

#### **Technical Publications**

Direction 5429007-1EN Rev. 1



# **Brivo NM 615 Nuclear Medicine Imaging System**

**Pre-Installation Manual** 











ПРЕДУПРЕЖД ЕНИЕ (BG)	<ul> <li>Това упътване за работа е налично само на английски език.</li> <li>Ако доставчикът на услугата на клиента изиска друг език, задължение на клиента е да осигури превод.</li> <li>Не използвайте оборудването, преди да сте се консултирали и разбрали упътването за работа.</li> <li>Неспазването на това предупреждение може да доведе до нараняване на доставчика на услугата, оператора или пациента в резултат на токов удар, механична или друга опасност.</li> </ul>
警告 (ZH-CN)	本维修手册仅提供英文版本。 • 如果客户的维修服务人员需要非英文版本,则客户需自行提供翻译服务。 • 未详细阅读和完全理解本维修手册之前,不得进行维修。 • 忽略本警告可能对维修服务人员、操作人员或患者造成电击、机械伤害或其他形式的伤害。
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警告 (ZH-TW)	本維修手冊僅有英文版。 • 若客戶的維修廠商需要英文版以外的語言,應由客戶自行提供翻譯服務。 • 請勿試圖維修本設備,除非 您已查閱並瞭解本維修手冊。 • 若未留意本警告,可能導致維修廠商、操作員或病患因觸電、機械或其他危險而受傷。
UPOZORENJE (HR)	<ul> <li>Ovaj servisni priručnik dostupan je na engleskom jeziku.</li> <li>Ako davatelj usluge klijenta treba neki drugi jezik, klijent je dužan osigurati prijevod.</li> <li>Ne pokušavajte servisirati opremu ako niste u potpunosti pročitali i razumjeli ovaj servisni priručnik.</li> <li>Zanemarite li ovo upozorenje, može doći do ozljede davatelja usluge, operatera ili pacijenta uslijed strujnog udara, mehaničkih ili drugih rizika.</li> </ul>
VÝSTRAHA (CS)	<ul> <li>Tento provozní návod existuje pouze v anglickém jazyce.</li> <li>V případě, že externí služba zákazníkům potřebuje návod v jiném jazyce, je zajištění překladu do odpovídajícího jazyka úkolem zákazníka.</li> <li>Nesnažte se o údržbu tohoto zařízení, aniž byste si přečetli tento provozní návod a pochopili jeho obsah.</li> <li>V případě nedodržování této výstrahy může dojít k poranění pracovníka prodejního servisu, obslužného personálu nebo pacientů vlivem elektrického proudu, respektive vlivem mechanických či jiných rizik.</li> </ul>











ADVARSEL (DA)	<ul> <li>Denne servicemanual findes kun på engelsk.</li> <li>Hvis en kundes tekniker har brug for et andet sprog end engelsk, er det kundens ansvar at sørge for oversættelse.</li> <li>Forsøg ikke at servicere udstyret uden at læse og forstå denne servicemanual.</li> <li>Manglende overholdelse af denne advarsel kan medføre skade på grund af elektrisk stød, mekanisk eller anden fare for teknikeren, operatøren eller patienten.</li> </ul>
WAARSCHUWING (NL)	<ul> <li>Deze onderhoudshandleiding is enkel in het Engels verkrijgbaar.</li> <li>Als het onderhoudspersoneel een andere taal vereist, dan is de klant verantwoordelijk voor de vertaling ervan.</li> <li>Probeer de apparatuur niet te onderhouden alvorens deze onderhoudshandleiding werd geraadpleegd en begrepen is.</li> <li>Indien deze waarschuwing niet wordt opgevolgd, zou het onderhoudspersoneel, de operator of een patiënt gewond kunnen raken als gevolg van een elektrische schok, mechanische of andere gevaren.</li> </ul>
WARNING (EN)	<ul> <li>This service manual is available in English only.</li> <li>If a customer's service provider requires a language other than english, it is the customer's responsibility to provide translation services.</li> <li>Do not attempt to service the equipment unless this service manual has been consulted and is understood.</li> <li>Failure to heed this warning may result in injury to the service provider, operator or patient from electric shock, mechanical or other hazards.</li> </ul>
HOIATUS (ET)	<ul> <li>See teenindusjuhend on saadaval ainult inglise keeles</li> <li>Kui klienditeeninduse osutaja nõuab juhendit inglise keelest erinevas keeles, vastutab klient tõlketeenuse osutamise eest.</li> <li>Ärge üritage seadmeid teenindada enne eelnevalt käesoleva teenindusjuhendiga tutvumist ja sellest aru saamist.</li> <li>Käesoleva hoiatuse eiramine võib põhjustada teenuseosutaja, operaatori või patsiendi vigastamist elektrilöögi, mehaanilise või muu ohu tagajärjel.</li> </ul>
VAROITUS (FI)	<ul> <li>Tämä huolto-ohje on saatavilla vain englanniksi.</li> <li>Jos asiakkaan huoltohenkilöstö vaatii muuta kuin englanninkielistä materiaalia, tarvittavan käännöksen hankkiminen on asiakkaan vastuulla.</li> <li>Älä yritä korjata laitteistoa ennen kuin olet varmasti lukenut ja ymmärtänyt tämän huolto-ohjeen.</li> <li>Mikäli tätä varoitusta ei noudateta, seurauksena voi olla huoltohenkilöstön, laitteiston käyttäjän tai potilaan vahingoittuminen sähköiskun, mekaanisen vian tai muun vaaratilanteen vuoksi.</li> </ul>











ATTENTION (FR)	<ul> <li>Ce manuel d'installation et de maintenance est disponible uniquement en anglais.</li> <li>Si le technicien d'un client a besoin de ce manuel dans une langue autre que l'anglais, il incombe au client de le faire traduire.</li> <li>Ne pas tenter d'intervenir sur les équipements tant que ce manuel d'installation et de maintenance n'a pas été consulté et compris.</li> <li>Le non-respect de cet avertissement peut entraîner chez le technicien, l'opérateur ou le patient des blessures dues à des dangers électriques, mécaniques ou autres.</li> </ul>
WARNUNG (DE)	<ul> <li>Diese Serviceanleitung existiert nur in englischer Sprache.</li> <li>Falls ein fremder Kundendienst eine andere Sprache benötigt, ist es Aufgabe des Kunden für eine entsprechende Übersetzung zu sorgen.</li> <li>Versuchen Sie nicht diese Anlage zu warten, ohne diese Serviceanleitung gelesen und verstanden zu haben.</li> <li>Wird diese Warnung nicht beachtet, so kann es zu Verletzungen des Kundendiensttechnikers, des Bedieners oder des Patienten durch Stromschläge, mechanische oder sonstige Gefahren kommen.</li> </ul>
ΠΡΟΕΙΔΟΠΟΙΗ ΣΗ (EL)	<ul> <li>Το παρόν εγχειρίδιο σέρβις διατίθεται μόνο στα αγγλικά.</li> <li>Εάν ο τεχνικός σέρβις ενός πελάτη απαιτεί το παρόν εγχειρίδιο σε γλώσσα εκτός των αγγλικών, αποτελεί ευθύνη του πελάτη να παρέχει τις υπηρεσίες μετάφρασης.</li> <li>Μην επιχειρήσετε την εκτέλεση εργασιών σέρβις στον εξοπλισμό αν δεν έχετε συμβουλευτεί και κατανοήσει το παρόν εγχειρίδιο σέρβις.</li> <li>Αν δεν προσέξετε την προειδοποίηση αυτή, ενδέχεται να προκληθεί τραυματισμός στον τεχνικό σέρβις, στο χειριστή ή στον ασθενή από ηλεκτροπληξία, μηχανικούς ή άλλους κινδύνους.</li> </ul>
FIGYELMEZTE TÉS (HU)	<ul> <li>Ezen karbantartási kézikönyv kizárólag angol nyelven érhető el.</li> <li>Ha a vevő szolgáltatója angoltól eltérő nyelvre tart igényt, akkor a vevő felelőssége a fordítás elkészíttetése.</li> <li>Ne próbálja elkezdeni használni a berendezést, amíg a karbantartási kézikönyvben leírtakat nem értelmezték.</li> <li>Ezen figyelmeztetés figyelmen kívül hagyása a szolgáltató, működtető vagy a beteg áramütés, mechanikai vagy egyéb veszélyhelyzet miatti sérülését eredményezheti.</li> </ul>
AÐVÖRUN (IS)	<ul> <li>Þessi þjónustuhandbók er aðeins fáanleg á ensku.</li> <li>Ef að þjónustuveitandi viðskiptamanns þarfnast annas tungumáls en ensku, er það skylda viðskiptamanns að skaffa tungumálaþjónustu.</li> <li>Reynið ekki að afgreiða tækið nema að þessi þjónustuhandbók hefur verið skoðuð og skilin.</li> <li>Brot á sinna þessari aðvörun getur leitt til meiðsla á þjónustuveitanda, stjórnanda eða sjúklings frá raflosti, vélrænu eða öðrum áhættum.</li> </ul>









AVVERTENZA (IT)	<ul> <li>Il presente manuale di manutenzione è disponibile soltanto in lingua inglese.</li> <li>Se un addetto alla manutenzione richiede il manuale in una lingua diversa, il cliente è tenuto a provvedere direttamente alla traduzione.</li> <li>Procedere alla manutenzione dell'apparecchiatura solo dopo aver consultato il presente manuale ed averne compreso il contenuto.</li> <li>Il mancato rispetto della presente avvertenza potrebbe causare lesioni all'addetto alla manutenzione, all'operatore o ai pazienti provocate da scosse elettriche, urti meccanici o altri rischi.</li> </ul>
警告 (JA)	<ul> <li>このサービスマニュアルには英語版しかありません。</li> <li>サービスを担当される業者が英語以外の言語を要求される場合、翻訳作業はその業者の責任で行うものとさせていただきます。</li> <li>このサービスマニュアルを熟読し理解せずに、装置のサービスを行わないでください。</li> <li>この警告に従わない場合、サービスを担当される方、操作員あるいは患者さんが、感電や機械的又はその他の危険により負傷する可能性があります。</li> </ul>
경고 (KO)	본 서비스 매뉴얼은 영어로만 이용하실 수 있습니다.     고객의 서비스 제공자가 영어 이외의 언어를 요구할 경우, 번역 서비스를 제공하는 것은 고객의 책임입니다.     본 서비스 매뉴얼을 참조하여 숙지하지 않은 이상 해당 장비를 수리하려고 시도하지 마십시오.     본 경고 사항에 유의하지 않으면 전기 쇼크, 기계적 위험, 또는 기타 위험으로 인해 서비스제공자,사용자 또는 환자에게 부상을 입힐 수 있습니다.
BRDINJUMS (LV)	<ul> <li>Šī apkopes rokasgrāmata ir pieejama tikai angļu valodā.</li> <li>Ja klienta apkopes sniedzējam nepieciešama informācija citā valodā, klienta pienākums ir nodrošināt tulkojumu.</li> <li>Neveiciet aprīkojuma apkopi bez apkopes rokasgrāmatas izlasīšanas un saprašanas.</li> <li>Šī brīdinājuma neievērošanas rezultātā var rasties elektriskās strāvas trieciena, mehānisku vai citu faktoru izraisītu traumu risks apkopes sniedzējam, operatoram vai pacientam.</li> </ul>
ĮSPĖJIMAS (LT)	Šis eksploatavimo vadovas yra tik anglų kalba.  • Jei kliento paslaugų tiekėjas reikalauja vadovo kita kalba – ne anglų, suteikti vertimo paslaugas privalo klientas.  • Nemėginkite atlikti įrangos techninės priežiūros, jei neperskaitėte ar nesupratote šio eksploatavimo vadovo.  • Jei nepaisysite šio įspėjimo, galimi paslaugų tiekėjo, operatoriaus ar paciento sužalojimai dėl elektros šoko, mechaninių ar kitų pavojų.
ADVARSEL (NO)	Denne servicehåndboken finnes bare på engelsk.  Hvis kundens serviceleverandør har bruk for et annet språk, er det kundens ansvar å sørge for oversettelse.  Ikke forsøk å reparere utstyret uten at denne servicehåndboken er lest og forstått.  Manglende hensyn til denne advarselen kan føre til at serviceleverandøren, operatøren eller pasienten skades på grunn av elektrisk støt, mekaniske eller andre farer.











