TrueBeam/TrueBeam STx/ Edge/VitalBeam Software v2.x

Installation Product Acceptance

P/N IPA-HT-2X_ICP-C | April 2017

Format TMP-GE-IPA-E

Manufacturer and European Representative

Manufacturer:

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Notice

Trademarks

Contacting Support

Support services are available without charge during the initial warranty period. If you seek information not included in this publication, call Varian Medical Systems support at the following locations:

- United States and Canada telephone support — + 1 888 827 4265
- United States and Canada Direct telephone support — + 1 650-213-1000
- European telephone Support — + 41 41 749 8844
- Fax (US) — + 1 702 938 4754
- Fax (Service Europe) — + 41 41 740 3340

All other countries please call your local service office

To contact the support location nearest you for Service, Parts or Support, see the list at the Varian Medical Systems website:

Worldwide Listing —
http://www.varian.com/us/oncology/services_and_support/contacts.html

Communicating Via the World Wide Web

If you have access to the Internet, you will find Varian Medical System support at the following location:

Oncology Systems — http://my.varian.com

If you have a Varian account, enter your username and password. Otherwise, first click create new account to get a username and password.

From *MyVarian* home page, click Contact Us from the *Support* list along the left side of the window.

If possible, please send all e-mail inquiries through the my.varian.com web site at http://my.varian.com/contactus; otherwise, use the following e-mails addresses for support:

Sending E-Mail

■ North America (North America and Canada)	support-americas@varian.com
■ Central & South America	soporte.al@varian.com
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■ China / Asia (China, Asia)	support-china@varian.com
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Document History

C	Apr 27, 2017	Section 1.6: Updated the pinch point safety label from "Caution" to "Warning" Section 2.1: Updated and reconfigured licenses verification in Table 1 and 2 to reflect the latest machine configuration options per Varian Product Management. Also included new licenses that available in TrueBeam V2.7.x in Table 3; Section 5.5: Removed the symmetrical jaws position accuracy verification; Data Table 5.5.1: Updated the independent jaws position accuracy verification to one that requires customer demonstration; Section 7.2: Added a note to download and use the latest Isolock software v3.2.x; Section 9.3.1: Updated the caution notification in regards to IC profiler activation by radiation beam; Section 9: Rearranged the beam verification with IC profiler by performing the symmetry and flatness before the beam energy verification; Section 9: Removed the field intensity verification test for FFF and low x-ray as the energy measurement using the copper wedge already provides accurate energy definition. Section 10: Updated the Dosimetry Verification procedure and added a note to indicate that only a single energy is used for the test; Data Table Section 10: Updated in conjunction with changes to the Dosimetry Verification procedure; Section 19.5: Removed note that stated EXIO and MMI verification is not applicable to VitalBeam; Section 21: Removed note that stated Calypso and OSMS is not applicable to VitalBeam;	M. Tham
B	Oct 25, 2016	Developed this revision into Lotus Notes; Section 1.4: Added CTB-GE-228 reference document; Section 1.6: Updated safety notices per latest requirements; Section 4.1: Updated the radiation survey instruction per latest requirements Table 11: Re-labelled FFF to HI per marketing definition, and corrected the ICP calibration file for FFF to standard photon equivalent; Added figures 25 to 27 in Section 9 for visual clarification	M. Tham
A	Aug 1, 2016	Initial Released	M. Tham P. Mallia J. Taylor

Contents

List of Figures

List of Tables

List of Data Tables

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Acceptance Data Form

Print all information clearly

Start Date of Acceptance Test: ____________________

Completion Date of Acceptance: ____________________

Status: ____________________

TrueBeam PCSN: ____________________

EDGE PCSN: ____________________

VitalBeam PCSN: ____________________

MLC PCSN: ____________________

RapidArc PCSN: ____________________

Couch PCSN: ____________________

Pitch & Roll Stage (PRS) PCSN: ____________________

XI MV (XM) PCSN: ____________________

XI KV (XK) PCSN: ____________________

PU MVD (MA) PCSN: ____________________

PU KVD (KA) PCSN: ____________________

PU KVS (SA) PCSN: ____________________

Optical Imaging (OI) PCSN: ____________________

Calypso PCSN: ____________________

OSMS PCSN: ____________________

ICVI PCSN: ____________________

VVS PCSN ____________________

BCCV PCSN: ____________________

Institution: ____________________

Address: ____________________

____

____

Customer Representative: ______________________________

Printed Name

____

Signature Date Signed (**mm/dd/yyyy**)

I confirm that products listed above have been tested and demonstrated to my satisfaction and that all products listed on the attached certification have been installed and are operating in accordance with their product specifications

Varian CSR Representative: ______________________________

Printed Name

____

Signature Date Signed (**mm/dd/yyyy**)

The signature above indicates that all applicable and required tests within this document have been satisfactorily performed and met the required product specification.

1. Introduction

1.1 Scope

This Installation Product Acceptance (IPA) procedure provides testing procedures and data recording tables to enable Varian to demonstrate the TrueBeam, TrueBeam STx, Edge or VitalBeam has been successfully installed and meets required manufacturer specifications.

This document is valid for TrueBeam Systems release version 2.0.x or later.

1.2 Instructions for Use

1.2.1 Lotus Notes Users

This **IPA** document is used as the source reference document by the Lotus Notes programmer to create an **IPAD** (Installation Product Acceptance Document) and a **CPAD** (Customer Product Acceptance Document) within Lotus Notes. The IPA is then used as a reference document by the user for test procedures only. All test data will be entered in the Lotus Notes generated IPAD and CPAD documents.

In order to expedite product installation time while maintaining Varian's high quality installation process, this **IPA** document includes tests that are performed solely by the Varian Customer Support Representative (CSR) and some tests that are performed with the customer. Tests to be performed with the customer are easily identified in the IPA document by a predetermined *Customer Demo Required* row at the bottom of the corresponding data table.

The **IPAD** is performed by the Varian CSR in Lotus Notes during the course of the installation. This document must be completely filled out by the Varian CSR.

The **CPAD** is printed out and performed with the customer. The CPAD will contain a combination of predetermined filled-out and blank tables to be used as follows:

- <u>Filled-out Data Tables</u>: Indicate tests the Varian CSR is responsible for performing during opportune times during the course of the installation and do not need to be repeated during customer acceptance testing. They are included in the CPAD to provide a permanent record of all tests for the customer. The Varian CSR completes and signs these tables.
- <u>Blank Data Tables</u>: Indicate tests that require customer demonstration and are completed and signed by the Varian CSR and the customer.

1.2.2 Non-Lotus Notes Users

Without Lotus Notes, it is not possible to generate the **IPAD** and **CPAD** documents mentioned above. Therefore, a printed copy of this **IPA** document will be used as the sole acceptance testing document for all test procedures and data recording.

In order to expedite product installation time while maintaining Varian's high quality installation process, this **IPA** document includes tests that are performed solely by the Varian Customer Support Representative (CSR) and some tests that are performed with the customer. Tests to be performed with the customer are easily identified in the IPA document by a predetermined ***Customer Demo Required*** row at the bottom of the corresponding data table.

Print out one copy of the latest revision of this IPA document from the PSE Data Center. During the course of the installation, complete all applicable tests in this IPA and fill out the corresponding data tables as follows:

- Data Tables without the ***Customer Demo Required*** row: Perform these tests during the course of the installation and fill out the data tables. Enter NA in any data table boxes that do not apply.
- Data Tables with the ***Customer Demo Required*** row: Perform these tests before customer acceptance testing to verify they pass, but leave the data tables blank. Repeat these tests again during customer acceptance testing and have the customer fill out the data tables. Enter NA in any data table boxes that do not apply.

1.2.3 Document Distribution

1.2.3.1 Lotus Notes Users

IPAD: When the installation is complete, the automated IPAD must be completely filled out by the VMS CSR, leaving no blank spaces. When completed and electronically signed, this document will be retained by Varian for proof of product performance and compliance to specification.

CPAD: When the installation is complete, the CPAD paper document must be completely filled out by the VMS CSR and customer, leaving no blank spaces. After all required tests are satisfactorily completed, distribute the document as follows.

- The customer and the Varian CSR must sign and date the cover page.
- Provide a copy of the signed and dated cover page, along with the original CPAD document, to the customer.
- Return only the original signed and dated cover page to Varian for permanent record. Varian does not require the full CPAD document.

1.2.3.2 Non-Lotus Notes Users

Note *For non-Lotus Notes users, this IPA document will serve as the official Regulatory required document of record. The document must adhere to the following regulatory guidelines.*

- *All data tables must be completely filled out, leaving no blank spaces.*
- *NA must be entered in all non-applicable data table boxes.*
- *No extra data is to be entered within the document, such as customer notes or additional recorded data. Customer can use a separate copy of the IPA for these entries if required.*
- *Any mistaken data must be crossed out with a single line and initialed and dated, with the corrected data entered next to it. For extensive data errors on a page, print out a new page and enter the correct data.*

IPA: When the installation is complete, the paper copy of this IPA must be completely filled out by the VMS CSR and the customer, leaving no blank spaces. After all required tests are satisfactorily completed, distribute the document as follows.

- Verify the document adheres to the guidelines mentioned in the Note above.
- The customer and the Varian CSR must sign and date the Acceptance Data page.
- Provide a copy of the signed and dated IPA document to the customer.
- Return the original signed and dated IPA document to the local office to be retained by Varian for proof of product performance and compliance to specification. The local office Field Office Administrator will scan this document into permanent record.

1.3 Conventions

This section presents the types of notes and precautionary notices used in the guide, along with their icons. The following notational conventions are used:

Note *A Note describes actions or conditions that help the user obtain optimum performance from the equipment or software.*

CAUTION **A CAUTION describes actions or conditions that can result in minor or moderate injury.**

WARNING **A WARNING describes actions or conditions that can result in serious injury or death.**

NOTICE **A NOTICE describes actions or conditions that can result in equipment damage, data loss, non-compliant operation, and/or other significant issues that do not involve injury.**

Stop *A Stop note describes actions or conditions that must be verified and/or satisfied before continuing.*

1.4 References

[1] RIG-HT-SLIM TrueBeam Rigging and Isocenter Manual

[2] CAL-HT-DS02x_SL TrueBeam/TrueBeam STX Version 2.x Configuration and Alignment

[3] CAL-HT-25XI TrueBeam X-Ray Imaging Calibration Manual

[4] CAL-HT-PU02X TrueBeam 2.x Positional Unit Calibration Manual

[5] SIM-HT-25 TrueBeam Software Installation Manual

[6] CTB-GE-791 TrueBeam Power Up Instructions

[7] TT-SR-01339 TrueBeam Isolock Instructions

[8] UG-GE-Profiler Sun Nuclear IC Profiler User Guide

[9] CTB-GE-228 Dosimetry Monitoring System Calibration

1.5 Abbreviations

AM	Accessory Mount
CCDS	Capacitive Collision Detection System
CPAD	Customer Product Acceptance Document (generated in Lotus Notes)
CSR	Customer Service Representative (Varian employee)
DF/FF	Dark Field and Flood Field
DICOM	Digital Imaging and Communications in Medicine
DMI	Digital Megavolt Imager
DR-X	Dose Rate, X= MU / Min
EA	Electron Applicator
EBC	Enhance Beam Conformance
E-Max	Refers to the highest electron installed on the machine
EXGI	External Gating Interface
EXIO	External Input/Output Module
FBIA	Fine Beam Isocenter Accuracy
FFDA	Final Field Defining Aperture
HDTSe-	High Dose Total Skin Electrons
HI	High-Intensity (High intensity energies without Flattening Filter)
ICVI	Integrated Conical Collimator Verification and Interlock System
IPA	Installation Product Acceptance
IPAD	Installation Product Acceptance Document (generated in Lotus Notes)
IRM	In-Room Monitor
IDU	Image Detection Unit
kV	Kilovolt
KVD	kV Detector
KVS	kV Source
LDR	Low Dose Rate
MCN	Motion Control Node
MLC	Multi-Leaf Collimator
MMI	Motion Management Interface
MVD	Mega Voltage Detector
ODI	Optical Distance Indicator
OSMS	Optical Surface Monitoring System
PCSN	Product Code and Serial Number
PRO	Position Read Out
PU	Position Unit
ROI	Region of Interest

SID	Source to Image Distance
SMC	Service Mode Console
SNC	Sun Nuclear Corporation
SSD	Source to Surface Distance
TC	Tissue Compensator
VEO	Varian European Operations
VMS	Varian Medical Systems
VVS	Varian Verification System
XI	X-Ray Imaging System
WS	Workstation

1.6 Safety

WARNING **The tasks listed in this procedure are to be performed by Varian-trained personnel only. Untrained personnel should not attempt any procedures or tests contained within this document. VARIAN is not liable for errors made by others using these instructions. This document is subject to change without notice.**

WARNING **Misuse or improper servicing of the linac systems can expose the operator, service technician, and/or the patient to one or more of the following hazards:**

- **Mechanical collision**
- **Electrical shock**

Any of these hazards could cause serious injury or death. Persons who service or maintain the system must read, understand, and be familiar with the material in the applicable product Safety Guide available at http://myvarian.com.

WARNING **Machine cover fasteners can wear and come loose over time, or the covers can be installed incorrectly. Always inspect primary and redundant fasteners for operation when any cover is removed.**

Never return the machine to clinical operation when the covers are compromised and not securely fastened in a way that could create a hazard, which could cause serious injury to patients.

WARNING **All external fastening screws on the machine should be in place and tightened to the proper torque to prevent possible serious injuries from falling objects.**

WARNING **Radiation exposure may cause serious injury or death. Never produce x-rays from the linac when anyone is in the treatment room or with the required treatment room door open. Always wear or carry your provided dosimetry device when working in the radiation environment. For clip-on dosimetry devices, make sure the device is attached to the trunk of your body. For additional radiation safety information, refer to the product Safety Guide, available at http://myvarian.com.**

WARNING **Lead poisoning is a serious and sometimes fatal condition if ingested in the body over a long period of time. Refer to the personal protective equipment (PPE) recommendations in the applicable product Safety Guide when handling lead to avoid ingesting or inhaling lead dust.**

CAUTION **Potential Radiation Exposure from Clinac, TrueBeam, and VitalBeam Systems**

High energy linear accelerators are capable of inducing radioactivity in matter. The process where non-radioactive substances become radioactive due to interactions with high-energy radiation is called activation. Metal parts that are in, or near contact with linear accelerator radiation beams with energy greater than 8 MV are susceptible to activation. These accelerator parts should be considered radioactive unless/until they have been checked with appropriate instrumentation and shown to be non-radioactive. While much of the created radionuclides decay within a short time (days or weeks), longer-lived radioactive materials, which can be detected even after a few years, are also produced.

Only trained radiation workers are authorized to handle radioactive materials. If you are performing maintenance tasks that may expose you to potentially radioactive components, always wear your assigned dosimeter(s), and follow any procedures communicated to you by the Varian Radiation Safety staff. Observe As Low As Reasonably Achievable (ALARA) practices and minimizes your exposure by working quickly and spending as little time as possible near unshielded radioactive parts.

The following areas of the linac are expected to contain radioactive metals:

- **BMAG/Orbital Chamber components**
- **All lead shielding components**
- **Structural steel components in the Gantry head**
- **Carrousel metal components and high energy flattening filters**
- **Ion Chamber assembly**
- **Target assembly and target drive metal components**
- **Collimator area metal components**

Additional information and guidance is provided in the following documentation:

- **TrueBeam/VitalBeam Safety Guide: Induction of Radioactivity**
- **Clinac Safety Guide: Induction of Radioactivity**
- **CTB-GE-924: Radionuclides Created in High Energy Linear Accelerators by Nuclear Activation Processes**
- **PFU-195: Shipping Activated Accelerator Components**
- **DDP-HT-HAXMAT: TrueBeam Hazardous Substances and Materials – Removal and Disposal**
- **DDP-HE-HAZMAT: High Energy Clinac Hazardous Substances and Materials – Removal and Disposal**
- **Instruction L6103: Handling and Shipping Radioactive Materials Associated with Varian Linear Accelerators (applies to the Americas)**
- **Instruction L12192: Radiation Safety – Information on Activated HE Linac Components for HW Field Service (applies to EMEA and APAC)**

The instructions L6013 (Americas) and L12192 (EMEA & APAC) can be obtained using the Varian Radiation Safety Website; see listings under "Quick Links": http://vmsnet.vms.ad.varian.com/CorpServices/RadiationSafety/Pages/Information.aspx

Do not attempt to return any potentially radioactive components unless specifically requested, and then only after review of the instructions provided in the previously mentioned documents.

WARNING **When servicing the machine the following risks exists that could cause minor to moderate injury.**

- **Pinch points. All pinch point labels should be observed to reduce the risk of injury.**
- **Exposed metal edges when the covers are removed. Use proper Personal Protective Equipment (PPE) to reduce the risk of injury, e.g., hard hats, gloves, safety goggles.**
- **Heavy lifting: Use proper lifting technique, and when possible, use mechanical fixtures or assistance when lifting heavy items to avoid injury**

1.7 Required Equipment/Tools

Varian Supplied	
1 each	Precision level, 6-8 inches (150 – 200 mm) and white tape
1 each	Sun Nuclear IC Profiler (Belair Item # 421 - IC Profiler Kit for Installation Acceptance)
1 each	Tape Measure with cm/mm divisions
1 each	Couch PRO Alignment Tool
1 each	IsoLock test tooling and software
1 each	50 cm Precision Metal (rigid) Ruler
1 each	External kV measurement tools which may include • UNFORS Xi • Fluke (or Nuclear Associates 07-523) line pair tool • Aluminum step wedge 07-456
1 each	Calibrated Front Pointer
1 each	ISOCAL, Las Vegas and Gating Phantoms
1 each	0.5 mm diameter wire (lead, tungsten, tantalum) P/N TM61451000
1 each	Leeds TOR [18FG]
	SNC profiler software installed on CSR laptop
	Latest serialized **Profiler_Support_files.exe** file downloaded from the PSE data center
	TrueBeam Test Plans available on PSE data center
	TrueBeam Dosimetry Spreadsheet Rev_xx.xls from the PSE data center
Hospital Supplied	
1 each	Electrometer and secondary ionization chamber (with appropriate buildup)
5 sheets	Ready Pack X-ray Film (Kodak X-Omat Type V, Carestream EDR2, or equivalent)or Gafchromic film (if no processor available)
1 each	Film processor (not needed for Gafchromic film)
5 sheets	Graph paper with mm increments (measure for accuracy)

1.8 IPA Tests Applicability

This acceptance procedure can be used for new installations, or for upgrades. Instructions are provided in note boxes under various test section headings stating the applicability of tests for each scenario. Enter **NA** in any data table boxes that do not apply.

1.9 Position Readout Scale Conventions

Note *IPA mechanical readouts are referenced to TrueBeam default scale IEC1217*

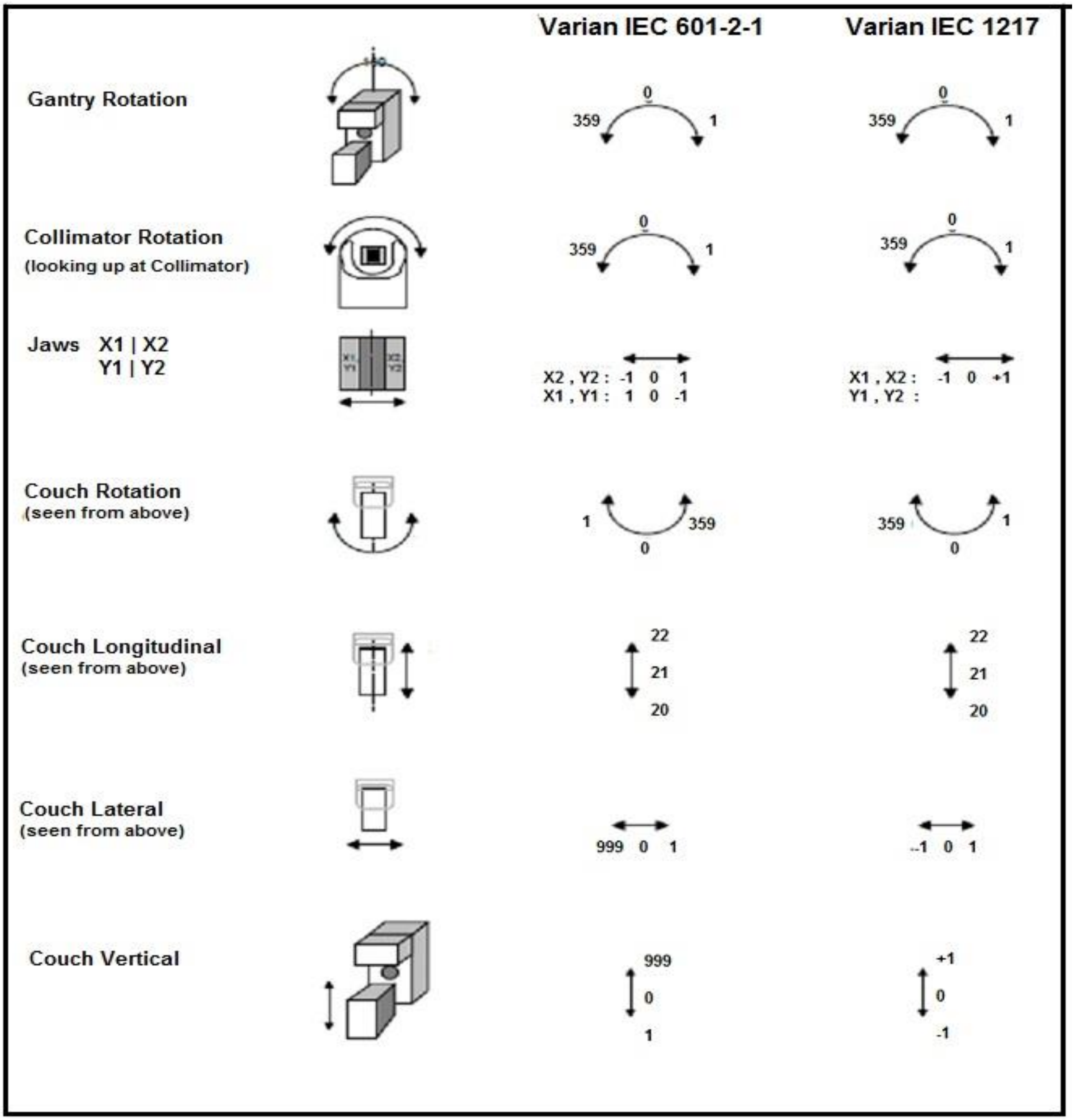


Figure 1: PRO Scale Conventions

1.9.1 Positional Unit Arms (Displayed PU Services) Application

		toward couch			**Imager Longitudinal**					*toward gantry*	
						view from radiation source out towards Isocenter (couch perpendicular to gantry)					
IEC61217	y_r		-10.0		0.0		20.0		40.0		
Varian IEC (601-2-1)			10.0		0.0		980.0		960.0		
		to the left			**Imager Lateral**					*to the right*	
						view from radiation source out towards Isocenter (imager rotation 0 deg)					
IEC61217	x_r	-25.0		-10.0		0.0		10.0		25.0	
Varian IEC (601-2-1)		975.0		990.0		0.0		10.0		25.0	
		down to floor			**Imager Vertical**						*up to ceiling*
						view from side of imager towards couch (IEC: 0.0 cm = Isocenter height)					
IEC61217	z_r	-40.0		-20.0		0.0		10.0		20.0	
Varian IEC (601-2-1)		40.0		20.0		0.0		990.0		980.0	

- **Sides of Gantry and Positioning Arm**

  The sides of gantry and mounted support arm are viewed from the treatment couch when facing the gantry.

- **Gantry Angles**

  Gantry angles are represented using IEC61217 scale.

  Gantry head up is equivalent to IEC61217 scale 0 deg.

  Gantry head down is equivalent to IEC61217 scale 180 deg.

- **Positioning Unit location**

  Imaging detector: The Support Arm position is given using the vertical, longitudinal and lateral distances between the center of the imaging layer and the isocenter. The positions are given in the following format: vertical / longitudinal / lateral.

  X-Ray source: The Support Arm position is given using the vertical and longitudinal distances between the focal spot and the isocenter.

- **Position Measurements**

  To measure the position of the MV Image Detection Unit (IDU 20) referred to isocenter, the following tools are used: a calibrated mechanical front pointer, the calibrated crosshair, a metric straight ruler (30 cm long), and a metric tape measure (for distances up to 100 cm).

- **Vertical Distances**

  To measure vertical distances between the detector surface and the isocenter height, use the calibrated front pointer positioned at isocenter and measure the distance between the detector surface and the bottom edge of the front pointer (isocenter height). Use the straight ruler for distances up to 30 cm and a metric tape measure for longer distances. Be careful reading the distance on the ruler or the tape measure because of the parallax effect.

- **Longitudinal and Lateral Distances**

  To measure longitudinal and lateral distances between the center of the detector surface (a cross is drawn) and the beam axis, use the calibrated crosshair and measure with a straight ruler (30 cm long) the distance between the center of the detector and the crosshair shadow projected on the detector surface by the light field.

2. Preliminary Machine Checkout

2.1 Software Licenses

Requirement

The following applicable licenses (per Sales Order) shall be installed on the TrueBeam workstation folder path *D:\VMSOS\License.* The licensing structure shown in the tables is defined by Varian Product Management.

Note *Some license features require configuration for clinical functionality. As an example, Varian Product Management has defined* ***Rapid Arc*** *and* ***VMAT*** *as mutually inclusive features and may be simultaneously enabled.*

VVS license if exist may be installed only in IRM workstation.

MPC offline license is installed on customer preferred workstation.

Disregard Offline QA license in sales order as it is currently not applicable

Test Method

1. Make a copy of license from TrueBeam folder ***D:\VMSOS\License\TrueBeamSNxxxx.lic,*** and copy to your Varian issued notebook.
2. Verify machine license configuration with WordPad or text viewer by comparing machine sales order to **TrueBeamSNxxxx.lic** as defined in tables in this section by checking **YES** or **NO**.

Note *If electronic copy of is available, use the word "lic" to search for all TrueBeam machine related license in sales order.*

3. Some optional packages come with a specific set of licenses. Compare the license file with the license features in Table 2 and Table 3, and check **YES** or **NO**.
4. If there are any discrepancies, please contact ***Varian Site Solution Project Management*** for resolution.
5. Record results.

Table 1: Base Machine Licenses			
Re	**License Feature**	**When Required**	**Installed?**
1	NDS Treatment	Basic Photon Treatment Delivery	Yes □ No □
2	NDS TBI	Total Body Treatment Delivery	Yes □ No □
3	NDS IMRT	IMRT Treatment Delivery	Yes □ No □
4	NDS MV Imaging Advanced	2D MV Radiographic and Cine image acquisition, review and match.	Yes □ No □
5	NDS SRS	High Dose/Field limits for Hypo fractionated treatments	Yes □ No □
6	NDS Dosimetry Acquisition	Portal Dosimetry acquisition	Yes □ No □
7	NDS_2D3D_Match	2D / 3D Match with DDR generation	Yes □ No □
8	NDS_On_Demand	Online addition of kV and MV imaging protocols to treatment fields, with automated generation of reference images	Yes □ No □
9	NDS_Image_Approval	Online Physician Approval of Images at Treatment Console (compatible with ARIA only)	Yes □ No □
10	MPC_Console	Machine Performance Check Console Mode	Yes □ No □
11	MPC_Offline	Machine Performance Check Offline Mode	Yes □ No □

Table 2: Optional Packages Licenses			
Re	**License Feature**	**When Required**	**Installed?**
1	NDS Electron	Electron Treatment Delivery	Yes □ No □
2	NDS RapidArc	RapidArc Treatment Delivery (Eclipse)	Yes □ No □
3	NDS VMAT	Load VMAT plan from 3rd party planning system	Yes □ No □
4	NDS Respiratory Gating	Respiratory Gating Treatment Delivery	Yes □ No □
5	NDS Dynamic MV Imaging	Respiratory gated MV image acquisition and online review	Yes □ No □
6	NDS Dynamic kV Imaging or NDS Resp Trig KV Imaging	Respiratory gated/synchronized kV image acquisition and online review.	Yes □ No □
7	NDS_Residual_Motion	Display and review of only fluoroscopy frames acquired within gating window during a gated treatment	Yes □ No □
8	NDS KV CBCT	KV CBCT image acquisition, review and match	Yes □ No □
9	NDS_Flouro_Overlay	Displays structures projections of Fluoro images	Yes □ No □
10	NDS_3DCBCT_Merged	Acquisition of kV CBCT with a long field of view, provided by merging of multiple indexed CBCT images	Yes □ No □
11	NDS_Time_Trig_kV_Imaging	Time Triggered KV Imaging	Yes □ No □
12	NDS_Gantry_Trig_kV_Imaging	Gantry Angle Triggered KV Imaging	Yes □ No □
13	NDS_MU_Trig_kV_Imaging	MU Triggered KV Imaging	Yes □ No □
15	NDS_Auto_Beam_Off	Automated treatment delivery beam hold, based on triggered image-based tracking of specified marker position	Yes □ No □
16	NDS_4DCBCT	4D kV CBCT image acquisition and online viewing	Yes □ No □
17	6 Dof ADI	6DOF capability for 3rd Party MMI device to Perfect Pitch couch via MMI/ADI connection	Yes □ No □
18	PACCV_PAVS	VVS Patient & Accessory Verification	Yes □ No □
19	PACCV_BCCV	VVS Conical Collimator Verification	Yes □ No □
20	PAVS	Patient & Accessory Verification System (on sales order prior to VVS released only)	Yes □ No □
21	NDS Research	Research/Development Mode enable	Yes □ No □
22	NDS Tracking	Tracking (for Development Mode only)	Yes □ No □

Table 3: Optional Purchasable Licenses (TrueBeam V2.7.x and above only)			
Re	**License Feature**	**When Required**	**Installed?**
1	NDS_Gated_CBCT	CBCT image acquisition, synchronized with respiration gating	Yes □ No □
2	NDS_4DCBCT_Match_Review	Online 4D CBCT image data acquisition, image review, and image match to 4D reference image	Yes □ No □
3	NDS_Short_Arc_CBCT	CBCT image acquisition using a 120-150 degree arc (within a 20-25 second breath hold)	Yes □ No □
4	NDS_DeltaCouchShift	Automated management of treatment plan-based shifts from initial set up to treatment isocenter	Yes □ No □
5	NDS_Virtual_Cone	Compact intensity modulated intracranial SRS treatment delivery, featuring full automation of non-coplanar delivery and MV imaging	Yes □ No □

Results

Data Table: Section 2.1 – Software Licenses	
Pass/Fail Criteria	**√ = OK**
TrueBeam license verification completed.	
Customer Demo Required	

3. Interlock Demonstration

3.1 Door Interlock

Requirement

The production of X-Rays will not be permitted while the treatment room door is open. An interlock equivalent with a message will be displayed at the workstation.

Test Method

1. This test is performed in Service mode.
2. Open the treatment room door. Press **Clear all**.
3. Try beam on with any KV Imaging Mode (if installed) via *XI tab > Acquisition > kV.*
4. Verify that the door interlock will prevent beam on.
5. Repeat test for MV Beam.
6. Record results in the data table.

Results

Data Table: Section 3.1 – Door Interlock	
Test	**√ = OK**
Door interlock prevents beam-on.	

4. Radiation Survey

4.1 Site Radiation Survey

WARNING ***Possible death or serious injury could result from radiation exposure if the TrueBeam is used to produce beam before a satisfactory radiation survey has been completed by a competent radiation expert.***

If dose rates in areas external to the treatment room exceed radiation levels recommended by the governing agency, the machine is not to be operated further until either the equipment or the facility is modified, or a temporary deviation issued. A temporary deviation may consist of operating at a limited dose rate, operating with restricted gantry angles, or a combination of both as determined by the qualified radiation expert. This survey is a preliminary check used to determine temporary safe installation environment and is not to be used as the data-gathering survey that will be conducted by the customer after installation.

Requirement

As soon as the linac is able to produce radiation, a qualified radiation safety expert, provided by the customer, shall conduct a preliminary radiation survey to verify that it is safe to allow beam-on. This is an initial room survey only, typically completed in less than 1 hour, which is solely intended to ensure Varian and customer personnel safety during the installation process. A thorough survey will be performed by the customer after product acceptance

Test Method

1. If the customer did not already receive the necessary survey form and instructions from the Project Manager, then download the applicable radiation survey form and instructions from the ***PSE data center > Environmental > Radiation Procedures & Information*** page.

Table 4: Radiation Survey Form and Instructions

Region	Survey Form	Survey Instructions
Americas	L9330A Customer's Radiation Safety Check at First Beam Delivery (Americas)	General Instructions: L9330 Initial Beam-on Radiation Survey of Customer LINAC Rooms (Global) Form-specific Instructions: See Form L9330A
EMEIA & APAC	L9206 Radiation Survey Form (APAC & EMEIA)	General Instructions: L9330 Initial Beam-on Radiation Survey of Customer LINAC Rooms (Global) Form-specific Instructions: L9205 Radiation Survey Linac Installations (APAC & EMEIA)

2. Perform the radiation survey with the customer radiation expert and fill out the radiation survey form. The form must be completely filled out and signed before continuing with beam testing. Return this form to Varian along with the product acceptance certificate at the end of the installation.
3. Record test results in the data table.

Results

Data Table: Section 4.1 – Site Radiation Survey	
Test Criteria	**√ = OK**
Work environment is safe for beam work and the Radiation Survey form is filled out and signed by the customer designated radiation expert.	

4.2 Collimator Transmission

Specification

Transmission through the moveable collimators shall not exceed 0.5% of the central beam intensity. Collimator transmission tests are performed during manufacturing testing of the system. This data is available from Varian via the link provided below.

http://myvarian.com/

Upon logging in to the above website, select **Product Documentation > Product (TrueBeam) > Document Type (Reference Material)**. The above data can be found in the ***TrueBeam/TrueBeam STx Type Tests*** document.

4.3 X-Ray Leakage

Specification

The average X-ray intensity measured over an area of 100 cm^2 at a distance of 1 meter from the primary beam shall not exceed 0.1% of the intensity at isocenter. Data is on file at Varian that represents a typical X-ray intensity for the TrueBeam. This data is available from Varian via the link provided below.

http://myvarian.com/

Upon logging in to the above website, select **Product Documentation > Product (TrueBeam) > Document Type (Reference Material)**. The above data can be found in the ***TrueBeam/TrueBeam STx Type Tests*** document.

5. Mechanical Verifications

5.1 Mechanical Isocenter Accuracy

Fine Beam Isocenter Accuracy (FBIA) specification is a standard feature on TrueBeam. It is not possible to precisely calculate FBIA using the customer's front pointers. FBIA will be verified in **Section 7.2:** Isocenter Verification with IsoLock.

