly convenient for anyone.

Insurance companies that serve Wake County have excluded DUHS facilities. For example, DUHS is notably excluded from the Blue Cross low cost Blue Value network.

*"BCBSNC was able to lower costs for the Blue Value plan by collaborating with UNC Health Care, REX Healthcare, WakeMed Health and Hospitals and Key Physicians, a medical home network of independent primary care practices, to reduce the price of coverage by as much as 15 percent\*. This smaller, more streamlined network of providers helps consumers control their costs without sacrificing benefits. Initially, Blue Value will be sold across the state, except in the Charlotte region." <sup>2</sup>*

For patients, this exclusion means extra cost in deductibles and coinsurance when they use DUHS facilities.

Approval of the DUHS application would also prevent or delay introduction of 3 Tesla capacities to the outpatient, non-research environment in Wake County.

DUHS had the option of replacing its high cost contract mobile in Cary Parkway with an owned fixed scanner. However, that facility is grandfathered under the Bipartisan Budget Act of 2015 to operate with the higher charge OPSS billing rates, because it was billing Medicare before November 2, 2015. Thus, the DUHS applicant appears to have made a strategic decision to optimize its revenues by keeping the high cost capacity in the high charge site and proposing to add a new facility on a delayed schedule that "may" offer lower charges.

For several reasons, this application does not promote the least costly alternative and is non-conforming to this criterion.

---

<sup>2</sup> Key IPA website NC Blue Cross <http://www.keymedicalhome.com/bluevalue/> accessed May 9, 2016.



**7. The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.**

As noted, the application provides no evidence that Durham Realty, Inc. intends to build the building that would house the MRI on the schedule proposed in the application. A medical office building requires the developer to file an Exemption request [131E-184(a) (9)]. However, according to the CON Section, no such Exemption request was filed prior to submission of the CON application. See correspondence in Attachment F.

Thus, the application is missing evidence of a resource essential to render this project operational at this location, and it is non-conforming to this criterion.

**12. Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.**

The application proposes to locate the project in a new building that does not yet exist. This is the most costly of all of the proposals, and most of the cost is associated with the building and site. In this case, the construction project will increase the cost of providing the service. Costs per procedure will be even higher if the project does not reach the volumes estimated in Section IV of the application.

The capital costs in Section VIII.2 are the highest of the three applicants, but cover only the costs to up fit a space in a building that does not exist. The application mentions and provides letters of intent from other DUHS departments to develop space in the building, but the application provides no drawings and no cost estimates for the building itself. Exhibit 19 contains only a site plan and the proposed floor plan for what appears to be a clinic with an MRI included. The application contains no dimensions for the proposed building. There is no commitment on the part of the proposed developer, Durham Realty, Inc. to build the building. Documentation provided in the application is limited to evidence that the developer purchased the site. However, even this is inconsistent. The cost of the site listed in VIII.2 does not match the cost in Exhibit 2 of the original application.

The high capital costs for this project and the number of extra rooms in the proposed floor plan suggest that this facility is intended to be a full diagnostic center. However, the application provides no information about need for such a center. The high capital cost make it non-conforming to this criterion and the absence of justification of the need of the population to be served for such a space would make it also non-conforming with criterion 3.

The application does not demonstrate that the means of construction will not increase the cost of providing the service and is non-conforming to this criterion.

- 18 a. **The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for the service for which competition will not have a favorable impact.**

#### **COST EFFECTIVENESS**

As noted above under review criterion 5 and 6 and as noted in Raleigh Radiology's application, Duke is a high cost provider. Its "allowable" rates for comparable procedures are consistently higher than that of other providers in the area (see Attachment E). Wake Key Community Care (WKCC) and Blue Cross clearly recognize this. DUHS and its affiliated providers are not members of either Blue Value or the WKCC ACO.

The application presents the intent to provide a freestanding outpatient site as evidence of a lower cost option that "may" offer lower charges than other DUHS locations in Wake County. A recipient of a CON is required to materially comply with representations in the application. Wording like "may" suggests that this applicant does not wish to be held accountable to charge structures presented in the application.

Its current pricing and history suggests that additional DUHS services will not have a positive increase on cost effectiveness. As a result, DUHS' application for the MRI at Duke Radiology Holly Springs does not confirm with criterion 18a.

# ***Attachment B***

---

Competitive Review of Wake Radiology, LLC, Application for  
Fixed MRI, Project ID# J-11172-16

***Competitive Review of –  
Wake Radiology, LLC Application for Fixed MRI, Wake Forest  
Project ID# J-11172-16***

---

**OVERVIEW**

This application to replace Wake Radiology’s four-day-a-week mobile MRI with a fixed 1.5 tesla Siemens Magnetom Aera MRI in Wake Forest is non-conforming with statutory review criteria: 3, 4, 5, 6,13(a),14, possibly 18a and Special Rule Performance Standard: 10 A NCAC .2703(b)(2).

**CON REVIEW CRITERIA**

According to GS 131E-183(a)... an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

3. **The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.**

The applicant identifies the population to be served by the proposed project as residents of Wake and Franklin Counties ( p 38) and proposes to provide most of its services to residents of those counties, increasing scans of Franklin County residents four-fold from 311 that it provided in 2015 to 1,342 in FY 2020 (p 57). Similarly, the applicant forecasts that scans of Wake County residents will increase from 763 to 2,176 in the same period. To accomplish this amazing increase in annual scans, the application indicates that when Novant Franklin County Medical Center closed in 2015, Wake Radiology added 87 scans from Franklin County over a six-month period ( p 57); then it forecasts that Wake Radiology will capture 90 percent of its forecast of what would have been Novant MRI Franklin scans ( p 49) . It ads this procedure count to its exceptional forecast Compound Annual Growth Rate of 37.3 percent for the “Wake Forest baseline.”

**Table 1 - Wake Forest Baseline Procedure Forecast for Wake Radiology**

Year	2017	2018	2019	2020	CAGR
Wake Forest Weighted Scans	1,402	2,284	2,889	3,630	37.3%

Source: Application page 49, Exhibit 22

Moreover, Forecasts in Exhibit 22 do not match the forecasts in Exhibit 6 (p 30).

**Table 2 - Wake Forest Baseline from Exhibit 6 Projected Fixed MRI Utilization**

Year	2017	2018	2019	2020
Wake Forest Weighted Scans	1,479	2,410	3,048	3,830

Source: Application page 30, Exhibit 6, data row 2

The assumptions for the utilization forecast for the new fixed MRI (p31) are aggressive and unsupported. Mathematically, the applicant needed them to reach the required 4,808 weighted procedures, but they are not realistic. When the aggressive CAGR fell short of the Year 03 performance standard, the application assumed an "added bump in utilization of 5.0 percent in year one and 4.0 percent in year two of operation," and "capture of ... 90 percent" of the applicant's forecast of Novant Health Franklin Medical Center's growth. As noted below that forecast is also overstated.

The "historic" CAGR of 7.26 percent calculated in Exhibit 20 is also inappropriate in this case. It includes startup years for the mobile; as might be expected in a start up, procedures increased 80+ percent between the first and second year. In subsequent years, the annual increase is actually much smaller, as illustrated in Table 3 below. In fact, Exhibit 20 shows that WRDI's fixed utilization in Raleigh dropped consistently from 2015 through 2016. A more realistic CAGR is in Table 3 below.

**Table 3 - Recalculated CAGR WRDI YE 2014 – 2016**

Location	2013	2014	2015	2016	CAGR 2014-2016
WRDI Raleigh	8,238	6,877	6,752	6,847	0%
WRDI Cary	3,198	4,152	3,681	4,412	3%
WRDI Garner	689	2,626	2,767	3,186	10%
WRDI Total Fixed	12,125	13,655	13,200	14,445	3%
Annual Change		0.13	(0.03)	0.09	

Source: Exhibit 20

The application added an 8 percent, one-year increase in the first year to an already inflated forecast and still did not generate sufficient procedures to meet performance standards.

It had to invent a way to borrow procedures from the closed Novant facility. The application's Franklin forecast for Novant does not allow for the fact that, in 2014, only 74 percent (580 / 787) of Novant's MRI patients came from Franklin County, according to the hospital's 2015 license renewal application, which is in Attachment G.

In Section III, the application also misleads the reader about population growth in Franklin County. Exhibit 8 cites total growth between 2016 and 2021 for both Wake and Franklin Counties, when the third project year is 2020. The North Carolina Office of Budget and Management expects Franklin County to grow less than one percent a year between 2016 and 2020, an increase of only 2,445 people.

**Table 4 - Franklin County Population Estimates**

2016	2017	2018	2019	2020	CAGR 2016 -2020
64,436	65,061	65,664	66,274	66,881	0.9%

Source: NCOSBM May 2016

Professing to focus on the Wake Forest area, application Exhibit 8 uses the entire population of Wake County to justify population growth. It fails to note that zip code 27614, which is included in its proposed MRI service area includes: WakeMed North, which provides MRI services.

Without this creative arithmetic, the proposed scanner in Wake Forest would not meet the required performance criterion in 10A NCAC 14C .2703(b)(4) of 4,808 weighted scans in Year 03, which is Federal Fiscal Year 2020.

Patient origin for the proposed fixed and the existing mobile unit are also confusing. In Exhibit 27, the application indicates that the mobile provided 763 scans to Wake County residents last year. Exhibit 28 says the fixed unit will provide 1616 MRI's to Wake County residents, double that by 2019, but it will quadruple the number of Franklin County scans.

The applicant overstates need in the population it proposes to serve and is non-conforming to this criterion.

**4. Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.**

The application argues that its own mobile scanner is inadequate, because it is only available four days a week and that it does not have a breast coil. The applicant has the power to change both of these factors, shifting more mobile days to Wake Forest and purchasing a breast coil. Neither action requires a Certificate of Need.

The application indicates that Wake Radiology will continue its own mobile MRI service in Wake Forest (p 50). This could mean that the proposed MRI would duplicate existing WRDI capacity, especially when the application shows that the mobile unit is not operating at the performance standard set by the state. With the mobile scanner still operating at its current location, approval of this application would give the applicant will excess capacity.

This discussion applies to Criteria 3 and 6, as well.

However, another far less costly solution is available to the applicant and the application is non-conforming with this criterion.

**5. Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs, as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.**

The application indicates in Section IX that the applicant will “expense startup costs and initial operating expenses.” However, it provides no interim year data in its proforma income statement for the new location. Without interim year operating statements, the application relies on reviewers’ imagination to determine the source of funds to hire the staff and organize the program prior to start of operations.

Without these data, the application does not demonstrate “availability of funds for capital and operating needs as well as immediate and long term financial feasibility of the proposal.” Moreover, with procedures overstated as discussed in Criterion 3, the application does not demonstrate long-term financial feasibility of providing services.

Moreover, charges reported on Form D suggest that this applicant will charge its self-pay patients more than its commercial patients. If this is true, the real value of its offer of \$100,000 in charity care for Wake Forest is, at best, over-stated. If not, the reasonableness of its proformas is questionable.

The proposal is non-conforming to this criterion.

**6. The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.**

The application fails to demonstrate the future of the mobile unit. It also fails to acknowledge the capacity of Raleigh Radiology Cary in its analysis of existing providers (p 58 and 60).

Clearly, the application is non-conforming to this criterion.

**13. The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:**

**(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;**

The fact that the applicant elected not to provide any information about the payor mix of its current mobile unit suggests that it may not be as generous to underserved populations as the application proposes. In Section VI, questions about history have no answers. The application justifies the response with a statement that the proposed MRI will be a new site. The fact that the applicant provided \$342,000 in charitable care from an organization with \$32,794,308 (Exhibit O) suggests that charitable care may have been 1.0 percent of gross revenue.

