# Guide to Good Laboratory Practice

Varian 400-MR Pub. No. 01-999338-00, Rev. B1106

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# Chapter 1. Introduction

#### Sections in this chapter:

- 1.1 "21 CFR Part 58, Subpart D -- Equipment," this page
- 1.2 "Yes/No Choice," page 8
- 1.3 "Glossary," page 8

Good Laboratory Practice (GLP) regulations (see FDA regulation 21 CFR part 58) dictate a system designed to assure the quality and integrity of the safety data attained from "nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products" (Section 58.1 Scope).

Although, for example, certain preliminary pharmacological studies and pharmacokinetic studies are still exempt from FDA regulations, laboratories have extended the reach of GLP to enable greater quality management throughout their processes.

Varian, Inc. is not responsible for compliance to GLP regulations, but the information detailed under the framework of this document, may or may not, depending on any individual customer's internal procedures, be used in conjunction with various SOPs to aid in creating a compliant environment.

# 1.1 21 CFR Part 58, Subpart D -- Equipment

GLP has several subparts covering the total suite of requirements. Subpart D, Equipment, contains those requirements for which analytical instrument vendors can aid compliance by providing certain capabilities, information, and tools. These areas are generally contained within the 4Q model - Design Qualification, Installation Qualification, Operational Qualification and Performance Qualification.

The definitions used in this manual are as follows (excerpted from "The Development and Application of Guidance on Equipment Qualification of Analytical Instruments", Peter Bedson, Mike Sargent, *Journal of Accreditation and Quality Assurance*, 1996, 1:265-274):

**Design Qualification** Defines the functional and operational specifications of the

instrument and details the conscious decisions in the selection of

the supplier.

Installation Qualification Establishes that the instrument is received as designed and

specified, that it is properly installed in the selected environment and that this environment is suitable for the operation of the

instrument.

**Operation Qualification** The process of demonstrating that an instrument will function

according to a series of predefined operational specifications in

the selected environment.

**Performance Qualification** The process of demonstrating that an instrument performs

according to a specification appropriate for its routine use.

Varian, Inc. has developed this guidance document to:

• Contain important information relating to the 4Q model in one location

• Provide an avenue for aiding the tracking of the various processes that occur during the individual qualification stages

## 1.2 Yes/No Choice

At several stages in this document, Yes/No choices are to be made. If the choice is YES, that criterion has been met. However, if the Customer or Varian Representative decide that a certain criterion has not been met and apply NO, then the various appendices at the end of the document allow the tracking of the corrective actions required until all the elements of that criterion have finally been concluded. This approach collects and maintains all of records pertaining to the elements in the document in one place.

# 1.3 Glossary

The following is a glossary of terms that are used in this manual.

**21 CFR Part 11** Code of Federal Regulations, Title 21, Food and Drugs, Part 11 "Electronic

Records: Electronic Signatures Final Rule", Federal Register 62 (54), 13429-

12466.

www.fda.gov/ora/compliance\_ref/part11/Default.htm

**21 CFR Part 58** Code of Federal Regulations, Title 21, Food and Drugs, Part 58 "Good

Laboratory Practices for Nonclinical Laboratory Studies", April 1, 2003.

www.fda.gov/ora/compliance\_ref/glp/default.htm

**administrator** The operating system login account that owns the VnmrJ system files. The name

of this administrator is selected during installation of VnmrJ for Secure Environments in the User Name: entry field. By default, the name vnmrI is

used. The password for this account should be kept secure.

Analytical A system that combines instrument, computer, and analytical method. system

AutoTest Automated test software used to demonstrate that a Varian NMR instrument

functions according to the operation specifications. AutoTest is designed to demonstrate key console and probe performance criteria, measuring the output using NMR data derived from a single sample. In this way, a large series of tests is automatically completed; data from one system is easily compared to similar

systems.

