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PETITION

Petition for Adjustment Need Determination for Fixed Cardiac Catheterization Equipment in Wake County

PETITIONER

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STATEMENT OF REQUESTED ADJUSTMENT

Rex Healthcare (Rex) respectfully petitions the State Health Coordinating Council (SHCC) to create an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Wake County in the *2016 State Medical Facilities Plan.*

BACKGROUND

Rex filed two petitions in 2014 related to fixed cardiac catheterization equipment (see Attachment 1 for copies of both petitions). The first, a methodology change petition, requested that the need for additional fixed cardiac catheterization capacity be determined by facility rather than by service area so that individual providers could address capacity needs in spite of potential surplus capacity within the county. The second, an adjusted need determination petition, requested an additional unit of fixed cardiac catheterization equipment in Wake County in order to address the capacity needs at Rex. The SHCC denied both of these petitions, at least in part based on the Medical Facilities Planning Section's conclusion that more time was needed to assess the need.

Since that time, the trends that drove Rex to submit the petitions in 2014 have continued and strengthened. As demonstrated in the discussion below, Rex needs additional fixed cardiac catheterization capacity and could develop it with a small capital expenditure by upgrading the software on existing equipment.

REASON FOR THE REQUESTED ADJUSTMENT

Rex's cardiac catheterization volume has increased substantially over the past four years necessitating additional capacity, which cannot be achieved without the requested need determination. As shown in Table 9W of the *Proposed 2016 State Medical Facilities Plan* (*SMFP*), Rex has a need for 5.00 units and has an inventory of only four units. Based on the *SMFP* data, Rex is operating at 100.1 percent of the assumed capacity of cardiac catheterization equipment. As shown in the table below, more recent utilization data from Rex indicate that its volume has grown since the Fiscal Year 2014 (FY 2014) time period that is represented in the *Proposed 2016 SMFP* and Rex currently demonstrates a need for 5.71 units of catheterization equipment or a deficit of nearly two units. Despite Rex's situation, the *Proposed 2016 SMFP* does not show a need for additional capacity in Wake County due to the underutilization of other providers.

Rex Cardiac Catheterization Utilization

	FY2011	*FY2012*	*FY2013*	*FY2014*	*FY2015**
Diagnostic	1,697	2,067	2,666	3,050	3,309
Interventional	820	1,033	1,350	1,689	2,028
Total Procedures	2,517	3,100	4,016	4,739	5,337
Weighted Procedures Total^	3,132	3,875	5,029	6,006	6,858
Annual Growth of Weighted Procedures	**4.3%**	**23.7%**	**29.8%**	**19.4%**	**14.2%**
Machines Required†	**2.61**	**3.23**	**4.19**	**5.00**	**5.71**

Source: Rex internal data.
*FY2015 volume based on nine months of data (October 1, 2014 to Jun 30, 2015) annualized.
^Weighted Procedures Total = Diagnostic + Interventional x 1.75
†Machines Required = Weighted Procedures Total ÷ 1,200 procedures (80 percent of 1,500 procedure capacity) per the *Proposed 2015 SMFP* methodology.

It is Rex's remarkable and unique growth, which has not been experienced by other cardiac catheterization providers in the state, that drives the need for an adjusted need determination for an additional unit of cardiac catheterization equipment in Wake County.

Rex's growth has been driven by unique circumstances, namely its affiliation in 2011 with Wake Heart & Vascular Associates (WHV), a leading cardiovascular practice in the Triangle. In 2013, WHV joined with Rex Heart & Vascular Specialists to create North Carolina Heart & Vascular, part of the UNC Heart & Vascular Network. The combined practice has nearly three dozen physicians working out of 15 offices in nine counties. Since its decision to affiliate with Rex

and UNC, WHV has relocated offices and patients to the Rex Hospital campus, and, along with that shift, much of its hospital-related patient care, including cardiac catheterizations. The result is dramatic growth in cardiac catheterization volume at Rex, which stands in stark contrast to the trends in the rest of Wake County and the state. Specifically, since 2011, Rex's weighted cardiac catheterization volume has grown 22 percent annually. In fact, while it operated at 100.1 percent of capacity in FY2014, Rex's utilization continued to increase over the past year (14.2 percent year over year growth) and now its labs are operating at 114.3 percent of their capacity. Because these factors impact Rex only and not other providers, an adjusted need determination is needed as the standard methodology cannot account for them.

Rex Cardiac Catheterization Utilization

	FY2011	*FY2012*	*FY2013*	*FY2014*	*FY2015**
Weighted Procedures Total	3,132	3,875	5,029	6,006	6,858
Units of Fixed Equipment^	3	4	4	4	4
Capacity†	4,500	6,000	6,000	6,000	6,000
Percent Utilization	**69.6%**	**64.6%**	**83.8%**	**100.1%**	**114.3%**

Source: Rex internal data.
* FY2015 volume based on nine months of data (October 1, 2014 to Jun 30, 2015) annualized.
^Rex operated three units of fixed equipment in FY2011 and added a unit in FY2012 pursuant to a prior Certificate of Need. See discussion below of recent addition of mobile equipment.
†Capacity = Units of Fixed Equipment x 1,500 procedure capacity per unit according to the *Proposed 2016 SMFP* methodology.

If Rex's utilization were to grow another 14.2 percent from 2015 to 2016, it would perform 7,830 weighted procedures or 131 percent of capacity. Given these factors, Rex believes it must act immediately in order to maintain the appropriate capacity needed to care for its patients.

Expanded Capacity at Rex

In order to accommodate this utilization, Rex operates extended hours and contracts with a mobile cardiac catheterization provider. Rex staffs two of its catheterization labs 12 hours per weekday (7:00 am to 7:00 pm) and the other two labs for 10 hours per weekday (7:00 am to 5:00 pm). Despite these hours, the last cath lab patient of the day departs after staffed hours, around 7:30 pm on weekdays on average based on current data. As discussed below, these last patients must fast for an extended period prior to their procedure and then stay in the hospital overnight for observation. The labs are not staffed on weekends as

they are used for emergencies only; however, the labs are in use for four hours each weekend day, on average, for these emergency cases.

Due to the severe capacity constraints and lack of other alternatives, Rex has contracted with FirstHealth to use its mobile catheterization lab since May 2015 in order to further expand capacity. This mobile unit has been at Rex for five days a week since that time. While this alternative has provided some relief to Rex's capacity issues, it is far from ideal. In order to reach the mobile unit, patients must exit the hospital, travel along a covered walkway, and enter a mobile trailer. The mobile unit's equipment is older and less technologically advanced than Rex's fixed equipment. As such, both patients and physicians would prefer to utilize the fixed labs, but unfortunately the mobile must be used due to the sheer volume of patients that Rex treats.

The most frustrating aspect of Rex's current capacity issues is that equipment in one of its existing peripheral vascular labs could be modified with a software upgrade with minimal expense so that it could be used as a cardiac catheterization laboratory. However, because of the regulatory limits on cardiac catheterization equipment (and the exclusion of grandfathered mobile units from those limits), Rex's best option to serve its patients, without the adjusted need determination requested in this petition, is to utilize mobile equipment parked in a trailer next to the hospital.

Prior Responses from the SHCC and the Medical Facilities Planning Section

Rex described similar growth trends and high utilization in its 2014 petition for an adjusted need determination for one unit of cardiac catheterization equipment in Wake County. The SHCC denied that petition following the recommendation of the Medical Facilities Planning Section in its Agency Report. Rex believes that the following discussion responds to the issues raised by the Medical Facilities Planning Section in denying Rex's 2014 petition and effectively demonstrates the need for additional capacity at Rex, particularly given the ongoing and increasing capacity constraints.

Statewide and Wake County Declines

The Agency Report on Rex's 2014 adjusted need determination petition begins by showing that cardiac catheterization volumes "*in the last 10 years* [in] *Wake County and NC have experienced declines greater than 10 percent and 18 percent, respectively*" and noting that Wake County, "*in recent years, has experienced a sharper decline in utilization than the state as a whole*" (pages 2-3, see Attachment 2 for Agency Report). The most recent cardiac catheterization utilization data as

shown in the *Proposed 2016 SMFP* shows that statewide utilization has continued to decline. However, Wake County's cardiac catheterization data shows a 3.7 percent increase in utilization over the last year (14,794 weighted procedures in FY2014 compared to 14,268 in FY2013).

Rex does not dispute that statewide and county-wide trends indicate declining utilization overall for cardiac catheterization over the past decade. **In fact, it is precisely because of these overall trends that Rex's sharp increase in utilization represents a unique circumstance that needs to be addressed through the adjusted need determination process**. The Agency Report on Rex's 2014 adjusted need determination petition agrees that Rex's circumstances are unique, stating that "the data presented in Rex's petition suggests that they have had **unique utilization trends in recent years**" (page 3, **emphasis added**).

Lack of Multi-Year Trend

While acknowledging Rex's unique circumstances, the Agency Report stated that "*Rex has only one year in the last five recent years of utilization greater than 80 percent. Application of the methodology does generate a deficit for this facility for this one year, but it is difficult to forecast the changes and trends in healthcare utilization based on one year's worth of data*" (page 4). Of note, Rex's 2014 petition showed that it had operated above 80 percent utilization for more than one year based on recent data (FY2014 year-to-date data). However, the Agency Report did not consider this year-to-date data because "*although the petitioner reports procedure volume from FY2014, this information is not used in this analysis per the practice of the agency. Analysis is conducted on only data used prior to and in the current Proposed 2015 State Medical Facilities Plan. The plan's data year is FY2013*" (page 3).

The *2016 Proposed SMFP* now provides the Medical Facilities Planning Section with <u>two years</u> of data showing Rex's utilization above 80 percent (100.1 percent utilization in FY2014). Moreover, Rex's internal data for FY2015 shows an annualized total of 6,858 weighted procedures or 114.3 percent utilization which would provide a three-year trend. There is no rule preventing the Medical Facilities Planning Section from considering more recent data. Given that its year-to-date data has proved reliable[1] and uses the same source as the Hospital License Renewal Application data, Rex urges the Medical Facilities Planning Section to consider it.

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[1] In its 2014 petition, Rex stated that its annualized FY2014 weighted total was 5,833 procedures. Rex's year-end total (as reported on its Hospital License Renewal Application and in the *Proposed 2016 SMFP*) was 6,006 weighted procedures, an understated (and more conservative) difference of only three percent.

The 2014 Agency Report concludes that "[c]*onsistent data trends over more than one year would be essential to ensure that cardiac catheterization services are not being duplicated in Wake County*" (page 5). Rex believes that its two- and three- year trends are more than adequate to demonstrate the need for additional capacity. Notably, the cardiac catheterization methodology in the *SMFP* only considers one year in determining need; it does not attempt to forecast changes or trends. In other words, if Rex were the only provider in its service area, a single year of utilization above the utilization threshold would result in a need determination for additional capacity. It is only because Rex is in a service area with other cardiac catheterization providers that a one year trend is insufficient.

More importantly, a longer timeline would force a provider to operate above capacity for more than four years due to the *SMFP* and Certificate of Need (CON) process. For example, if the SHCC were to approve Rex's current petition, the *2016 SMFP* would include a need determination for an additional cardiac catheterization unit in Wake County and Rex could submit a CON sometime in 2016 to develop that unit. Even if the CON application is approved under an expedited review, it would require four and one-half months after submission to begin development at a minimum. So if the SHCC were to find that Rex currently demonstrates a need for additional capacity, it would be at least a year until Rex could develop that capacity and possibly even longer. At that point, Rex would have been operating above capacity for four years. No reasonable approach to healthcare planning would require an even longer time horizon to demonstrate the need for a service like cardiac catheterization which is essential to emergency life-saving treatment.

Potential for Duplication of Health Services

In recommending denial of Rex's 2014 adjusted need determination petition, the Agency Report noted that "[t]*he standard methodology considers procedure volume and number of machines of the entire service area. Thus, Rex's deficit is offset by a surplus of machines in Wake County as a whole . . . Therefore, approval of this petition may introduce duplication of health services into Wake County*" (page 4). Again, Rex does not dispute that other providers have underutilized equipment in Wake County; however, **it is precisely because there are several significantly underutilized cardiac catheterization providers in Wake County that Rex's situation represents a unique circumstance that needs to be addressed through the adjusted need determination process**.

Of note, while Table 9W of the *Proposed 2016 SMFP* indicates that WakeMed has more than two cath labs of excess capacity, WakeMed's recent actions suggest that it needs all of its cath lab capacity. In June 2015, WakeMed submitted an

exemption request and received approval to replace one of its nine cardiac catheterization labs (see Attachment 3). If WakeMed truly had unnecessary capacity, then it would not be making a significant capital investment in order to replace an existing lab.

In order for a need for an additional cardiac catheterization unit to be generated in Wake County using the *SMFP* methodology, Rex would have to operate at 203 percent of its capacity (which obviously would be impossible), if utilization at each of the other facilities in Wake County remained at 2014 levels. While other providers in North Carolina have exceeded 100 percent of the capacity standard by performing procedures at night or on weekends, none has achieved over 150 percent of capacity. Moreover, utilization in excess of 100 percent has myriad negative implications as detailed below.

Conversely, the other facilities in Wake County would need to add 6,812 weighted procedures (2,628 additional procedures at WakeMed, 977 at WakeMed Cary, and 3,207 at Duke Raleigh) in order to effectively utilize their existing capacity so that Rex's utilization could generate additional need. For perspective on the 6,812 additional weighted procedures needed at other facilities, Rex's 2014 cardiac catheterization utilization is 6,006 weighted procedures. Thus, the other facilities in Wake County would need to add volume equivalent to Rex in total and then over 800 more in order to reach effective utilization of existing capacity. **From Rex's perspective, absent the adjusted need determination requested in this petition, it will never be able to acquire additional fixed cardiac catheterization capacity, no matter how needed because other providers in its community are so underutilized.** Rex discussed this same dynamic in its 2014 petition, but the Agency Report did not respond to this issue. Rex urges the Medical Facilities Planning Section to consider that Rex's unique circumstances indicate that a duplication of cardiac catheterization equipment in Wake County is necessary.

Faced with similar unique circumstances, the SHCC approved a petition by Duke Raleigh for an adjusted need determination for one additional linear accelerator in Service Area 20 (Wake and Franklin counties) in the *2014 SMFP*. The SHCC acted specifically to alleviate Duke Raleigh's lack of linear accelerator capacity despite the absence of an overall need in the service area and in spite of the underutilization of multiple providers. Rex believes that its issue is very similar. As shown in the excerpt below in the October 2, 2013 Technology Committee report to the SHCC on this petition, additional capacity was found to be needed based on the overutilization of Duke Raleigh:

Petitioner: Duke University Health Systems dba Duke Raleigh Hospital

- **Request**: Duke Raleigh Hospital requested an adjusted need determination for one additional linear accelerator to meet a perceived unmet need in Service area 20 (Wake and Franklin Counties).

- **Committee Recommendation**: The Committee discussed the petition and agency report, which recommended denial of the petition request. The discussion included an update on one CON approved linear accelerator that was approved on February 2011 but has not been developed. This project is still on target to become operational in early 2014. The linear accelerator standard methodology demonstrates that the current inventory, including the CON approved linear accelerator to be developed, is providing sufficient access to linear accelerator services in Service Area 20. However, the consensus of the Committee recognized that Duke Raleigh is unable to increase its inventory to meet demonstrated excess patient demand. Therefore, the Committee recommends to the SHCC that the petition request be approved for one additional linear accelerator in Service Area 20.

Just as Duke Raleigh was not able to increase its linear accelerator capacity to meet the demands of its patients, Rex cannot increase its cardiac catheterization capacity to care for its patients. Duke Raleigh was overutilized while other facilities had excess capacity **and there was a linear accelerator approved for the service area that had yet to be developed**. Rex similarly is overutilized and its volumes continue to grow while other facilities in Wake County are substantially underutilized.

The SHCC's discussion at its October 2, 2013 meeting further underscores the similarities between the Duke Raleigh linear accelerator petition and Rex's current petition. In response to a request for greater detail about the Technology Committee's reasons for recommending approval of Duke Raleigh's petition, Dr. Dennis Clements, III stated, "*the linear accelerator presently operating in Duke Raleigh Hospital is basically over capacity. That unlike other things, like an MRI, where you may go get one and then if you need a different MRI you can go somewhere else. Most of these are cancer patients and once you get standardized on one machine you have to stay on that machine. You have maybe ten twenty maybe more procedures on that machine. The machine tends to be associated with a hospital, often with oncologists in that hospital. And so I think that was part of the issue*" (transcribed from the audio recording of the October 2, 2013 SHCC meeting). Rex's cardiac catheterization services and its physicians are similarly associated with one hospital and that capacity is not interchangeable as the SHCC determined in the case of Duke Raleigh.

On the same topic, Dr. Pulliam stated, "[t]*he other thing we can't lose sight of, and again I don't live around Raleigh, but if one facility is attracting a tremendous number of patients, they're attracting them for some reason. They probably offer something the others don't. There is a level of expertise possibly. It's hard to say. And I don't think we should constrain those who are doing the job right and well to the fact, to the point that*

they need more capacity just because we have these rules that might somehow try to redistribute the care" (transcribed from the audio recording of the October 2, 2013 SHCC meeting). Rex and its physician partners have been tremendously successful in attracting a growing number of cardiology patients since 2011 due to its quality, innovation, and overall patient care. Rex should not be penalized by its success. The SHCC recognized and alleviated Duke Raleigh's capacity issues in 2013 and Rex believes that it faces the same issue with the cardiac catheterization and requests that the SHCC act accordingly.

As with linear accelerator capacity in the Duke Raleigh case, there is cardiac catheterization capacity available at other Wake County facilities, yet Rex's volume continues to grow. Both the *2015 SMFP* and *Proposed 2016 SMFP* show that Rex's utilization continues to grow despite operating well above capacity and at much higher utilization than any other provider. Yet, the underutilized capacity at other Wake County facilities is not alleviating the overutilization at Rex. This is because of the nature of cardiac catheterization services as compared to other services. The idea of ensuring that additional capacity is not prematurely allocated is central to the goal of suppressing **unnecessary** duplication, a central tenet of the CON statute. Preventing duplication may be reasonable for certain services, particularly those for which the service or procedure is merely one adjunct to the overall diagnostic process and treatment plan. For example, a patient needing an MRI scan to support a diagnosis may choose an MRI provider separate from his physician or hospital, without it negatively impacting his diagnosis or treatment, particularly on an outpatient basis, as the vast majority of MRI scans are provided.

Other services, however, are much more central to the overall process of diagnosis and treatment, require a physician present to perform the procedure, and may be performed more often on an inpatient basis than other procedures. Such is the case for cardiac catheterization services. The cardiology practice, which is comprised a team of providers, including medical, invasive, interventional and surgical cardiologists, has been chosen by the patient to provide his or her care. This team is central to the diagnosis and treatment, and the interventional cardiologist is directly involved with performing the procedure on the patient. The physicians that perform cardiac catheterizations at Rex do not have privileges at any other facility and so cannot treat their patients at another hospital which may have excess capacity. Since those physicians have been chosen by the patient to provide his or her care, the notion of the physician referring the patient to a physician at another facility, just because there may be more cardiac catheterization capacity available there, is extraordinarily unlikely, as well as being disruptive to the continuity of care. Physicians and patients are increasingly reluctant to shift to another site of care under the control of a

different healthcare system for care as it can lead to disruptions in the continuity and quality of care. The utilization of a particular facility is thus driven primarily by physician and patient preference, not the available capacity at a facility. For these reasons, Rex does not believe that its need for additional cardiac catheterization capacity can be served by underutilized capacity at other facilities. Under these circumstances, responsible healthcare planning requires **necessary duplication**.

Historical data from North Carolina's competitive cardiac catheterization markets provides strong evidence that capacity at underutilized facilities does not alleviate the needs of overutilized cardiac catheterization facilities. Rex performed a detailed review of the last ten years of utilization for each of the counties in North Carolina with multiple cardiac catheterization providers (Catawba, Forsyth, Guilford, Iredell, Mecklenburg and Wake counties, excluding Durham, where both providers are part of the Duke University Health System). Further, based on Rex's review of data there is no evidence to suggest that the addition of cardiac catheterization capacity to a provider harms the cardiac catheterization services at other facilities in the market. Each market was analyzed in detail in Rex's 2014 petition which is included in Attachment 1.

Historic Ability to Operate at High Utilization

The Agency Report on Rex's 2014 adjusted need determination petition states that "*both Rex Hospital and WakeMed operated at over 80 percent of capacity for five and eight years, respectively, of the 10 year time frame. In some of those years, utilization was well over 100 percent for both facilities. The petitioner argues that utilization greater than 80 percent poses difficulties for both providers and patients. While higher facility utilization does come with challenges, previous historical trends have demonstrated several years' volumes over 80 percent have occurred in Wake County*" (page 4). Rex is operating above 80 percent of capacity today and has for almost three years consistently, with no end in sight. High utilization levels are possible, but are detrimental to patient care. The Agency Report acknowledges that there are challenges of operating at these levels. Rex would encourage the SHCC to consider that these challenges are not just logistical or operational but they impact people's lives. As noted below, high utilization levels mean that patients wait longer (hours and days) to get the care they need, or that a patient must be removed from a room in the middle of a scheduled procedure in order to accommodate an emergency, or that patients and their families spend a night in the hospital, instead of at home. Scheduled procedures, while not emergency cases, are needed to improve the health of these patients and the delays that may result from overcapacity equipment results in delays in their recovery and return to normal life. Rex and WakeMed operated at high utilization levels ten years

ago, surely, but they also understood that the *SMFP* would (and did) provide additional capacity through need determinations. Both WakeMed and Rex added capacity to alleviate the high utilization levels. The current situation in Wake County is very different. Absent the adjusted need determination requested in this petition, Rex will never be able to acquire additional cardiac catheterization capacity, no matter how needed because other providers in its community are so underutilized.

The SHCC should also understand that high utilization levels are more difficult for Rex to achieve today than in the past due to several factors:

- There is more variability in the types and length of cardiac catheterization procedures provided by Rex than in past. Historically, cardiac catheterization procedures could be reasonably expected to require 60 to 90 minutes to complete and were either standard diagnostic or interventional cases. Today, Rex's cases are extremely variable in terms of length (anywhere from 60 minutes to four hours) and type (Transcatheter Aortic Valve Replacements (TAVRs), mitral clips, chronic total occlusions, etc. in addition to standard diagnostic and interventional cases).
- New technology and tools are used for Rex's cases which add to the logistical complexity of operating the labs efficiently.
- Rex now uses its labs for teaching with the recent launch of a fellow program for UNC-Chapel Hill Medical School with fellows in each of Rex's cath labs, five days a week.
- Rex now conducts research in its labs. In the first six months of 2015 (January to July), Rex physicians who are not part of North Carolina Heart and Vascular conducted 26 studies including over 500 patients through the clinical practice in Rex's cardiac catheterization labs. Rex estimates that the research conducted by North Carolina Heart and Vascular physicians over that same period was three times as much as their colleagues.

All of these factors make the high utilization of Rex's cath labs more challenging than in year's past. While Rex is intimately aware of these factors in its own cardiac catheterization labs, it is not specifically aware of the circumstances at WakeMed. However, it is likely that WakeMed has also experienced the change in the variability of catheterization cases and introduction of new technology and tools that reduce a facility's ability to operate at consistently at high utilization levels. This may explain why WakeMed is replacing one of its existing cardiac catheterization labs despite operating at 61 percent of capacity.

Of note, the Agency Report on Rex's 2014 adjusted need determination petition overstates Rex and WakeMed's historic utilization percentages. Specifically, the Agency Report notes that "[t]*he number of machines assigned to each facility is not based on the number that were actually operated by the facility, but the number of machine listed in the inventory for each facility in each year's state medical facility plan"* (page 4). In other words, the analysis did not match utilization with the actual number of machines providing the utilization. Rex reviewed the facilities' hospital licensure renewal application from the pertinent years in order to determine the number of machines that were actually operated by the facility (revisions are highlighted in yellow and bolded). As the revised table below shows, Rex never operated over 100 percent of capacity until 2014 and WakeMed only operated above 100 percent of capacity in one year.

Revised Tables 4 & 5
from 2014 Agency Report on Rex Adjusted Need Determination Petition
Wake County Cardiac Catheterization Procedures by Facility from 2004 to 2013

		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Duke Raleigh	Total weighted procedures	0	1,288	202	357	262	770	967	701	366	447	393
	No of machines	0	1	2	2	2	2	2	2	2	3	3
	Procedures for 100% Utilization	0	1,500	3,000	3,000	3,000	3,000	3,000	3,000	3,000	4,500	4,500
	Utilization	0%	86%	7%	12%	9%	26%	32%	23%	12%	10%	9%
Rex Hospital	Total weighted procedures	4,206	3,897	4,015	3,557*	3,616	3,489	3,002	3,132	3,875	5,029	6,006
	No of machines	**3**	**3**	3	3	3	3	3	3	4	4	4
	Procedures for 100% Utilization	4,500	4,500	4,500	4,500	4,500	4,500	4,500	4,500	6,000	6,000	6,000
	Utilization	93%	87%	89%	79%	80%	78%	67%	70%	65%	84%	100%
WakeMed	Total weighted procedures	11,709	11,984	11,698	11,657	12,312	12,108	12,618	12,130	10,535	8,570	8,172
	No of machines	**8**	**8**	8	**8**	**8**	9	9	9	9	9	9
	Procedures for 100% Utilization	12,000	12,000	12,000	12,000	12,000	13,500	13,500	13,500	13,500	13,500	13,500
	Utilization	98%	100%	97%	97%	103%	90%	93%	90%	78%	63%	61%
WakeMed Cary	Total weighted procedures	567	498	405	418	393	325	382	325	282	222	223
	No of machines	1	1	1	1	1	1	1	1	1	1	1
	Procedures for 100% Utilization	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500
	Utilization	38%	33%	27%	28%	26%	22%	25%	22%	19%	15%	15%
Wake County (Total)	Total weighted procedures	16,482	17,667	16,319	15,988	16,583	16,692	16,969	16,287	15,057	14,268	14,794
	No of machines	12	13	14	14	14	15	15	15	16	17	17
	Procedures for 100% Utilization	18,000	19,500	21,000	21,000	21,000	22,500	22,500	22,500	24,000	25,500	25,500
	Utilization	92%	91%	78%	76%	79%	74%	75%	72%	63%	56%	58%

Source: *2006-2015 SMFP; Proposed 2016 SMFP.* 2005-2015 Hospital License Renewal Applications.
*Rex Hospital 2007 weighted procedures revised to match *2009 SMFP* which excludes cases performed on a temporary mobile unit in that year.