According to the US Census Quick Facts, for the period 2010-2014, 15.4 percent of Franklin County persons were below poverty level.<sup>1</sup>

In section VI.14, the application indicates that payor mix is based on the existing payor mix of MRI services offered at the Wake Forest office. If this is true, why does the application refuse to answer the question when it is asked in Section VI.12 and VI.13. Notably, when patient origin of the mobile site supported its argument, the application found it reasonable to present information (Exhibit 27).

The application fails to demonstrate access to underserved populations by its existing service, thus is non-conforming to this criterion.

---

<sup>1</sup> United States Census Bureau, Quick Facts, Franklin County, North Carolina, accessed on line May 2016.



14. **The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.**

On page 67, the application states that “at this time there are no immediate plans to use the new Wake Forest MRI Office for training purposes.”

The application is non-conforming to this criterion.

- 18 a. **The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for the service for which competition will not have a favorable impact.**

#### **COMPETITION**

Wake Radiology operates four fixed and one mobile MRI scanner in Wake County. It would not be a new provider of fixed MRI services.

#### **COST EFFECTIVENESS**

Wake Radiology proposes the highest charges among all applicants and has traditionally had a history of high charges for MRI services, that translates to

#### **QUALITY**

The application makes unsubstantiated claims about quality “favorability ratings.”

#### **ACCESS**

It is questionable that the application conforms to this criterion. It may duplicate an existing site for applicant and utilization forecasts appear both inconsistent and overstated.

According to GS 131E-183(b... the department is authorized to adopt rules in addition to these criteria

The following is a discussion of the rules for MRI.

## **NCAC 14C.2700: CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER**

### **10A NCAC 14C.2703: PERFORMANCE STANDARDS**

(b) An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:

- (2) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];

The service area is Wake County. On page 29 the application indicates that its existing mobile unit in Wake County did only 2,124 adjusted (weighted scans) in 12 months ending 3/31/16. The application is non-conforming to this criterion.

- (3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

- (A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,
- (B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,
- (C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,
- (D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or
- (E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;

To make these forecasts work, the application uses unreasonable forecasts for the proposed new scanner. Because the application is non-conforming with statutory criterion 3, it must also be non-conforming with this criterion.