OSTRZEŻENIE (PL)	<ul> <li>Niniejszy podręcznik serwisowy dostępny jest jedynie w języku angielskim.</li> <li>Jeśli serwisant klienta wymaga języka innego niż angielski, zapewnienie usługi tłumaczenia jest obowiązkiem klienta.</li> <li>Nie próbować serwisować urządzenia bez zapoznania się z niniejszym podręcznikiem serwisowym i zrozumienia go.</li> <li>Niezastosowanie się do tego ostrzeżenia może doprowadzić do obrażeń serwisanta, operatora lub pacjenta w wyniku porażenia prądem elektrycznym, zagrożenia mechanicznego bądź innego.</li> </ul>
ATENÇÃO (PT-BR	<ul> <li>Este manual de assistência técnica encontra-se disponível unicamente em inglês.</li> <li>Se outro serviço de assistência técnica solicitar a tradução deste manual, caberá ao cliente fornecer os serviços de tradução.</li> <li>Não tente reparar o equipamento sem ter consultado e compreendido este manual de assistência técnica.</li> <li>A não observância deste aviso pode ocasionar ferimentos no técnico, operador ou paciente decorrentes de choques elétricos, mecânicos ou outros.</li> </ul>
ATENÇÃO (PT-PT)	<ul> <li>Este manual de assistência técnica só se encontra disponível em inglês.</li> <li>Se qualquer outro serviço de assistência técnica solicitar este manual noutro idioma, é da responsabilidade do cliente fornecer os serviços de tradução.</li> <li>Não tente reparar o equipamento sem ter consultado e compreendido este manual de assistência técnica.</li> <li>O não cumprimento deste aviso pode colocar em perigo a segurança do técnico, do operador ou do paciente devido a choques eléctricos, mecânicos ou outros.</li> </ul>
ATENŢIE (RO)	<ul> <li>Acest manual de service este disponibil doar în limba engleză.</li> <li>Dacă un furnizor de servicii pentru clienţi necesită o altă limbă decât cea engleză, este de datoria clientului să furnizeze o traducere.</li> <li>Nu încercaţi să reparaţi echipamentul decât ulterior consultării şi înţelegerii acestui manual de service.</li> <li>Ignorarea acestui avertisment ar putea duce la rănirea depanatorului, operatorului sau pacientului în urma pericolelor de electrocutare, mecanice sau de altă natură.</li> </ul>
OCTOРОЖНО! (RU)	<ul> <li>Данное руководство по техническому обслуживанию представлено только на английском языке.</li> <li>Если сервисному персоналу клиента необходимо руководство не на английском, а на каком-то другом языке, клиенту следует самостоятельно обеспечить перевод.</li> <li>Перед техническим обслуживанием оборудования обязательно обратитесь к данному руководству и поймите изложенные в нем сведения.</li> <li>Несоблюдение требований данного предупреждения может привести к тому, что специалист по техобслуживанию, оператор или пациент получит удар электрическим током, механическую травму или другое повреждение.</li> </ul>











UPOZORENJE (SR)	<ul> <li>Ovo servisno uputstvo je dostupno samo na engleskom jeziku.</li> <li>Ako klijentov serviser zahteva neki drugi jezik, klijent je dužan da obezbedi prevodilačke usluge.</li> <li>Ne pokušavajte da opravite uređaj ako niste pročitali i razumeli ovo servisno uputstvo.</li> <li>Zanemarivanje ovog upozorenja može dovesti do povređivanja servisera, rukovaoca ili pacijenta usled strujnog udara ili mehaničkih i drugih opasnosti.</li> </ul>
UPOZORNENIE (SK)	<ul> <li>Tento návod na obsluhu je k dispozícii len v angličtine.</li> <li>Ak zákazníkov poskytovateľ služieb vyžaduje iný jazyk ako angličtinu, poskytnutie prekladateľských služieb je zodpovednosťou zákazníka.</li> <li>Nepokúšajte sa o obsluhu zariadenia, kým si neprečítate návod na obluhu a neporozumiete mu.</li> <li>Zanedbanie tohto upozornenia môže spôsobiť zranenie poskytovateľa služieb, obsluhujúcej osoby alebo pacienta elektrickým prúdom, mechanické alebo iné ohrozenie.</li> </ul>
ATENCION (ES)	<ul> <li>Este manual de servicio sólo existe en inglés.</li> <li>Si el encargado de mantenimiento de un cliente necesita un idioma que no sea el inglés, el cliente deberá encargarse de la traducción del manual.</li> <li>No se deberá dar servicio técnico al equipo, sin haber consultado y comprendido este manual de servicio.</li> <li>La no observancia del presente aviso puede dar lugar a que el proveedor de servicios, el operador o el paciente sufran lesiones provocadas por causas eléctricas, mecánicas o de otra naturaleza.</li> </ul>
VARNING (SV)	<ul> <li>Den här servicehandboken finns bara tillgänglig på engelska.</li> <li>Om en kunds servicetekniker har behov av ett annat språk än engelska, ansvarar kunden för att tillhandahålla översättningstjänster.</li> <li>Försök inte utföra service på utrustningen om du inte har läst och förstår den här servicehandboken.</li> <li>Om du inte tar hänsyn till den här varningen kan det resultera i skador på serviceteknikern, operatören eller patienten till följd av elektriska stötar, mekaniska faror eller andra faror.</li> </ul>
OPOZORILO (SL)	<ul> <li>Ta servisni priročnik je na voljo samo v angleškem jeziku.</li> <li>če ponudnik storitve stranke potrebuje priročnik v drugem jeziku, mora stranka zagotoviti prevod.</li> <li>Ne poskušajte servisirati opreme, če tega priročnika niste v celoti prebrali in razumeli.</li> <li>če tega opozorila ne upoštevate, se lahko zaradi električnega udara, mehanskih ali drugih nevarnosti poškoduje ponudnik storitev, operater ali bolnik.</li> </ul>











<b>DIKKA</b>	1
(TR)	

- Bu servis kılavuzunun sadece ingilizcesi mevcuttur.

   Eğer müşteri teknisyeni bu kılavuzu ingilizce dışında bir başka lisandan talep ederse, bunu tercüme ettirmek müşteriye düşer. Servis kılavuzunu okuyup anlamadan ekipmanlara müdahale etmeyiniz.
- Bu uyarıya uyulmaması, elektrik, mekanik veya diğer tehlikelerden dolayı teknisyen, operatör veya hastanın yaralanmasına yol açabilir.

## **Revision History**

Revision	Date	<b>Description of Changes</b>	Chapter/Pages
1	October 2011	New Manual	All











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Preface Safety

## **Preface**

# Safety



## **WARNING**

- This document **must** be read in conjunction with the *System Overview and Safety Manuals* (for Operators and for Service Users), which contain all safety-related information and instructions for the use and servicing of the system. All users must read and understand the system safety features and safety operations before using the system.
- The images in this manual are for demonstration only. There may be minor differences that do not affect functionality.

The System Overview and Safety Manual covers information regarding:

- Intended use:
  - Medical purpose
  - Patient population
  - Operator profile

- Detailed system description
  Safety:
- Startup and shutdown procedures
- - General safety warnings and instructions
  - Safety mechanisms, procedures and labels
  - Operator and patient safety during clinical operation
  - Equipment and data safety

The Service Safety Manual covers additional service-related safety information not included in the System Overview and Safety Manual, such as:

- Spatial Orientation
- Service Clearance

- Service-related safety mechanisms and procedures 

  EMC and Service Tools information
  - Service-related Safety Labels











Preface Safety

#### **Safety Labels in This Document**

This manual addresses three safety classifications:



## **▲ DANGER**

The most severe label describes conditions or actions which result in a specific hazard. You **will cause severe or fatal personal injury,** or substantial property damage, if you ignore these instructions.



### **▲ WARNING**

This label identifies conditions or actions which result in a specific hazard.

You **may cause severe personal injury**, or substantial property damage, if you ignore these instructions.



## **A** CAUTION

This label applies to conditions or actions that have potential hazard.

You can cause minor injury or property damage if you ignore these instructions.









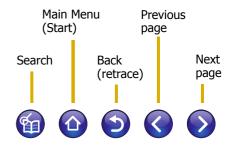


## **System Documentation Set and Online Access**

The service manual set is accessible from the Start page in the documentation CD.

Click any of the links or buttons to access the relevant information, or use the **Search** to search across all documents.

The navigation bar at the bottom of each page in this document enables you to page back and forth, to retrace your steps, and to access the **Search** index and **Start** Main Menu from any page.











Preface How To Print this Document

## **How To Print this Document**

This document is created using A5 sheet size. Use the following guidelines when printing:

Print			One page per sheet (A5 or A4/Letter)				
Dialog	Property*	Two pages per sheet (A4 or Letter)	<b>A5</b> is recommended for a compact book and paper saving <b>A4/Letter</b> is recommended when large format and print are needed				
		12 14	12	12 13			
Main	Page Scaling	Fit to Printable Area (removes	s extra white margins)	N/A			
	Orientation	Landscape					
	Double-sided	Double	e-sided or (Print on Both Sides)				
Printer Properties	Page direction / Binding	Open to Side (or Open to Left)	Open to Top or (Flip pages Up)	Open to Side or (Open to Left)			
(Advanced)	Number of pages per sheet	2	1	1			
	Page Borders  Print Page Borders separation between t		N/A	N/A			

<sup>\*</sup> Names of properties and options can differ, depending on your specific printer driver











Preface Conventions in This Document

## **Conventions in This Document**

#### **IMPORTANT**

Calls attention to important comments.

#### **NOTE**

Contains tips and general comments.

