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MRI Gradient Subsystem Accelerated Reliability Test Using Nominal Day Usages

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Abstract:
This paper present a state of art to resolve MRI gradient subsystem unreliability by discovering its many failures and predicting its life before product launch by performing system reliability test as per nominal usage scenario, generating data during the test and computational of generated data using Big Data methodology. Using time of flight 3 dimensional (TOF3D) pulse sequence, a method has presented to stress the gradient subsystem to prove its long life (usually 10 years or more) within few months of accelerated reliability test based on hospital usage condition called as “Nominal Usage”. A computational algorithm has developed to calculate the gradient coil vibration energy stress over the 10 years of product life based on “nominal hospital usage condition” and scientifically matched with few months of reliability test by stressing the system using stringent TOF3D pulse sequence technique. We accelerated the test and perform 60 days of the test to prove the gradient coil reliability of 10 years of service life.
***Keywords**: Gradient subsystem life, Gradient coil, Life prediction using big data, Gradient coil reliability, MRI gradient coil.*

INTRODUCTION

From the last few decades, Magnetic Resonance Imaging (MRI) is one of the most popular medical imaging due to its advantage as non-ionization radiation compared to X-Ray or PET, etc systems. As the MRI system is complex and expensive, hence its unreliability over the long product life (usually >10 years) at customer place is the biggest issue for all Medical Device Manufacturer. All Medical Device manufacturer covers their system unreliability by providing frequent serviceability (almost every month), which increase the customer cost of ownership. This paper presents a state of art to resolve the MRI gradient subsystem unreliability before product launch by doing an accelerated reliability test [1]. Section II has a briefover view of the MRI system and especially about the gradient subsystem. Section III of this paper explained the method to develop a nominal usage scenario based on hospital data. A nominal day workflow has also developed for a typical MRI system. The next section of this paper evaluated different kinds of stress conditions and identified the most stringent pulse sequence-based data analysis, which can stress the system most and accelerate the test [2-3]. Section IV describes the test cycle using time of flight 3 dimension (TOF3D) pulse sequences and break time. Test time has calculated based on test cycle stress conditions and overall gradient subsystem life. Section V has described the gradient coil accelerated reliability test result [2-3]. During the reliability test, enormous data was generated, which was

May – June 2020
ISSN: 0193-4120 Page No. 10159 - 10164

analyzedusingbigdataandpredictedthesystemlifebasedon the test result. Last section VI described the conclusion and future scope related to gradient subsystem lifeprediction.

MRI GRADIENT SUBSYSTEMOVERVIEW

A MRI system mainly consists of magnet, gradient, RF subsystems. The magnet subsystem will produce the maindirections (X, Y, Z). A magnetic gradient is applied in each axis using the gradient coil. Thus magnetic field varies linearly along each axis. The magnetic field will be added or subtracted from the main magnetic field B0 based on the gradient field applied. Due to varying magnetic field, the resonance frequency will be different for the protons at a different place in the anatomy (human body) planned for imaging.Aradio-frequence(RF)coilexcitestheseprotonsby applying to transmit power and once the proton relaxes it produces reflected power, which is detected by the same RF coil. Reflected RF power forms the image dataset in the k space. Fourier transforms of k space produce the anatomical image. There are different ways, gradient and RF power can be applied based on pulse sequencetechniques.During the usage in hospitals, the MRI gradientsubsystemexperiencemanydifferentfailuremodesandsystembreakdowns.Someofthepredominantfailuresaregradientcoil broken, overheating of gradient coil, shimcoilfailure,failure in gradient amplifier, gradient coil andshimcoiltemperaturesensorfailures.Themainreasonforfailureisdueto excessive gradient coil vibration & heat exerteddueto varying magnetic fields inside gradient andshim coils.InsectionIV,adataanalyzedandproducedtoshowthatdifferent pulse sequences with differentgradienttechniquesexertdifferentvibrationtothegradientcoilandotherpartsofgradientsubsystem,whichrelatestogradientsubsystemlife.One of the big disadvantages of the MRI systemislongerscanning time, which makes gradient subsystemreliabilityorlifetestmorechallengingtoperformatthelabbeforeproductlunch as it takes several yearsto complete the life testifplanned to prove the reliability. Hence ascientificmethodsuchasbigdataanalysisanddataminingtechniqueneededtoperform the accelerated life test in shorter test duration toprove the gradient subsystem life.