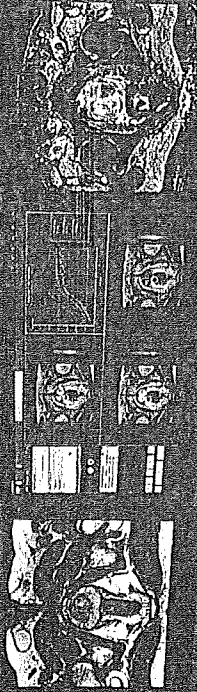
# *Attachment C*

---

Article: 3T versus 1.5T Siemens Magnetom MRI

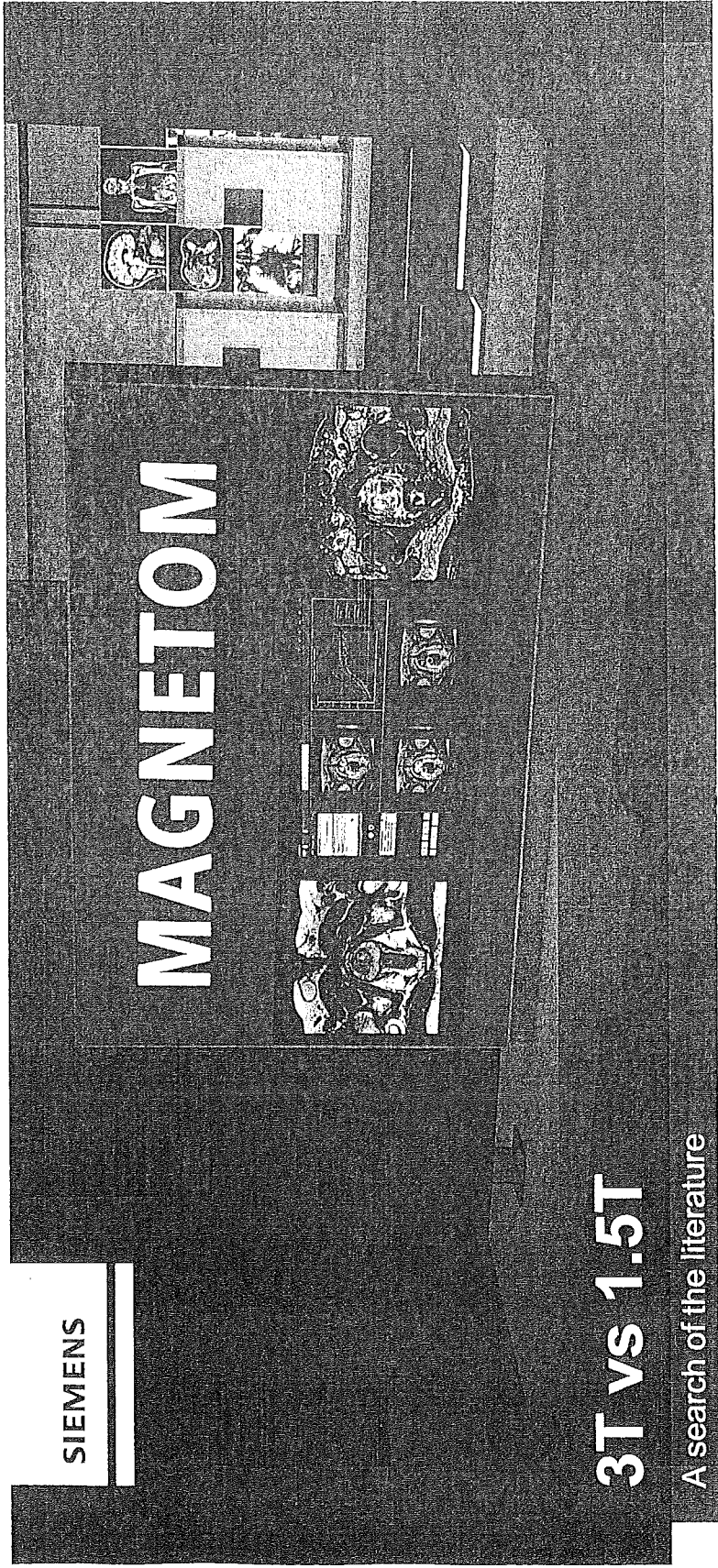
SIEMENS

# MAGNETOM



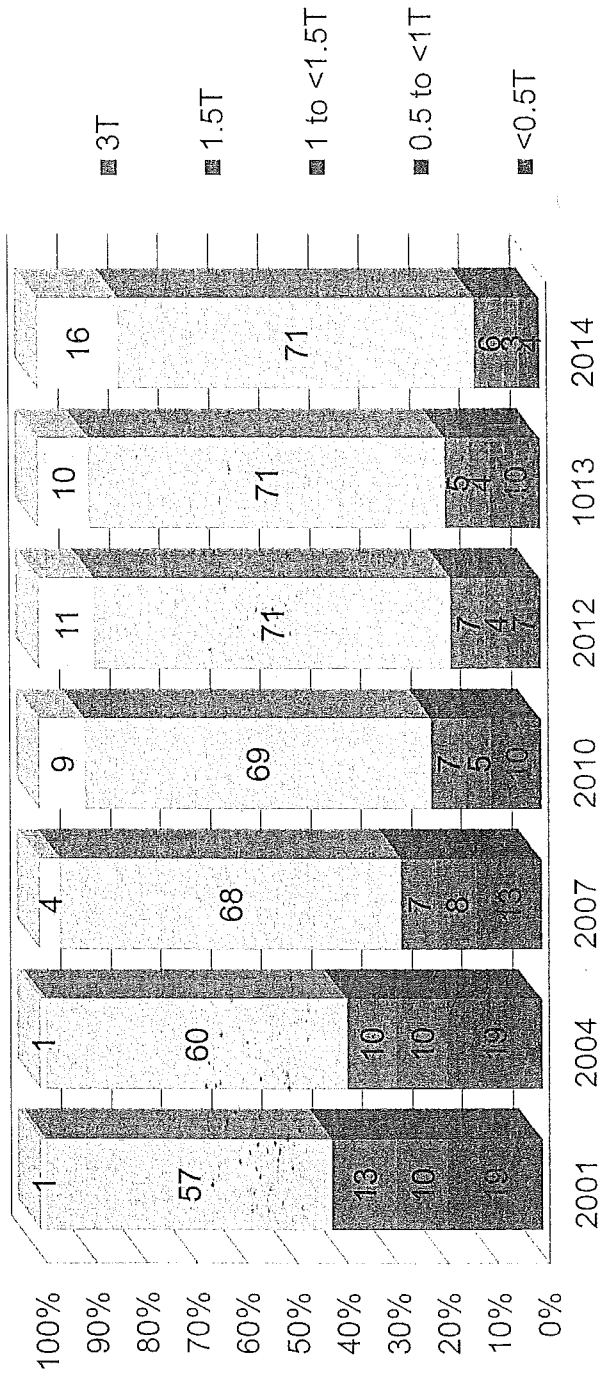
## 3T vs 1.5T

A search of the literature



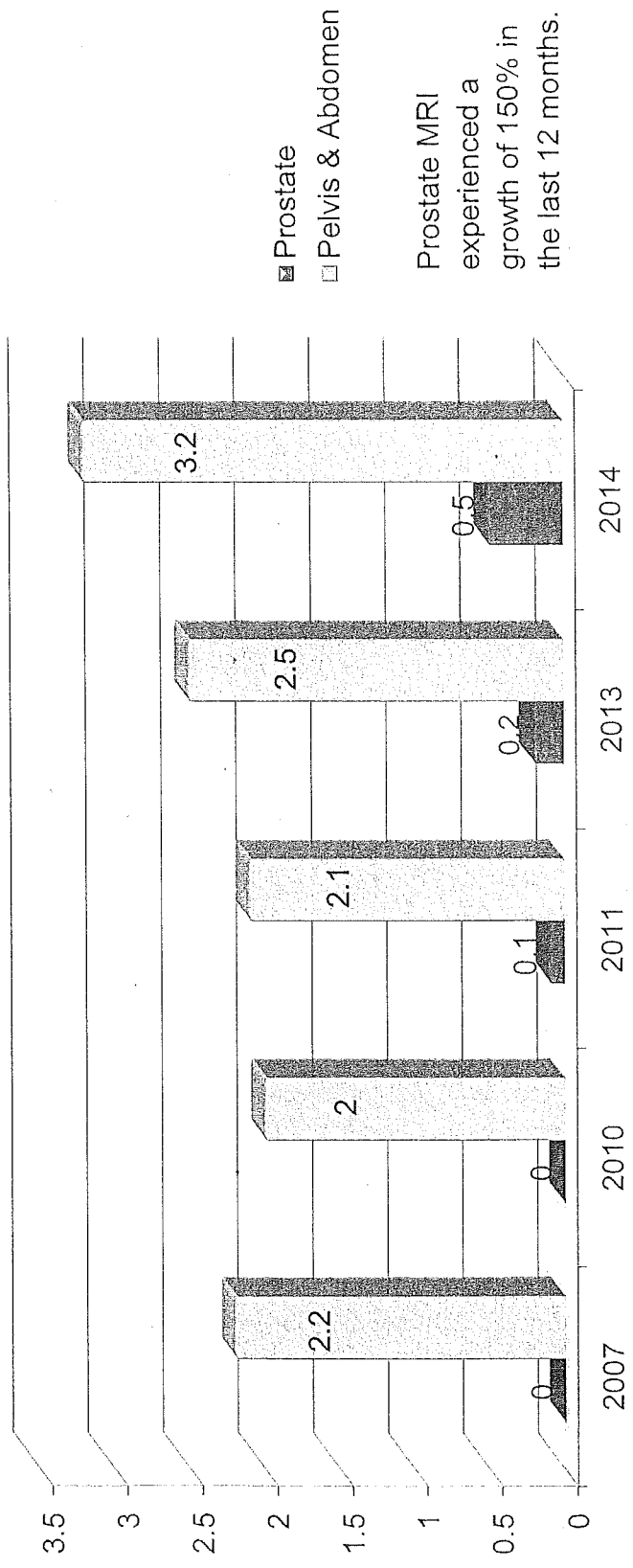
# SIEMENS

## Field Strength of MR % of Installed Base



**SIEMENS**

## High Procedure Growth Areas (Millions)

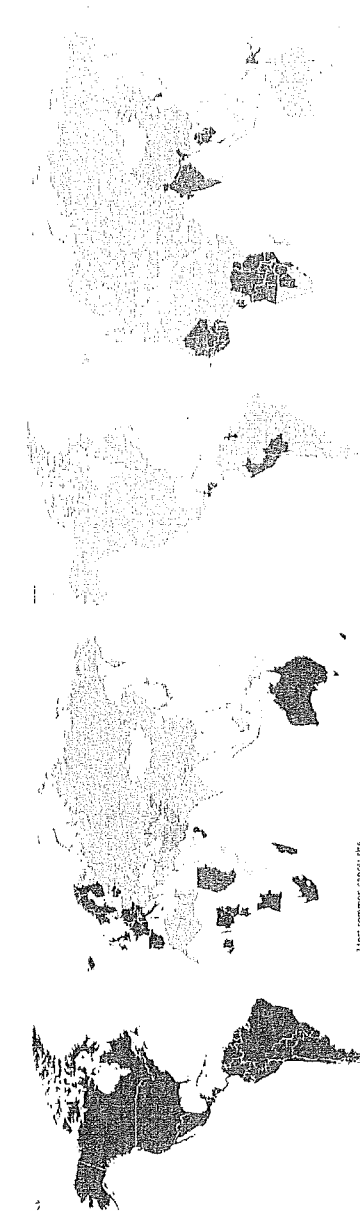


SIEMENS

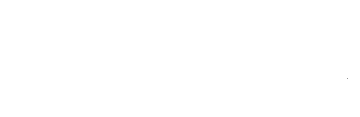
# MIR Men's Health Men's and Women's Cancer rates globally

## Most common cancer site per country (2008)

Men



Women



Most common cancer site

- Bladder
- Breast
- Cervix uteri
- Colon & rectum
- Esophagus
- Kaposi sarcoma
- Liver
- Lung & bronchus
- Non-Hodgkin lymphoma
- Ovary
- Prostate
- Stomach
- Thyroid
- No data

## MR Men's Health 3T vs 1.5T

SIEMENS

### Prostate Imaging

- Institutions desiring to commence a service line for prostate imaging have a strong preference to NOT use an endorectal coil for the procedure.
- Without an endorectal coil SNR challenges at 1.5T arise that are overcome with 3T.



3T Prostate  
Image with  
Body Array

Academy  
**RADIOLOGY**

Articles & Issues For Authors Journal Info Subscribe AUR More Periodicals

Previous Issue August 2004 Volume 11, Issue 8, Pages 857-862 Search Advanced Search

Next Article

### MRI imaging of the prostate at 3 tesla

Comparison of an external phased-array coil to imaging with an endorectal coil at 1.5 tesla

W. R. Hodge, MD, Lisa Fedorczak, MD, William C. Denson, MD, Holman K. Khandji, MD, Emaan F. Lebakoski, PhD, Ihab M. Raftoyiannis, MD

### Conclusion

Prostate image quality at 3T with a torso phased-array coil can be comparable with that of endorectal 1.5-T imaging. These findings suggest that additional options are now available for magnetic resonance imaging of the prostate gland.



**MR Men's Health**  
**Tim Open Architecture – Coils for Prostate Imaging**

SIEMENS

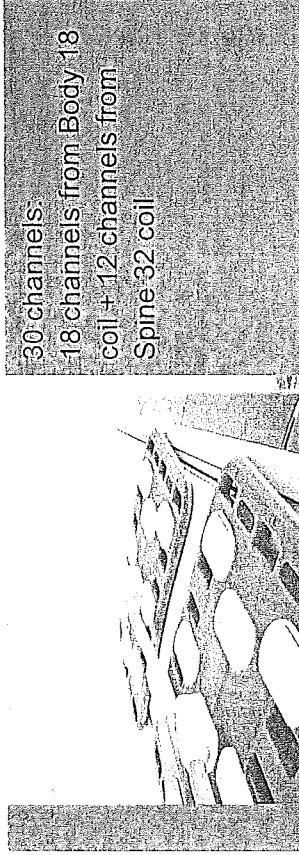
**JOURNAL OF  
 LOCAL  
 COMPUTE ASSISTED  
 TOMOGRAPHY**

Comparison of Phased-Array 3.0-T and Endorectal 1.5-T Magnetic Resonance Imaging in the Evaluation of Local Staging Accuracy for Prostate Cancer

Park, Euyng Kwan MD<sup>1</sup>; Kim, Bohyun MD<sup>1</sup>; Kim, Chan Kyo MD<sup>2</sup>; Lee, Hyun Aeo MD<sup>2</sup>; Kwon, Ghee

**Conclusions:**

The 3.0-T phased-array MRI is equivalent to the 1.5-T endorectal MRI in evaluating local staging accuracy for prostate cancer without significant loss of imaging quality.



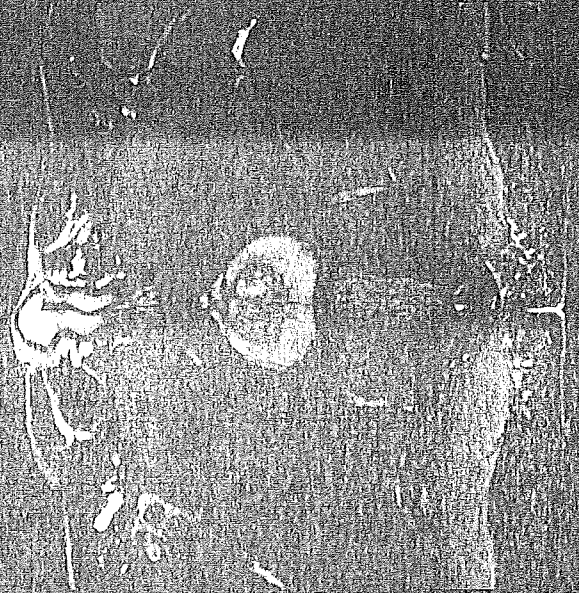
30 channels  
 18 channels from Body 18 coil + 12 channels from Spine 32 coil

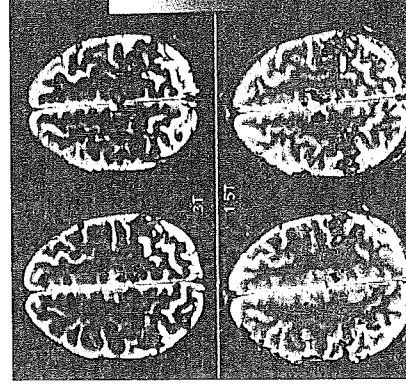
3T Coronal TSE Prostate

**MR Men's Health  
Prostate morphology:**

**SIEMENS**

**3T yields excellent resolution with body/spine coil combination only (no endorectal coil)**





## fMRI

- Functional MRI relies on small variations in SNR when acquiring a BOLD activation scan. The theoretical doubling of SNR at 3T enhances the BOLD effect compared to 1.5T.
- Images on right display the marked differences in activation maps from 3T vs 1.5T.

## Epileptic Disorders

ACCUEIL | NUMÉRO EN COURS | SPÉCIALISÉES | ARCHIVES | ACHETER UN NUMÉRO | ESPA

RÉDACTION | EN SAVOIR PLUS

MR imaging of epilepsy: State of the art at 1.5 T and potential of 3 T [Published with neuroimaging sequences.]

Volume 5, numéro 1, March 2003

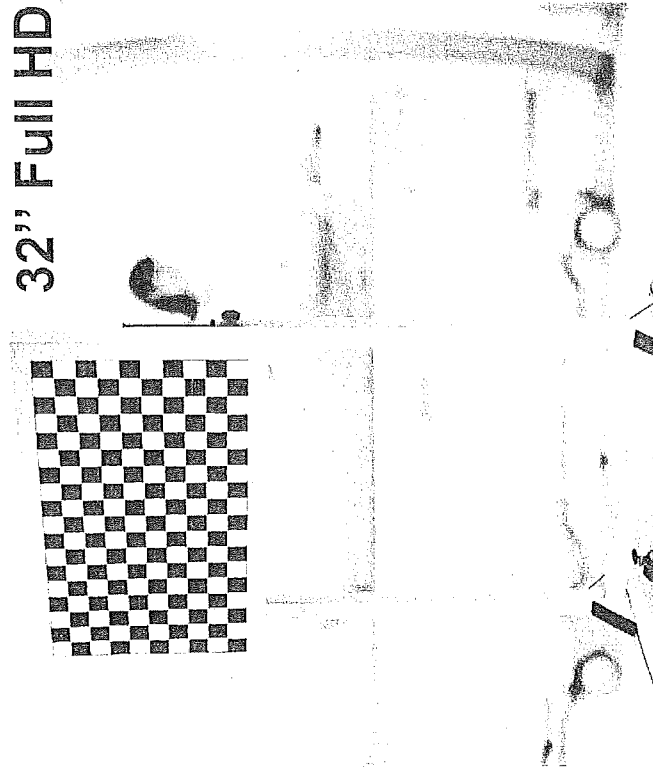
## CONCLUSION

Magnets with field strength of 3 T and above have been mainly used for research applications, however the benefits of high field strength for MRS and fMRI are obvious incentives for the use of 3 T systems in routine clinical investigations.

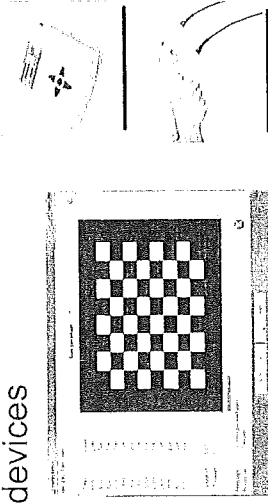
SIEMENS

NNL Basic fMRI System for Siemens: The tools to perform fMRI.