The following conventions are used throughout the manual:

Description	Example
Keys on the operator keyboard, hand-held controller and gantry	<set>, <ctrl></ctrl></set>
Software interface buttons	[OK], [Apply], [Cancel]
Names of items in the graphical interface including:  Names of dialog boxes, windows, tabs, areas and lists  Menu items  Field and icon labels	Configuration tab; To Do List File menu Gantry icon; Properties field
System messages	Press Y to continue.
System parameters whose actual values must be defined by the user	Type-in the Patient ID
Hyperlinks	Figure 3-1
Paths	~/opt/tacqdb
References to other documents	Operator Manual
End of a procedure	<b>◆</b>











# **Chapter 1: General System Requirements**

## 1.1 Objectives & Overview

This manual provides all information necessary to prepare the site for the installation of the system, taking into consideration the information required for different professionals such as architects, construction engineers, electrical contractors, and all other personnel involved in construction and preparation of the site.

#### **IMPORTANT**

- Good site preparation is essential for a smooth and efficient installation and for proper functioning of the system. Poor site planning may compromise system efficiency and/or patient comfort.
- The information provided in this Pre-Installation Manual is general in its nature, and must always be used in conjunction with the drawings and specifications prepared specifically for your site.











## 1.2 Customer Responsibilities

It is the customer's responsibility to prepare the site in accordance with all the specifications provided in this manual, and in conjunction with the site-specific drawings. It is essential to verify all aspects of the site configuration before construction is started, as subsequent changes can be costly or impractical.

A detailed checklist is provided in App.A, Customer Checklist. It is the customer's responsibility to ensure that all requirements in the checklist are fulfilled and that the site conforms with all the specifications and requirements in this manual.

The customer is responsible for all aspects of site preparation, including, but not limited to, the following tasks:

- Assigning a project coordinator (see Project Coordination, p.1-4)
- Planning and construction or renovations required for installation of the system, in accordance with the specifications included in this manual, including:
  - Room Size, Layout and Considerations, p.2-7
  - Equipment Description and General Construction Requirements, p.2-1 and Special Construction Requirements, p.3-1
  - Environmental HVAC Requirements, p.4-1
  - Electrical Requirements, p.5-1
  - Network Requirements, p.6-1











- Complying with all national, state, or local regulatory requirements for the country in which the installation occurs, for example:
  - Fire control devices as required by local codes
  - Permits, inspections, radiation licensing etc.
  - Earthquake-related regulations
- Assuring regulatory compliance for the use of radioactive isotopes and preparation of the required isotopes (see Using Radioactive Isotopes, p.1-3)
- Safe storage of the system and auxiliary equipment prior to and during installation
- Floor tile removal and replacement in area of table and gantry
- Ensuring adequate accessibility for all system components and auxiliary equipment to the site

## 1.2.1 Using Radioactive Isotopes

Since the system involves the use of radioactive isotopes, compliance with Nuclear Regulatory Commission regulations, or similar regulatory requirements (depending on the country), must be adhered to and all permissions obtained well in advance. It is recommended that regulatory compliance is arranged early in the site planning process.

It is essential that all preparations are completed so that required source materials can be obtained prior to installation, including calibration sources. Take into consideration that these sources may have fairly long delivery lead times, yet may also have a short half life, so that it may not be advisable to store them over long periods of time.









## 1.2.2 Project Coordination

The site project coordinator is the primary contact and liaison between GE Healthcare and all siterelated functions, including the purchaser, the construction planners, architects and contractors, and other site administrative personnel.

To insure a successful installation, it recommended that the site nominates a single site project coordinator, preferably a person familiar with similar medical construction projects, manages the entire project. Ideally, the project coordinator is involved in every phase from pre-installation and installation, from conceptual planning through to system start up, working closely with GE Healthcare to ensure that the client upholds all requirements in this Pre-Installation Manual.

## 1.3 Delivery Requirements

The system is packed for shipment with minimum tear-down of components.



## **A CAUTION**

The system components are sensitive to excessive mishandling, including dropping, shock, vibration, tipping or hoisting. Vibration damage to components may not be evident until after system installation is complete.

- The gantry, console, and table must **never** be dropped. A drop from a height greater than 1 cm (½") may induce structural damage to the frame or other major components.
- To avoid damage to sensitive components, dock-to-dock shipment is recommended. Other methods are acceptable, provided the system is not dropped or otherwise mishandled.











## 1.3.1 General Transportation and Delivery Precautions

## **General Temperature Precautions**

Extreme temperatures must be avoided during system transportation and delivery. Ensure that the system is not exposed, for an extended period of time, to temperatures or humidity outside the following specifications.

Temperature: below -34° and above +5° C (-29°/+140°F)

Humidity: 5% to 95%

#### **NOTE**

Component Freezing occurs if the system is exposed to temperatures below  $-18^{\circ}$  C ( $0^{\circ}$  F) for a period of longer than two days. Allow a minimum of 12 hours for the system to adjust to ambient room temperature, prior to installation.











#### **Detector Head Precautions**



## **A** CAUTION

- The detector head is fragile and must always be handled with extra care.
- The detector head is extremely sensitive to temperature gradients (sudden changes in temperature).

Failing to comply with the following instructions could cause irreversible damage to the detector heads.

The detector head must be transported in its original package, which is designed to provide good mechanical stabilization as well as a certain amount of thermal insulation.

- As soon as the detector head is unloaded from the transportation vehicle, it must be moved to a temperature-controlled area, while still in the original container, until it is ready to be installed into the system.
- If the temperature in the storage or installation areas differs from that of the delivery route and/or ambient temperature, a stabilization period of 1 hour per 3° C (5.4° F) difference must be allowed.











## 1.3.2 Delivery Unloading Area and Equipment

- The minimal unload area adjacent to the delivery truck is 15m x 15m (50' x 50'). Make sure that the unloading and storage areas are large enough to maneuver a forklift with crates.
- It is recommended that the delivery site is selected to provide the shortest and smoothest route for component conveyance:
  - If delivered on the installation day, as close as possible to the scan room for installation
  - If delivered prior to the installation day, as close as possible to the storage area
- If a forklift is required in order to unload or move system components:
  - Allocate a forklift that is capable of lifting more than the maximum weight of the heaviest unit (see Table 1-1, B615 Components and Clearance — Metric, p.1-10 or Table 1-2, B615 Components and Clearance — Imperial, p.1-12).
  - Take into account sufficient floor space to maneuver the forklift near the delivery truck.











## 1.3.3 Conveyance of Crated System Components Within the Site

Regardless of whether the system is being delivered from the unloading area to storage, from the unloading area to unpacking area for installation or from storage to the installation area, take care to adhere to the following guidelines:

- Ensure that there is a free path, including an elevator if necessary, to wheel the components to the installation area.
- Verify that the route selected has sufficient clearance and load carrying capacity (see Table 1-1, B615 Components and Clearance — Metric, p.1-10 or Table 1-2, B615 Components and Clearance — Imperial, p.1-12).
- The subsystems may be lifted only with a forklift and only when attached to their original shipping pallets.



## **A** CAUTION

Lifting of the gantry without its original shipping pallet or using a crane may damage the system and is prohibited.

- If the outer crating is removed after delivery, do not detach the subsystems from their original shipping pallets before they are conveyed to the scan room for installation.
- The center of gravity of each item, including lifting height and position, is marked on the subsystem crate. When conveying the subsystems within the site, and particularly if there are slopes in the delivery path, make sure to take the center of gravity into account.
- Always lower system components at the slowest reasonable rate.











- 1.3.3 Conveyance of Crated System Components Within the Site
- If the system components are to be transferred from an unloading site outside the building, special facilities must be provided to ensure smooth conveyance.
- Uneven temporary ramps may cause vibrations that could damage some components.
- System components may be moved via flat-bed tow truck or by rolling them across smooth sidewalks or other paved surfaces.
- When moving the gantry off a flat-bed tow truck, attach the straps to the lowest point possible on the dolly.











## 1.3.4 Crated and Uncrated Weights, Measurements and Clearance

The following tables provide you with crate and component measurements, weights and other data, in order to assist you in planning conveyance routes and storage areas. The order of the components in the list constitutes the recommended order of conveyance and delivery to the scan room for installation. The information is provided in metric and imperial formats, as follows:

- Table 1-1, B615 Components and Clearance Metric, p.1-10
- Table 1-2, B615 Components and Clearance Imperial, p.1-12

**Table 1-1: B615 Components and Clearance — Metric** 

	Crated				Uncrated					
	Crate size (cm) (without dollies) (Height x Width x Depth/Length)	<b>Weight</b> (kg)	Minimal dimensions (cm)*					Weight (kg)		
Component name			Door width	Corridor / elevator width	Corridor / elevator length	Width of corridors with 90° turns <sup>†</sup>	Height			
Pre-installation kit <sup>‡</sup>	75 x 40 x 175	15	any	any	any	any	any	15		
NM gantry	220x150x168	1765	140	140	222	250	200	1590 (with dollies)		
Table	140x90x300	562	100	100	283	250	any	390		
NM acquisition station	80 x 60 x 60	30	any	any	any	any	any	20		
Peripherals & accessories	115 x 100 x 150	50	any	any	any	any	any	50		
Collimators on carts	170 x 90 x 115	273 (heaviest coll. set)	55	55	100	112	150	233 (heaviest coll. set)		









Table 1-1: B615 Components and Clearance — Metric (cont.)

	Crated			Uncrated					
	nent name  Crate size (cm) (without dollies) (Height x Width x Depth/Length)	<b>Weight</b> (kg)	Minimal dimensions (cm)*					Weight (kg)	
Component name			Door width	Corridor / elevator width	Corridor / elevator length	Width of corridors with 90° turns†	Height		
Optional Items									
ECG Trigger Monitor	May vary but not	May vary							
Xeleris (optional)	more than 80x80x80	but not more than 15	Any	Any	Any	Any	Any	<13	
Monitor									

<sup>\*</sup> The minimum door width required in order to bring the system components into the scan room also depends on the width of the corridor leading to the room. When planning or measuring the width of the scan room door, use the graphs provided in Figure 1-2: B615 Relative Required Width for Corridor and Scan Room Door, p.1-15 in order to verify that the measurements comply with the requirements.

- <sup>†</sup> The corridor width required in order to move system components from unloading area to scan room depends on the angles of turns in the corridor. See Figure 1-3: B615 Required Corridor Width for 90° Turns, p.1-16 for the required width when the angle is 90°.
- ‡ May be delivered a few days prior to system delivery, as part of the final room check and preparation for installation.











**Table 1-2: B615 Components and Clearance — Imperial** 

	Crated			Uncrated					
	Crate size (") (without dollies) (Height x Width x Depth/Length)	Weight (lb)	Minimal dimensions ( ")*					Weight (lb)	
Component name			Door width	Corridor / elevator width	Corridor / elevator length	Width of corridors with 90° turns <sup>†</sup>	Height		
Pre-installation kit <sup>‡</sup>	29.5 x 15.7 x 68.9	33	any	any	any	any	any	33	
NM gantry	86.6x59x66.1	3892	55.1	55.1	88.6	98.4	78.75	3506 (with dollies)	
Table	55x35.4x118.1	1239	39.4	39.4	111.4	98.4	any	860	
NM acquisition station	31.5 x 23.62 x 23.62	66	any	any	any	any	any	44	
Peripherals & accessories	45.3 x 39.4 x 59	110	39.4	43.3	59	70.8	any	110	
Collimators on carts	67x35.4x45.3	601 (heaviest coll. set)	22	22	39.4	45.3	59	514 (heaviest coll. set)	
Optional Items									
ECG Trigger Monitor	May vary but not	May vary							
Xeleris (optional)	more than	but not	Any	Any	Any	Any	Any	<28.6	
Monitor	31.5x31.5x31.5	> 33							

<sup>\*</sup> The minimum door width required in order to bring the system components into the scan room also depends on the width of the corridor leading to the room. When planning or measuring the width of the scan room door, use the graphs provided in Figure 1-2: B615 Relative Required Width for Corridor and Scan Room Door, p.1-15 in order to verify that the measurements comply with the requirements.