5.1.1 Isocenter Tuner Stand Position Results

Note *Although there are no specifications for Isocenter Tuner values, the following listed values in Sections 5.1.1 and 5.1.2 are required to achieve the specifications for isocenter testing later.*

Requirement

- Gantry Skew shall be ±0.004" inch (±0.10 mm)
- Gantry Sag shall be ±0.014 inch (±0.36 mm)
- Stand Position Radial shall be ±0.003 inch (± 0.08 mm)
- Stand Position Transverse shall be ±0.003 inch (±0.08 mm)

Test Method

1. Perform Isocenter Tuner software testing for stand positioning according to procedure in RIG-HT manual.
2. Record results in the data table.

Results

Data Table: Section 5.1.1 – Isocenter Tuner Stand Position Results			
Axis	**Requirement**		**Actual (Indicate inch or mm)**
	inch	**mm**	
Gantry Skew	±0.004	±0.10	
Gantry Sag	±0.014	±0.36	
Stand Position Radial	±0.003	±0.08	
Stand Position Transverse	±0.003	±0.08	

5.1.2 Isocenter Tuner VEO Tuning Results

Requirement

All VEO turntable adjustment points shall be ≤ 0.002 inch (≤ 0.05 mm).

Test Method

1. Perform Isocenter Tuner software testing for VEO Tuning according to RIG-HT manual.
2. Record results in the data table.

Results

Data Table: Section 5.1.2 – Isocenter Tuner VEO Tuning Results			
Adjustment Point	Nominal Value (Pull Up Only)		Actual (Indicate inch or mm)
	inch	mm	
Screw 2	≤ 0.002	≤ 0.05	
Screw 3	≤ 0.002	≤ 0.05	
Screw 4	≤ 0.002	≤ 0.05	
Screw 5	≤ 0.002	≤ 0.05	
Screw 6	≤ 0.002	≤ 0.05	
Screw 7	≤ 0.002	≤ 0.05	
Screw 8	≤ 0.002	≤ 0.05	
Screw 9	≤ 0.002	≤ 0.05	
Screw 10	≤ 0.002	≤ 0.05	

5.2 Front Pointer Distance Alignment Verification

Note *The Front Pointers provided with the TrueBeam system are only intended as isocenter distance indicators, primarily for Physics use. Due to mechanical variances and tolerances within these removable parts, they are not intended to represent the location of the isocentric sphere in any other planes. The following test will verify the distance alignment of the 'master' Front Pointer rod, which will be used for other verification tests later.*

Requirement

The Front Pointer shall accurately indicate the Target to Surface distance at 100 cm within ± 0.5 mm.

Test Method

1. Insert the Front Pointer tray with the Front Pointer rod that has index marks ranging from 95 to 101. Accurately align the rod to the 100 cm index line.

2. Position the couch to 0° with the couch top at isocenter.
3. Without disturbing the Front Pointer, position gantry at 90°.
4. Attach a small strip of white tape (with a vertical line on it) to the front edge of the couch top.
5. Move the couch axes to accurately align the end of the Front Pointer tip to the taped line.
6. Rotate gantry to 270° and verify the tip of the Front Pointer is again aligned to the taped line.
7. Record results in the data table.

Results

Data Table: Section 5.2 – Front Pointer Distance Alignment Verification		
Test	**Requirement**	**√ = OK**
Front Pointer is aligned to 100 cm TSD.	100 cm ± 0.05	

5.3 Field Light Alignment Verification

Note *Since the light field source does not rotate with the collimator, it is necessary to use two surfaces that rotate with the collimator to verify light field run-out. The crosshair film and an inserted piece of paper in the bottom of the 25X25 applicator are used as surfaces.*

The crosshair assembly must be installed but crosshair alignment is not critical. This test only requires visual observation of crosshair movement but not crosshair alignment.

Requirement

- The field light source run-out shall be ≤ 1.0 mm using an independent shadow source in the collimator for both bulb 1 and bulb 2.
- The difference of projected field light position for bulb 2 shall be ≤ 0.5 mm from the projected position of bulb 1.

Test Method

Table 5: Field Light Alignment Verification Setup	
Gantry Angle	0°
Collimator Starting Angle	90°
Field Size	35 x 35 cm
Accessory Require	25 x 25 cm applicator with standard mold frame inserted. Field Light Alignment Fixture (EDGE only)

1. Setup the test per Table 5.
2. **For TrueBeam /TrueBeam STx and Vital Beam with applicator installed:**
   - Tape a piece of paper to the 25x25 cm mold frame.
   - Rotate collimator to 90°.

- Using a fine point pen, accurately bisect each of the projected crosshair lines with a single mark on the paper.
- In Service mode, under the **CAROUSEL/ FIELD LIGHT** tab, select **Bulb 1** field light and turn on the field light.
- Rotate collimator from 90° to 270°. Make another single mark on the paper.
- Measure and record crosshair run-out for both lines and verify worst-case field light run-out specification.
- Repeat the process but with **Bulb 2** field light selected and use a different color pen to mark the projected crosshair lines.
- On the paper, measure the distance between the mark lines of **Bulb 1** and **Bulb 2** at position 90° and 270° respectively. Record the worst–case distance difference.

3. For EDGE with field light alignment fixture installed :

- Rotate collimator to 90°.
- In Service mode, under the CAROUSEL/ FIELD LIGHT tab, select Bulb 1 field light and turn on the field light.
- On the alignment fixture, loosen the spring loaded screw at the bottom of reference plate and align the marked lines to the crosshair projection.
- Rotate collimator from 90° to 270°.
- Measure and record crosshair run-out for both lines and verify worst-case field light run-out specification.
- Repeat the process but with **Bulb 2** field light selected.
- Measure the distance between the deviation points of **Bulb 1** and **Bulb 2** at position 90° and 270° respectively. Record the worst–case distance difference.

4. Record results in the data table.

Results

Data Table: Section 5.3 – Field Light Alignment Verification		
Optical Test	**Specification (mm)**	**Actual**
Field Light Run-Out Bulb 1	≤ 1.0	
Field Light Run-Out Bulb 2	≤ 1.0	
Difference between Field Light Bulb 1 and Bulb 2	≤ 0.5	

5.4 Crosshair Alignment and Jaw Parallelism

Note *Crosshair alignment accuracy is critical for proper mechanical alignments of the MLC, collimator and couch rotation axes and also for the kV imaging system. Therefore, observe the following guidelines:*

- *The crosshair run-out must be < 0.5 mm (although the spec is ≤ 1.0 mm).*
- *The radial crosshair line (used for calibrating the MLC and collimator/couch rotation axes) must be as parallel as possible to the MLC leaf banks.*

The MLC is the primary field collimation device in present day clinical applications and jaws are basically used for shielding. Therefore, the MLC should be the mechanical reference for all other alignments.

Since crosshair lines and jaws may not be precisely orthogonal, accurately align the parallelism of the radial crosshair line to the MLC leaf banks and accept any deviation (up to 2.5 mm) on jaws parallelism with crosshair line. Varian's orthogonality spec. is 1° which equates to 6.1 mm over a distance of 35 cm but practicality requires a tighter value of ≤ 2.5 mm over 35 cm (≤ 0.4°).

Specification

- The crosshair intersection shall intersect mechanical isocenter within ≤ 1.0 mm radius at 100 cm TSD.
- The upper and lower jaws shall be parallel with the crosshairs within ± 2.5 mm as measured at the edges of a 35 cm field at 100 cm TSD. (See previous note.)
- The difference in crosshair run-out between Bulb 1 and Bulb 2 shall be ≤ 0.5 mm.

Test Method

Table 6: Crosshair Alignment Test Setup	
Gantry Angle	0°
Collimator Starting Angle	90°
Field Size	35 x 35 cm
Couch top	100 cm TSD
Tool	Graph paper on couch top aligned to crosshairs

1. Download the **TrueBeam IPA** zip file from the ***PSE Website > TrueBeam > Software Downloads*** section.
2. Extract the downloaded file to the following folder on the TrueBeam WS (create folders if necessary):
   - *D:\VMSOS\AppData\TDS\Input\Service*
   - *D:\VMSOS\AppData\TDS\Input\Daily QA*
   - *D:\VMSOS\AppData\TDS\Input\Treatment*
3. Log in to Service mode using the Service user right.

4. Select **Plans** tab and select the MLC static (120 or HD) DICOM plan or StatMLC80.mlc plan in the following directory (see Figure 2):

   D:\VMSOS\AppData\TDS\Input\Service\TrueBeam IPA\STD 120MLC (or HDMLC or 80MLC)

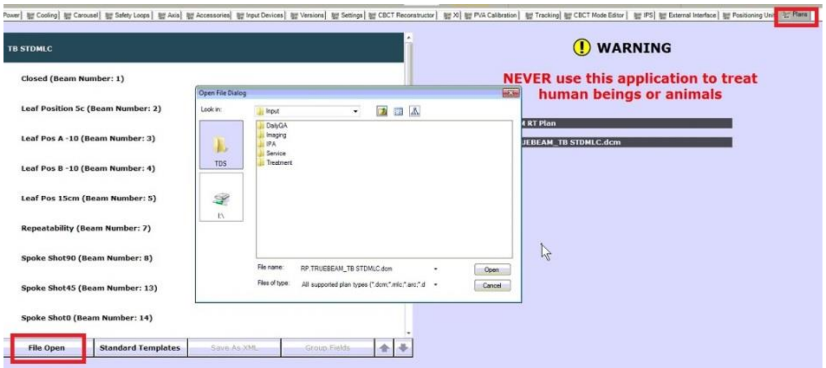


Figure 2: Opening Plan in Service Mode

5. Press "**Continue**" in the DICOM RT Plan Load Warning windows.
6. Select the **Repeatability** field and verify that it is highlighted.
7. Select **MLC** tab and then click on the **Go to Plan** button at the bottom of the screen. The MLC will drive to the field. See Figure 3.
8. Enter the treatment room and verify the gantry is leveled head-up and couch top is at 100 cm SSD.
9. Turn on the field light and accurately align the graph paper to the crosshair line that is parallel to the MLC leaf tips.
10. On the graph paper, measure the distance between the crosshair line and MLC leaf tips at both ends of projected field light. Verify the MLC leaf banks are as parallel as possible to the crosshair line
11. After verifying the parallelism of the crosshair line to the MLC leaf banks, retract the MLC by pressing the **Retract** button at the bottom of the screen. See Figure 3.

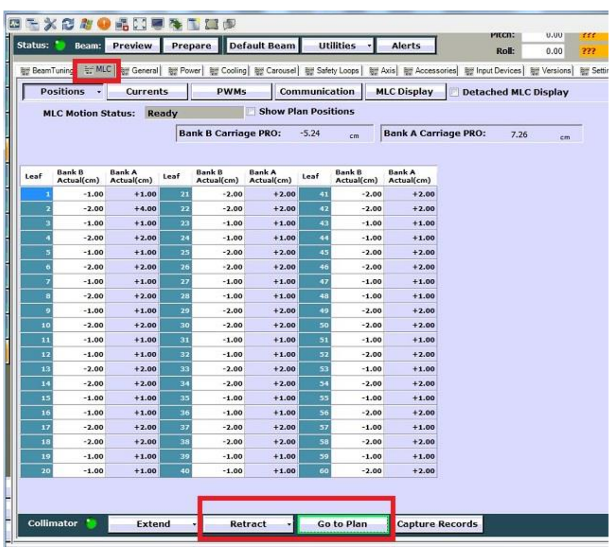


Figure 3: MLC Tab in Service Mode

12. Setup the test according to Table 6.
13. Turn on the field light, and verify that Bulb 1 is selected.
14. Rotate collimator from 90° to 270°, and verify crosshair run-out specification in the data table.
15. Verify each crosshair line parallelism to the X and Y jaws as follows:
    A. Independently drive each of the X-jaws until both jaws are 1 cm away from one end of the projected crosshair line. Leave the Y-jaws at 35 cm.
    B. Measure the distance between the crosshair line and each X-jaw at the other end of the crosshair line. Verify specification in the data table, and record the result.
    C. Repeat this test for the transverse crosshair line with the Y-jaws at 1 cm and X-jaws at 35 cm. Verify specifications in the data table, and record the result. Due to slight non-orthogonality between the two crosshair lines, this line will typically exhibit more parallelism deviation than the radial crosshair line.
16. Select Bulb 2 and rotate collimator from 90° to 270°.
17. Verify the difference in crosshair run-out between Bulb 1 and Bulb 2 is ≤ 0.5 mm.
18. Record results in the data table.

Result

Data Table: Section 5.4 – Crosshair Alignment and Jaw Parallelism		
Test	**Spec @ 100 cm TSD**	**Actual**
Crosshair Run-Out	≤ 1.0 mm (radius)	
Radial Crosshair and X-Jaw Parallelism	≤ 2.5 mm over 35 cm (≤ 0.41°)	
Transverse Crosshair and Y-Jaw Parallelism	≤ 2.5 mm over 35 cm (≤ 0.41°)	
Difference in Crosshair Run-Out Bulb 1 to Bulb 2	≤ 0.5 mm	
Customer Demo Required		

5.5 Jaw Position Readout (PRO)

5.5.1 Asymmetric Mode (Independent Jaws) PRO

Note *Most graph paper is not 100% accurate over large distances. Therefore, it is recommended to use a precision metal ruler for this test. It is only necessary to measure the central area of each jaw since jaw parallelism was already verified.*

Graph paper can be used instead of a ruler, if the gridlines have been measured and determined to be accurate enough for use.

Specification

Jaw position measured from the beam centerline to the 50% isodensity line for each of the upper and lower jaws shall coincide with the independent jaw digital PRO displays to an accuracy of ± 2 mm and ± 1 mm respectively at 100 cm TSD.

Test Method

1. Level gantry at the head-up position.
2. Using a calibrated front pointer, set the couch top to 100 cm TSD.
3. Place a white paper on the couch top (unless graph paper will be used per the previous note).
4. Place a 50 cm precision metal ruler in the center of the light field with the ruler surface at 100 cm TSD. Accurately align the center of the ruler to the crosshair. If using graph paper, align the crosshairs to the center of the graph paper with the graph paper at 100 cm TSD.
5. Independently drive each jaw to the positions shown in the data table, and verify digital PRO specifications. Make the best effort to accurately align the 50% isodensity point of the projected jaw shadow to the target position on the ruler (or graph paper).
6. Record results in the data table.

Result

Data Table: Section 5.5.1 – Asymmetric Mode (Independent Jaws) PRO				
Jaw	Jaw Position (cm)		Specification (cm)	√ = OK
	IEC601	IEC 1217		
Y1	-2	2	± 0.2	
Y1	5	-5	± 0.2	
Y1	19	-19	± 0.2	
Y2	-2	-2	± 0.2	
Y2	5	5	± 0.2	
Y2	19	19	± 0.2	
X1	-1	1	± 0.1	
X1	9	-9	± 0.1	
X1	19	-19	± 0.1	
X2	-1	-1	± 0.1	
X2	9	9	± 0.1	
X2	19	19	± 0.1	
Customer Demo Required				

5.6 MLC Static Leaf Positioning Accuracy Test

Specification

The actual position of each leaf shall coincide with the MLC plan within ± 1.0 mm at 100 cm SSD for each field listed in the following table.

Test Method

Table 7: MLC Leaf Positioning Test Setup	
Gantry Angle	Leveled at 0°
Collimator Angle	90°
Field Size	40 x 40 cm
Couch top	100 cm TSD
Tool	Graph paper on couch top aligned to crosshairs

1. Setup the axes and tool per Table 7.
2. Using the same steps in Section 5.4 of opening and loading plan in Service mode, select **Leaf Position 5cm** field from MLC static (120 or HD) DICOM plan or StatMLC80.mlc plan.
3. Drive MLC to the selected field.
4. Measure the MLC leaf positions relative to the crosshair. Verify the MLC leaves are within ± 1.0 mm of the planned 5 cm positions.
5. Record results in the data table.
6. Repeat the test procedure for the remaining leaf plan positions in the data table.

Results

Data Table: Section 5.6 - MLC Static Leaf Positioning Accuracy Test			
Leaf Plan Position	**Field Name**	**Specification per leaf (mm)**	**√ = OK**
5.0 cm	Leaf Position 5 cm	± 1.0	
-10.0 cm (A side)	Leaf Position A -10	± 1.0	
-10.0 cm (B side)	Leaf Position B -10	± 1.0	
15.0 cm	Leaf Position 15 cm	± 1.0	
Customer Demo Required			

5.7 MLC Leaf Position Repeatability

Specification

Leaf positioning recorded before and after running autocycle for at least ten fields should match within ± 0.5 mm.

Test Method

1. Setup the axes and tool per Table 7.
2. Using the same steps in Section 5.4 of opening and loading plan in Service mode, select **Repeatability** field from the MLC (120 or HD or 80 MLC) static DICOM plan.
3. Drive MLC to the selected field.
4. Mark the actual leaf positions on the graph paper. It might be easier to draw a line across each row of leaves. For bank and leaf number reference, leaf 2A is the most retracted leaf in the pattern.
5. Select the **Utilities** drop down menu and then select **Cycle MLC**.

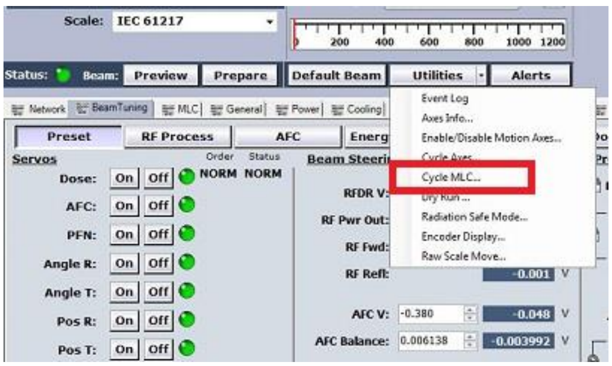


Figure 4: Selecting Cycle MLC in Service Mode

6. Open MLC XML static plan located in folder *D:\VMSOS\AppData\TDS\Input\Service\TrueBeam IPA\STD 120MLC (or HDMLC or 80MLC)* and autocycle through at least ten fields.
7. After autocycle is completed, close the MLC Autocycle window.
8. Reload the **Repeatability** field.
9. Verify the leaf positions to the previous measurements. Leaf positioning should be repeatable within ± 0.5 mm.
10. Record results in the data table.

Results

Data Table: Section 5.7 – MLC Leaf Position Repeatability			
Leaf Plan	**XML Field Name**	**Specification (per leaf)**	**√ = OK**
Repeatability	Repeatability	± 0.5 mm	
Customer Demo Required			

5.8 Gantry Rotation PRO

Specification

The true angular position of the gantry shall coincide with the gantry PRO display to an accuracy of ± 0.3°.

Test Method

Note *The recommended gantry leveling surface is the front section of the Interface Mount (near the rangefinder hole). If using a magnetic level, the rear plate on the Interface Mount may be used if it matches the front surface level.*

1. Level the gantry at each position shown in the data table, and verify PRO meets specification per the data table.
2. Record results in the data table.

Results

Data Table: Section 5.8 – Gantry Rotation PRO		
Gantry Angle	**Specification (°)**	**PRO (°)**
180°	± 0.3	
90°	± 0.3	
0°	± 0.3	
270°	± 0.3	
180° E	± 0.3	

5.9 Collimator Rotation PRO

Note *This test will utilize the radial crosshair line (the line parallel to the X-jaws) as a collimator angle reference indicator. Per the alignment requirements in Section 5.4, this line has been accurately aligned to be parallel with the MLC leaf banks and the X-jaws. Therefore, this line accurately represents collimator angle and will be used for the PRO checks in the following tests.*

To verify the collimator rotation PRO alignment is done correctly according to above requirement, this is the only PRO verification demonstrated to the customer in CPAD.

Specification

The true angular position of the collimator shall coincide with the PRO to an accuracy of ± 0.5°.

Test Method

1. Rotate gantry to the head-up position and set the jaws to X = 5 cm and Y = 40 cm.
2. Rotate collimator to 90° to position the radial crosshair line into the transverse plane.

3. Using a piece of tape on the Turntable, mark a reference dot on the tape at the intersection of the projected crosshair.
4. Rotate gantry about 20° in the CW and CCW directions and observe the coincidence of the reference dot with both ends of the projected crosshair line.
5. If not coincident, continue to make small collimator rotation corrections until the projected crosshair line tracks the reference dot while rocking the gantry. This will be the collimator mechanical 90° position.
6. Level gantry at the head-up position and set jaws to 20 x 20 cm.
7. Align a piece of graph paper to the crosshairs on the couch top at 100 cm TSD. Due to slight non-orthogonality between the crosshair lines, make sure the crosshair line that is parallel to the X-jaws is accurately aligned to the graph paper. This may result in the other crosshair line having equal and opposite deviations at each end of the crosshair line. This is acceptable since only the X-jaw crosshair line will be used as the collimator angle indicator.
8. Verify collimator PRO meets specification for the 90° position per the data table.

Note *In the following step, the crosshair line may shift slightly from the graph paper line due to minor crosshair run-out, which was measured earlier in Section 5.4. If this is the case, just make sure the crosshair line and graph paper line are parallel to each other to indicate 90° of rotation. Do not realign the graph paper.*

9. Rotate collimator to the other two positions in the data table by rotating until the X-jaw crosshair line is again aligned to the graph paper at each angle. Disregard the Y-jaw crosshair line due to its potential for minor non-orthogonality. Verify PRO meets specification at each position per the data table.
10. Record results in the data table.
11. Do not disturb the test setup. This will be used for the next test.

Results

Data Table: Section 5.9 – Collimator Rotation PRO		
Collimator Angle	**Specification (°)**	**PRO (°)**
90°	± 0.5	
0°	± 0.5	
270°	± 0.5	
Customer Demo Required		

5.10 Couch Rotation PRO

Specification

The couch rotation shall coincide with the PRO to an accuracy of ± 0.4°.

Test Method

1. With the gantry, couch, collimator, and jaws still positioned from the previous test, rotate collimator back to the 0° position on the graph paper. Make sure the crosshair line that is parallel to the X-jaws is accurately aligned to the graph paper since this line will be used as

the angle reference indicator for the couch rotation axis. The collimator must be accurately positioned to 0° before continuing.

2. Mark the center of the crosshair intersection on the graph paper with a small dot.
3. Fully open the jaws.
4. Release couch Longitudinal brake and float the couch top forward and backward to verify the dot remains on the X-jaw crosshair line at both edges of the field. If so, the couch is at mechanical center. If not, adjust the couch rotation until the dot tracks the crosshair line.
5. Lock couch brake and realign the graph paper to the crosshairs. Make sure the X-jaw crosshair line is accurately aligned since this will be the angle indicator for the following couch rotation checks.
6. Verify couch PRO meets specification for the 0° position per the data table.

Note *The crosshair lines will shift away from the graph paper lines during couch rotation in the following step. It is only important to make sure the X-jaw crosshair line is parallel to the graph paper lines. This shift (or run-out) is expected because the Stand position has been mechanically adjusted so the couch rotational axis will split the difference between gantry sag and skew at all gantry angles. Essentially, the couch is rotating on an arc around the circumference of the isocentric sphere. If the crosshair line did not shift during rotation, the Stand would be incorrectly positioned and there would be a large couch isocentric deviation with the gantry head down.*

7. Rotate couch to 90° and 270° until the X-jaw crosshair line is again parallel with the graph paper line. Verify the PRO meets specification at positions per the data table.

Results

Data Table: Section 5.10 – Couch Rotation PRO			
Couch Angle		**Specification (°)**	**PRO (°)**
IEC 601	**IEC1217**		
90°	90°	± 0.4	
0°	0°	± 0.4	
270°	270°	± 0.4	

5.11 Couch Longitudinal PRO

Specification

The couch longitudinal position shall coincide with the PRO to an accuracy of ± 2 mm.

Test Method

1. Position couch to 0° with the couch top at 100 cm TSD.
2. Install the Varian provided tape measure into the LOK-BAR PRO Alignment Tool. Align the 140 cm mark on the tape measure with the sight window scribe marks. Fasten the LOK-BAR onto the couch top at the 0 index location with the end of the tape measure extended towards the gantry.

3. Support the end of the tape measure to keep it level and float the couch top until the crosshair and tape measure are aligned to each of the target positions in the data table. Verify the PRO meets specification at each position per the data table.

Results

Data Table: Section 5.11 – Couch Longitudinal PRO		
Longitudinal Position (cm)	**Specification (cm)**	**PRO (cm)**
20	± 0.2	
150	± 0.2	

5.12 Couch Lateral PRO

Specification

The couch lateral travel shall coincide with the digital display to an accuracy of ± 2 mm.

Test Method

1. Installed the LOK-BAR PRO Alignment Tool (without tape measure) onto the couch top at the 0 index location.
2. Center the couch top laterally by aligning the crosshair to the scribe mark on the LOK-BAR.
3. Verify digital PRO meets specification for the 0 cm position per the data table.
4. Tape a precision 50 cm ruler on the couch top with the center of the ruler aligned to the crosshair intersection.
5. Release the couch lateral brake and float the couch top to the target positions in the data table. Verify the PRO specifications at each position per the data table.

Results

Data Table: Section 5.12 – Couch Lateral PRO			
Lateral Position (cm)		**Specification (cm)**	**PRO (cm)**
IEC 601	**IEC 1217**		
980	-20	± 0.2	
0	0	± 0.2	
20	+20	± 0.2	

5.13 Couch Vertical PRO

Note *If Couch Compensation was disabled during this test, please re-enable it now. Refer to SIM-HT to enable Couch Compensation in System Administration.*

Specification

The couch vertical travel shall coincide with the PRO to within ± 2 mm.

Test Method

1. Level gantry at the head-up position.
2. Set the couch to longitudinal position 140 cm.
3. Using a calibrated front pointer, position the couch top (without service panel) to 100 cm TSD.
    - Front pointer should contact center of couch top in-line with the position 0 index location.
4. Setup the Varian provided tape measure for reference measurements as follows:
    A. Hang the lip of the tape measure over the bottom edge of the Interface Mount and extend it all the way to the turntable. Do not make contact between the metal tape measure and any electrical circuits in the collimator.

    B. Move the tape measure or rotate the collimator as required until the tape measure just makes contact with the side edge of the couch top while making sure the tape is perpendicular to the floor (not tilted).

    C. Secure the tip of the tape measure to the collimator with tape.

    D. Place a piece of white tape on the side of the couch top and make a reference mark on the tape to coincide with any mm mark on the tape measure. This point defines the reference value for 100 cm TSD.
5. Verify PRO meets specification for the 0 cm IEC position per the data table.
6. Vertically drive the couch to the other two target positions in the data table by adding or subtracting the delta distance from the reference mark value on the tape measure. Verify PRO meets specification at both positions per the data table.
7. Do not disturb the test setup as it will be used for the next test.

Results

Data Table: Section 5.13 – Couch Vertical PRO			
Vertical Position (cm)		**Specification (cm)**	**PRO (cm)**
IEC 601	**IEC 1217**		
965	+35	± 0.2	
0	0	± 0.2	
50	-50	± 0.2	

5.14 PerfectPitch Couch Pitch & Roll Verification

Note *This section is applicable to TrueBeam System installed with Varian PerfectPitch couch only. Skip to next section and mark NA in data tables if not applicable.*

5.14.1 Pitch & Roll PRO Accuracy

<u>Specification</u>

The couch Pitch and Rolls axis shall coincide with the PRO to within ± 0.25°

<u>Test Method</u>

1. This test is performed in Service mode with Varian IEC scale selected.
2. Level gantry at head up position.
3. Fully open the X/Y jaws and turns on the field light.
4. Move the couch to position: LNG 140 cm / VRT 0 cm / LAT 0 cm.
5. Place and center the dual axis digital level box to approximately ± 1 cm to the center of the Crosshair projection on the couch top. If dual axis digital level box is not available, the test can be done with a single axis digital level place along the Pitch or Roll axis.

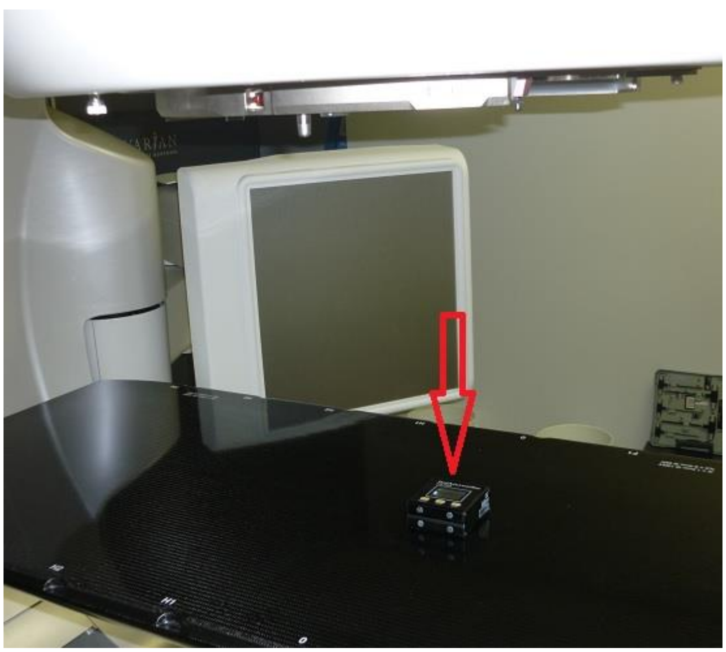


Figure 5: Positioning Digital Level Box on Couch top

6. Using the Axis positioning function in Service mode, enter Program value of 0.0° for Pitch and click Go To (see Figure 6). Execute the auto motion using hand pendant or side panel.

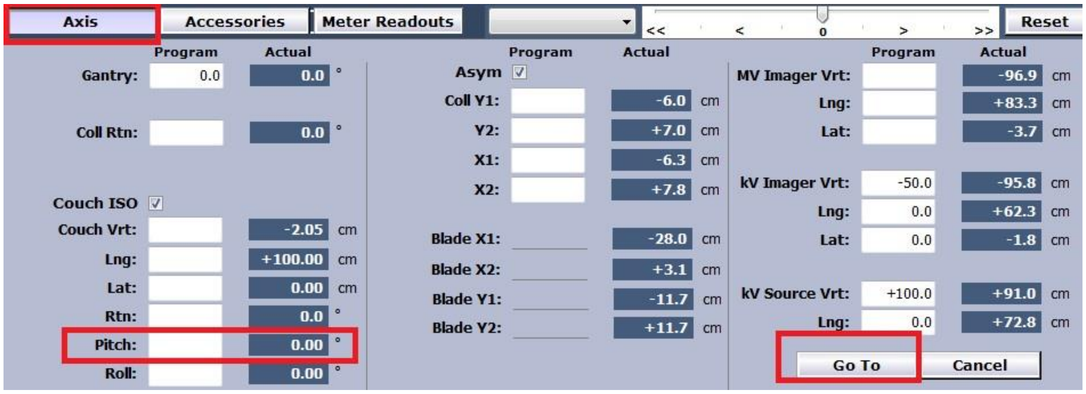


Figure 6: Entering Target Pitch Position in Service Mode

7. Verify the value shown on the digital level meets specification. Record results in the data table.
8. Repeat Step 6 and 7 to verify Pitch PRO accuracy at 3.0° and -3.0°.
9. Reposition Pitch to level.
10. Repeat steps 5 to 8 by entering and verifying the target positions for Roll axis. Record results in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 5.14.1 – Pitch & Roll PRO Accuracy			
Axis	**Position (°)**	**Specification (°)**	**Actual Digital Level (°)**
Pitch	0.0	± 0.25	
Pitch	3.0	± 0.25	
Pitch	-3.0	± 0.25	
Roll	0.0	± 0.25	
Roll	3.0	± 0.25	
Roll	-3.0	± 0.25	
Customer Demo Required			

5.14.2 Pitch & Roll Positioning Accuracy

Stop *This verification test can be done only after the KV imaging system is calibrated.*

Specification

The positioning accuracy of relative angular pitch and roll move of ≤ 3.0º at isocenter shall be ≤ 0.5 mm.

Test Method

1. This test is performed in Service mode.
2. Verify that Couch ISO box is checked for this test. (See Figure 7)

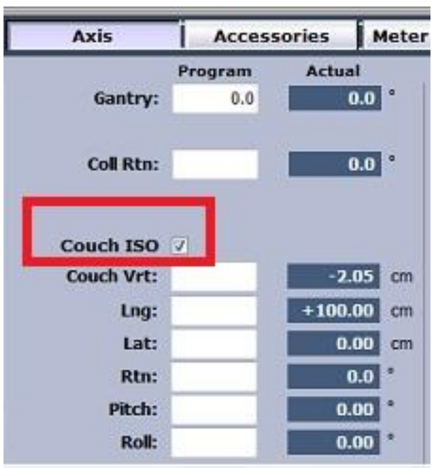


Figure 7: Couch ISO Checked in Service Mode

3. Move couch to position LNG 100 cm / VRT -2.5 cm / LAT 0 cm / ROT 0°, Pitch and Roll 0.0º.
4. Place the Isocenter Cube (PN: TM55150000) on the couch top and align to Isocenter using lasers or crosshairs. Move the couch vertically if necessary. It is advisable to tape and secure the cube to prevent it from sliding when couch top is tilted in later steps.

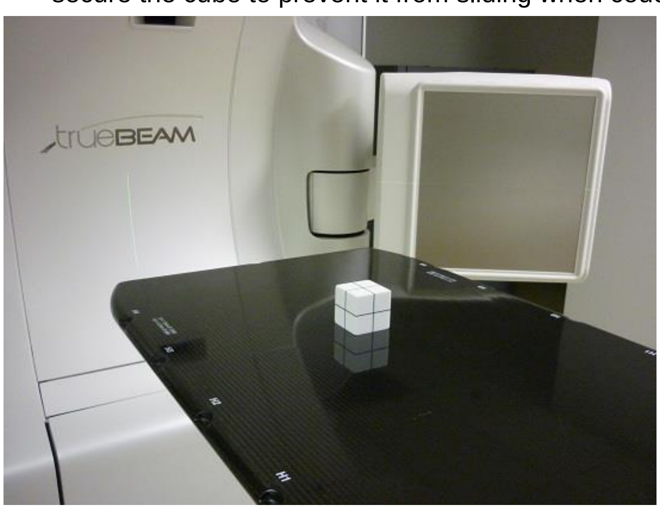


Figure 8: Isocenter Cube on Couch Top

5. Select XI tab > Acquisition > kV. Acquire High Quality Single images using 50 kVp / 20 mA / 20 ms / Small Focal Spot with gantry at 0º and 90º.