Changing Capabilities at Nearby Facilities

The Agency Report on Rex's 2014 adjusted need determination petition also considered the changing capabilities at other nearby facilities noting that "*a facility located in a contiguous county was approved to perform interventional procedures, even though it does not have an open heart surgery on site. A similar request in a different county located near Wake County is being evaluated by the Agency. This may have some impact on procedure volumes in Wake County and could potentially accelerate the decline of cardiac catheterization procedures performed in Wake County*". It is Rex's understanding that the Agency Report is referring to the initiation of an interventional catheterization services at Johnston Health (in Johnston County, which is adjacent to Wake County) and Central Carolina Hospital (in Lee County, which is near Wake County. Rex believes that these new interventional programs have not decreased its need. In fact, the available data suggests that Rex's need has grown in spite of the initiation of these programs. As noted above, catheterization volume served by Wake County providers increased 3.7 percent over the last year indicating a reversal in the historical decline of volume in the county. Rex is Johnston Health's partner in developing its interventional service and based on the evidence to-date, Rex believes that Johnston Health's program has not had led to any decline in Rex's volumes. Johnston Health began providing interventional catheterizations in January 2015 and has performed 133 such procedures through June. Over that same time period, Rex performed 174 interventional procedures per month on average and has recorded its highest monthly volumes for FY2015. For comparison purposes, Rex averaged 156 interventional procedures per month in the months of FY2015 prior to the initiation of Johnston Health's program and 141 interventional procedures per month in FY2014.

FY2015 Year-to-Date Rex Interventional Procedures

	Procedures
October	166
November	146
December	155
Average for Months Prior to Johnston Health Interventional Program Initiation	**156**
January	167
February	166
March	214
April	178
May	154
June	165
Average for Months Following Johnston Health Interventional Program Initiation	**174**

Source: Rex internal data.

As the data above show, Johnston Health's interventional program has not resulted in a decline at Rex; in fact, the opposite appears to be true. Rex does not have any information on the state of Central Carolina's program, however, it's clear that Rex's interventional volumes are growing regardless of that program's status.

Summary

In summary, Rex's cardiac catheterization labs are overcapacity and the volume continues to grow unabated. The SHCC denied an adjusted need determination petition in 2014 that would have allowed Rex to add capacity. In turn, Rex has responded in detail to the issues raised by the Medical Facilities Planning Section in recommending denial of Rex's 2014 petition. Given the need for additional catheterization capacity at Rex and the unique circumstances in Wake County that preclude a future need determination under the standard methodology, Rex believes that an adjusted need determination is the only avenue that will allow it to serve its growing number of patients.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

The most obvious adverse effect of the failure to approve the petition is the negative impacts that Rex's continuing capacity constraints have on patient safety, quality, and convenience. As volume continues to increase, the *SMFP*

methodology will not provide additional capacity. The ability to provide timely emergency procedures, high quality and convenient outpatient diagnostic procedures, and seamless care within the Rex system will increasingly be more challenging.

Challenges with High Utilization

The *SMFP* methodology allocates additional units of catheterization once existing capacity in the service area reaches 80 percent utilization. The criteria and standards for cardiac catheterization equipment used by the CON Section require providers to demonstrate that any new equipment will be utilized at 60 percent or above. These standards recognize that providers cannot operate at or near 100 percent of capacity because some time must be allowed for emergencies or unforeseen delays. Due to its high cath lab utilization, Rex has no extra time during the day, and any emergency or delay can multiply, impacting the rest of the days' patients, as well as staff and physicians. Unlike other diagnostic or even interventional services, the unique qualities of cardiac catheterization make operating at high utilization difficult for the facility, for physicians, and most importantly, for patients. The following discussion explains some of these challenges.

Emergency Cases

Cardiac catheterization, particularly for patients presenting with ST-elevated myocardial infarction, or STEMI, is provided on an emergency basis to save patients' lives. When a hospital's labs are operating at 100 percent of capacity and a patient presents with a need for emergency intervention, the lack of an available lab can lengthen the time until that care is available. In such instances at Rex, the cardiologist and cath team deal with the issue in an effective, evidence-based manner. The clinical team determines if a patient can be safely removed from a room or if a case can be completed expeditiously. If the selected patient is in the middle of the procedure but has yet to have his or her procedure completed, the patient is removed from the room with the sheath left in place until another room becomes available to complete the case. Clearly, this is not optimal patient care for the delayed patient, and it can delay treatment of the emergency patient. At facilities with adequate capacity, such a scenario would be much less likely to occur. As the SHCC is no doubt aware, prolonged door-to-balloon or symptom-to-balloon times have been correlated with increased mortality after primary percutaneous coronary intervention (PCI). As a result, the American College of Cardiology has established as part of its "Door-to-Balloon" campaign (known as the "D2B Alliance") that patients should receive interventional treatment within fewer than 90 minutes from the time the patient

arrives at the hospital. The Joint Commission has also adopted this parameter as a core quality measure. As part of this 90-minute guideline, the D2B Alliance advocates that the cath lab team be available to perform the procedure within 20 to 30 minutes of the patient's arrival at the hospital. When a provider is operating at 100 percent of capacity, it is significantly more challenging to meet this lifesaving guideline.

Extended Hours

Although cardiac cath is an invasive procedure, the majority of patients are outpatients, and most return home the same day. In Rex's cath labs, cases begin at 7:00 am. Most of those patients who are treated earlier in the day go home the same day, particularly those who have only diagnostic procedures. However, due to Rex's full schedule, many patients begin their cases in the late afternoon or evening and then must be monitored for an average of four hours post procedure. These patients, many of whom are older and often have elderly caregivers, are understandably reluctant or unable to leave the hospital and be driven home late at night. As a result, many of these patients must stay overnight rather than being discharged the same day. These overnight stays are an unnecessary healthcare cost and are a substantial inconvenience to patients and their families. While these patients may not be emergency cases, they are scheduled procedures which are needed to diagnose and improve the health of these patients, and the delays that may result from equipment operating near or above capacity result in extended recovery and a postponed return to normal life.

Unpredictable Case Times

Rex strives to schedule its cath labs as effectively as possible, but the nature of the procedure and the current variability in procedures performed in the lab makes it difficult to be precise and inevitably unpredicted delays occur. Because the standard of care is to schedule patients for a diagnostic procedure and then extend the case for an intervention if a stenosis or blockage is found, it is very difficult to consistently predict the length of a case. Cath labs could operate more efficiently if a diagnostic cath was performed and the patient was then brought back at another time for the intervention. However, this would delay care, increase radiation and contrast dose to the patient, and most significantly require a second catheterization procedure increasing the cost of care. This inability to consistently predict the length of each case, particularly in the context of Rex's high utilization, leads to delays for patients, staff, and physicians. For patients, the delay may result in an unnecessary overnight stay or an extended period of fasting. Catheterization patients are typically under physicians' orders to not eat

or drink (NPO) for a period of time prior to their procedures; for patients scheduled for a morning procedure, this period often begins at midnight. Patients whose procedures are unexpectedly delayed until later in the day must therefore endure an unusually long time before they are able to eat or drink, which clearly impacts patient comfort and satisfaction

Staffing Issues

The uncertainty, delays, and emergencies that Rex experiences are also burdensome for physicians and staff. Delays for physicians result in delays for all of their patients, both in and out of the hospital. Since physicians normally have clinic hours after their cases are finished, if a physician is delayed at the hospital then they cannot see patients in their office on time. Moreover, Rex cannot efficiently staff its cath labs in this high utilization environment as staff routinely work overtime which decrease their job satisfaction and adds unnecessary costs.

Increased Maintenance Costs

Finally, Rex's high utilization necessitates that any routine maintenance occur overnight or on the weekends, which is more costly than if completed during work hours. Rex's schedule simply has no room for unscheduled (not routine) downtime of a machine. The consistent overuse of the equipment may also increase the amount of maintenance required, which will add cost and lead to increased downtime, scheduled and unscheduled.

ALTERNATIVES CONSIDERED

As described above, the status quo is already creating a situation in which maintaining a high quality of care is challenging, particularly considering the need for emergent catheterization procedures. Moreover, without an adjusted need determination, the current methodology in the *SMFP* would require Rex to operate at an impossible 203 percent of capacity in order to overcome the underutilized cardiac cath capacity at other facilities in Wake County. Rex would need to achieve that utilization and then wait for two or more years: a year at that volume to be reported on its licensure application, a year for that volume data to be incorporated into the planning process for the next *SMFP*, and at least six months, if not another year, to file the CON, have it reviewed, and, if granted, develop the additional lab. The status quo will not provide additional access, and therefore, it is not a valid consideration.

Rex is already expanding its capacity through the use of a mobile catheterization service. While this solution alleviates capacity constraints to some degree, it is

not an optimal long-term solution for a provider with sufficient volume to sustain an additional fixed catheterization lab and a robust cardiac program.

Finally, Rex filed a petition in the spring of 2014 for a methodology change that requested that the cardiac catheterization methodology determine the need for additional capacity based on the utilization of individual facilities rather than the aggregate utilization of all of the facilities in the service area. This change would have allowed providers in need of additional capacity to generate a need determination regardless of the underutilization of other providers in the service area. However, the SHCC denied that petition and the Agency Report indicated an opposition to a methodology that would consider the need for individual facilities.

Given that none of the other potential alternatives are suitable, Rex seeks the adjusted need determination proposed in this petition.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION

Rex does not believe the proposed change will result in unnecessary duplication of health resources. As set forth above and in its 2014 adjusted need determination petition, other providers in Wake County appear to have capacity on their existing equipment but Rex's volume continues to grow despite its high utilization levels. Moreover, the utilization data from the last ten years in competitive cardiac catheterization markets demonstrates that excess capacity does not relieve high utilization at other providers nor does the addition of capacity in a service area harm existing providers. Therefore, while the proposed change would increase the number of linear accelerators in the Wake County, the expansion is necessary to provide adequate access.

Rex believes that the SHCC's approach to capacity planning in other services indicates that the allocation of capacity based on the utilization of specific facilities does not result in unnecessary duplication. Specifically, the current acute care bed and PET methodologies use facility-specific methodologies and, as a result, need determinations for acute care beds and PET scanners are generated by facilities regardless of the utilization of other facilities within the same service area. Moreover, the SHCC's approval of Duke Raleigh's petition for additional linear accelerator capacity in Wake County specifically included a discussion of the merits of allowing a provider to increase capacity based on its utilization, regardless of capacity at other providers.

As noted above, Rex understands that the approval of this petition does not guarantee that it can obtain a CON for an additional unit of fixed cardiac catheterization equipment. However, the SHCC should be reasonably confident that the additional capacity will go where it is most needed given that only hospitals can be approved for cardiac catheterization equipment and other hospitals in the county each have significant excess capacity.

EVIDENCE OF CONSISTENCY WITH THE THREE BASIC PRINCIPLES

Rex believes the petition is consistent with the three basic principles: safety and quality, access, and value.

Safety and Quality

Quality and safety are clearly enhanced through the development of additional cardiac catheterization capacity. Without sufficient capacity, particularly for a service often provided on an emergent basis, like interventional cardiac catheterization, quality can suffer and patient care may not be optimal. Without this adjusted need determination, Rex could operate its cardiac catheterization equipment at high utilization levels indefinitely without any possibility of acquiring additional capacity. Cardiac catheterization services must be available immediately for emergency patients who present to a hospital. These emergency situations often require a patient to be taken out of a room before the case is finished. Emergency patients inevitably delay scheduled patients or cause rescheduling. The American College of Cardiology has established that patients should receive interventional treatment within fewer than 90 minutes from the time the patient arrives at the hospital. When a provider is operating at nearly 100 percent of capacity, it is more challenging to meet this lifesaving guideline.

If the demand for cardiac catheterization services at a facility exceeds its reasonable capacity, then any delays result in patients beginning their procedures late in the day, thus requiring a more expensive and inconvenient overnight stay, or waiting until a later scheduled time. Scheduled procedures, while not emergency cases, are needed to improve the health of these patients and the delays that may result from overcapacity equipment results in delays in their recovery and return to normal life. Increased utilization also causes stress on the cardiac catheterization equipment leading to increased maintenance issues. The downtime needed to address these maintenance issues can cause additional delays in treatment and further exacerbates the overutilization of the equipment.

If patients and physicians are forced to access care at another facility which has available capacity, they may encounter disruptions in the continuity of care. Physicians and providers work every day to improve the systems of care which leverage information technology, multidisciplinary teams, and processes of care to deliver the right care at the right time to the right person. Rex's electronic medical record allows providers to access all of the patient's records including relevant diagnostic tests that can provide vital information to guide the care of the patient. A facility under the control of another healthcare system cannot provide that same system of care to an unfamiliar physician and patient. As a result, safety and quality will be enhanced with the proposed adjusted need determination.

Access

Additional cardiac catheterization capacity is needed to provide sufficient access for Rex patients. In particular, Rex is a leading provider of care to the elderly population in Wake County. According to 2015 Hospital License Renewal Application data, Rex provides a greater percentage of its inpatient and emergency services care to the Medicare population than any other facility in the county. Elderly patients, in particular, need sufficient access to cardiac catheterization services. Moreover, North Carolina Heart and Vascular, the cardiology physician practice at Rex Hospital see patients in 15 offices in nine counties. Increasing these physicians' access to cardiac catheterization capacity will in turn broaden the access for these patients across a broad region, including areas where no cardiac catheterization capacity exists or is only provided on a diagnostic basis. For example, patients in Franklin, Harnett, and Sampson counties who see North Carolina Heart and Vascular physicians in local offices will have greater access to cardiac catheterization services, which are not available in their home county.

Value

The petition also promotes value. As discussed above, overutilization of cardiac catheterization capacity sometimes results in expensive and inconvenient overnight stays for patients that could have been discharged on the same day. Additional catheterization lab capacity will ensure that patients—both inpatients and outpatients—receive care in a timely manner, enabling patients to be discharged within an appropriate timeframe, which will prevent unnecessary expenditures by the patients and payors. Delays in needed treatment or unanticipated overnight stays at the hospital add to healthcare expenditures. Rex's high utilization has necessitated that it contract for a mobile catheterization

unit and this ongoing monthly expense would be unnecessary if Rex could develop an additional fixed unit by upgrading the software of an existing piece of equipment so that it could be used in cardiac catheterization procedures. Additionally, Rex's capacity issues necessitate that any routine maintenance occur overnight or on the weekends, which is more costly than if completed during work hours. Increased utilization also causes stress on the cardiac catheterization equipment leading to increased maintenance issues, which increases cost. The downtime needed to address these maintenance issues can cause additional delays in treatment and further exacerbates the overutilization of the equipment. Finally, Rex cannot efficiently staff its cath labs in this high utilization environment as staff routinely work overtime which decrease their job satisfaction and adds unnecessary costs.

CONCLUSION

In conclusion, Rex requests that the SHCC approve the petition for an adjusted need determination of one cardiac catheterization unit in Wake County. Rex believes the unique circumstances in the county warrant additional capacity. Specifically:

- Since 2011, Rex's partnerships with its cardiologists have resulted in 22 percent annual growth in cardiac catheterization volumes.
- Rex's fixed cardiac catheterization labs are currently operating at 114.3 percent of capacity, which would make it the highest utilized provider in the state.
- Rex's utilization levels make it more difficult to deliver optimal care, particularly given the emergent nature of conditions requiring cardiac intervention, consistent with the Basic Principles of the *SMFP.*
- Absent the adjusted need determination requested in this petition, Rex will never be able to acquire additional cardiac catheterization capacity no matter how needed as other providers in its community are sufficiently underutilized.

Thank you for your consideration.

Attachment 1

PETITION

Petition for Change to Cardiac Catheterization Need Determination Methodology

PETITIONER

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STATEMENT OF THE PROPOSED CHANGE

Rex Healthcare (Rex) respectfully petitions the State Health Coordinating Council (SHCC) to change the Cardiac Catheterization Need Determination Methodology in *2015 State Medical Facilities Plan (2015 SMFP)*. Specifically, Rex requests that the threshold for additional cardiac catheterization equipment be applied to each hospital, or in the case of hospitals under common ownership in the same service area, to each group of hospitals. Need determinations would be granted once equipment is appropriately utilized irrespective of the utilization of other hospitals in the same service area. Rex proposes the following changes to Chapter 9: Cardiac Catheterization Need Determination Methodology, Methodology 1:

Step 5: ~~Sum the number of units of fixed cardiac catheterization equipment required for all facilities in the same cardiac catheterization equipment service area as calculated in Step 4. (NOTE: The sum is rounded to the nearest whole number.)~~

Subtract the total planning inventory for each facility from the number of units of fixed cardiac catheterization equipment required as calculated in Step 4. The difference is the surplus or deficit of units of fixed cardiac catheterization equipment. (*Note: Deficits will appears as positive numbers; surpluses, as negative numbers.)*

Step 6: ~~Subtract the number of units of fixed cardiac catheterization equipment required in each cardiac catheterization equipment service area from the total planning inventory for each cardiac catheterization equipment service area. The difference is the number of units of fixed cardiac catheterization equipment needed.~~

The number of units of fixed cardiac catheterization equipment needed in a service area is determined as follows:

a) The threshold for a need determination for additional units of fixed cardiac catheterization equipment is a projected deficit of 0.1 or more units as calculated in Step 5.

b) The threshold is applied individually to each hospital, and a need determination is generated irrespective of surpluses at other hospitals in the service area, unless there are other hospitals in the service area under common ownership.

c) If two or more hospitals in the same service area are under common ownership, the surpluses and deficits for those hospitals are totaled as calculated in Step 5. The threshold for a need determination for hospitals under common ownership in the same service area is a total projected deficit of 0.1 or more.

d) The projected need determinations of all facilities and owners in the service area will be summed to determine the total number of units of fixed cardiac catheterization equipment needed in the service area.

Qualified Applicants
Any qualified applicant may apply for a certificate of need to acquire needed cardiac catheterization capacity. An applicant is a qualified if it is an existing hospital without fixed cardiac catheterization equipment, or if its existing cardiac catheterization equipment is operating at an average of 1,200 weighted procedures per unit of fixed cardiac catheterization equipment as reported in the current State Medical Facilities Plan under which the application is being reviewed.

Based on Rex's review of the 2014 Hospital License Renewal Applications and Inventory of Medical Equipment Forms, the proposed change will result in an additional need determination in Wake County for the *2015 SMFP*. Please see Attachment 1 for detailed tables comparing the results of the current methodology and the proposed methodology. As discussed below, Rex believes the proposed change is needed in order to provide access to cardiac catheterization services, that it will not have adverse effects on providers or consumers, will not result in unnecessary duplication, and is consistent with the Basic Principles of the *SMFP*.

BACKGROUND

The various methodologies in the *SMFP* generally consider need based either on the entire service area or each individual provider. The current cardiac catheterization methodology determines need based on the entire service area, and as a result, individual providers may have a significant deficit, but no need is determined to exist in the area because of the surplus at other providers. The idea of ensuring that additional capacity is not prematurely allocated is central to the goal of suppressing unnecessary duplication, a central tenet of the CON statute. This approach may be reasonable for certain services, particularly those for which the service is merely one adjunct to the overall diagnostic process and treatment plan. For example, a patient needing an MRI scan to support a diagnosis may choose an MRI provider separate from his physician or hospital, without it negatively impacting his diagnosis or treatment, particularly on an outpatient basis, as the vast majority of MRI scans are provided. Other services, however, are much more central to the overall process of diagnosis and treatment, require a physician present to perform the procedure, and may be performed more often on an inpatient basis than other procedures. Such is the case for cardiac catheterization services. The cardiologist is central to the diagnosis and treatment, as he or she is directly involved with performing the procedure on the patient. Since that physician has been chosen by the patient to provide his or her care, the notion of the physician referring the patient to a physician at another facility, just because there may be more capacity available there, is extraordinarily unlikely. Although cardiologists may be privileged at multiple hospitals, they typically choose a single facility at which to perform most of their procedural work. The utilization of a particular facility is thus driven primarily by physician and patient preference, not the deficit or surplus at a facility. Therefore, a facility-specific methodology for cardiac catheterization is more appropriate than a service area-based methodology.

As noted above, other methodologies within the *SMFP* use a facility-specific approach, consistent with the proposed change, including the methodologies for acute care beds and PET scanners. In contrast, the existing fixed cardiac catheterization need determination methodology calculates projected need based on the aggregate need within each service area. However, since cardiac catheterization services are limited to hospital providers, and since most service areas include only one hospital, the vast majority of facilities have a need methodology that is, in essence, facility-based. Specifically, in the 39 cardiac catheterization service areas, all but seven (7) of them have only one fixed cardiac catheterization provider. In each of these service areas, the need methodology bases its calculation on the utilization of a single facility, and so the methodology is effectively facility-specific for the majority of state. In the remaining seven service areas in which there are two or more providers of fixed cardiac catheterization services, the need methodology calculates projected need based on the aggregate need of all providers in the service area. As such, the utilization of a single facility is subordinate to overall utilization. Please note, however, that the Durham/Caswell Service Area includes two hospitals under the common ownership of Duke University Health System; thus, as a result, the proposed methodology will have

no impact on this service area.[1] Therefore, only six (6) service areas will be affected by the proposed change in the methodology.

Rex believes that for services such as cardiac catheterization, a service area-based methodology can perpetuate imbalances between highly utilized and underutilized providers. Underutilized equipment offsets the need expressed by well-utilized equipment and prevents the creation of additional need determinations which would allow high utilization providers to acquire more capacity and operate at more appropriate utilization levels. Even some methodologies which determine need on a service area basis attempt to mitigate this imbalance by excluding chronically underutilized facilities. In order to ensure that underutilized providers cannot diminish the need of overutilized providers, Rex proposes that only providers operating their fixed cardiac catheterization equipment at appropriate utilization levels be qualified applicants for additional fixed capacity. By failing to adjust the methodology as proposed, well-utilized facilities may be forced to operate above appropriate utilization levels and may not be able to deliver optimal care consistent with the Basic Principles of the *SMFP*, as discussed below.

Similar to other methodologies, the cardiac catheterization need methodology considers the units of equipment needed by dividing the number of weighted procedures by some percentage of the total capacity of the equipment—in this case, 80 percent. For cardiac catheterization, the capacity is defined as 1,500 diagnostic-equivalent procedures, so 80 percent is 1,200 diagnostic-equivalent procedures. The cardiac catheterization methodology differs somewhat from other need methodologies for other types of services as it currently requires the number of units of equipment needed to be rounded to the nearest whole number. In other words, the need for a second unit of cardiac catheterization equipment is not generated until a need for 1.5 units is shown. Therefore, to trigger a need determination, the existing cardiac catheterization equipment in a county must actually perform 600 procedures over the stated threshold (1,200 procedures) (e.g., a need for at least 0.5 units of equipment is required to generate a need determination for one additional unit of equipment; 0.5 x 1,200 procedures = 600 procedures). As a result of this step, providers located in counties with only one piece of cardiac catheterization equipment are forced to perform 1,800 procedures per year, or 120 percent of defined capacity, before a need is triggered for additional equipment. Under the proposed facility-based methodology, each provider will be evaluated on its own and will be required to perform above capacity in order to generate a need. This burden on providers is due to the lack of a "tiering" approach for facilities/counties with less total capacity in the cardiac catheterization methodology, unlike the "tiered" approaches used in the acute care bed, operating room and MRI methodologies. As noted above, cardiac catheterization is a much different service than most of the other regulated services in the *SMFP* in that it is often used for emergency procedures. Most

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[1] Under the proposed methodology change, if two or more hospitals in the same service area are under common ownership, their surplus or deficit of equipment is totaled and then evaluated against the threshold for a need determination. Please see the revised Step 6.c above for the specific language.

other equipment-based services, including MRI, PET, lithotripsy, gamma knife and linear accelerator treatments, are rarely, if ever used for emergency cases. Thus, with those services, when equipment reaches or exceeds capacity, patients may be inconvenienced, but rarely is emergency treatment potentially delayed as a result. Given these factors, Rex proposes that a need determination be generated when a provider reaches the capacity of its current equipment. In order to avoid potential issues related to rounding, as experienced relative to the home health methodology in recent years, Rex proposes that the threshold for a need determination for additional units of fixed cardiac catheterization equipment be defined as a projected deficit of 0.1 or more units.

Although Rex believes the proposed change is important, and though it will change the methodology statewide, it does not believe it will have a far-reaching impact. As the SHCC is aware, since 2003, cardiac catheterization volume has decreased statewide, although it does appear to have stabilized in recent years. Given this trend, it is unlikely that many providers will generate a need in the near future. However, Rex believes the methodology should evolve to reflect changes in healthcare, including the increasing alignment between physicians and hospitals in single systems of care, which has led to substantial shifts of patients among providers. Notably, Rex has experienced a substantial increase in its cardiac catheterization volume recently (more than 20 percent increase in weighted procedures in each of the last two years) due to its increased alignment with its cardiologists. In this context, the cardiac catheterization methodology must be more flexible in responding to the needs of specific facilities and the patients and physicians who choose to utilize them.

REASON FOR THE REQUESTED ADJUSTMENT

Rex believes that the cardiac catheterization methodology should determine need on a facility-specific basis, which would provide an equitable approach and only impact a minority of the hospitals across the state. Highly utilized providers would be able to generate need determinations, regardless of underutilized providers in the same service area. Underutilized providers would be prevented from applying for any need determinations as they would not be qualified applicants. It should be noted any need determination generated under the proposed change would still be subject to Certificate of Need review, whereby any qualified provider could apply for, and demonstrate the need to acquire, additional cardiac catheterization equipment. Finally, the threshold for a need determination should be lowered so that in order to ensure that need determinations are generated when providers reach capacity (especially given the use of cardiac catheterization equipment for patients on an emergency basis).

The proposed change will further the efforts of those healthcare systems that are working to improve their quality and continuity of care. As noted above, patients and physicians generally do not wish to utilize a site of care under the control of a different provider. Under the proposed change, systems will have a process to acquire needed cardiac catheterization equipment.

Rex also believes this change would be consistent with other recent recommendations from the SHCC. Specifically, the *2014 SMFP* includes an adjusted need determination for a linear accelerator in Service Area 20 resulting from a petition from Duke Raleigh Hospital (DRH). The SHCC concluded that even with a significant surplus of linear accelerator capacity in the service area, the need shown by the utilization at DRH was not mitigated by the surplus capacity of other providers in the service area or the pending implementation of two additional linear accelerators. One of the central themes of the DRH petition was that the available capacity at other providers was "not available as a practical matter to alleviate demand" on its unit. Rex believes that to the degree this notion motivated the SHCC to allocate another linear accelerator in the service area, the same rationale should lead to the approval of this proposed change in the cardiac catheterization methodology.

Additionally, the *2013 SMFP* included an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Robeson County resulting from a petition from Southeastern Regional Medical Center (SRMC). The SHCC concluded that SRMC's utilization of its one existing fixed cardiac catheterization unit demonstrated the need for additional equipment as it exceeded 100 percent of defined capacity, yet did not generate a need determination due to the rounding factor in the methodology. Rex believes that its proposed changes to the rounding rules for cardiac catheterization equipment will alleviate this issue for the future.

The approval of this methodology change will provide a clear and consistent path for highly utilized providers to generate need determinations and thus prevent potentially repetitive special need adjustment requests from the facilities in the service areas that are inequitably treated in the current methodology.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

As noted above, the current fixed cardiac catheterization need determination methodology can perpetuate imbalances between highly utilized and underutilized providers in the same service area. An underutilized provider diminishes the need demonstrated by a highly utilized provider. A provider could operate above the utilization standards indefinitely and not be able to acquire additional capacity, if another provider in its community was sufficiently underutilized. Physicians and patients are increasingly reluctant to shift to another site of care under the control of a different healthcare system for their care as this can lead to disruptions in the continuity and quality of care. There is no remedy for the patients, physicians, and providers in such a situation for cardiac catheterization services outside of a methodology change, as proposed, or a special need adjustment.