**Batch** A specific quantity or lot of a test or control article that has been characterized

according to Section 58.105(a). (58.3)

**Control article** Any food additive, color additive, drug, biological product, electronic product,

medical device for human use, or any article other than a test article, feed, or water that is administered to the test system in the course of a nonclinical laboratory study for the purpose of establishing a basis for comparison with the

test article. (58.3)

FDA United States Food and Drug Administration (www.fda.gov)

FID An NMR term that stands for Free Induction Decay. A FID is the time-domain

data acquired by the NMR spectrometer. The frequency-domain NMR spectrum

is then obtained from the FID by Fourier transform.

**GAP** Good Auditing Practices

**GLP** Good Laboratory Practices

**GMP** Good Manufacturing Practices

IQ Installation Qualification. Applies to new and used equipment that is to be

installed. See IQ, OQ, PQ.

**IQ, OQ, PQ** Installation Qualification, Operational Qualification, and Performance

Qualification. Verification of equipment and instruments used for FDA (and

other regulatory bodies) and client audits.

NMR Nuclear Magnetic Resonance. A scientific technique for determining molecular

structure.

Nonclinical laboratory study In vivo or in vitro experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety. The term does not include studies utilizing human subjects or clinical studies or field trials in animals. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical

or chemical characteristics of a test article. (58.3)

**noncontrolled** Data and records that are not controlled, monitored, or audited by a regulatory

compliant system, or system administrator. See controlled.

**OQ** Operational Qualification. Verification of equipment or instrument performance

to prove operation before and after movement. See IQ, OQ, PQ.

Part 11 The Electronic Records; Electronic Signatures section of the Title 21-Food and

Drugs regulation.

**permissions** Granted in the OS by the system administrator to allow users access to files or

resources.

PQ Performance Qualification or Performance Verification. Operational verification

that is performed at least annually for equipment and instruments. See IQ, OQ,

PQ.

**qualify** In terms of electronic records regulations, a company has the SOPs and software

in place so that their records qualify as compliant.

raw data Any laboratory worksheets, records, memoranda, notes, or exact copies thereof,

that are the result of original observations and activities of a nonclinical laboratory study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. (58.3)

**record** Directories where FID and processed data are saved.

**root path** Directory path of a primary directory.

**SOP** Standard Operating Procedures. A company or site has SOPs in place for

regulatory compliance, among other things.

trusted data Same as controlled data, which is protected, monitored, and audited under

VnmrJ for Secure Environments.

**VnmrJ** Data acquisition, processing, and display software for Varian, Inc. NMR

spectrometer systems.

XML The eXtensible Markup Language used for data exchange. VnmrJ uses XML to

format data for the Locator database.

# Chapter 2. Design Qualifications

Sections in this chapter:

- 2.1 "400-MR and Magnet Specifications," this page
- 2.2 "Standards Compliance," page 11
- 2.3 "Instrument Selection Criteria," page 14

Varian, Inc. is one of the world's leading suppliers of NMR spectrometers and the major provider of research level, high magnetic field functional MRI spectrometers. Innovative design for NMR performance is the trademark of Varian's line of spectrometers. Engineering to the highest standards and using leading-edge technologies has brought to the NMR community spectrometers that support all applications without compromise.

# 2.1 400-MR and Magnet Specifications

A full suite of specification for the 400-MR is available in Appendix A, "400-MR System Specifications," and additional information can be requested from Varian, Inc.

Individual probe specification sheets are available upon request and should be appended to this document and summarized in Table 1.

Probe description and P/N	Specification sheet attached Yes/No (see next column)	Reason for 'No' attachment	Customer Signature/Date

Table 1. Probe Specification List

# 2.2 Standards Compliance

Varian's continuing commitment to the highest standards of design, manufacture, and inhouse servicing of NMR spectrometers is confirmed by compliance with:

- ISO 9001 (see Figure 1)
- All applicable directives required for CE conformity (see Figure 2)