## 32" Full HD



- Stimulus presentation and workflow software
- In-Room LCD Monitor for stimulus presentation
- Response collection and synchronisation devices



**NNL**  
NordicNeuroLab

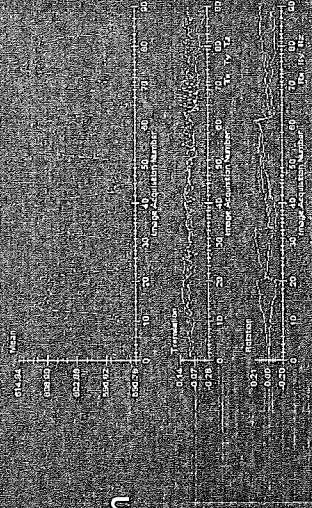
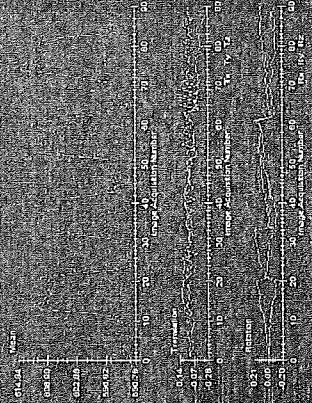
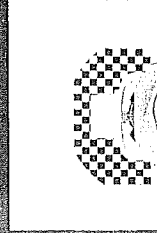
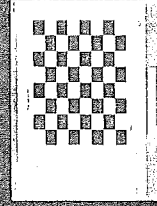
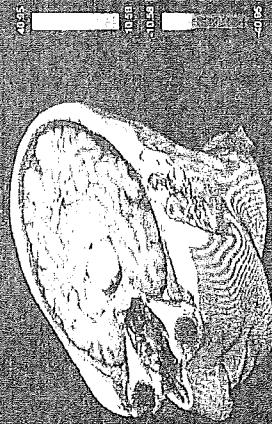
# BOLD Evaluation Real-time map calculation and ROI evaluation

Combined statistical and cluster-size threshold

3D suprathreshold cluster selection

Average time-course display for multiple ROIs

Display of motion correction parameters in three translation planes and rotation angles



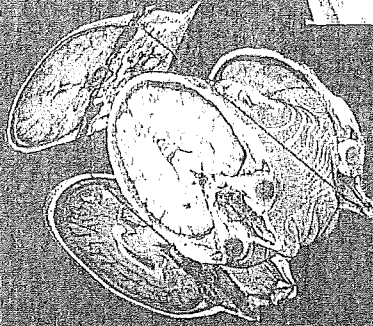
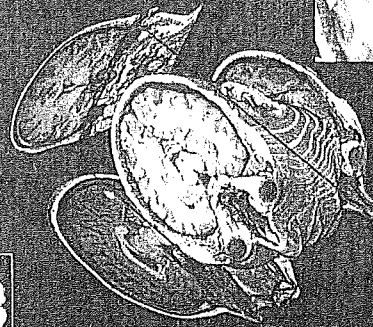
SIEMENS

**ZOOMit**  
High-resolution BOLD imaging. ZOOMit is only available at 3T

**Full FoV epi**



**Zoomed epi**



## MR Women's Health 3T vs 1.5T

SIEMENS

### Breast Imaging

- In the USA Breast MRI has become a significant percentage of all MR's performed after several years of significant growth.
- 3T, due to SNR improvements and fat sat superiority has become the field strength of choice for diagnostic breast MR.



3T Breast  
Images

Improving outcomes of screening breast MRI with practice evolution: initial clinical experience with 3T compared to 1.5T.

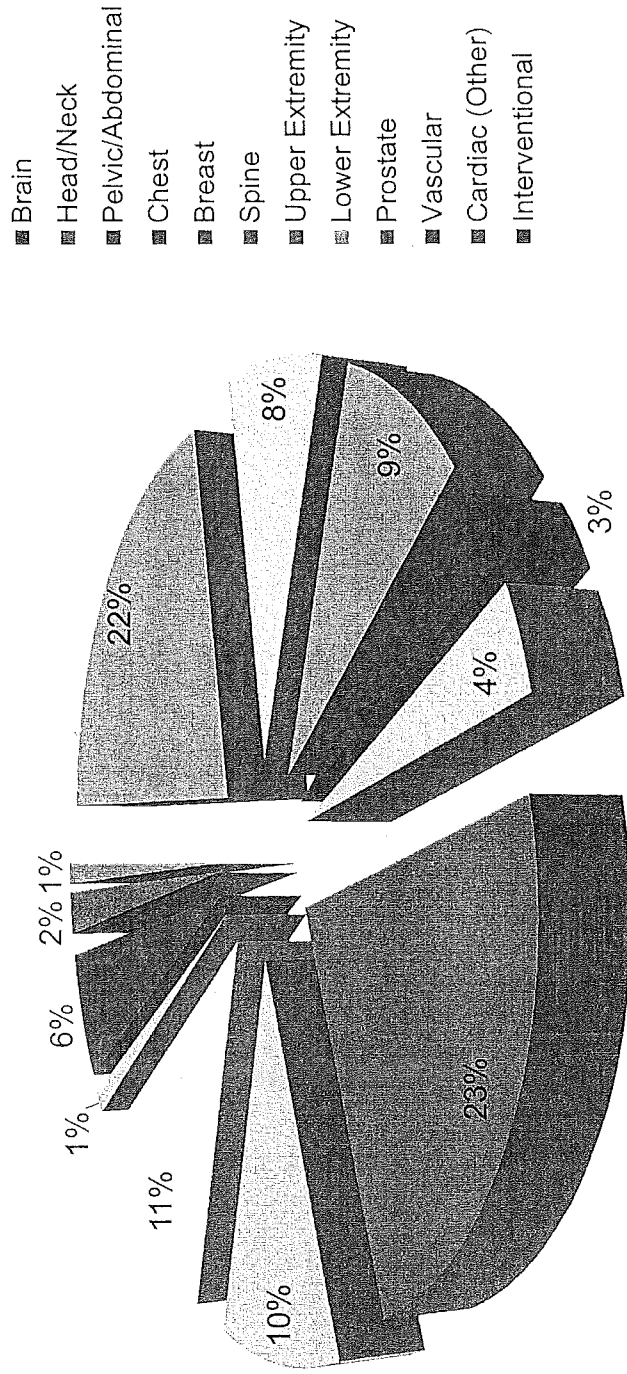
Laurenco AP<sup>1</sup>, Donegan L, Khalil H, Mainiero MB.

### CONCLUSION:

Transition to 3T breast MRI in a screening population resulted in increased BI-RADS 4/5 interpretations, positive predictive value of biopsy recommendations, and cancer detection rate.

SIEMENS

# Market Overview: Procedure Mix 2014 (%)



34.9 million procedures

Unrestricted © Siemens AG 2015 All rights reserved.

Magnetic Resonance



SIEMENS

**Zwanger Pesiri Contact**

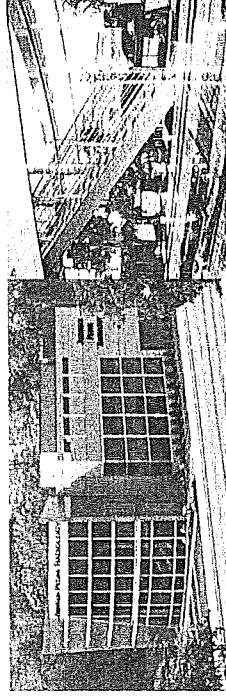
**Robert Day**

Chief Operating Officer at Zwanger Pesiri Radiology  
Greater New York City Area Medical Practice

Education: Zwanger pesiri Radiology  
State University of New York College at Cortland