ALTERNATIVES CONSIDERED

File a Petition for a Special Need Adjustment

As noted above, the current cardiac catheterization methodology is unequitable and perpetuates imbalances between providers. A petition in the summer for a special need adjustment would, at best, result in a one-time allocation and would fail to address the problematic aspects of the current methodology. While Rex believes a special need determination can remedy the growing issues for cardiac catheterization capacity in Wake County, it would not address potential issues in other counties or issues that arise in future years. For these reasons, Rex has chosen to file a methodology change petition. However, if the SHCC determines that this methodology change is not desirable and would prefer a special need adjustment request to remedy these issues, Rex respectfully requests that the SHCC express this preference during its deliberations on this proposal.

Exclude Chronically Underutilized Facilities

The operating room methodology excludes chronically underutilized facilities in order to remedy the imbalances between highly utilized and underutilized providers. Rex does not believe this approach is appropriate for the cardiac catheterization methodology for several reasons. First, there is no consensus around an appropriate definition of a chronically underutilized cardiac catheterization provider. Such a definition would need to account for the emergency, life-saving nature of the service and its subsequent vital importance in many communities, regardless of utilization. More importantly, the majority of the state is already treated with a facility-specific methodology, effectively, and an extension of that approach to the remainder of the state would provide the needed remedy. Finally, the number of cardiac catheterization units in each service area is much lower than the number of operating rooms, and most providers have at least modest utilization levels. Thus, the exclusion of chronically underutilized facilities would not be as useful for this methodology. However, Rex does propose that only appropriately utilized facilities be qualified applicants for additional cardiac catheterization equipment.

UNNECESSARY DUPLICATION

Rex does not believe the proposed change will result in unnecessary duplication of health resources. The current acute care bed and PET methodologies use facility-specific methodologies consistent with the change proposed by Rex for cardiac catheterization. Need determinations for acute care beds and PET scanners are generated by facilities regardless of the utilization of other facilities within the same service area. Based on its adoption of these methodologies, it is clear that the SHCC understands that this approach to healthcare planning does not result in the unnecessary duplication of health resources. In fact, as discussed above, this approach provides a more specific and flexible methodology for allocating healthcare resources, as needed, across the state.

BASIC PRINCIPLES

Safety and Quality

The proposed methodology change will provide a process for facilities to generate cardiac catheterization capacity regardless of the utilization of other providers. Without this methodology change, a provider could indefinitely operate its cardiac catheterization equipment at high levels of utilization without any possibility of acquiring additional capacity through the current methodology. In such a situation, a facility may not be able to provide optimal safety and quality of care. Cardiac catheterization services must be available immediately for patients who present to a hospital with certain cardiology issues. These emergency situations inevitably delay scheduled patients or cause rescheduling. If the demand for cardiac catheterization services at a facility exceeds its reasonable capacity, then these delays and reschedules result in patients beginning their procedures late in the day, thus requiring a more expensive and inconvenient overnight stay, or waiting until a later scheduled time. Scheduled procedures, while not emergency cases, are needed to improve the health of these patients and the delays that may result from overcapacity equipment results in delays in their recovery and return to normal life. Increased utilization also causes stress on the cardiac catheterization equipment leading to increased maintenance issues. The downtime needed to address these maintenance issues can cause additional delays in treatment and further exacerbates the overutilization of the equipment. If patients and physicians are forced to access care at another facility which has available capacity, they may encounter disruptions in the continuity of care. Physicians and providers work every day to improve the systems of care which leverage information technology, multidisciplinary teams, and processes of care to deliver the right care at the right time to the right person. A facility under the control of another healthcare system cannot provide that same system of care to an unfamiliar physician and patient. As a result, safety and quality may be reduced without the proposed change in the methodology.

Access

The proposed change will enable the development of additional access to cardiac catheterization equipment, as needed throughout the state. Seven service areas are inequitably treated under the current methodology. Any potential need within these service areas could be indefinitely suppressed by underutilization, for whatever reason, at another provider in the same service area. In these areas, access to care for patients of all types is impacted.

Value

The proposed change will enable providers throughout the state to provide greater healthcare value. As noted above, facilities that have a process to add capacity as needed will be able to provide safer and higher quality services than if forced to operate overcapacity. Delays in needed treatment or unanticipated overnight stays at the

hospital add to healthcare expenditures. Overutilized equipment requires greater maintenance which creates additional expenses.

CONCLUSION

In conclusion, Rex requests that the SHCC approve the petition to change the cardiac catheterization need determination methodology. The proposed change would extend the facility-specific approach to cardiac catheterization need determinations to the entire state, rather than just to the majority of providers, and ensure the a need determination is generated when additional capacity is needed. As such, the methodology will become more specific and flexible to the changing needs of the citizens of North Carolina.

Thank you for your consideration.

Attachment 1

Cardiac Catheterization Equipment Service Areas	Facility	Total Planning Inventory	2013 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Total No. of Additional Machines Required by Facility	No. of Machines Needed
Catawba	Catawba Valley Medical Center	1	658	0.55	0	
	Frye Regional Medical Center	4	4,408	3.67	0	
	TOTAL	**5**		**4**		**0**
Forsyth	N.C. Baptist Hospital	5	3,606	3.00	0	
	Novant Health Forsyth Medical Center	8	4,612	3.84	0	
	TOTAL	**13**		**7**		**0**
Guilford	Cardiovascular Diagnostic Center	1	830	0.69	0	
	Cone Health	7	5,245	4.37	0	
	High Point Regional Health System	4	3,973	3.31	0	
	TOTAL	**12**		**8**		**0**
Iredell	Davis Regional Medical Center	1	441	0.37	0	
	Iredell Memorial Hospital	1	1,194	1.00	0	
	Lake Norman Regional Medical Center	1	53	0.04	0	
	TOTAL	**3**		**1**		**0**
Mecklenburg	Carolinas Medical Center (CMC)	7	6,804	5.67	0	
	CMC Mercy-Pineville	4	3,552	2.96	0	
	CMC-University	1	39	0.03	0	
	Novant Health Matthews Medical Center	1	765	0.64	0	
	Novant Health Presbyterian Medical Center	4	3,447	2.87	0	
	TOTAL	**17**		**12**		**0**
Wake	WakeMed	9	8,570	7.14	0	
	WakeMed Cary	1	222	0.19	0	
	Duke Raleigh Hospital	3	447	0.37	0	
	Rex Hospital	4	5,029	4.19	0	
	TOTAL	**17**		**12**		**0**

Grey colored cells indicate changes from current methodology

Cardiac Catheterization Equipment Service Areas	Facility	Total Planning Inventory	2013 Procedures (Weighted Totals)	Machines Required Based on 80% Utilization	Total No. of Additional Machines Required by Facility	No. of Machines Needed	Need Determinations
Catawba	Catawba Valley Medical Center	1	658	0.55	(0.45)	0	
	Frye Regional Medical Center	4	4,408	3.67	(0.33)	0	
	TOTAL						**0**
Forsyth	N.C. Baptist Hospital	5	3,606	3.00	(2.00)	0	
	Novant Health Forsyth Medical Center	8	4,612	3.84	(4.16)	0	
	TOTAL						**0**
Guilford	Cardiovascular Diagnostic Center	1	830	0.69	(0.31)		
	Cone Health	7	5,245	4.37	(2.63)		
	Cone Health Total				***(2.94)***	***0***	
	High Point Regional Health System	4	3,973	3.31	(0.69)	0	
	TOTAL						**0**
Iredell	Davis Regional Medical Center	1	441	0.37	(0.63)	0	
	Iredell Memorial Hospital	1	1,194	1.00	(0.00)	0	
	Lake Norman Regional Medical Center	1	53	0.04	(0.96)	0	
	TOTAL						**0**
Mecklenburg	Carolinas Medical Center (CMC)	7	6,804	5.67	(1.33)		
	CMC Mercy-Pineville	4	3,552	2.96	(1.04)		
	CMC-University	1	39	0.03	(0.97)		
	Carolinas HealthCare System Total				***(3.34)***	***0***	
	Novant Health Matthews Medical Center	1	765	0.64	(0.36)		
	Novant Health Presbyterian Medical Center	4	3,447	2.87	(1.13)		
	Novant Health Total				***(1.49)***	***0***	
	TOTAL			**12**			**0**
Wake	WakeMed	9	8,570	7.14	(1.86)		
	WakeMed Cary	1	222	0.19	(0.82)		
	WakeMed Total				***(2.67)***	***0***	
	Duke Raleigh Hospital	3	447	0.37	(2.63)	0	
	Rex Hospital	4	5,029	4.19	0.19	1	
	TOTAL						**1**

PETITION

Petition for Special Need Adjustment for Fixed Cardiac Catheterization Equipment in Wake County

PETITIONER

Rex Healthcare
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STATEMENT OF REQUESTED ADJUSTMENT

Rex Healthcare (Rex) respectfully petitions the State Health Coordinating Council (SHCC) to create an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Wake County in the *2015 State Medical Facilities Plan.*

BACKGROUND

Since 1894, Rex Hospital has provided healthcare, including cardiovascular services, to residents of Raleigh, Wake County, and the surrounding area. Rex Hospital, a member of UNC Health Care, provides the highest quality of care to patients and their families regardless of their ability to pay. Rex is a leader in cardiology in Raleigh, Wake County, and through its physician partners, Eastern North Carolina. From expert surgeons and cardiologists to highly-trained nurses, Rex's heart and vascular team provides exceptional care in the most critical situations for patients. Each of its nurses is trained in advanced cardiac life support (ACLS) in order to manage cardiac arrest in its early stages. Rex offers a variety of diagnostic and procedure options including cardiac catheterization, electrophysiology (EP), and open heart surgery. Notably, Rex was the first provider in Wake County to offer trans-catheter aortic valve replacement (TAVR), an advanced heart valve replacement procedure that provides an option for patients who are too sick or weak to undergo open heart surgery.

The *State Medical Facilities Plan* last added a unit of fixed cardiac catheterization equipment to Wake County in 2006; Rex applied for and was approved to

develop that unit. Since that time, Wake County's population has grown 23 percent according to the North Carolina Office of State Budget and Management. While statewide cardiac catheterization volume is declining, Rex's cardiac catheterization utilization has increased 23 percent annually since 2011. The following discussion highlights the unique utilization trends faced by Rex and demonstrate the need for the requested special need adjustment.

REASON FOR THE REQUESTED ADJUSTMENT

Rex's cardiac catheterization volume has increased substantially over the past three years necessitating additional capacity, which cannot be achieved without the requested need determination. As shown in Table 9W of the *Proposed 2015 State Medical Facilities Plan* (*SMFP*), Rex has a need for 4.19 units and has an inventory of only four units. As shown in the table below, more recent utilization data from Rex indicate that its volume has grown since the Federal Fiscal Year 2013 (FFY 2013) time period that is represented in the *2015 SMFP* and Rex now demonstrates a need for 4.86 units of catheterization equipment.

Rex Cardiac Catheterization Utilization

	FFY 2011	*FFY 2012*	*FFY 2013*	*FFY 2014**
Diagnostic	1,697	2,067	2,666	3,055
Interventional	820	1,033	1,350	1,587
Total Procedures	2,517	3,100	4,016	4,642
Weighted Procedures Total^	3,132	3,875	5,029	5,833
Machines Required†	**2.61**	**3.23**	**4.19**	**4.86**
Annual Growth of Weighted Procedures	**4.3%**	**23.7%**	**29.8%**	**16.0%**

Source: Rex internal data.
*FFY 2014 volume based on eight months of data (October 1, 2013 to May 26, 2014) annualized.
^Weighted Procedures Total = Diagnostic + Interventional x 1.75
†Machines Required = Weighted Procedures Total ÷ 1,200 procedures (80 percent of 1,500 procedure capacity) per the *Proposed 2015 SMFP* methodology.

After annual growth in excess of 20 percent in the prior two years, Rex cardiac cath volume has sustained a strong 16 percent growth rate since FFY 2013, the base data year shown in the *Proposed 2015 SMFP*. Rex's growth has been driven by unique circumstances, namely its affiliation in 2011 with Wake Heart & Vascular Associates (WHV), a leading cardiovascular practice in the Triangle. In 2013, WHV joined with Rex Heart & Vascular Specialists to create North Carolina Heart & Vascular, part of the UNC Heart & Vascular Network. The

combined practice has nearly three dozen physicians working out of 19 offices in ten counties. Since its decision to affiliate with Rex and UNC, WHV has relocated its primary clinic and most of its physician offices to the Rex Hospital campus, and, along with that shift, much of its hospital-related patient care, including cardiac catheterizations. The result is dramatic growth in cardiac catheterization volume at Rex, which stands in stark contrast to the trends in the rest of Wake County and the state. In fact, while it operated at 84 percent of capacity in FFY 2013, Rex's utilization has increased even further over the past year and now its labs are operating at 97 percent of capacity.

Rex Cardiac Catheterization Utilization

	FFY 2011	*FFY 2012*	*FFY 2013*	*FFY 2014**
Weighted Procedures Total	3,132	3,875	5,029	5,833
Units of Equipment^	3	4	4	4
Capacity†	4,500	6,000	6,000	6,000
Percent Utilization	**70%**	**65%**	**84%**	**97%**

Source: Rex internal data.
*FFY 2014 volume based on eight months of data (October 1, 2013 to May 26, 2014) annualized.
^Rex operated three units of equipment in FFY 2011 and added a unit in FFY 2012 based on a prior CON.
†Capacity = Units of Equipment x 1,500 procedure capacity per unit according to the *Proposed 2015 SMFP* methodology.

Rex's weighted cardiac catheterization procedures have grown at a compound annual growth rate of 23 percent since 2011. If Rex's utilization were to grow 23 percent from 2014 to 2015, it would perform 7,176 weighted procedures or 120 percent of capacity. In fact, Rex will reach 100 percent of its cardiac cath capacity if it only grows 2.9 percent from its FFY 2014 utilization. Given these factors, Rex believes it must act immediately in order to maintain the appropriate capacity needed to care for its patients.

According to the *Proposed 2015 SMFP*, Rex was the third highest utilized cardiac cath provider in North Carolina in 2013 and one of only three operators above 80 percent utilization.

Highest Utilized Cardiac Cath Providers in 2013

	Weighted Procedures	*Current Inventory*	*Capacity*	*Percent Utilization*
Cape Fear Valley Medical Center	3,906	3	4,500	87%
New Hanover Regional Medical Center	6,459	5	7,500	86%
Rex Healthcare	5,029	4	6,000	84%

Source: *Proposed 2015 SMFP.*

As shown above, Rex is operating at 97 percent of capacity in 2014, which would make it the highest utilized provider in the state. In fact, based on Rex's 2014 volume (5,833 weighted procedures), even if Rex were to add another unit immediately, bringing its inventory to five units of equipment, **it would still be operating at 78 percent of capacity** (78 percent = 5,833 procedures ÷ 5 units x 1,500 procedures per unit of capacity).

The two other providers in the table above are the only cardiac cath providers in their service areas. As such, their volume and capacity constraints are the sole drivers of additional need for additional units of cardiac cath equipment. In fact, in recent years, need determinations for additional units of equipment have been generated in New Hanover County, but the provider has petitioned to have that need removed. In contrast, Rex is in a service area with three other providers, none of whom has the same level of utilization. If Rex were the only provider in its service area, its 2014 utilization (showing a need for 4.86 units) would generate a need determination for an additional unit of capacity under the *SMFP* methodology. However, since the *SMFP* methodology is based on the average utilization of all providers in a service area, Rex is unable to meet the demand of its patients and physicians because other providers are underutilized.

Challenges with High Utilization

The *SMFP* methodology allocates additional units of catheterization once existing capacity in the service area reaches 80 percent utilization. The criteria and standards for cardiac catheterization used by the Certificate of Need Section require providers to demonstrate that any new equipment will be utilized at 60 percent or above. These standards recognize that providers cannot operate at or near 100 percent of capacity because some time must be allowed for emergencies or unforeseen delays. Due to its high cath lab utilization, Rex has no extra time during the day, and any emergency or delay can multiply, impacting the rest of the days' patients, as well as staff and physicians. Unlike other diagnostic or even interventional services, the unique qualities of cardiac catheterization make

operating at high utilization difficult for the facility, for physicians, and most importantly, for patients. The following discussion explains some of these challenges.

Emergency Cases

Cardiac catheterization, particularly for patients presenting with ST-elevated myocardial infarction, or STEMI, is provided on an emergency basis to save patients' lives. When a hospital's labs are operating at 97 percent of capacity and a patient presents with a need for emergency intervention, the lack of an available lab can lengthen the time until that care is available. In such instances at Rex, the cardiologist and cath team deal with the issue in an effective, evidence-based manner. The clinical team determines if a patient can be safely removed from a room or if a case can be completed expeditiously. If the selected patient is in the middle of the procedure but has yet to have his or her procedure completed, the patient is removed from the room with the sheath left in place until another room becomes available to complete the case. Clearly, this is not optimal patient care for the delayed patient, and it can delay treatment of the emergency patient. At facilities with adequate capacity, such a scenario would be much less likely to occur. As the SHCC is no doubt aware, prolonged door-to-balloon or symptom-to-balloon times have been correlated with increased mortality after primary percutaneous coronary intervention (PCI). As a result, the American College of Cardiology has established as part of its "Door-to-Balloon" campaign (known as the "D2B Alliance") that patients should receive interventional treatment within fewer than 90 minutes from the time the patient arrives at the hospital. The Joint Commission has also adopted this parameter as a core quality measure. As part of this 90-minute guideline, the D2B Alliance advocates that the cath lab team be available to perform the procedure within 20 to 30 minutes of the patient's arrival at the hospital. When a provider is operating at nearly 100 percent of capacity, it is significantly more challenging to meet this lifesaving guideline.

Extended Hours

Although cardiac cath is an invasive procedure, the majority of patients are outpatients, and most return home the same day. In a typical day for Rex's cath labs, cases begin at 7:00 am. Most of those patients who are treated earlier in the day go home the same day, particularly those who have only diagnostic procedures. However, due to Rex's full schedule, many patients begin their cases in the late afternoon and then must be monitored for an average of four hours post procedure. These patients, many of whom are older and often have elderly caregivers, are understandably reluctant or unable to leave the hospital and be

driven home late at night. As a result, many of these patients must stay overnight rather than being discharged the same day. These overnight stays are an unnecessary healthcare cost and are a substantial inconvenience to patients and their families. While these patients may not be emergency cases, they are scheduled procedures which are needed to diagnose and improve the health of these patients, and the delays that may result from equipment operating near or above capacity result in extended recovery and a postponed return to normal life.

Unpredictable Case Times

Rex strives to schedule its cath labs as effectively as possible, but the nature of the procedure makes it difficult to be precise and inevitably unpredicted delays occur. Because the standard of care is to schedule patients for a diagnostic procedure and then extend the case for an intervention if a stenosis or blockage is found, it is very difficult to consistently predict the length of a case. Cath labs could operate more efficiently if a diagnostic cath was performed and the patient was then brought back at another time for the intervention. However, this would delay care, increase radiation and contrast dose to the patient, and most significantly require a second catheterization procedure increasing the cost of care. This inability to consistently predict the length of each case, particularly in the context of Rex's high utilization, leads to delays for patients, staff, and physicians. For patients, the delay may result in an unnecessary overnight stay or an extended period of fasting. Catheterization patients are typically under physicians' orders to not eat or drink (NPO) for a period of time prior to their procedures; for patients scheduled for a morning procedure, this period often begins at midnight. Patients whose procedures are unexpectedly delayed until later in the day must therefore endure an unusually long time before they are able to eat or drink, which clearly impacts patient comfort and satisfaction

Staffing Issues

The uncertainty, delays, and emergencies that Rex experiences are also burdensome for physicians and staff. Delays for physicians result in delays for all of their patients, both in and out of the hospital. Since physicians normally have clinic hours after their cases are finished, if a physician is delayed at the hospital then they cannot see patients in their office on time. Moreover, Rex cannot efficiently staff its cath labs in this high utilization environment as staff routinely work overtime which decrease their job satisfaction and adds unnecessary costs.

Increased Maintenance Costs

Finally, Rex's high utilization necessitates that any routine maintenance occur overnight or on the weekends, which is more costly than if completed during work hours. Rex's schedule simply has no room for unscheduled (not routine) downtime of a machine. The consistent overuse of the equipment may also increase the amount of maintenance required, which will add cost and lead to increased downtime, scheduled and unscheduled.

Rex's Need Is Unique to the Service Area

For a minimal capital investment, Rex could modify existing vascular equipment with additional software to create an additional cardiac catheterization unit. However, Rex requires a need determination as well as a subsequent certificate of need to do so. While Rex clearly demonstrates a large and growing need for additional capacity, the cardiac catheterization methodology in the *SMFP* determines need on a service area basis. Thus, Rex's deficit of cardiac catheterization capacity is erased by the surplus of capacity at other facilities in Wake County. As shown in the excerpt below from Table 9W of the *Proposed 2015 SMFP*, all other Wake County cath providers are underutilized and, as a result, there is a surplus of 5.11 units.

Table 9W of *Proposed 2015 SMFP*: Wake County

	Total Planning Inventory	*Machines Required Based on 80% Utilization*	*Deficit/(Surplus)*
Rex Hospital	4	4.19	0.19
WakeMed	9	7.14	(1.86)
WakeMed Cary	1	0.19	(0.81)
Duke Raleigh	3	0.37	(2.63)
Total	**17**	**12**	**(5.11)**

Source: *Proposed 2015 SMFP.*

As the *SMFP* allocates additional cardiac catheterization equipment based on the need for Wake County in total, the excess capacity at WakeMed, WakeMed Cary, and Duke Raleigh restricts the ability of Rex to add capacity now and in the future. Of note, Duke Raleigh has the third largest surplus of cardiac catheterization units among all providers in the North Carolina.

If utilization at each of the other facilities in Wake County remained at 2013 levels, Rex would have to operate at 245 percent of its capacity (which obviously would be impossible) in order for a need for an additional cardiac catheterization

unit to be generated in Wake County using the standard methodology. While other providers in North Carolina have exceeded 100 percent of the capacity standard by performing procedures at night or on weekends, none has achieved over 150 percent of capacity. Moreover, utilization in excess of 100 percent has myriad negative implications as detailed above.

Conversely, the other facilities in Wake County would need to add 6,361 weighted procedures (2,230 additional procedures at WakeMed, 978 at WakeMed Cary, and 3,153 at Duke Raleigh) in order to effectively utilize their existing capacity so that Rex's utilization could generate additional need. For perspective on the 6,361 additional weighted procedures needed at other facilities, Rex's 2014 cardiac catheterization utilization is 5,833 weighted procedures. Thus, the other facilities in Wake County would need to add volume equivalent to Rex in total and then over 500 more in order to reach effective utilization of existing capacity. **From Rex's perspective, absent the special need adjustment requested in this petition, it will never be able to acquire additional cardiac catheterization capacity, no matter how needed because other providers in its community are so underutilized.**

Clearly, there is cardiac catheterization capacity available at other Wake County facilities. The idea of ensuring that additional capacity is not prematurely allocated is central to the goal of suppressing unnecessary duplication, a central tenet of the CON statute. This approach may be reasonable for certain services, particularly those for which the service or procedure is merely one adjunct to the overall diagnostic process and treatment plan. For example, a patient needing an MRI scan to support a diagnosis may choose an MRI provider separate from his physician or hospital, without it negatively impacting his diagnosis or treatment, particularly on an outpatient basis, as the vast majority of MRI scans are provided. Other services, however, are much more central to the overall process of diagnosis and treatment, require a physician present to perform the procedure, and may be performed more often on an inpatient basis than other procedures. Such is the case for cardiac catheterization services. The cardiology practice, which is comprised a team of providers, including medical, invasive, interventional and surgical cardiologists, has been chosen by the patient to provide his or her care. This team is central to the diagnosis and treatment, and the interventional cardiologist is directly involved with performing the procedure on the patient. Since those physicians have been chosen by the patient to provide his or her care, the notion of the physician referring the patient to a physician at another facility, just because there may be more capacity available there, is extraordinarily unlikely, as well as being disruptive to the continuity of care. Although cardiologists may be privileged at multiple hospitals, they typically choose a single facility at which to perform most of their procedural

work. Physicians and patients are increasingly reluctant to shift to another site of care under the control of a different healthcare system for care as it can lead to disruptions in the continuity and quality of care. The utilization of a particular facility is thus driven primarily by physician and patient preference, not the available capacity at a facility.

Moreover, the central theme of healthcare reform both past and present is the need for greater efficiency and integration in the delivery of healthcare. Hospitals and physicians are working together with the benefit of information technology to deliver coordinated services to patients. At Rex, patients see their cardiologist in the adjacent medical office building and receive their ancillary tests such as X-ray, Echo, and EKGs in the hospital. All of that data, including information from their referring primary care physician is captured in Rex's electronic medical record which is available to physicians (and even to the patients themselves through an online portal). This integrated database has numerous benefits for patient care. For example, if a physician notices something of interest in a patient's EKG, he/she can review that patient's entire history of EKG results from all of UNC/Rex Healthcare to see if that issue has been consistent in that patient's medical history, rather than ordering an unnecessary additional test. The medical record also enables the cardiologist to understand the most appropriate way to treat the patient, based on any possible future scheduled procedures. For example, if a patient is scheduled for another surgical case at a future date, such as a hip replacement, the cardiologist can access that information in the patient's medical record prior to the catheterization. In such a case, if the hip replacement is scheduled after the cardiac cath, the cardiologist may choose to use a bare-metal stent instead of a drug-eluding one to reduce the risk of hemorrhage during the future surgical case. While other healthcare systems in the region have electronic medical records or allow the cardiologist to bring the patient's medical record from a different facility, these workarounds cannot achieve the level of integration (and the resulting patient benefits) within UNC/Rex Healthcare.

For these reasons, Rex does not believe that its need for additional cardiac catheterization capacity can be served by underutilized capacity at other facilities. There is no remedy for Rex's patients and physicians for cardiac catheterization services outside of a special need adjustment.

The *SMFP* implicitly recognizes this dynamic in its acute care bed methodology which allocates bed need based on facility-specific need regardless of the presence of underutilized facilities in the service area. For example, the *Proposed 2015 SMFP* has a need determination for 26 beds in Mecklenburg County based

on the bed deficit of one system even though the other system shows a surplus of 24 beds. This instance is representative of understanding shown by the *SMFP* and the SHCC that underutilized assets at one provider do not meet the needs of other providers.

More pointedly, the SHCC approved a petition by Duke Raleigh for an adjusted need determination for one additional linear accelerator in Service Area 20 (Wake and Franklin counties) in the *2014 SMFP*. The SHCC acted specifically to alleviate Duke Raleigh's lack of linear accelerator capacity despite the absence of an overall need in the service area and in spite of the underutilization of multiple providers. Rex believes that its issue is very similar. As shown in the excerpt below in the October 2, 2013 Technology Committee report to the SHCC on this petition, additional capacity was found to be needed based on the overutilization of Duke Raleigh:

Petitioner: Duke University Health Systems dba Duke Raleigh Hospital

- **Request**: Duke Raleigh Hospital requested an adjusted need determination for one additional linear accelerator to meet a perceived unmet need in Service area 20 (Wake and Franklin Counties).