## **ISO Compliance Certificate**



Figure 1. ISO Certificate of Conformance

# **CE Conformity**

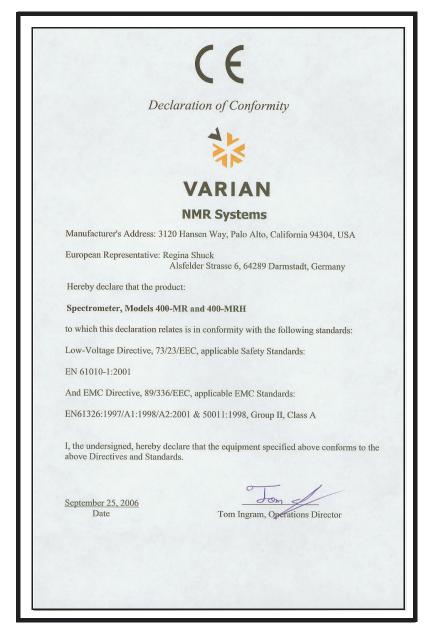


Figure 2. CE Declaration of Conformity

# 2.3 Instrument Selection Criteria

In many cases, instrument selection is based upon criteria related to specific applications, data management, data processing techniques, or specific site criteria, Table 2. provides a place to record such criteria. This table can be copied so that additional pages can be appended to this document.

**Table 2.** Instrumentation Selection Criteria.

Selection Criteria	Description of, name of document or other path that identifies additional criteria. append copies of appropriate pages as necessary.	Customer Name/Signature/Date

# Chapter 3. Installation Qualifications

#### Sections in this chapter:

- 3.1 "Review the Installation Planning Guide," this page
- 3.2 "Site Survey," page 16
- 3.3 "Review and Confirmation of Shipped Items," page 16
- 3.4 "Computer Audit," page 16
- 3.5 "System Installation Checklist," page 19
- 3.6 "Supercon Shim Values," page 20

Various factors pertain to the installation of an instrument in a selected environment.

# 3.1 Review the Installation Planning Guide

Reviewing the applicable *Pre-Installation Instructions* for the 400-MR will aid determination of site suitability and provide specifications for such requirements as operating temperature, humidity, provision for air and electrical supply.

Pre-Installation Instructions Rev. No.	Reviewed Yes/No	Customer Name/Signature/Date

*Pre-installation Instructions* for the 400-MR spectrometer is available from Varian Inc. Sales Representatives or the local Sales Office. A list of sales representatives and local sales offices is located at:

http://www.varianinc.com/cgi-bin/nav?products/nmr/contact\_nmr/sales\_offices&cid=JKQOKLIJFI.

# 3.2 Site Survey

A site survey can be purchased for the 400-MR if required. The site survey is performed before the installation to check the site suitability specifically for vibrations, temperature, humidity control, and external rf interference.

Site Survey Required Yes/No	If Yes, Performed on Date	Corrective action? Yes/No and description. If Yes, see "Site Survey Corrective Actions," page 33	Varian Representative Name/Signature/Date	Customer Name/ Signature/Date

# 3.3 Review and Confirmation of Shipped Items

All of the sales orders should be reviewed and checked for accuracy.

Sales Order No.	Correct? Yes/No and description. If No see "Review and Confirmation of Shipped Items Corrective Actions," page 34	Varian Representative Name/Signature/Date	Customer Name/ Signature/Date

# 3.4 Computer Audit

The computer audit documents information on each computer (please copy and append this chart for additional computers if more than three computers are required for the installation).

The Varian and customer representative's signatures in these forms certify that the information in these forms is accurate and that all computers to be used to run Varian's MR workstation software, VnmrJ, or to run other software to process data obtained on this spectrometer, have been included in the audit (including those previously registered as part of purchases of other Varian NMR spectrometers).