A = Zoom Function tool **B = Grid** **C = Ball Detection tool**

Figure 9: Function Tools on PVA Screen

6. On the PVA screen, turn on the Grid for both acquired images.
7. Using the Zoom function tool, magnify the images to see the ball and grid intersection.
8. Select the Ball Detection tool and then click on balls in the two acquired images. The Ball detection tool will automatically detect the center of selected ball image and provides the offset values from the Grid lines. See Figure 10.

   Offset from Grid = (Horizontal X coordinate, Vertical Y coordinate) cm

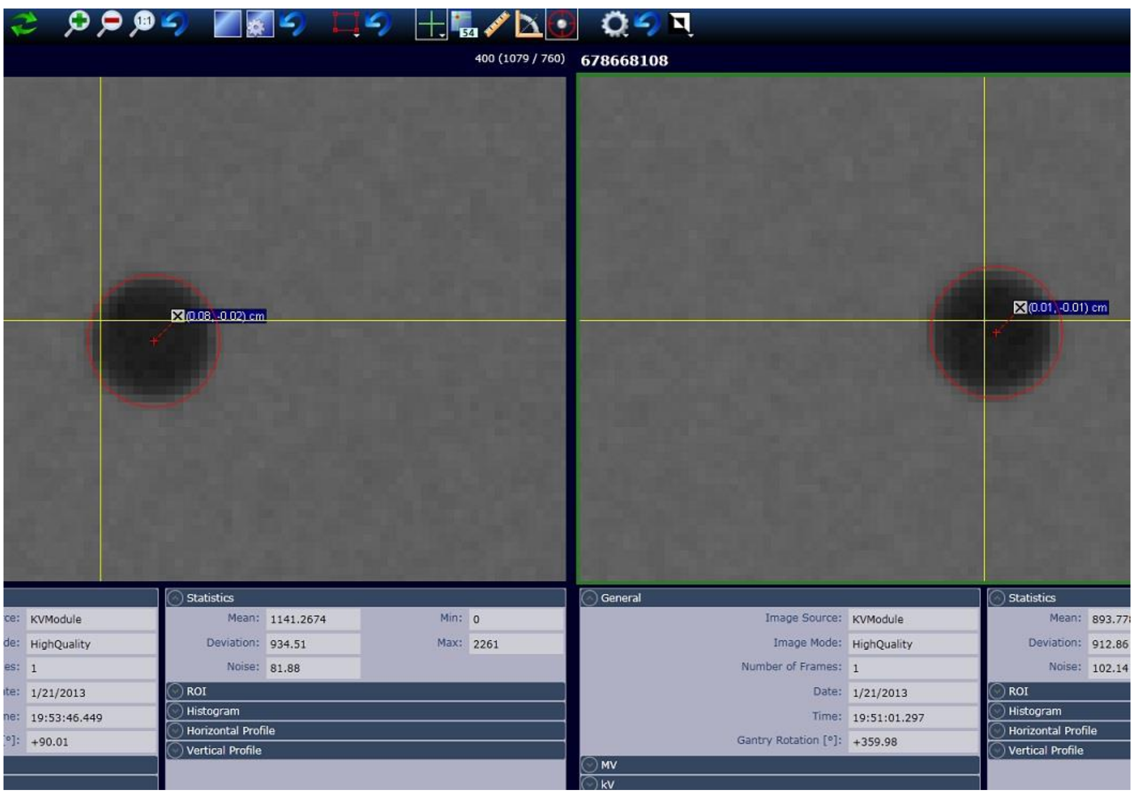


Figure 10: Ball Detection Tool in PVA Screen

9. Using the offset values from previous step, enter the new target positions on the service screen (see Figure 11) and use remote motion to shift the couch to align the cube precisely to center of Grid.

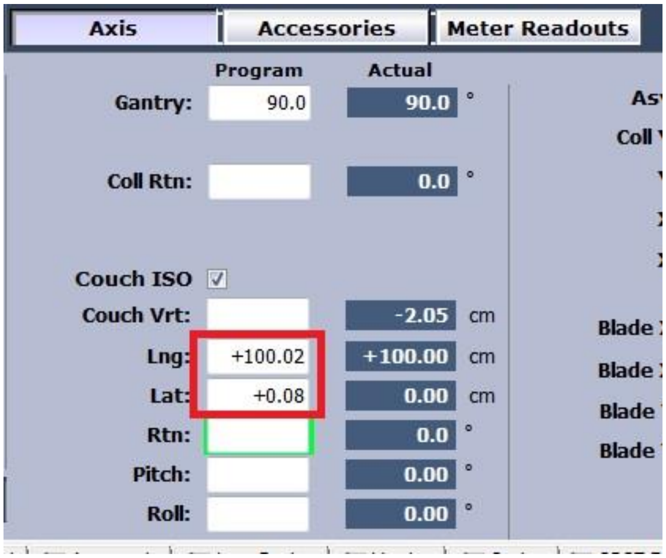


Figure 11: Entering Target Couch Linear Shift Positions

10. Repeat the steps 5 to 9 until ball is aligned within ≤ 0.1mm from center of Grid.

11. Apply isocentric Pitch and Roll motions by entering +3.0º for Pitch and Roll axis in Service mode and press "Go to" to execute the motion. This will not only move Pitch and Roll axis but also the compensated LNG / LAT / VRT translations.

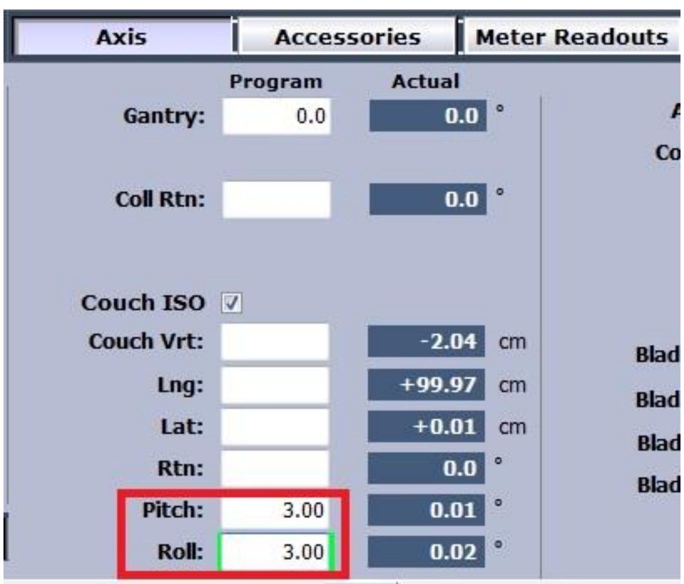


Figure 12: Entering Target Pitch and Roll Positions

12. Repeat steps 5 to 8. Verify ball remains within 0.5mm (0.05 cm) from Grid using Ball Detection tool. Record result in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 5.14.2 – Pitch & Roll Positioning Accuracy		
Pitch & Roll Delta Move	**Specification**	**√ = OK**
3.0°	≤ 0.5 mm	
Customer Demo Required		

5.15 Optical Distance Indicator (ODI)

Specification

The ODI shall indicate the Target to Surface Distance (TSD) to an accuracy of ± 1 mm at 100 cm TSD and to an accuracy of ± 5 mm for all other distances.

Test Method

1. Use the same setup as the previous Couch Vertical PRO test.
2. Position a piece of white paper on the couch top at isocenter using the Front Pointer.
3. Turn on the Field Light and project the crosshairs and ODI rangefinder display on the paper.
4. Verify the ODI meets specification for the 100 cm position.
5. Sequentially drive the couch vertical position to 80.0 and 130.0 cm. Verify the ODI display meets specification at both distances.
6. Record results in the data table.

Results

Data Table: Section 5.15 – Optical Distance Indicator (ODI) Couch Vertical PRO		
TSD (cm)	**Specification (cm)**	**Actual (cm)**
80	± 0.5	
100	± 0.1	
130	± 0.5	
Customer Demo Required		

6. Accessory System Verifications

The accessory system is composed of the following sub-assemblies:

1. Collimator Controller PCB (main node PCB)
2. Interface Mount (I/M)
3. Accessory Mount (A/M)
4. Electron Applicators (E/A)
5. Tissue Compensator (I/C)

Requirement

- The accessory detection system shall give a clear indication of an accessories related interlock, if there is an accessory hardware failure or an accessory mismatch. This includes faulty accessory latches, faulty switches, invalid codes, and communication problems.
- The IRM shall display the accessory installed.
- In the event of an applicator collision, all external axis motions shall be disabled. These axes include gantry, couch, collimator, MV, and KV arms. All motions will cease to function until the collision condition has been removed and the collision button on the collimator has been reset.

6.1 Accessory Communications and Switch Verification

This test will sequentially add each of the collimator accessory subsystems to verify proper communications to the collimator Controller. It will also test all of the interlock switches.

Test Method

Interface Mount (I/M) Slot 1:

1. Select the **Accessories** tab to view the status information of the accessory system. With the I/M in its static state, verify the green LEDs on both sides of the I/M are ON.
2. Press the I/M latch bar and verify the LEDs turn red and return to green when the latch is released. View the described switch status in the Service mode **Accessories** tab for a change in state when activated. Verify the presence of Routine Interlock 4016.
3. Test the Tray Install Switch by activating by hand and verifying the change in state on the Service mode screen.
4. Record results in the data table.

Accessory Mount (A/M) Slot 2:

1. Attach the A/M, and verify that green LEDs are ON.
2. Press the A/M latch bar, and verify the LEDs turn red and return to green when released.
3. Sequentially press both Accessories Mount releases (in the pillar mount) to release the A/M from each side. Verify the LEDs on the (I/M) turn red and return to green when the A/M is properly latched. View each switch status in the Service mode **Accessories** tab for a change of state when activated as indicated in Slot 1 status LEDs. Verify the presence of Routine Interlock 4032.
4. Test the Tray Install Switch by activating it by hand, and verifying the change in state on the Service mode screen.
5. Record results in the data table.

Electron Applicators (E/A) Slot 3:

1. Sequentially install each electron applicator into the Accessory Mount. Verify the red/green LEDs on both sides of the I/M are green when latched and red when not latched.

2. Remove the Final Field Defining Aperture (FFDA) insert, and verify that slot 3 Tray Install Switch LED is not green. Verify each switch in the Service mode **Accessories** tab changes state when activated.

A. Verify the correct E/A codes are displayed in the NAME box of the Accessories tab.

B. Set up the lowest electron energy in a Fixed mode, and select the correct applicator size. Verify accessory related Routine Interlock clears, and the jaws drive to a preset size per Table 8. Repeat this test for the highest electron energy, and verify the jaws drive to a different size and both interlocks clear. Verify the selection of an incorrect applicator results in an accessory related Routine Interlock.

C. All electron applicators contain a collision detection touch guard. Apply pressure to one side of the touch guard sensor. The red collision switch on the Interface Mount should illuminate, and the external motor functions should cease to operate. Verify the presence of the routine interlock, 4020 and 1006. Press the collision reset switch, and verify that motor functions are restored. Repeat test for all 4 sides of the touch guard.

D. With the last E/A installed, press the Accessory Mount thumb switches to attempt to release the A/M. Verify the A/M cannot be removed with an electron applicator installed.

E. Record results in the data table.

Table 8: Electron Applicators Preset Sizes vs Energies (cm)

Applicator	4/6 MeV	9 MeV	12 MeV	15 MeV	16 MeV	18 MeV	20/22 MeV
	X x Y	X x Y	X x Y	X x Y	X x Y	X x Y	X x Y
6 x 6	20 x 20	20 x 20	11 x 11	11 x 11	11 x 11	11 x 11	11 x 11
10 x 10	22 x 22	20 x 20	15 x 15	15 x 15	15 x15	15 x 15	14 x 14
15 x 15	22 x 22	20 x 20	19 x 19	19 x 19	18 x18	18 x 18	17 x 17
20 x 20*	27 x 27	25 x 25	25 x 25	23 x 23	23 x 23	22 x 22	22 x 22
25 x 25*	32 x 32	30 x 30	30 x 30	28 x 28	28 x 28	27 x 27	27 x 27
10 x 6	16 x 13	16 x 13	16 x 11	16 x 10	16 x 10	16 x 10	16 x 10

Tissue Compensator Mount (T/C) Slot 4:

1. If provided, attach the T/C and verify the green LEDs on both side of I/M are ON. Press the T/C latch bar, and verify the LEDs turn to red and return to green when the latch is released. Verify the latch switch in the Service mode **Accessories** tab change state when activated.
2. Record results in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 6.1 – Accessory Communications and Switch Verification		
Accessory	**Requirement**	**√ = OK**
Interface Mount Slot 1	Functioning	
Accessory Mount Slot 2	Functioning	
Accessory Mount latch switches (2)	Functioning	
Electron Applicators Slot 3	Functioning	
Electron Applicator Codes Read Properly	Functioning	
Electron Applicator's FFDA Reader	Functioning	
Electron Applicator Collision Touch Guard	Functioning	
Tissue Compensator Sot 4	Functioning	

6.2 Wedge Communications Verification

Requirement

Each wedge tray shall provide a unique code for angle and orientation that must be validated by the user to clear the accessory related routine interlock.

Test Method

1. Mode up any X-ray energy.
2. Sequentially install each wedge in all four orientation angles, and verify the correct wedge and orientation are displayed on the IRM monitor screen.
3. Select the corresponding wedge in the **Accessories** section of Service mode, and verify the accessory related routine interlock clears.
4. Verify that an accessory related routine interlock is active with an incorrect wedge selected (only necessary to test one wedge).
5. Repeat tests for the lower wedges using the Tissue Compensator (Slot 4) if the option is available.
6. Record results in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 6.2 – Wedge Communications Verification		
Accessory	**Requirement**	**√ = OK**
Upper Wedges (optional)	Routine Interlock Functioning	
Lower Wedges (optional)	Routine Interlock Functioning	
Incorrect Wedge Selected (upper)	Routine Interlock Functioning	
Incorrect Wedge Selected (lower)	Routine Interlock Functioning	

7. Radiation Isocenter and Beam Stability Verification

7.1 Coincidence of Light Field and X-Ray Field

Note *The MLC is the primary field collimation device in present day clinical applications and jaws are basically used for shielding. Therefore, Light field and X-ray field coincidence is verified using the MLC only.*

Light and X-ray source position will not vary between use of different collimation techniques (jaws versus MLC leafs).

<u>**Specification**</u>

Each of the light field and X-ray field edges shall coincide within ± 1.5 mm at 100 cm TSD. Field edges will be defined by MLC leaves.

<u>**Test Method**</u>

1. Setup the TrueBeam per the following table.

Table 9: Light Field vs. X-Ray Field Test Setup		
Gantry Angle	0°	
Collimator Angle	0°	
Field Size (X,Y jaws)	Preset in selected plan	
Couch top	100 cm TSD	
Tool	X-Ray Film aligned to crosshairs on couch top	
MLC Plan Location	MLC Model	MLC Field
D:\VMSOS\AppData\TDS\Input\Service\TrueBeam IPA\STD 120MLC\Static_120MLC	Standard 120 MLC	LF vs X 10x10 cm
D:\VMSOS\AppData\TDS\Input\Service\TrueBeam IPA\80 MLC\Static_80MLC	Standard 80 MLC	LF vs X 10x10 cm
D:\VMSOS\AppData\TDS\Input\Service\TrueBeam IPA\HDMLC\Static_HDMLC	HD MLC	LF vs Xray 8x8

2. Log in to Service mode.

3. Using the same steps in Section 5.4 of opening and loading plan:

A. Select the applicable MLC field listed in the setup table field from MLC static DICOM or MLC type plan.

B. Drive MLC to the selected field.

C. Turn on the field light. Use a small pin or a ballpoint pen to mark the edges of the field on the film package at the 50% density region.

D. Click on the **Default Beam** button. Select X-ray energy to be tested. Enter the appropriate MU for the film in use.

E. Press **Prepare** on the control console to load the plan.

F. Press **MV Ready** and then **MV Beam On**.

G. Develop the film and compare the 50% isodensity lines of the X-ray field edges to the field light edges.

H. Record results in the data table.

I. Mark films with test parameters, and have customer store films for future reference.

4. Repeat until all applicable energies are completed.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 7.1 – Coincidence of Light Field and X-Ray Field				
Energy	**Energy (MV)**	**Field Size (cm)**	**Specification per edge (mm)**	**√ = OK**
X-ray 1		10x10 (8x8 for HD120)	± 1.5	
X-ray 2		10x10 (8x8 for HD120)	± 1.5	
X-ray 3		10x10 (8x8 for HD120)	± 1.5	
X-ray 4		10x10 (8x8 for HD120)	± 1.5	
X-ray 5		10x10 (8x8 for HD120)	± 1.5	
6MV HI	6	10x10 (8x8 for HD120)	± 1.5	
10MV HI	10	10x10 (8x8 for HD120)	± 1.5	
Low X-ray Imaging	2.5	10x10 (8x8 for HD120)	± 1.5	
Customer Demo Required				

7.2 Isocenter Verification with IsoLock

Specification

- Central axis X-ray beam variation due to rotation of the gantry and collimator shall be confined to a sphere of ≤ 0.5 mm radius.
- Central axis X-ray beam variation due to rotation of the couch, gantry, and collimator shall be confined to a sphere of ≤ 0.75 mm radius.

Note *Download and use the latest Isolock V3.2.x for this test.*

Refer to TT-SR-01339 for setup and user instructions. Verify the Isocenter meets specification using IsoLock before performing the test in the CPAD.

Test Method

1. Log in to Service mode with HASP rights.
2. Position gantry, collimator, and couch to the **0° IEC** position.

NOTICE **The XML plans require the couch in the 0° IEC position before rotating the gantry. Always follow this rule to avoid gantry and couch collisions as they can occur in Service mode.**

Perform a full gantry rotation to verify the gantry is clear to rotate without collisions.

IsoLock captures the images with the MVD at -25 cm (IEC 1217).

3. Attach the couch extension to the head end of the couch top and lock the securing mechanism.
4. Install the IsoLock Couch Mount Assembly and rod onto the end of the IGRT Couch Extension. Secure it in place by tightening the column assembly thumb screw. Secure the rod by tightening the thumb screws.
5. Set the X and Y micrometers to their center position.
6. Install the tungsten ball on the end of the rod.
7. Mount the IsoLock Disk Fixture on the interface mount and secure it in place by tightening the grip knobs.
8. Extend the MV Imager by pressing the **Extend** button with **MV** selected on the Hand Pendant.
9. Looking at the shadow projected on the MV images, align the tungsten ball to the center opening of the disk as follows:
   A. Move the couch top longitudinal axis and the left-right position of the micrometer to position the ball in the center of the disk field light aperture.
   B. Rotate gantry to 90° and adjust the vertical height of the couch so the ball is in the center of disk field light aperture.
10. Under the **Plans** tab, click **File Open.**
11. Navigate to location of the IsoLock beam plans and open *Isocenter-MLC120.xml* plan (*Isocenter-MLC120HD.xml* for HD MLC option or *Isocenter-MLC80.xml for 80 MLC*).

Note *For VitalBeam with 80 MLC, the Isolock beam plans are located at; D:\VMSOS\AppData\TDS\Input\Service\TrueBeam IPA\80 MLC\Isolock Beam Plans*

12. Press **Prepare** on the control console. Move the axis into position as required by the plan and execute the plan.
13. Upon successful completion of the plan, export the images as a session to be analyzed by the IsoLock application.

Note ***Isocenter-MLC120.xml (or equivalent)*** *plan captures 63 images at different gantry and collimator angles. If the plan fails to complete successfully due to a system malfunction or interlocks, delete the image session and restart the plan*

14. Clear the session to delete the saved images in preparation to start a new session.

Note *Perform* ***Clear Session*** *so that a new session can be saved independently. IsoLock program requires two image sessions to be independently saved.*

15. Under the **Plans** tab, click **File Open**. Open Isocenter-Couch-MLC120.xml plan. (Isocenter-Couch-MLC120HD.xml for HD MLC or Isocenter-Couch-MLC80.xml for 80 MLC)

Note ***Isocenter-Couch-MLC120.xml (or equivalent)*** *plan captures 13 images at different Couch angles.*

16. Using the IsoLock application, analyze each of the sessions individually, and verify specifications.

Note *The IsoLock application displays analysis in microns and inches. To convert microns to mm, divide microns by 1000.*

17. Record results in the data table.

Results

Data Table: Section 7.2 – Isocenter Verification with IsoLock		
Isocenter Axis	**Specification (mm radius)**	**Actual**
Gantry and Collimator	≤ 0.5	
Couch, Gantry and Collimator	≤ 0.75	
Customer Demo Required		

7.3 Beam Stability vs. Gantry Rotation

NOTICE **To prevent damage to the equipment, verify the gantry can rotate a full 360° without risk of collision before performing the following tests.**

Requirement

During 360° of gantry rotation, the dose rate shall remain stable within ± 10% (± 15% for Low X-ray Imaging) and no interlocks shall occur.

Test Method

1. Log in to Service mode using Hasp right
2. Select the **Tests** tab and then select **Custom Scan** (see Figure 13).

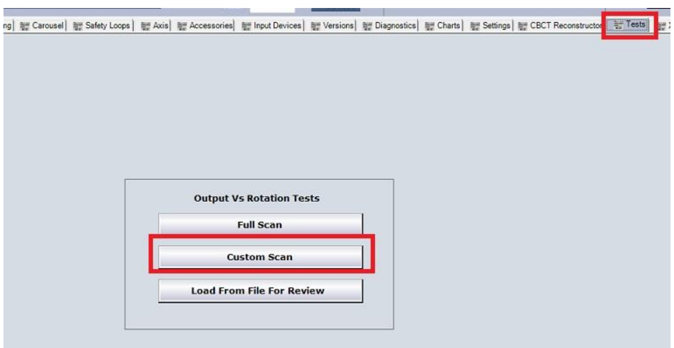


Figure 13: Selecting Output vs Rotation Test

3. In Pre-Condition Check window, turn OFF Dose Servo only and then click **Start Test.**
4. Click on the **+** icon (see Figure 14). In the pop up window, check energies to be tested (Low X-ray Imaging, X-Ray 1 and Lo-e). Set the Angle 1 to 179° and Angle 2 to 181°. This will set the Start/Stop point between the 2 angles covering 358° of gantry rotation. Click Apply when done.

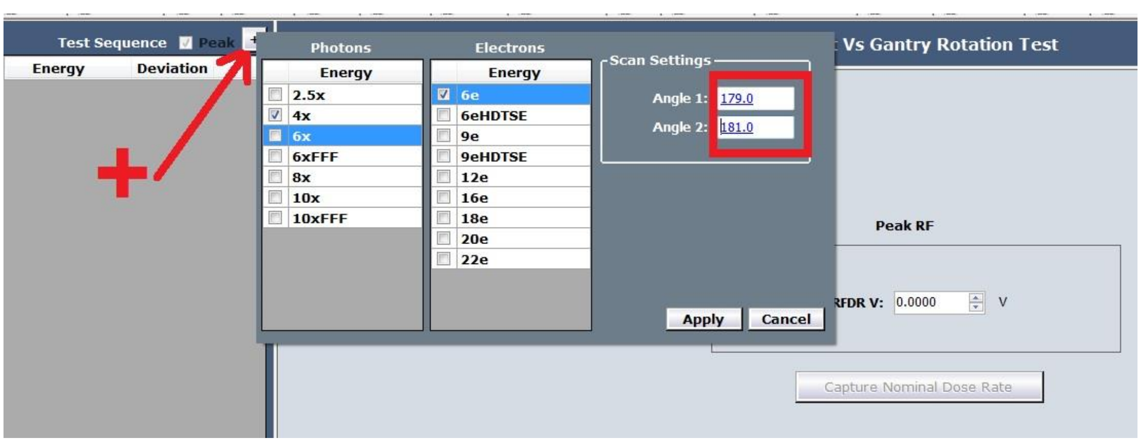


Figure 14: Selecting Energies and Setting Rotation Angles

5. The system will automatically set up first selected energy at Default dose rate.
6. Follow the instruction at the bottom of the screen to move gantry to head up position.
7. Beam on and allow dose rate to stabilize. Press “Capture Nominal Dose Rate” to proceed. (see Figure 15)

Note *The output and dose rate should already peak before starting this test, hence RFDR V should require any adjustment.*

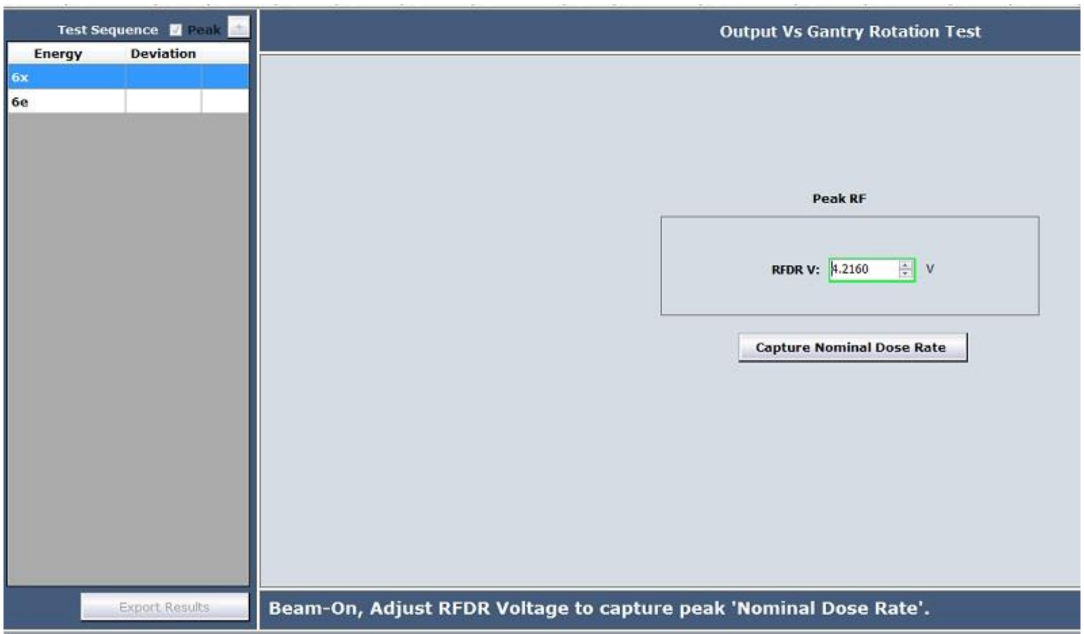


Figure 15: Screen to Capture Nominal Dose Rate at Gantry Head Up

8. Follow the instructions at the bottom of the screen to move gantry to the starting angle and then rotating to the stop angle. The application will record dose rates for the entire start/stop section.
9. When completed, the application will stop the beam the result will be displayed on the screen. (see Figure 16)
10. The application will automatically load next energy in line and repeat the procedure.
11. Record results in the data table.

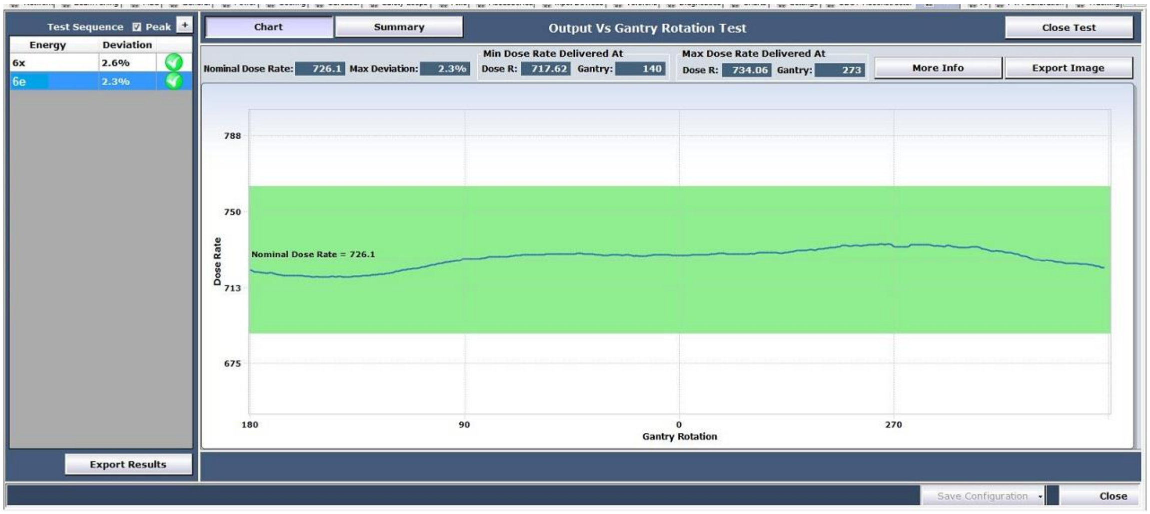


Figure 16: Output Vs Gantry Rotation Test Result

Results (enter N/A in any boxes that do not apply)

Data Table: Section 7.3 – Beam Stability vs. Gantry Rotation			
Energy (MV)	**Test**	**Stability Requirement**	**√ = OK**
Low X-ray Imaging	During full gantry rotation, dose rate remains stable within requirement and no interlock occur.	± 15 %	
X-Ray 1		± 10 %	
Lo-e		± 10 %	

8. Integrated Conical Collimator Verification and Interlock System (ICVI)

Note *Enter NA in all data tables in this section if ICVI is not purchased.*

8.1 Enabling ICVI

Requirement

The ICVI shall be enabled to use in a machine treatment administration system.

Test Method

1. From Major Mode on TrueBeam workstation, log in to System Administration.
2. Select **Treatmen**t tab and **Clinical** sub-tab (see Figure 17).
3. Change the "**Enforce electronics verification of conical collimator**" to **Yes**.
4. Record result in the data table.

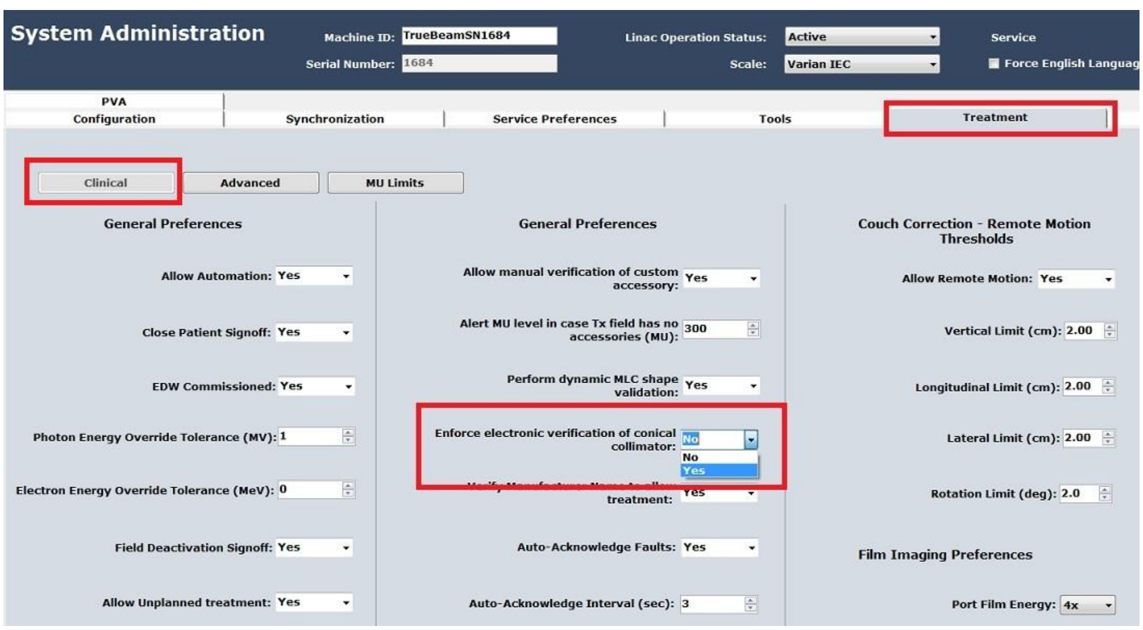


Figure 17: Enabling ICVI in System Administration

Results (enter N/A in any boxes that do not apply)

Data Table: Section 8.1 – Enabling ICVI	
Test Criteria	**√ = OK**
ICVI has been enabled in machine treatment administration system.	

8.2 Conical Collimator Recognition

Requirement

- Each available conical collimator shall have a unique identification code and shall be uniquely recognized when install on ICVI mount.
- Visible label that corresponds to the aperture size is marked on each conical collimator.

Test Method

1. This test is done in Service mode.
2. On Service mode screen, select the Accessories tab (Figure 18).
3. Rotate the gantry to head down position.
4. Install the ICVI mount onto the interface mount of the machine.
5. Insert one of the conical collimator to the ICVI mount and lock in place.
6. Verify that the identification code of the conical collimator is correctly recognized by the system (Figure 18) and matches the label on the conical collimator per Data Table Section 8.2.

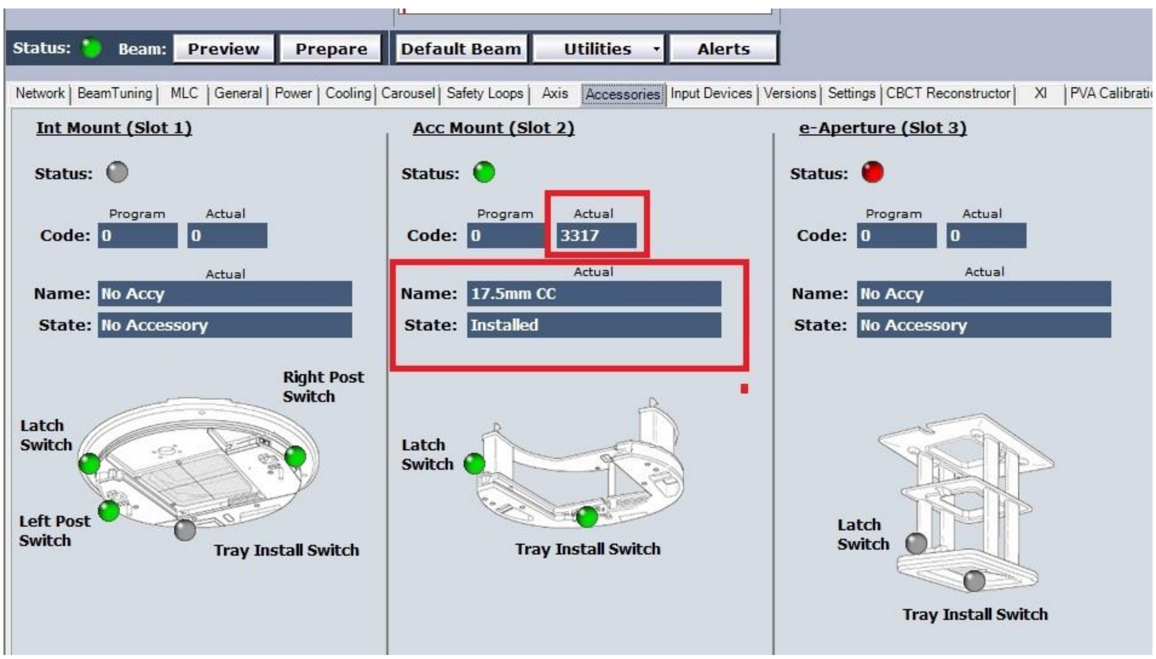


Figure 18: Conical Collimator Recognition in Service Mode

7. Record result in the data table.
8. Repeat steps 4 to 6 for all available conical collimators.

Results (enter N/A in any boxes that do not apply)

Data Table Section 8.2 – Conical Collimator Recognition			
Conical Collimator Aperture Size (mm)	**Conical Collimator Identification Code**	**Label on Conical Collimator**	**√ = OK**
4	3268	4mm CC	
7.5	3315	7.5mm CC	
5	3269	5mm CC	
10	3274	10mm CC	
12.5	3316	12.5mm CC	
15	3279	15mm CC	
17.5	3317	17.5mm CC	

8.3 Mount Alignment Verification

Note *This section verified the mechanical alignment of ICVI mount only. No radiation test is necessary.*

Section 7.2: Isocenter Verification with IsoLock must be completed and passed before proceeding with this section.