- **Committee Recommendation**: The Committee discussed the petition and agency report, which recommended denial of the petition request. The discussion included an update on one CON approved linear accelerator that was approved on February 2011 but has not been developed. This project is still on target to become operational in early 2014. The linear accelerator standard methodology demonstrates that the current inventory, including the CON approved linear accelerator to be developed, is providing sufficient access to linear accelerator services in Service Area 20. However, the consensus of the Committee recognized that Duke Raleigh is unable to increase its inventory to meet demonstrated excess patient demand. Therefore, the Committee recommends to the SHCC that the petition request be approved for one additional linear accelerator in Service Area 20.

As stated in the committee recommendation above, just as Duke Raleigh was not able to increase its linear accelerator capacity to meet the demands of its patients, Rex cannot increase its cardiac catheterization capacity to care for its patients. Duke Raleigh was overutilized while other facilities had excess capacity and there was a linear accelerator for the service area that had yet to be developed. Rex similarly is overutilized and its volumes continue to grow while other facilities in Wake County are substantially underutilized.

The SHCC's discussion at its October 2, 2013 meeting further underscores the similarities between the Duke Raleigh linear accelerator petition and Rex's current petition. In response to a request for greater detail about the Technology Committee's reasons for recommending approval of Duke Raleigh's petition, Dr. Dennis Clements, III stated, "*the linear accelerator presently operating in Duke Raleigh Hospital is basically over capacity. That unlike other things, like an MRI, where*

you may go get one and then if you need a different MRI you can go somewhere else. Most of these are cancer patients and once you get standardized on one machine you have to stay on that machine. You have maybe ten twenty maybe more procedures on that machine. The machine tends to be associated with a hospital, often with oncologists in that hospital. And so I think that was part of the issue" (transcribed from the audio recording of the October 2, 2013 SHCC meeting). As noted above, Rex believes the cardiac catheterization services and their physicians are similarly associated with one hospital and that capacity is not interchangeable as the SHCC determined in the case of Duke Raleigh.

On the same topic, Dr. Pulliam stated, "[t]*he other thing we can't lose sight of, and again I don't live around Raleigh, but if one facility is attracting a tremendous number of patients, they're attracting them for some reason. They probably offer something the others don't. There is a level of expertise possibly. It's hard to say. And I don't think we should constrain those who are doing the job right and well to the fact, to the point that they need more capacity just because we have these rules that might somehow try to redistribute the care*" (transcribed from the audio recording of the October 2, 2013 SHCC meeting). Rex and its physician partners have been tremendously successful in attracting a growing number of cardiology patients since 2011 due to its quality, innovation, and overall patient care. Rex should not be penalized by its success. The SHCC recognized and alleviated Duke Raleigh's capacity issues in 2013 and Rex believes that it faces the same issue with the cardiac catheterization and requests that the SHCC act accordingly.

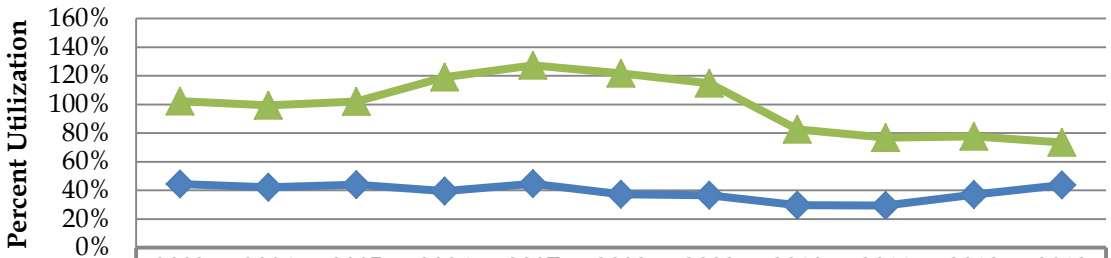
The SHCC's position in this area is supported by historical data in competitive cardiac catheterization markets. Rex performed a detailed review of the last ten years of utilization for each of the counties in North Carolina with multiple cardiac cath providers (Catawba, Forsyth, Guilford, Iredell, Mecklenburg and Wake counties, excluding Durham, where both cath providers are part of the Duke University Health System). Based on Rex's review of the data <u>there is no evidence to suggest that underutilized cardiac catheterization capacity alleviates the needs of overutilized cardiac catheterization facilities or that the addition of cardiac catheterization capacity to a provider harms the cardiac catheterization services at other facilities in the market</u>. Each market is analyzed below in detail.

CATAWBA COUNTY

Frye Regional Medical Center (Frye) in Catawba County operated at or above 100 percent of the *SMFP*-defined capacity of its cardiac catheterization equipment from 2003 until 2009. Frye operated at these high utilization levels despite the underutilization of the cath equipment at Catawba Valley Medical Center (CVMC), which never exceeded 45 percent of capacity over the past ten

years. Frye's utilization was such that a need was generated in the *2008 SMFP* for an additional unit of equipment despite CVMC's underutilization. Please note that this need generation was only possible because there was only one other provider in the county whose surplus was small (less that one of unit of excess capacity). Frye applied to develop that equipment, was approved, and began operation of its fourth unit in 2010. In the years following the addition of capacity at Frye, CVMC's cath utilization has increased and its 2013 utilization is just 12 procedures below its highest utilization in the last ten years.

Catawba County Cardiac Catheterization Utilization



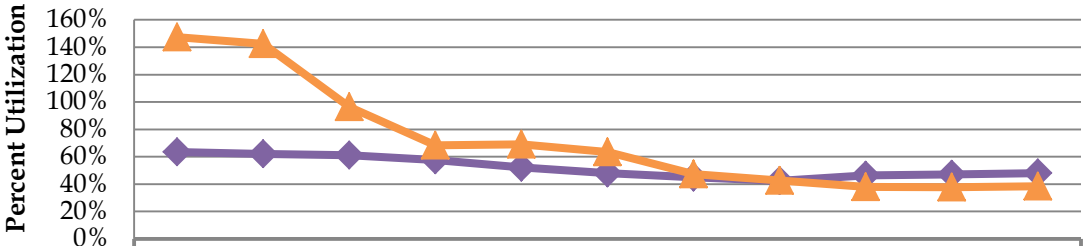
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
CVMC % Utiliz.	44%	42%	44%	40%	45%	37%	37%	30%	29%	37%	44%
CVMC Wgtd. Procs.	664	631	659	594	669	557	549	445	440	555	657
Frye % Utiliz.	102%	99%	102%	119%	127%	122%	115%	83%	77%	78%	73%
Frye Wgtd. Procs.	4,601	4,474	4,593	5,353	5,727	5,482	5,171	4,951	4,612	4,662	4,408

Note: CVMC operated one unit of cardiac catheterization equipment throughout the time period; Frye operated three units from 2003 to 2009, and four units from 2010 to 2013.
Source: *2005* to *Proposed 2015 SMFPs* and 2004 to 2014 License Renewal Applications.

FORSYTH COUNTY

Novant Health Forsyth Medical Center (Forsyth) operated above or near 100 percent of the *SMFP*-defined capacity of its cardiac catheterization equipment from 2003 to 2005. Forsyth operated at these high utilization levels despite the underutilization of the cath equipment at North Carolina Baptist Hospital (Baptist), which never exceeded 63 percent utilization over that same time period. Baptist's cardiac cath volume declined in every year from 2003 to 2010, and this consistent trend appears unrelated to Forsyth's increase in capacity in 2005 and 2009. Nonetheless, Baptist's utilization began increasing in 2011 and now is at its 2008 levels. Overall, volume in the county has increased since 2011 indicating that some regions are experiencing growth in cardiac catheterization utilization despite statewide trends of decreasing utilization.

Forsyth County Cardiac Catheterization Utilization



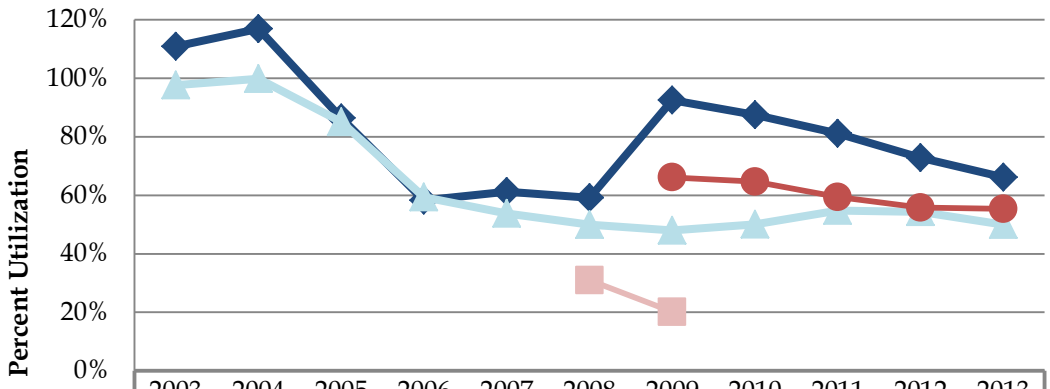
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Baptist % Utiliz.	63%	62%	61%	58%	52%	48%	45%	42%	46%	47%	48%
Baptist Wgtd. Procs.	4,759	4,656	4,586	4,325	3,910	3,601	3,376	3,169	3,478	3,536	3,606
Forsyth % Utiliz.	147%	142%	96%	68%	69%	63%	47%	43%	38%	38%	38%
Forsyth Wgtd. Procs.	11,059	10,681	8,684	6,157	6,223	5,702	5,667	5,101	4,550	4,511	4,612

Note: Baptist operated five units of cardiac catheterization equipment throughout the time period; Forsyth operated five units from 2003 to 2005, six units from 2005 to 2008, and eight units from 2009 to 2013.
Source: *2005* to *Proposed 2015 SMFPs* and 2004 to 2014 License Renewal Applications.

GUILFORD COUNTY

From 2003 until 2008, utilization at High Point Regional Health System (High Point) and Cone Health (Cone) were very similar, with high utilization in 2003 and 2004 followed by decline and then stabilization. While Cone Health's volume also declined in 2006, that loss was consistent with its trend since 2004 and does not appear to be a result of High Point's addition of one unit in 2006. Greensboro Heart Center (GHC) opened in 2008, and while utilization at both High Point and Cone declined in that year, it subsequently rebounded. In particular, High Point's utilization spiked in 2009, the same year that Cardiovascular Diagnostic Center (CDC), owned by Cone Health, opened. High Point's utilization remained above its 2008 levels through 2013. Thus, the additional capacity at CDC appears to not have negatively impacted High Point. Moreover, the development of CDC has increased volume for the Cone Health system overall (Cone Health and CDC combined) as its utilization also remained above 2008 levels through 2013.

Guilford County Cardiac Catheterization Utilization



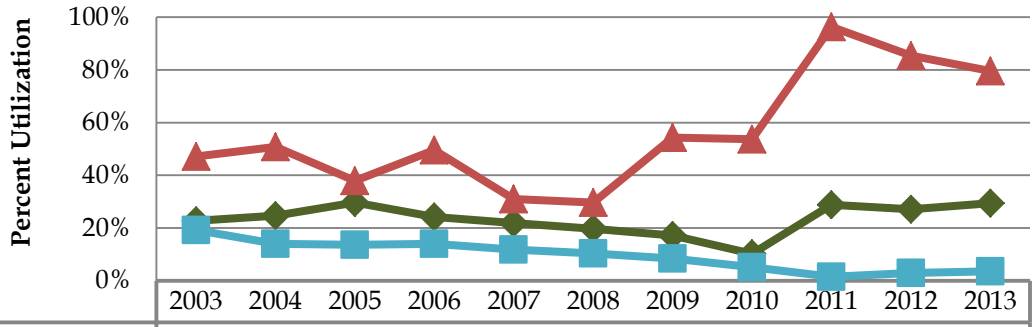
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
High Point % Utiliz.	111%	117%	86%	58%	61%	59%	93%	88%	81%	73%	66%
High Point Wgtd. Procs.	4,990	5,264	3,887	3,495	3,676	3,550	5,552	5,252	4,870	4,371	3,973
Cone % Utiliz.	98%	100%	85%	59%	54%	50%	48%	50%	55%	54%	50%
Cone Wgtd. Procs.	10,257	10,484	8,933	6,238	5,651	5,244	5,044	5,261	5,749	5,701	5,245
CDC % Utiliz.							66%	65%	59%	56%	55%
CDC Wgtd. Procs.							992	970	891	837	830
GHC % Utiliz.						31%	20%				
GHC Wgtd. Procs.						464	302				

Note: High Point operated three units of cardiac catheterization equipment from 2003 to 2005, and four units from 2006 to 2013. Cone operated seven units throughout the time period. GHC and CDC each operated one unit. High Point's 2008 weighted procedures are based on its 2009 Hospital License Renewal Application and not on the incorrect data shown in *SMFP* tables.
Source: *2005* to *Proposed 2015 SMFPs* and 2004 to 2014 License Renewal Applications.

IREDELL COUNTY

From 2003 to 2010, no cardiac catheterization provider in Iredell County operated above 80 percent of the *SMFP*-defined capacity of its cardiac catheterization equipment. However, Iredell Regional Medical (Iredell) began operating above 90 percent from 2011 to 2013 and this utilization does not appear to have been alleviated by available capacity at other providers. Utilization at Davis Regional Medical Center (Davis) increased alongside Iredell's volume in 2011, but has declined since that time. Utilization at Lake Norman Regional Medical Center (Lake Norman) declined only slightly as Iredell reached its high levels of utilization.

Iredell County Cardiac Catheterization Utilization



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Davis % Utiliz.	23%	25%	30%	24%	22%	20%	17%	10%	29%	27%	29%
Davis Wgtd. Procs.	342	370	446	363	328	295	258	153	432	407	441
Iredell % Utiliz.	47%	51%	38%	50%	31%	30%	54%	54%	96%	85%	80%
Iredell Wgtd. Procs.	708	762	569	743	466	445	814	806	1,445	1,281	1,194
Lake Norman % Utiliz.	19%	14%	14%	14%	12%	10%	8%	5%	2%	3%	4%
Lake Norman Wgtd. Procs.	289	211	204	211	178	156	126	77	23	44	53

Note: Davis, Iredell, and Lake Norman each operated one unit of cardiac catheterization equipment throughout the time period.
Source: *2005* to *Proposed 2015 SMFPs* and 2004 to 2014 License Renewal Applications.

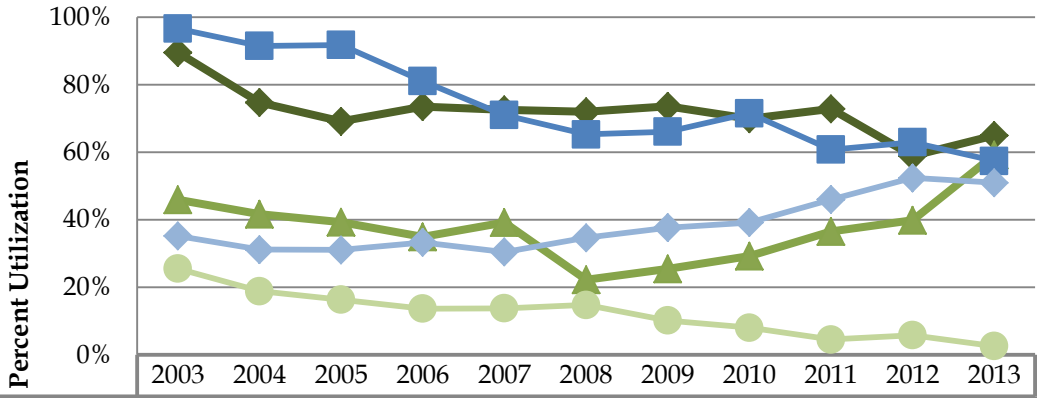
MECKLENBURG COUNTY

Mecklenburg County is unique statewide as two hospital systems, Carolinas HealthCare System and Novant Health, each operate two or more hospitals with cardiac catheterization equipment: Carolinas Medical Center (CMC), CMC-Mercy/Pineville (CMC-M/P), and CMC-University (CMC-U) within Carolinas HealthCare System and Novant Health Presbyterian Medical Center (Presby) and Novant Health Matthews Medical Center (Matthews) within Novant Health. Capacity at other providers, even within their own parent healthcare system, does not appear to have alleviated high utilization at CMC or Presby in the 2003 to 2010 time period. For example, while CMC operated at between 69 and 90 percent from 2003 to 2010, its sister hospitals, CMC-U and CMC-M/P operated at a maximum of 46 percent of capacity. Similarly, Presby operated at between 65 and 97 percent from 2003 to 2010 and Matthews operated below 39 percent. Since 2010, it appears that Carolinas HealthCare System and Novant Health are more effectively rationalizing services among their hospitals as utilization has declined at CMC and Presby and increased at CMC-M/P and Matthews. CHS made specific efforts to shift tertiary business to CMC-Pineville in an effort to decompress CMC through the transfer of assets under multiple CON projects, and that appears to have increased utilization at CMC-Pineville with only modest decreases at CMC. Also, of note, Mecklenburg County cardiac

catheterization equipment (in total and at each of the facilities) has remained unchanged since 2003.

Rex contends that the experience in Mecklenburg County indicates that underutilized cardiac catheterization capacity does not alleviate the needs of cardiac catheterization overutilization at other facilities unless a hospital system, in coordination with its physicians, specifically plans for and directs that business to shift. Such a shift does not occur naturally.

Mecklenburg County Cardiac Catheterization Utilization



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
CMC % Utiliz.	90%	75%	69%	74%	73%	72%	74%	70%	73%	59%	65%
CMC Wgtd. Procs.	9,403	7,856	7,268	7,718	7,623	7,561	7,734	7,344	7,649	6,188	6,822
CMC-M/P % Utiliz.	46%	42%	39%	35%	39%	22%	25%	29%	37%	40%	59%
CMC-M/P Wgtd. Procs.	2,759	2,501	2,358	2,098	2,354	1,332	1,527	1,758	2,195	2,394	3,552
CMC-U % Utiliz.	26%	19%	16%	14%	14%	15%	10%	8%	5%	6%	3%
CMC-U Wgtd. Procs.	383	283	245	205	207	222	153	121	68	87	39
Presby % Utiliz.	97%	92%	92%	81%	71%	65%	66%	72%	61%	63%	57%
Presby Wgtd. Procs.	5,799	5,492	5,510	4,865	4,262	3,918	3,967	4,295	3,649	3,780	3,447
Matthews % Utiliz.	35%	31%	31%	33%	30%	35%	38%	39%	46%	52%	51%
Matthews Wgtd. Procs.	528	468	466	500	457	520	566	588	690	786	765

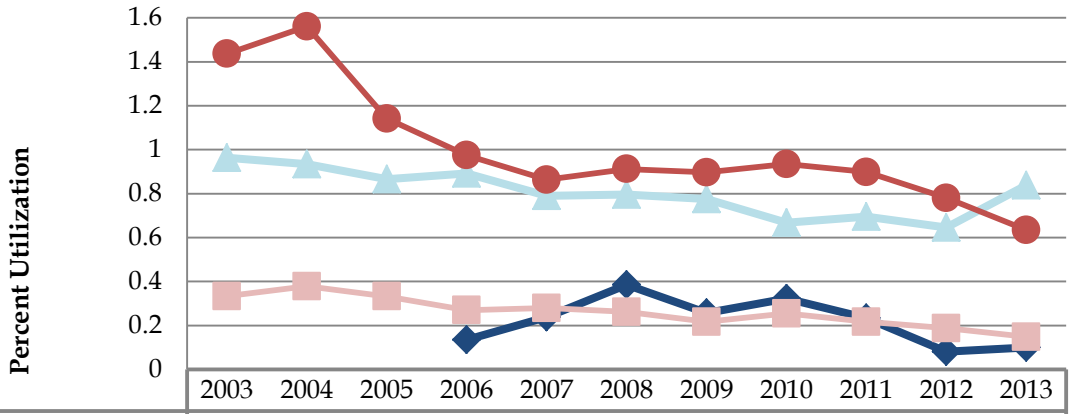
Note: The capacity of CMC (seven units), CMC-M/P (four units), CMC-U (one unit), Presby (four units), and Matthews (one unit) was unchanged throughout the time period.
Source: *2005* to *Proposed 2015 SMFPs* and 2004 to 2014 License Renewal Applications.

WAKE COUNTY

Both WakeMed and Rex operated above or near 100 percent of the *SMFP*-defined capacity of their cardiac catheterization equipment from 2003 to 2006 despite the underutilization of the cath equipment at WakeMed Cary (a sister hospital of WakeMed), which never exceeded 38 percent utilization over that same time period. Between 2005 and 2007, all providers except WakeMed Cary added

capacity and volume at each facility has largely remained flat with the exception of the recent increase at Rex due to the affiliation with WHV and a corresponding decrease at WakeMed.

Wake County Cardiac Catheterization Utilization



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Duke Raleigh % Utiliz.				13%	24%	38%	26%	32%	23%	8%	10%
Duke Raleigh Wgtd. Procs.				202	357	1,154	770	967	701	366	447
Rex % Utiliz.	96%	93%	87%	89%	79%	80%	78%	67%	70%	65%	84%
Rex Wgtd. Procs.	4,333	4,206	3,897	4,015	3,557	3,581	3,489	3,002	3,132	3,875	5,029
WakeMed % Utiliz.	144%	156%	114%	97%	86%	91%	90%	93%	90%	78%	63%
WakeMed Wgtd. Procs.	10,772	11,709	11,984	11,698	11,657	12,312	12,108	12,618	12,130	10,535	8,570
WakeMed Cary % Utiliz.	33%	38%	33%	27%	28%	26%	22%	25%	22%	19%	15%
WakeMed Cary Wgtd. Procs.	499	567	498	405	418	393	325	382	325	282	222

Note: Duke Raleigh began operation of one unit of fixed equipment in 2006 and added 2nd unit in 2006 and a 3rd unit in 2012.Rex operated two units from 2003 to 2005, three units from 2006 to 2011, and four units in 2012 and 2013. WakeMed operated five units in 2003 and 2004, seven units in 2005, eight units in 2006, and nine units from 2007 to 2013. WakeMed Cary operated one unit through the 2003 to 2013 time period.
Source: *2005* to *Proposed 2015 SMFPs*.

COUNTY DATA SUMMARY

To reiterate, Rex believes that historical data from the last ten years in every county with competing cardiac catheterization providers show that underutilized cardiac catheterization capacity does not alleviate the needs of overutilized cardiac catheterization overutilization facilities and that the addition of cardiac catheterization capacity to a provider does not harm the cardiac catheterization services at other facilities in the market. It should also be noted that in some of these service areas, including Wake County, the available capacity at some facilities cannot be used to alleviate the overutilization at others. Specifically, some providers within a service area use cardiac catheterization for diagnostic procedures only, while some perform both diagnostic and elective

(scheduled) interventional procedures. Facilities with open heart surgical capabilities and emergency PCI capabilities, such as Rex, cannot rely on capacity at facilities without these capabilities. Wake County EMS protocols require the transport of STEMI patients to the closest hospital with these capabilities; within Wake County, Rex is one of only two facilities. Thus, the capacity of WakeMed Cary and Duke Raleigh should arguably not be considered as mitigating the capacity constraints at Rex. Further, as noted above, physicians and patients are choosing care at Rex over other facilities, which will continue to drive need for capacity at Rex, notwithstanding available capacity at other facilities.

These findings support the need for Rex's requested special need adjustment. The existing underutilized capacity in Wake County will not alleviate Rex's capacity needs as the historic above indicate. Moreover, this historic data analysis also demonstrates that the addition of cardiac catheterization capacity at Rex will not harm other providers in the market.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

The most obvious adverse effect of the failure to approve the petition is the negative impacts that Rex's continuing capacity constraints have on patient safety, quality, and convenience as detailed above. As volume continues to increase, the *SMFP* methodology will not provide additional capacity. The ability to provide timely emergency procedures, high quality and convenient outpatient diagnostic procedures, and seamless care within the Rex system will increasingly be more challenging.

ALTERNATIVES CONSIDERED

As described above, the status quo is already creating a situation in which maintaining a high quality of care is challenging, particularly considering the need for emergent catheterization procedures. Moreover, without a special need determination, the current methodology in the *SMFP* would require Rex to operate at an impossible 245 percent of capacity in order to overcome the underutilized cardiac cath capacity at other facilities in Wake County. Rex would need to achieve that utilization and then wait for two or more years: a year at that volume to be reported on its licensure application, a year for that volume data to be incorporated into the planning process for the next *SMFP*, and at least six months, if not another year, to file the CON, have it reviewed, and, if granted, develop the additional lab. The status quo will not provide additional access, and therefore, it is not a valid consideration.

Rex has also considered expanding its capacity through the use of a mobile catheterization service. While this service may be helpful to rural providers, as the SHCC is aware, it is not an optimal long-term solution for a provider with sufficient volume to sustain an additional fixed catheterization lab and a robust cardiac program. Within the past couple years, the SHCC approved the development of shared fixed catheterization labs in Scotland and Lee counties to replace mobile service, in part due to the issues surrounding the use of mobile catheterization at higher volume sites. Moreover, the number of available mobile catheterization labs in the state is limited, largely under the control of a main competitor of Rex (Duke), and subject to contracts with providers; thus, the availability of a mobile catheterization lab for long-term use at Rex is inadequate.

Finally, Rex filed a petition in the spring of 2014 for a methodology change that requested that the cardiac catheterization methodology determine the need for additional capacity based on the utilization of individual facilities rather than the aggregate utilization of all of the facilities in the service area. This change would have allowed providers in need of additional capacity to generate a need determination regardless of the underutilization of other providers in the service area. However, the SHCC denied that petition and the Agency Report indicated an opposition to a methodology that would consider the need for individual facilities.

Given that none of the other potential alternatives are suitable, Rex seeks the adjusted need determination proposed in this petition.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION

Rex does not believe the proposed change will result in unnecessary duplication of health resources. As set forth above, other providers in Wake County appear to have capacity on their existing equipment, but the utilization data from the last ten years in competitive cardiac catheterization markets demonstrates that this excess capacity does not relieve high utilization at other providers nor does the addition of capacity in a service area harm existing providers. Therefore, while the proposed change would increase the number of linear accelerators in the Wake County, the expansion is necessary to provide adequate access.

Moreover, Rex believes that the SHCC's approach to capacity planning in other services indicates that the allocation of capacity based on the utilization of specific facilities does not result in unnecessary duplication. Specifically, the current acute care bed and PET methodologies use facility-specific methodologies and, as a result, need determinations for acute care beds and PET

scanners are generated by facilities regardless of the utilization of other facilities within the same service area. Moreover, the SHCC's recent approval of Duke Raleigh's petition for additional linear accelerator capacity in Wake County specifically included a discussion of the merits of allowing a provider to increase capacity based on its utilization, regardless of capacity at other providers.