# Information about your site (please print): Company/University Address Principal User

Fax Console S/N Delivery (month/day) Sales Order No. Information on each computer (additional forms are on the back of this page). As

Spectrometer type \_

required by SOPs, include computers directly attached to the spectrometer, computers (networked or non-networked, on-site or off-site) used to process NMR data using Varian's VnmrJ software, and computers (on-site and off-site) used to process data collected on this

Phone

Information on con	nputer of (e.g.	, 1 of 3)		
Manufacture		Model no.		
Computer S/N	Computer S/N Purchased from			
Peripherals:	Internal hard disk (Mbytes)			
	CD-ROM drive model		Serial no.	
	Printer model			
	Plotter model			
	Terminal model			
	Other peripheral			
Computer function:	NMR host			
-	Workstation running VnmrJ			on-site or off-site
	Workstation running other N	MR software		on-site or off-site
	Workstation running VnmrJ	and other NMR software		on-site or off-site
VnmrJ version		Operating system		
The above computer	audit was performed durin	g installation of the sy	stem.	
Varian Representative	9		Date	
run VnmrJ software have been included,	ormation on this form is according to run other software to pas required, in the audit (in r Varian NMR spectromete	process data obtained o	n this spec	trometer,
Customer Representa	ative		Date	

Use these forms for additional computers. If more forms are needed, copy this page. Attach all copies to the Computer Audit.

	nputer of (e.g.,	-		
		Purchased from		
Memory (Gbytes)		Screen size (in.)		
Peripherals	Internal hard disk (Mbytes)			
	CD-ROM drive model		Serial no.	
	Printer model			
	Plotter model			
	Terminal model		Serial no.	
	Other peripheral			
Computer function:	NMR host			
	Workstation running VnmrJ			on-site or off-site
	Workstation running other NM	R software		on-site or off-site
	Workstation running VnmrJ ar	d other NMR software		
Vmmr Lvareien		Operating eyetem		
vnmrJ version		Operating system		
	nputer of (e.g.,			
Information on con	nputer of (e.g.,	3 of 3)		
Information on con		3 <b>of 3)</b> Model no.		
Information on con  Manufacture  Computer S/N	nputer of (e.g.,	3 of 3) Model no. Purchased from		
Information on con Manufacture Computer S/N Memory (Gbytes)	nputer of (e.g.,	3 of 3) Model no. Purchased from		
Information on con Manufacture Computer S/N Memory (Gbytes)	nputer of (e.g.,	Model no. Purchased from Screen size (in.)		
Information on con Manufacture Computer S/N Memory (Gbytes)	nputer of (e.g.,	Model no. Purchased from Screen size (in.)	Serial no.	
Information on con Manufacture Computer S/N Memory (Gbytes)	Internal hard disk (Mbytes)	Model no. Purchased from Screen size (in.)	Serial no.	
Information on con Manufacture Computer S/N Memory (Gbytes)	Internal hard disk (Mbytes) CD-ROM drive model Printer model	Model no. Purchased from Screen size (in.)	Serial no. Serial no. Serial no.	
Information on con Manufacture Computer S/N Memory (Gbytes)	Internal hard disk (Mbytes) CD-ROM drive model Printer model Plotter model	Model no. Purchased from Screen size (in.)	Serial no. Serial no. Serial no.	
Information on con Manufacture Computer S/N Memory (Gbytes) Peripherals:	Internal hard disk (Mbytes) CD-ROM drive model Printer model Plotter model Terminal model Other peripheral	Model no. Purchased from Screen size (in.)	Serial no. Serial no. Serial no.	
Information on con Manufacture Computer S/N Memory (Gbytes) Peripherals:	Internal hard disk (Mbytes) CD-ROM drive model Printer model Plotter model Terminal model Other peripheral	Model no. Purchased from Screen size (in.)	Serial no. Serial no. Serial no.	
Information on con Manufacture Computer S/N Memory (Gbytes) Peripherals:	Internal hard disk (Mbytes) CD-ROM drive model Printer model Plotter model Terminal model Other peripheral	Model no. Purchased from Screen size (in.)	Serial no. Serial no. Serial no.	on-site or off-site
Information on con Manufacture Computer S/N Memory (Gbytes)	Internal hard disk (Mbytes) CD-ROM drive model Printer model Plotter model Terminal model Other peripheral  NMR host Workstation running VnmrJ	Model no. Purchased from Screen size (in.)	Serial no. Serial no. Serial no. Serial no.	on-site or off-site

# 3.5 System Installation Checklist

Fill in the system installation checklist. If corrective action is required (No check box selected), use "System Installation Corrective Actions Checklist," page 34.