NOMINAL USAGESCENARIO

Topredictthelifeofthegradientsubsystemandreliability, it is very important to analyze the actual hospital usage scenariooftheMRIsystem.Afteranalyzingseveraldata sets from different hospitals and the web, the following data sets were collected to define the nominal usagescenario.

- Hospital 1: one-year exam data on 8 MRIsystems
- Hospital 2: one-year exam data on 8 MRIsystems
- Other web sources[4-7]

Oncedatasetswereidentified,wedevelopthenominalday usage profile as shown in Figure1.

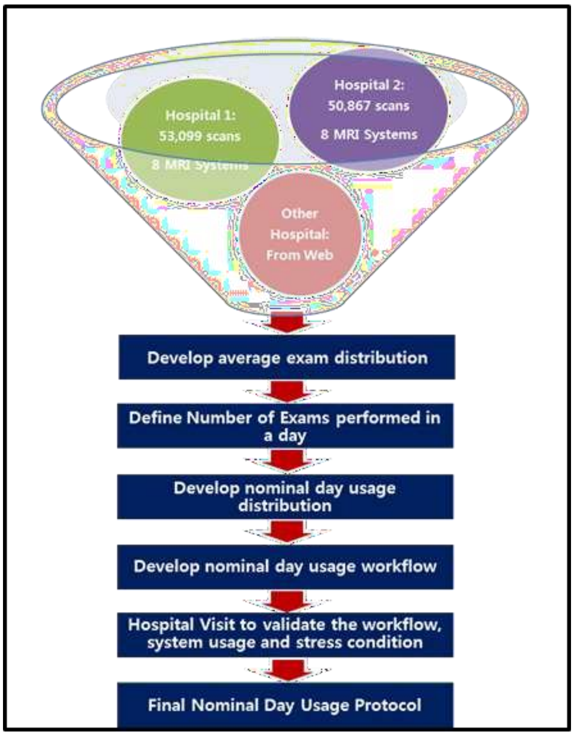

Figure 1. Strategy to develop "Nominal Day

Usage” of MRISystem

A. *Data mining to Determine ExamDistribution*

We collected the yearly MRI scan done on 2 hospitals and develop exam distribution based on the actual usage environment. In hospital 1 approximately 50867 exams and hospital2approximately53099examswereperformedo fthe various anatomical region “Brain, Neck, Cervical Spine, Lumbar Spine, Liver, Abdomen, lower extremities (hand, wrist, knee, ankle), upper extremities (shoulder, thigh)” in a year. After data mining, exam distribution was developedfor hospital 1 and 2 and then averaged it to make the data more nominal. Later, these exam distributions further averaged with other exam distribution data from the National Health Service(NHS)tomakeitmorerealisticasshowninFigure2. The National Health Service is a very reliable source of healthcare information and data from the UnitedKingdom.

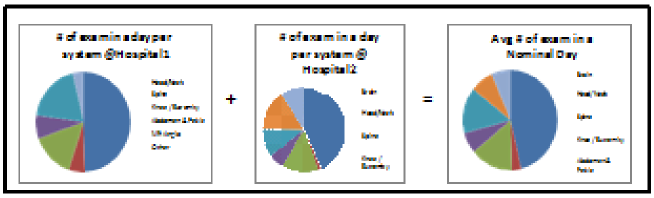

Figure 2. MRI Exam Distribution

Based on these analyses, the following exam distribution was developed:

Brain:31%
Head & Neck:
6% Spine:21%
Extremities: 15%
MR angiography: 8%
Abdomen & Pelvis: 11%
Other: 8%

B. *Average Number of Exams in aDay*

The next step is to find out the average number of MRI exams performed in a day.Typically,6daysinaweekand50weeksinayearhospitals across the globe use the MRI system to get a faster returnon investment(ROI).