As noted above, Rex understands that the approval of this petition does not guarantee that it can obtain a certificate of need for an additional unit of fixed cardiac catheterization equipment. However, the SHCC should be reasonably confident that Rex would be approved given the underutilization of other providers in the service area, Rex's demonstrated need for additional capacity, and the requirement that cardiac catheterization equipment shall only be approved for development on hospital sites.

EVIDENCE OF CONSISTENCY WITH THE THREE BASIC PRINCIPLES

Rex believes the petition is consistent with the three basic principles: safety and quality, access, and value.

SAFETY AND QUALITY

Quality and safety are clearly enhanced through the development of additional cardiac catheterization capacity. Without sufficient capacity, particularly for a service often provided on an emergent basis, like interventional cardiac catheterization, quality can suffer and patient care may not be optimal. Without this adjusted need determination, Rex could operate its cardiac catheterization equipment at high utilization levels indefinitely without any possibility of acquiring additional capacity. Cardiac catheterization services must be available immediately for emergency patients who present to a hospital. These emergency situations often require a patient to be taken out of a room before the case is finished. Emergency patients inevitably delay scheduled patients or cause rescheduling. The American College of Cardiology has established that patients should receive interventional treatment within fewer than 90 minutes from the time the patient arrives at the hospital. When a provider is operating at nearly 100 percent of capacity, it is more challenging to meet this lifesaving guideline.

If the demand for cardiac catheterization services at a facility exceeds its reasonable capacity, then any delays result in patients beginning their procedures late in the day, thus requiring a more expensive and inconvenient overnight stay, or waiting until a later scheduled time. Scheduled procedures, while not emergency cases, are needed to improve the health of these patients and the delays that may result from overcapacity equipment results in delays in

their recovery and return to normal life. Increased utilization also causes stress on the cardiac catheterization equipment leading to increased maintenance issues. The downtime needed to address these maintenance issues can cause additional delays in treatment and further exacerbates the overutilization of the equipment.

If patients and physicians are forced to access care at another facility which has available capacity, they may encounter disruptions in the continuity of care. Physicians and providers work every day to improve the systems of care which leverage information technology, multidisciplinary teams, and processes of care to deliver the right care at the right time to the right person. Rex's electronic medical record allows providers to access all of the patient's records including relevant diagnostic tests that can provide vital information to guide the care of the patient. A facility under the control of another healthcare system cannot provide that same system of care to an unfamiliar physician and patient. As a result, safety and quality will be enhanced with the proposed adjusted need determination.

ACCESS

Additional cardiac catheterization capacity is needed to provide sufficient access for Rex patients. In particular, Rex is a leading provider of care to the elderly population in Wake County. According to 2014 Hospital License Renewal Application data, Rex provides a greater percentage of its inpatient and emergency services care to the Medicare population than any other facility in the county. Elderly patients, in particular, need sufficient access to cardiac catheterization services. Moreover, North Carolina Heart and Vascular, the cardiology physician practice at Rex Hospital see patients in 19 offices in ten counties. Increasing these physicians' access to cardiac catheterization capacity will in turn broaden the access for these patients across a broad region, including areas where no cardiac catheterization capacity exists or is only provided on a diagnostic basis. For example, patients in Franklin, Harnett, and Sampson counties who see North Carolina Heart and Vascular physicians in local offices will have greater access to cardiac catheterization services, which are not available in their home county.

VALUE

The petition also promotes value. As discussed above, overutilization of cardiac catheterization capacity sometimes results in expensive and inconvenient overnight stays for patients that could have been discharged on the same day.

Additional catheterization lab capacity will ensure that patients—both inpatients and outpatients—receive care in a timely manner, enabling patients to be discharged within an appropriate timeframe, which will prevent unnecessary expenditures by the patients and payors. Delays in needed treatment or unanticipated overnight stays at the hospital add to healthcare expenditures. Rex's high utilization necessitates that any routine maintenance occur overnight or on the weekends, which is more costly than if completed during work hours. Increased utilization also causes stress on the cardiac catheterization equipment leading to increased maintenance issues, which increases cost. The downtime needed to address these maintenance issues can cause additional delays in treatment and further exacerbates the overutilization of the equipment. Finally, Rex cannot efficiently staff its cath labs in this high utilization environment as staff routinely work overtime which decrease their job satisfaction and adds unnecessary costs.

CONCLUSION

In conclusion, Rex requests that the SHCC approve the petition for an adjusted need determination of one cardiac catheterization unit in Wake County. Rex believes the unique circumstances in the county warrant additional capacity. Specifically:

- Since 2011, Rex's partnerships with its cardiologists have resulted in 23 percent annual growth in cardiac catheterization volumes.
- Rex's cardiac catheterization labs are currently operating at 97 percent of capacity, which would make it the highest utilized provider in the state.
- Rex's utilization levels make it more difficult to deliver optimal care, particularly given the emergent nature of conditions requiring cardiac intervention, consistent with the Basic Principles of the *SMFP.*
- Absent the special need adjustment requested in this petition, Rex will never be able to acquire additional cardiac catheterization capacity no matter how needed as other providers in its community are sufficiently underutilized.

Thank you for your consideration.

Attachment 2

Technology and Equipment Committee
Agency Report
Petition for Special Need Adjustment for Fixed Cardiac Catheterization Equipment in Wake County in the Proposed 2015 State Medical Facilities Plan

Petitioner:
Rex Healthcare
4420 Lake Boone Trail
Raleigh, NC 27607

Contact:
Erick Hawkins
System Vice President, Heart and Vascular Services
(919) 784-4586
Erick.Hawkins@rexhealth.com

Request:
Rex Healthcare (Rex) respectfully petitions the State Health Coordinating Council (SHCC) to create an adjusted need determination for one additional unit of fixed cardiac catheterization equipment in Wake County in the 2015 *State Medical Facilities Plan.*

Background Information:
The Proposed 2015 State Medical Facilities Plan (SMFP) provides two standard need determination methodologies for cardiac catheterization equipment. Methodology One is the standard methodology for determining need for additional fixed cardiac catheterization equipment and Methodology Two is the need determination methodology for shared fixed cardiac catheterization equipment. Application of these methodologies to utilization data in the Proposed 2015 SMFP does not generate a need determination for fixed or shared fixed cardiac catheterization equipment in Wake County.

Chapter Two of the North Carolina Proposed 2015 SMFP allows persons to petition for an adjusted need determination in consideration of "unique or special attributes of a particular geographic area or institution…," if they believe their needs are not addressed by the standard methodology. Rex has submitted a petition to add a need determination for one unit of fixed cardiac catheterization equipment in Wake County. Rex is requesting the adjusted need determination based on "the unique utilization trends faced by Rex".

There are several providers in Wake County that offer cardiac catheterization services. Wake County has a total of 17 cardiac catheterization machines in the Proposed 2015 SMFP. Of those, Rex has a current total inventory four machines. Using the standard methodology of 80% utilization, the number of calculated machines for Wake County and Rex is 11.89 and 4.19

respectively. Thus, in the Proposed 2015 SMFP Rex has a 0.19 machine deficit and Wake County has a 5.11 machine surplus as seen in Table 1 below.

Table 1: Wake County Fixed Cardiac Catheterization Equipment from 2004 to 2013

		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Duke Raleigh Hospital	Total Number of Procedures	0	1288*	202	357	262	770	967	701	366	447
	No of Machines in Inventory	0	0	1	1	2	2	2	2	3	3
	Machines required based on 80% Utilization	0.00	1.07	0.17	0.30	0.22	0.64	0.81	0.58	0.30	0.37
Rex Hospital	Total Number of Procedures	4,206	3,897	4,015	3,646	3,616	3,489	3,002	3,132	3,875	5,029
	No of Machines in Inventory	2	2	3	3	3	4	4	4	4	4
	Machines required based on 80% Utilization	3.50	3.25	3.35	3.04	3.01	2.91	2.50	2.61	3.23	4.19
WakeMed	Total Number of Procedures	11,709	11,984	11,698	11,657	12,312	12,108	12,618	12,130	10,535	8,570
	No of Machines in Inventory	5	7	8	9	9	9	9	9	9	9
	Machines required based on 80% Utilization	9.76	9.99	9.75	9.71	10.26	10.09	10.52	10.11	8.78	7.14
WakeMed-Cary	Total Number of Procedures	567	498	405	418	393	325	382	325	282	222
	No of Machines in Inventory	1	1	1	1	1	1	1	1	1	1
	Machines required based on 80% Utilization	0.47	0.42	0.34	0.35	0.33	0.27	0.32	0.27	0.23	0.19
County Totals	Total Number of Procedures	16,482	17,667	16,319	16,077	16,582	16,692	16,969	16,287	15,057	14,268
	No of Machines in Inventory	8	10	13	14	15	16	16	16	17	17
	Machines required based on 80% Utilization	13.74	14.72	13.60	13.40	13.82	13.91	14.14	13.57	12.55	11.89

Note: The number of machines assigned to each facility is not based on the number that were actually operated by the facility, but the number of machines listed in the inventory for each facility in each year's state medical facility plan.

*Duke Raleigh reported 1288 procedures on the 2006 HLRA, but no fixed cardiac catheterization machine was reported in the plan as in use and procedures were not reported as mobile.

2006-2014 SMFP's; Proposed 2015 SMFP

Analysis/Implications:

In the face of steady increases and aging of the population, in NC cardiac catheterization has remained fairly stable over the last decade. Table 2 illustrates the compound annual growth rate (CAGR) and the overall change in the weighted procedures for both Wake County and NC from 2004 to 2013. In Wake County, the last 10 years of data shows an average annual CAGR of -1.09%, a decline, while the NC CAGR over the same time period had an average annual decline of - 2.02%. This indicates a slow and steady reduction in the number of procedures in both regions, with Wake County experiencing a slower decline than the state overall. These figures add up significantly when looking at the cumulative change percentage. In the last 10 years Wake County and NC have experienced declines greater than 10% and 18%, respectively.

Table 2: Wake and NC Cardiac Catheterization Growth from 2004-2013													
		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	CAGR 2004-2013	CHANGE
Wake	Total Procedures (weighted)	15,919	17,667	16,319	16,077	16,582	16,692	16,969	16,287	15,057	14,268	-1.09%	-10.37%
	Annual Change		10.99%	-7.63%	-1.48%	3.14%	0.66%	1.66%	-4.02%	-7.55%	-5.24%		
		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	CAGR 2004-2013	CHANGE
NC	Total Procedures (weighted)	134,801	129,104	118,892	113,643	119,910	115,865	115,017	114,567	112,060	109,885	-2.02%	-18.48%
	Annual Change		-4.23%	-7.91%	-4.41%	5.51%	-3.37%	-0.73%	-0.39%	-2.19%	-1.94%		

2014 SMFP

Table 3 below serves to further evaluate the actual changes in procedure volumes as compared to Table 2. When analyzing the Wake County and statewide data over the same time frames as those used in the petition, excluding FFY 2014, the picture looks a little different. While the CAGR from 2004-2013 indicates a slow, steady decline, the more recent numbers as shown in Table 3 indicate a steeper drop in Wake County with a CAGR of -4.32% as compared to the statewide CAGR of -1.38%. Thus, demonstrating that Wake, in recent years, has experienced a sharper decline in utilization than the state as a whole.

Table 3: Wake and NC Cardiac Catheterization Growth from 2011-2013						
		2011	2012	2013	CAGR 2011-2013	CHANGE
Wake	Total Procedures (weighted)	16,287	15,057	14,268	-4.32%	-12.40%
	Annual Change		-7.55%	-5.24%		
		2011	2012	2013	CAGR 2011-2013	CHANGE
NC	Total Procedures (weighted)	114,567	112,060	109,885	-1.38%	-4.09%
	Annual Change		-2.19%	-1.94%		

2014 SMFP

The petition provides procedure data at Rex Healthcare from 2011 through 2014 to demonstrate increased and unique utilization rates. An important point to note is that although the petitioner reports procedure volumes from FY2014, this information is not used in this analysis per the practice of the agency. Analysis is conducted on only data used prior to and in the current Proposed 2015 State Medical Facilities Plan. The plan's data year is FY2013.

Despite the decline in total procedures in Wake County, the data presented in Rex's petition suggests they have had unique utilization trends in recent years. The petition cites an increase in procedure volume as a result of the professional affiliation with Wake Heart & Vascular Associates (WHV). However, the utilization data demonstrates a few points pertinent to the discussion.

First, as seen in Table 4, Rex has only one year in the last five recent years of utilization greater than 80%. Application of the methodology does generate a deficit for this facility for this one year, but it is difficult to forecast the changes and trends in healthcare utilization based on one year's worth of data.

Additionally, this one year of utilization creates the deficit of 0.19 machines for Rex. The standard methodology considers procedure volume and number of machines of the entire service area. Thus, Rex's deficit is offset by a surplus of machines in Wake County as a whole. Table 5 demonstrates there is a 56% utilization rate in this service area. According to Table 5 there has been a drop in the last three years of utilization from 68% to 56%. Therefore, approval of this petition may introduce duplication of health services into Wake County, further eroding the already declining utilization rates.

Finally, both Rex Hospital and WakeMed operated at over 80% capacity for five and eight years, respectively, of the 10 year time frame (Table 4). In some of those years, utilization was well over 100% for both facilities. The petitioner argues that utilization greater than 80% poses difficulties for both providers and patients. While higher facility utilization does come with challenges, previous historical trends have demonstrated several years' volumes over 80% have occurred in Wake County.

Table 4: Wake County Cardiac Catheterization Procedures by Facility from 2004 to 2013

		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Duke Raleigh Hospital	Total weighted procedures	0	1,288*	202	357	262	770	967	701	366	447
	No of Machines	0	0	1	1	2	2	2	2	3	3
	Procedures for 100% Utilization	0	0	1,500	1,500	3,000	3,000	3,000	3,000	4,500	4,500
	Utilization	0%	0%	13%	24%	9%	26%	32%	23%	8%	10%
Rex Hospital	Total weighted procedures	4,206	3,897	4,015	3,646	3,616	3,489	3,002	3,132	3,875	5,029
	No of Machines	2	2	3	3	3	4	4	4	4	4
	Procedures for 100% Utilization	3000	3000	4,500	4,500	4,500	6,000	6,000	6,000	6,000	6,000
	Utilization	140%	130%	89%	81%	80%	58%	50%	52%	65%	84%
WakeMed	Total weighted procedures	11,709	11,984	11,698	11,657	12,312	12,108	12,618	12,130	10,535	8,570
	No of Machines	5	7	8	9	9	9	9	9	9	9
	Procedures for 100% Utilization	7500	10500	12,000	13,500	13,500	13,500	13,500	13,500	13,500	13,500
	Utilization	156%	114%	97%	86%	91%	90%	93%	90%	78%	63%
WakeMed Cary	Total weighted procedures	567	498	405	418	393	325	382	325	282	222
	No of Machines	1	1	1	1	1	1	1	1	1	1
	Procedures for 100% Utilization	1500	1500	1,500	1,500	1,500	1,500	1,500	1,500	1,500	1,500
	Utilization	38%	33%	27%	28%	26%	22%	25%	22%	19%	15%

Note: The number of machines assigned to each facility is not based on the number that were actually operated by the facility, but the number of machines listed in the inventory for each facility in each year's state medical facility plan.

*Duke Raleigh reported 1288 procedures on the 2006 HLRA, but no fixed CC machine was reported in the plan as in use and procedures were not reported as mobile.

2006-2014 SMFP's; Proposed 2015 SMFP

Table 5: Wake County Cardiac Catheterization Procedures from 2004 to 2013

		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Wake County	Total weighted procedures	16,482	17,667	16,319	16,077	16,582	16,692	16,969	16,287	15,057	14,268
	No of Machines	8	10	13	14	15	16	16	16	17	17
	Procedures for 100% Utilization	12,000	15,000	19,500	21,000	22,500	24,000	24,000	24,000	25,500	25,500
	Utilization	137%	118%	84%	77%	74%	70%	71%	68%	59%	56%

2006-2014 SMFP's; Proposed 2015 SMFP

Other factors to consider regarding this petition include the changing capability of facilities. Recently, based on changes in recommended guidelines for interventional procedures, a facility located in a contiguous county was approved to perform interventional procedures, even though it does not have an open heart surgery program on site. A similar request in a different county located near Wake County is being evaluated by the Agency. This may have some impact on procedure volumes in Wake County and could potentially accelerate the decline of cardiac catheterization procedures performed in Wake County. Therefore, changes in medical practice makes predicting utilization for facilities difficult.

Consistent data trends over more than one year would be essential to ensure cardiac catheterization services are not being duplicated in Wake County. Additionally, if cardiac catheterization procedure volumes continue to decline as anticipated, Rex's volume may decrease as well. In essence, this could lower the facility's overall utilization below 80% and below the methodology's deficit threshold.

Agency Recommendation:

Given available information and comments submitted by the August 15, 2014 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends denial of the petition. The current declining trend in cardiac catheterization volumes, the surplus of machines in Wake County, the changes in regulations and medical practice, indicate approving the proposed change would result in unnecessary duplication of services. The Agency supports the standard methodology for fixed cardiac catheterization equipment.

Attachment 3

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

July 1, 2015

W. Stan Taylor, Vice President, Corporate Planning
WakeMed
3000 New Bern Avenue
Raleigh NC 27610

Exempt from Review – Replacement Equipment

Record #:	**1616**
Facility Name:	WakeMed
FID #:	943528
Business Name:	WakeMed Raleigh Campus
Business #:	2030
Project Description:	Replace cardiac catheterization equipment
County:	Wake

Dear Mr. Taylor:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 19, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(f). Therefore, you may proceed to acquire, without a certificate of need, the Philips Xper FD 20 cardiac catheterization system. This determination is based on your representations that the unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

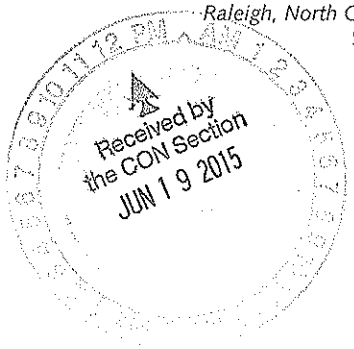
Michael J. McKillip
Project Analyst

Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR
Assistant Chief, Healthcare Planning
Acute and Home Care Licensure and Certification Section, DHSR

WakeMed
WakeMed Health & Hospitals
3000 New Bern Avenue
Raleigh, North Carolina 27610
919-350-8000

June 19, 2015



Ms. Martha Frisone, Assistant Chief
Mr. Michael J. McKillip, Project Analyst
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Request for Exemption from Certificate of Need Review to Replace Cardiac Catheterization Equipment at WakeMed Raleigh Campus

Dear Ms. Frisone and Mr. McKillip:

This letter is to inform you of WakeMed's intent to replace the cardiac catheterization equipment located in Room 4 at WakeMed Raleigh Campus. The equipment in Room 4 was purchased in 2005 and utilizes technology which is outdated and no longer meets current standards of care. It will be replaced with a Philips Allura Xper FD20, which has state-of-the-art imaging technology (see Attachments 1 and 2). It will be able to perform coronary diagnostic and therapeutic interventions, peripheral vascular procedures, and electrophysiology procedures, all of which are currently provided at WakeMed Raleigh Campus.

The proposed capital cost is $2,691,599, which includes the equipment and renovation of the room (see Attachment 3 for a certified cost estimate of the project). The footprint of the room will not change; however, renovation is required to configure the room for the new equipment and to meet current building codes.

The original equipment in Room 4 was purchased prior to 1993, when a certificate of need was not required for cardiac catheterization equipment. See Attachment 4, which includes pages from WakeMed's 1992 licensure renewal application indicating that it operated four pieces of cardiac catheterization equipment. The equipment was replaced the first time as part of Project I.D. J-4947-93, which was approved to expand the Heart Center at WakeMed Raleigh Campus (see Attachment 5). It was replaced again in 2005 with the current equipment, which did not require a certificate of need.

The project was approved by WakeMed's Board of Directors on June 2, 2015. Renovation will begin upon receipt of your approval and it is expected that the project will be completed in November 2015. At that time, the current equipment will be removed from service within the state of North Carolina and will no longer be used by WakeMed (see Attachment 6).

Applicable certificate of need standards are shown below:

(f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the two million dollar ($2,000,000) threshold set forth in G.S. 131E-176(22a) if all of the following conditions are met:

(1) The equipment being replaced is located on the main campus.

(2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.

(3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

(g) The Department shall exempt from certificate of need review any capital expenditure that exceeds the two million dollar ($2,000,000) threshold set forth in G.S. 131E-176(16)b. if all of the following conditions are met:

(1) The sole purpose of the capital expenditure is to renovate, replace on the same site, or expand the entirety or a portion of an existing health service facility that is located on the main campus.

(2) The capital expenditure does not result in (i) a change in bed capacity as defined in G.S. 131E-176(5) or (ii) the addition of a health service facility or any other new institutional health service facility or any other new institutional health service other than that allowed in G.S. 131E-176(16)b.

(3) The licensed health service facility proposing to incur the capital expenditure shall provide prior written notice to the Department along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

WakeMed believes that this request meets all of criteria shown above. The equipment being replaced is located on WakeMed Raleigh Campus, which is the main campus and is a licensed health service facility. The capital expenditure will not result in the addition of a health service facility or any other new institutional health service. The replacement equipment will be placed in the same room as the old equipment. This letter and supporting documentation serve as providing prior written notice to the Department that WakeMed Health & Hospitals meets the exemption criteria of this subsection.

Thank you for your consideration of this request. If you have any questions or need additional information, please contact me at 919-350-8108.

Sincerely,

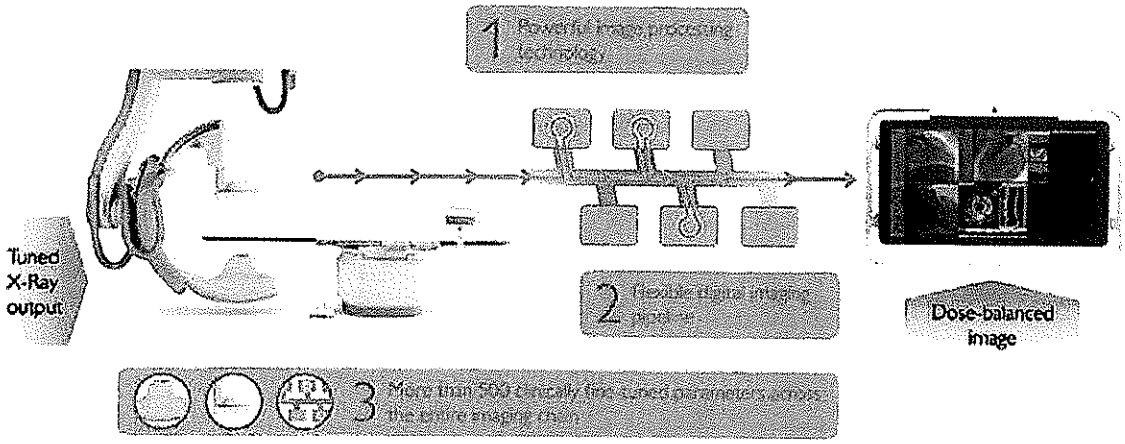
W. Stan Taylor
Vice President, Corporate Planning

Attachment 1

Intended for distribution in the United States of America.

ClarityIQ technology

X-ray dose is a main concern for physicians working with an interventional X-ray system. In interventional X-ray, a reduction in X-ray exposure has generally been associated with a decrease in image quality. In the recently introduced AlluraClarity family with ClarityIQ technology, provides high quality imaging for a full range of clinical procedures at ultra low dose levels.



Executive summary

During interventions you want to see with confidence – every time. AlluraClarity with ClarityIQ technology gives you this confidence. Philips' AlluraClarity family – a revolutionary new generation of interventional X-ray systems – provides high quality imaging for a full range of clinical procedures at ultra low dose levels.

ClarityIQ technology is enabled by Philips state-of-the-art computer technology. It is based on three pillars:

- Powerful image processing technology
- Flexible digital imaging pipeline
- Clinically fine-tuned parameters across the entire imaging chain

Key enhancements for the powerful image processing came from a total system optimization in stead of an optimization of individual components. These are:

- Real-time, fully automatic reduction of motion artifacts for DSA and Roadmap Pro through Automatic Motion Control
- Stronger temporal noise reduction on moving objects like the heart via motion compensation
- Stronger spatial noise reduction via larger neighborhoods and better signal recognition
- More powerful image enhancement capabilities

The flexible digital imaging pipeline allows the AlluraClarity systems to do a lot more processing within the processing power available and time constraints. In order to use ClarityIQ technology to its full potential, over 500 system parameters have been fine-tuned for each application area.

Besides patient X-ray dose reductions, ClarityIQ technology is anticipated to achieve a significant staff dose reduction.

PHILIPS

Introduction

Over the last decades, interventional X-ray technologies have made a tremendous contribution to the health and well-being of many people around the world. With the continuous improvements in diagnostics and treatment, minimally invasive procedures are on the rise and will continue to increase in the future.

Unfortunately, these imaging modalities use ionizing radiation that has been proven to cause damage to DNA and increase the chance of developing cancer later in life. In fact, pediatric populations have a greater lifetime risk of developing radiation-induced cancers than adult patients[1] (figure 1).

We appreciate that performing minimally invasive treatment on seriously overweight patients often adds another significant challenge to those you already face. Image quality tends to degrade with above-average BMIs, particularly when the excess weight is in the abdominal area. This can naturally lead to frustration; you cannot see what you want to in order to proceed with the intervention.
Of course, you could increase the amount of X-ray dose used. Yet an increase in abdominal width of just 3 cm necessitates twice the level of radiation in order to maintain image quality. This can increase risks to patient and staff.

As a result, radiation exposure from medical sources to patients and staff is expected to increase. The main source of patient X-ray is CT, followed by interventional X-ray devices.[2] Market research shows that radiation dose is the number one concern[3] for physicians who are using an interventional X-ray system.

In interventional X-ray, a reduction in X-ray exposure has generally been associated with a decrease in image quality (IQ). Philips, as a market leader in interventional X-ray, has a history of providing industry leading image quality and X-ray dose reduction measures. In the recently introduced AlluraClarity family with ClarityIQ technology, Philips has achieved high quality imaging for a full range of clinical procedures at ultra low dose levels.

Clinical evidence to date is based on a study conducted in the interventional neuroradiology department at the Karolinska University Hospital, Stockholm, Sweden.[1] This study showed that on average, 80% of the cumulative air kerma could be attributed to DSA exposure, 19% to fluoroscopy, and 1% to three-dimensional techniques.

This document has been prepared to provide more information for the US-market about ClarityIQ technology and the differences between the Allura Xper and AlluraClarity systems. It starts with an introduction of how X-ray dose can be lowered. The technology is then explained in detail: the three pillars of ClarityIQ and their effect on patient dose.

In this paper, by "patient dose" without further specification, patient entrance dose is meant: the radiation measured in the center of the X-ray beam without backscatter. This is equivalent to the Reference Air Kerma, measured at the Patient Entrance Reference Point (PERP)[4] (equal to the formerly used Interventional Reference Point (IRP)). Insight is also provided on the changes that have been made to the acquisition settings for the AlluraClarity systems that are responsible for the significant dose reduction achieved.