Con	npa	ny/University			
		Address			
	F	Principal User			
		Phone		Spectrometer type	
		Fax		Console S/N	
	Sal	es Order No.		Magnet S/N	
Ship	ome	ent Damage:			
		tallation Preparation:			
			console		essory
		e pressure:	air		N <sub>2</sub>
		conditioning:			
		ogens (liters):	LHe		LN
Test	ting	and Customer Familiariza	tion:		
Т		eptance tests and computer a			
yes	no	Acceptance tests procedures	s finished		
yes	no	Test results forms completed signed	d and		
yes	no	Computer audit completed a	nd signed		
2. \$	Sys	tem documentation review			
yes	no	Software Object Code Licens object code license regardle			titutes acceptance of
yes	no	Varian and OEM manuals	•	,	
yes	no	Explanation of warranty and	where to telephone for	or information	
3. I	Mad	gnet demonstration			
yes		Posting requirements for ma	anetic field warning s	ians	
yes	no	Warning signs posted	3	<b>5</b> -	
yes		Cryogenics handling and saf	ety		
yes	no	Magnet refilling	•		
		Flowmeters			
yes	no	Homogeneity disturbances			
4. (	Cor	nsole and probe demonstration	ın		
		ON! Avoid possible preamp. d		obe is connected and	d tuned to resonance.
yes		Loading programs	amage, mane care pr		
_		Experiment setup			
		Basic operation to obtain typ	ical spectra		
		ner Representative:			Date
		Representative:			Date

# 3.6 Supercon Shim Values

Fill in the following information:

wagnet Frequ	ency and Seri	iai number:				
Magnet Frequency						
Serial Number						
Measurement in:						
Amps						
Measurement	1. Date:	2. Date:	3. Date:			
Z0						
Z1						
Z2						
Z3						
Z4						
х						
Υ						
ZX						
ZY						
XY						
X2-Y2						
Drift						
Spacers						
Main Field Current						
Customer Signature:						
Varian Representative Signature:						

# Chapter 4. Operation Qualifications

Sections in this chapter:

- 4.1 "AutoTest," this page
- 4.2 "AutoTest Sample," page 21
- 4.3 "List of Tests Performed by AutoTest," page 24

An NMR spectrometer is a complex instrument, available with a variety of optional items and capable of performing a variety of different experiments. AutoTest (Figure 3) is used to demonstrate that an instrument functions according to a series of operation specifications.

The customer's representative or a Varian representative can run the Operations Qualifications test. The customer SOP dictates the operator. Operations qualification testing by a Varian Inc. representative is not included in standard installation, warranty, or service contracts. A specific quotation, purchase order, and sales order are required. The sales order number can be recorded in this chapter. Sales Order \_\_\_\_\_\_\_.

## 4.1 AutoTest

The AutoTest software is designed to demonstrate key console and probe performance criteria, measuring the output using NMR data derived from a single sample. In this way, a large series of tests is automatically completed; data from one system is easily compared to similar systems.

Autotest has a variety of straightforward screens that allow the basic configuration to be set up (operator name, console type etc.) (Figure 3). A library of tests is provided (Figure 4). A history log graphically represents the data over time (Figure 5) and a report page provides a textual output for each test (Figure 6). The report can be printed providing a hard copy record.

Some tests run by AutoTest have specifications attached; some use visual data inspection. For quick reference, all tests are listed in 4.3 "List of Tests Performed by AutoTest," page 24. System specifications are listed in the *Console Acceptance Tests and Specifications* manual.

For an OQ process, it is recommended that all applicable tests for the instrument are run. This same suite can be run after service calls, probe changes, or other major operations, according to the organization's SOPs.