<sup>‡</sup> May be delivered a few days prior to system delivery, as part of the final room check and preparation for installation.











<sup>†</sup> The corridor width required in order to move system components from unloading area to scan room depends on the angles of turns in the corridor. See Figure 1-3: B615 Required Corridor Width for 90° Turns, p.1-16 for the required width when the angle is 90°.

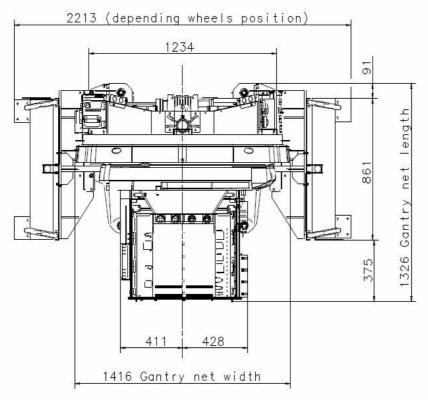


Figure 1-1: NM Gantry on Dolly Measurements (mm)









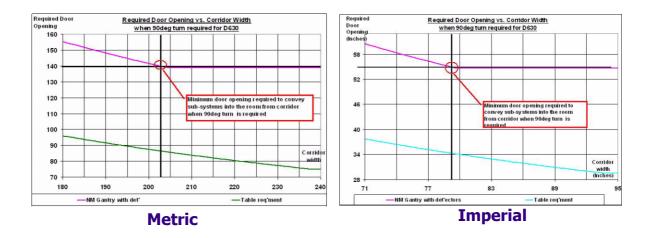


Figure 1-2: B615 Relative Required Width for Corridor and Scan Room Door









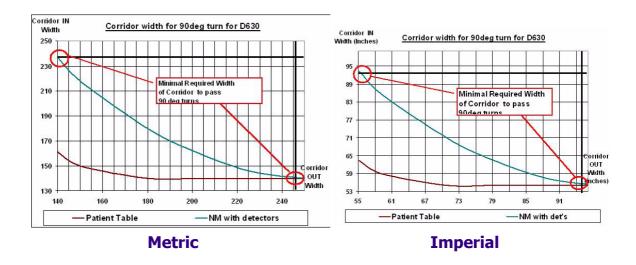


Figure 1-3: B615 Required Corridor Width for 90° Turns









## 1.4 Product Storage and Handling Requirements

All components must be stored in their original crating.

## 1.4.1 Storage Requirements

If the system is to be stored before installation, store in a temperature and humidity controlled environment, and protect from weather, dirt and dust. Storage longer than 12 months is not recommended.

Meeting these requirements prevents rust and corrosion from forming on bearing surfaces due to condensation.



## **A CAUTION**

Component freezing occurs if the system is exposed to temperatures below  $-18^{\circ}$  C ( $0^{\circ}$  F) for a period of longer than two days.

Gradually adjust the system to ambient room temperature prior to installation, with a change of no more than  $3^{\circ}$  C (5.4° F) per hour.











**Table 1-3: Storage Conditions** 

Conditions	orage )		
Storage temperature	+4° to +27°C	40° to +80°F	
Maximum temperature rate of change	3°C/hr.	5°F/hr.	
Relative humidity (non-condensing)	Between 20% and 60%		
Maximum relative humidity rate of change	5%/hr		
Air pressure	Between 700 hPa	and 1060 hPa	











# Chapter 2: Equipment Description and General Construction Requirements

#### This chapter provides the following:

- Equipment and System Components, p.2-2
   Describes the system and its components
- Room Size, Layout and Considerations, p.2-7

Provides guidelines for determining the size and layout of the scan and operator rooms and of the above components, including example layouts of typical rooms, illustrating the position and dimensions of the components.

Room Structural Requirements, p.2-17

Provides floor, ceiling and wall requirements, and acoustic and vibration specifications for the scan room and the operator room.

Seismic Requirements, p.2-33

Provides center of gravity information for the different system components.











# 2.1 Equipment and System Components

The figures in this section illustrate the different system components.

• Figure 2-2: B615 Gantry, p.2-4

■ Figure 2-3: B615 Table Views, p.2-5

■ Figure 2-4: B615 Collimator Cart, p.2-6











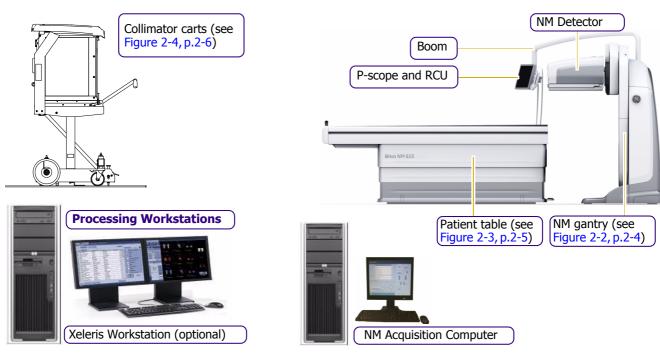


Figure 2-1: B615 Scan Room Components











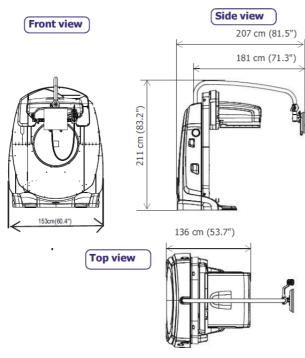
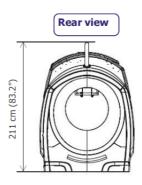


Figure 2-2: B615 Gantry



**Note**: Dimensions are in cm (")











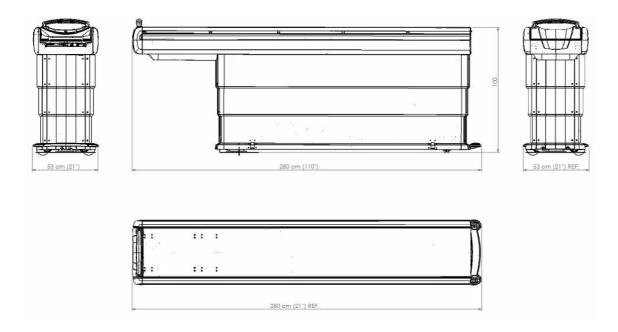


Figure 2-3: B615 Table Views











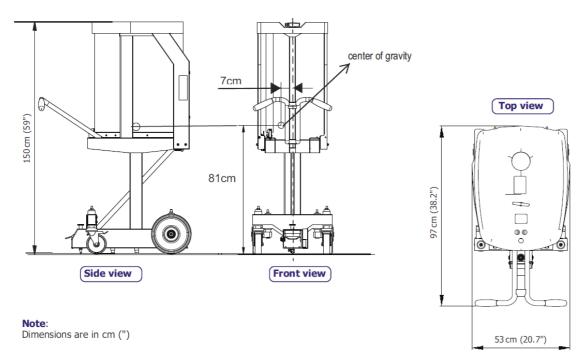


Figure 2-4: B615 Collimator Cart











# 2.2 Room Size, Layout and Considerations

The system requires a main Scan Room, which contains the following sub-systems:

**Table 2-1: B615 Components in Scan and Console Rooms** 

Scan Room				
Fixed Components (seeFigure 2-1, p.2-3)	Moving Components			
NM Gantry	Collimator carts			
Patient table				
NM acquisition station				
MDP				

This section provides guidelines for determining the size and layout of the scan and operator rooms and of the above components, and example layouts of typical rooms, illustrating the position and dimensions of the components.

The room layouts provided take into consideration all aspects of operation, operator and patient requirements and service clearance requirements.









#### **Egress**

The room layouts, diagrams and dimensions in this manual provide the required clearances for proper equipment operation and service only. The customer/purchaser is responsible for compliance with federal, state and/or local codes regarding facility egress and related facility requirements.

# 2.2.1 Room Dimension Requirements

#### **NOTE**

The minimal and standard scan rooms described in this manual may not comply with specific local/regional/country/ state requirements (such as OSHA in the USA). Take into consideration the local regulations in force when planning room dimensions and layout.

# Minimal scan room size, without operator room ( $L \times W \times H$ )

5.12 m x 3.74 m x 2.3 m (16' 9" x 12' 3" x 7' 6") (see Figure 2-5: B615 Minimal Room Layout, p.2-10)

# 2.2.2 Room Layout Drawings

This section provides typical sample room layouts, illustrating the position and dimensions of the scan room and of the system components, including:

- Figure 2-5: B615 Minimal Room Layout, p.2-10
- Figure 2-6: B615 Standard Room Layout, p.2-11











The room layout dimensions take into consideration all aspects of operation, operator and patient requirements, safety regulations and service clearance requirements (see Room Layout Considerations, p.2-14).











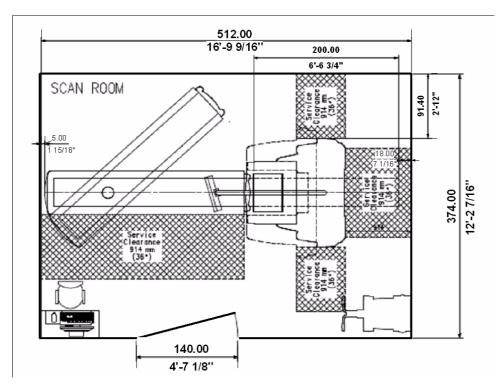


Figure 2-5: B615 Minimal Room Layout









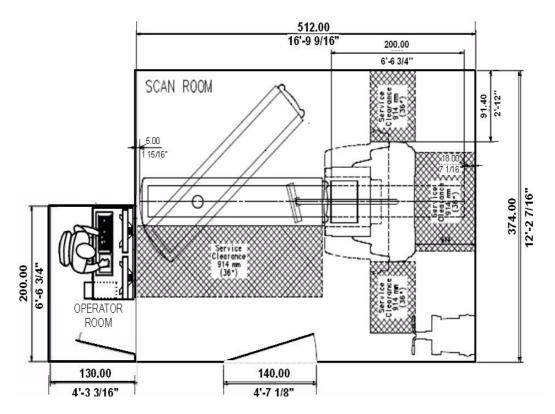


Figure 2-6: B615 Standard Room Layout











# 2.2.3 System Mechanical Curves

Figure 2-7: B615 Component Movement Curves, p.2-13 illustrates the table and gantry movement. In addition, the ECG trigger monitor and collimator carts can be moved to different locations in the scan room, as demonstrated in the room layout illustrations in Figure 2-5: B615 Minimal Room Layout, p.2-10 and Figure 2-6: B615 Standard Room Layout, p.2-11.

#### NOTE

In order to prevent collision with the gantry display boom, do not mount any equipment from the ceiling.