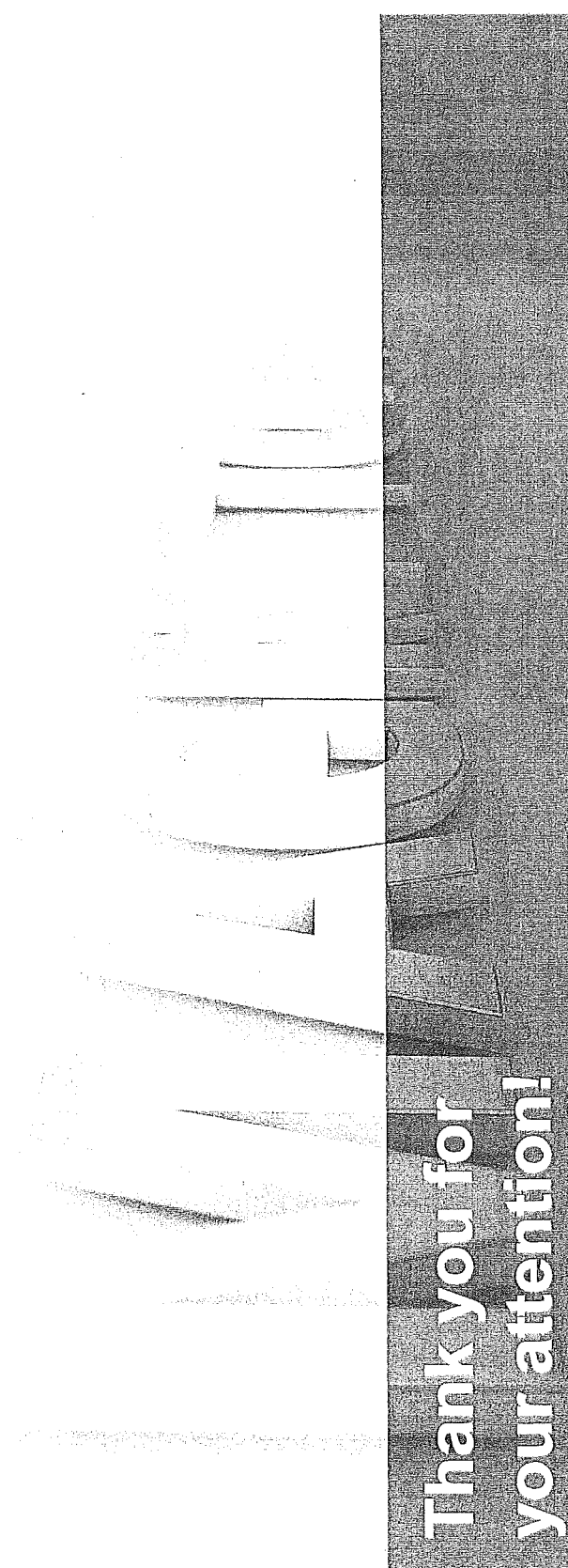
**ZWANGER-PESIRI  
RADIOLOGY**



**Corporate Headquarters**  
150 Sunrise Highway  
Lindenhurst, New York 11757  
United States

Phone: 631-225-7200

SIEMENS



**Thank you for  
your attention!**

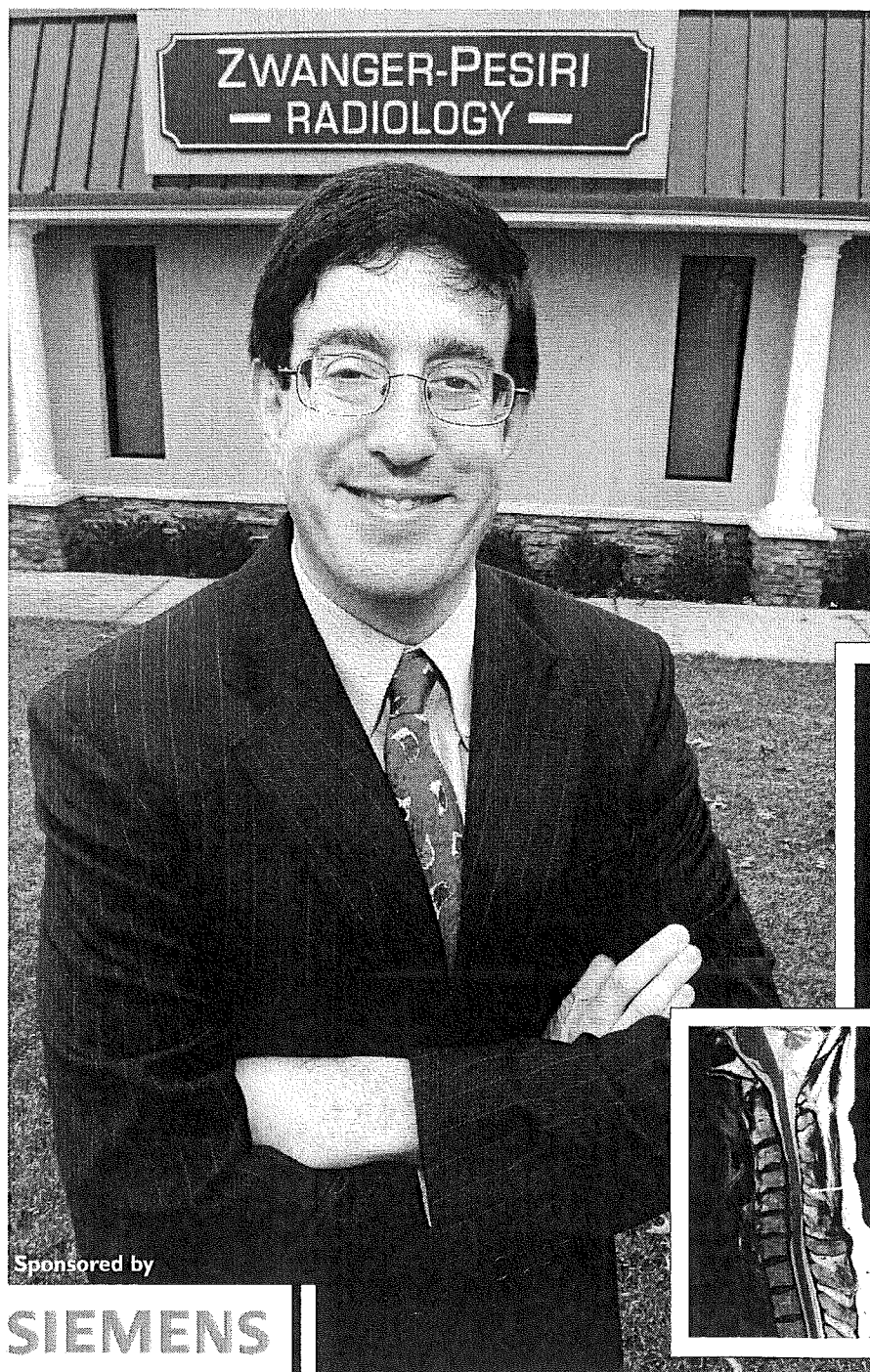
# ***Attachment D***

---

Article: 3T Tool for Maximum Business and Clinical Productivity

# 3T MRI

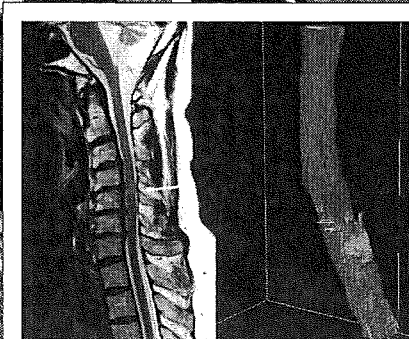
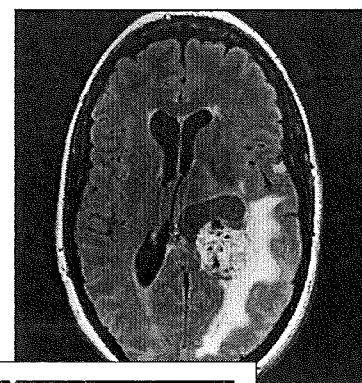
Tool for Maximum Business  
and Clinical Productivity



A Special Section in

**MEDICAL  
IMAGING**

**IMAGING  
ECONOMICS**



Sponsored by

**SIEMENS**

# Expanding Business and Clinical Options Using 3T MRI

*New high-field magnets give radiologists the ability to choose between fine, anatomical detail and increased examination speed*

By Dana Hinesly

**A** 3T MRI system gives an imaging provider new choices. The full potential of these magnets, commercially available for approximately the past 2 years, is starting to be discovered in richer detail. Linda Moy, MD, assistant professor of radiology at New York University (NYU), says, "With the increased signal-to-noise ratio, you can use it to get really fine anatomical detail, or you can use it to take the images even faster. You also

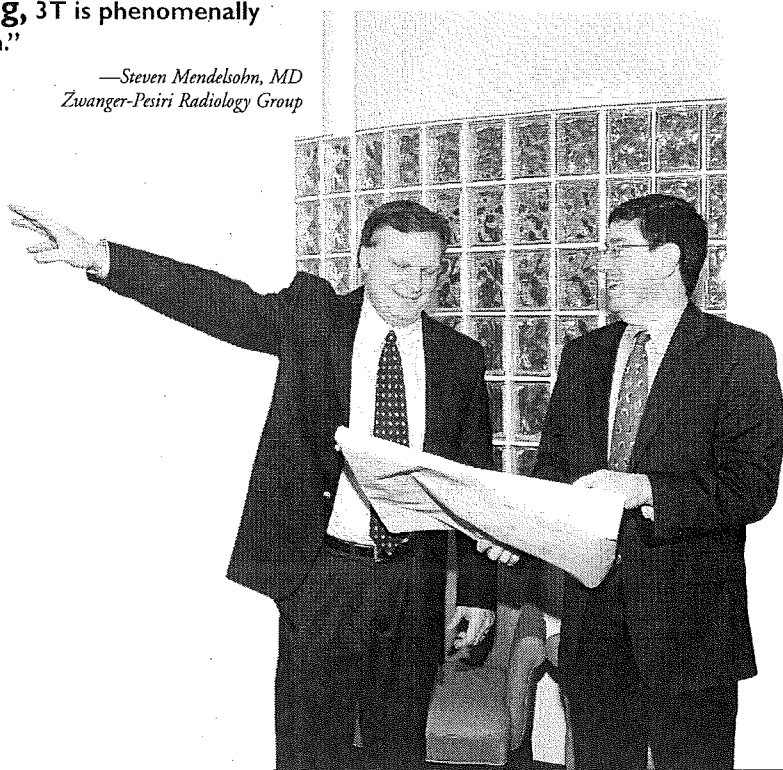
**"For orthopedic imaging, 3T is phenomenally better than even the 1.5T system."**

—Steven Mendelsohn, MD  
Zwanger-Pesiri Radiology Group

can use it to do a new type of functional imaging, which is much harder to perform at 1.5T; 3T gives radiologists more options. Think of it as extra currency."

That surplus can be spent in a number of ways, the most prevalent being improved images. In some specialties, the more powerful magnet simply outperforms its 1.5T counterpart. The two main areas in which 3T is significantly superior are musculoskeletal and neurological imaging, according to Steven Mendelsohn, MD, of Zwanger-Pesiri Radiology Group, which operates six imaging centers in New York. "The 3T does a tremendous job with musculoskeletal images, clearly delineating tears in any of the muscle structures that will affect the knee, the shoulder, or smaller joints," he says. "For orthopedic imaging, 3T is phenomenally better than even the 1.5T system."

Scanning at 3T is best for visualizing the smaller bony parts, such as the wrist, fingers, and hands, as well as for obtaining hip arthrograms or unilateral hip MRI. Timothy M. Cotter, MD, director of MRI at 3T Imaging, Morton Grove, Ill, says, "The 3T is also very good at looking for articular-cartilage abnormalities. It increases your confidence because



Robert Day, RT, chief technologist, (left) and Steven Mendelsohn, MD, review plans for a new Zwanger & Pesiri imaging center under construction in East Setauket, on Long Island, NY.

**“If we know a patient is going to be uncooperative—claustrophobic, for example—telling her that she has to be in the magnet for only 15 minutes, not a half-hour, increases the chance that the patient can complete the study.”**

—Linda Moy, MD  
New York University

your visualization of the articular-cartilage region is so much greater at 3T.” When it comes to neuroimaging, 3T is significantly better for detection of de-myelinating disease, such as multiple sclerosis, in the spinal cord. Because it shines in specific arenas, the 3T is subject to triage at many centers. “We have both 1.5T and 3T magnets, side by side, in two of our offices right now,” Mendelsohn says. “Our top priority is to put the musculoskeletal cases on the 3T, because the results are dramatically better. Then come the neuro cases, then body imaging, and then fine imaging for back pain, herniated discs, and metastatic disease.”

On their own, finer detail and improved diagnosis might be enough to justify the capital investment needed to acquire a 3T system; however, these scanners not only produce better-quality images, but they also generate the images in considerably less time. In general, this can make a difference in patient throughput at an imaging center. For some examinations, such as breast MRI, it also plays a significant role in improving patient care. “If we know a patient is going to be uncooperative—claustrophobic, for example—telling her that she has to be in the magnet for only 15 minutes, not a half-hour, increases the chance that the patient can complete the study on a 3T scanner that she wouldn’t be able to do on a 1.5T system, because of the shorter scan time.”

Rapid scans also help alleviate concerns about any potential for adverse affects associated with higher specific absorption rates. “For breast MRI, that really has not been an issue, and I think it’s because we have been able to reduce the scan time significantly,” Moy says.

motionless for a half-hour. At NYU, the team has used the 3T system to cut study time almost in half, resulting in reduced motion artifact. A bilateral routine breast examination, for instance, takes 25 minutes on the 1.5T scanner and about 13 minutes on the 3T.

#### Finding the Best Fit

Although image quality is improved because the patient is able to remain still, Moy reports that the images are comparable to those generated by NYU’s 1.5T magnet. Clinicians must decide for themselves whether to use shorter study times and produce images equal to those from a 1.5T system or invest a bit more time in a slower scan, generating higher-quality images. Exactly how a facility decides to apply these two options varies from one organization to another.

“We have a pretty full day, every day, on the 3T system; until now, we haven’t really used the benefit of the fact that you can go more quickly at 3T,” Cotter says. “Right now, we are doing really high-quality stuff and not really pushing the time, because we don’t need to yet.” Striking the ideal balance between these two capabilities of a 3T system, higher image quality and faster scanning, holds the potential to help facilities remain profitable, even in the face of substantial cuts in reimbursement as a result of the Deficit Reduction Act. (See “The Potential Impact of the DRA” on page S4.)

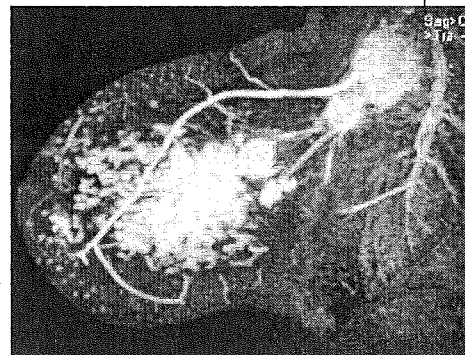
The increased speed can also be manipulated to make it possible for imaging providers to create extra time slots during the day to work patients into the schedule when necessary. Zwanger-Pesiri Radiology allows for the

More rapid scanning also improves image quality, according to Moy, because a prone patient has difficulty remaining

same amount of scan time whether the procedure is slated for the 1.5T system or the 3T MRI. Brain, spine, and orthopedic cases get 15-minute time slots; breast MRI and cardiac studies will get 30 minutes. “We can get an extra 10 or 15 minutes each hour, so we can have an opening each hour or every 2 hours, which is something we don’t really get on the 1.5T system,” Mendelsohn says. “It really gives us the latitude and the ability to add onto the 3T.” For many referring clinicians, this type of immediate access is very attractive, making it possible for their patients to be scanned on the same day that they determine that imaging is needed.

#### Reaching Referral Sources

Referring physicians will not be able to take advantage of such capabilities, of course, if they are not aware of them. Letting the medical community know about the advantages of a 3T magnet is an important step for imaging providers. When getting the message out about the new technology, Cotter recommends emphasizing the increased image quality available with the 3T. “The easiest thing to market is image quality; that will ring in some doctors’ ears,” he advises.



Lateral breast MR image at 3T exhibits multifocal ductal carcinoma in situ with lymph node involvement, as confirmed with PET.

Image courtesy of Linda Moy, MD, New York University.