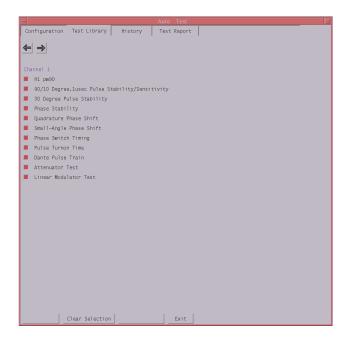
# 4.2 AutoTest Sample

AutoTest uses 0.1% <sup>13</sup>C methanol, 0.1% acetonetrile in 1% H<sub>2</sub>O/99.8% D<sub>2</sub>O.

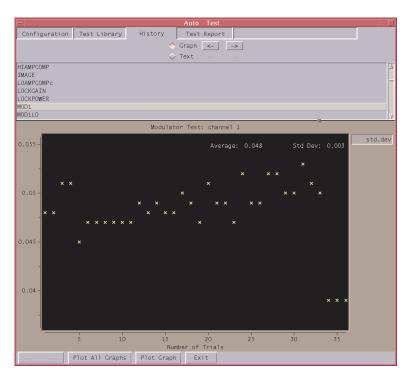
The sample is doped with gadolinium chloride at a concentration of 0.30 mg/ml, which produces a  $^1\text{H}$  T1 relaxation time of about 50 to 75 ms. The sample supplied with every spectrometer, has an expiration date of one year and is available for order using Varian P/N 01-901855-06, 5-mm sample.



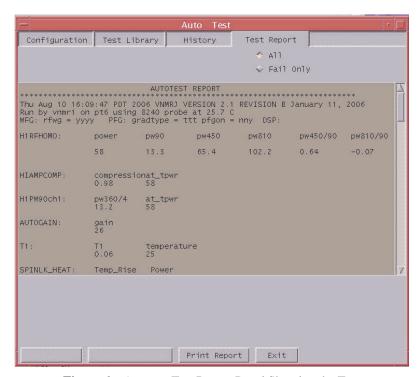
Figure 3. Autotest Configuration Panel with All Standard Tests Selected



**Figure 4.** Autotest Test Library Showing the Full List of Available Channel 1 Tests



**Figure 5.** Autotest History Panel Showing the Graphical Output of the MOD1 Test



**Figure 6.** Autotest Test Report Panel Showing the Text of a Completed Report

# 4.3 List of Tests Performed by AutoTest

For more detail, AutoTest is fully documented in the *AutoTest for VnmrJ*, Pub. No. 01-999247-00.

RF homogeneity test: <sup>1</sup>H

RF homogeneity test: <sup>13</sup>C

Water resonance frequency

 $T_1$ 

<sup>1</sup>H PW90 determination

<sup>13</sup>C PW90 determination

High-band amplifier compression

Low-band amplifier compression

<sup>13</sup>C phase modulation decoupling profile

GARP-1 modulation

WALTZ-16 modulation

XY-32 modulation

MLEV-16 modulation

<sup>13</sup>C adiabatic decoupling profiles

STUD modulation

WURST modulation

Receiver gain tests

Small-angle phase test

90° pulse stability (see Note 1)

Phase cycle cancellation – 2 scans (see Note 2)

Phase cycle cancellation - 4 scans (see Note 2)

30° amplitude stability (see Note 1)

Pulse turnon time

Attenuator linearity tests

400 MHz systems and above

Attenuator linearity test (reduced power)

400 MHz systems and above

Modulator linearity (tpwr = 40)

Modulator linearity (tpwr = -16)

Phase stability error

Gradient level for 10 G/cm along Z

X-gradient echo stability (10 G/cm)

Z-gradient recovery stability (10 G/cm)

Z-axis signal recovery (rect)

Z-axis signal recovery (sine)

Gradient phase cycle cancellation – 4 scans (see note 2)

Gaussian 90° stability

Gaussian 13° phase error

GaussianSLP 13° phase error

Temperature rise in spinlock test

Lock power test: corr. coef.

Lock gain test: corr. coef.