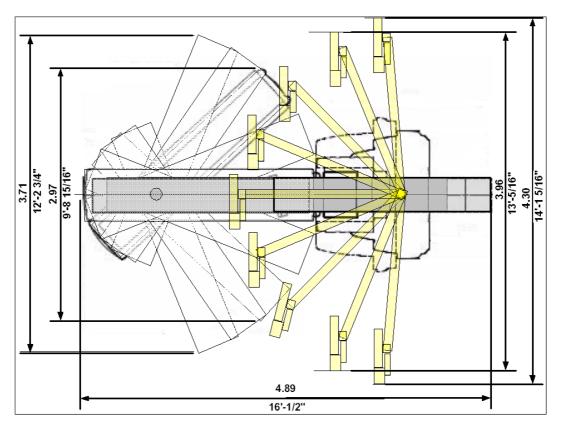
Table slanted at	Farthest point relative to system's center line
67.5°	186 cm (73")
55°	172 cm (67.7')
42.5°	148.5 cm (58.5")











**Figure 2-7: B615 Component Movement Curves** 









# 2.2.4 Room Layout Considerations

This section describes the considerations you must take into account when selecting a site and planning the room size and layout. In addition, it is the responsibility of the customer to ensure that all aspects of the scan and operator rooms conform with the local requirements.

## **Scan Room Dimensions and System Placement**

The room size and shape and the placement of the system components must enable optimal functional and working conditions, including the best possible relative positioning of the gantry, patient table and acquisition console in operator room, including:

- Operator access in scan room, around the gantry and patient table in order to:
  - Assist patient positioning
  - Perform examination routines
  - Act efficiently and quickly in case of an emergency, including easy access to emergency switch
- Operation-related considerations:
  - Enable access for hospital beds, including maneuvering and positioning the bed and moving the front of the patient table during collimator exchange
  - Storage of the collimator carts (one for each set of collimators) when not in use
  - ECG Trigger Monitor cable position and lengths and storage when not in use
  - Space for storage and usage of ECG Trigger Monitor











- Installation and service considerations:
- Location of power connections
- Access to communication lines (Ethernet, external hardcopy device)
- Floor loading capacity and weight of system components, including storage and path of collimator carts
- Service clearance areas (see App.C, Regulatory Clearances)
- Storage cabinet for storage of service tools (optional). Depending on the room layout, it
  is recommended that sufficient area is allocated for the cabinet.

## **Operator room**

- Operator field of view, enabling direct view of patient table in bore, or taking into consideration viewing via remote closed-circuit camera in the scan room and screen in the operator room
- Space, power and network connections for additional equipment such as PACS workstation, image printer, etc.

# **Proximity of scan room to other utilities**

- Avoid detrimental influences from surrounding rooms, such as:
  - Radioactive or magnetic sources
  - A local wireless environment.
  - Vibrations











- 2.2 Room Size, Layout and Considerations 2.2.4 Room Layout Considerations
- Plan the optimal proximity of the scan room to related utilities. In addition to patient comfort, take into consideration that background radiation activity from such utilities could negatively affect image quality and system calibration. These utilities include:
  - Waiting/injection areas, toilets
  - Viewing and processing rooms
  - Radionuclide storage and preparation area
  - Office facilities
  - Smoke detectors that use/have radioactive activity











# 2.3 Room Structural Requirements

#### Room requirements consist of the following:

- Floor Requirements, p.2-18, including floor strength, anchoring, levelness and flatness, vibration and conductivity
- Floor Loading Requirements, p.2-19
- Ceiling Requirements, p.2-30
- Wall Requirements, p.2-30
- Acoustic Specifications, p.2-31
- Vibration Specifications, p.2-31











# 2.3.1 Floor Requirements

## 2.3.1.1 Floor Strength

In order to enable mounting of the system floor anchors, concrete floors must have a minimum cube strength of f'c = 4350 psi (30 MPa) at 28 days (curing time) for 25/30 concrete, and must be at least 140 mm (5.5") thick.

#### NOTE

Concrete strength is determined by the "Cylinder Test" (used in the USA) or "Cube Test" (used in Europe), where a cylinder or cube of concrete is cast, cured for the appropriate time and then compressed between two parallel faces until failure. The stress at the failure is taken to be the compressive strength of the concrete. The 25/30 concrete required for the system installation is concrete with a strength of 25 in the cylinder test (resulting 3625 psi), or strength of 30 in the cube test (resulting 4350 psi).

It is the customer's responsibility to have appropriate tests performed to determine and measure concrete strength, and to obtain a constructor engineer's assessment for the floor load capability.



# **▲ CAUTION**

If the system is installed on a floor type thinner than a 140 mm (5.5") concrete floor, the customer shall, at their expense, provide acceptable anchoring and mounting methods that meet all structural specifications provided in sections 2.3.1.2 and 2.3.1.3 of this manual.

In addition, the customer shall ensure that the floor strength in the collimator cart storage area and along the movement routes for collimator exchange are suitable for the collimator cart load (approx. 250 kg each).











# 2.3.1.2 Floor Loading Requirements

**Table 2-2: Weights of Components** 

Component	Weight (Kg)	Weight (Imperial)	Load Distribution	Comments
NM gantry (with HEGP collimators mounted on system)	1595 kg	3517 lb	4 pads, Ø83 mm each: +514 kg each on front pads +283 kg each on rear pads	
Patient table	390 kg	860	4 wheels + axis anchored to floor	Weight of table without patient
Collimator cart (with HEGP on cart)	233 kg	514	4 wheels	COG point at 81 cm height; may be more than one collimator cart in scan room
Acquisition station	(insignificant)			
Personnel and patient	< 500 kg	< 1102	Variable	Normally 3-4 people in room during scan or service operations
LEHR collimator	62 kg	137		1 per system/cart
LEGP collimator	55 kg	121		1 per system/cart
MEGP collimator	103 kg	227		1 per system/cart
HEGP collimator	131 kg	288		1 per system/cart









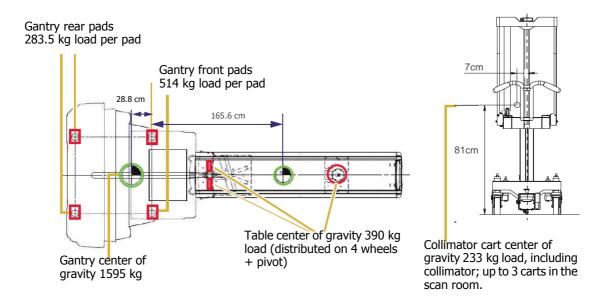


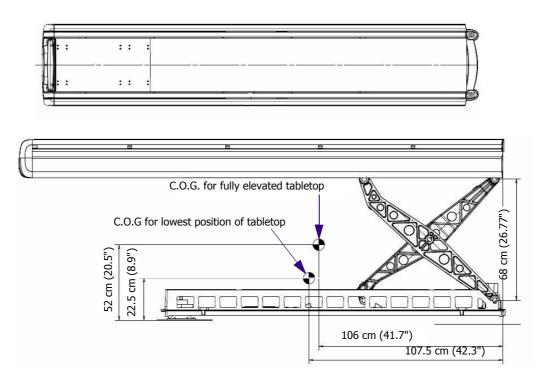
Figure 2-8: B615 Floor Loading and Center of Gravity Points for Gantry and Cart











**Figure 2-9: B615 Table Center of Gravity Points** 









## 2.3.1.3 Floor Anchoring

The system's floor anchors are designed for use **only** on concrete floors that meet the minimal 140 mm (5.5")concrete floor requirements.



# **A** CAUTION

For concrete floors thinner than 140 mm or different floor types other anchoring methods might be required. These must comply with the minimum load requirements (see Floor Loading Requirements, p.2-19) and must be installed and tested at the customer's expense, by the customer's structural contractor. The selected anchoring method must have a pulling tensile force of 37.7 kN on each of the anchors bolting the NM Gantry to the floor.

In such a case, the alternative anchors shall be installed during system installation, and this must be coordinated with the installation team. For anchor point information, see Figure 2-10: B615 Floor Anchor Points, p.2-23.

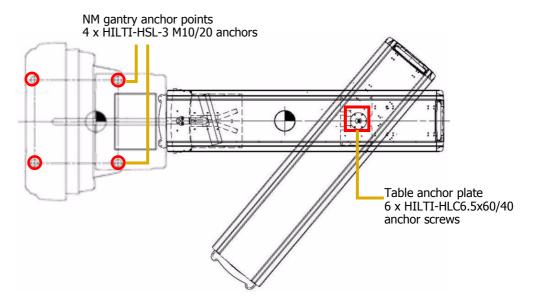












**Figure 2-10: B615 Floor Anchor Points** 









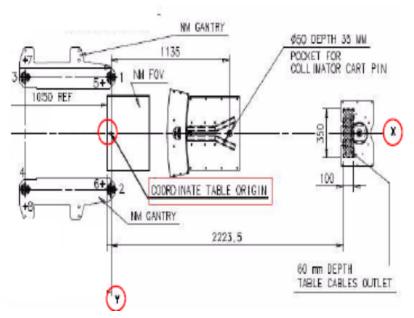


Figure 2-11: B615 Drilling Map









No.	х	Y	Drill Hole	Hole Depth	Anchored Part	Hole Purpose	Drilling Method	Anchor Type	Torque Nm.	Section
1	-0.00	405.00								
2	-0.00	-405.00				Main Anchor				Figure 2-12
3	-810.00	405.00			NM Contro	IVIAITI ATICIOI	Metal Drilling	HILTI HSL-3 M10/	35	Figure 2-12
4	-810.00	-405.00		90						
5	-80.00	365.00	Ø15.0	90 NM Gantry 215.0			Template	20	33	
6	-80.00	-365.00	Ø 15.0			Alternative Anchor	Template	20		Figure 2.10
7	-810.00	530.00				Alternative Anchor				Figure 2-10
8	-810.00	-530.00								

Table 2-3: B615 Drilling and Anchor Chart

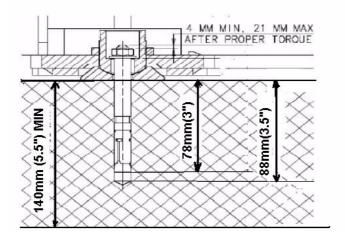


Figure 2-12: B615 Gantry Anchoring









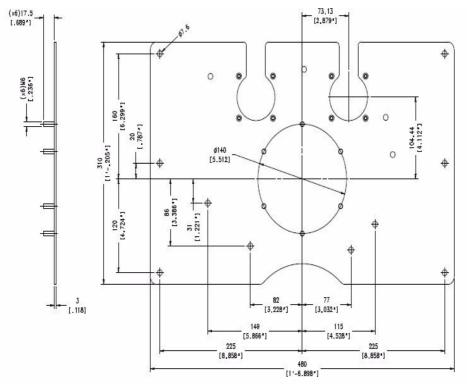


Figure 2-13: Patient Table Pivot Floor-Plate Anchoring Holes











#### 2.3.1.4 Floor Levelness and Flatness

The scan room floor must be leveled, and its surface must be smooth.