**"In the future, the level of detail 3T provides is going to translate into additional surgeries and newer surgeries to help prevent the long-term progression toward degenerative joint disease and osteoarthritis."**

—Timothy M. Cotter, MD  
3T Imaging

The specialists who most appreciate the improved results are neurologists, orthopedists, and surgeons. "The images are more than just pretty: They help in diagnostic confidence and in arriving at a more definite answer."

Word of the improved images also is making its way into the patient population, and some imaging centers receive calls asking about the MRI technology being used. Putting out notice that a new 3T system is in place could prove beneficial. "I think that is a very good marketing strategy, because by doing it, you give patients the extra advantage," Cotter says. "They are going to be their own best advocates, as far as trying to push for the best technical imaging possible."

Another strategy for keeping a 3T MRI unit busy is to create collaborations with other imaging centers that are unable to afford the new technology. "We are working on creating a relationship with one of the local hospitals. Right now, unless you have an established program, you really can't do breast MRI because you need to have someplace for the patients to go if they have an abnormality," Cotter says. The goal is for 3T Imaging to provide access to a state-of-the-art MRI scanner for locations that are unable or unwilling to obtain a system on their own. In return, the imaging centers can add a few studies to the day. "We would be able to offer breast MRI on our 3T scanners," he says. "It's just a matter of how to best serve the patient."

When 3T scanners were introduced, the biggest complaint associated with them was the additional artifact created by the better signal-to-noise ratio. Such concerns are a thing of the past, according to Mendelsohn. "During the first couple of months of operating the 3T, you have to deal with artifact," he says. Once you develop your base and your technical skill sets, according to Mendelsohn, artifacts are less of a problem.

The systems themselves can be rather noisy, but this can be avoided. "Although the magnet may inherently be a bit noisier, if people pay attention to the construction of the MRI room and keep the acoustics in mind, they can make the magnet very quiet," Mendelsohn says. He recommends working with experienced engineers to address any type of vibrational problem. Adjustments can include such features as

sound-absorbing walls, along with properly securing the magnet. "Doing it right doesn't really cost a tremendous amount of money and, in the total scheme of things, is not that much," Mendelsohn says. "If you are prepared, you do not need to be able to hear it outside the room."

### Molding the Future

By and large, the future looks bright for 3T magnets. As clinical trials continue, and protocols similar to those that exist for 1.5T machines

are put in place, the increased visibility of the systems is likely to advance not only diagnosis, but treatments as well. "In the future, the level of detail 3T provides is going to translate into additional surgeries and newer surgeries to help prevent the long-term progression toward degenerative joint disease or osteoarthritis," Cotter says. "The clinical quality of the 3T is definitely going to shine."

Dana Hinesly is a contributing writer for Imaging Economics and Medical Imaging

## The Potential Impact of the DRA

Early in 2006, the Deficit Reduction Act (DRA) of 2005 was signed into law. Slated to go into effect in 2007, the regulations limit payments for imaging services performed in nonhospital outpatient settings. Among various other changes, the legislation limits the technical-component reimbursement for outpatient imaging to the Hospital Outpatient Prospective Payment System payment. It also reduces payment for contiguous imaging procedures performed at the same time by 25%. Mammography is not subject to either change.

According to Steven Mendelsohn, MD, of Zwanger-Pesiri Radiology Group (which has six imaging centers throughout New York), "The DRA will radically affect all outpatient practices because it essentially reduces payments on CT scans and MRI by about 25% to 30%," Mendelsohn adds that the new mandate will force imaging providers to pay closer attention to the bottom line. "Once they analyze the cost of each component, they will be able to improve efficiency. For example, if they can operate safely with only one MRI technologist per machine, then they will do so."

Two bills concerning access to medical imaging have been introduced: one in the Senate (S 3795) and one in the House of Representatives (HR 5704). If passed, they would require a 2-year moratorium on the cuts in reimbursement for medical imaging. Currently, the proposed legislation is working its way through Congress. If the delay is not enacted, independent centers like 3T Imaging, Morton Grove, Ill.—where Timothy M. Cotter, MD, is a partner and director of

MRI—will have to arrive at new strategies for maintaining a profitable business.

"Right now, there is a larger margin of profit, therefore, you can go with the 3T system, understanding that you're going to be able to capture business from the area," Cotter says. "The fact that you are reimbursed the same amount for 1.5T or 3T means that if the overhead goes up considerably, it's going to change your perspective." One solution might be leveraging the faster speed of the 3T system to increase patient throughput at the imaging center. With more studies being done, profit margins would be able to remain intact.

Although one may speculate that concerns about the DRA would dampen sales of 3T, sales of the high-field magnets continued to grow as a percentage of the market in 2006, according to Christopher Boyea, Ultra High Field marketing manager, MRI, Siemens Medical Solutions, Malvern, Penn.

"Obviously, 3T is more expensive, and the DRA may have the unfortunate effect of decreasing the number of 3T magnets that are sold," Mendelsohn says. "I say 'unfortunate' because I think 3T is a significant step in improvement in MRI. The question is whether imaging centers will stop buying them to save money or realize, instead, that buying newer equipment potentially can enable them to scan better and faster. They can make the difference up with an increase in volume and an increase in productivity."

—D. Hinesly

# Advanced Neuroimaging at 3T

**At 3T**, the clinical utility of MRI expands dramatically; when it is paired with total imaging matrix (Tim) technology from Siemens Medical Solutions, Malvern, Pa, the results are a better signal-to-noise ratio (SNR), the suppression of artifacts, and more rapid scanning. These increase patient throughput and make it possible to scan more case types.

In difficult areas of imaging, the most rewarding improvements are seen at 3T. Neuroradiology includes some notoriously challenging procedures, often for life-threatening conditions. It has been a relief for neuroradiologists to see the expansion of 3T MRI into these arenas.

As Meng Law, MD, explains, diffusion tensor imaging (DTI) of the cervical spinal cord with Tim can help the neuroradiologist differentiate between multiple sclerosis (MS) and spinal-canal stenosis and can track MS progression. In spondylosis, DTI can separate edema from gliosis. DTI also may be useful in spinal-cord trauma, masses, and vascular lesions, as well as in amyotrophic lateral sclerosis.

Neeraj B. Chepuri, MD, reports on a case in which 3T MRI prevented a patient from losing language capabilities. The patient needed to have a large capillary hemangioblastoma removed from the brain. Using 3T functional MRI (fMRI), the surgeon was able to plan an approach that avoided the Wernicke language-processing area; 3 days after surgery, the patient had regained full language abilities.

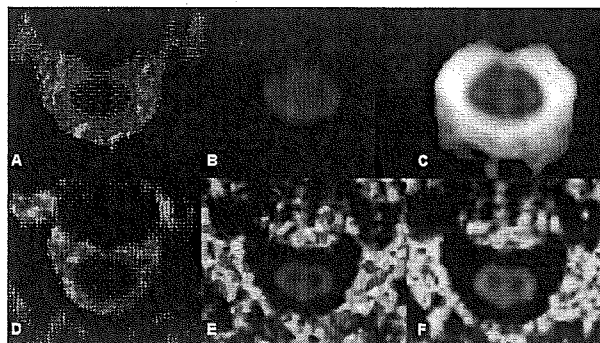
## Diffusion Tensor Imaging of the Cervical Spinal Cord at 3T

By Meng Law, MD

Clinical use of diffusion-weighted imaging and DTI of the human spinal cord faces a number of technical challenges. The small size of the spinal cord necessitates the use of small voxel sizes for spatial resolution, at the expense of SNR. Images may be degraded as a result of macroscopic motion related to cerebrospinal-fluid pulsation, patient breathing/swallowing, or gross patient

analysis of DTI maps, care must be taken to avoid including cerebrospinal fluid in the regions of interest, which would produce a misleading change in DTI metrics (decreased fractional anisotropy and increased mean diffusivity). The synergistic advantage of combining DTI of the cervical spinal cord at 3T with parallel imaging techniques using Siemens Medical's Tim technology is that together, they provide increased SNR, create increased temporal resolution (more rapid scanning), and overcome some artifacts, such as susceptibility and physiological motion. This synergy produces improved reproducibility and wider clinical applicability for DTI of the cervical spinal cord at 3T.

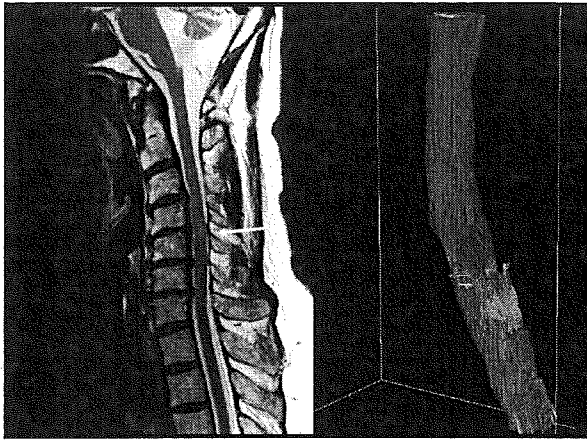
DTI has shown promise in the evaluation of white-matter-tract integrity, and has been demonstrated to be able to detect changes due to spinal-canal stenosis affecting the spinal cord,<sup>4,5</sup> typically consisting of decreased fractional anisotropy and increased mean diffusivity. These changes in fractional anisotropy and mean diffusivity may not be sufficient to differentiate between potentially reversible edema



*Figure 1. Diffusion tensor imaging maps through the cervical spinal cord at the C4/5 level comparing A (whisker plot), B (color fractional anisotropy), and C (black-and-white fractional anisotropy) at 1.5T (top row) and 3T (bottom row) [Magnetom Trio with Tim technology from Siemens Medical Solutions].*

motion. Local-field inhomogeneity also contributes to image degradation.<sup>1,2</sup> Echo planar DTI can be performed in a reasonable amount of time for clinical use, and single-shot techniques may limit the adverse effect of in-plane bulk motion to some extent. New techniques using parallel imaging,<sup>3</sup> as well as pulse triggering or cardiac gating, should further minimize image degradation. In the





**Figure 2.** (A) Sagittal T2 weighted image in a patient with neck pain, demonstrating some abnormal increased T2 signal within the spinal cord at the C4/5 level (white arrow). (B) Diffusion tensor imaging and fiber tractography at 3T (Magnetom Trio with Tim technology from Siemens Medical Solutions) demonstrates abnormal diffusion within the posterior columns of the spinal cord in patients with MS.

and irreversible gliosis in patients with spondylosis. The evaluation of the diffusion eigenvalues (from which fractional anisotropy is calculated) may, however, assist in identifying subgroups of patients with axonal damage (longitudinal diffusion eigenvalues) versus reversible edema (transverse diffusion eigenvalues).<sup>6</sup> This has important implications for whether a patient would benefit from neurosurgical decompression instead of more conservative medical management. The improved SNR, shorter scanning times, and resultant decrease in motion artifacts at 3T allow more reliable and robust data sets than those obtained at 1.5T, permitting this analysis (see Figure 1, page S5). The maps obtained at 3T demonstrate improved SNR and better delineation of the spinal cord's gray matter from white matter. The combination of higher SNR at 3T, parallel imaging, and shorter scan times improves image quality and decreases artifacts associated with scanning the spinal cord.

A common clinical problem faced by the neuroradiologist is finding abnormal T2 signal within the cervical spinal cord and deciding whether the changes are due to degenerative spinal-canal stenosis or to primary demyelination, as seen in MS (see Figure 2). In a patient with some mild degenerative spinal-canal stenosis, the differential diagnoses are cord edema and myelomalacia from degenerative spinal stenosis (versus primary demyelinating disease from MS). In degenerative spinal stenosis, the changes in diffusion usually affect the anterior spinal cord.