## Chapter 4. Operation Qualifications

# Chapter 5. Performance Qualifications

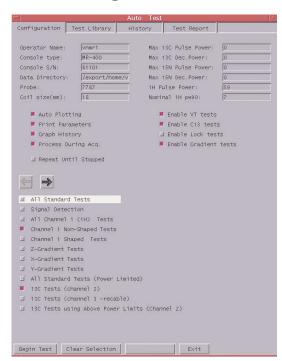
#### Sections in this chapter:

- 5.1 "AutoTest for Maintenance Testing," this page
- 5.2 "AutoTest Sample," page 28
- 5.3 "Additional Performance Qualification Tests," page 28

Autotest can also be used for routine maintenance testing. The customer's representative or the Varian representative can run the performance qualifications test. The customer SOP dictates the operator. Performance qualification by a Varian Inc. representative is not included in standard installation, warranty, or service contracts. A specific quotation, purchase order, and sales order are required. The sales order number can be recorded in this chapter.

# 5.1 AutoTest for Maintenance Testing

The AutoTest software is designed to demonstrate key console and probe performance criteria. However, for PQ, rather than run a full suite, individual tests should be chosen to best represent some of the more important criteria for the organization (see Figure 7). These tests can be run as required by the organization SOPs. The value of each selected test can be compared against earlier tests over time and against the values measured for the same test run during an OQ operation.



**Figure 7.** AutoTest Configuration panel showing a minimized selection of tests, potentially suitable for a PQ operation

# 5.2 AutoTest Sample

AutoTest uses 0.1%  $^{13}$ C methanol, 0.1%  $^{15}$ N acetonitrile in 1% H<sub>2</sub>O/99.8% D<sub>2</sub>O.

The sample is doped with gadolinium chloride at a concentration of 0.30 mg/ml, which produces a  $^1\text{H}$  T1 relaxation time of about 50 to 75 ms. The sample supplied with every spectrometer, has an expiration date of one year and is available for order using Varian P/N 01-901855-06, 5-mm sample.

## 5.3 Additional Performance Qualification Tests

Additional tests using a particular sample with a documented result can be applied to an SOP. These tests can be documented in Table 3.

*Note:* A Varian Inc. quotation for performance qualification services may include sample preparation and validation.:

Table 3. Additional Performance Qualification Tests

Test	Sample	Result	Customer Representative Signature	Varian Sales Order (if applicable)

# Appendix A. 400-MR System Specifications

#### Sections in this chapter:

- "Compact, high performance 2 channel NMR spectrometer," this page
- "High band Linear Amplifier," page 31
- "Broadband Linear Amplifier," page 32
- "Additional Optional Modules," page 32
- "Varian 400 MHz Magnet," page 32

## Compact, high performance 2 channel NMR spectrometer

## Frequency Sources

Frequency ranges: 18 5 - 245 MHz & 370 - 425 MHz

Frequency resolution of 0.1 Hz (not including phase continuous frequency shifting)

## High Band Linear Amplifier

For 1H & 19F, 50 watts pulsed power

#### Lowband, Linear Amplifier

For <sup>109</sup>Ag - <sup>31</sup>P, 300 watts pulsed power, 18.5-245 MHz

#### RF Controller

Power PC & FPGA

64MB RAM & 32MB Flash

> 30 MB controller memory per RF channel for waveform definition:

#### Phase Shift Generation

50 ns minimum event time and 12.5 ns timing resolution

50 ns settling time

0.044° phase resolution

0.04° phase accuracy

#### Coarse amplitude control

79 dB in 1 dB steps

## Fine amplitude control

60 dB in 4096 linear steps

50 ns minimum event time and 12.5ns timing resolution

50 ns settling time

## Phase Coherent and Phase Continuous Frequency Shifting

50 ns minimum event

50 ns settling time

Infinitesimally fine resolution for infinitely long pulse

#### PFG Controller

Power PC & FPGA

64MB RAM & 32MB Flash

> 30 MB controller memory for PFG channel for waveform definition:

## Gradient Shaping

12.5 ns timing resolution

Gradient amplitude control in ±32,768 linear steps

Minimum gradient pulse length 2.4 ms

# Preamplifiers

High band (<sup>19</sup>F and <sup>1</sup>H) GaAs FET preamplifier.