Note *Refer to CAL-AC-ICVI for detail setup. Verify mount alignment is completed and meets requirement per CAL-AC-ICVI manual before performing the test in the CPAD.*

Requirement

- Mount alignment deviation with a conical collimator installed shall confined to ≤ 0.20 mm from collimator rotation axis at isocenter plane

Note *Specification of 0.20 mm (0.008”) at the isocenter plane is approximately equal to 0.15 mm (0.0059”) at the level of the conical collimator due to beam divergence factor of 1.35*

Stop *The ICVI mount if installed, shall be removed prior to this demonstration with customer. This step is to demonstrate that the alignment requirement can be achieved at the time the ICVI mount and conical collimator are installed for verification without any further adjustment to prior alignment by Varian CSR. This step in part showing reproducibility to meet requirement after removal and re-installation.*

Test Method

Note *This verification test utilizes micrometer stage and the Starrett 709ACZ (or equivalent) dial indicator from the Winston Lutz test kit.*

1. Log in to Service mode and IEC scale selected
2. Position couch to 0°. If Perfect Pitch couch is installed, level the PRS.
3. Position the gantry to 180°.
4. Rotate the collimator to 90°.
5. Install the ICVI mount on the interface mount and then insert the 17.5 mm (or 15 mm) conical collimator with locking ring in place.
6. Mount the micrometer stage from the Winston Lutz test kit onto the couch top interface.
7. Install and position the Starrett 709ACZ dial indicator (or equivalent), ensuring there is adequate contact with interior surface of the cone. The movement direction of the dial indicator needle is roughly in line with the longitudinal direction of the couch. Use the micrometer stage to adjust the dial indicator to be approximately in the center of its measurement range.

Figure 19: Dial Indicator Setup

8. Slowly rotate the collimator from 90° to 270° while observing the deviation of the dial indicator.
9. Record the maximum deviation (2 extreme needle deflection points) in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 8.3 – Mount Alignment Verification		
Test Criteria	**Maximum Deviation Requirement at Conical Collimator level (mm)**	**Actual Maximum Deviation (mm)**
Alignment Deviation to Collimator Axis Rotation	≤ 0.15	
Customer Demo Required		

9. Beam Energy & Profiles Verification

9.1 Definitions

Inplane (radial): Vertical plane in line with the accelerator gun and target.

Crossplane (transverse): Vertical plane that is at right angles to the inplane.

FWHM: Full Width Half Maximum is the central 80% region of the actual field size defined by the 50% intensity points.

Dmax: Abbreviation for depth of maximum ionization.

Flatness: Per Varian protocol, field flatness is calculated as follows:

Maximum variation from the mean dose intensity delivered within the central 80% FWHM region measured at 100 cm TSD at a depth of 10 cm. The mean (normalized to 100%) is the median of the maximum and minimum intensity points within the FWHM. The flatness value is measured as a ± value from the mean [(max-min)/2].

Symmetry: Per Varian protocol, field symmetry is calculated as follows:

Maximum difference between the dose intensity delivered to any two points which are equidistant and symmetrical about the central axis and within the 80% FWHM region measured at 100 cm TSD at a depth of 10 cm.

Note *This point-to-point symmetry analysis protocol is more sensitive than other protocols that typically average each half of the field profile and then compare the averages. As a result, Varian protocol symmetry analysis results are typically higher than other protocols.*

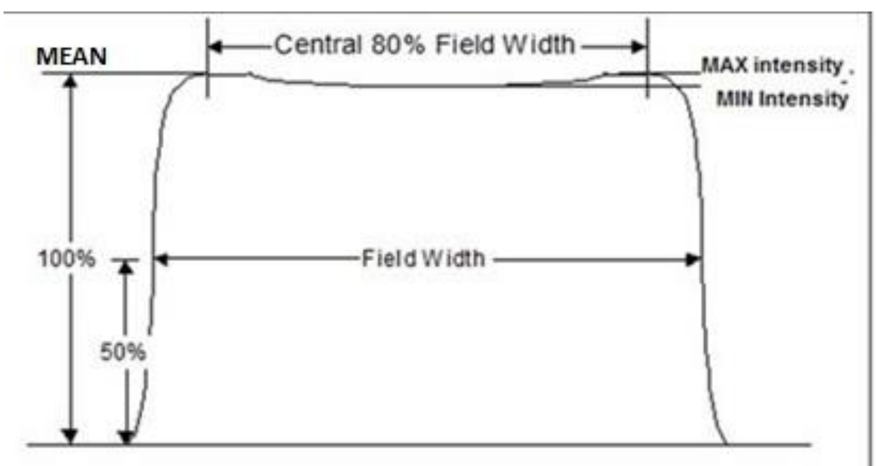


Figure 20: Flatness Definition

9.2 X-Ray and Electron Beam Conformance Option

Beam Conformance is a purchasable feature that consists of three possible options that are described in Table 10.

Varian recommends the **Enhanced Beam Conformance Specification** option alone, versus the addition of the **Beam Conformance to Customer Reference Data** options, as this will ensure tighter beam conformance for all future installed systems.

The tighter **Enhanced Beam Conformance (EBC)** energy specifications are listed in the data tables *section 9.6 and section 9.7*

Table 10: X-Ray and Electron Beam Conformance Option	
Refer to the X-*Ray & Electron Beam Conformance Specifications RAD10174* brochure for more information about these options.	**Sales Order Catalog #**
Enhanced Beam Conformance Specification (standard for EDGE) This is the most common and preferred option. This is not a matching service to customer reference data, or to any particular machine data. Instead, it ensures conformance to Varian's published *Reference Beam Data (upon available)*. This new data provides tight tolerances for X-ray and electron beam performance specifications. This option involves demonstrating that the beam energy for X-rays and electron energies meet the *Enhanced Beam Conformance (EBC) Specifications*, and then guarantees point to point conformance of field intensity profiles to Varian published Representative Beam Data. There is an EBC tolerance specification column in the Depth of Ionization tables within this IPA document that is used for this option. After demonstrating these energy specifications, the field intensity conformance specifications for the inplane and crossplane profiles are essentially "guaranteed" and are confirmed by the customer during beam commissioning. This allows a more rapid transition from acceptance testing to commissioning. Systems that are compatible with the **Enhanced Beam Conformance Specification** option include TrueBeam platforms (TrueBeam, TrueBeam STx, Edge and VitalBeam) and Clinac platforms (Clinac iX, Trilogy, Novalis Tx, CX, DMX, DHX). Cross-platform matching is not guaranteed. See RAD 10174 for more details.	**xxx001027006**
Beam Conformance to Customer Reference Data – X-Rays **Beam Conformance to Customer Reference Data – Electrons** These two separate options are less common, and <u>each one must be separately purchased and listed on the sales order, in addition to the Enhanced Beam Conformance Specification option stated above</u>. These options are considered a beam matching service because they involve onsite refinement of the X-ray and/or electron energy depth of ionization and field intensity performance to conform to customer reference data. However, the reference data must conform to the original Varian published specifications for the designated reference system. If the customer reference data is outside of the *Enhanced Beam Conformance* specifications (listed in the Depth of Ionization data tables in this IPA), it is strongly recommended to only "detune" the new system to the upper or lower limits of the *Enhanced Beam Conformance* specifications to get as close as possible without exceeding the enhanced specifications. This will allow future machines to match better. These options are more labor intensive as they require beam data comparison to site beam reference data that must be collected on the same scanning system. Systems that are compatible with **Beam Conformance to Customer Reference Data** include TrueBeam platforms (TrueBeam, TrueBeam STx, Edge and VitalBeam) and Clinac platforms (Clinac iX, Trilogy, Novalis Tx, CX, DMX, DHX, EX). Cross-platform matching is not guaranteed. See RAD 10174 for more details.	**xxx001027008** **xxx001027009**

9.3 Sun Nuclear IC Profiler Preparation and Set Up

9.3.1 IC Profiler Beam Array Device Set Up

CAUTION **The copper traces in the IC Profiler unit and its copper wedge accessory can become activated when exposed to radiation beams with energy greater than 8 MV. Only trained radiation workers are authorized to handle radioactive materials.**

When working in the Treatment Room, always wear your assigned dosimeter(s), and observe As Low As Reasonably Achievable (ALARA) practices. Minimize your exposure by working quickly and spending as little time as possible handling the copper wedge after it have been exposed to radiation.

Using the IC Profiler, with the combination of a Copper wedge, or an Aluminum Wedge, along with Solid water buildup, will be referred to as the measurement 'Setup' and 'Setup' components.

When working with this measurement setup, observe the following guidelines to minimize device radioactivity and potential radiation exposure.

- **Do not leave the measurement Setup in the primary radiation beam when not performing measurements. Moving the Setup to the back of the couch top or to a counter top will greatly minimize potential radioactivity.**
- **Minimize the amount of dose delivery to the measurement Setup when performing photon beam energy measurements. Only run the required measurements and avoid running excessive dose (MU).**
- **Never leave the Setup in the primary beam path, during beam on, when not taking measurements.**
- **When handling the copper wedge accessory after measurements, wait at least 5 minutes and then quickly remove the device and place it on a counter top away from the immediate work area. The device should only be handled for less than 1 minute. Keep the device at arm's length while transporting it.**
- **If a Survey Meter is available, then use it to measure the amount of radioactivity before handling setup components after exposure to radiation beams with energy greater than 8 MV.**
- **When realigning the Setup, after it has been exposed to radiation, align the device to the crosshairs as quickly as possible. Minimize the amount of time spent near the Collimator area.**
- **When all measurements are finished, allow the copper wedge to 'cool down' for at least 1 hour before repacking it. The devices can be left on the couch or a counter top away from the immediate work area. Minimize the amount of time required to pack the devices.**

After packing the device in the shipping case, move the case to an unpopulated area and do not ship it for at least one day.

Stop *Before using the SNC application, the latest **Profiler_Support_files.exe** file must be downloaded from the PSE data center (Product Specific Pages > Other Products > Scanning Equipment) and installed on the service laptop.*

This executable file contains the normalization files for each specific IC Profiler unit, which is frequently updated to ensure that the latest energy calibration files are selectable within the SNC application.

***This download and file execution must be performed each time before using an IC Profiler unit**. Refer to the UG-GE-Profiler for download and installation instructions.*

1. Set up the IC Profiler per the following figure. Refer to UG-GE-Profiler manual if necessary.

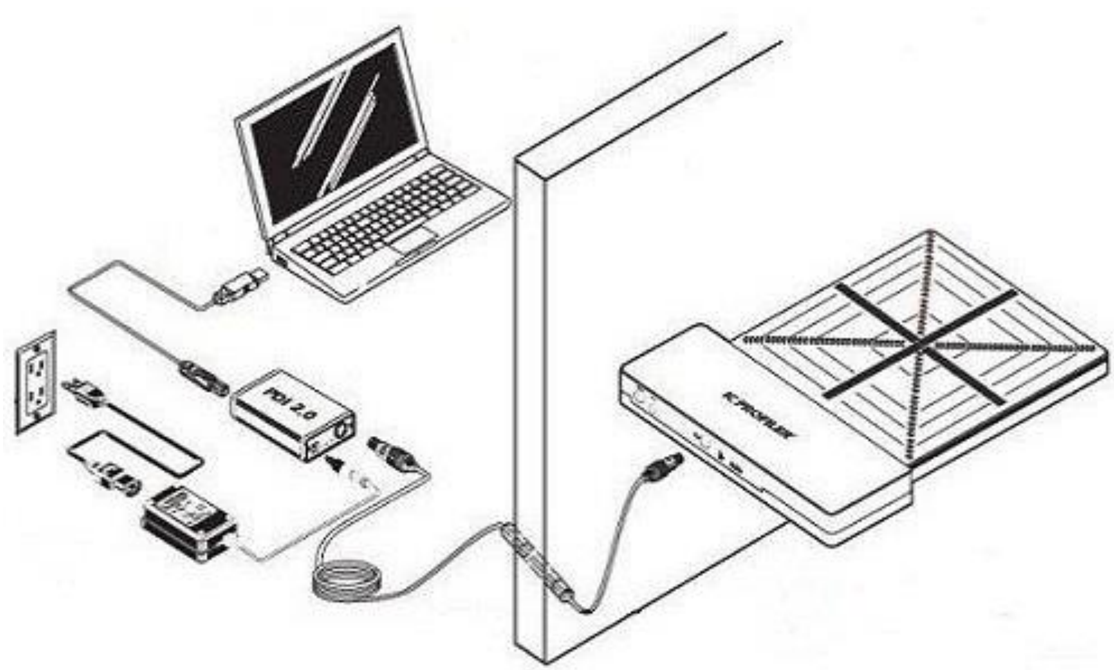


Figure 21: IC Profiler Set Up

2. After installing the latest profiler support files (mentioned in the **Stop** note above), launch the SNC software application on the service laptop.
3. Navigate to the *Setup* > *Analysis* screen and select the **Energy** tab (Figure 22).
4. Select the appropriate **Analysis** files for the serial number of the IC Profiler unit (Figure 23), and click **OK**.

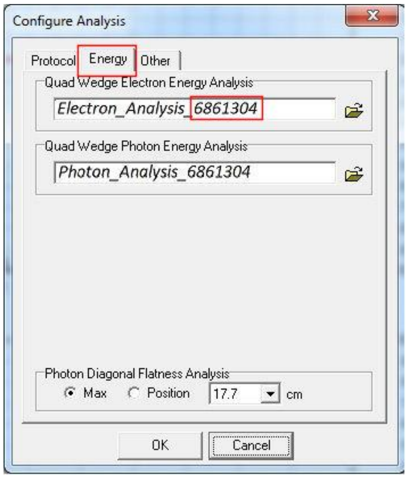


Figure 22: SNC Configure Analysis Screen

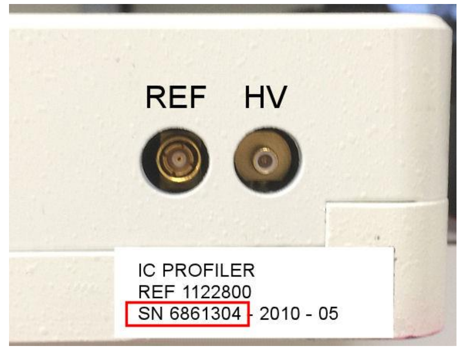
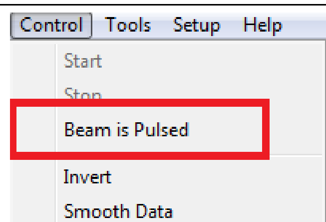


Figure 23: IC Profiler SN Label

5. Set up the machine and IC Profiler per the following table. These conditions will be used for all beam measurements unless specified otherwise in later set up tables.

Table 11: Set Up Conditions	
Gantry Angle	Leveled head-up
Collimator Angle	Mid-position
Couch Position	Mid-position
Servos	All ON (including PFN and DOSE)
ICP Panel Orientation	ICP on couchtop with electronics facing away from the gantry (Y+ to gantry)
ICP Panel Alignment	ICP panel aligned to crosshairs
SSD	99 cm (to top of ICP panel)
SNC Application Control Menu Settings	 **NOTE:** Due to the low output of 2.5X, uncheck **Beam is Pulsed** for 2.5X only. Make sure it is checked for **all** other energies.

Stop ***The accuracy of determining the beam energy using ICP is affected by beam profile that is not symmetrical. Hence it is essential to adjust and verify the beam is symmetrical within specification before performing the beam energy verification using ICP. The proceeding tests in this document is arranged to perform the symmetry before the energy verification. In the case where necessary energy adjustment is make, the flatness and symmetry verifications of that energy must be repeated.***

9.4 Photon/FFF Symmetry and Flatness

Note *Flattening filter free (FFF), also referred to as High Intensity (HI), and low X-ray imaging (2.5X) do not have flatness specification since these beam profiles are not flat.*

Flatness Requirement

The maximum variation in integrated dose between the minimum and maximum points, within the central 80% of the inplane and crossplane central axes shall not exceed the requirements listed in the data tables.

Note *Tests data have demonstrated that profiler flatness analysis results are higher than equivalent water phantom measurements. The requirements listed in the data tables ensure than flatness will meet the standard flatness specifications per Varian protocol when measurements are taken using a water phantom.*

Symmetry Requirement

The maximum variation in integrated dose between any two corresponding points equidistant from the beam centerline within the central 80% of the radial and transverse major axes shall not exceed 2.0% for photon and FFF, and 3% for the low X-ray imaging energy (2.5X).

Test Method

1. Sequentially acquire profiles for all applicable energies using the set up conditions in Table 12, and analyze each profile after it is completed.
   - Make sure that the correct calibration file is set in the SNC display for each energy. This can be selected before or after the profile is acquired, but must be correct for the analysis results.
   - Verify that the correct energy is displayed in the SNC display (Figure 25). If not, use the *Setup* > *Set Energy* menu to set the correct energy. Energy can be changed before or after the profile is acquired without affecting the profile.

Note *For 2.5X , select the energy as "Other" from the menu option and then set as "X-Ray FFF" type per Figure 24*

   - For 2.5X, uncheck **Beam is Pulsed** in the **Control** menu. Make sure that it is checked for all other energies.
   - Verify that the profiles are normalized to 100% at the central axis.
   - Record flatness and symmetry results (Figure 26) in the data table, and verify that all values meet specification.
   - Save each recorded profile.

Figure 24: 2.5X Energy Type Selection

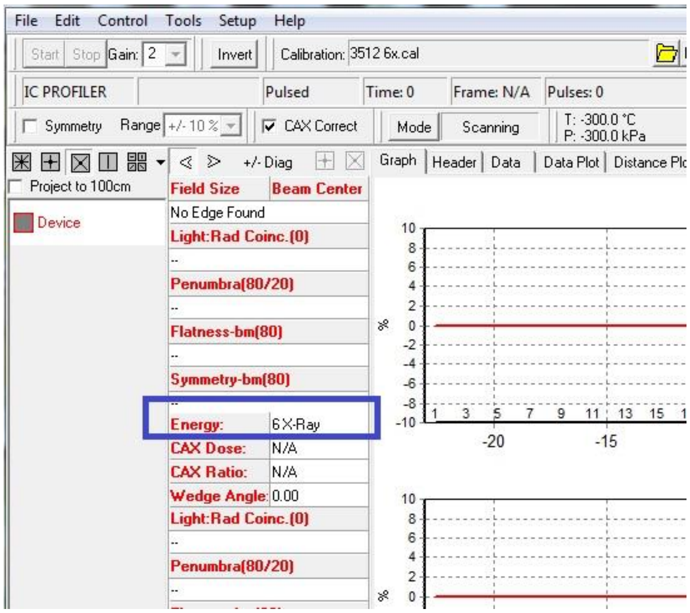


Figure 25: Verify Energy Selected

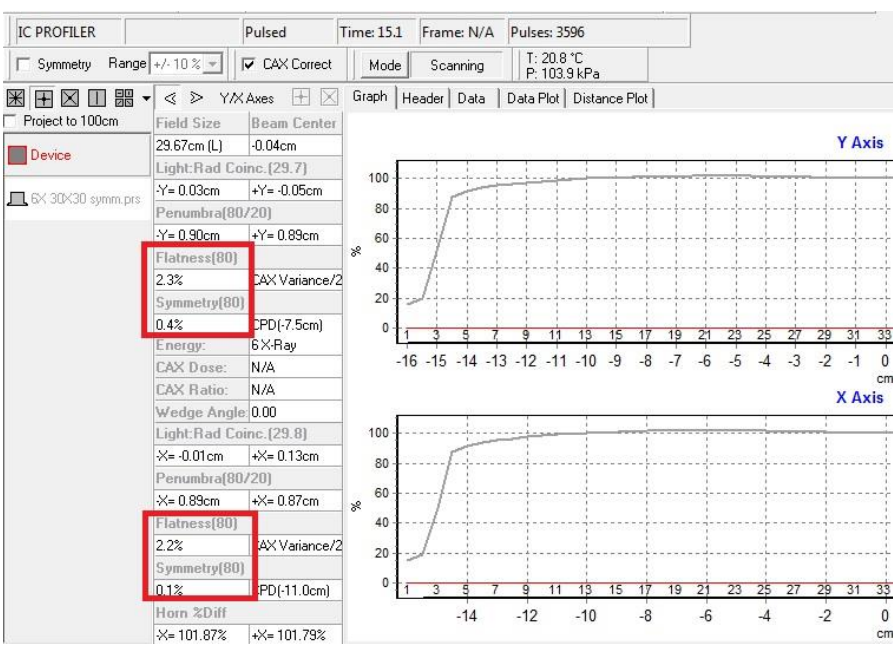
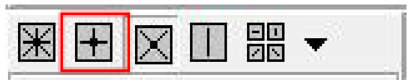


Figure 26: Profile Flatness and Symmetry Results

Table 12: Test Setup for Photon Field Flatness and Symmetry Measurements						
SSD	99 cm (to top of ICP panel)					
ICP Buildup	See below					
ICP Accessory	None					
ICP Profile View	 Select **Primary Axis** view					
Energy (MV) BJR 11/17	**ICP Cal File**	**ICP Gain**	**Dose Rate (MU/min)**	**Dose (MU)**	**Field Size (cm²)**	**Buildup (cm)**
4	#### 4x.cal	4	250	100	12 x 12 & 30 x 30	9
6	#### 6x.cal	4	400			
8	#### 8x.cal					
10	#### 10x.cal					
15/16	#### 15x.cal					
18/20	#### 18x.cal					
20/25	#### 20x.cal					
6FFF	#### 6x.cal	2	400		10 x 10 & 30 x 30	
10FFF	#### 10x.cal	2	400			
2.5	#### 2.5x.cal	8	60	60	30 x 30	4
Save Profiles as	[*energy*]**x** [*Field size*] **Symm.prs** (e.g., **6x 30x30 Symm.prs**)					

Note *Low X-Ray Imaging profiles are verified using 30 X 30 cm field size only and have to be run in continuous beam mode, which is automatically selected when the* ***Beam is Pulsed*** *control selection is deselected.*

<u>Results (enter N/A in any boxes that do not apply)</u>

Data Table: Section 9.4 - Photon/FFF Symmetry and Flatness (Inplane)

Energy (MV)		**Field Size (cm²)**	**Flatness Req. (%)**	**Actual Flatness**	**Symmetry Req. (%)**	**Actual Symmetry**
X-ray 1				±		
X-ray 2				±		
X-ray 3		12 x 12	± 3.7	±	≤ 2	
X-ray 4				±		
X-ray 5				±		
X-ray 1				±		
X-ray 2				±		
X-ray 3		30 x 30	± 3.0 (± 3.7 for 20 MV)	±	≤ 2	
X-ray 4				±		
X-ray 5				±		
6FFF		10 x 10				
10FFF					≤ 2	
6FFF						
10FFF		30 x 30				
2.5X					≤ 3	

Customer Demo Required

Data Table: Section 9.4 - Photon/FFF Symmetry and Flatness (Crossplane)						
Energy (MV)		**Field Size (cm²)**	**Flatness Req. (%)**	**Actual Flatness**	**Symmetry Req. (%)**	**Actual Symmetry**
X-ray 1		12 x 12	± 3.7	±	≤ 2	
X-ray 2				±		
X-ray 3				±		
X-ray 4				±		
X-ray 5				±		
X-ray 1		30 x 30	± 3.0 (± 3.7 for 20 MV)	±	≤ 2	
X-ray 2				±		
X-ray 3				±		
X-ray 4				±		
X-ray 5				±		
6FFF		10 x 10			≤ 2	
10FFF						
6FFF		30 x 30				
10FFF						
2.5X					≤ 3	
Customer Demo Required						

9.5 Electron Field Flatness & Symmetry

Flatness Requirement

The maximum variation in integrated dose between the minimum and maximum points within the central 80% of the inplane and crossplane central axes shall not exceed the specifications listed in the data table.

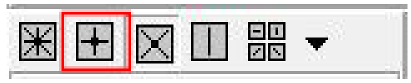
Note *Tests data have demonstrated that Profiler flatness analysis results are higher than equivalent water phantom measurements. The requirements listed in the data tables ensure than flatness will meet the standard the flatness specifications per Varian protocol when measurements are taken using a water phantom.*

Symmetry Requirement

The maximum variation in integrated dose between any two corresponding points equidistant from the beam centerline within the central 80% of the inplane and crossplane central axes shall not exceed requirements listed in the data table.

Test Method

1. Sequentially acquire profiles for all applicable energies using the set up conditions in the following table, and analyze each profile after it is completed.
   - Make sure that the SSD is changed for the HDTSE energies.
   - Make sure that the correct calibration file and energy is set in the SNC display for each energy.
   - Verify that the profiles are normalized to 100% at the central axis.
   - Record results in the data table, and verify that all values meet specification.
   - Save each recorded profile.

<table>
<tr><th colspan="8">Table 13: Test Setup for Electron Field Flatness and Symmetry Measurements</th></tr>
<tr><td colspan="2">SSD</td><td colspan="6">See below (distances are measured to top of ICP panel)</td></tr>
<tr><td colspan="2">ICP Buildup</td><td colspan="6">See below</td></tr>
<tr><td colspan="2">ICP Accessory</td><td colspan="6">None</td></tr>
<tr><td colspan="2">ICP Profile View</td><td colspan="6"> Select Primary Axis view</td></tr>
<tr><th>Energy (MeV)</th><th>ICP Cal File</th><th>ICP Gain</th><th>Dose Rate (MU/min)</th><th>Dose (MU)</th><th>Field Size (cm²)</th><th>SSD (cm)</th><th>Buildup (mm)</th></tr>
<tr><td>6</td><td>#### 6e.cal</td><td rowspan="8">4</td><td rowspan="8">500</td><td rowspan="8">100</td><td rowspan="8">15 x 15 Applicator & 25 x 25 Applicator</td><td rowspan="8">100</td><td>0</td></tr>
<tr><td>9</td><td>#### 9e.cal</td><td>5</td></tr>
<tr><td>12</td><td>#### 12e.cal</td><td>10</td></tr>
<tr><td>15</td><td>#### 16e.cal</td><td>18</td></tr>
<tr><td>16</td><td>#### 16e.cal</td><td>18</td></tr>
<tr><td>18</td><td>#### 18e.cal</td><td>20</td></tr>
<tr><td>20</td><td>#### 20e.cal</td><td>25</td></tr>
<tr><td>22</td><td>#### 22e.cal</td><td>25</td></tr>
<tr><td>6 HDTSe-</td><td>#### 6HD.cal</td><td rowspan="2">1</td><td rowspan="2">2500</td><td rowspan="2">100</td><td rowspan="2">36 x 36</td><td rowspan="2">74</td><td>0</td></tr>
<tr><td>9 HDTSe-</td><td>#### 9HD.cal</td><td>5</td></tr>
<tr><td colspan="2">Save Profiles as</td><td colspan="6">[energy]e [Field size] Symm.prs (e.g., 6e 30x30 Symm.prs)</td></tr>
</table>

Note *When installing applicators make sure that the FFDA insert is fully seated and level in the bottom of the applicator. Any misalignment or tilt on the FFDA may result in misleading profiles.*

Results (enter N/A in any boxes that do not apply)

Data Table: Section 9.5 - Electron Field Flatness & Symmetry (Inplane)						
Energy (MeV)		**Field Size (cm²)**	**Flatness Req. (%)**	**Actual Flatness (%)**	**Symmetry Req. (%)**	**Actual Symmetry (%)**
E1		25 x 25 Applicator	± 5.4 (± 6.0 for 6e)	±	≤ 2	
E2				±		
E3				±		
E4				±		
E5				±		
E6				±		
E7				±		
E8				±		
E1		15 x 15 Applicator	± 5.4 (± 6.0 for 6e)	±	≤ 2	
E2				±		
E3				±		
E4				±		
E5				±		
E6				±		
E7				±		
E8				±		
6 HDTSe-		36 x 36	No Spec	N/A		
9 HDTSe-				N/A		
Customer Demo Required						

Data Table: Section 9.5 - Electron Field Flatness & Symmetry (Crossplane)						
Energy (MeV)		**Field Size (cm^2)**	**Flatness Req. (%)**	**Actual Flatness (%)**	**Symmetry Req. (%)**	**Actual Symmetry (%)**
E1		25 x 25 Applicator	± 5.4 (± 6.0 for 6e)	±	≤ 2	
E2				±		
E3				±		
E4				±		
E5				±		
E6				±		
E7				±		
E8				±		
E1		15 x 15 Applicator	± 5.4 (± 6.0 for 6e)	±	≤ 2	
E2				±		
E3				±		
E4				±		
E5				±		
E6				±		
E7				±		
E8				±		
6 HDTSe-		36 x 36	No Spec	N/A		
9 HDTSe-				N/A		
Customer Demo Required						

9.6 Photon Energy Verification

Photon energy will be measured with the Sun Nuclear IC Profiler (ICP) using a copper wedge accessory. The copper wedge is an ICP accessory that allows the measurement of photon beam energy, including FFF modes. The wedge is thin near the middle of the beam and gets progressively thicker at the edges. This means that higher energy beams create a wider profile.

During the profile analysis, a mathematical relationship is established between the copper wedge profile and water phantom data at 10 cm. This relationship is then used to produce the profile D10 value analysis.

NOTICE

It is important to make sure that the correct wedge Analysis file is used with the corresponding serial numbered wedge.

Verify the beam is symmetrical within specification before performing the beam energy verification using ICP. In the case where necessary energy adjustment is make, the flatness and symmetry verifications of that energy must be repeated.

Note *If the **Enhanced Beam Conformance** option was purchased, the data table tolerance values listed in the **EBC** column must be met for all depth specifications.*

*If the **Beam Conformance to Customer Reference Data – X-Rays** option was purchased, the data table tolerance values listed in either the **TOL1** or **EBC** columns must be met for all depth specifications. Achieving either specification is acceptable since it may be necessary to slightly tune beyond the EBC specifications to match an existing machine. Varian will not detune a system beyond the **TOL 1** values, and recommends remaining within the EBC tolerances for future machine installations.*

9.6.1 Copper Wedge Photon Energy Measurement with ICP

Specification

The PDD10 values (displayed as D10 in the SNC application) acquired with the ICP and copper wedge accessory shall meet the specifications shown in the data table.

Test Method

1. Sequentially acquire profiles for all applicable energies using the set up conditions in Table 14 and analyze each profile after it is completed.
   - Make sure that the correct calibration file is set in the SNC display for each energy. This can be selected before or after the profile is acquired, but must be correct for the analysis results.
   - Verify that the correct energy is displayed in the SNC display (Figure 25). If not, use the *Setup* > *Set Energy* menu to set the correct energy. Energy can be changed before or after the profile is acquired without affecting the profile.
   - For 2.5X, uncheck **Beam is Pulsed** in the **Control** menu. Make sure that it is checked for all other energies.
   - Record the **Photon D10** value (Figure 27) in the data table, and verify that all values meet specification.
   - Save each recorded profile.

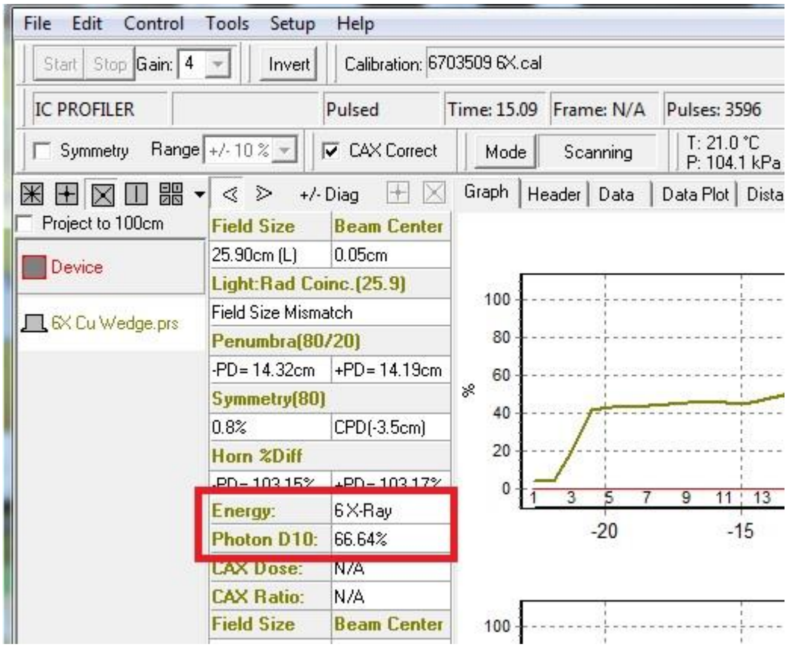
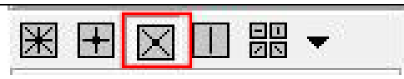


Figure 27: Photon D10 Result

<table>
<tr><th colspan="6">Table 14: Test Setup for Copper Wedge Photon Energy Measurements</th></tr>
<tr><td colspan="2">SSD</td><td colspan="4">99 cm (to top of ICP panel)</td></tr>
<tr><td colspan="2">ICP Buildup</td><td colspan="4">None</td></tr>
<tr><td colspan="2">ICP Accessory</td><td colspan="4">Quad Copper Wedge (placed on top of ICP and aligned to crosshairs)</td></tr>
<tr><td colspan="2">ICP Profile View</td><td colspan="4"> Select Diagonal Profile view</td></tr>
<tr><th>Energy (MV)
BJR 11/17</th><th>ICP Calibration File</th><th>ICP Gain</th><th>Dose Rate
(MU/min)</th><th>Dose
(MU)</th><th>Field Size
(cm²)</th></tr>
<tr><td>2.5</td><td>#### 2.5x.cal</td><td>8</td><td>60</td><td rowspan="10">100</td><td rowspan="10">30 x 30</td></tr>
<tr><td>4</td><td>#### 4x.cal</td><td>8</td><td>250</td></tr>
<tr><td>6</td><td>#### 6x.cal</td><td rowspan="8">4</td><td rowspan="8">400</td></tr>
<tr><td>8</td><td>#### 8x.cal</td></tr>
<tr><td>10</td><td>#### 10x.cal</td></tr>
<tr><td>15</td><td>#### 15x.cal</td></tr>
<tr><td>18</td><td>#### 18x.cal</td></tr>
<tr><td>20</td><td>#### 20x.cal</td></tr>
<tr><td>6HI</td><td>#### 6x.cal</td></tr>
<tr><td>10HI</td><td>#### 10x.cal</td></tr>
<tr><td colspan="6">#### represents the ICP serial number. Each ICP unit requires its own specific calibration files, which are actually normalization files that make all the detector outputs equal for a given charge.
The calibration file can be applied at any time, either before or after the profile is acquired.
Always select the appropriate calibration file from the folder icon next to the Calibration pull down arrow.