Evaluation of the spinal cord has become increasingly important in both the diagnosis of MS and the follow-up care of MS patients, as changes in the spinal-cord function of MS patients have been shown to correlate with clinical disability.<sup>7</sup> DTI changes in MS patients recently have been detected in the cervical spinal cord using a sagittal DTI technique and evaluating large regions of interest using histogram analysis.<sup>8,9</sup> It is generally accepted, however, that the lesions of primary demyelination have a predilection for the posterior columns of the spinal cord; therefore, analysis of DTI metrics in different regions of the spinal cord may demonstrate spatial differences. Bot et al investigated the spinal cords of postmortem MS patients using high-field MRI with histopathologic correlation.<sup>10</sup> Histopathology showed significant axonal loss, increased axonal diameter, and decreased myelin density in normal-appearing spinal cord in MS patients. Using DTI, fractional anisotropy is significantly lower in the normal-appearing spinal cord of MS patients in the lateral, posterior, and central cord, compared with controls.<sup>11</sup> Hence, DTI can help in differentiating MS from other causes of abnormal spinal-cord signal by demonstrating changes in fractional anisotropy and mean diffusivity within the posterior columns (versus changes occurring within the anterior columns in degenerative spinal-canal stenosis). Measurement of DTI metrics in the cervical spinal cord may prove useful not only in aiding the diagnosis of MS and correlating with clinical disability, but in monitoring disease progression and therapeutic effects, as well.

DTI at 3T also shows promise in the evaluation of other spinal-cord pathologies. Besides MS and degenerative spinal-canal stenosis, it has potential applications in other disorders affecting the cord, such as amyotrophic lateral sclerosis, spinal-cord mass lesions, spinal-cord trauma, and vascular lesions of the cord, as well as in the evaluation of recovery from spinal-cord injury.<sup>2,12</sup> Improvements in coil technology, coupled with optimization of pulse sequences and parallel imaging techniques at 3T, will soon make DTI even more accessible and reproducible in clinical practice. This, in turn, will benefit many patients with spinal-cord disease.

*Meng Law, MD, is associate professor of neurosurgery and radiology at the New York University Medical Center.*

## References

- Maier SE, Marnata H. Diffusion tensor imaging of the spinal cord. *Ann N Y Acad Sci.* 2005;1064:50–60. Available at: <http://www.annalsnyas.org/cgi/content/abstract/1064/1/50>. Accessed November 9, 2006.
- Clark CA, Werring DJ. Diffusion tensor imaging in spinal cord: methods and applications—a review. *NMR Biomed.* 2002;15:578–586. Available at: <http://www3.interscience.wiley.com/cgi-bin/abstract/101521429/ABSTRACT>. Accessed November 9, 2006.
- Tsuchiya K, Fujikawa A, Suzuki Y. Diffusion tractography of the cervical spinal cord by using parallel imaging. *AJNR Am J Neuroradiol.* 2005;26:398–400. Available at: <http://www.ajnr.org/cgi/content/full/26/2/398>. Accessed November 9, 2006.
- Marnata H, Jolesz FA, Maier SE. Apparent diffusion coefficient and fractional anisotropy in spinal cord: age and cervical spondylosis-related changes. *J Magn Reson Imaging.* 2005;22:38–43. Available at: <http://www3.interscience.wiley.com/cgi-bin/abstract/110542104/ABSTRACT>. Accessed November 9, 2006.
- Facon D, Ozanne A, Fillard P, Lepointre JF, Tournoux-Facon C, Ducreux D. MR diffusion tensor imaging and fiber tracking in spinal cord compression. *AJNR Am J Neuroradiol.* 2005;26:1587–1594. Available at: <http://www.ajnr.org/cgi/content/abstract/26/6/1587>. Accessed November 9, 2006.
- Hesseltine S, Law M, Lopez S, Bobb J, Johnson G. Diffusion tensor imaging of the human spinal cord: determination of normal regional metrics. Paper presented at: International Society of Magnetic Resonance Medicine; May 6–12, 2006; Seattle. Available at: <http://www.ismrm.org/06/ep3.htm>. Accessed November 14, 2006.
- Lin X, Tench CR, Turner B, Blumhardt LD, Constantinescu CS. Spinal cord atrophy and disability in multiple sclerosis over four years: application of a reproducible automated technique in monitoring disease progression in a cohort of the interferon  $\beta$ -1a (Rebif) treatment trial. *J Neural Neurosurg Psychiatry.* 2003;74:1090–1094. Available at: <http://jnnp.bmj.com/cgi/content/abstract/74/8/1090>. Accessed November 9, 2006.
- Valsasina P, Rocca MA, Agosta F, et al. Mean diffusivity and fractional anisotropy histogram analysis of the cervical cord in MS patients. *Neuroimage.* 2005;26:822–828.
- Agosta F, Benedetti B, Rocca MA, et al. Quantification of cervical cord pathology in primary progressive MS using diffusion tensor MRI. *Neurology.* 2005;64:631–635. Available at: <http://www.neurology.org/cgi/content/abstract/64/4/631>. Accessed November 9, 2006.
- Bot JCI, Blezer EA, Kampschorst W, et al. The spinal cord in multiple sclerosis: relationship of high-spatial-resolution quantitative MR imaging findings to histopathologic results. *Radiology.* 2004;233:531–540. Available at: <http://radiology.rsnajis.org/cgi/content/abstract/233/2/531>. Accessed November 9, 2006.
- Hesseltine SM, Law M, Bobb J, et al. Diffusion tensor imaging in multiple sclerosis: assessment of regional differences in the axial plane within normal-appearing cervical spinal cord. *AJNR Am J Neuroradiol.* 2006;27:1189–1193. Available at: <http://www.ajnr.org/cgi/content/abstract/27/6/1189>. Accessed November 9, 2006.
- Schwartz ED, Chin CL, Shumsky JS, et al. Apparent diffusion coefficients in spinal cord transplants and surrounding white matter correlate with degree of axonal dieback after injury in rats. *AJNR Am J Neuroradiol.* 2005;26:718. Available at: <http://www.ajnr.org/cgi/content/abstract/26/1/718>. Accessed November 9, 2006.

## Functional Brain MRI: A Case Presentation

By Neeraj B. Chepuri, MD

A 47-year-old woman presented to Abbott Northwestern Hospital, Minneapolis, in June 2006 because of a visual disturbance that she described as decreased acuity and jumpiness in her right visual field, as well as some incoordination in her right hand and leg as well as increasing headaches. This prompted a brain MRI, which demonstrated a large mass in the trigone of the left lateral ventricle. The majority of the mass enhanced intensely, indicating

a vascular nature for the lesion. A perilesional cyst also was present. Marked edema was present in the left temporal and parietal lobes. The initially suspected diagnosis was choroid-plexus papilloma (versus choroid-plexus carcinoma). The possibility of an intraventricular meningioma also was raised, but this was thought less likely due to the extensive edema within the adjacent brain tissues.

Due to the patient's symptoms and the large amount of edema and mass effect secondary to the tumor, a decision was made, with the patient, to attempt a gross total resection. Because of the proximity of the lesion to the left temporal lobe and the desire to preserve language function, preoperative functional MRI (fMRI) was performed. A

lateral approach through the temporal lobe was considered.

A story-reading paradigm was employed and blood-oxygen-level dependent (BOLD) fMRI was performed. The functional activation map for this paradigm is shown in Figure 1A, superimposed on an anatomical axial fluid-attenuated inversion-recovery (FLAIR) image. As shown, the patient's Wernicke area (partially responsible for language processing) was located directly in the path of the contemplated surgical resection (arrow). After

consultation between the neurosurgeon and neuroradiologist, the neurosurgeon's decision was to alter the path of resection through the brain in an attempt to avoid the area of Wernicke activation. A surface-rendered view of the brain with overlaid functional activations is shown in 1B. The arrow represents the Wernicke language-processing area.

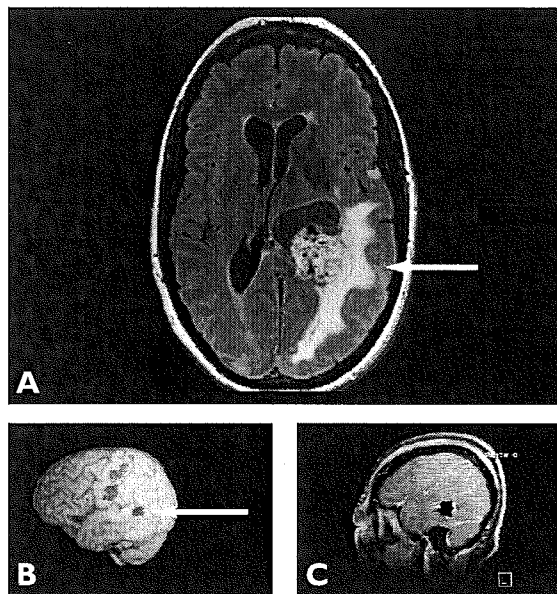
During surgery, a highly vascular, cherry-red mass was noted in the lateral ventricle. A gross total resection was performed. Final pathology revealed a diagnosis of capillary hemangioblastoma.

Follow-up brain MRI revealed no residual contrast enhancement in the left lateral ventricle, confirming the intraoperative impression of gross total resection. Sagittal postoperative MRI (1C) compared with the volume-rendered preoperative MRI with functional overlay (1B) shows that the preoperative strategy of avoiding the Wernicke area was achieved. The resection tract was through an area of the left temporal lobe approximately 10 mm inferior to the Wernicke activation demonstrated on the preoperative fMRI.