It is recommended that the floor in the entire scan room is leveled and flattened. If this is not possible, it is a minimum requirement for the gantry/table installation area to be level and flat.

The floor levelness requirement is essential for proper alignment of the table and the gantry, which affects accurate patient positioning, collimator exchange and other aspects of system functionality. Table level may not be achievable if overall floor levelness does not conform to these specifications.



## **A CAUTION**

- The use of floor shims is not suitable to achieve floor levelness.
- Do not use fill material to compensate for holes or depressions in the floor surface. If necessary, level and flatten the entire floor area.

#### **NOTE**

Instructions for determining floor flatness and levelness are provided in the system's *Installation Manual*.











**Table 2-4: Floor Leveling Specifications** 

Item	Requirement
Floor leveling area	512 cm $\times$ 374 cm (16'-9" $\times$ 12'-2") (covering the entire planned area of table and gantry installation, depending on room layout)
Slope	3 mm (0.125") over 3048 mm (120")
Flatness	The surface must be smooth, with deviations of no more than 0.5 cm $(^3/_{16}")$ between depressions and high spots in any 150 cm (60") throughout the room or system installation area
Floor surface	A single poured surface

#### 2.3.1.5 Floor Vibration

Floor vibration requirements are included in the general vibration requirements (see Vibration Specifications, p.2-31).











## 2.3.1.6 Floor Conductivity

The purpose of this section is to measure the electrical conductivity of the floor surface to the "GND" (Ground).

- The surface of the conductive floor shall provide a patch of electrical conductivity between all persons and equipment making contact with the floor.
- Using a DVM, measure the impedance between the upper surface of the floor where the NM Gantry is planned to be positioned, and the System power supply GND terminal in the room.
   The readout needs to be less than 35 M Ohm.
- Repeat the measurement in the area where the Patient Table will be positioned. The readout needs to be less than 35 M Ohms.











## **2.3.1.7 Additional Floor Requirements**

The floor finish must take into consideration magnetic field and EMI considerations (see EMI Considerations, p.3-3).

# 2.3.2 Ceiling Requirements

Scan room height must be at least 2.3 meters (7' 6.5").

# 2.3.3 Wall Requirements

## **Operator room window**

If there is an operator room, the operator must be able to view the patient from the operator room during a scan. The location of the window depends on the position of operator room relative to the scan room. It is recommended that the window is positioned in front of the console so that the operator can look down the length of the bore.

The recommended patient viewing window dimensions are approximately 120 cm wide by 110 cm high  $(48" \times 42")$ .

Consult a qualified radiological health physicist for radiation protection requirements for the window glass (lead content and thickness), in accordance with Radiation Protection and Shielding Requirements, p.3-1 and with local requirements.











## **Radiation protection**

For details on wall, door and window radiation protection, (see Radiation Protection and Shielding Requirements, p.3-1).

#### **Other**

Verify that all walls conform with local regulations, such as washability.

# 2.3.4 Acoustic Specifications

The system creates acoustic noise. In compliance with IEC 601-1-1standard the measured noise (at 1m distance away from the system) is less than 70 db. It is recommended that the wall and ceiling surface is of a sound dampening material so that the noise is not reverberated and amplified.

# 2.3.5 Vibration Specifications

The system components are sensitive to vibration in the frequency range of 0.5 to 20 Hz, depending on the amplitude of the vibration. It is the customer's responsibility to contract a vibration consultant or qualified engineer to verify that these specifications are met and implement an appropriate solution.

To minimize vibrations, the system must be installed on a solid floor, as far as possible from the following vibration sources:











Outside building	Inside building	Other
■ Parking lots	<ul><li>Hallways</li></ul>	Hospital power plants
<ul><li>Roadways</li></ul>	■ Elevators	containing pumps, motors, air handling equipment and air
<ul><li>Subways</li></ul>		conditioning units
<ul><li>Heliports</li></ul>		
■ Trains		

## **Steady State Vibration**

The maximum steady state vibration transmitted through the floor should not exceed  $0.001 \text{ m/s}^2$  RMS maximum single frequency above ambient baseline from 0.5 to 80 Hz (measured in any 1 hour during a normal operating period).

#### **Transient Vibration**

The behavioral characteristics must be such that any measurable transient disturbance must also be minimized to less than  $0.01 \text{ m/s}^2$  peak-to-peak.











# **2.4 Seismic Requirements**

Seismic requirements are determined and specified by the hospital design professional of record and must be approved by the specific state or country agency. Seismic attachment hardware shown on seismic calculations may differ from hardware supplied with system. Any additional hardware that is required will be the responsibility of the institution and/or their contractor. For additional center of gravity information, see Table 2-5, p.2-33.

**Table 2-5: Subsystem Centers of Gravity and Anchoring Points** 

Component	Center of Gravity Location (cm)			Regular Anchoring	Additional Anchoring in Seismic Areas	See also
	X	Y	z		iii Seisiiie Areas	
Table	106	25	52	Anchor plate + 6 screws 6 x HILTI-HLC 6.5 x 60/40	No additional anchoring required	Figure 2-9, p.2-21
NM gantry	0*	10.1	98	4 x HILTI HSL-3 M10/20 anchors	Can add 4 anchoring points using four redundant anchoring holes on NM gantry	Figure 2-10, p.2-23
Collimator carts	48.5	19.5	81	Carts cannot be anchored, for collimator exchange	as they must move freely in the room	Figure 2-4, p.2-6

<sup>†</sup> In the most unfavorable configuration











# **Chapter 3: Special Construction Requirements**

# 3.1 Radiation Protection and Shielding Requirements

Radiation shielding regulations differ from one country or state to another. It is the customer's responsibility to ensure that radiation protection and shielding comply with such regulations and requirements during site preparation and system installation and operation.

# **3.1.1 Background Radiation**

When the system is calibrated, background radiation from surrounding areas may adversely affect calibration. Therefore all radiation sources must be suitably shielded, including:

- Waiting/Injection areas
- Radionuclide storage and preparation area (sometimes known as "hot lab")

As a general guideline, if the anticipated background radiation in the Scan Room will be higher than 0.1mR/h (1microGy/h), then lead shielding with sufficient thickness must be installed.

#### **NOTE**

In most cases, a 2-5 mm lead wall will sufficiently reduce background radiation levels. To optimize costs, it is recommended that you consult with a specialist to determine the minimum lead thickness for the planned installation site.











# 3.1.2 Scan Room Shielding

The system involves the use and storage of radio nuclides. Appropriate barriers such as walls, lead-shielded glass, lead shields, etc. must be installed to protect staff from unnecessary exposure to radiation.

Patients become significant sources of radioactivity; therefore consideration should be given to maximize the distance between the patient and operator during the uptake and acquisition phases of scan procedures.

Scatter-room shielding requirements must be reviewed by a qualified radiological health physicist taking into consideration:

- Scatter radiation levels within the scanning room
- Equipment Placement
- Weekly projected workloads (#patient/day technique (kvp\*ma)
- Materials used for construction of walls, floors, ceilings, doors and windows
- Access to surrounding scan room areas
- Equipment in surrounding scan room area (e.g. film developer, film storage)



## **A CAUTION**

Specific room shielding requirements should be determined by local regulatory considerations, facility policy and if available, the facility physicist.











### 3.2 Magnetic Field Considerations

### **Low Frequency Magnetic Field**

N/A

### **Static Magnetic Field Limits**

In order to avoid interference on the system, the static field limits from the surrounding environment must be less than 1 Gauss in both the scan and the operator rooms.

### 3.3 EMI Considerations

### 3.3.1 Electrostatic Discharge Environment & Recommendations

In order to reduce electrostatic discharge interference, install a charge dissipative floor material to avoid electrostatic charge buildup.

The relative humidity shall be at least 30 percent.

The dissipative material shall be connected to the system ground reference, if applicable.











### 3.3.2 Electro-Magnetic Interference (EMI)

#### **NOTE**

If power sub-stations exist under or above the scan room, or near the operator room, consider EMI testing to determine if your proposed room meets the published acceptable EMI room limits. This also includes high voltage lines under the scan or operator room floor.

#### **EMI Reduction**

If fields of excessive EMI are known or suspected to be present, consult GE Healthcare Sales & Service for recommendations. Consider the following if you attempt to reduce EMI:

- External field strength decreases rapidly with distance from source of magnetic field.
- External magnetic field leakage of a three-phase transformer is much less than that of a bank of three single phase transformers of equivalent power rating.
- Large electric motors are a source of substantial EMI.
- High-powered radio signals are a source of EMI. Ensure sufficiently good screening of cables and cabinets.











**Table 3-1: Electro-Magnetic Interference (EMI) Constraints** 

Component	Ambient magne	tic fields	System attributes	Comments		
	Static	AC	affected			
Gantry & Table	< 10 <sup>-4</sup> tesla (1,000 milligauss)	< 10 <sup>-6</sup> tesla (10 milligauss) peak	Imaging performance	<b>↑ WARNING</b>		
Color Monitor	< 10-3 tesla (10,000 milligauss)	NA	Color purity and display geometry	The gantry produces an electromagnetic field that radiates outward in all directions.		
Console / Computer Equipment	< 10 <sup>-3</sup> tesla (10,000 milligauss)	NA	Data integrity	The UPS provides a consistent power supply in normal conditions and during a site-wide power outage.  Do not place sensitive electronics, for example		
Magnetic Media	< 10 <sup>-3</sup> tesla (10,000 milligauss)	NA	Data integrity	console or computer equipment within 1 m of the gantry or 1 m of the UPS, in any direction (including above or below)  Note: The UPS and gantry are not classified as sensitive electronics.		









### 3.3.3 Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified in App.B, EMC Compliance, Table B-2, EMC Immunity Guidance and Declaration, p.B-2. The customer must assure that the system is installed and used in such an environment.

### **3.3.4 Recommended Separation Distances**

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

#### NOTE

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

For transmissions between 150 kHz & 2.5 GHz, adhering to the recommended distance separation will reduce disturbances recorded at the image level, but may not eliminate all disturbances. However, when installed and operated as specified herein, the system will maintain its essential performance by continuing to acquire, display, and store diagnostic quality images safely. For example, in order to avoid image interference risks, a 1 W mobile phone (800 MHz to 2.5 GHz carrier frequency) must be placed 2.3 meters away from the system.











# **Chapter 4: Environmental HVAC Requirements**



### **▲ WARNING**

Ratings and duty cycles of the system apply only if site environment meets the standards of this section. If environmental specifications are not respected, system operation and image quality may be affected.

The environmental conditions listed in this chapter are essential to maintain proper cooling for the system. These conditions must be maintained at all times, including overnight, weekends and holidays. Only when the system is shut down, for example for major repair, may the air conditioning also be shut down.

Failure to adhere to these requirements can lead to image quality issues.



### **A WARNING**

If air conditioning is not functioning correctly, the system must be shut down.











### **4.1 General Guidelines**

Maintaining constant temperature and humidity levels is essential in order to ensure system functionality over time.

Overheating or underheating, or changes in humidity that exceed the requirements provided in this section can cause technical difficulties and system failures and can cause damage to system components. You must conform to the requirements in Table 4-1, p.4-2 both during system storage and in as long as the system is operational after installation.

Cooling requirements do not include cooling for room lighting, personnel or other equipment.