For more information about the AlluraClarity family or ClarityIQ technology, please contact your local Philips sales representative.

Lowering X-ray dose

According to the recommendations of the International Commission on Radiological Protection[5] the guiding principle for every exposure of human beings to ionizing radiation should be the ALARA principle: As Low As Reasonably Achievable. However, there is a strict relation between IQ (and information content in the image) and patient dose. The required IQ varies: during catheter introduction a lower IQ is acceptable than during stent placement.

For interventional X-ray procedures this requires a high level of flexibility from the X-ray system. The X-ray dose depends highly on the anatomy of the patient and the projections used. Also, the wide range of clinical tasks and types of procedures requires a range of image quality. As an example, consider two different tasks: localization and characterization.

For **localization**, fluoroscopy images can be used. X-ray images are used to visualize devices and pathology in relation to other anatomy, such as visualizing a catheter as the user navigates to a target area. Images of a lesser quality can be used for localization, meaning images with high noise and low contrast and sharpness. For **characterization**, exposure or DSA images can be used. X-ray images are used to characterize and thereby diagnose pathology, such as identifying the specific characteristics of small cerebral

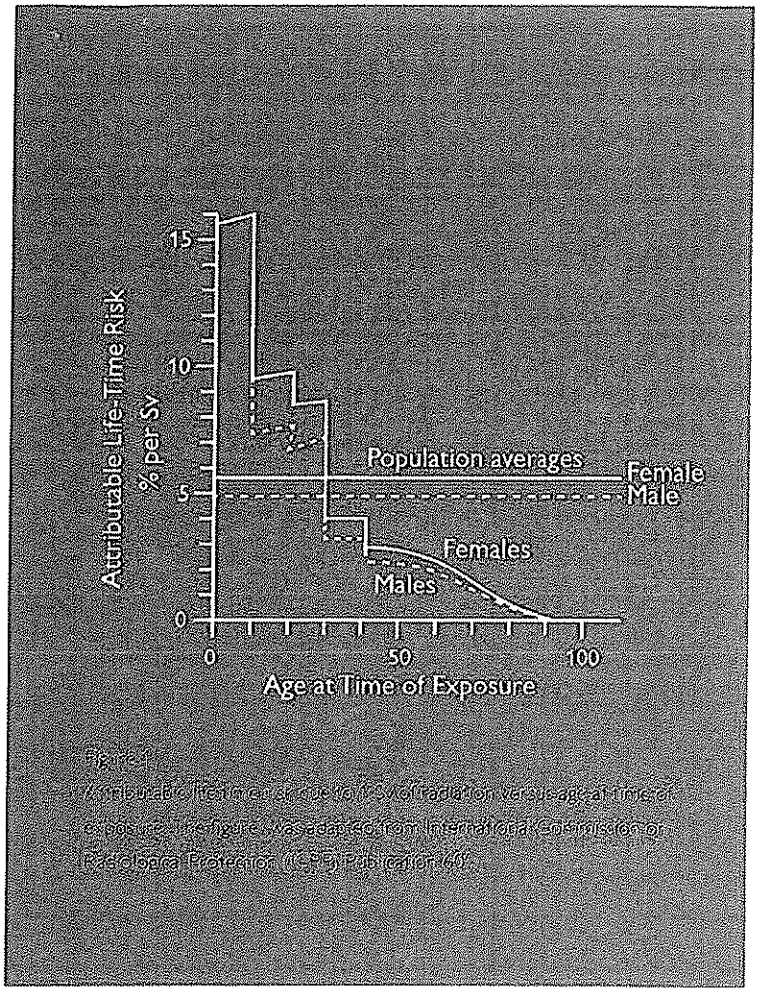


Figure 1:
Attributable lifetime risk (LAR) of radiation versus age at time of exposure. The figure was adapted from International Commission on Radiological Protection (ICRP) Publication 60.

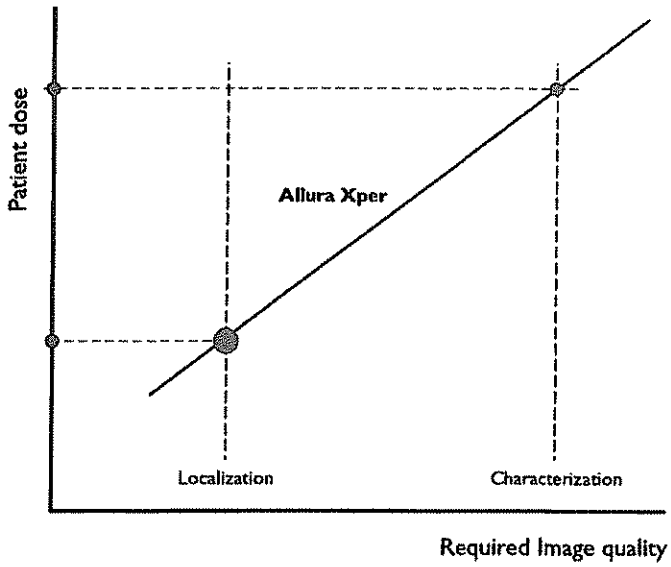


Figure 2: Graph of the relationship between IQ and patient X-ray dose for the Allura Xper. The positions for localization and characterization were chosen arbitrarily and will be different for each application. Patient thickness and projections will also affect the graph.

vessels. This requires high quality images, meaning images with high contrast and sharpness and low noise.
A rule of thumb is that applying a higher patient dose produces better image quality, for the same patient and projection. Conversely, that means applying a lower X-ray dose produces lower quality images. This is depicted in Figure 2. This figure shows the relation between X-ray dose and IQ for a given patient and projection. On the horizontal axis, the level of IQ required for the task is given. The vertical axis shows the patient X-ray dose applied by the system. Because there is no widely recognized method to measure the IQ,[7] no units are shown. No units are shown for patient dose as well, since the dose depends highly on the patient anatomy and the chosen projection.

The optimal relation between IQ and dose is represented by the diagonal line shown in Figure 2. In reality the shape of this line will depend on the units chosen. To keep things simple, it will be considered as a linear relation. Any point on this line can be created by tuning the system. Points below the line are not possible. If one would operate at a point above the line, this would not adhere to the ALARA principle, since too much X-ray dose would be applied for the required image quality. The principle is the same for other types of examinations, including electrophysiology, cardiology, endovascular, and neuroradiology procedures. One could even consider plotting all procedures in the same figure. This figure would have EP on the bottom left and neuroradiology on the top right.

Now, thanks to ClarityIQ technology, the AlluraClarity family takes a big step forward in providing high-quality imaging at ultra low dose levels.
The next section explains how this improvement was achieved.

ClarityIQ technology

ClarityIQ technology is enabled by Philips state-of-the-art computer technology. It is based on three pillars, see also Figure 3.

- Powerful image processing technology
- Flexible digital imaging pipeline
- Clinically fine-tuned parameters across the entire imaging chain

ClarityIQ technology touches every part of the AlluraClarity system, from tube to display, to enable ultra low dose settings. Where the Allura Xper system needs a certain amount of patient dose to create an image of sufficient image quality for a given procedure, the AlluraClarity system needs only a fraction of that patient dose. The new ClarityIQ image processing technologies have allowed us to use ultra low dose settings.

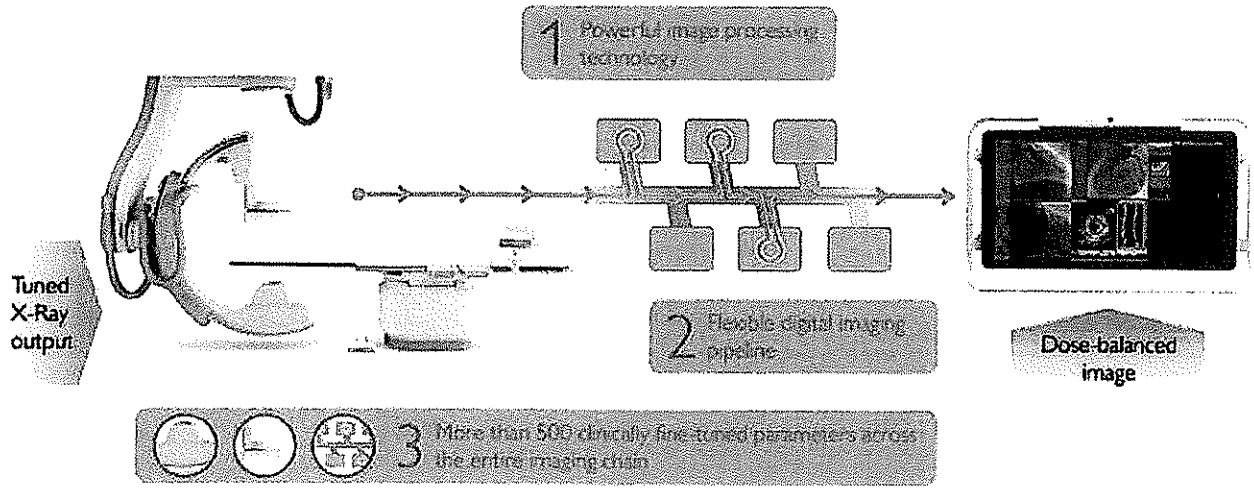


Figure 3: The three pillars of ClarityIQ technology, enabling the large patient dose reduction for the AlluraClarity family, compared to the Allura Xper series.

Powerful image processing technology

ClarityIQ technology incorporates powerful state-of-the-art image processing technology, developed by Philips Research, all working in real-time, enabled by the latest computing technology. It:

- Corrects for patient or accidental table motion, automatically and in real-time on live images
- Reduces noise and artifacts, also on moving structures and objects
- Enhances images and sharpens edges

Image processing, and specifically noise reduction, enhances image quality without increasing patient dose. One can also view this as follows: with image processing, less patient dose is required to create an image that is comparable in image quality to an image created without image processing at higher patient dose levels. This was demonstrated in Figure 2.

Image processing has a major effect on image quality. Explaining the individual image processing parameters is beyond the scope of this paper. However, the main image processing blocks used will be discussed.

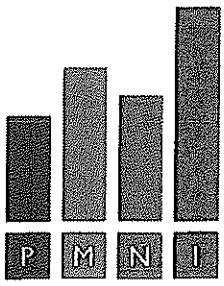


Figure 4: Image processing elements for ClarityIQ technology

ClarityIQ uses the following powerful image processing technology:

- Real-time Pixel shift (P) with Automatic Motion Control
- Motion compensation (M)
- Noise reduction (N)
- Image enhancement (I)

See also Figure 4.

Real-time Pixel shift (P) with Automatic Motion Control

In Digital Subtraction Angiography (DSA) procedures, subtraction is done to enhance visualization of vessels by removing disturbing background structures like soft tissue or bones from the image. Patient or accidental table movements can create motion artifacts during subtraction, visible as black and white structures. With surfaces that look rough under X-ray, like the inside of the skull with its calcifications, additional noise-like artifacts can occur in the image, even with small movements.

Real-time Pixel shift aligns images with each other before subtraction, so that fewer motion artifacts will appear. It is already used in Philips interventional X-ray systems, however, this is usually a post processing function that requires an operator to manually correct the images. The AlluraClarity system now performs pixel shifting automatically and in real-time using the Automatic Motion Control (AMC) feature.

The AMC feature compares images taken prior to injection (mask image) with images containing contrasted vessels (live image or contrast image). AMC finds the optimal alignment with sub-pixel accuracy before subtraction. AMC is performed on every single image in the run – fully automatically, in real-time – without requiring any user interaction.

This:

- Reduces subtraction artifacts
- Produces a better starting image for additional image processing elements to act upon, which allows, for instance, stronger noise reduction and contrast enhancement
- Saves time for the user by eliminating all manual steps

AMC is also used for the Roadmap Pro functionality.

The AlluraClarity is the only X-ray system on the market today that provides real-time, fully automatic motion control during DSA. In most conventional systems, the procedure requires the user to manually shift the mask image, which achieves less precise results compared to automatic pixel shifting. Some systems use automatic pixel shift, however it does not perform in real-time and still requires some user interaction, like clicking a release button. Other suppliers do not have automatic pixel shift technology at all.

The alignment with Automatic Motion Control is so sophisticated that stationary objects which are not linked to the movements of the patient (such as shutters, wedges, head rest, markers) will now appear in the image. However, these objects are usually outside the clinically relevant area, see Figure 5.

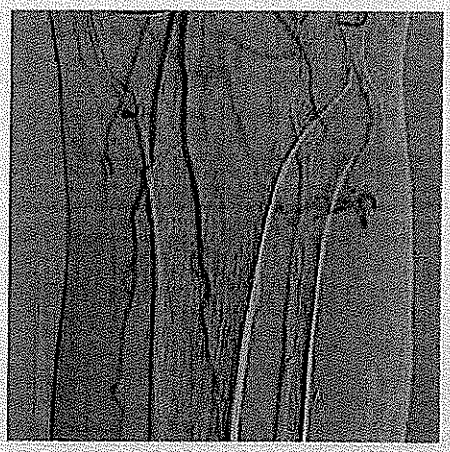


Figure 5a

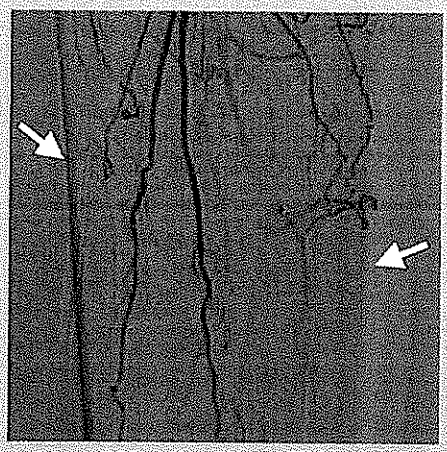


Figure 5b

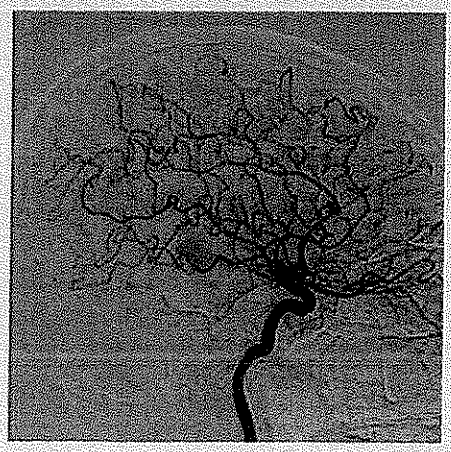


Figure 5c

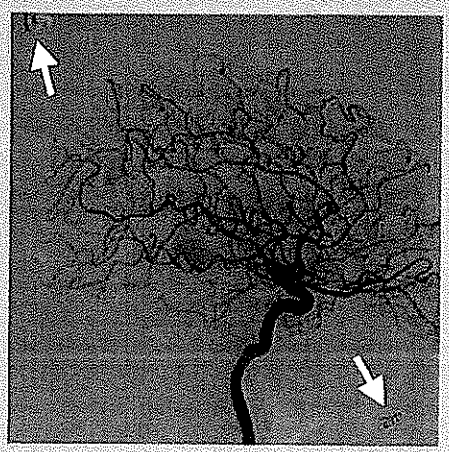


Figure 5d

Figure 5: Two examples of Automatic Motion Control applied to an image of a leg (a, b) and a head (c, d). The figures on the left (a, c) show a real-life example without AMC and the figures on the right (b, d) show the same images, corrected with AMC. Notice the edges of stationary objects that appear, such as the edges of wedges (b) and the "Sin" marker and the screw of the head rest (d).

Through better image alignment and fewer motion artifacts, a better starting image is created for other image processing algorithms to act upon, such as noise reduction and image enhancement. This allows stronger noise reduction processing and higher contrast enhancement to be applied as explained in the next sections.

Noise reduction (N)

Noise is a random phenomenon. Noise reduction first makes a distinction between the random nature of the noise and the more or less constant signal for X-ray absorption of the anatomy and objects, such as catheters or coils. The different characteristics between noise and signal are used to filter out a large part of the noise. This results in an enhanced image quality.

Noise reduction consists of both temporal and spatial noise reduction. Temporal refers to processing that is carried out over time, so over subsequent images, and spatial refers to processing carried out over an area within one image. The sophisticated algorithms distinguish between signal/objects and noise. As noise is random it can be reduced by averaging the pixel intensity over multiple pixels in time or in space. This averaging is called filtering.

The filtering algorithms applied are adaptive, meaning they perform different operations on noise than they do on a vessel or catheter.[8] There are two ways to reduce noise in an image: one is to apply more X-ray dose and the other is to apply better noise reduction algorithms. ClarityIQ technology uses novel noise reduction algorithms to enhance the quality of the image, and because of this provide hgh-quality imaging at ultra low dose levels.

Temporal noise reduction

Temporal noise reduction reduces noise by averaging several frames over time: the more frames that are averaged, the higher the noise reduction. The signal-to-noise ratio is increased by approximately the square root of the number of frames averaged ($=\sqrt{n}$). That is, if 16 frames are averaged (n=16), the signal-to-noise ratio would be increased by a factor of 4 ($=\sqrt{16}$).

Motion detection is essential when performing temporal noise reduction. Without being able to detect motion, ghost images of moving structures would appear, see Figure 6.

Image processing algorithms used in conventional X-ray systems prevent ghosting by performing motion detection. When motion is detected the temporal filter is switched off in the area of the image where motion is detected. This prevents ghosting, but at the same time it reduces the number of frames that can be used for temporal noise reduction in the presence of motion. The AlluraClarity family

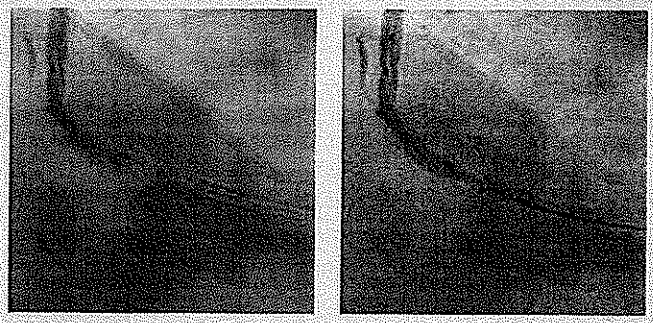


Figure 6a Figure 6b

Figure 6: Example of motion compensation. Figure 6a shows a temporally filtered image of the heart without motion compensation applied. Figure 6b shows the same image filtered with motion compensation applied.

offers a new **Motion compensation (M)** feature that aligns the moving structures before averaging, so that more frames can be used and stronger temporal filtering can be applied. This results in better noise reduction for stationary and moving structures, see Figure 7.

Please note that this Motion compensation feature is different from the Automatic Motion Control (AMC) feature. AMC aligns entire images before subtraction, while motion compensation aligns moving objects in parts of the image before applying temporal noise reduction.

Spatial noise reduction

Spatial noise reduction finds the noise within a single image and filters out the noise pixel by pixel, by averaging it with the pixels surrounding it in its so-called neighborhood. For (potentially) clinical relevant features, the averaging adapts to structures, such as vessels and guidewires to avoid blurring, see Figure 8.

When performing spatial noise reduction, it takes a great deal of processing power to average the neighborhood for every single pixel in the image. These processing power requirements increase with the square of the size of the neighborhood. ClarityIQ technology makes use of the latest processing capabilities to support these higher processing power requirements and thereby allows the system to average significantly larger neighborhoods with the new spatial filtering algorithms. Since more surrounding pixels are used for averaging, more noise is reduced. Taking into account a larger neighborhood also makes it possible to identify clinically relevant structures with greater specificity, so that stronger spatial filtering can be applied with less blurring of the signal, see Figure 9.

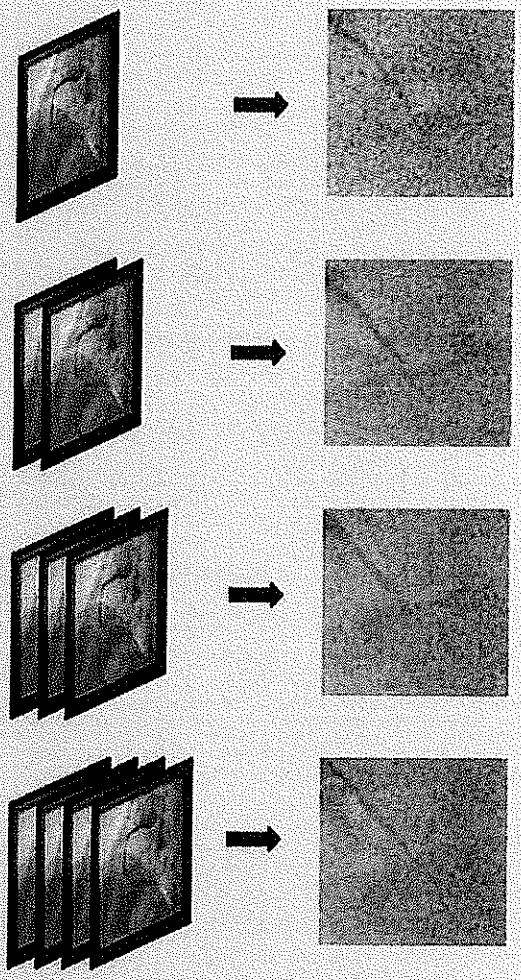


Figure 7: Example of temporal noise reduction. The noise is filtered by averaging over several frames. The signal is aligned (motion compensation) and then averaged. From top to bottom, the effect on the noise of using more images is shown.

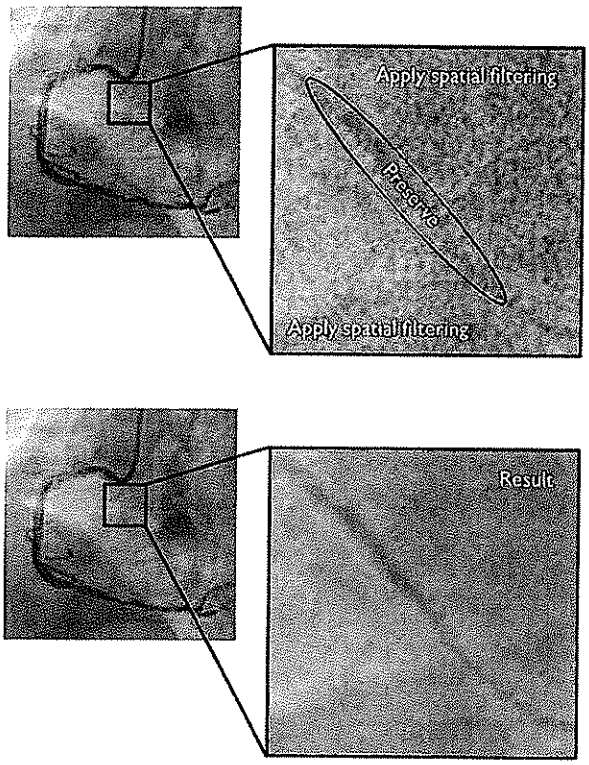


Figure 8: Example of spatial noise reduction. The signal or clinically relevant features and noise are distinguished. The noise is filtered out, while the signal is preserved.

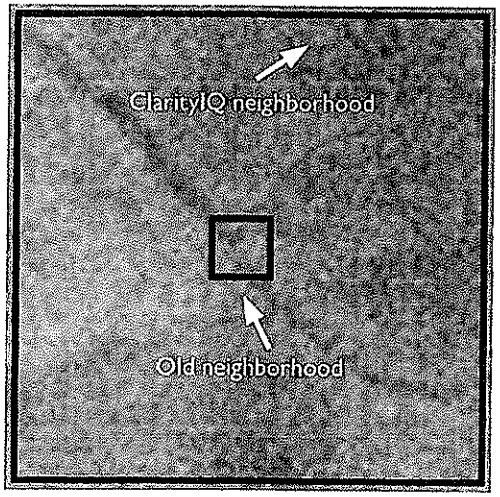


Figure 9: The old neighborhood used for spatial noise reduction (small square) and the new neighborhood (large square) now used with ClarityIQ technology. Averaging over a larger surface or neighborhood will reduce more noise. A larger neighborhood also makes it easier to identify clinically relevant structures, while avoiding signal distortion.

The result of these enhancements in spatial and temporal filtering enable high-quality imaging at ultra low dose levels.

Image enhancement (I)

Image enhancement creates different flavors for images. It performs edge enhancement, contrast enhancement, harmonization (reducing background contrast), brightness control, and other image enhancements. Image enhancement has a limited effect on the objective image quality,[9] as it mainly enhances subjective image quality. It allows images to be adapted to the user's preference and experience. Some users like very sharp images, while others prefer high contrast or low noise images. If one of the attributes is enhanced, the others are automatically reduced.

Image enhancement makes use of so-called spatial frequencies. Low frequencies correspond to shapes that change slowly in space (background, lungs), while high frequencies correspond to fine details and abrupt spatial changes in the image (catheters, but also noise). Like an audio equalizer, each frequency can be independently controlled and enhanced.

An example of image enhancement is shown in Figure 10. Note that this is a very simple example that shows only harmonization and edge enhancement. In reality, much more advanced enhancements, such as contrast dependent and intensity dependent processing are performed.

ClarityIQ technology makes use of advanced algorithms to apply more powerful enhancements across all frequencies. This greatly enhances the visualization of small details for applications, such as neuroradiology.

Flexible digital imaging pipeline

To support good hand to eye coordination for the physician manipulating the catheter, it is important to display images with with shortest delay. This means that imaging pipeline needs to use the available processing power in an efficient way. The imaging pipeline is a series of special algorithms, which perform specific image processing operations on the data received from the detector to achieve better image quality.

The AlluraClarity system uses a flexible digital imaging pipeline which has been designed to carry out the individual image processing algorithms in a more efficient way. Unlike many conventional systems that carry out image processing in a sequential manner, the digital imaging pipeline of the AlluraClarity system performs many image processing blocks in parallel. This enables the system to process more images, more quickly.