</td></tr>
<tr><td colspan="2">Save Profiles as</td><td colspan="4">[energy]x Cu Wedge.prs (e.g., 6x Cu Wedge.prs)</td></tr>
</table>

Results (enter N/A in any boxes that do not apply)

Data Table: Section 9.6 - Photon Energy Verification				
Energy (MV) BJR 11 / 17	**Photon D10**			**Actual**
	Spec (%)	**Tolerance (%)**		
		TOL 1	**EBC**	
2.5	52.0	± 2	N/A	
4	63.0			
6	67.2			
8	71.0			
10	74.1			
15 / 16	77.4	± 1	± 0.5	
18 / 23	80.2			
20 / 25	82.0			
6FFF	64.3			
10FFF	71.8			
TOL 1 = Tolerance specification for system without Enhance Beam Conformance option **EBC** = Optional Enhanced Beam Conformance tolerance specification. EBC specifications do not apply to the 2.5 MV imaging energy.				
Customer Demo Required				

9.7 Electron Energy Verification

Note *If the **Enhanced Beam Conformance Specification** option was purchased, the data table tolerance values listed in the **EBC** column must be met for all depth specifications.*

*If the **Beam Conformance to Customer Reference Data – Electrons** option was also purchased, the data table tolerance values listed in either the **TOL1** or **EBC** columns must be met for all depth specifications. Achieving either specification is acceptable since it may be necessary to slightly tune beyond the EBC specification to match an existing machine. Varian will not detune a system beyond the TOL 1 values, and recommends remaining within the EBC tolerances for future machine installations.*

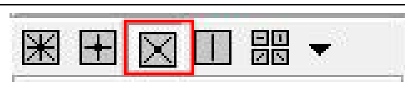
Specification

The R50% Wedge Defining Field values acquired with the ICP and aluminum quad wedge accessory shall meet the specifications shown in the data table.

R50 is defined as the probe depth that corresponds to 50% ionization (profile normalized to 100%).

Test Method

1. Sequentially acquire profiles for all applicable energies using the set up conditions in the following table, and analyze each profile after it is completed.
   - Make sure that the SSD is changed from the previous photon energy measurements.
   - Make sure that the correct calibration file and energy is set in the SNC display (Figure 25) for each energy.
   - Record results in the data table, and verify that all values meet specification.
   - Save each recorded profile.

Table 15: Test Setup for Electron Energy Measurements					
SSD	**100 cm** (to top of ICP panel)				
ICP Buildup	None				
ICP Accessory	Aluminum Quad Wedge (placed on top of ICP panel and aligned per instructions on the wedge)				
ICP Profile View	 Select **Diagonal Profile** view				
Energy (MeV)	**ICP Cal File**	**ICP Gain**	**Dose Rate (MU/min)**	**Dose (MU)**	**Field Size (cm²)**
6	#### 6e.cal	4	500	100	25 x 25 cm Applicator
9	#### 9e.cal				
12	#### 12e.cal				
15	#### 16e.cal				
16	#### 16e.cal				
18	#### 18e.cal				
20	#### 20e.cal				
22	#### 22e.cal				
Save Profiles as	[*energy*]**e Al Wedge.prs** (e.g., **6e Al Wedge.prs**)				

Results (enter N/A in any boxes that do not apply)

Data Table: Section 9.7 - Electron Energy Verification				
Energy (MeV)	**R50% Wedge Defining Field**			**Actual (cm)**
	Spec (cm)	**Tolerance (cm)**		
		TOL 1	**EBC**	
6	2.32	± 0.1	± 0.07 (6e & 9e) ± 0.08 (12e - 22e)	
9	3.52			
12	4.91			
15	6.19			
16	6.52			
18	7.41			
20	8.10			
22	8.59			
TOL 1 = Tolerance specification for system without Enhance Beam Conformance option **EBC** = Optional Enhanced Beam Conformance tolerance specification				
Customer Demo Required				

9.8 Upload Profiles to PSE FTP Site

After the profiler scans are completed, copy all saved profiles into a new folder named according to the PCSN e.g, H192096. Upload the folder to PSE FTP site under the directory Profiler_Scans > IPA_Profiles (link ***ftp://pse.oscs.varian.com/Profiler_Scans/IPA_Profiles).***

10. Dosimetry Verifications

Note *Only a single energy is tested as all energies shared the common dosimetry hardware. 6MV is the primary energy selected for the test. If 6MV is not available, use any other available photon (8MV to 20MV). If no standard photon is available, use 6FFF.*

When completed and signed, the Data Table in this section indicates that all required dosimetry tests meet specification. The actual integration data and worksheet to calculate the test results is provided using an Excel spreadsheet tool, which is available from the PSE Data Center. After the spreadsheet is filled out, it is the users responsibility to verify all tests meet the specifications listed in the Data Table

Use only with TrueBeam Dosimetry Spreadsheet-H or later*.*

Dosimetry calibration was already performed in the factory. Depending on the protocol used by the hospital, the absolute dose calibration should be relatively close. Therefore, it is not necessary to calibrate the absolute dose during these tests. Instead, the dose integration data shall represent relative data for the sole purpose of verifying the specifications. The final absolute dosimetry calibration (which is ultimately the responsibility of the hospital) should be performed by the customer after completion of the acceptance testing.

NOTICE

When calibrating the absolute dose, the dosimetry system should be adjusted so that 1 MU displayed on the console corresponds to the delivery of 1 cGy of dose at the depth of dose maximum (Dmax) in water for a 10×10 cm field (for X-Rays) or a 15×15 cm field (for electrons) at 100 cm TSD. Calibration in any other manner may compromise the reliability of the system and the TrueBeam warranty as expressed in Varian's Terms and Conditions of Sale.

Specification

Specifications for all Dosimetry reproducibility tests are listed in the Excel Spreadsheets and the data table.

Test Method

1. Download the **TrueBeam Dosimetry Spreadsheet-xx** file (at least rev H) from ***PSE Data Center > TrueBeam > documents*** section.
2. Log in to Service mode and verify that all servos are ON.
3. Follow the instructions in the excel spreadsheet and run all of the required integrations for all applicable energies.
4. Verify all test results meet specifications in the Excel spreadsheet, and record results in the data table.

Results

Data Table: Section 10 – Dosimetry Verifications		
Dosimetry Test Criteria	**Specification (whichever is greater)**	**√ = OK**
Short Term Dose Reproducibility	± 1.0% or 1 MU	
Dose Reproducibility with Dose (MU)	± 1.0% or 1 MU	
Dose Reproducibility with Dose Rate (MU/Min)	± 1.0% or 1 MU	
Dose Reproducibility with Gantry Angle	± 1.5% or 1.5 MU	
Customer Demo Required		

11. Dynamic Therapy and RapidArc (VMAT) Verifications

Note *Offline QA application must already be installed and properly set up in the Service WS. Refer to SIM-HT manual to install and Appendix A of this document to run the application*

1. If not already done so, download the following files:
   - *TrueBeam IPA* file from the ***PSE Website > TrueBeam > Software Downloads*** section.
2. Extract the downloaded files to the following two folders on the TrueBeam WS:
   - *D:\VMSOS\AppData\TDS\Input\Service*
   - *D:\VMSOS\AppData\TDS\Input\Daily QA*
   - *D:\VMSOS\AppData\TDS\Input\Treatment*

11.1 Enhanced Dynamic Wedge

<u>Specification</u>

- The MU RMS value shall be ≤ 0.20 MU.
- The Jaw Position RMS value for the jaw moving during the EDW shall be ≤ 0.15 cm.

<u>Test Method</u>

1. From the Major Mode screen, log in to **Machine QA** using the Service log in.
2. Select **Open Plan** and select the EDW plan in the following directory that corresponds to the appropriate energy:

   D:\VMSOS\AppData\TDS\Input\Daily QA\TrueBeam IPA\TB_EDW
3. Open the first EDW test plan listed with the parameters shown in the data table.
4. Select **Machine Override**.
5. In the **External Beam Override** dialog box, log in using the Service login.
6. Select the following buttons: **Select All > Next > Convert > Done**.
7. Move all axes to planned position.
8. Press **Prepare** on the control console. Press **MV Ready** until the **MV Beam ON** button lights and then press **MV Beam On**.
9. Verify no Fault Interlocks activate while running the plan. The test must run with no fault interlocks to have a valid data set for **Offline QA**.
10. Repeat the same steps to run the second EDW plan listed in the data table.
11. Using the *Offline QA* application, open the trajectory BIN file that was created for the specified plan.
12. Select **Position Statistics**.
13. Verify the **Position RMS error** under the **Observations While Beam is ON Only** column (for the jaw moving during the test) meets specification.

14. Verify the **MU RMS error** under the **Observations While Beam is ON Only** column meets specification.
15. Record results in the data table.

Results

Data Table: Section 11.1 – Enhanced Dynamic Wedge									
Energy	Dose (MU)	Wedge Orient	COLL Y1 (cm)		COLL Y2 (cm)	EDW Angle	Specification		√ = OK
			IEC601	IEC 1217			MU RMS error	Jaw Position RMS error	
X-ray 1	100	Y1-IN	20.0	-20.0	10.0	10°	≤ 0.20 MU	≤ 0.15cm	
X-ray 1	100	Y2-OUT	10.0	-10.0	20.0	10°			

11.2 Arc Dynamic

NOTICE **To prevent damage to the equipment, verify the gantry can rotate a full 360° without risk of collision before performing the following tests.**

Specification

- Plans must be completed without any Faults being asserted.
- Arc 1 field drives the MLC leaves at a speed of 2.5 cm/sec.
- The Gantry Position RMS error shall be ≤ 0.50°.
- The MU RMS error shall be ≤ 0.20 MU.

Test Method

1. From the Major Mode screen, log in to **Machine QA** using the Service login.
2. Select **Open Plan** and select the **MLC Arc** plan in the following directory that corresponds to the appropriate energy:

   D:\VMSOS\AppData\TDS\Input\Daily QA\TrueBeam IPA\STD 120MLC (or HDMLC or 80MLC)
3. Select **Machine Override**.
4. In the **External Beam Override** dialog box log in using the service login.
5. Select the following buttons: **Select All** > **Next** > **Convert** > **Done**.
6. Select the **ARC 1** field.
7. Press **Prepare** on the control console.
8. Move axes to planned positions.
9. Press **MV Ready** and then **MV Beam On**.
10. Allows the treatment to complete.

11. Repeat Step 8 to Step 11 for the **ARC 2** field.

12. Using the OFFLINE QA application, open the trajectory BIN file that was created for the specified plan.

13. Confirm the plans execute without any interlocks being asserted. Select **Position Statistics**. Confirm the **Gantry Position RMS** error and **MU RMS** error are within specifications.

14. Select **Leaf**. Confirm the **Actual Leaf Velocity** for Arc 1 field reaches the maximum velocity of 2.5 cm/sec. The **Actual Leaf Velocity** (dark blue line) typically lies directly behind the **Expected Leaf Velocity** (light blue line) other than some small variations.

15. Record results in the data table.

Results

Data Table: Section 11.2 – Arc Dynamic						
Energy	**Total Arc Degrees**	**Dose (MU)**	**Effective MU/°**	**Specification**		**√ = OK**
				Gantry Position RMS error	**MU RMS error**	
X-Ray 1	180° (Arc 1 field)	54	0.3	≤ 0.5°	≤ 0.20 MU	
	45° (Arc 2 field)	900	20.0			
MLC leaf velocity reaches velocity of 2.5 cm/sec when executing **Arc 1** field.						
The MLC executed all test treatments above without any interlocks being asserted.						
Customer Demo Required						

11.3 Moving Window IMRT Test with Gantry at 90° and 270°

This test ensures the tested MLC will be able to perform dynamic (sliding-window) IMRT treatment.

NOTICE **To prevent damage to the equipment, verify the gantry can rotate a full 360° without risk of collision before performing the following tests.**

Note *This test is not an energy dependent test. The energy for this test is not important. The plan for any photon energy available on the machine may be used.*

Specification

- This test must be completed without any Fault interlock being asserted.
- Leaf Position Deviation from intended position shall be ≤ 0.15 cm.

Test Method

1. Enter the treatment room, and verify the gantry is clear to rotate for Dynamic Arcs.

2. In **Machine QA** mode, select **Open Pla**n and browse to the MLC Sliding Window plan in the following applicable directory:

   D:\VMSOS\AppData\TDS\Input\Daily QA\ TrueBeam IPA\STD 120MLC (or HDMLC or 80MLC)

3. Select the MLC Sliding Window DICOM plan.
4. Select **Machine Override**.
5. In the **External Beam Override** dialog box log in using the service login.
6. Select the following buttons: **Select All > Next > Convert > Done**.
7. Select the **Gantry 270 field**.
8. Press **Prepare** on the control console.
9. Move axes to planned position.
10. Press **MV Ready** and then **MV Beam On**.
11. Allow the treatment to complete.
12. Repeat Steps 6 through Step 9 for the others in the **Gantry 90 field**.
13. Confirm the plans execute without any faults asserted.
14. Using the **Offline QA** application, open the trajectory **.bin** file that was created for the specified plan.
15. Select **Leaf Histogram**. Under the **Leaf Positions Histogram Data** section, verify there are no readings with deviations > 0.15 cm.
16. Record results in the data table.

Results

Data Table: Section 11.3 – Moving Window IMRT Test with Gantry at 90° and 270°		
Specification	**√ = OK**	
	Gantry 90°	**Gantry 270°**
The MLC executed the treatment plan without any faults.		
Leaf Position Deviation from intended position is ≤ 0.15cm.		
Customer Demo Required		

11.4 RapidArc (VMAT) Verification

Note ***Not applicable for VitalBeam with MLC80.***

NOTICE **To prevent damage to the equipment, verify the gantry can rotate a full 360° without risk of collision before performing the following tests.**

Specification

- Plans must be completed without any Faults being asserted.
- The Gantry Position RMS error shall be ≤ 0.50°.
- The MU RMS error shall be ≤ 0.20 MU.

Test Method

1. From the Major Mode screen, log in to **Machine QA** using the Service login.
2. Select **Open Plan** and select the RapidArc plan in the following directory that corresponds to the lowest available X-ray energy and type of MLC:

   D:\VMSOS\AppData\TDS\Input\Daily QA\TrueBeam IPA\RA_VMAT_M120 (or RA_VMAT_HD)
3. Select **Machine Override**.
4. In the **External Beam Override** dialog box log in using the service login.
5. Select the following buttons: **Select All** > **Next** > **Convert** > **Done**.
6. Press **Prepare** on the control console.
7. Move axes to planned positions.
8. Press **MV Ready** and then **MV Beam On**.
9. Allows the treatment to complete.
10. Repeat the test with highest available X-ray energy.
11. Using the OFFLINE QA application, open the trajectory BIN file that was created for the specified plan.
12. Confirm the plans execute without any interlocks being asserted. Select **Position Statistics**. Confirm the **Gantry Position RMS** error and **MU RMS** error are within specifications.
13. Record results in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 11.4 – RapidArc (VMAT) Verification				
Energy	**Actual Energy**	**Specification**		**√ = OK**
		Gantry Position RMS error	**MU RMS error**	
Lowest X-ray		≤ 0.50°	≤ 0.20 MU	
Highest X-ray				
All RapidArc plans executed without any interlocks asserted.				
Customer Demo Required				

12. LaserGuard and Collision Protection System

LaserGuard provides an infrared protection zone below the collimator to prevent gantry collisions with patients and objects.

12.1 Protection Zone Area Verification

Requirement

With collimator and gantry at 0°, the protection zone area is centered and parallel to the Interface Mount and meets the following requirements:

- 177.8mm handle protrusion of the T-shaped gauge (100012420-01) shall clear the protection zone.
- 36.9mm Gauge Plug (100011752-02) shall clear the protection zone.
- 2mm Gauge Shim (100011752-06) used with the 36.9mm Gauge Plug shall penetrate the protection zone on either side of the zone.

Test Method

1. Position gantry and collimator to 0°.
2. Verify LaserGuard Control is enabled in System Administration.
3. Install T-shaped gauge on Interface Mount (shown in Figure 28), and verify red LED is not illuminated on gantry LSG indicator and on the in room monitor LSG icon.

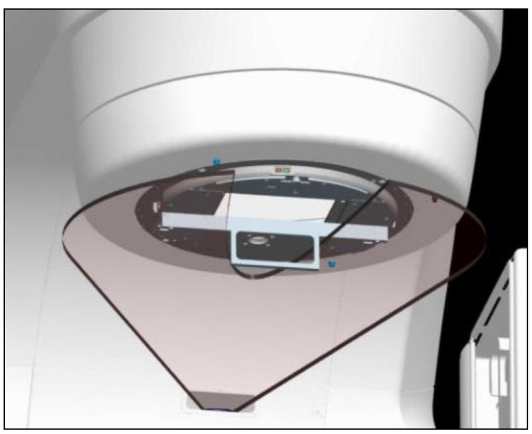


Figure 28: Protection Zone with T-Shaped Gauge Installed (Gantry 0°)

4. Attach 36.9 mm Gauge Plug (medium-height Plug) over Accessory Mount alignment pin (shown in Figure 29). Verify LSG does not trigger and the red indicator LED does not illuminate.
5. Place Gauge Plug over opposite alignment pin and verify red indicator LED does not illuminate.
6. Reattach medium-height Gauge Plug at each location with 2 mm shim in place. Verify LSG triggers and the red LED illuminates.
7. Record test results in the data table.

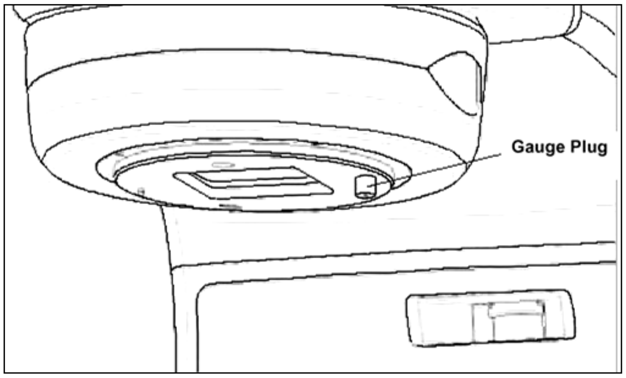


Figure 29: Gauge Plug Installed

Results

Data Table: Section 12.1 – Protection Zone Area Verification	
Test Criteria	**√ = OK**
177.8 mm handle protrusion of the T-shaped Gauge clears the protection zone.	
36.9 mm Gauge Plug clears the protection zone.	
36.9 mm Gauge Plug with 2 mm shim penetrates the protection zone on both sides.	
Customer Demo Required	

12.2 Protection Zone Tilt Verification

Requirement

With collimator at 90° and gantry at 0°, the protection zone tilt alignment is 3° relative to the Interface Mount (shown in Figure 30) and meets the following requirements:

- 26 mm Gauge Plug (100011752-01) attached to rear Interface Mount pin (Stand side) shall clear the warning zone.
- 47.8 mm Gauge Plug (100011752-03) attached to front Interface Mount pin (couch side) shall clear the warning zone.
- 2 mm shim added to either Gauge Plug shall penetrate the warning zone.

Test Method

1. Rotate collimator to 90°.
2. Attach 26 mm (shortest) and 47.8 mm (longest) Gauge Plugs as shown in Figure 30 (long plug in front and short plug in back). Verify yellow LED (on the Laser Unit body) does not illuminate.
3. One at a time, add the 2 mm shim to each Gauge Plug and verify yellow LED illuminates. Shim must only be added to one plug at a time.
4. Record test results in the data table.

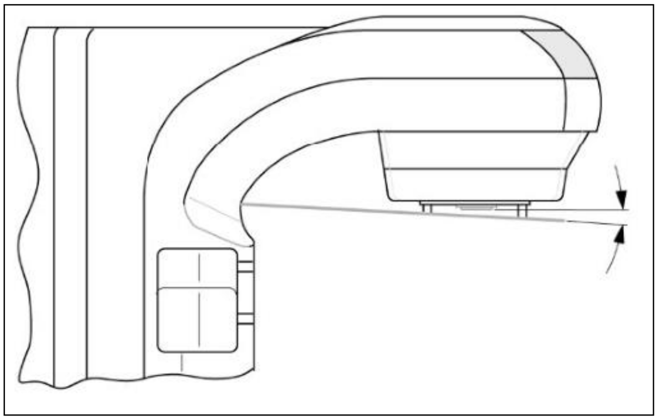


Figure 30: Tilt Alignment Test

Results

Data Table: Section 12.2 – Protection Zone Tilt Verification	
Test Criteria	**√ = OK**
26 mm Gauge Plug attached to rear Interface Mount pin clears the warning zone.	
47.8 mm Gauge Plug attached to front Interface Mount pin clears the warning zone.	
Each Gauge Plug with 2 mm shim penetrates the warning zone (yellow LED).	
Customer Demo Required	

12.3 Motion Stop Function Verification

Requirement

With treatment room door closed, gantry motion should stop when an intrusion into the protection zone occurs. The red LSG indicator LED should illuminate.

Test Method

1. In service mode enable Laser Guard control with the door open.
2. Place provided foam collision block on couch top in a position that will cause the collimator to hit the block before it hits any portion of the couch (Figure 31).
3. Using a pendant, carefully rotate gantry towards the block to penetrate the collision zone. Verify the following:
   - Gantry motion stops.
   - Red indicator LED is illuminated on the gantry display and IRM.

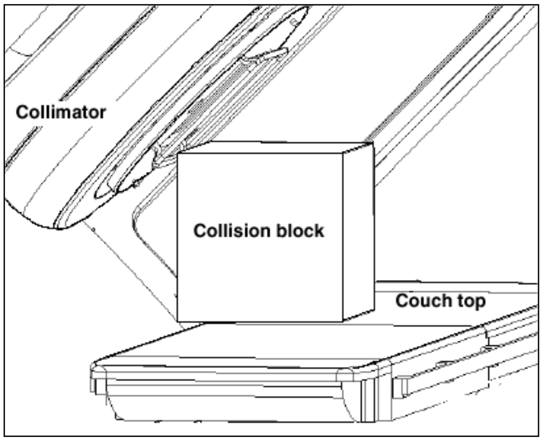


Figure 31: Collision Block Test

Results

Data Table: Section 12.3 – Motion Stop Function Verification	
Test Criteria	**√ = OK**
With treatment room door closed, gantry motion stops when an intrusion into the protection zone occurs. The red LED illuminates on the gantry and console LSG indicators.	
Customer Demo Required	

12.4 Collision Override Function Verification

Requirement

The side panel clearance override button shall be capable of overriding the LSG collision condition to back away from an existing collision.

Test Method

1. With the LSG collision activated from the previous setup, at the couch side panel press and hold one of the Motion Enable buttons and the Clearance Override button until you can verify using the Pendant that the machine will allow the axes to clear the obstruction.

Results

Data Table: Section 12.4 – Collision Override Function Verification	
Test Criteria	**√ = OK**
Collision Override Verification	
Customer Demo Required	

12.5 PU Arm Motion Interlock

Note ***All KVD and KVS tests in this section are not applicable to VitalBeam without the KV option.***

Requirement

A collision detection system is built into the PU motion system. If any collision (including KVS collimator CCDS) is detected, an audible indication shall sound and a collision shall be displayed with all major motions stopped. A manual reset at collimator touch guard or couch is required to restore major motions once the collision is cleared.

Test Method

1. This test is performed in Service mode.
2. **MVD imager cover** – While rotating the gantry, firmly press the MVD imager cover and verify that a collision is detected. All external motions should be disabled and an audible sound should be heard. Reset the collision. Record results in the data table.
3. **MVD arm paddles -** While rotating the gantry, sequentially press all MVD arm paddles and verify that a collision is detected. All external motions should be disabled and an audible sound should be heard. Reset the collision. Record results in the data table.
4. **KVD imager cover** – While rotating the gantry, firmly press the KVD imager cover and verify that a collision is detected. All external motions should be disabled and an audible sound should be heard. Reset the collision. Record results in the data table.
5. **KVD arm paddles -** While rotating the gantry, sequentially press all KVD arm paddles and verify that a collision is detected. All external motions should be disabled and an audible sound should be heard. Reset the collision. Record status in the data table.
6. **KVS cover CCDS** – While rotating the gantry, gently place palm of hand on KVS collimator base (e.g. center front cover) to activate CCDS. Verify that a collision is detected. All external motions should be disabled and an audible sound should be heard. Reset the collision. Record status in the data table.
7. **KVS arm paddles -** While rotating the gantry, sequentially press all KVS arm paddles and verify that a collision is detected. All external motions should be disabled and an audible sound should be heard. Reset the collision. Record status in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 12.5 – PU Arm Motion Interlock		
Collision Test	**Specification**	**√ = OK**
MVD Imager Cover	■ All external motions stopped ■ Collision is activated ■ Audible indication okay	
MVD Arm Paddles		
KVD Imager Cover		
KVD Arm Paddles		
KVS Cover CCDS		
KVS Arm Paddles		
Customer Demo Required		

12.6 PU Arm Motion Collision Override

Note ***All KVD and KVS tests in this section are not applicable to VitalBeam without the KV imaging option.***

Requirement

In the event of a collision where at least one arm collision is present and there is a need to move the arm away from the collision, an override can be performed.

Test Method

1. This test is performed in Service mode.
2. Create a collision by pressing and holding a collision paddle on an arm. KVS CCDS will require organic object (e.g., palm of human hand) to be within 1 cm of KVS collimator cover to activate a collision.
3. Press and hold a collision reset button while moving the motion away from the collision.
4. Verify PU arms move at a slow speed.
5. Record status in the data table.

Results

Data Table: Section 12.6 – PU Arm Motion Collision Override		
Collision Override Check	**Specification**	**√ = OK**
At least one collision paddle and a collision reset button are continuously depressed.	PU arm motion enabled at slow speed	
Customer Demo Required		

13. Positioning Unit (MVD, KVD, AND KVS)

Note ***All KVD and KVS tests in this section are not applicable to VitalBeam without the KV option.***

13.1 Vertical Motion Run-out

Specification

The longitudinal and lateral position of the PU arms at -80.0/0/0.0 cm shall be within ±2 mm referenced to the longitudinal and lateral position at 0.0/0.0/0.0 cm. This verifies system calibration for longitudinal and lateral run-out. The KVD portion of this test requires in-room ceiling lasers to be accurately aligned.

Test Method

1. This test is performed in Service mode.
2. Rotate gantry to head-up position. Remove both kV and MV detector covers.
3. Position MVD arm at 0.0/0.0/0.0 cm. Using a piece of white tape, draw a small reference mark (+) on the imager that is aligned to projected crosshair intersection for MVD.
4. Then move the arm to -80.0/0.0/0.0 cm by using the Axis Position Screen. Measure the amount of lateral and longitudinal run-out with metric ruler.
5. Record results.
6. Retract MVD arm.
7. Rotate the gantry 90º IEC.
8. Repeat test for KVD arm using reference mark (+) on imager panel that is accurately aligned to ceiling lasers.
9. Record results, and retract the KVD arm.
10. Install detector (MVD and KVD) covers after tests have been completed.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 13.1 – Vertical Motion Run-out		
MVD Vertical Movement from 0 cm to -80 cm	**Specification (mm)**	**Actual Run-out**
Lateral Run-out	≤ 2.0	
Longitudinal Run-out	≤ 2.0	
KVD Vertical Movement from 0 cm to -80 cm	**Specification** (mm)	**Actual Run-out**
Lateral Run-out	≤ 2.0	
Longitudinal Run-out	≤ 2.0	

13.2 Vertical Accuracy

Specification

The vertical accuracy shall be within ±2 mm of the displayed position. The imaging layer is 12 mm panel surface for MVD and 18 mm below panel surface (with grid) for KVD. The X-Ray tube is 143 mm beyond the KV collimator surface.

Test Method

1. This test is performed in Service mode.

2. Rotate the gantry to head-up position. Remove the kV and MV detector cover and the KVS cover.

3. Position the MVD at 0.0/0.0/0.0 cm by using the Axis Position Screen in Service mode. Use the calibrated mechanical front pointer to measure true position.

4. Verify result in the data table.

5. Position the MVD at -50.0/0.0/0.0 cm using the Axis Position screen. Position calibrated mechanical front pointer to 100.0 cm. Use metric tape or ruler to measure true distance from the tip of mechanical front pointer to MVD panel surface.

6. Verify result, remove front pointer and retract MVD arm.

7. Position the KVD at 0.0/0.0/0.0 cm using the Axis Position screen. Use crosshair projection and verify vertical alignment with black line drawn on the side of the kV detector housing. The black line indicates the top of the image detection layer. Use metric ruler to measure true position between crosshair projection and black line.

8. Verify result in the data table.

9. Position the KVD at -50.0/0.0/0.0 cm using the Axis Position screen. Move couch top (vertical) towards isocenter and couch longitudinal near +80.0 cm.

10. Use a metric ruler placed on couch top and measure true distance from machine crosshair projection to top of KVD IDU (including Grid).

11. Verify result in the data table and retract KVD arm.

12. Position the KVS at 100/0.0 cm (VRT / LNG) using the Axis Position screen.

13. Use a metric ruler placed on couch top and measure true distance from machine crosshair projection to KVS collimator filter deck surface.

14. Verify status in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 13.2 – Vertical Accuracy		
Displayed MVD Position	**Specification**	**√ = OK**
0 / 0 / 0 cm	98.8 cm ± 0.2 cm	
-50.0 / 0 / 0 cm	48.8 cm ± 0.2 cm	
Displayed KVD Position	**Specification**	**√ = OK**
0 / 0 / 0 cm	0.0 cm ± 0.2 cm	
-50.0 / 0 / 0 cm	48.2 cm ± 0.2 cm	
Displayed KVS Position (VRT / LNG	**Specification**	**√ = OK**
100 / 0.0 cm	85.7 cm ± 0.2 cm	
Customer Demo Required		

13.3 Lateral & Longitudinal Accuracy (MVD and KVD)

Specification

The lateral and longitudinal axes positioning of the imager panel shall coincide with the displayed PRO to within ± 1 mm tested at 50 below Isocenter.

Test Method

1. This test is performed in Service mode.
2. Remove the kV and MV detector cover.
3. With gantry at 0° IEC, position the MVD arm at -50.0/0.0/0.0 cm using the Axis Position screen.
4. Using white tape, mark the side wall laser line (for longitudinal) and sagittal laser line (for lateral) projected on the panel.
5. Using Axis Position screen, move the MVD arm to -50.0 / +10.0 / +10.0 cm.
6. Using a ruler, measure the distance of travel between the tape reference marks and the laser lines.
7. Repeat the process for MVD arm position -50.0 / -10.0 / -10.0 cm.
8. Verify status in the data table.
9. Rotate gantry to 90° IEC.
10. Repeat the position accuracy test for KVD using the overhead laser lines as reference.

<u>Results (enter N/A in any boxes that do not apply)</u>

Data Table: Section 13.3 – Lateral & Longitudinal Accuracy (MVD and KVD)		
Displayed MVD Position	**Specification**	**√ = OK**
LAT 10.0 cm	10.0 cm ± 0.1 cm	
LNG 10.0 cm	10.0 cm ± 0.1 cm	
LAT -10.0 cm	-10.0 cm ± 0.1 cm	
LNG -10.0 cm	-10.0 cm ± 0.1 cm	
Displayed KVD Position	**Specification**	**√ = OK**
LAT 10.0 cm	10.0 cm ± 0.1 cm	
LNG 10.0 cm	10.0 cm ± 0.1 cm	
LAT -10.0 cm	-10.0 cm ± 0.1 cm	
LNG -10.0 cm	-10.0 cm ± 0.1 cm	
Customer Demo Required		

13.4 Travel Range (MVD and KVD)

<u>Specification</u>

The following travel ranges shall be possible at MVD and KVD -50.0/0.0/0.0 cm. This allows PU Arms to make full use of its travel range without reaching its mechanical limits.

- MVD Longitudinal:
  - Travel range shall be -20.0 cm to +24.0 cm from isocenter for IDU 20 panel.
  - Travel range shall be -13.5 cm to +30.5 cm from isocenter for DMI panel.
- MVD Lateral: Travel range shall be -16.0 cm to +15.5 cm from isocenter.
- KVD Longitudinal: Travel range shall be -22.0 cm to +24.0 cm from isocenter.
- KVD Lateral: Travel range shall be -18.5 to +15.5 cm from isocenter.

<u>Test Method</u>

Note *Travel range test is to verify travel distance achievable within the software limits. This test is based on the PRO values on the screen only and no actual measurement is required.*

1. This test is performed in Service mode.
2. Position the MVD arm at -50.0/0.0/0.0 cm.
3. Slowly move the arm with the hand pendant longitudinally and laterally to both limits.
4. Record the PRO values display on the in-room monitor at travel limits for each axis.
5. Repeat for KVD arm.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 13.4 – Travel Range (MVD and KVD)			
MVD Travel Range at VRT -50 cm		**Specification (cm)**	**PRO (cm)**
Longitudinal (DMI panel)	Min	≤ -13.5	
	Max	≥ +30.5	
Longitudinal (IDU 20 Panel)	Min	≤ -20.0	
	Max	≥ +24.0	
Lateral	Min	≤ -16.0	
	Max	≥ +15.5	
KVD Travel Range at VRT -50 cm		**Specification (cm)**	**PRO (cm)**
Longitudinal	Min	≤ -22.0	
	Max	≥ +24.0	
Lateral	Min	≤ -18.50	
	Max	≥ +15.5	

13.5 Dynamic Stability

Note *The same procedure applies to VitalBeam without the KV option. IsoCal can be run with MV imaging only.*

Specification

The dynamic motion shall be within 0.5 mm for MV and kV detectors at -50.0/0.0/0.0 cm. This is PASS / FAIL test.