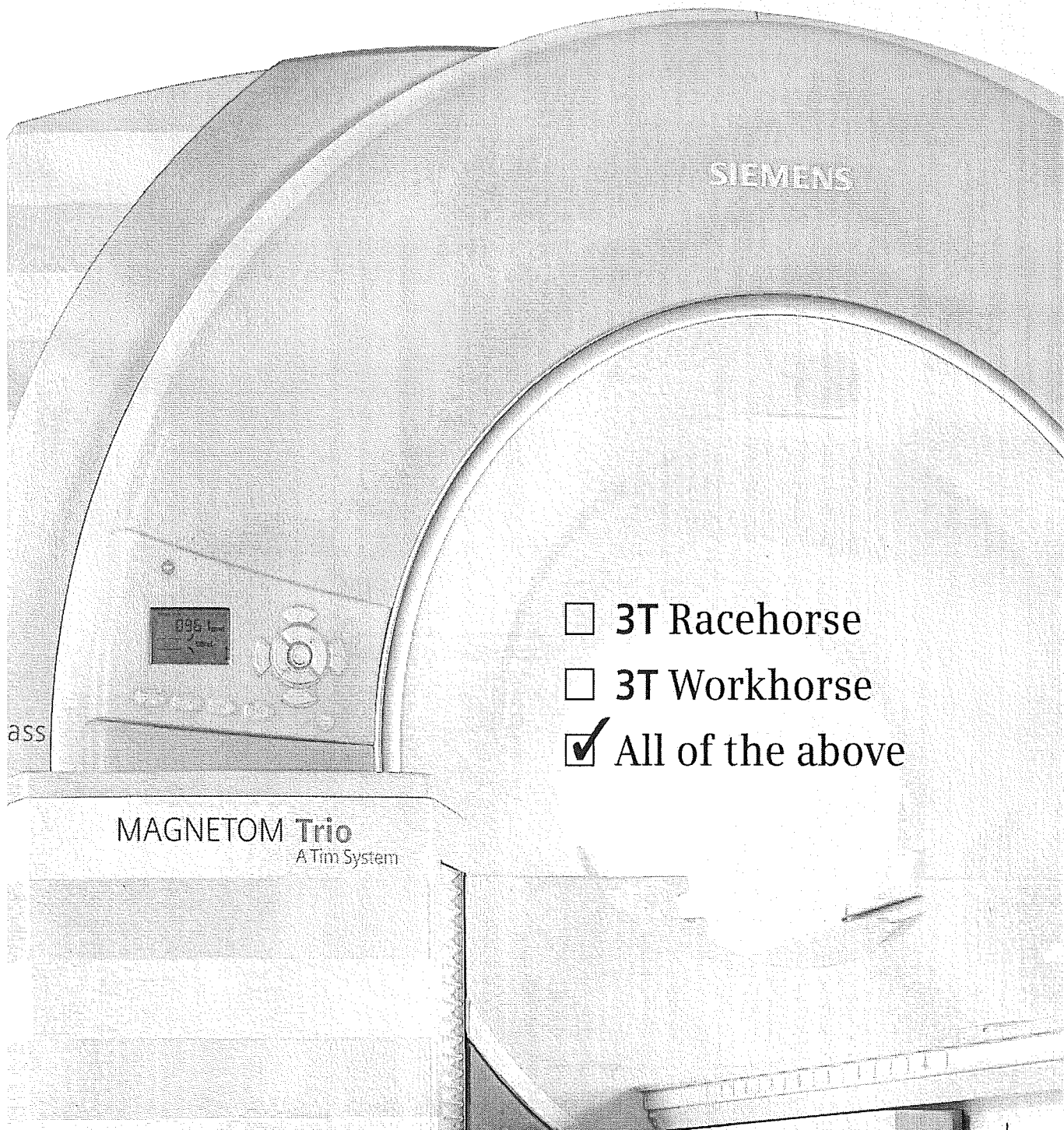
Clinically, the patient did have some word-finding difficulty in the immediate postoperative period. After approximately 3 days, however, the patient regained full verbal abilities and had no residual language deficit thereafter. It was felt that some edema associated with the operative tract may have caused temporary dysfunction of the neuronal cells within the Wernicke area, resulting in a temporary language deficit. A permanent deficit may have been avoided, however, since no transections were performed in the region of the Wernicke area.

This case presentation shows the value of preoperative fMRI in planning surgical resection of tumors. In particular, the use of a 3T magnet for fMRI in this patient provided a better SNR and allowed greater confidence in locating the language-processing areas in this patient's brain. Because of the greater confidence achieved with the 3T scanner, the neurosurgeon altered his surgical approach to the patient's brain tumor and avoided causing a permanent language deficit.

*Neeraj B. Chepuri, MD, is chair of the radiology department at Abbott Northwestern Hospital, and a member of the neuroradiology section at Consulting Radiologists Ltd, Minneapolis.*



**Figure 1.** (A) A functional activation map is superimposed on an anatomical axial FLAIR image of patient, revealing that patient's Wernicke area was located in path of contemplated resection (arrow). (B) A surface-rendered view of the brain is overlaid with functional activations (arrow indicates Wernicke area). (C) Sagittal postoperative MRI compared with volume-rendered preoperative MRI shows that Wernicke area was avoided.



- 3T Racehorse
- 3T Workhorse
- All of the above

**MAGNETOM Trio**  
A Tim System

**Proven Outcomes in Clinical 3T MRI.**

It's time to think differently about 3T. MAGNETOM Trio™ is the only 3T with the power of Tim, Total imaging matrix technology. For 3T that works hard and works fast. Tim makes 3T simple to use for all clinical applications and all body parts. Available with up to 102 seamlessly integrated coils and up to 32 RF channels for ultra-fast scan times and high image resolution. MAGNETOM Trio. From the most routine to the most challenging. It's time to let it take you to the next level.

[www.siemens.com/medical/mr](http://www.siemens.com/medical/mr) 1-888-826-9702

**SIEMENS**  
medical

# *Attachment E*

---

Data: Treatment Cost Estimator Results – Duke University Health System, Wake Radiology, LLC, and Raleigh Radiology, LLC

Durham, NC 27704

# Estimated Treatment Cost Results

~~MRSA~~ **Rhiparthritis with Joint**, 25 miles from 27605 - [Modify Your Search](#)

Duke Regional Hospital  
[About These Results - Disclaimers](#)  
3643 N Roxboro St  
Durham, NC 27704

Blue Options, Blue Advantage  
**\$1,538**

**Adam Braithwaite**

Duke Raleigh Hospital  
3400 Wake Forest Rd  
Raleigh, NC 27609

Blue Options, Blue Advantage  
**\$1,557**

**Tedric Boyse**

Duke Raleigh Hospital  
3400 Wake Forest Rd  
Raleigh, NC 27609

Blue Options, Blue Advantage  
**\$1,586**

**Morgan Camp**

Duke Raleigh Hospital  
3400 Wake Forest Rd  
Raleigh, NC 27609

Blue Options, Blue Advantage  
**\$1,594**

**Duke Raleigh Hospital**

3400 Wake Forest Rd  
Raleigh, NC 27609

Blue Options, Blue Advantage  
**\$1,599**

**Robert Vogler**

Duke Raleigh Hospital  
3400 Wake Forest Rd  
Raleigh, NC 27609

Blue Options, Blue Advantage  
**\$1,600**

**Thomas Hash**

Duke Raleigh Hospital

Blue Options, Blue Advantage  
**\$1,610**

# Melanie Ehinger Estimated Treatment Cost Results

Blue Value  
**\$800**

**MRI Lower Limb with Joint**, 25 miles from 27605 - Modify Your Search

169 Rawls Rd  
Asheboro, NC 27501  
About These Results - Disclaimers

Blue Options, Blue Advantage  
**\$800**

## Raleigh Radiology

Blue Value  
**\$1,025**

166 Springbrook Ave  
Ste 103 Spring Branch Md Pavilion  
Clayton, NC 27520

Blue Options, Blue Advantage  
**\$1,025**

## Raleigh Radiology

Blue Value  
**\$1,025**

1212 Cedarhurst Dr  
Raleigh Radiology Cedarhurst  
Raleigh, NC 27609

Blue Options, Blue Advantage  
**\$1,025**

## Raleigh Radiology

Blue Value  
**\$1,025**

839 Durham Rd  
Ste A Raleigh Radiology Wake Forest  
Wake Forest, NC 27587

Blue Options, Blue Advantage  
**\$1,025**

## Joshua Mitchell

Blue Value  
**\$1,106**

Rex Hospital  
4420 Lake Boone Trl  
Raleigh, NC 27607

Blue Options, Blue Advantage

# Estimated Treatment Cost Results

WakeMed  
3000 New Bern Ave  
Raleigh, NC 27610

MRI Lower Limb with Joint, 25 miles from 27605 - Modify Your Search

Blue Options, Blue Advantage  
**\$1,187**

Russell Wilson  
WakeMed  
3000 New Bern Ave  
Raleigh, NC 27610

Blue Options, Blue Advantage  
**\$1,187**

Wake Radiology Diagnostic Imaging  
8300 Health Park  
Ste 221  
Raleigh, NC 27615

Blue Value  
**\$1,350**

Blue Options, Blue Advantage  
**\$1,350**

Wake Radiology Diagnostic Imaging  
1101 Grace Park Dr  
Morrisville, NC 27560

Blue Value  
**\$1,350**

Blue Options, Blue Advantage  
**\$1,350**

Wake Radiology Diagnostic Imaging  
300 Ashville Ave  
Ste 100  
Cary, NC 27518

Blue Value  
**\$1,350**

Blue Options, Blue Advantage  
**\$1,350**

# ***Attachment F***

---

Correspondence: Request for Copy of Duke University Health  
System Exemption Request for Medical Office Building



## Kelly Ivey

---

**From:** Evans, Stephanie <stephanie.evans@dhhs.nc.gov>  
**Sent:** Wednesday, May 11, 2016 8:01 AM  
**To:** Nancy Lane  
**Subject:** FW: Request for Correspondence copy Medical office building  
**Attachments:** Wake Duke University Health System 1603 Exemption.pdf; 1831 Wake Duke University Health System Exemption.pdf

Please read Bernetta's message below and please see the attachments.

### Stephanie Evans

Certificate of Need  
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section  
North Carolina Department of Health and Human Services

919-855-3872 office  
[stephanie.evans@dhhs.nc.gov](mailto:stephanie.evans@dhhs.nc.gov)

809 Ruggles Drive  
2704 Mail Service Center  
Raleigh, NC 27699-2704



*Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties.*

---

### Twitter YouTube

Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this e-mail in error, please notify the sender immediately and delete all records of this e-mail.

---

**From:** Williams, Bernetta  
**Sent:** Tuesday, May 10, 2016 2:04 PM  
**To:** Evans, Stephanie; Mckillip, Mike  
**Subject:** RE: Request for Correspondence copy Medical office building

I have not received an exemption request for a medical office building at New Hill, in Holly Springs.

---

**From:** Nancy Lane [<mailto:nlane@pda-inc.net>]  
**Sent:** Tuesday, May 10, 2016 12:45 PM  
**To:** Evans, Stephanie  
**Cc:** 'Kelly Ivey'  
**Subject:** Request for Correspondence copy Medical office building

Good Afternoon Stephanie,

This is to formally request a copy of correspondence from Duke University Health System or Durham Realty, Incorporated, requesting an exemption for a medical office building at New Hill, Holly Springs North Carolina.

Thanks for your help.

Nancy

Nancy M. Lane

**PDA, Inc.**  
2016 Cameron Street  
PO Box 12844  
Raleigh, North Carolina 27605  
919-754-0303  
919-754-0328 FAX

[www.pdaconsultants.com](http://www.pdaconsultants.com)

[nlane@pda-inc.net](mailto:nlane@pda-inc.net)

CONFIDENTIALITY NOTICE: This message is confidential and intended solely for the use of the person (s) to whom it is addressed. If you are not the person named, or responsible for delivering it to that person, be aware that disclosure, copying, distribution or use of this information is strictly PROHIBITED. If you have received this communication in error, or are uncertain as to its proper handling, please immediately notify the sender, delete this e-mail and destroy any copies in any form immediately.

---

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.

# ***Attachment G***

---

Excerpt: Novant Health Franklin Medical Center, 2015 Hospital  
License Renewal Application, MRI Services Patient Origin

All responses should pertain to October 1, 2013 through September 30, 2014.

**Patient Origin - MRI Services**

Facility County: **Franklin**

In an effort to document patterns of utilization of MRI Services in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. **The total number of patients reported here should be equal to or less than the total number of MRI procedures reported in Table 10a. on page 16.**

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance	1	37. Gates		73. Person	1
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville	3	75. Polk	
4. Anson		40. Greene		76. Randolph	1
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax	14	78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen		45. Henderson		81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe		47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell		50. Jackson		86. Surry	
15. Camden		51. Johnston	3	87. Swain	
16. Carteret		52. Jones		88. Transylvania	
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	1
19. Chatham		55. Lincoln		91. Vance	45
20. Cherokee		56. Macon		92. Wake	46
21. Chowan		57. Madison		93. Warren	31
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus		60. Mecklenburg	1	96. Wayne	1
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	1
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash	39	100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	2
31. Duplin		67. Onslow		102. South Carolina	1
32. Durham		68. Orange		103. Tennessee	0
33. Edgecombe	5	69. Pamlico		104. Virginia	6
34. Forsyth	1	70. Pasquotank		105. Other States	3
35. Franklin	580	71. Pender	1	106. Other	0
36. Gaston		72. Perquimans		Total No. of Patients	787

Are mobile MRI services currently provided at your hospital? Yes \_\_\_\_\_ No X