# of scans/day in Hospital 1 = (50867/50*6*8) = 21.2 # of scans/day in Hospital 2 = (53099/50*6*8) = 22.1
# of scans/day as per NHS = (1980000/50*6*304) = 21.7 Average number of exams in a day = (21.2+22.1+21.7)/3 =
21.7

C. *Nominal Day UsageDistribution*

Using exam distribution and the number of exams performed in a day, we develop nominal day usage distribution.Atypicaltargetdiagnosisalsoappliedwitheach examtocorrectlyestimatethepulsesequenceusedtoperform the MRIscan.

D. *Nominal Day UsageWorkflow*

Based on hospital workflow to perform the MRI system scans throughout the day and nominal day exam distribution developed in the previous section, we develop the MRI workflow as per steps shown in Figure 1.

E. *Validate the Usage Workflow by HospitalVisit*

We visited one of the most prestigious multispecialty hospital in South Korea and study the MRI system used throughout the day to validate our nominal day usage workflow. Our study was focused to study about stress on gradientsubsystembasedonthepulsesequenceapplied,time gaps between each pulse sequence, and break between two exams.

F. *Final Nominal Day UsageProtocol*

Based on all previous steps, we finalized the nominal day usageprotocol.Wedeterminethetimetoperformthenominal day protocol in our lab as approximately 5.8hours.

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GRADIENT SUBSYSTEM STRESS CONDITIONS

As described in Section I of this paper, the MRI system undergoesthroughdifferentstressthroughouttheday. Oneof these stresses is excessive vibration due to the gradient coil due to the varying magnetic field. Each exam identified in section III of this paper needs to have a different pulse sequence,whichexertsdifferentvibrationtogradientcoiland magnet system based on kind of varying magneticfield.

A. Pulse Sequences & VibrationEnergy

A model has developed to calculate vibration energy applied based on different pulse sequence parameters. Figure 5 shows vibration energy applied by different pulse sequences, which reveals that the TOF3D pulse sequence exertsmaximumvibration~58Jtogradientcoilandhence the MRI system, which way higher than all other pulsesequence techniques.

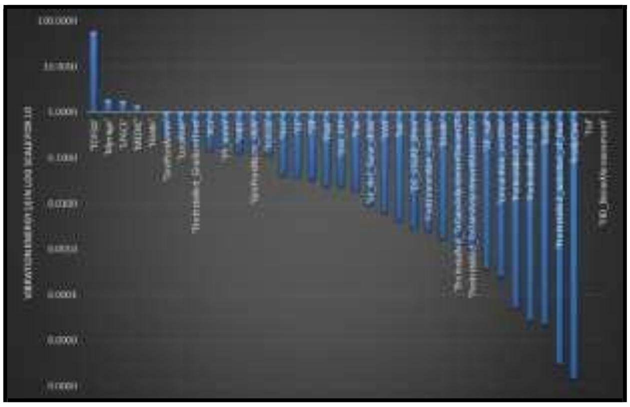


Figure 3. Vibration Energy (log scale with base 10) Vs MRI Pulse Sequence

B. Life Time Analysis using VibrationEnergy

Based on the nominal day usage profile consist of 21 exams,whichhaspredefinedpulsesequencesbasedontarget diagnosisofanatomyasdescribedinsectionIII,gradientcoil vibration energy is calculated. In one day, gradient coil undergoes through193.3J.

ACCELERATED RELIABILITY TESTRESULT

Usuallyacceleratedreliabilitytestisperformedonasystem with many unknown failure modes, which is difficult to identify by analysis (FMEA) or normal verification or reliability test. We perform the accelerated reliability test usinganominaldayusagescenariorepresentingitsactuallife in the hospital. During the test, we found several failures, which was fixed and the test is continued till the gradient subsystemachieveapredeterminedtargetannualservicelife.

A. Defining TestCycle

In section IV of this paper, vibration energy applied to the MRI system is maximum (58J) during the TOF3D pulse sequence.Basedonmanypermutationandcombinationatest cycle was developed consisting of 10 TOF3D pulse sequences test with 1-hour break to accelerate the system reliabilitytest.VibrationEnergyappliedinonetestcycleis

Joule.