Test Method

1. This test is performed in Service mode within **PVA Calibration** tab.
2. Setup the IsoCal phantom and plate.
3. On the PVA Calibration screen, select **Details** tab.
4. In the **Select Modality** drop down menu, select "**Geometry**"
5. Select Isocenter **Verification** and then click **Calibration** to run IsoCal verification.

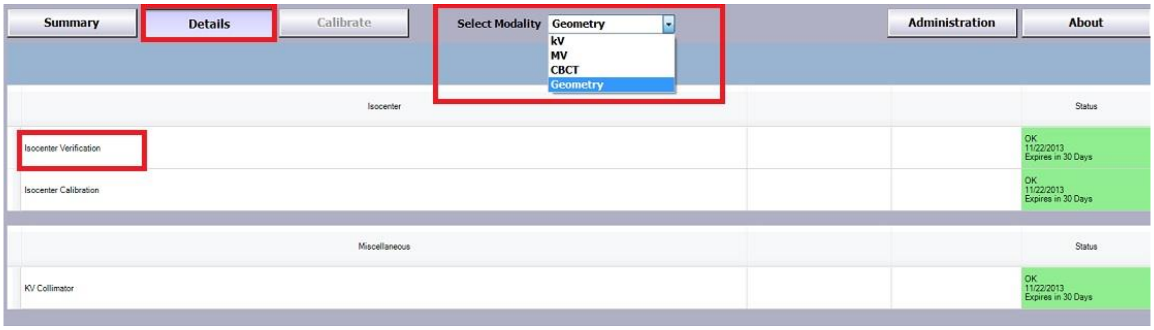


Figure 32: Selecting Isocenter Calibration Verification

6. Record IsoCal verification status (PASS / FAIL) in the data table. See Figure 33.

- Green Bar represents a passed test.
- Red Bar represents a failed test.

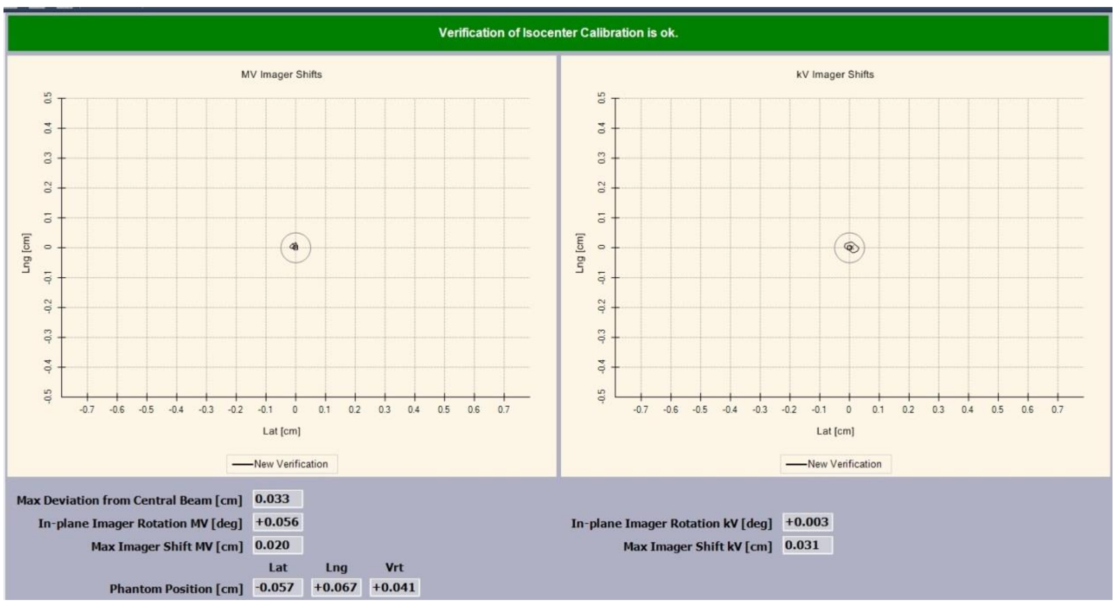


Figure 33: IsoCal Results (Passed Shown for System with KV option)

Results

Data Table: Section 13.5 – Dynamic Stability		
ISOCAL Results	**Specification**	**√ = OK**
	ISOCAL Verification Passed	
Customer Demo Required		

14. MV Imaging Acquisition

14.1 Chassis to Ground Resistance Verification for DMI

Note *This test only applies to the DMI panel. If this panel is not installed, enter NA in the data table.*

This test is to verify that the DMI panel is not shorted to ground that may introduce system noise to the imager.

Requirement

The resistance between the chassis of DMI panel and ground shall be ≥ 1 MΩ.

Test Method

1. Remove the front cover of the gantry to gain access to motion control nodes (MCN)
2. Move the MVD to position 0.0/0.0/0.0 cm.
3. Using DVM, measure the resistance between the power supply chassis of the DMI panel and the ground point of the MVD MCN (see Figure 34).
4. Record status in the data table.

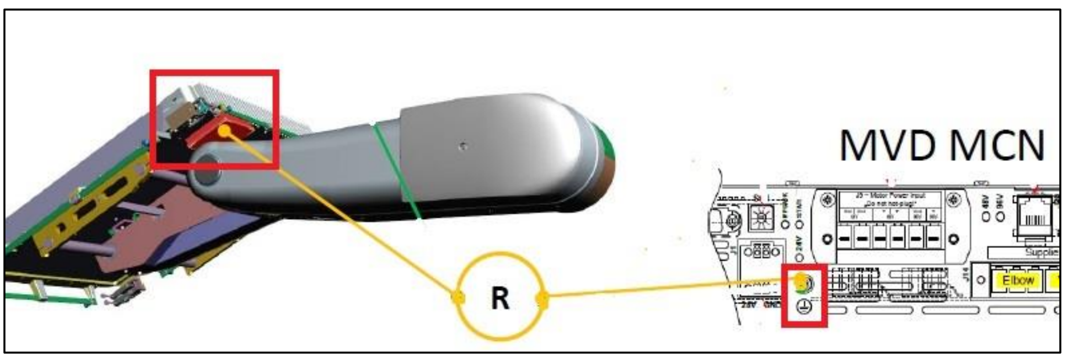


Figure 34: Measuring Chassis to Ground Resistance of DMI Panel

Results (enter N/A if the DMI panel is not installed)

Data Table: Section 14.1 – Chassis to Ground Resistance Verification for DMI		
Test Criteria	**Specification**	**√ = OK**
Chassis to Ground Resistance	≥ 1 MΩ	

14.2 No Radiation Images

14.2.1 Dark Field Image

Specification

- **For IDU 20**: The mean pixel value shall be in the range of 2000 to 5000 pixels for a Full Resolution (1024 x 768) Dark Field image.
- **For DMI**: The mean pixel value shall be in the range of 400 to 800 pixels for a Full Resolution (1280 x 1280) Dark Field image.

Test Method

1. This test is performed in Service mode.
2. In *XI tab* > *Acquisition* > *MV* tab, select **Image Mode > Highres-DF**.
3. Press **Acquire**.

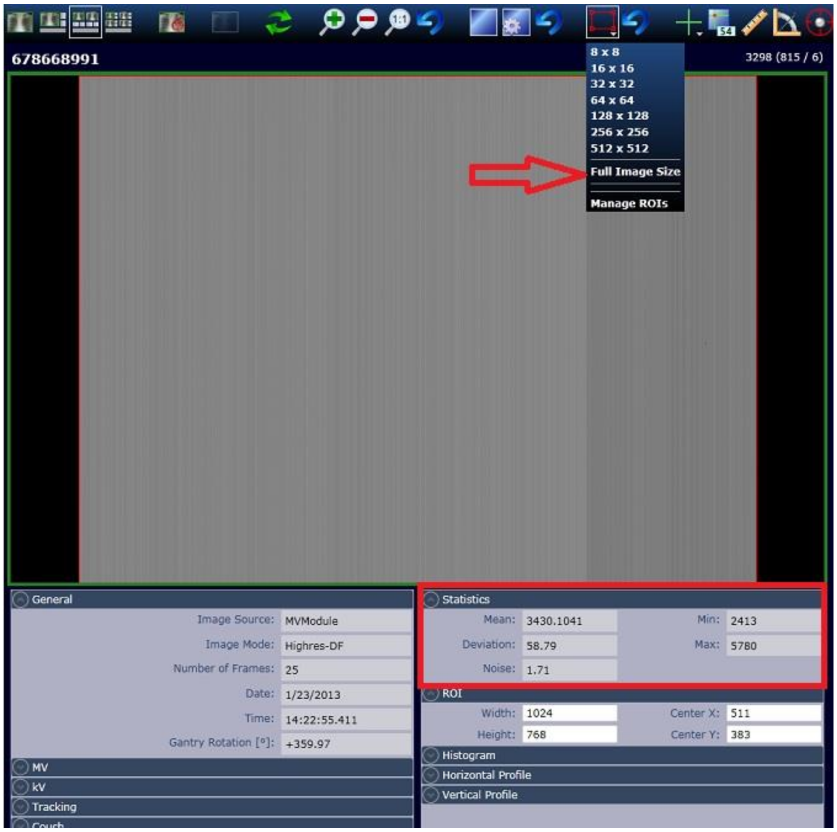


Figure 35: MV Highres-DF Image

4. Enable ROI and expand it to Full Image Size (1024 x 768 for IDU 20, 1280 x1280 for DMI) and read the Mean value in the Statistics.
5. Record results in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 14.2.1 – Dark Field Image		
Dark Field Image, Full Res	**Specification**	**Actual Mean**
Pixel Statistics, Mean Value (DMI)	+400 ≤ Mean ≤ +800	
Pixel Statistics, Mean Value (IDU 20)	+2000 ≤ Mean ≤ +5000	

14.2.2 Noise Image

Specification

The result of two DF images (acquired shortly after each other) subtracted shall be a homogeneous grey image whereby the Standard Deviation (SDev) pixel value shall be < 10.

Test Method

1. This test is performed in Service mode.
2. In **XI tab > Task > MV** tab, select **Test Imaging Chain**, and press **Start**.
3. Images will be acquired automatically; scroll down to the Noise Image.
4. Enable ROI and expand it to Full Image Size (1024 x 768 for IDU 20, 1280 x1280 for DMI) and read the Deviation value in the Statistics.
5. Record results in the data table.

Results

Data Table: Section 14.2.2 – Noise Image		
Noise Image	**Specification**	**Actual SDev**
Standard Deviation	< 10	

14.3 Pixel Correction

Specification

High Resolution maximum number of defective lines shall meet the following:

- DMI panel is ≤ 5
- IDU 20 panel ≤ 2

High Resolution maximum number corrected pixels (total defects) is ≤ 20,000.

Low Resolution maximum number corrected pixels (total defects) is ≤ 11,000.

Test Method

1. In Service mode, select **PVA Calibration** tab.
2. On the PVA Calibration screen (right monitor), click on **Details**.
3. In the **Select Modality** drop down menu, select **MV**.

4. Right click on the cell in the column **Pixel Correction** and a row **High Quality** and select **Calibrate Selected Steps**.
5. Record results.
6. Right click on the cell in the column **Pixel Correction** and a row **Low Dose** and select **Calibrate Selected Steps**.
7. Record results.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 14.3 – Pixel Correction		
Total Corrected Pixels	**Specification**	**Actual Corrected Pixels count**
Highres = High Quality	≤ 20000	
Lowres (512 x 384) = Low Dose	≤ 11000	
Neighbor Lines	**Specification**	**Actual**
Defective Lines (Highres)	≤ 5	
Defective Lines (IDU 20, Highres)	≤ 2	

14.4 Radiation Images

14.4.1 Contrast Resolution

Specification

Contrast detail resolution defines the imager's ability to display objects with low contrast for a given energy and dose. It is determined by taking images of the MV Las Vegas phantom with a high and low energy mode. The different hole depths correspond to different object contrasts depending on the beam energy.

Table 16: Contrast Detail Resolution Specifications

Imaging Mode	Photon Energy	Minimum Visible Holes in PV Phantom
Low X-Ray Imaging	2.5 MV	A, B, C, D, E, F
Low X	4 - 8 MV	A, B, C, D, E
10X or greater	10 - 25 MV	A, B, C, D

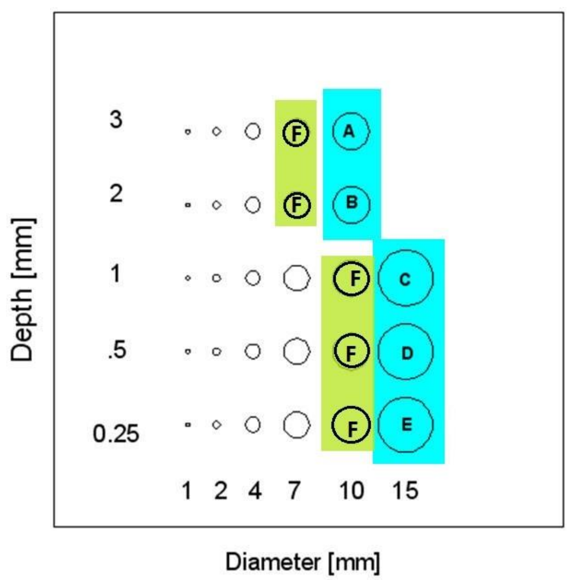


Figure 36: Contrast Detail Specification

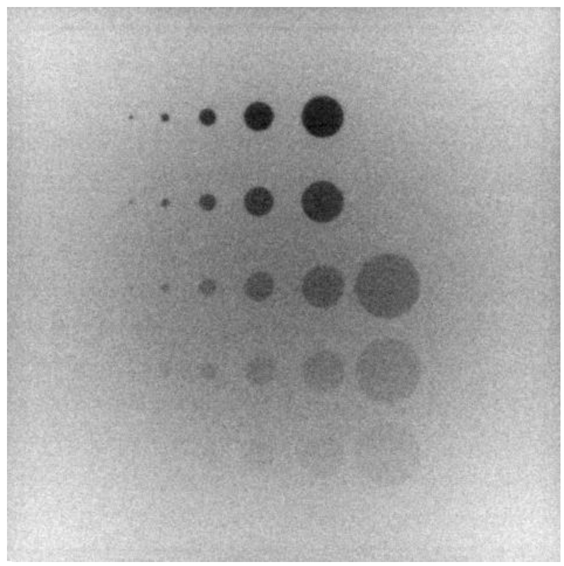


Figure 37: Typical Phantom Image (Low-X)

Test Method

1. This test is performed in Service mode.
2. Place the couch top to isocenter (use aligned in-room lasers if possible) and place phantom tool on couch top. Use machine crosshairs to center the phantom.

Note *Make sure DMI panel is powered ON for at least 2 hours before final calibration is performed for acceptance. Warm-up time is required for pixel leakage stabilization in the detector.*

3. In **XI tab > Acquisition > MV** select ***Highres*** **Single Imaging Mode** for Low X. Move the arm to -50.0/0.0/0. Recommended collimator value is a **13 x 13** cm² field with the phantom aligned at isocenter.

Note *TrueBeam supports multiple photon configurations. For example if machine is delivered with 4 MV, 6 MV, and 8 MV;* ***LOW X*** *should be considered the lowest X-Ray energy (e.g.: 4 MV).*

4. Acquire the **Highres** image.
5. Analyze the image for the contrast specification and record all visible holes per energy according to **Contrast Specification**.
6. Repeat test for Low X-ray Imaging and High X if applicable.
7. Record results in the data table.

Note *TrueBeam supports multiple photon configurations. For example if machine is delivered with 6MV, 10 MV, 15 MV and 18 MV;* ***HIGH X*** *should be considered the highest X-Ray energy (e.g. 18 MV).*

Results (enter N/A in any boxes that do not apply)

Data Table: Section 14.4.1 – Contrast Resolution			
Photon Energy		**Specification**	**√ = OK**
Low X-Ray Imaging		Holes Visible (A,B,C.D,E,F)	
	MV (Low-X)	Holes Visible (A,B,C.D,E)	
	MV (High-X)	Holes Visible (A,B,C.D)	
Customer Demo Required			

14.4.2 Small Object Detection

Specification

A 0.5 mm diameter wire (lead, tungsten, or paperclip) placed diagonally at isocenter can be detected.

Test Method

1. This test is performed in Service mode.

2. In **XI tab > Acquisition > MV** and select **Highres Single Imaging Mode for Low X**.
3. Acquire an image with a 0.5 mm diameter wire (P/N TM61451000) placed diagonally at isocenter.

Note *All machines come with a 0.5 mm diameter tungsten wire P/N TM61451000.*

4. Record results in the data table.
5. Repeat for Low X-Ray Imaging if applicable.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 14.4.2 – Small Object Detection			
Photon Energy		**Specification**	**√ = OK**
Low X-Ray Imaging		Wire Is Visible	
	MV (Low-X)		
Customer Demo Required			

14.5 Dosimetry Integration (Portal Dosimetry Option)

Specification

Integration check will define the linearity of pixel counts relative to the dose. The image detector is placed at 0/0/0 cm. The accumulated pixel value shall not deviate more than 2% relatively to the programmed dose. This test will require a license to acquire integrated images.

Test Method

Table 17: Setup for Dosimetry Integration Test	
Gantry Angle	0°
Collimator Angle	0°
Field Size (X,Y jaws)	10 x 10 cm
MVD Position	0 / 0 / 0
Energy	Low-X
MU setting	50, 100 and 200

1. In Service mode, select ***XI tab > Acquisition > MV*** and highlight **Dosimetry Continuous Mode**.
2. Position the MVD to isocenter 0/0/0.
3. Open the jaws to a field size of 10 cm x 10 cm.
4. Select Low-X and set Dose to 50 MU.

Note *Do not mouse click on **Acquire** button on **XI tab** as this will give incorrect results by causing the panel to read out frames before MV Beam On.*

5. Press **Prepare, MV Ready** and **MV Beam On** when ready to acquire the Integrated Image.

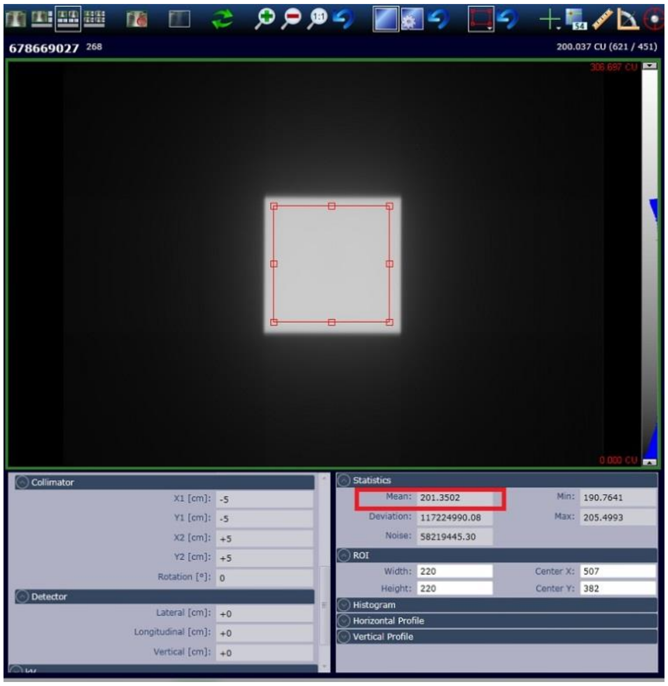


Figure 38: Mean Value of ROI within Open Field (200 MU test shown)

6. On PVA screen, Use the Window Level tool to optimize the 10 x 10 cm² image.
7. Use the ROI drop down menu and select 128 x 128 ROI. Place the ROI approximately in the center of the 10 x 10 cm² image. Use mouse to drag the edges of ROI until it is just within the 10 x 10 cm² image**.** (See Figure 38).
8. Obtain pixel Mean value.
9. Record result in the data table.
10. Do not close or move the ROI on the active image window.
11. Repeat for 100 MU and 200 MU respectively.
12. Perform calculation in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 14.5 - Dosimetry Integration (Portal Dosimetry Option)			
Delivered MUs	**Mean Value**	**Expected**	**Integrated Value in % (to be Calculated ==>)** **(100 / Mean for 100 MU) * Mean of Dose**
50		50% (± 2%)	
100		100%	Reference (100%)
200		200% (± 2%)	
Customer Demo Required			

15. X-Ray Generator Verification

Note *This section does not apply for VitalBeam without KV option. Enter NA in all data tables.*

15.1 kVp, mA, and ms Accuracy

Specification

There are 2 types of X-ray generator used:

- VMS200 generator for TrueBeam with long stand
- EMD generator for TrueBeam with slim stand

Table 18: EMD Generator Accuracy Specifications

X-Ray Factor	Specification
kVp	± (5% + 2 kVp)
mA	± (5% + 0.5 mA)
Exposure Time	± (5%+0.2ms)

Table 19: VMS200 Generator Accuracy Specifications

X-Ray Factor	Specification
kVp	± (5% + 1 kVp)
mA	± (5% + 1 mA)
Exposure Time	± (10%+1) between (1 and 4 ms) ± (2%+0.5) between (5 and 6300 ms)

Test Method

1. This test is performed in Service mode.
2. In **XI tab > Acquisition > KV,** beam on for each listed technique in Data Table Section 15.1.

Note *The UNFORS "Platinum" can measure both **mA and kV** simultaneously (i.e. same time) while the UNFORS "Basic" unit can only measure **mA or kV** (i.e. manually). Recent UNFORs firmware upgrade may require using the "cursor" method for reading time (ms) values on short duration pulses (e.g.: 20 ms or less) from KV Generator.*

3. **kVp Measurement**:
   - A. Position the gantry at 90° IEC.
   - B. Move KVS to 100/0 cm with kV collimator blades set to fully OPEN.
   - C. Move KVD to -50/0/0 cm.

D. Place the UNFORS XI R/F detector within 50 cm of the X-Ray tube target. Align the sensor pack perpendicular to the longitudinal axis of the X-Ray tube. To avoid the heel effect, do not place the sensor pack towards the anode side of the X-Ray tube.

E. Set up UNFORS to measure kVp.

4. mA Measurement:

A. Set up UNFORS to measure mA. **For VMS200 generator only:** refer to **Tech Tip TT-II-01342** for specific instructions with G1542 Metal Insert Tube

5. Record the kVp, mA, and ms values in the data table.

6. Verify the recorded values are within the specifications.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 15.1 – kVp, mA, and ms Accuracy (EMD Generator)								
Small Focal Spot (Single High Quality kV)								
Technique			**Specification**			**Actuals**		
kVp	**mA**	**ms**	**kVp**	**mA**	**ms**	**kVp**	**mA**	**ms**
60	25	100	55 - 65	23.25 - 26.75	94.8 - 105.2			
60	80	100	55 - 65	75.5 - 84.5	94.8 - 105.2			
90	20	100	83.5 - 96.5	18.5 - 21.5	94.8 - 105.2			
90	25	200	83.5 - 96.5	23.25 - 26.75	189.8 - 210.2			
120	80	20	112 - 128	75.5 - 84.5	18.8 - 21.2			
Large Focal Spot (Single High Quality kV)								
Technique			**Specification**			**Actuals**		
kVp	**mA**	**ms**	**kVp**	**mA**	**ms**	**kVp**	**mA**	**ms**
60	25	100	55 - 65	23.25 - 26.75	94.8 - 105.2			
60	200	100	55 - 65	189.5 - 210.5	94.8 - 105.2			
100	200	20	93 - 107	189.5 - 210.5	18.8 - 21.2			
100	200	200	93 - 107	189.5 - 210.5	189.8 - 210.2			
120	100	100	112 - 128	94.5 - 104.5	94.8 - 105.2			
120	200	100	112 - 128	189.5 - 210.5	94.8 - 105.2			

Data Table: Section 15.1 – kVp, mA, and ms Accuracy (VMS200 Generator)								
Small Focal Spot (Single High Quality kV)								
Technique			**Specification**			**Actuals**		
kVp	**mA**	**ms**	**kVp**	**mA**	**ms**	**kVp**	**mA**	**ms**
60	25	100	56 - 64	22.75 - 27.25	97.5 - 102.5			
60	80	100	56 - 64	75 - 85	97.5 - 102.5			
90	20	100	84.5 - 95.5	18 - 22	97.5 - 102.5			
90	25	200	84.5 - 95.5	22.75 - 27.25	195 - 205			
120	80	20	113 - 127	75 - 85	19.1 - 20.9			
Large Focal Spot (Single High Quality kV)								
Technique			**Specification**			**Actuals**		
kVp	**mA**	**ms**	**kVp**	**mA**	**ms**	**kVp**	**mA**	**ms**
60	25	100	56 - 64	22.75 - 27.25	97.5 - 102.5			
60	200	100	56 - 64	189 - 211	97.5 - 102.5			
100	200	20	94 - 106	189 - 211	19.1 - 20.9			
100	200	200	94 - 106	189 - 211	195 - 205			
120	100	100	113 - 127	97.5 - 102.5	97.5 - 102.5			
120	200	100	113 - 127	189 - 211	97.5 - 102.5			

15.2 Half Value Layer (HVL) with Digital Fluoroscopy (Canada and USA only)

Specification

The Half Value Layer (HVL) is a function of tube potential and the total filtration for diagnostic X-Ray units are published in CFR, volume 21, 1020.30, paragraph ‘M’, Table 1.

For 100 kVp, the HVL is equivalent to a minimum of 2.7 mm of Aluminum.

For 70 kVp, the HVL is equivalent to a minimum of 1.5 mm of Aluminum.

Test Method

1. HVL measurements are made with the kV setup used previously. The HVL reading in the example above is the amount of aluminum required to cut the dose in half.
2. The unfiltered dose is read with UNFORs by acquiring a 70 kV test image.
3. The filtered dose value is 50% of the unfiltered dose reading.
4. Record the unfiltered dose value displayed on the UNFORS Xi program. The filtered dose value will be half of unfiltered dose value.
5. Record the amount of aluminum displayed on the UNFORS Xi program required to reduce the dose by half.
6. Repeat above steps for a 100 kV test image.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 15.2 – Half Value Layer (HVL) with Digital Fluoroscopy (Canada and USA only)				
	Unfiltered mGy	**Filtered mGy**	**Specification**	**mm of Aluminum**
70 kVp			> 1.5 mm	
100 kVp			> 2.7 mm	

15.3 Air Kerma Test Verification

Specification

The kV Air Kerma (in Gy absorbed dose) value must be within 35% tolerance between displayed clinically (e.g., PVA) and measured UNFORS values.

Table 20: Air Kerma Specifications	
kV Tube	GS-1542
kV Generator	EMD or VMS 200
Tolerance (skin dose [uGy])	PVA Displayed AK vs UNFORS Measured AK ± 35%

Test Method

1. This test is performed in Treatment mode with a Dicom RT test patient.
2. Verify the following machine setup.

Table 21: Air Kerma Setup	
Gantry	90°
Couch Vertical	-15 cm (IEC 61217) , see Note below
KVS	100/0 cm
KVD	-50/0/0 cm
KVS Blades	Automatic
Bowtie	None
kV Filter	Titanium
KV Mode	Dynamic Gain
UNFORs Mounting Bracket and Probe	On couch top

Note *The UNFORS mounting fixture is 30 cm in length, so if couch vertical is set 15.0 cm below isocenter, the UNFORs probe will be positioned 15.0 cm above isocenter for the Air Kerma measurement. Xi UNFORS measurement chamber should be oriented perpendicular to the X-Ray tube (see UNFORS manual). UNFORS unit scaling is set to Gy for this test but the UNFORS Xi View application will display results in µGy. The conversion must be done manually prior to recording results. (e.g.: 100 µGy = 0.1 mGy).*

3. Position the UNFORS test fixture on top of the couch. Use the lasers or crosshairs projection to align the probe at approximately position 15/0/0 cm (see Figure 39). This position will simulate absorbed dose at patient skin level.

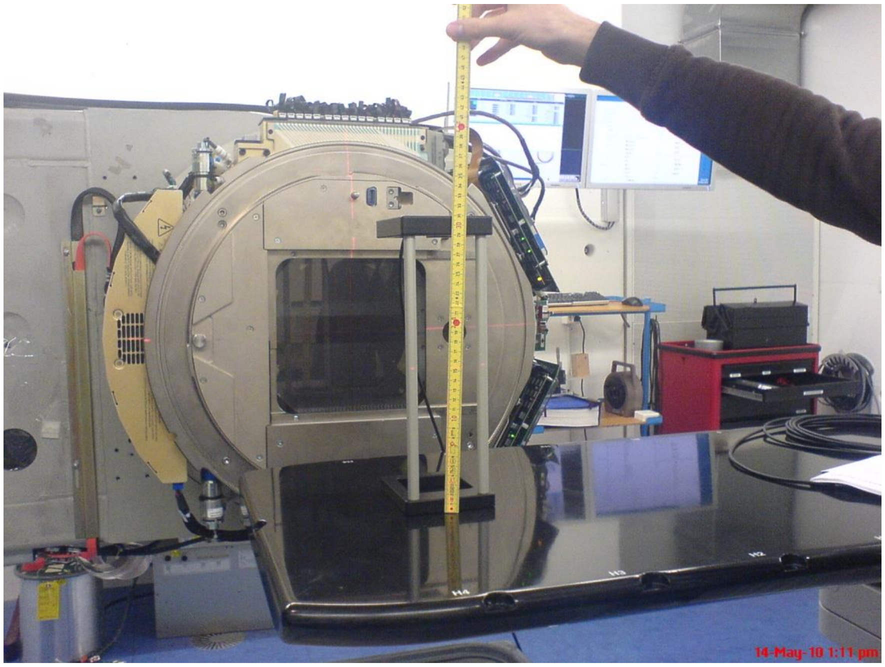


Figure 39: Air Kerma Setup with Probe at Position 15/0/0 cm

4. Launch Treatment application and select *Tools* > *File* mode.
5. Browse to *D:\VMSOS\AppData\TDS\Input\Treatment\TrueBeam IPA\SVS CAP HET_Catphan* folder and select DICOM RT plan **_RP.SVS CAP HET_Catphan.dcm**.
6. Perform any machine overrides.
7. Select field CBCT-CBCT and click **ADD > Add Imaging** at bottom of screen.

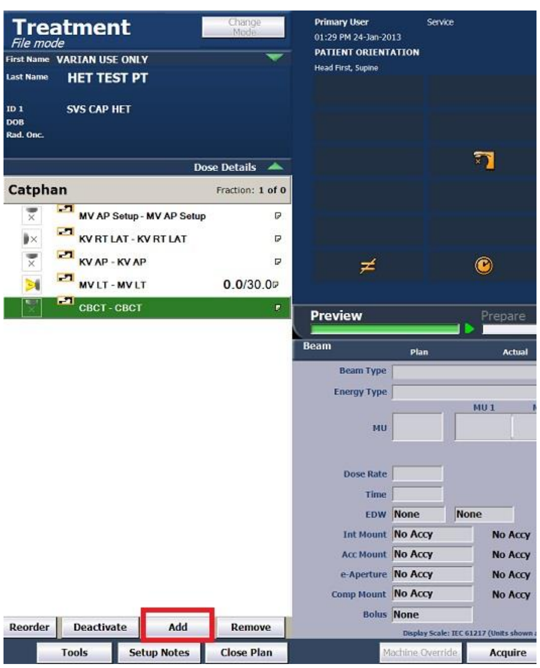


Figure 40: Click Tab to Add Imaging Setup

8. On the **Modify Imaging** window, select **Modality > KV**. Press **OK** to continue.

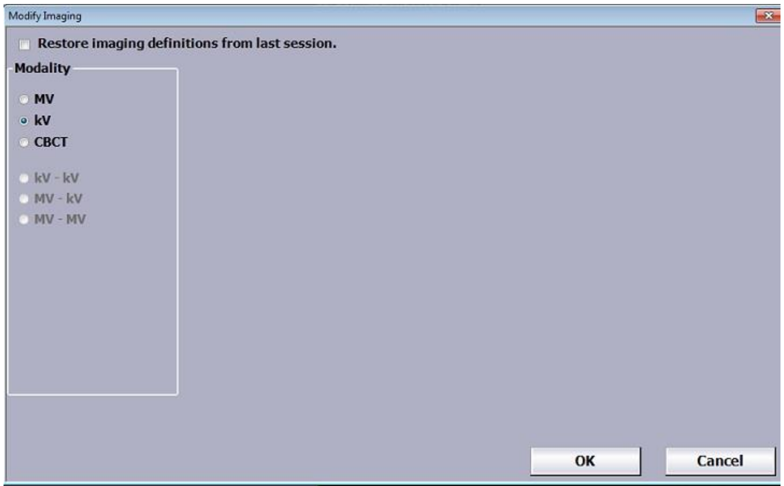


Figure 41: Selecting Imaging Modality

9. Expand the kV tab highlighted on the PVA screen and change kV and mAs (use default mA) according to the techniques in the data table. Select Small Focus and Titanium KV filer for all techniques in this test. Press OK when done.

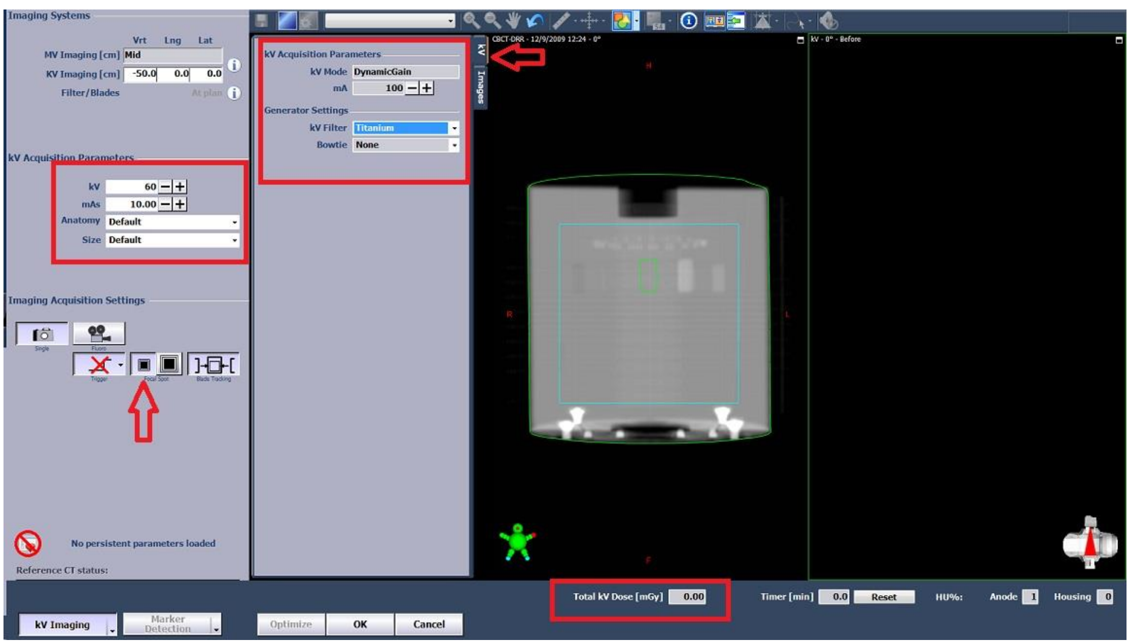


Figure 42: PVA Screen to Set Up KV Parameters.