This parallel processing is further accelerated by a staging mechanism. Each stage in the pipeline begins processing as soon as data are available, so the system does not have to wait for the entire image to be received from the previous stage before starting the next processing step. This results in much more efficient

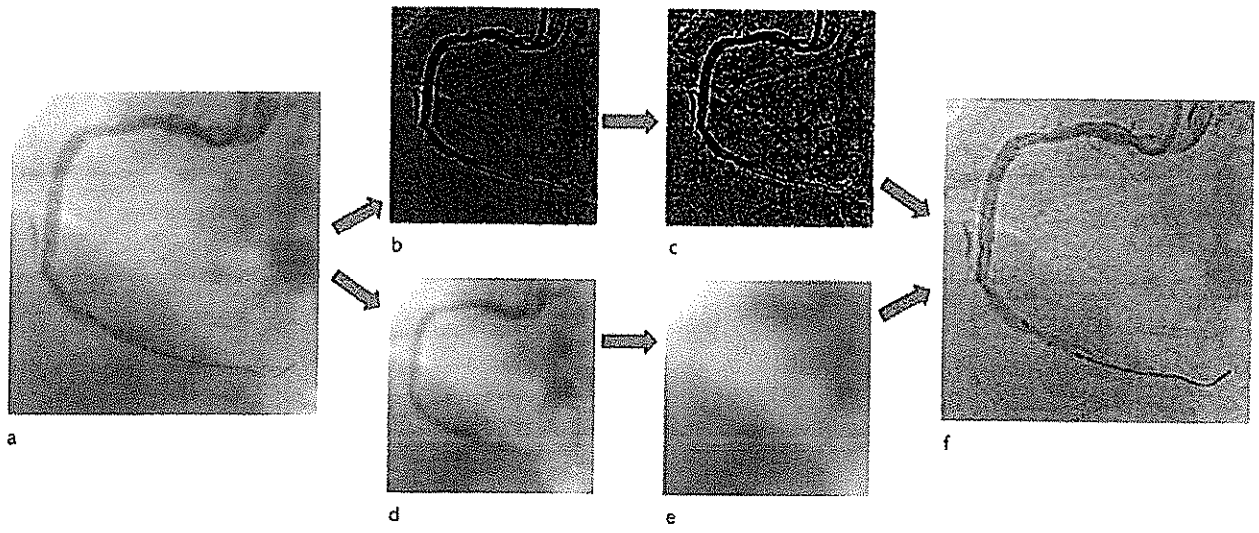


Figure 10: Example of image enhancement. Figure 10a is the original image. This is processed in the spatial frequency domain. For simplicity, only a high frequency image (b) and a low frequency image (d) are displayed here. The high frequency image, containing small details, is enhanced (c), while the low spatial frequency image, containing mainly background, is reduced (e). The final image (f) after its re-transformation to the spatial domain is a sharpened and harmonized version of the original image.

performance compared to conventional systems. More extensive image processing can take place in the same amount of time, with no noticeable delay between acquisition and display.

Besides reducing time delays, this flexible design also allowed developers to select the optimal combination of processing steps for specific applications. For example, the Real-time Pixel shift module will be applied for interventional neuroradiology procedures to enhance visualization of tiny vessels, while motion compensation will be used for interventional cardiology to apply stronger temporal noise reduction to images of the beating heart. For interventional neuroradiology, motion compensation for temporal filtering is less applicable since less motion and lower frame rates are involved, see Figure 11a and 11b. This sophisticated design allows the AlluraClarity systems to do a lot more processing within the processing power available and time constraints.

Besides optimizing the modules within the imaging pipeline, specific parameters within the P, M, N and I modules are also further optimized for each application area. Depending on the application area, the modules will even apply different algorithms. For example, different temporal noise reduction algorithms are used for different frame speeds. At lower frame speeds, fewer frames are averaged and the algorithms are optimized to deal with that in the best way. This allows the imaging system to perform optimally for the entire range of clinical applications.

An example of the flexibility of the pipeline is shown in Figure 12.

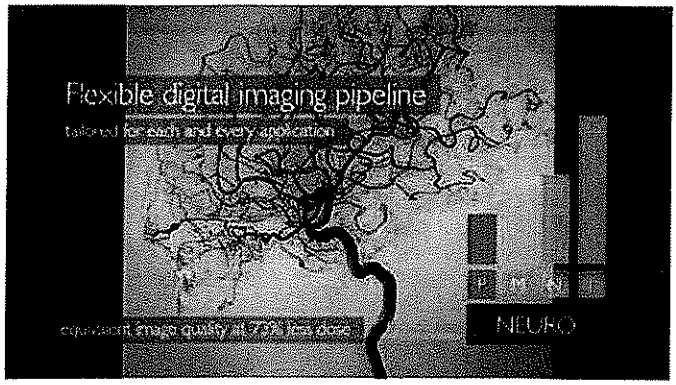


Figure 11a: The real-time pixel shift, noise reduction, and image enhancement modules are used for interventional neuroradiology procedures

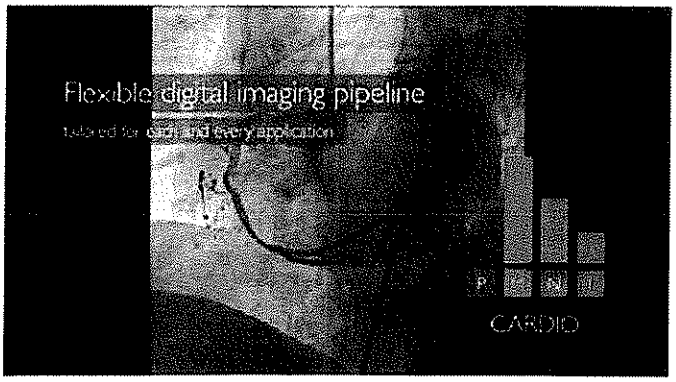


Figure 11b: The motion compensation, noise reduction and image enhancement modules are used for interventional cardiology

Clinically fine-tuned parameters across the entire imaging chain

In order to use ClarityIQ technology to its full potential, over 500 system parameters (tube, detector, image processing) have been fine-tuned for each application area.

The EPX database of system parameters

The heart of the Philips Allura Xper and AlluraClarity Interventional X-ray systems is formed by a large database of all system settings. This EPX[10] database (Examination, Patient, and X-ray information) is a structure of data on system level that contains predefined parameter settings for different procedures that can be performed with the system.

The image processing system consists of many sophisticated components that can be changed or programmed and the final image quality depends on the combination of individual programming parameters used. The content of the EPX database has been defined and fine-tuned during system development, to ensure the right image quality at the lowest possible dose for each application. Parameters that control the "flavor" of the images, such as contrast, brightness, and sharpness can be changed by the user on the user interface.

Fine-tuning system parameters in clinical practice

The flexible digital imaging pipeline allows a new level of clinical flexibility to be achieved with the AlluraClarity system. However, the image quality of different applications is very subjective so feedback from clinicians is required to create and validate these settings. The only way to set the parameters in the EPX database is by optimizing the IQ and X-ray dose for every single application and procedure in clinical practice over a period of time. This ensures that the imaging results are relevant for the full spectrum of clinical applications. More information about the X-ray dose-related system parameters is provided in the next section.

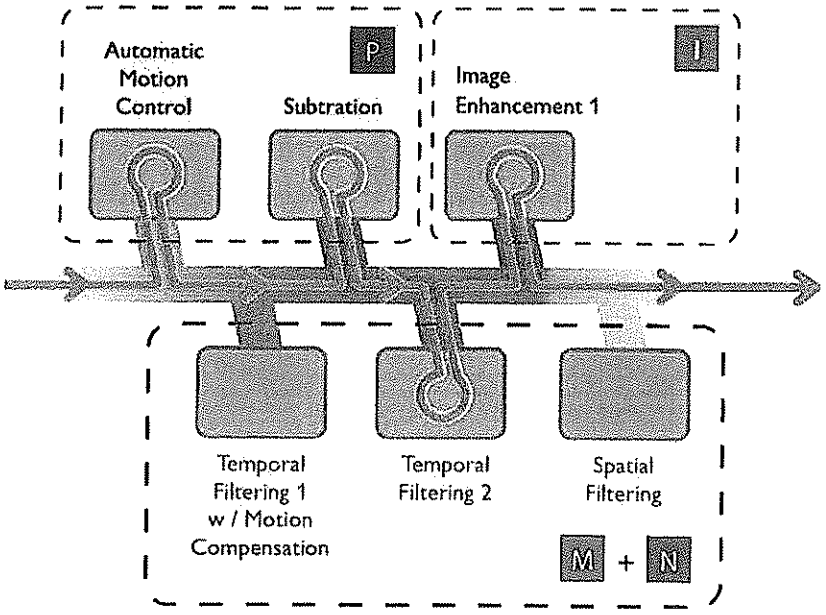


Figure 12: Illustration of the flexible digital imaging pipeline. In this imaginary example, the image goes through the subsequent processing steps of AMC, subtraction, temporal filtering and image enhancement. The letters P, M, N and I refer to the modules mentioned in Figure 4.

During the development of the AlluraClarity family, the EPX parameters for each clinical procedure were fine-tuned in leading hospitals during normal operation. After thorough preparation in the Philips development department, an initial EPX was installed, including image acquisition and image processing parameters. Several physicians then used this procedure setting in their daily work and provided feedback on the image quality and X-ray patient dose. In an interactive process that sometimes took several months to complete, the parameters were fine-tuned. All possible patient sizes (from small to obese) and a large range of different examinations during that period were included in the settings.

X-ray dose reduction for various clinical applications

This section provides examples of the significant patient X-ray dose reductions achieved with ClarityIQ technology for some of the most frequently used clinical applications. Patient X-ray dose levels will be shown for exposure or fluoroscopy techniques, for various water-equivalent thicknesses of a patient. "Water-equivalent thickness" means the thickness of an object with the same X-ray absorption properties, when it would consist entirely of water. Note that the water-equivalent thicknesses of the patient depends on the projections used: the steeper the angulation, the more tissue needs to be penetrated by the beam, and the higher the water equivalent thickness will be.

This section will also provide some insights into the X-ray dose related parameters that have been adjusted in order to achieve the X-ray dose reductions.

Philips' AlluraClarity family – a revolutionary new generation of interventional X-ray systems – provides high quality imaging for a full range of clinical procedures at ultra low dose levels. Dose reductions can be achieved for almost the entire range of patient thicknesses and projections.[11]

Fluoroscopy and exposure in the Allura Xper and AlluraClarity systems

Before explaining the X-ray dose values, it is important to understand how the Allura Xper and AlluraClarity are designed. The Allura Xper and the AlluraClarity systems both have three fluoroscopy flavors on its user interface (buttons are labeled I, II, and III, with I having the lowest dose and III the highest IQ).

Figure 13: Position and labeling of the three fluoroscopy flavors on the user interface of the AlluraClarity and Allura Xper systems

The philosophy here is that the user can start by using the lowest dose setting and switch to higher dose levels if better IQ is required (for example for large size patients or steep projections). This choice of fluoro settings allows users to apply the lowest possible X-ray dose during procedures, according to the ALARA principles. Fluoroscopy parameters and X-ray dose levels are set according to the selected application (head, abdomen, etc.). The fluoro settings differ per application, so the system actually has far more fluoro flavors than the three buttons on the user interface might suggest.

For exposure, the Allura Xper system has one flavor per procedure. The AlluraClarity can have more exposure flavors, with different patient dose rates, for greater flexibility in having the appropriate X-ray dose and image quality. These settings can be enabled by a Philips Field Service Engineer or Application Specialist if desired. All exposure settings have been tuned and validated in a clinical setting.

X-ray dose parameters adjusted to lower X-ray dose

So what X-ray dose related parameters have been adjusted in order to achieve the dose reductions possible with the AlluraClarity? In general, X-ray dose reduction can be achieved by modifying the following parameters:

- Amount of copper filtration: mm Cu
- Tube potential in kilo-volts: kV
- Pulse duration in milli-seconds: ms
- Tube current in milli-amperes: mA

When preparing the X-ray patient dose related parameters for the AlluraClarity systems, the parameters of the Allura Xper systems were used as the starting reference.

Copper filtration

Based on the industry-leading MRC X-ray tube, it was possible in the Allura Xper system to use copper filtration for many applications to reduce the low-energy radiation in the beam. For the AlluraClarity system the amount of copper filtration has been increased even further, again making optimal use of the high tube output of the MRC tube.

For AlluraClarity, 0.4 mm Cu[12] is used, if sufficient tube power is available. In most cases, at least 0.1 mm Cu is used. Inserting 0.1 mm copper into the radiation beam without modifying the other parameters, like mA, ms, and kV, reduces X-ray dose by about 50%. Increasing copper from 0.1 mm to 0.4 mm reduces X-ray radiation dose by about an additional 50%.

After the maximum amount of copper filtration possible was applied, other parameters were changed, like mA and ms, depending on the application. This is explained in more detail in the next sections.

Please note that within a chosen application or procedure, the amount of copper filtration is fixed over the full range of patient thicknesses, for both the AlluraClarity and Allura Xper system, independent of system usage. That means, for example that the copper filter will never be removed, even when imaging very large patients. The focus size will also not be changed, not even when using steep angles or a large source to image distance (SID). Using fixed copper filtration and focal spot size in all situations, ensures a consistent balance between patient X-ray dose and IQ throughout the procedure, without any sudden changes in X-ray dose or IQ when changing projections.

How Philips filters out soft radiation

The Allura Xper and AlluraClarity systems use strong SpectraBeam copper (Cu) filters in fluoro and exposures to remove unwanted "soft radiation", low energy X-rays that are for a large part absorbed in the patient and therefore do not reach the image detector. In this way, filtering significantly reduces patient X-ray dose and scattered radiation for the staff while maintaining a high image quality.

However, because the SpectraBeam filters are such strong barriers, conventional X-ray tubes cannot sustain the high output and heat load that is necessary to drive enough useful X-rays through the filter. Fortunately, the MRC tubes used in the Allura Xper and AlluraClarity systems were specially designed for such high-powered performance. In MRC tubes, the additional heat conduction via the spiral-groove bearing allows an extremely high average continuous load. This means that, in practice, working speed is not restricted by the limitations of the anode or rotor system, as it is in conventional tubes.

In the next sections, the dose values for specific clinical applications are given based on the largest detector format. If a smaller detector format is chosen, noise will become more apparent in the image, due to magnification. In order to keep the noise impression the same for the various detector formats, Air Kerma (AK) values[13] will increase when smaller detector formats are used.

Cardiac exposure

For cardiac exposure our standard settings for AlluraClarity can allow for much lower dose than those for Allura Xper.

While the Allura Xper has one exposure flavor, the AlluraClarity can have multiple exposure flavors for some cardiac procedures (e.g. Left & Right Coronary 15 fps). The Low Dose setting can be used for small patients or when extra low patient X-ray dose levels are required.

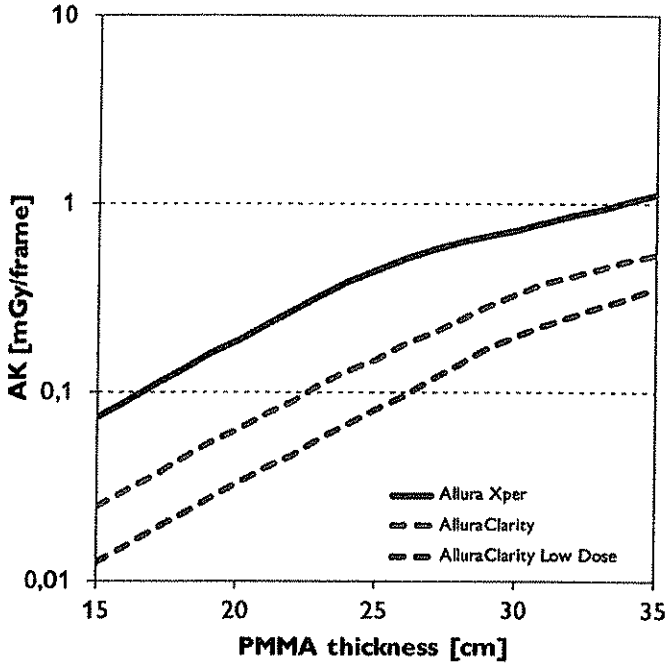


Figure 14: Cardiac exposure patient dose comparison for the Left Coronary 15 fps procedure, measured with an SID of 1 m for the largest detector format, measuring point is the PERP. The values have been measured on two separate FD10 systems (one AlluraClarity system and one Allura Xper system). Typical equivalent water thicknesses for interventional cardiology are around 25.8 cm with a standard deviation of 4 cm.

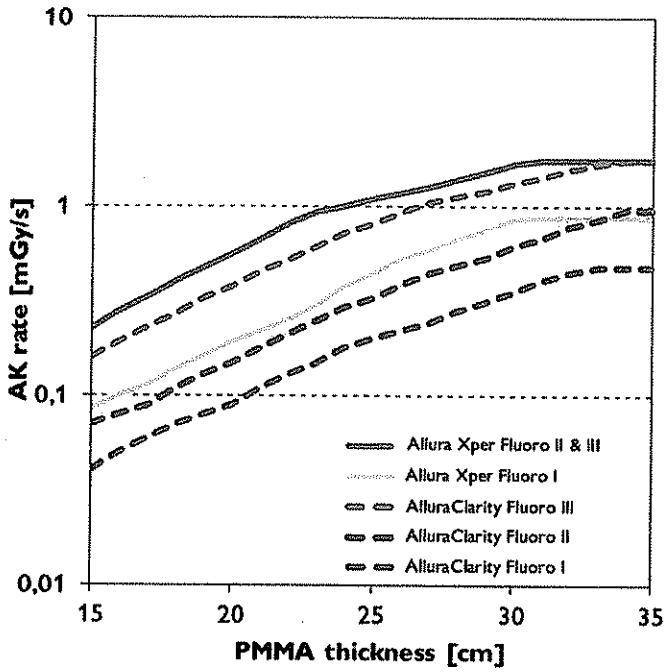


Figure 15: Cardiac fluoro patient dose rate comparison measured with an SID of 1 m for the largest detector format, measuring point is the PERP. Measurements have been performed on two separate FD10 systems (AlluraClarity and Allura Xper). The dose rates of Allura Xper Fluoro II and III are equal, the difference is in the frame speed: 15 and 30 fps respectively

Figure 14 shows the patient dose for the different flavors for different patient equivalent thicknesses in centimeters of water[14] for the Allura Xper and AlluraClarity systems for the Left Coronary 15 frames per second (fps) procedure. The dose values in the graph are valid for systems with an FD10 detector.

For cardiac exposure, X-ray dose has been reduced by adding copper filtration. Table 1 compares the Allura Xper and AlluraClarity settings for X-ray dose reduction and filtration.

Other parameters for the AlluraClarity system like kV, mA, ms, have stayed the same as those of the Allura Xper system. Pulse durations are kept below 10 ms, to keep motion blur (unsharpness due to movements of the heart) as low as possible.

Cardiac fluoroscopy

For cardiac fluoro our standard settings for AlluraClarity can allow much lower dose than those for Allura Xper. This section is valid for systems with an FD10 detector.

Figure 15 shows the patient entrance dose rate for the different fluoro flavors for different patient thicknesses.

The AlluraClarity fluoro flavor II was tuned to apply approximately the same IQ as the Allura Xper fluoro flavor II. The fluoro flavor III of AlluraClarity corresponds approximately to the Allura Xper fluoro flavor II with respect to dose.

Parameter	Allura Xper	AlluraClarity	AlluraClarity Low Dose
Copper filtration	None	0.1 mm Cu	0.4 mm Cu

Table 1: Cardiac exposure copper filtration parameters for Left Coronary 15 fps.

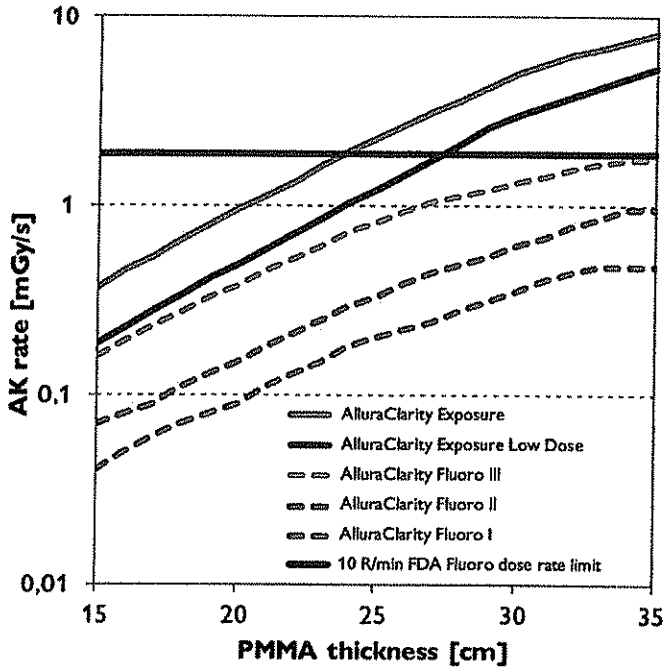


Figure 16: Comparison of patient dose rates settings for cardiac exposure and cardiac fluoroscopy for the AlluraClarity system with an SID of 1 m for the largest detector format, measuring point is the PERP. Note that patient dose rates for exposure are now close to fluoroscopy

For cardiac fluoro, going from the Allura Xper flavor II and AlluraClarity flavor III to the AlluraClarity flavor II, X-ray dose was reduced by first increasing copper filtration from 0.1 to 0.4 mm. As a second step, going from AlluraClarity flavor II to AlluraClarity flavor I, the pulse duration has been decreased from 4 ms to 2 ms, as shown in Table 2. For adult interventional cardiology, reducing pulse durations can help to reduce motion blur, while increasing copper filtration to 0.9 mm brings relatively few benefits compared to 0.4 mm, and tube power may become a limiting factor.

It is standard practice to measure at X-ray dose at a 20 cm object thickness, however, actual patient thicknesses are much higher and can easily reach up to 35 cm. It is therefore more relevant to show the dose reduction over a range of thicknesses. Figure 16 shows what this means in clinical practice. It compares patient dose rates for cardiac exposure and cardiac fluoroscopy for the AlluraClarity system. As shown, for the entire range of relevant patient thicknesses, the patient entrance dose rates for exposure have been lowered significantly and they are now very close to the patient entrance dose rates settings for fluoroscopy. The fluoro and exposure flavors cover a wide range of dose levels, suitable for each and every situation.

For thinner patients, the low exposure flavor could even be called fluoroscopy, and fluoroscopy flavor II might even be sufficient for diagnosis, using the Fluoro Store feature. For very challenging patients and angles, it is only a small step in dose from fluoroscopy flavor III to the AlluraClarity Low Dose exposure flavor.

Parameter	Allura Xper II	AlluraClarity III	AlluraClarity II	AlluraClarity I
Typical patient dose rates[15,16]	1.2 mGy/s	0.9 mGy/s	0.4 mGy/s	0.2 mGy/s
Copper filtration	0.1 mm Cu	0.1 mm Cu	0.4 mm Cu	0.4 mm Cu
Typical[16] pulse duration	4 ms	4 ms	4 ms	2 ms

Table 2: Cardiac fluoro EPX parameters. Please note that the order of the buttons in the table is the opposite as the order on the user interface (lowest dose fluoro button I is located on the left hand side on the user interface)

Pediatric exposure

For pediatric exposure our standard settings for AlluraClarity can allow for much lower dose than those for Allura Xper. Allura Xper systems offer different settings for four different weight groups: below 5 kg, 5-15 kg, 15-70 kg, and above 70 kg. AlluraClarity is designed in such a way that a division into only two different weight groups is sufficient, namely below 40 kg and above 40 kg.

In Figure 17 the patient entrance dose per frame is shown as function of the equivalent patient thickness for comparable pediatric exposure programs of the Allura Xper and AlluraClarity systems. The blue line represents the Allura Xper system with the following settings: 5-15 kg and 15 fps program. The greenline represents the AlluraClarity system with settings: below 40 kg and 15 fps program. All AlluraClarity pediatric settings below 40 kg use 0.4 mm copper filtration and a small focal spot.

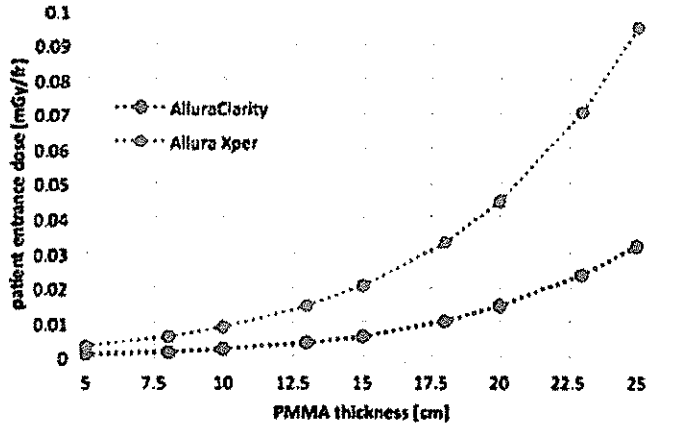


Figure 17:

Patient exposure dose rate comparison for the AlluraClarity pediatrics 15 fps low dose procedure (below 40 kg settings) with the Allura Xper pediatrics 15 fps low contrast procedure (5-15 kg settings).The measurements have been performed on systems with an FD20 detector, with detector formats of 27 cm and a fixed SID of 105 cm.

The patients are represented by PMMA blocks of variable thickness positioned at a fixed distance from the X-ray source[13]. The dose values have been measured at the entrance point of the PMMA blocks and corrected to obtain values at the patient entrance reference point (according to IEC 60601-2-43).[17]

Pediatric fluoroscopy

As with the pediatric exposure settings, the pediatric fluoroscopy standard settings for AlluraClarity allow for much lower dose than those for Allura Xper. For the AlluraClarity systems the default fluoro flavor is the lowest fluoro flavor I. If higher image quality is required, the user can switch to the higher fluoro flavors II or III. The same two weight groups as for pediatric exposure are distinguished for pediatric fluoroscopy.

Table 3 shows the patient entrance dose rate for the three fluoro flavors of an AlluraClarity system with an FD10 detector and settings below 40 kg. A patient equivalent thickness of 15 cm (PMMA) is chosen as a representative value, but it is noted that actual pediatric patient thickness may be highly variable.
All AlluraClarity pediatric settings below 40 kg use 0.4 mm copper filtration and a small focal spot; the pulse duration is maximum 3 ms.

Parameter	AlluraClarity I	AlluraClarity II	AlluraClarity III
Patient entrance dose rate (15 cm equivalent patient thickness)	0.025 mGy/s	0.037 mGy/s	0.051 mGy/s

Table 3: Patient entrance dose rate for AlluraClarity fluoroscopy flavors I, II, III with settings below 40 kg, valid for an equivalent patient thickness of 15 cm.

In Figure 18 the patient entrance dose rate is shown as function of the patient equivalent thickness for comparable pediatric fluoroscopy programs of the Allura Xper and AlluraClarity systems.. The blue line represents the Allura Xper system with the following settings: 5-15 kg, 15 fps, low fluoro flavor. The green line is for the AlluraClarity system with settings: below 40 kg, 15 fps, fluoro flavor I (default).

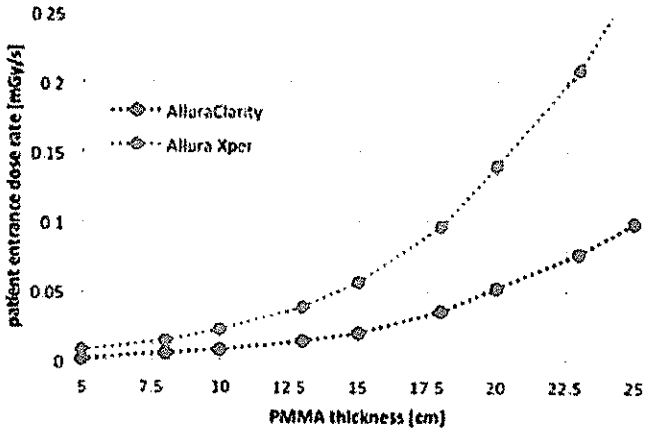


Figure 18:

Pediatric patient fluoroscopy dose comparison for the AlluraClarity pediatrics default low fluoro flavor(below 40 kg settings, 15 fps) with the Allura Xper low fluoro flavor (5-10kg settings, 15 fps). The measurements have been performed for systems with an FD20 detector, with detector formats of 25 cm and a fixed SID of 105 cm.