Active (linear) transmit/receive switch.

1 μs recovery, 1 μs switching time.

# Lowband (109Ag - 31P) preamplifier

Active (linear) transmit/receive switch.

1 μs recovery, 1.5 μs switching time.

#### **DDR Controller**

Power PC & FPGA

64MB RAM & 32MB Flash

## DirectDigital™ Receiver

Digitizer/ Max over sampling rate, 14 bit at 80 MHz, (eff. 20 bit, 10 KHz)

Maximum spectral width, 5 MHz

Maximum spectral width with no quadrature images, 5 MHz

On-the-fly Digital filtering

#### Lock Controller

Power PC & FPGA

64MB RAM & 32MB Flash

## Adaptive 2H Lock

2H frequency +/- 1 MHz

Quadrature detection with simultaneous sampling during lock capture.

Continuous field correction for short-term field fluctuations.

## Synchronization with External Events

3 TTL output line per RF channel for user programming

1 additional Ethernet connection

# Broadband (109Ag - 31P) preamplifier

Active (linear) transmit/receive switch.

1 μs recovery, 1.5 μs switching time.

High dynamic range, low noise and fast recovery.

*Note*: Nuclei using frequency ranges 61 to 72 MHz and 130 to 143 MHz are not supported and cannot be viewed.

Note: Deuterium observe uses the lock channel.

## **High band Linear Amplifier**

Nominal power	50 W
Nuclei	<sup>1</sup> H, <sup>19</sup> F
Max pulsed power (W)	50
Max CW power (W)	15
Full power duty cycle (%)	10
Full power pulse length (ms)	250
Rise time (ns)	200
Droop (%)	5
Unblank/Blank time (μs)	1

## **Broadband Linear Amplifier**

Nominal power	300 W
Frequency (MHz)	185 - 245
Nuclei	$^{109}$ Ag - $^{31}$ P
Max pulsed power (W)	300 (full range)
Max CW power (W)	30
Full power duty cycle (%)	10
Full power pulse length (ms)	100
Rise time (ns)	200
Droop (%)	5
Unblank/Blank time (µs)	1

# **Additional Optional Modules**

#### **Hardware Accessories**

Low Temperature Sample

Management

#### **Software Accessories**

NMRAnalyst Analyzes data from the carbon-carbon connectivity

experiment, revealing carbon connectivities at previously unattainable levels of sensitivity

DOSY Analyzes data from Diffusion Ordered Spectroscopy

experiments

## Varian 400 MHz Magnet

Drift	< 8 Hz/hr
Superconducting shim coils	Z1, Z2, Z3, X, Y, ZX, ZY, XY, X2-Y2
Radial 5G Stray Field from Magnet Center	55 cm/21.7 inches
Axial 5G Stray Field from Magnet Center	100 cm/39.4 inches
Axial 5 G height above floor	208 cm/81.9 inches

Axial 5 G depth below floor N/A

System weight, operational 650 kg

Min. ceiling height

Min. ceiling height (optional transfer)

294 cm/115.7 inches

260.5 cm/102.6 inches

Liquid helium refill volume 95 L

Liquid helium hold time < 270 days (9 months)

# Appendix B. Corrective Actions

- "Site Survey Corrective Actions," this page
- "Review and Confirmation of Shipped Items Corrective Actions," page 34
- "System Installation Corrective Actions Checklist," page 34

# **Site Survey Corrective Actions**

Action Required (from description)	Completed Yes/No	Customer Name/Signature/Date

# **Review and Confirmation of Shipped Items Corrective Actions**

Action Required (from description)	Completed Yes/No	Customer Name/Signature/Date

# **System Installation Corrective Actions Checklist**

Completed Yes/No	Customer Name/Signature/Date
	Completed Yes/No

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