10. On control console, press **Prepare** and then **KV Beam On** to acquire the Dynamic Gain image.
11. After image is acquired, record the Total KV Dose [mGy] value (Air Kerma) shown in PVA screen and UNFORS measured value. Calculate deviation percentage per the formula:

Note *PVA displays Air Kerma as the cumulative value between acquired kV images. It is recommended to record* ***absolute difference*** *in displayed values between consecutively acquired images. Alternatively, exit Treatment mode and then relaunch and reload the test patient between consecutive images to reset the displayed dose.*

$$Deviation\ (\%) = \frac{DisplayedAK - MeasuredAK}{DispalyedAK} \times 100$$

12. Press **Preview** on control console. Change KV parameters until all techniques listed in the data table are completed.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 15.3 – Air Kerma Test Verification					
RF Mode UNFORS	**kVp**	**mAs**	**Displayed KV Dose [mGy] (DisplayedAK)**	**Measured Dose [mGy] (MeasuredAK)**	**Deviation [%]**
RF High	60	10.0			
	90	10.0			
	120	6.3			

16. KV Imaging Acquisition

Note *This section does not apply for VitalBeam without KV option. Enter NA in all data tables.*

16.1 Radiation Images

16.1.1 High Contrast Resolution

Specification

The imaging system shall resolve 1.25 (lp/mm) using Huttner or 1.30 (lp/mm) using Fluke (Nuclear Associates) line pairs per millimeter in low resolution mode.

Table 22: kV Imaging High Contrast Resolution	
Tool	**Specification**
Huttner	1.25 lp/mm
Fluke (Nuclear Associates) X-ray Test Pattern	1.30 lp/mm

Test Method

1. This test is performed in Service mode.
2. Position the gantry at 90° IEC.
3. Move KVS to 100/0 cm.
4. Move KVD to -50/0/0 cm.
5. Make sure that beam path is clear of any objects or filtration (e.g. Foil and Filter are out of beam) and the kV blades should be fully open.
6. Place the high contrast resolution test tool Fluke (Nuclear Associates model # 07-523), or Huttner type 18 at a diagonal angle on the center of the kV panel cover.
7. In **XI tab > Acquisition > kV,** acquire a ***DynamicGainFluoro*** image with **50 kVp / 50 mA / 10 ms / Large Focal Spot / ABC OFF** technique.
8. Select zoom function from toolbar and draw an area around the test tool to magnify the test tool. Adjust the window and level scroll bars for the sharpest display. It may be easier to distinguish the line pairs with the room lights off.
9. Record results in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 16.1.1 – High Contrast Resolution		
Image Mode	**Specification**	**Visible Line Pairs / millimeter**
DynamicGainFluoro	Huttner: 1.25 lp/mm Nuclear Associates: 1.30 lp/mm	
Customer Demo Required		

16.1.2 Gray Scale Linearity

Specification

The imaging system shall display 11 uniform shades of gray (from black to white) using the Fluke (Nuclear Associates 07-456).

Test Method

1. This test is performed in Service mode.
2. Position the gantry at 90° IEC.
3. Move KVS to 100/0 cm and KVD to -50/0/0 cm.
4. Make sure that beam path is clear of any objects or filtration (e.g. Foil and Filter are out of beam). Use PU Services to collimate kV blades to a smaller field around the test tool as this will result in a better image.
5. Place a step wedge penetrometer test tool on the center of the kV panel cover.
6. In *XI tab > Acquisition > kV*, acquire a ***DynamicGainFluoro*** image with **75 kVp / 50 mA / 10 ms / Large Focal Spot / ABC OFF** technique.
7. Maintain kVp while fine-tuning the mA and ms technique to maximize the number of gray levels visible on image. Use of window/level may be required.
8. Record results in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 16.1.2 – Gray Scale Linearity		
	Specification	**√ = OK**
Visible Number of Gray Shades	11	
Customer Demo Required		

16.1.3 Low Contrast Sensitivity

Specification

Using the Leeds test object type TOR [18 FG]. The imaging system shall resolve a minimum of 2.33% sensitivity in fluoro mode.

Table 23: Contrast Sensitivity Table with Leeds Test Object TOR [18 FG]	
Disk Number	**Contrast Sensitivity %**
12	2.33

Test Method

1. This test is performed in Service mode.
2. Position the gantry at 90° IEC.
3. Move KVS to 100/0 cm and KVD to -50/0/0 cm.
4. Tape a 1 mm copper filter on the source face (collimator faceplate). Verify that the collimation does not exceed the edges of the copper filtration.
5. Make sure that the beam path is clear of any objects or filtration.
6. Use arrow indicator on the test tool and place the tool on the center of the kV panel cover.
7. Reset CCDS in Service mode *Positioning Unit > KVS Collimator > CCDS > Reset CCDS*. Clear any active collision on collimator Touch Guard before leaving treatment room.
8. In *XI tab > Acquisition > kV*, acquire a ***DynamicGainFluoro*** image with **75 kVp / 25 mA / 10 ms / Large Focal Spot / ABC off** technique.
9. Adjust the window/level until a small white circle is visible within the white square and the small black circle is visible within the black square.

Note *Turn off the console area lights and view the image. The image is best viewed at a distance approximately four times the diameter of the displayed field.*

10. For the Leeds TOR[18FG] tool there are 18 low-density disks embedded in the phantom in a 9 disk arc at the top of the image and a 9 disk arc at the bottom. Starting with the darkest disc (disk 1 at roughly 10 o'clock) count to the lowest density disc that can be resolved. Refer to Contrast Sensitivity Table to note the disk number in the provided box.
11. Record results in the data table.
12. Remove the 1mm copper filter after the test is completed.
13. Reset CCDS in Service **mode** *Positioning Unit > KVS Collimator > CCDS > Reset CCDS*. Clear any active collision on collimator touch guard.

Table 24: Contrast Sensitivity Table with Leeds Test Object TOR [18FG]	
Disk Number	**Contrast Sensitivity %**
1	14.9
2	13.2
3	11.4
4	9.7
5	7.8
6	6.7
7	5.99
8	4.7
9	3.99
10	3.47
11	3.01
12	2.33
13	2.01
14	1.61
15	1.45
16	1.22
17	1.03
18	0.81

Results (enter N/A in any boxes that do not apply)

Data Table: Section 16.1.3 – Low Contrast Sensitivity		
	Specification	**Actual**
Number of Visible Leeds Disks	≥ 12	
Customer Demo Required		

17. KVS Collimator

Note *This section does not apply for VitalBeam without KV option. Enter NA in all data tables.*

17.1 KVS Blades Travel Range

Specification

The collimator blades X1, X2, Y1, and Y2 shall have minimum travel range of -3 cm to +25 cm at isocenter. Verify these positions by driving kV blades as displayed by PVA Calibration.

Test Method

1. This test is performed in Service mode within PVA Calibration tab.
2. Level the gantry at head up position.
3. In PVA Calibration, select **Details tab** and then select **Modality > KV**
4. Select Test **Image** on the High Quality mode.
5. Change the Tracking mode to manual.
6. Change the blades position: Y1 = -25 cm; Y2 = -3 cm; X1 = -25 cm; X2 = -3 cm.
7. Press OK to move blades; no beam on is necessary.
8. Verify blades move to positions.
9. Record status in the data table.
10. Repeat test with blades at: Y1 = 3 cm; Y2 = 25 cm; X1 = 3 cm; X2 = 25 cm.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 17.1 – KVS Blades Travel Range			
	Specification (IEC 61217 scale)		**√ if OK**
	Min	**Max**	
X1	≥ 3.0 cm	≤ -25.0 cm	
X2	≤ - 3.0 cm	≥ 25.0 cm	
Y1	≥ 3.0 cm	≤ - 25.0 cm	
Y2	≤ - 3.0 cm	≥ 25.0 cm	

17.2 KVS Filter Foil

Specification

There are two foil positions (Titanium and Open) port for KVS collimator. Verify these positions are mechanically centered as displayed by PVA.

Test Method

1. This test is performed in Service mode within PVA Calibration tab.
2. In PVA Calibration, select Details tab and then select Modality > KV
3. Select Test Image on the High Quality mode.
4. Change the Tracking mode to manual.
5. From kV Filters drop down menu, select Titanium.
6. Press OK; no beam on is necessary.
7. Verify that the position readout for the kV filter now displays Titanium.
8. Visually inspect the kV Filter position on the KVS collimator. The Titanium filter should be centered on the X-Ray tube exit window. The white line on the collimator face plate indicates the center of the X-Ray tube exit window.
9. Record results in the data table.
10. From kV Filters drop down menu, select None.
11. Press OK; no beam on is necessary.
12. Visually inspect the kV Filter position on the KVS collimator. No filter should be centered on the X-Ray tube exit window.
13. Record status in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 17.2 – KVS Filter Foil		
Filter Foil Position	**Specification**	**√ if OK**
Titanium	Foil Inside Beam Path	
None	Foil Outside Beam Path	

17.3 kV Filter Shape

Specification

There are two Filter Shape positions (HALF and FULL) BOWTIE for KVS collimator. Verify these positions are mechanically centered as displayed by the PVA application.

Test Method

1. This test is performed in Service mode within **PVA Calibration** tab.
2. In PVA Calibration, select **Details tab** and then select **Modality > KV**
3. Select **Test Image** on the High Quality mode.
4. Change the Tracking mode to manual.
5. From **Bowtie** drop down menu, select **Full Fan**.
6. Press **OK**; no beam on is necessary.
7. Verify the position readout for the Bowtie now displays Full Fan.
8. Visually inspect the Bowtie position on the KVS collimator. The filter should be centered on the X-Ray tube exit window. The white line on the collimator face plate indicates the center of the X-Ray tube exit window. The hole in the assembly should be aligned to the white line.
9. Record results in the data table.
10. From **Bowtie** drop down menu, select **Half Fan**.
11. Press **OK**; no beam on is necessary.
12. Visually inspect the Bowtie position on the KVS collimator. The filter should be centered on the X-Ray tube exit window. The white line on the collimator face plate indicates the center of the X-Ray tube exit window. The hole in the assembly should be aligned to the white line.
13. Record results in the data table.
14. From **Bowtie** drop down menu, select **None**.
15. Press **OK**; no beam on is necessary.
16. Visually inspect the Bowtie position on the KVS collimator. No filter should be centered on the X-Ray tube exit window.
17. Record status in the data table.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 17.3 – kV Filter Shape		
Bowtie Filter Position	**Specification**	**√ if OK**
Full Fan	Centered	
Half Fan	Centered	
None	X-Ray Beam Path Unobstructed	

18. CBCT Image Acquisition

Note *This section does not apply for VitalBeam without KV option. Enter NA in all data tables.*

18.1 Density Resolution (HU Calibration)

Specification

This procedure verifies the accuracy of the HU calibration (± 50 HU) using the PVA Calibration tool to calculate the HU values of the Catphan phantom. See Catphan manual for module and density target orientation.

Test Method

1. This test is performed in Service mode within **PVA Calibration** tab.
2. Place the Catphan Phantom onto the couch and align it to the wall lasers.
3. In PVA Calibration, select **Details tab** and then select **Modality > CBCT**.
4. Acquire a **Test Scan** on the ***Head*** mode.
5. Select and expand the Transversal view. Use Window level tool to adjust the image.
6. Referring to Figure 43, select **Histogram** tab (labeled A) on the tool bar and then move the mouse curser to click on Air substance (labeled B) on the image. Right mouse click within the Histogram window and then select “Show Statistics” (labeled C).

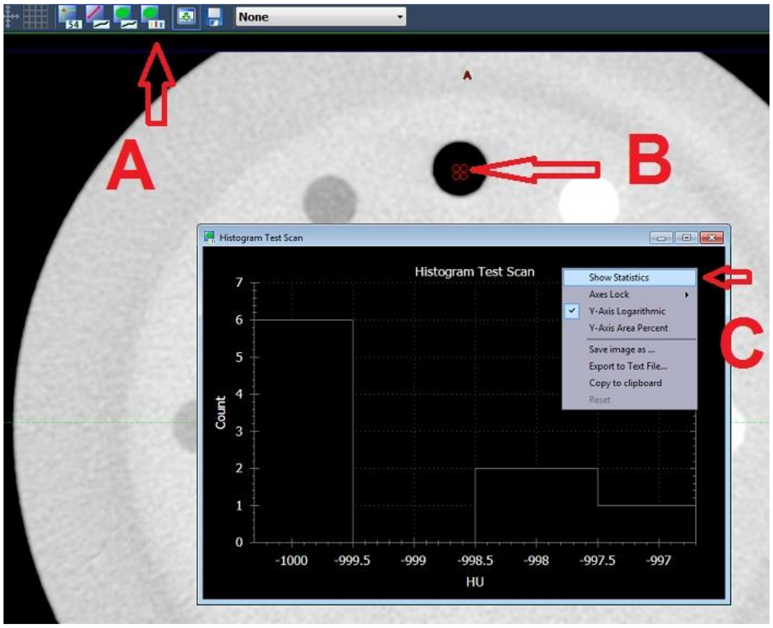


Figure 43: Selecting Statistics for Substance

7. Using mouse, right click on the ROI and select 7 x 7 mm. Use mouse to drag and placed ROI within the homogenous substance of the Catphan Phantom specify in the data table (see Figure 45)

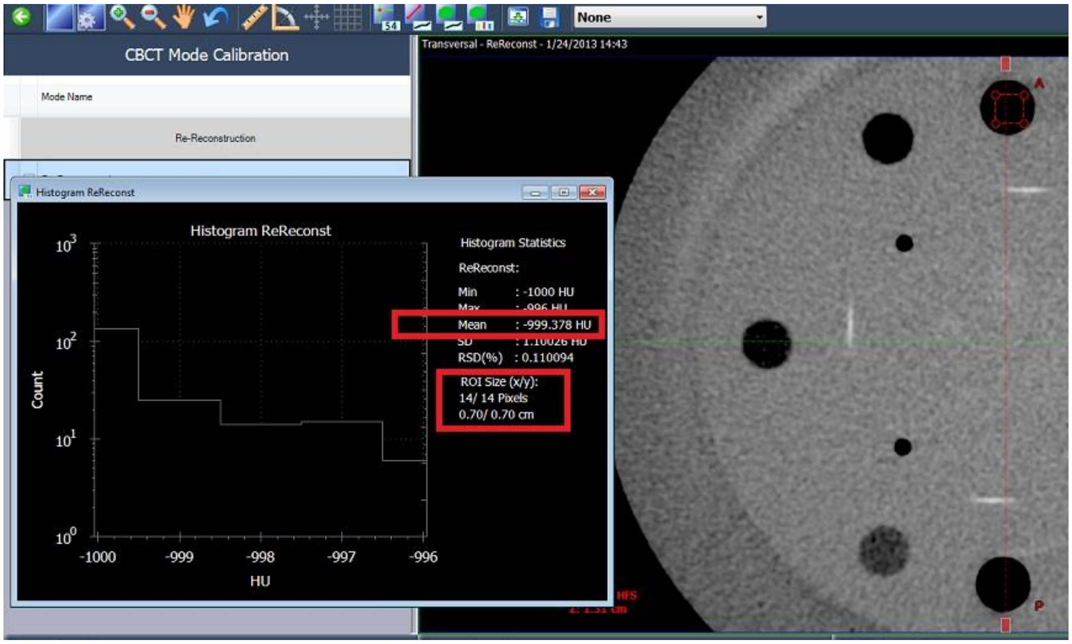


Figure 44: Placing ROI within Substance for Mean Value

8. Determine the HU mean value.
9. Record results. Enter NA if not applicable.
10. Repeat the above steps for the CBCT mode ***Pelvis*** using same ROI size.

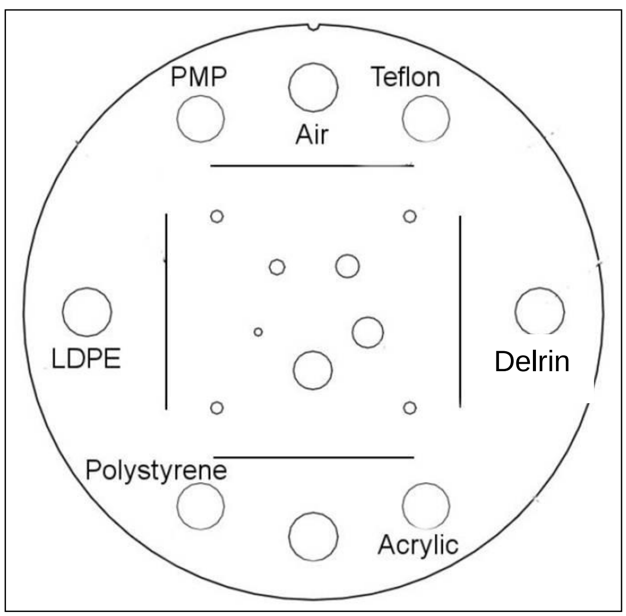


Figure 45: Catphan Phantom

Results (enter N/A in any boxes that do not apply)

Data Table: Section 18.1 – Density Resolution (HU Calibration)		
CBCT Mode Head Material	**Specification**	**Actual**
Air	- 1000 ± 50	
Acrylic	120 ± 50	
LDPE	- 100 ± 50	
CBCT Mode Pelvis Material	**Specification**	**Actual**
Air	- 1000 ± 50	
Acrylic	120 ± 50	
LDPE	- 100 ± 50	
Customer Demo Required		

18.2 Spatial Linearity Measurements (Distance)

Specification

This procedure verifies the distance measurement using the distance measuring tool to measure the distance between four holes (three Air and one Teflon) spaced 50 mm apart on the Catphan phantom.

Test Method

1. Using the same ***Head*** scan from previous section, verify the distance by measuring the distances between the verification holes located on Catphan phantom using the **Measure** tool on the tool bar.
2. Record results.
3. Repeat the above steps for CBCT mode ***Pelvis***.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 18.2 – Spatial Linearity Measurements (Distance)		
CBCT Mode	**Specification**	**Actual**
Head	50 mm ± 0.5 mm	
Pelvis	50 mm ± 0.5 mm	
Customer Demo Required		

18.3 Image Uniformity Measurements

Specification

This procedure determines the Image Uniformity of the scanned image. This must conform to a value measured at the Image Uniformity Module of the Catphan phantom. See Data Table: Section 18.3 Image Uniformity Measurements for specifications.

Test Method

1. Using the same Head scan from previous section, select the correct image slice that displays the Image Uniformity module by using the Page Up / Page Down keys. See Catphan manual for module orientation.
2. Use the toolbar and select the **Histogram** tab, and then show Statistics. With the mouse curser placed at the corner circle of ROI, right click and select the defaults 20 x 20 mm size.
3. Measure the **Mean** value of each homogenous substance of the Catphan Phantom by placing the ROI on each of the outlined regions as in Figure 46.
4. Record the values in the data table.

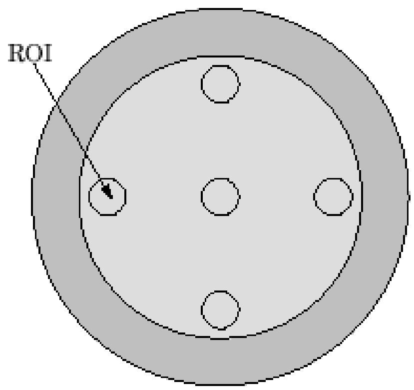


Figure 46: ROI Placement for Uniformity Measurements

5. Verify the difference between mean HU Value **Center ROI #5** (reference value) and mean HU values for each of the peripheral ROIs (**#1 Left; #2 Top** ; **#3 Right** & **#4 Bottom**)
6. Repeat the above steps for CBCT mode ***Pelvis***.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 18.3 – Image Uniformity Measurements				
Standard-Dose Head Scan	**HU Value**	**HU Value Center (#5)**	**Calculation** **HU Difference**	**Specification**
	A	**B**	**C = A - B**	
Left (#1)				± 30 HU
Top (#2)				
Right (#3)				
Bottom (#4)				
Standard-Dose Pelvis Scan	**HU Value**	**HU Value Center (#5)**	**Calculation** **HU Difference**	**Specification**
	A	**B**	**C = A - B**	
Left (#1)				± 30 HU
Top (#2)				
Right (#3)				
Bottom (#4)				
Customer Demo Required				

18.4 High Contrast Resolution

Specification

This procedure verifies the Spatial Resolution of the scanned image using the High Resolution Module in the Catphan Phantom. Default CBCT slice thickness shall be 2 mm.

Test Method

1. Using the same Head scan from previous section, select the correct image slice that displays the High Resolution module by using the Page Up/ Page Down keys. See Catphan manual for module orientation. Switch off the control room lights, if required.
2. Using the Window/Level and zoom function, verify the line pair / cm.
3. Record results.
4. Repeat the above steps for CBCT mode ***Pelvis***.

Table 25: Contrast Sensitivity Table with Leeds Test Object TOR [18FG]			
Line Pair/cm	**Gap Size**	**Line Pair/cm**	**Gap Size**
1	0.500 cm	12	0.042 cm
2	0.250 cm	13	0.038 cm
3	0.167 cm	14	0.036 cm
4	0.125 cm	15	0.033 cm
5	0.100 cm	16	0.031 cm
6	0.083 cm	17	0.029 cm
7	0.071 cm	18	0.028 cm
8	0.063 cm	19	0.026 cm
9	0.056 cm	20	0.025 cm
10	0.050 cm	21	0.024 cm
11	0.045 cm		

Results (enter N/A in any boxes that do not apply)

Data Table: Section 18.4 – High Contrast Resolution		
CBCT Mode	**Specification**	**Actual**
Head Scan [2.0 mm default slice]	≥ 6 line pair/cm	
Pelvis Scan [2.0 mm default slice]	≥ 4 line pair/cm	
Customer Demo Required		

18.5 Low Contrast Resolution

Specification

Note This test section applicable to Pelvis scan only

This procedure verifies Low Contrast Resolution of scanned image using the Low Contrast Sensitivity Module in the Catphan Phantom. See data table for specifications.

Test Method

1. Using the same Pelvis scan from previous section, select the correct image slice that displays the Low Contrast Sensitivity module by using the Page Up / Page Down keys. See Catphan manual for module orientation. Switch off the control room lights as required.
2. Using the Window/Level and zoom functions, verify the Low Contrast Targets.
3. Record results.

Table 26: Supra-Slice 1% Target Diameters
2.0 mm
3.0 mm
4.0 mm
5.0 mm
6.0 mm
7.0 mm
8.0 mm
9.0 mm
15.0 mm

Results (enter N/A in any boxes that do not apply)

Data Table: Section 18.5 – Low Contrast Resolution		
CBCT Mode Pelvis	**Specification**	**Actual**
Supra - Slice 1%	Target Size: 15 mm	
Customer Demo Required		

19. Miscellaneous Items

19.1 Laser Configuration Form

Requirement

Federal law requires Varian Medical Systems to maintain specific records for system lasers.

1. Fill out the following data table.

Data Table: Section 19.1 – Laser Configuration Form				
Site Name				
Address				
City				
State/Zip			Country	
PCSN			Installation Date	
Ceiling Laser Serial Number				
Laser PN – DN				
Laser Manufacturer:	☐ LAP	☐Gammex	☐Diacor	☐Other
Sagittal Laser Serial Number				
Laser PN – DN				
Laser Manufacturer:	☐ LAP	☐Gammex	☐Diacor	☐Other
Right Lateral Laser Serial Number				
Laser PN – DN				
Laser Manufacturer:	☐ LAP	☐Gammex	☐Diacor	☐Other
Left Lateral Laser Serial Number				
Laser PN – DN				
Laser Manufacturer:	☐ LAP	☐Gammex	☐Diacor	☐Other
Backpointer Laser Serial Number				
Laser PN – DN				
Laser Manufacturer:	☐ LAP	☐Gammex	☐Diacor	☐Other
Backpointer Laser Serial Number				
Laser PN – DN				
Laser Manufacturer:	☐ LAP	☐Gammex	☐Diacor	☐Other
Barcode Scanner Laser Serial Number				
Laser PN – DN				
Laser Manufacturer:	☐ LAP	☐Gammex	☐Diacor	☐Other

19.2 FDA Form 2579 Submission (USA Only)

Requirement

FDA Form 2579 is completed fully and submitted for USA only.

Test Method

1. Complete and submit FDA Form 2579 for USA sites.
2. Enter NA if not applicable.

Data Table: Section 19.2 – FDA Form 2579 Submission (USA Only)		
FDA Form Submission	**Specification**	**√ if YES**
Pass/Fail Criteria	FDA Form 2579 Submitted	

19.3 Second Channel Integrity Check (SCIC)

Requirement

The SCIC option shall be set to either **Enable** or **Disable** per the customer's preference and OIS.

Test Method

1. Log in to TrueBeam System Administration with an OSP user login.
2. Set SCIC preference to **YES** for **VARIAN ARIA OIS** environment or per the customer's preference.

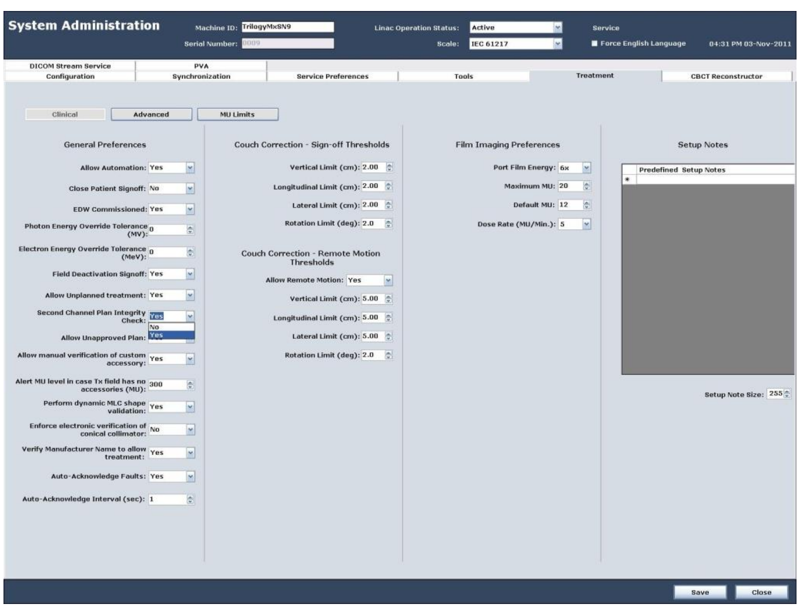


Figure 47: SCIC Preference YES with ARIA

3. Set SCIC preference to **NO** for **<u>3rd Party TPS or OIS</u>**.

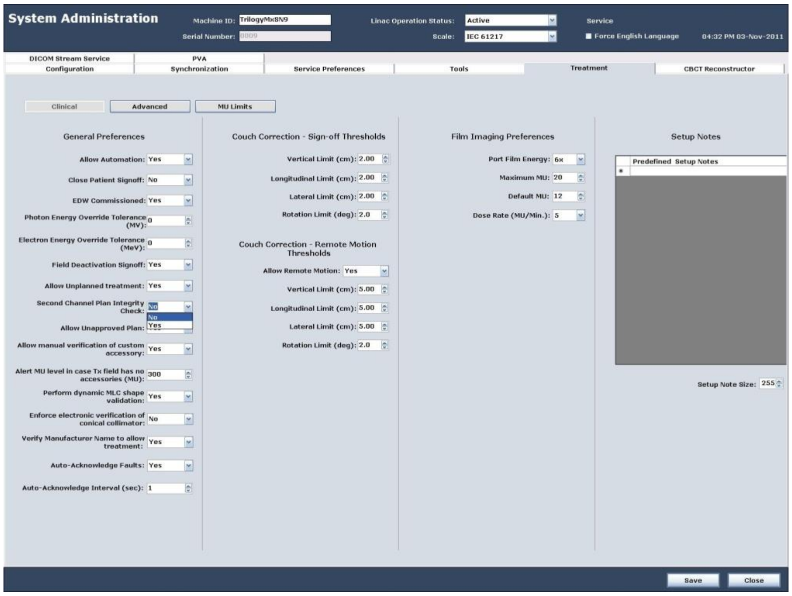


Figure 48: SCIC Preference NO for 3rd Party TPS or OIS

4. Record results.

<u>Results</u>

Data Table: Section 19.3 – Second Channel Integrity Check (SCIC)	
Pass/Fail Criteria	**√ = OK**
Set SCIC preference according to customer preference.	
Customer Demo Required	

19.4 Optical Imaging Gated MV Beam with DICOM RT Mode

Note *Enter NA in the data table of this section if Optical Imaging is not purchased.*

Requirement

System shall track gating Marker Block B501928, hold-off MV Beam according to simulated breathing cycle, and save a copy of the treatment record.

Test Method

1. This test is performed in Treatment mode with a DICOM RT test patient.
2. If machine is installed with PerfectPitch couch top, verify the Pitch and Roll are leveled at showing 0.0° on PRO screen.
3. Setup the gating phantom (Powered ON) on the couch top (near isocenter).
4. Launch Treatment application.
5. Using file mode, open test patient **TrueBeam_SVS_GATING_rev_x** in folder; D:/*VMSOS\AppData\TDS\Input\Treatment\TrueBeam IPA*

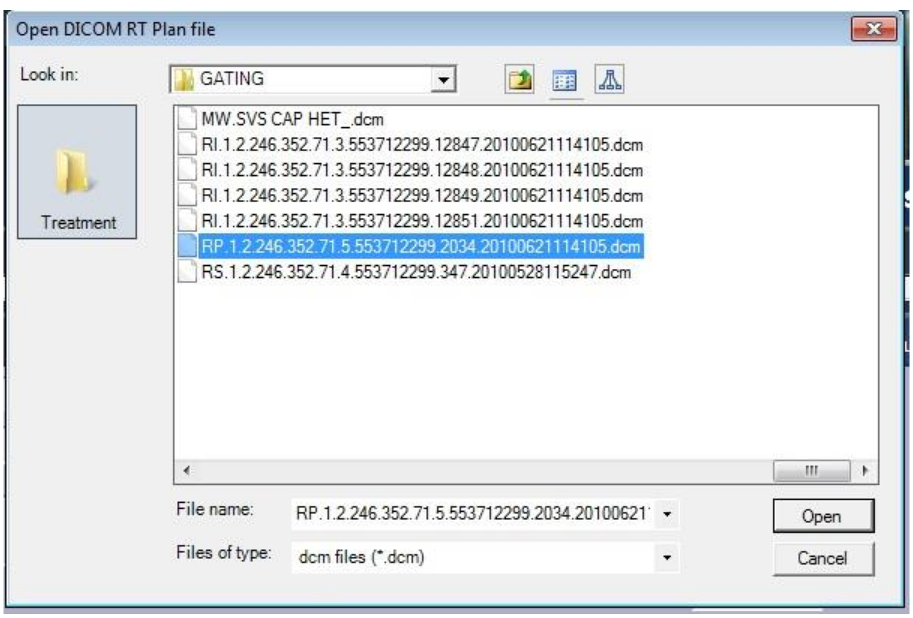


Figure 49: Opening Gating Dicom RT File

6. Click Apply on the pop up Motion Management Devices window to accept preferences for current session only. (see Figure 50)

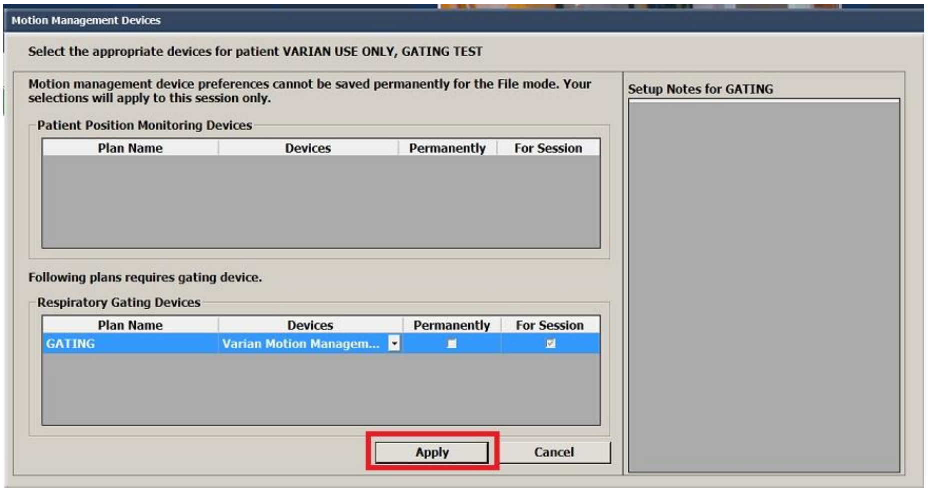


Figure 50: Motion Management Device Screen

7. Perform any Machine Overrides.

8. On the right side monitor, select **Amplitude Gating** shown in Figure 51. Click **Next**.

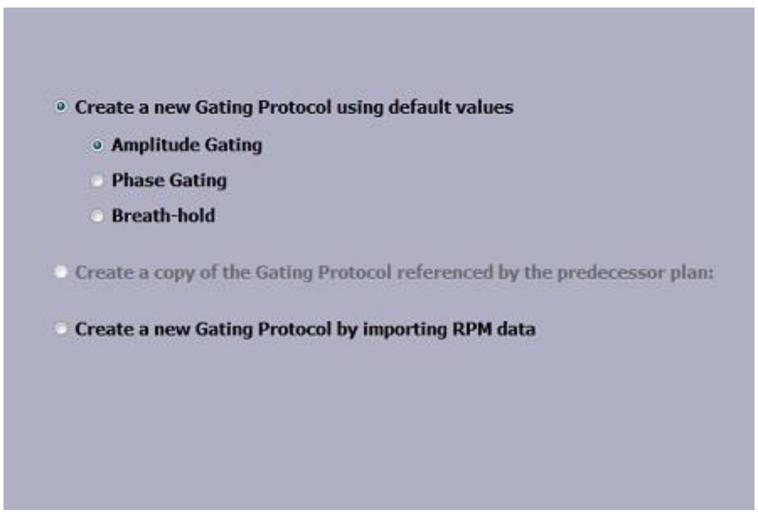


Figure 51: Amplitude Gating Selected

9. Set the Gating Setup as shown Figure 52 in and click **Next**.

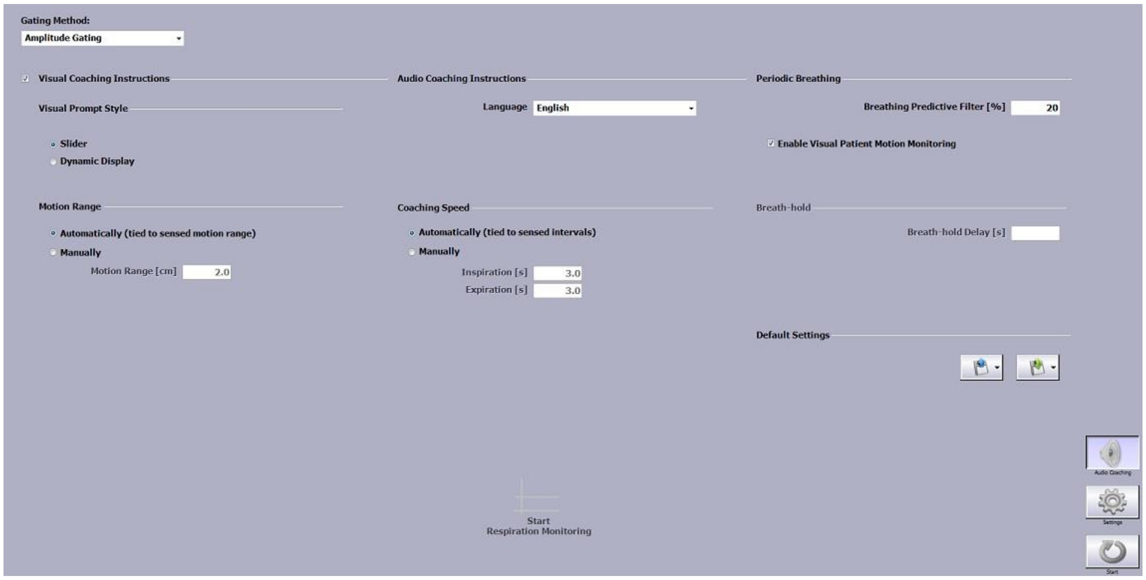


Figure 52: Gating Setup Screen

10. The Gating system will start to detect and learn the breathing pattern. Once the learning pattern is achieved, the breathing curve will be shown as in Figure 53.