Vibration energy applied in a nominal day = 193.3 Joule Number of clinical day/week = 6

Number of clinical weeks/year = 50 Product Life = 10

Lifetime vibration energy = 193.3 Joule

Vibration energy applied in a test cycle = 580.3 Joule Acceleration factor = $(580.3 / 193.3)^{1.5} = 5.2$

Time to complete one test cycle = 2.29 hours Test hours per day = 24 hours

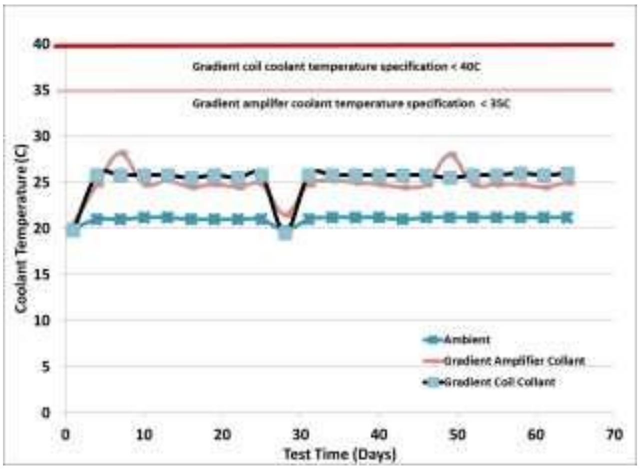
Acceleration factor due to time = 24 / 2.29 = 10.5 Total acceleration factor = 5.2 x 10.5 = 54.5

Time to complete the test = (10 x 50 x 6) / 54.5

= 55 days

B. *Performing Test*

We perform the test for 60 days on a 3T MRI system to provethegradientsubsystem10yearsoflife.Duringthetest, the gradient subsystem has broken downseveral times due to fire in gradient subsystem terminal block, gradient coil sensors failure, overheating of gradient coil, and some software failures. These failures have fixed and the test is continuedtillitachievedagradientsubsystempredetermined life. We monitored the followingparameters:



- Gradient subsystem terminalblock
- Gradient coiltemperature
- Gradient coil coolanttemperature
- Gradient amplifiertemperature
- And several other parameters for software &system

C. *Analyzing the Test Results andFailures*

We analyzed test results and identified all the issues,fixed itandcontinuethetestuntilachieveditreachedequivalent10 years of targetlife.

Figure 4 shows the gradient and shim coil thermal performance.Wetookanaverageofdifferentsensorsreading andmaximumtemperatureofadaytoplotthegraph.Itshows both gradient and shim coil has stable performance as the maximum temperature limit is80C.

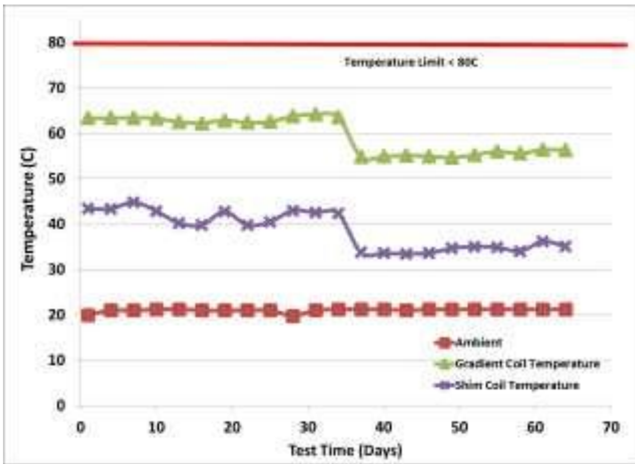


Figure 4. Gradient subsystem performance

Figure 5. Gradient subsystem coolant temperature performance

Figure 5 plot the thermal performance of the gradient coil and amplifier coolant temperature. There is no abnormality observed except for some fluctuation in a few days.Gradient coil and amplifier temperature limits are were 40C and35C,respectively.

During the test, several other issues found related to software,whichwasfixedandthetestwascontinuedtomeet 10 years of targetlife.

CONCLUSION

Using the nominal day usage scenario, it is possible to perform an accelerated reliability test of MRI gradient coil representing its 10 years life. We performed 60 days of accelerated reliability test for a gradient subsystem of a 3T MRI system to prove 10 years of service life before the product launch. This concept can be further applied in other complex medical devices or other complex non-medical device subsystems and systems.

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