Locate a wall air-conditioning vent at floor level beside and behind gantry to meet gantry cooling needs and to provide patient comfort. Do not locate any cooling vents directly above the gantry. Air returns above the gantry are recommended.

Table 4-1: Requirements for Ambient Temperature, Humidity and Altitude

	Maximum	Minimum	Recommended	Maximum rate of change
Temperature	26°C (79°F)	18°C (64°F)	22°C (72°F)	3°C/hr (5°F/hr)
Humidity	60% non-condensing relative humidity	30% non-condensing relative humidity		5%/hr
Altitude	2400 m (7,875 ft.)	-150 m (-492 ft.)		









## 4.2 Heat Output

**Table 4-2: B615 Heat Output in Scan Room** 

System Component	BTU/hr	Watt	Comments
Gantry	3412	1,000	
Table	682	200	
Recommended subtotal	4,094	1,200	
NM acquisition station	256	75	(computer only)
Recommended subtotal without options	256	75	
System total	4,350	1,275	Cooling requirements do not include cooling for room lighting, personnel or other equipment

## 4.3 Air Quality

The system is especially sensitive to the presence of sulfide, chloride and nitrate contaminates, with sulfur being the most damaging element. If high levels of contaminates exist, it is recommended that appropriate air filtration systems are installed.

If the site is intended for use of products for Aerosol/Gas Ventilation Scintigraphy, special precautions should be taken according to local laws and safety regulations, and room planning should be coordinated with the local Radiation Safety Officer.









# **Chapter 5: Electrical Requirements**

#### **5.1 Power Feed**

A dedicated feeder run from the facility main isolation transformer is recommended to power the system. If a dedicated distribution transformer is provided for the scanner, the minimum recommended transformer size is 6 kVA, rated 2.4% regulation at unity power factor.

In all cases, qualified personnel must verify that the transformer and feeder, at point of take-off, plus the run to the system meet all the requirements provided in this document.

**Table 5-1: B615 System Power Characteristics** 

Maximum power demand	6 kVA @ 0.85 PF	
Continuous (average) power demand at maximum duty cycle	2.5 kVA	
Maximum allowable total source regulation	6%	
Minimum recommended transformer size	8 kVA	









Electrical Requirements 5.1 Power Feed

The following tables (Table 5-2, B615 Nominal Line Voltage Ranges, p.5-2 and Table 5-3, Power Supply Requirements, p.5-3) are based on the use of copper wire, rated 75 C and run in steel conduit. The current rating (ampacity) is determined in accordance with the National Electrical Code (NFPA 70), Table 310-16 (2002).

#### **NOTE**

Ampacity, or Current Rating, is the RMS current which a device can carry within specified temperature limitations in a specified environment, depending upon: a) temperature rating, b) power loss, c) heat dissipation.

The ampacity for a power cable depends on properties of the conductor and the insulation and on environmental conditions adjacent to the cable.

The minimum feeder size is determined by the current rating (ampacity) of the circuit protection device listed below. In some cases a larger size may be necessary in accordance with local regulations for total source.

The Minimum Feeder Wire Size is 8 (8 is a wire code).

**Table 5-2: B615 Nominal Line Voltage Ranges** 

Nominal line voltage (volts)	208	220	230	240
Hi-Line Limit, +10% (volts)	230	242	253	264
Lo-Line Limit, -10% (volts)	187	198	207	216
Continuous line current (amp)	12	11.5	11	10.5
Maximum line current (amp)	29	27	26	25
Minimum recommended circuit protection rating (amp)	40	30	30	30











## **5.2 Power Supply Requirements**

The system must receive its power supply via a dedicated feeder run from the nearest Main Distribution Panel (MDP).

#### NOTE

According to local regulations, a primary power disconnect device must be provided on the power line supplying the gantry.

The system is designed to operate on a one-phase plus neutral, or two-phase, three-wire power source (depending on input voltage).

**Table 5-3: Power Supply Requirements** 

	Characteristics	Comments		
Line voltage specifications	208 to 240 VAC			
Line frequency specifications	50 or 60 Hz +/- 3 Hz			
Measured kVa load characteristics	6 kVA	Maximum power demand	6 kVA	@ 0.85 PF, at a selected technique of Rotation 3RPM, L shape with LEHR collimator
		Average (continuous) power demand	2.5 kVA	at maximum duty cycle









**Table 5-3: Power Supply Requirements (cont.)** 

	Characteristics	Comments
Input impedance		
Fuse or Circuit Breaker Ratings	40 A	
Power requirements for equipment not powered from the system	In scan room and in operator room: 2 one-phase regular power outlets for service tools (such as vacuum cleaner, electric drill, soldering iron etc.)	For service activities
Power stability (transient etc) requirements	Maximum transient voltages should be limited to 1500 V peak	Sags and surges of the power line must not exceed the absolute range limits shown in Table 5-2, B615 Nominal Line Voltage Ranges, p.5-2.
Inrush current		

Total load regulation as measured at the system mains input terminals must not exceed 6%. The capacity of the facility transformer and the size and length of feeder wires directly affect the load regulation presented to the system.

#### **NOTE**

■ The electrical rating is described on the system rating label attached to the gantry.











Electrical Requirements 5.3 Grounding

## **5.3 Grounding**

The system has been designed to use an equal potential grounding system. The required ground system is shown in Figure 5-1: B615 System Grounding Map, p.5-5.

The primary grounding point is located at the gantry base.

All exposed metal surfaces in the patient vicinity are grounded to the reference ground point.

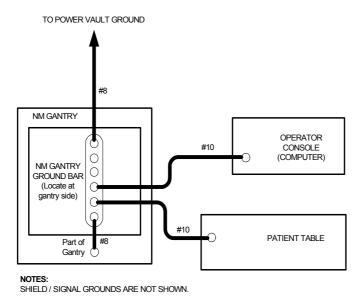


Figure 5-1: B615 System Grounding Map









### **5.3.1 Grounding of System Input Power**

Make sure to comply with both of the following grounding requirements:

#### Connecting to the gantry base

Connect the metal conduit, raceway, or the armor of the armored cable used to power the system, to the system gantry ground.

#### Grounding wire

Only if required by local electrical code:

- Run a dedicated 8 (8 mm<sup>2</sup>) or larger insulated copper ground wire with the phase wires from the main distribution panel to the system gantry ground.
- Connect the ground wire to the MDP through which it passes, in accordance with local codes.
- Ensure that the resistance between the gantry ground and the facility earth ground does not exceed 0.5 Ohm.
- Ensure that the total resistance between the gantry ground and earth does not exceed
   2 Ohm.

#### **NOTE**

The shield or armor of armored cable is not sufficient for this purpose.











Electrical Requirements 5.4 Interconnections

### **5.4 Interconnections**

It is recommended that all cables are run inside ducts or conduits, as indicated in Figure 5-2: B615 Example of Suggested Cable Ducts Routing in Standard Room, p.5-7, which illustrates cable ducts for the recommended scan room size.

Ensure adequate duct or conduit sealing to prevent penetration of liquids or other objects that may damage the cables.

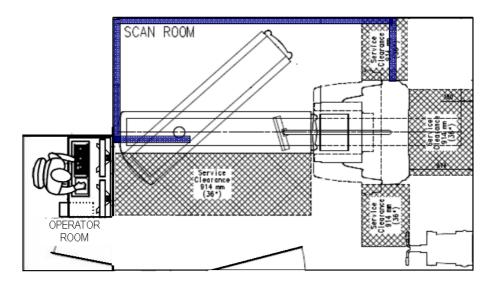


Figure 5-2: B615 Example of Suggested Cable Ducts Routing in Standard Room











Electrical Requirements 5.4 Interconnections

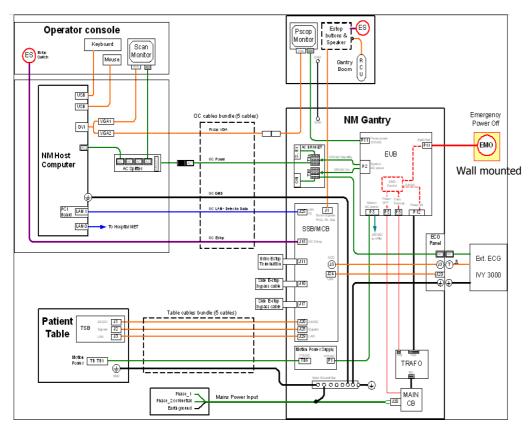


Figure 5-3: B615 Cable Wiring Diagram











## **5.5 System Cable Information**

This section provides technical information regarding system cables connecting different subsystems, in order to facilitate the planning of cable routing.

**Table 5-4: B615 Sub-system Inter-connection Cables** 

Start / Destination		H/V Length in			
From	То	Separation (Y or N)	Meters	Description	
Wall	Gantry	Y	12	NM mains power	
Gantry	Table	N	12	Table bundle	
Gantry	Operator Console	N	10	OC bundle	
Gantry	ЕМО	N	20	EMO (Emergency Off)	









### 5.6 Typical Customer Supplied Cables and Wiring

### **5.6.1 Primary Power Disconnect**

In order to service the system safely, the customer must have a lockout/tagout (LOTO) compatible Mains Disconnect Panel (MDP) installed in the examination room. The MDP must be visible when servicing the system.

### MDP with lockout /tagout (LOTO):

In order to install the system, the customer must have a lockout /tagout (LOTO) compatible Main Disconnect Panel (MDP) installed in the room.

The MPD and the lockout /tagout must be visible when servicing the system.

## 5.7 Lighting Specifications

### **Scan Room Lighting**

The lighting should be planned so there is sufficient light for:

- Scan preparation
- Scan setup
- Patient unloading
- System servicing











The lighting should be designed so that it can be dimmed or otherwise changed in order to minimize discomfort for patients lying supine for extended periods on the patient table with the ceiling in view.

#### **NOTE**

- Scan room lighting above the gantries and patient table area should consist of fluorescent lights only (no direct sunlight or direct bright light from filament light bulbs).
- During system servicing in the scan room, a relatively bright light is required in the area behind and around the gantry.

### **Operator Room Lighting**

The lighting should be planned taking into account that operators will be working with computer monitors and reading digital images during much of the day. Reflections in monitors should be avoided, and other ergonomic factors taken into account.

The operator room lighting must also take into account that relatively bright light is required while servicing the acquisition station.

#### 5.8 Power Line Outlets for Service

It is recommended to install at least two standard power outlets in the scan room and in the operator room, to be used for electrically powered service tools. The exact location of these outlets should be defined according to regulatory and service clearances around the system.











# **Chapter 6: Network Requirements**

The system requires the following network connections:

- BBNC Broad-Band Network Connection (required): broad-band network connection wall jack, located within 1 m (39") of console location, for internal hospital networking and InSite broadband connectivity.
- Local Area Network (LAN) (required)
  - LAN connections are usually required in the operator room for:
    - Xeleris processing station
    - Main system
    - DICOM LAN printer (optional)

The LAN & WAN Networks sockets/outlets (minimum 3) must be available in the operator room with a distance of 1 m (39") from the designated location of the operator console, processing workstations (Xeleris) and LAN printer installed in the operator room.