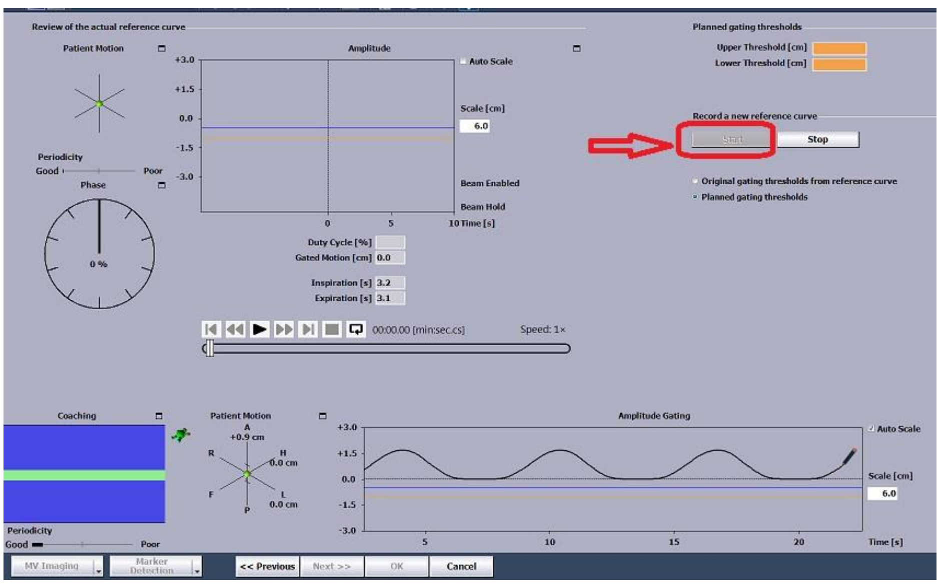


Figure 53: Acquire Breathing Pattern

11. Select **START** as shown in Figure 53 to acquire Reference Curve. After ~ 10 seconds, click **Stop** to stop acquisition.

12. The acquired reference curve shall be shown as in Figure 54. Drag the blue and orange gating threshold lines on the reference curve to set a desire gated period. Select **OK** to continue.

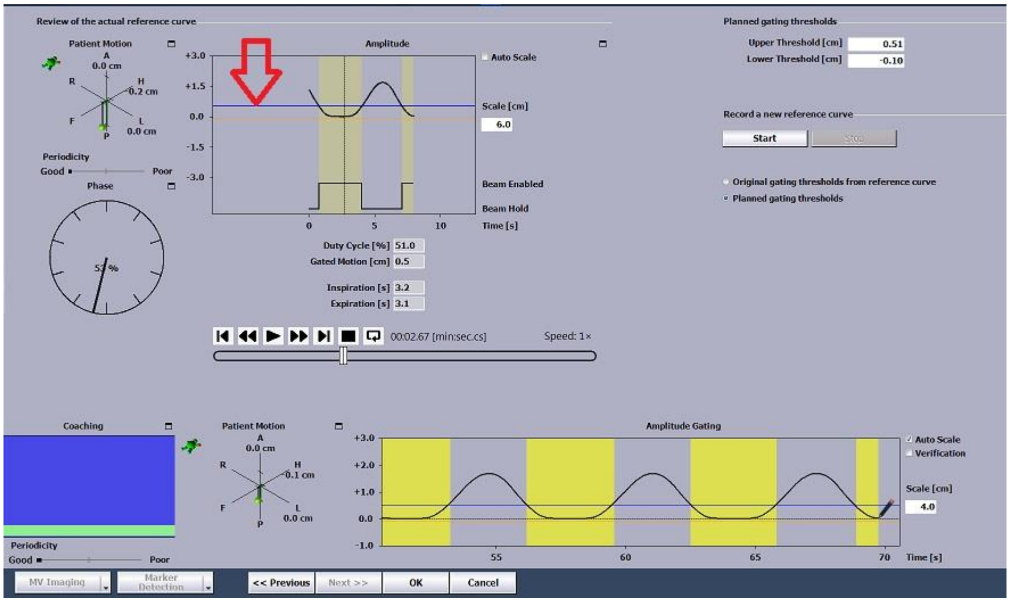


Figure 54: Changing Threshold on Reference Curve

13. Depending upon position, acquire new couch position as shown in Figure 55 and then click Apply to continue. Do not reposition Gating phantom outside NDI camera detection zone by moving couch. Click **OK** to the expected PVA error message that indicates changes to the couch positions in the selected field.

Figure 55: Acquiring Couch Positions

14. Go in to treatment room and verify audio coaching can be heard from the in-room speakers.

15. Exit treatment room. Beam on when ready.

16. Verify beam hold is functioning according to beam set thresholds.

17. When the field is completed, Sign off and save the patient with a unique filename before closing.

18. Using Windows explorer, browse to *D:\VMSOS\AppData\TDS\Output\Treatment\Record* folder. Verify a copy of the treatment history of the Gating patient is saved onto a local directory.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 19.4 – Optical Imaging Gated MV Beam with DICOM RT Mode	
Pass/Fail Criteria	**√ = O.K**
Audio coaching can be heard in the treatment room.	
Gated beam treatment field successfully completed.	
Saved copy of treatment record onto a local directory.	
Customer Demo Required	

19.5 EXIO and MMI Functionality Verification

This section is to verify that EXIO hardware and interfaces are working properly during installation. This section shall be performed even if MMI option is not purchased but EXIO hardware installed. If EXIO hardware is not available for the system, then enter NA in the data tables for this section.

19.5.1 EXIO Loopback Testing

Requirement

Confirm the operation of the EXIO Subcomponent's RS422 and Digital I/O channels without having any signals leave the PCB.

Test Method

Note *No testing hardware is required to perform this test.*

1. Log in to Service mode as Hasp user
2. Select tab: External Interface > EXIO > Loopback Diagnostics > Internal
3. Test the Digital Channels:
   A. Select Channel 1.
   B. Click one of the buttons in the **DO** (digital output) column.
   C. The corresponding LED in the **DI** (digital input) column will toggle state.
   D. All eight digital channels shall be tested in this manner.
4. Repeat step 3 for remaining channel 2 to 6.
5. Test the serial channel:
   A. In the Serial Data Communications pull down menu, click one of the data selections.
   B. Click **Send** to transfer the data and verify serial data is displayed in the text box
6. Record tests status in the data table.
7. Before exiting the EXIO > Loopback diagnostics screen, select loopback mode**: None**

Results (enter N/A in any boxes that do not apply)

Data Table: Section 19.5.1 – EXIO Loopback Testing	
Test Criteria	**√ = OK**
All Internal EXIO tests passed.	

19.5.2 MMI – EXGI Simulator Test

Note *This testing can only be performed by Varian CSR by referencing to instructions in SIM-HT.*

This procedure tests the EXIO sub-controller connections 1 - 4 using loopback cable PN 100058451-01.

There are six connections at the rear of the EXIO sub-controller. Connections 1 through 4 connect to external gating devices. Connections 5 and 6 are utilized by Varian personnel for testing purpose only and shall not be tested here.

Requirement

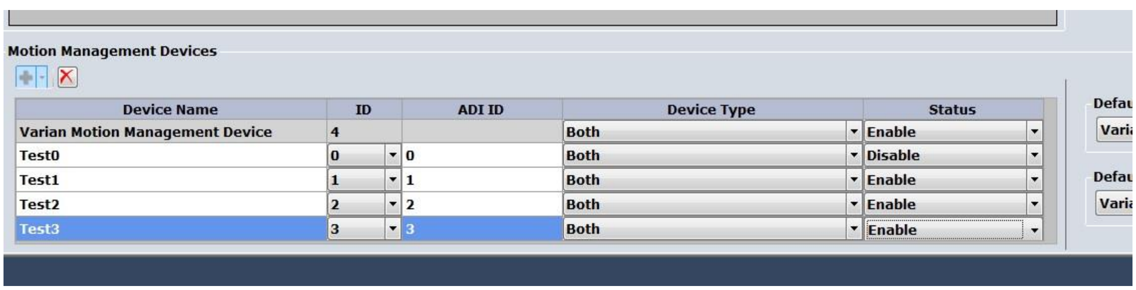
- Must be able to Assert and Release **CDOS** from the EXGI Simulator.
- Must be able to **Gate Beam** (Assert and Release) from the EXGI Simulator.

Test Method

1. Adding MMI devices:

A. Add four devices (0-3) in System Administration. For instructions on how to add these devices refer to SIM-HT-20, section: Adding a MMI Device to TrueBeam 2.0.

B. See Figure 56 for an example of the added devices in System Administration. These devices will be for EXGI simulator testing in this section.



Device Name	ID	ADI ID	Device Type	Status
Varian Motion Management Device	4		Both	Enable
Test0	0	0	Both	Disable
Test1	1	1	Both	Enable
Test2	2	2	Both	Enable
Test3	3	3	Both	Enable

Figure 56: Example of Configuring MMI Devices for Testing

2. Setup the EXGI simulator and loopback cable per the SIM-HT-20, section: EXGI Simulator Testing.

3. See either Table 27 or Table 28 (single console cabinet) for the loopback cable and simulator configurations specific to this test.

Table 27: Loopback cable / Simulator configuration		
Gating Device EXIO_in	**Simulator channels EXIO_out**	**EXGI Simulator Channel**
EXIO channel 1 PP-J23	EXIO channel 5 PP-J32	Channel 1
EXIO channel 2 PP-J26		Channel 2
EXIO channel 3 PP-J29		Channel 3
EXIO channel 4 PP-J31		Channel 4
EXIO channel 1 PP-J2	EXIO channel 6 PP-J33	Channel 1

Table 28: Loopback cable / Simulator configuration (Single Console Cabinet)		
Gating Device EXIO_in	**Simulator channels EXIO_out**	**EXGI Simulator Channel**
EXIO channel 1 PP-J161	EXIO channel 5 PP-J165	Channel 1
EXIO channel 2 PP-J162		Channel 2
EXIO channel 3 PP-J163		Channel 3
EXIO channel 4 PP-J164		Channel 4
EXIO channel 1 PP-J161	EXIO channel 6 PP-J166	Channel 1

4. With the EXGI Simulator, Click “Assert” and “Release” **CDOS** for each Gating Device channel. Figure 57 is an example of a successful assertion of **CDOS** test

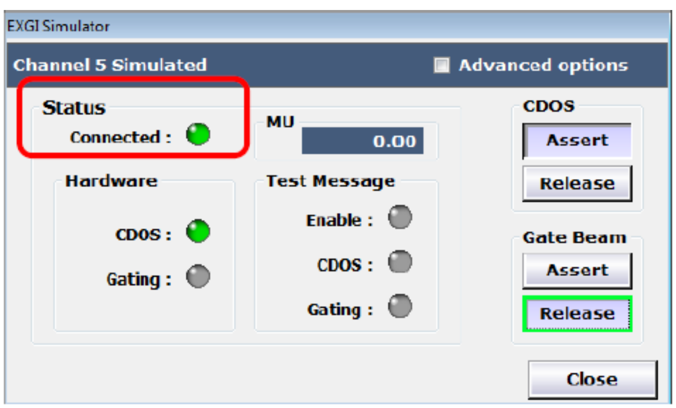


Figure 57: Successful CDOS Exertion Test

5. With the EXGI Simulator, click “Assert” and “Release” **Gate Beam** for each Gating Device channel. See Figure 58 for an example of a successful **Gate Beam** assertion test.
6. Record tests status in the data table.

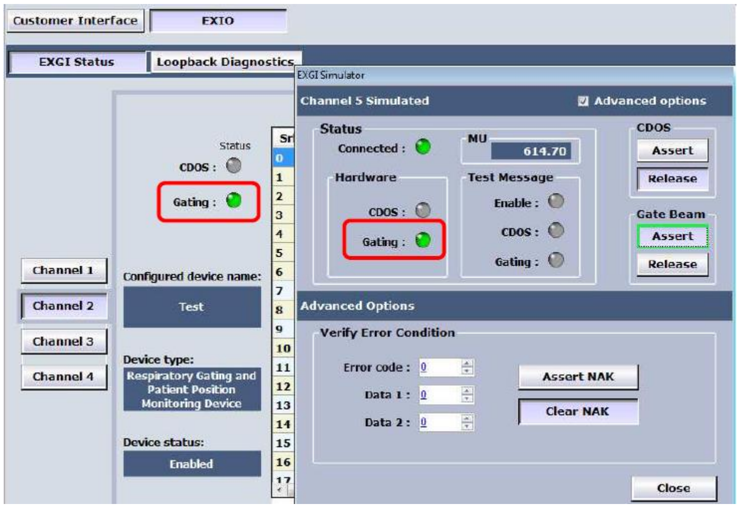


Figure 58: Successful of Gate Beam Assertion Test

<u>Results (enter N/A in any boxes that do not apply)</u>

Data Table: Section 19.5.2 – MMI – EXGI Simulator Test	
Test Criteria	**√ = OK**
CDOS test successful for all tested channels.	
Gate Beam test successful for all tested channels,	

20. Varian Verification System (VVS) Installation

Requirement

VVS installation and IPA completed when included in sales order.

Test Method

1. Verify that VVS is installed and IPA-AC-HTVVS completed.
2. Enter NA if not purchased or is not installed at this time.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 20 - Varian Verification System (VVS) Installation	
Test Criteria	**√ = OK**
VVS installation and IPA-AC-HTVVS completed.	
Customer Demo Required	

21. Calypso and Optical Surface Monitoring system (OSMS)

Requirement

Calypso and OSMS installation and IPAs completed when included in sales order.

Test Method

3. Verify that Calypso is installed and IPA-CL completed.
4. Verify that OSMS is installed and IPA-OM completed.
5. Enter NA if not purchased or is not installed at this time.

Results (enter N/A in any boxes that do not apply)

Data Table: Section 21 - Calypso and Optical Surface Monitoring system (OSMS)	
Test Criteria	**√ = OK**
Calypso installation and IPA-CL completed.	
OSMS installation and IPA-OM completed.	
Customer Demo Required	

22. Customer Documentation

22.1 Delivery of Customer Documentation

Requirement

The customer shall be provided with customer documentation for this Varian product. Customer documentation includes any of the following in either paper or electronic format: Customer Release Notes (CRNs), Instructions for Use, Safety Manuals, Reference Guides, Data Books, and any other customer reference documents shipped with this product.

Test Method

1. From the PSE Data Center, download the language appropriate Customer Release Notes (CRNs) for the installed software version of each installed product.
   - If specified, load the CRN files, and any other required documentation, as directed by the appropriate HIM, SIM or STB and inform the customer of the location of these files.
   - If not specified, load the files in a new **Customer Documentation** folder on the applicable workstation desktop and inform the customer of this folder location.
2. Inform the customer of the location at their site of all paper and electronic customer documentation for all installed products.

Results

Data Table: Section 22.1 – Delivery of Customer Documentation	
Test Criteria	**√ = OK**
Customer documentation for this product has been delivered to the customer.	
Customer Demo Required	

22.2 Access to My.Varian.com

Note *This section is for instructional information only. No actual website demonstration is required. Customer can access the website at their leisure.*

Enter NA in the data table if this task was previously demonstrated to the customer.

Requirement

1. Explain to the customer how to access the MyVarian webpage (https://my.varian.com) and how to create a personal login account by clicking on the link **Create new account**.
2. Explain that after logging in to the **MyVarian** website, the customer should click on the link **Product Documentation** in the menu on the left. Select the desired product and select the desired **Document type***:*
   - Select **CTBs** to display all the related Customer Technical Bulletins for the product.
   - Select **Release Notes** to display all the related Customer Release Notes for the product.
   - Select **Safety Notifications** to display all the related PNL-FSNs for the product.
3. Explain to the customer that it is their responsibility to remain up-to-date with the latest available CTBs and CRNs for their purchased products.

Results

Data Table: Section 22.2 – Access to My.Varian.com	
Test Criteria	**√ = OK**
Customer has been instructed how to locate CTBs, CRNs and PNL-FSNs on the **MyVarian** website.	
Customer understands their responsibility to remain up to date with product CTBs and CRNs.	
Customer Demo Required	

23. Customer Basic Operational Training

Note *This section contains basic TrueBeam operational information to allow the customer to start beam commissioning work prior to Applications training. It is customer's option to skip this section if already familiar with the machine operation.* ***No signature is required****.*

Complete training conducted by Varian Applications Specialist at a scheduled date coordinated between the customer and Applications department.

Table 29: Customer Basic Operational Training
Modulator
Identify the START button.
Explain the presence of HV in the modulator and the Crowbar noise when opening the door.
Explain the doors must be closed to clear the MOD interlock.
Stand
SF6 gas system nominal pressure [32 psig]--demonstrate how to refill.
Explain the water level check and how to refill water (distilled only).
Couch
Explain proper pendant storage position (Routine Interlock and holder light indicator).
Demonstrate couch longitudinal and lateral brakes (also cause Routine Interlock if released).
Demonstrate axes motion (including the arms) using pendant.
Collimator and Accessories
Explain crosshair cannot be cleaned with water or cloth.
Explain Interface Mount LEDs and latches.
Demonstrate Accessory Mount install and removal and tray latch.
Demonstrate Electron applicators and collision protection (touchguard).
Explain that Electron applicators cannot be stored with weight on the touch guards.
Console
Explain the control console operations.
Explain the major mode options and standard login (SysAdmin).
Safety Circuit, Power Down and Power Up
Identify the location of all the machine EMO switches (control console, modulator, Stand, and couch) and the customer EMO switches.
Identify the location of Emergency Disconnect Switch (normally located on the GE breaker panel). Explain the difference of Emergency Disconnect Switch and normal EMO switches.
Put system to Standby state and turn off all console computers. Demonstrate machine power off by pressing the Emergency Disconnect Switch.
Demonstrate resetting of Emergency Disconnect Switch and system power up sequence.
Demonstrate all axes initialization using the "Axes Initialization" option in Major Mode.
Login to Treatment mode and load a test patient. Demonstrate emergency off by pressing one of the EMO switches. Reset EMO switch and restart machine. Explain that Axes Initialization is required if EMO switch is pressed in any mode other than Treatment. No demonstration is required.

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Appendix A Using Offline QA Application

Note *Refer to SIM-HT to install Offline QA Application in the Service WS.*

1. Double click the *OfflineQA.exe* icon on the Service WS's desktop.
2. Log in with PassKey HASP Basic rights.
3. Click **Review** in the left column of the screen.
4. Click on the "browse" icon. See Figure 59.

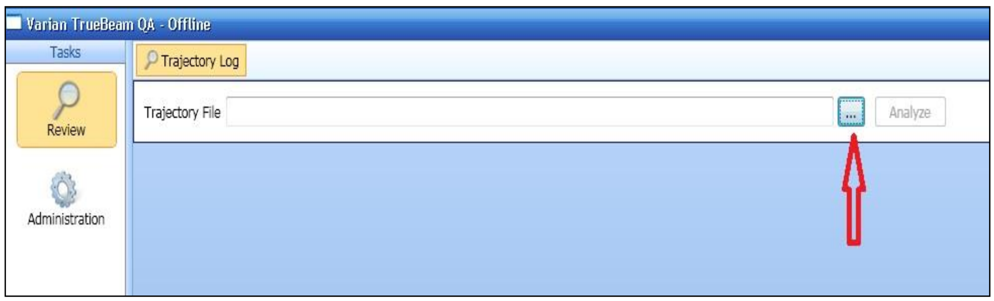

Figure 59: Offline QA Review Screen

5. Browse to the shared *Daily QA* folder on the TrueBeam WS and select the **.bin** file to be analyzed.

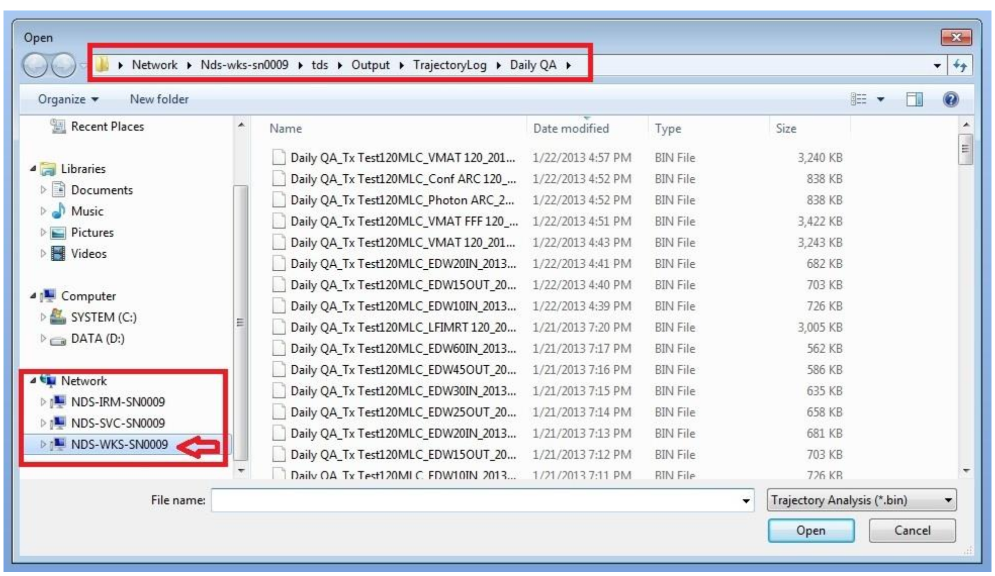

Figure 60: File Selection Window

6. Click the **Analyze** button in the upper right corner of the screen. This will open the file for the selected field.

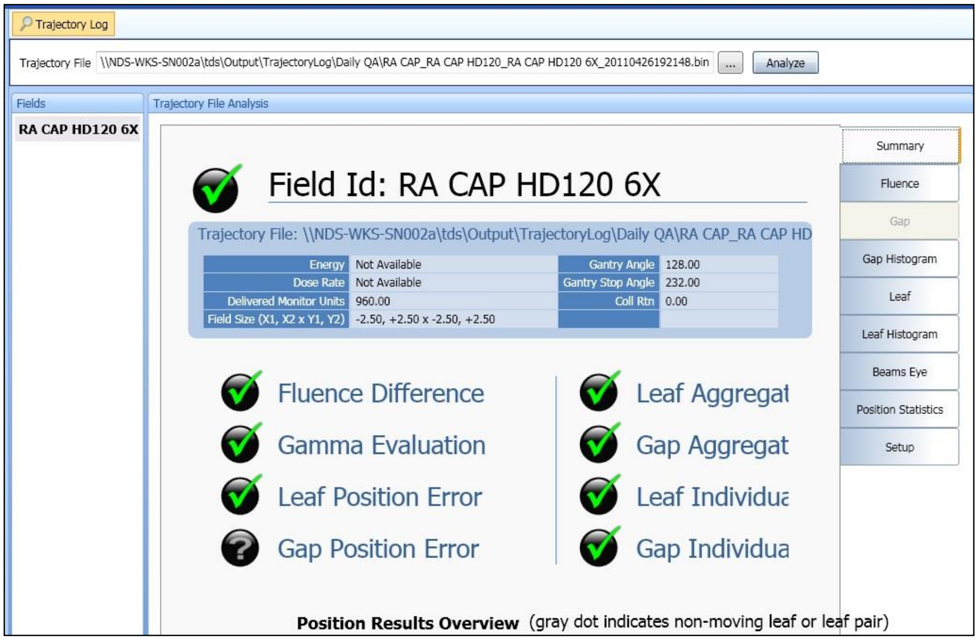

Figure 61: Selection of File for Review

7. Select the **Setup** tab on the right side column on the screen, and verify the set values are the same as shown in the following figure. If not, edit the values accordingly.

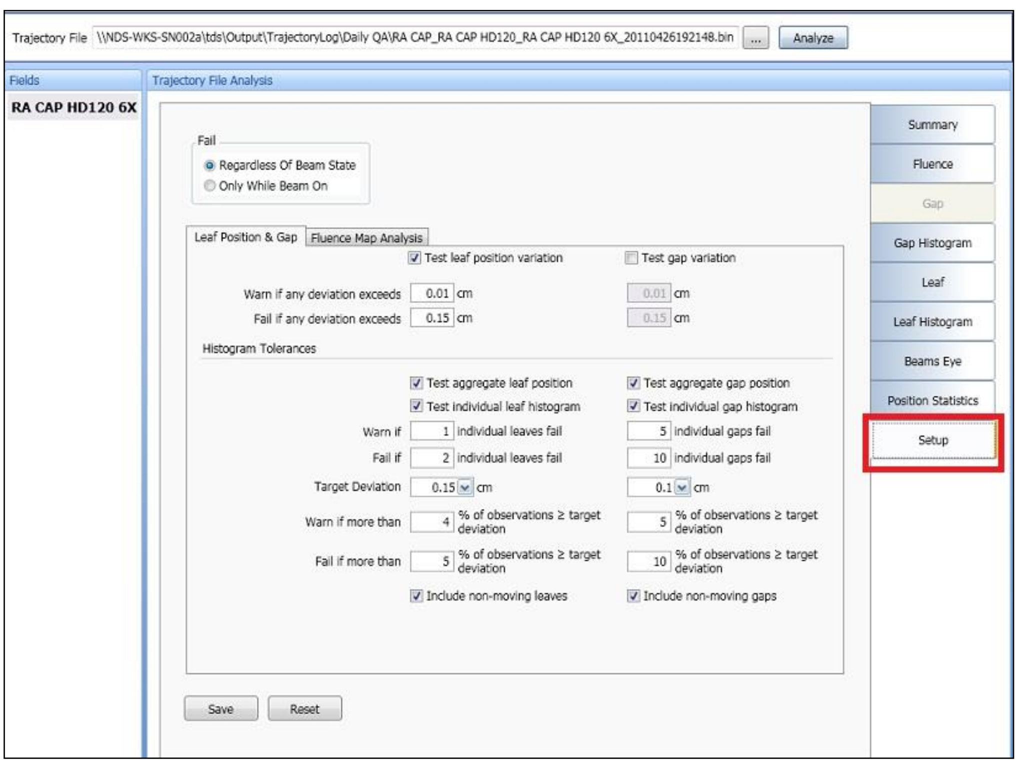

Figure 62: Setup Screen

8. Select the Position Statistic as shown in Figure 63. Verify the values meet the specification of the executed test plan.

A. Jaws Position RMS Error

B. Gantry Position RMS Error

C. MU RMS Error

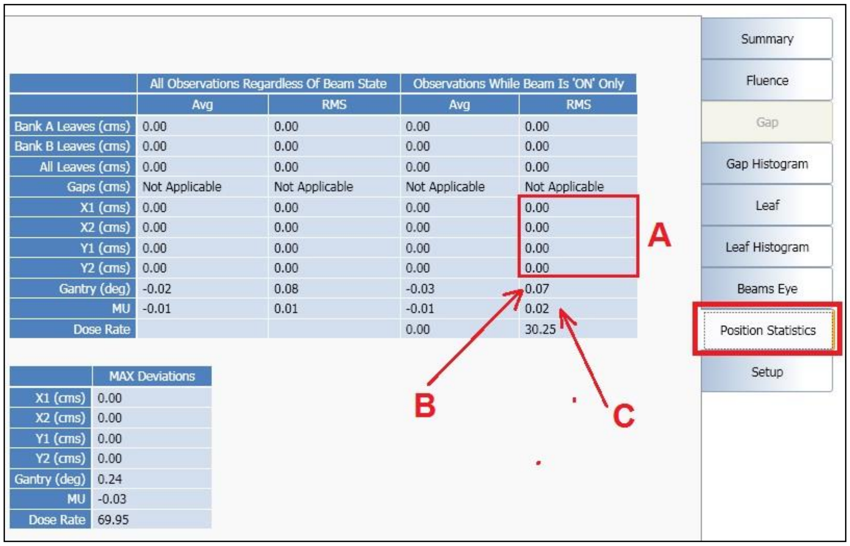

Figure 63: Example of Position Statistics Screen

9. Select the **Leaf** tab, and verify all required measurements meet specification. Use the small arrows at the top of the screen to move through the leaf numbers for each bank.

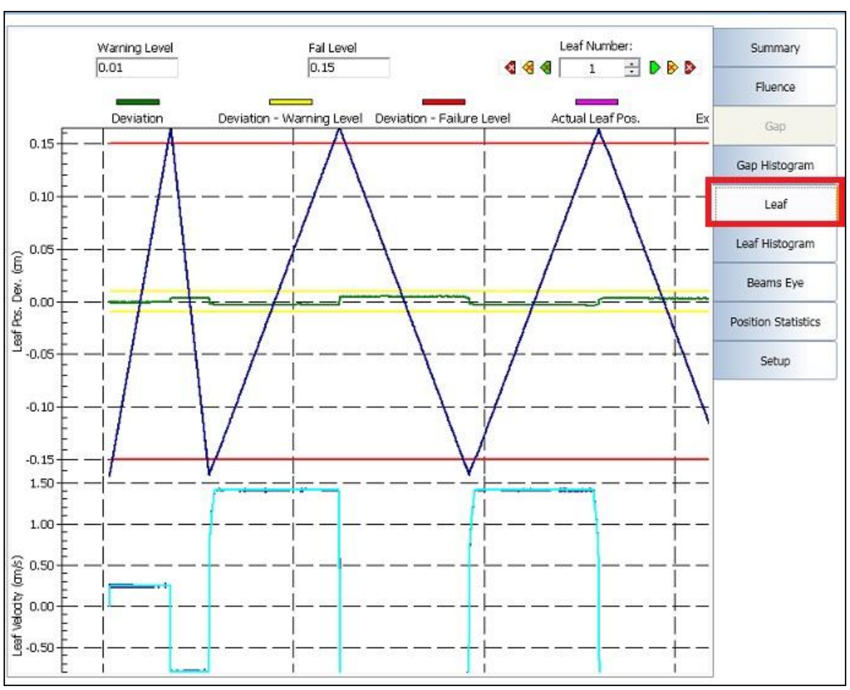

Figure 64: Example of Leaf Screen

10. Select the **Leaf Histogram** tab, and verify all required measurements meet specification.

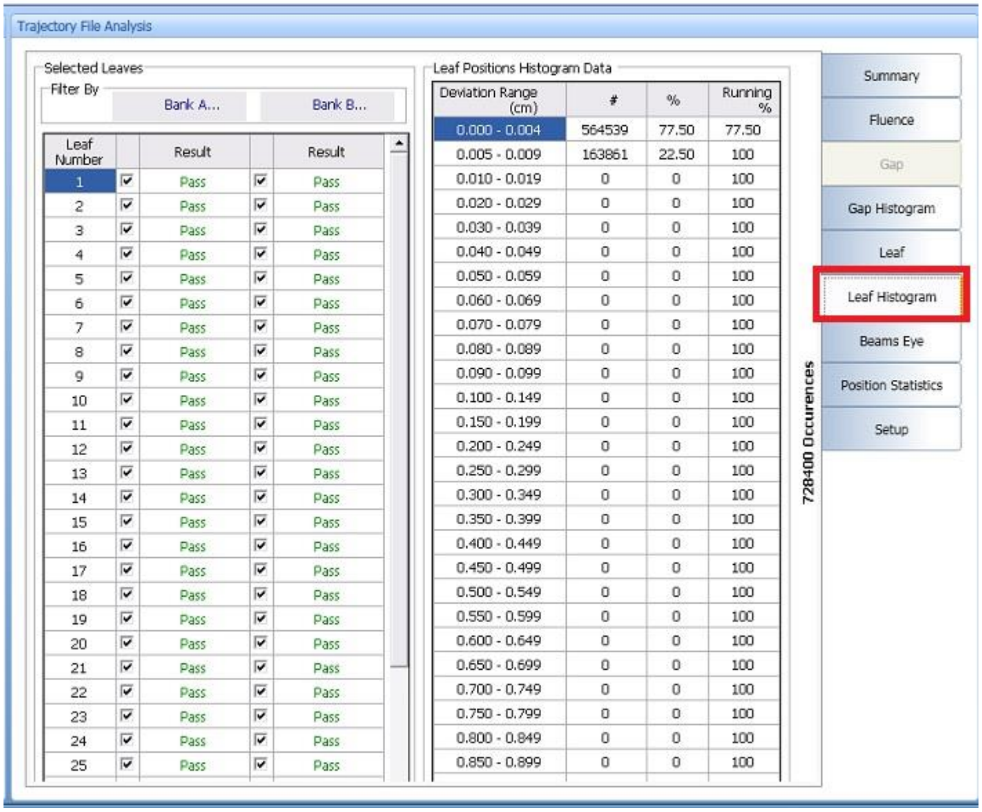

Figure 65: Example of Leaf Histogram Screen