The patients are represented by PMMA blocks of variable thickness positioned at a fixed distance from the X-ray source[14]. The dose values have been measured at the entrance point of the PMMA blocks and corrected to obtain values at the patient entrance reference point (according to IEC 60601-2-43).[17]

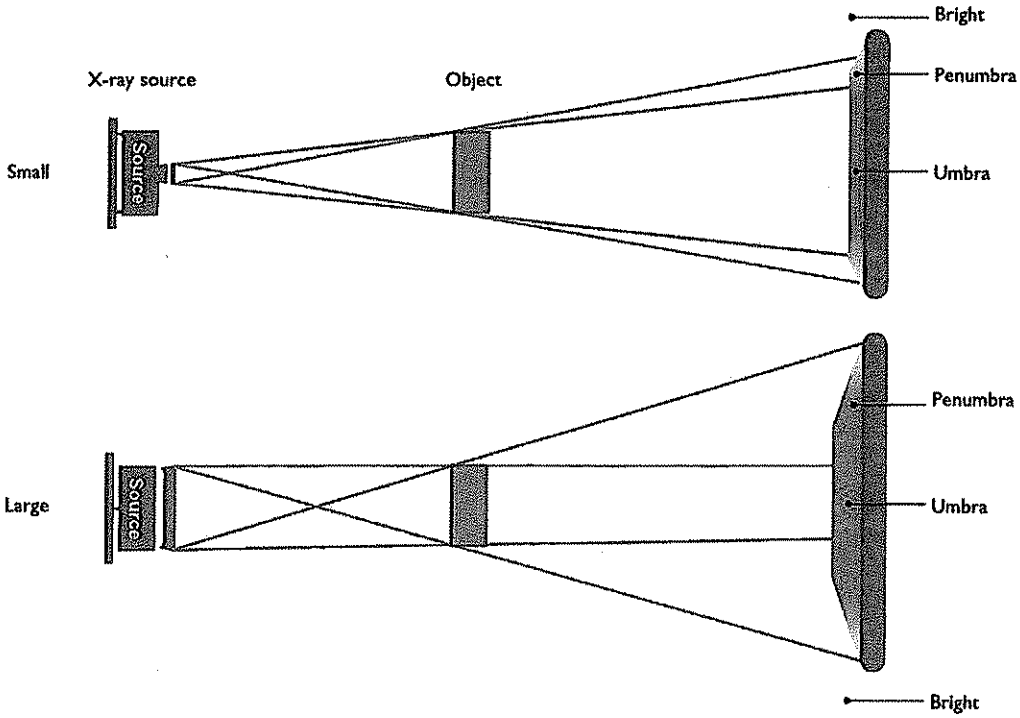


Figure 19: Exaggerated illustration of the effect of a large and small focal spot on the sharpness of a relatively small object in an image.

Neuro DSA exposure

For neuro DSA exposure the Neuro Cerebral 2 fps procedure will be described.

For this procedure a different X-ray dose reduction strategy was followed. It focused on reducing the tube current rather than using more copper filtration. This enabled the use of the small focal spot of the tube (which allows approximately half of the tube current of the large focal spot). The main advantage of using a small focal spot is the increased sharpness of the image, which is very important when visualizing tiny cerebral vasculature, see Figure 19.

Figure 20 shows the patient entrance dose for different patient thicknesses in for the Allura Xper and AlluraClarity systems for the Neuro Cerebral 2 fps procedure. Patient X-ray dose rates are given for systems with an FD20 detector.

The main acquisition parameters are given in Table 4. Besides smaller tube currents enabling the use of the small focal spot, also the range of patient thicknesses for which the kV is kept constant was increased and the kV was lowered for the AlluraClarity system. This results in more contrast and a constant contrast impression for a wider range of patients.

Parameter	Allura Xper	AlluraClarity
Focal spot	Large (0.7)	Small (0.4)
Filtration	0.1 mm Cu	0.1 mm Cu
Typical tube potential	78 kV	75 kV

Table 4: Neuro Cerebral 2fr/s acquisition parameters. Focal spot sizes are given for FD20 systems. The focal spot sizes for FD10 systems are 0.5 (small) and 0.8 (large).

Neuro fluoro

Our experience with the clinical tuning sites has been that the lowest dose flavor I was the setting most frequently used in neuroradiology. Therefore, the target for neuro fluoro has been to reduce X-ray dose by 50% for fluoro flavor i, going from 2.5 R/min for Allura Xper to 1.2 R/min for AlluraClarity.

Figure 21 shows the patient entrance dose rate for the different fluoro flavors for different patient thicknesses. All dose values in this section are valid for systems with an FD20 detector. The data in this section are also valid for the second phase of Roadmapping in interventional neuroradiology.

The expected effect of ClarityIQ on staff dose

It is known that adding copper filtration has less of an effect on reducing staff dose than on reducing patient dose[18], however, it is still expected that the staff dose savings with ClarityIQ technology will be significant.

The main reason for this difference is that dose received by the staff is scatter radiation of the patient. The skin of the patient acts as a kind of additional filter, removing part of the low energy radiation. This is the same effect as copper filtration, and therefore the use of copper filtration has less effect on the staff dose reduction.

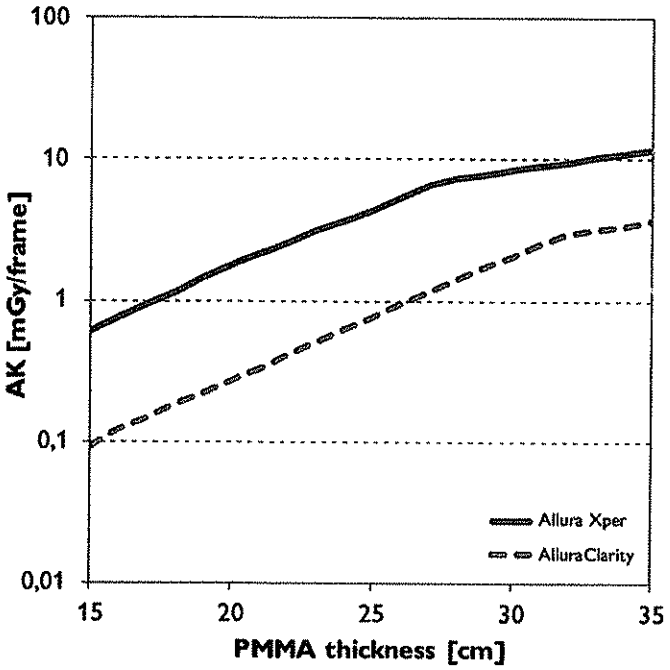


Figure 20: Neuro DSA Cerebral 2 fps patient dose comparison measured with an SID of 1 m for the largest detector format, measuring point is the PERP. Measurements have been performed on two separate FD20 systems (AlluraClarity and Allura Xper). Typical equivalent water thicknesses for interventional neuroradiology are around 23.7 cm with a standard deviation of 1.9 cm.

Parameter	Allura Xper III	AlluraClarity III	AlluraClarity II	AlluraClarity I
Typical[19] patient dose rates	0.6 mGy/s	0.3 mGy/s	0.15 mGy/s	0.08 mGy/s
Copper filtration	0.1 mm Cu	0.1 mm Cu	0.4 mm Cu	0.4 mm Cu
Typical tube current	160 mA	135 mA	160 mA	60 mA

Table 5 Neuro fluoro EPX parameters. Note that for endovascular fluoroscopy the same patient dose levels and parameter settings are valid.

When tube currents (mA) or pulse durations (ms) are reduced, the relative portion of soft radiation in the beam (beam quality) does not change.

Via simulations of X-ray penetration to the various organs in the human body, factors can be found that show the relative effect of copper filtration on staff dose compared to patient dose. Typical factors are given in the Instructions for Use for the Allura Xper[20] and AlluraClarity systems and are repeated in Table 5.

Amount of Cu	Staff dose relative to patient dose
-	1.0
0.1 mm	1.2
0.4 mm	1.36

Table 6: Relation between patient dose and staff dose when copper filtration is used.

So the relation between staff dose reduction and patient dose reduction depends on changes in the beam quality, as the following examples will show.

1. For the AlluraClarity system, the patient dose reduction between cardiac fluoro flavor II and I is 50% by reducing pulse durations, while the beam quality remains the same. This means that the staff dose is also expected to be reduced by 50%.
2. In Cardiac exposure the reduction between Allura Xper and AlluraClarity is 50% by going from no copper to 0.1 mm copper filtration. Compared to patient dose, staff dose with 0.1 mm copper will be a factor of 1.2 higher than without copper filtration, see Table 6. Therefore 50% * 1.2 = 60% staff dose remains. A staff dose reduction of 100% - 60% = 40% is expected, instead of 50%.

In these examples it is assumed that all other factors such as use of system (angulation, collimation) and user behavior (use of lead screens, stepping out of the room or standing in the shadow of a colleague) are equal.

So the effect of ClarityIQ technology on staff dose savings is anticipated to be significant, also when X-ray dose has been achieved by introducing more copper filtration.

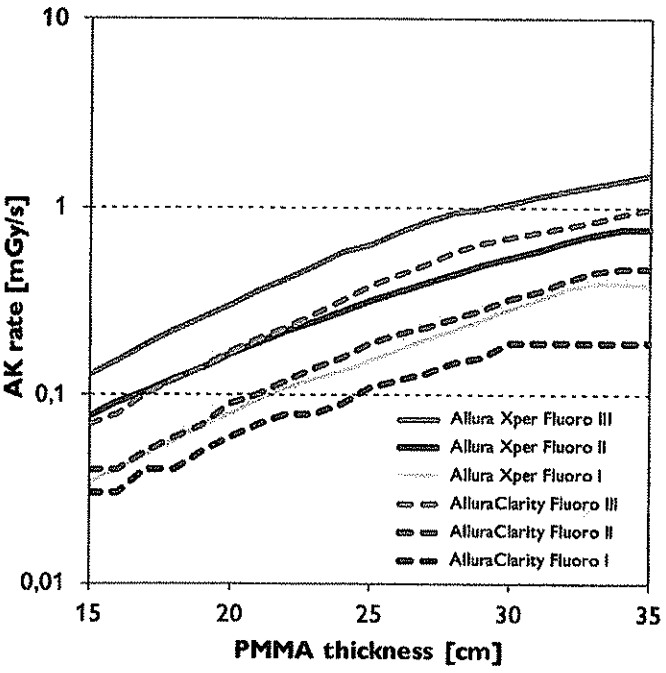


Figure 21: Vascular & Neuro fluoro patient dose rate comparison, measured with an SID of 1 m for the largest detector format, measuring point is the PERP. Measurements have been performed on two separate FD20 systems (AlluraClarity and Allura Xper).

Table of abbreviations

ADRC	Automatic Dose Rate Control
AK	Air Kerma
ALARA	As Low As Reasonably Achievable
AMC	Automatic Motion Control
CT	Computed Tomography
DSA	Digital Subtraction Angiography
EPX	Examination, Patient, and X-ray information
FPS	Frames per second
I	Image enhancement
IQ	Image quality
IRP	Interventional Reference Point
KERMA	Kinetic Energy Released per unit Mass
M	Motion compensation
N	Noise reduction
P	Real-time Pixel shift
PEDR	Patient entrance dose rate
PERP	Patient Entrance Reference Point (previously called IRP)
PMMA	Polymethyl methacrylate
SID	Source to image distance

Definitions

Allura Xper system	Philips interventional X-ray system introduced in 2003 and regularly enhanced since then. Many systems are still sold today.
AlluraClarity system	Latest generation Philips interventional X-ray system, introduced in July 2012. The AlluraClarity family uses ClarityIQ technology, which results in a dramatic radiation dose reduction while maintaining equivalent image quality compared to the Allura Xper system.
Roadmap Pro	A Roadmap is created by superimposing live subtracted fluoro with a vessel mapping image. Roadmap Pro offers a flexible range of features to support all anatomical areas and types of interventions.
Imaging pipeline	Series of special algorithms which perform specific image processing operations on the data received from the detector to achieve high image quality.

References

[1] BEIR 2006. Health Risks From Exposure to Low Levels of Ionizing Radiation: BEIR VII. Washington, DC: National Academic Press; 2006.

[2] Sources and Effects of Ionizing Radiation, UNSCEAR 2008 Report. United Nations Scientific Committee on the Effects of Atomic Radiation, New York, 2010.

[3] In an extensive market study on unmet needs conducted by Strategyn, radiation exposure related issues were the number 1, 2, 4 and 7 most important needs from a list of about 50 needs. This study was conducted with about 300 interventional cardiologists, radiologists, electrophysiologists, and surgeons in Germany and the US.

[4] IEC 60601-1-3:2008, 3.43, IEC 60601-2-54:2009, 203.5.2.4.5.101 (d).

[5] International Commission on Radiological Protection ICRP publication 103. Ann ICRP 2007;37:1–332.

[6] ICRP. 1991.1990 Recommendations of the International Commission on Radiological Protection.ICRP Publication 60. Ann. ICRP 21 (1-3)

[7] AAPM report No. 125, "Functionality and Operation of Fluoroscopic Automatic Brightness Control/Automatic Dose Rate Control Logic in Modern Cardiovascular and Interventional Angiography Systems, 2012

[8] In the design and development of the image processing algorithms, special attention has been given to the fact that no clinical content may be removed, added, or changed. This has been thoroughly evaluated both in-house, using a database of "difficult" clinical images and in lengthy clinical evaluations in hospitals.

[9] Image enhancement can, however, have a significant impact on objective image quality measurements, such as noise, sharpness and contrast. Therefore, using objective image quality parameters after image enhancement is not useful.

[10] For more information about the EPX parameters, see Gislason, A.J., et al, "Allura Xper cardiac system implementation of automatic dose rate control," Aug 2011, Philips white paper number 4522.962.71201.

[11] At large patient thicknesses, less dose reduction may be achieved. This can be explained by the limitations (legal or system) that occur in extreme cases, when the maximum patient X-ray dose is reached. For thicknesses above this maximum level, the X-ray dose can no longer increase and IQ will decrease instead. Since the AlluraClarity family uses lower X-ray doses at equivalent image quality levels, it reaches these limitations at larger thicknesses than the Allura Xper system. So the smaller dose reduction at larger thickness is accompanied by better IQ.

[12] When copper filtration is used, 1 mm of aluminum is also used. This is approximately equal to an additional 0.1 mm of copper. When 0.4 mm Cu is mentioned, in practice this is 1 mm Al + 0.4 mm Cu = 0.5 mm Cu equivalent.

[13] Reference Air Kerma (Rate) for AlluraClarity family and Allura Xper FD series. Document version 8.0, document number 4522.203.12121.

[14] In the measurements, polymethyl methacrylate (PMMA) is used instead of water. This has similar X-ray properties.

[15] For fluoroscopy in some countries there is a legal maximum of 10 R/min, measured at 30 cm in front of the detector. For example, for an SID of 1.0 meters on the Allura FD10 (for which PERP=0.615 m), the X-ray dose measured in the PERP is $((1.0-0.3))/0.615)^2 = 1.30$ times higher than measured at 30 cm in front of the detector. With 1.0 R = 8.77 mGy/min, the 10 R/min limit becomes a limit of 114 mGy/min in the PERP at an SID of 1.0 meter.

[16] Typical: at water-equivalent patient thicknesses typical for interventional cardiology. Typical patient thicknesses are 25.8 cm water equivalent with a standard deviation of 4 cm.

[17] AlluraClarity FD20 vs AlluraXper FD20; Patient entrance dose comparison. XCX612-130069. The values given are measured in-house with an experimental setup that closely follows the IEC standard on patient entrance dose measurements.

[18] Reduction of radiation exposure while maintaining high-quality fluoroscopic images during interventional cardiology using novel X-ray tube technology with extra beam filtering. A. Den Boer et al., Circulation 1994;89;2710 – 2714.

[19] Typical: at water-equivalent patient thicknesses typical for interventional neuroradiology. Typical patient thicknesses are 23.7 cm water equivalent with a standard deviation of 1.9 cm.

[20] Instructions for use for Philips Allura Xper FD series. Supplementary Information Document version 8.0, Philips number 4522.203.02191, May 2012.

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Please visit www.philips.com/AlluraClarity

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WakeMed Raleigh Campus, Room 4 Cardiac Catheterization Equipment **Attachment 2**

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Cardiac Catheterization	Cardiac Catheterization
Manufacturer of Equipment	Philips	Philips
Tesla Rating for MRIs	NA	NA
Model Number	722018	Allura Xper FD20
Serial Number	10	Available upon delivery
Provider's Method of Identifying Equipment	Fixed Asset Tag	Fixed Asset Tag
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date of Acquisition of Each Component	May 20, 2005	October 2015
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.)	NA	$2,619,599
Total Cost of Equipment	$1,130,044	$1,657,845
Fair Market Value of Equipment	NA	$1,657,845
Net Purchase Price of Equipment	NA	$1,657,845
Locations Where Operated	WakeMed Raleigh Campus, Room 4	WakeMed Raleigh Campus, Room 4
Number Days In Use/To be Used in N.C. Per Year	Available 365 days/year; in operation 240 days/year	Available 365 days/year; in operation 240 days/year
Percent of Change in Patient Charges (by Procedure)	NA	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0%
Type of Procedures Currently Performed on Existing Equipment	Diagnostic & interventional cardiac catheterization	NA
Type of Procedures New Equipment is Capable of Performing	NA	Diagnostic & interventional cardiac catheterization, electrophysiology

Attachment 3

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name: WakeMed Raleigh Campus Cardiac Catheterization Replacement Equipment, Room #4

Provider/Company: WakeMed Health & Hospitals

A. **Site Costs**				
(1) Full purchase price of land.....				
Acres _____ Price per Acre				
(2) Closing costs.....				
(3) Site Inspection and Survey.....				
(4) Legal fees and subsoil investigation				
(5) Site Preparation Costs				
Soil Borings.....				
Clearing-Earthwork...				
Fine Grade For Slab...				
Roads-Paving.....				
Concrete Sidewalks....				
Water and Sewer.....				
Footing Excavation....				
Footing Backfill.....				
Termite Treatment....				
Other (Specify).....				
Sub-Total Site Preparation Costs			$0	
(6) Other (Specify)				
(7) **Sub-Total Site Costs**				$0
B. **Construction Contract**				
(8) Cost of Materials				
General Requirements				
Concrete/Masonry				
Woods/Doors & Windows/Finishes				
Thermal & Moisture Protection				
Equipment/Specialty Items				
Mechanical/Electrical				
Other (Specify)				
Sub-Total Cost of Materials.....			$284,788	
(9) Cost of Labor.....			$348,075	
(10) Other (Specify).....			$63,286	
(11) **Sub-Total Construction Contract**				$696,149
C. **Miscellaneous Project Costs**				
(12) Building Purchase.....				
(13) Fixed Equipment Purchase/Lease			$1,657,845	
(14) Movable Equipment Purchase/Lease			$175,000	
(15) Furniture			$7,605	
(16) Landscaping			$0	
(17) Consultant Fees				
Architect and Engineering Fees		$73,500		
Legal Fees.....				
Market Analysis.....				
Other (Specify).....		$2,500		
Other (Specify).....				
Sub-Total Consultant Fees			$76,000	
(18) Financing Costs (e.g. Bond, Loan, etc.).				
(19) Interest During Construction.				
(20) Other (Specify)			$7,000	
(21) **Sub-Total Miscellaneous..**				$1,923,450
(22) **Total Capital Cost of Project** (Sum A-C above)				$2,619,599

I certify that, to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.

(Signature of Licensed Architect or Engineer)

I assure that, to the best of my knowledge, the above capital costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

(Signature of Office Authorized to Represent Provider/Company)

(Title of Officer)

Attachment 4

DEPARTMENT OF HUMAN RESOURCES
DIVISION OF FACILITY SERVICES
HEALTH CARE FACILITIES BRANCH
701 BARBOUR DRIVE
PO BOX 29530
RALEIGH, NORTH CAROLINA 27626-0530
TELEPHONE (919) 733-2786

Please don't write on this

file copy

OFFICE USE ONLY			
Lic. #			
Provider #			
Hospital Type			
Lic. Bed. Cap.			
General	Rehab.	Psych.	
LTC Hospice	NF	Chemical Detox	Depend. Trtment

1992 APPLICATION FOR LICENSE TO OPERATE A HOSPITAL
PLEASE TYPE OR PRINT ALL INFORMATION

Legal Identity of Applicant: Wake County Hospital System, Inc.
(full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service for which this form is submitted)

Name(s) under which the hospital or services are advertised or presented to the public: (d/b/a's)

Primary: Wake Medical Center
Other:
Other:

Are the above names identical to the names on the current license? YES X NO ___
If no, please check the reason for the change:

Change of Ownership [ ] Name change only [ ] Other (specify)_____

Facility Site Address: 3000 New Bern Avenue

City: Raleigh County: Wake Zip Code: 27610

Facility Mailing Address: P. O. Box 14465

City: Raleigh County: Wake Zip Code: 27620-4465

Chief Executive Officer: Raymond L. Champ Title: President
-Designated Agent (individual) responsible to the governing body (owner) for the management of the licensed facility-

AUTHENTICATING SIGNATURE: The undersigned submits application for the above named hospital in accordance with G.S. 131E, Article 5, and rules and codes adopted thereunder and certifies the accuracy of this information.

Chief Executive Officer:

Name (Please Type): Raymond L. Champ Title: President

Signature: Raymond L. Champ Date: 12/2/91

NOTE: Please identify the contact person for questions regarding this form.

Name W. Stan Taylor Telephone (919) 250-8108

DFS-4032 Rev. 8/91

OPERATING ROOMS AND OTHER PROCEDURE ROOMS

A. Report surgical operating rooms built to meet specifications and standards for operating rooms utilized by the Construction Section of the Division of Facility Services and which are fully equipped to perform surgical procedures. Rooms not meeting this definition should be included in Part C. below.

Use	No. of Rooms	Inpatient Cases	Ambulatory Cases
Rooms in use solely for inpatient surgery			xxxx
Rooms in use solely for ambulatory surgery		xxxx	
Rooms in use and shared - inpatient/outpatient surgery	16	7,164	3,453
Rooms not in use	1	xxxx	xxxx
TOTAL OPERATING ROOMS	17		

B. Of the rooms in A. above, please report the number of surgical operating rooms and cases by any dedicated use.

Dedicated Use *	No. of Rooms	Inpatient Cases	Ambulatory Cases
General	2	1,413	353
Orthopedics	2	1,118	880
Ophthalmology (one room dedicated to		22	33
Otolaryngology all three uses)	1	133	155
Plastic Surgery		91	21
Gynecology	2	821	1,556
Open Heart	4	1,012	xxxx
Thoracic (other than open heart)		59	xxxx
Urology	2	301	301
Caesarean Section			xxxx
Neurosurgery	2	1,398	127
Other (specify) Vascular	1	796	27
Rooms Not in Use	1	xxxx	xxxx
Total OR's (should equal total in A above)	17	7,164	3,453

*primary use, not totally dedicated

C. Other rooms not equipped or meeting all the specifications for an operating room, dedicated to the performance of other procedures. (Do not list a room for more than one use.)

Use	No. of Rooms	Cases
Lithotripsy	Mobile	26
Cardiac catheterization (diagnostic)	4	3,301
Cardiac catheterization (angioplasty)	2	1,158
Obstetric delivery	30	3,903
Cystoscopy		
Endoscopy	2	1,672
YAG Laser		
Sutures		
Cast Procedures		
Other (specify)_____		

Attachment 5

State Of North Carolina

Department Of Human Resources
Division Of Facility Services
Certificate Of Need

Project Identification Number J-4947-93 Effective Date April 30, 1994

Issued to: Wake County Hospital System, Inc., Wake Medical Center
3000 New Bern Avenue, P. O. Box 14465
Raleigh, NC 27620-4465

The North Carolina Department of Human Resources, pursuant to the North Carolina Health Planning and Resource Development Act of 1978, G.S. § 131-175, et seq., as amended and recodified, G.S. §131E-175, et seq., hereby finds and certifies that the new institutional health service proposed by the person listed above is consistent with, or as conditioned is consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. The findings of the Department are attached hereto and incorporated by reference.

This Certificate affords the person listed above the opportunity to proceed with development of the proposed new institutional health service in a manner consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. This Certificate includes and is limited to:

SCOPE: See Reverse Side

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: 3000 New Bern Avenue, Raleigh, NC

MAXIMUM CAPITAL EXPENDITURE: $21,080,444.00

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: August 1, 1994

This Certificate is limited to the person listed above and is not transferable or assignable. This Certificate may be withdrawn as provided in G.S. §131E-189, and the rules and regulations promulgated thereunder.

Issuance of this Certificate does not supplant provisions or requirements embodied in codes, ordinances, statutes other than G.S. §131E-175, et seq., rules regulations or guidelines administered or enforced by municipal, state or federal agencies or the agent thereof.

Assistant Director
~~Chief, Certificate of Need Section~~
Division of Facility Services

DFS-8001CN (Rev. 3/85)

SCOPE: Construct a 113,350 square foot, four story addition to Wake Medical Center for the relocation and consolidation of selected existing cardiac services at Wake Medical Center, and for the development of leasable medical office space and family care space. The ground floor of the building will house patient registration, pre-registration testing and leasable medical office space; the first floor will house leasable medical office space; the second floor will house diagnostic and therapeutic cardiac services; and, the third floor will house a 26 room Family Care Center (i.e., unlicensed hotel-style rooms). The project also includes the construction of a 250 space parking garage and the acquisition of replacement and other medical equipment.

CONDITIONS:

1. Wake County Hospital System, Inc. shall materially comply with all representations made in its certificate of need application.

2. At completion of this project, Wake County Hospital System, Inc. shall have no more than four cardiac catheterization/cardiac angioplasty rooms and one electrophysiology room.

3. Wake County Hospital System, Inc. shall not develop or provide pediatric cardiac catheterization/angioplasty as part of this project.

4. In the scope of this project, Wake County Hospital System, Inc. shall not acquire equipment or incur expenses for any items listed in Table II.3 Detailed Capital Projects Budget that are not included in the project's proposed capital expenditure in Section VIII of the application.

5. Wake County Hospital System, Inc. shall include in its progress reports for development of this project all costs related to renovation of existing space in the hospital that is being vacated or remodeled as a result of this project.

6. Prior to the issuance of the certificate of need, Wake County Hospital System, Inc. shall acknowledge in writing to the CON Section acceptance and compliance with all conditions stated herein.

Conditions acknowledged and accepted in letter dated April 14, 1994.

TIMETABLE:

Completion of preliminary drawings----------July 1, 1994
Completion of final drawings and specifications----------November 1, 1994
Approval of final drawings and specifications by Construction Section, DFS----------January 3, 1995
Approval of Site by Construction Section, DFS----------February 1, 1995
Contract Award----------March 1, 1995
25% completion of construction----------August 1, 1995
50% completion of construction----------December 1, 1995
75% completion of construction----------May 1, 1996
Completion of construction----------September 30, 1996
Occupancy/offering of service(s)----------October 1, 1996
Ordering equipment----------January - June 1996
Arrival of equipment----------January - June 1996
Operation of equipment----------June - October 1996