- In the scan room it is recommended to have one LAN socket/outlet available in close proximity to the gantry for service engineer activities actions.
- Wide Area Network (WAN) (optional)











# **Appendix A: Customer Checklist**

The checklist must be completed by the customer and delivered to GE prior to installation.

#### **IMPORTANT**

This checklist is general in nature and is intended to assist the customer in verifying site preparation. The checklist does not cover all details in this manual, and it is the customer's responsibility to fully prepare the site, taking into account all details and specifications set out in this manual.

Site Information Contact Information	<b>Contact Persons</b>	Name	Telephone	email
Site name	Site project coordinator			
Department	System administrator			
Street	Chief technologist			
City, State, Zip	Facilities engineer			
Country	Shipping/Receiving			
Telephone	Physician			
Fax	Other			

Safety Declaration						
I haveby confirm that the velocant site percental have read the Cafety and	Name					
I hereby confirm that the relevant site personnel have read the <i>Safety and System Overview Manual</i> , in conjunction with this Site Preparation Manual.	Position					
System overview riaman, in conjunction with this site reparation riaman	Signature					
Completion Sign Off	Completion Sign Off					
Thereby confirm that we installation is complete and that I have evening and	Name					
I hereby confirm that pre-installation is complete and that I have examined and confirmed all items in the Pre-Installation Customer Checklist	Position					
Committee an remain and the tree processing content of the charge	Signature					











**Table A-1: Deviation from Specifications in Site Preparation Manual** 

Description		Personal Details	
Floor &	I hereby confirm that the site takes full responsibility for the	Name	
Anchoring	floor and anchoring methods differing from the specifications in this manual	Position	
		Signature	

### **Table A-2: Site Preparation Time-table**

Description			See	Comments
	Project schedule verified with GE			
	3rd party vendors scheduled			
	Can meet the committed site ready date			
	Construction completion date matches delivery date			
Scheduling	Delivery date scheduled for			
	Installation dates scheduled for			
	Applications/Training date scheduled for			
	Site Ready date scheduled for			
	First Use date scheduled for			









### **Table A-3: Room Preparation**

Description		Status	See	Comments
	Site layout drawings completed and approved			
	Radiologist health physician has reviewed the room layout			
Pre-construction	3rd party vendors identified:			
Post-construction:	■ Length			
Room measurements and layout	■ Height			
layout	■ Width			
Servicing clearance	Meets requirements			
Egress	Sufficient egress space			
0	Floor tolerates specified loads			
Structural and floor preparation	Floor leveling meets requirements			
	Floor flatness meets requirements			
Ducts	Ducts installed in floor, according to approved room layout			
	Ducts meet requirements (size, depth, sealing, high voltage separation)			











### **Table A-3: Room Preparation (cont.)**

Description			See	Comments
	Main Distribution Panel (MDP) meets requirements and is installed			
Electricity requirements	Power line meets requirements			
	Wall outlets available for installation & service tools			
	Air-conditioning meets requirements for system thermal loads			
Environmental conditions	Air-conditioning meets humidity requirements			
Conditions	Magnetic field in camera room is < 1 Gauss			
	Room is clean and free of dust, ready for installation			
Doom shiolding	Shielding of scan room meets requirements			
Room shielding	Shielding of operator room meets requirements			
	External exposure light installed			
Safety	Planned location of emergency button in scan room is easily accessible by operator			
Interlock system installed				











### **Table A-4: Unloading, Conveyance and Storage**

Description			See	Comments
Temporary storage	System will be delivered on first install day  or  Some or all crated components will be stored until installation date			
	If stored, storage area meets requirements  Site has sufficient storage area			
	Is a loading dock with 112 cm (44") truck-height available?			
Loading dock	Full-size truck can access loading dock <b>or</b> Site will arrange for short truck delivery			
Unloading by forklift	Site has forklift with weight capacity to lift a			
Rigging (required if halls/ elevator/doors access is not available)	Rigging company details:  Name:  Contact person:  Phone:			
	Rigging company has insurance policy  Insurance policy of rigger company is attached			











### **Table A-4: Unloading, Conveyance and Storage (cont.)**

Description			See	Comments
Pallet truck	Site has pallet truck  or  Site will arrange for pallet truck			
Delivery route	Delivery route is defined by site and meets requirements			
	Delivery route is tested by site			
Installation room	Room can be locked during installation			
Suitability of halls, elevators	All door openings, hallways are large enough			
and doors for conveyance of all	Pathways can tolerate weight			
components, when mounted on moving kit/wheels	Elevator openings and size are large enough			
moving kit/wheels	Elevator can tolerate weight			
<b>Note:</b> All items must refer to	Patient table can clear all 90° corners			
conveyance as follows:	Gantry can clear all corners			
<ul><li>From truck to installation room (crated or uncrated)</li></ul>	Inclines on the route to the camera room are suitable (weight, size and incline angle)			
or	State the incline angle			
<ul><li>From truck to storage (crated)</li><li>&amp; from storage to installation</li></ul>	There are delicate carpets or tiles along the conveyance route			
room (crated or uncrated)	Floor protection is supplied for delicate surfaces			
Waste materials	Site has arranged for disposal of empty wooden cases, foam blocks and large cardboard boxes after installation			











#### **Table A-5: Network**

Description	Description				Comments
Network cabling and hardware	Installation complete				
Broadband	Installed and tested				
Network definitions and testing	Acquisition station site IP address defined and				
	Xeleris workstation site IP address defined and	· ·			
	CT console site name, hostname and IP address defined and tested				
	AW workstation site na IP address defined and				
<b>Network Definition De</b>	tails		1		
Item	Hostname IP		Wired (Y/N)	DICOM Port	AE Title
NM Acquisition Station					
Processing host					
Hardcopy host					
LAN Net Mask					
Gateway to other networks					











**Table A-6: Radioactive Isotopes for System Calibration** 

Description	Status	See	Comments	
Basic calibration	Site has license for Tc <sup>99m</sup>			
basic calibration	Tc <sup>99m</sup> will be available during installation			
	Co <sup>57</sup> (Rectangular Flood Source)			
Isotopes to be used at	TI <sup>201</sup>			
site are available for	I <sup>131</sup>			
installation.  Note: Specify age and strength in Comments	I <sup>123</sup>			
	In <sup>111</sup>			
	Ga <sup>67</sup>			
	Xe <sup>133</sup> (inhalation gas)			











# **Appendix B: EMC Compliance**

This equipment complies with IEC60601-1-2 standard for medical electrical equipment.

The system is suitable to be used in an electromagnetic environment, in compliance with the limits and recommendations provided in the following tables:

- Emission Compliance level and limits
- Immunity Compliance level and recommendations to maintain equipment clinical utility

**Table B-1: EMC Emission Declaration** 

<b>Emissions Test</b>	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	NA	The system is suitable for use in all establishments other than domestic and those directly connected to the public
Voltage fluctuations/ flicker emissions IEC 61000-3-2	NA	low-voltage power supply network that supplies buildings used for domestic purposes.









**Table B-2: EMC Immunity Guidance and Declaration**\*

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 6 kV Air: ± 8 kV	Contact: ± 6 kV Air: ± 8 kV	Floors must be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ± 2 kV  Input/output lines: ± 1 kV	Power supply lines: ± 2 kV  Input/output lines: ± 1 kV	Mains power quality should be that of typical commercial or hospital environment.
Surge IEC 61000-4-5	Line-line: ± 1 kV Line-earth: ± 2 kV	Line-line: ± 1 kV Line-earth: ± 2 kV	Mains power quality should be that of typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U <sub>T</sub> <sup>†</sup> (> 95% dip in U <sub>T</sub> ) for 5 sec	< 5% U <sub>T</sub> <sup>†</sup> (> 95% dip in U <sub>T</sub> ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.











**Table B-2: EMC Immunity Guidance and Declaration (cont.)**\*

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-8			<b>Note:</b> $U_T$ is the AC mains voltage prior to application of the test level.
Conducted RF IEC 61000-4-6	3 <sub>VRMS</sub> 150 kHz to 80 MHz	3 <sub>VRMS</sub> 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from
Radiated RF IEC 61000-4-3 (alternative method: IEC 61000-4-21)	3 <sub>V/m</sub> 80 kHz to 2.5 GHz	3 <sub>V/m</sub> 80 kHz to 2.5 GHz	the equation appropriate for the frequency of the transmitter.  For recommended separation distances, see Table B-3, p.B-4.

<sup>\*</sup> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.











<sup>†</sup> UT is the a.c. mains voltage prior to application of the test level.

Table B-3: Separation Distances for Portable and Mobile RF Communications Equipment

Rated Max Transmitter Output (Watts)	Separation distance according to frequency of transmitter (meters)			Comments
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5GHz	Where <b>P</b> is the maximum output power rating of
	$d = \left[\frac{3.5}{3}\right] \sqrt{P}$	$d = \left[\frac{3.5}{3}\right] \sqrt{P}$	$d = \left[\frac{7}{3}\right] \sqrt{P}$	the transmitter in watts (W) according to the transmitter manufacturer and <b>d</b> is the recommended separation distance in meters (m).
0.01	0.:	12	0.23	Field strengths from fixed RF transmitters, as
0.1	0.37		0.74	determined by an electromagnetic site survey*, should be less than the compliance level in each
1	1.17		2.33	frequency range <sup>†</sup> .
10	3.69		7.38	Interference may occur in the vicinity of equipment marked accordingly.
100	11	.7	23.3	equipment marked accordingly.

<sup>\*</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation the system.











<sup>†</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

# **Appendix C: Regulatory Clearances**

### **C.1 Regulatory Clearances**

MINIMUM CLEARANCES UNDER U.S. FEDERAL REGULATIONS AND NATIONAL STANDARDS: 29 CFR 1910 (OSHA), NFPA 70E (STANDARD FOR ELECTRICAL SAFETY IN THE WORKPLACE), AND NFPA 101 (LIFE SAFETY CODE):

Figure C-1: B615 Regulatory Clearance Requirements, p.C-1 is a map of clearance requirements for U.S. regulatory compliance. See clearance tables on the following pages for detailed dimensional clearances. Please note all systems installed in the United States must comply with all Federal and local regulations. For installations outside the United States, country-specific or other local regulatory clearance requirements must be met. See Service Clearances, p.11 for additional information.

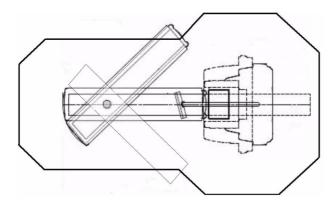


Figure C-1: B615 Regulatory Clearance Requirements











### **C.1.1 Regulatory Code Description**

Egress: 29 CFR 1910 Subpart E (OSHA) and NFPA 101 (Life Safety Code) define the minimum requirements for means of egress. The requirement most applicable to equipment installation and room layout is minimum width of exit access. Under OSHA 1910.37(f)(6), the minimum width of exit access shall in no case be less than 28 in. from any potentially occupied point in the room.

Under NFPA 101 (2006 edition) 7.3.4.1, the minimum width of any means of egress is 36 in. However, NFPA allows this to be reduced to 28 in. around furniture or equipment, provided that a 36 in. clearance would otherwise be available without moving permanent walls.

Electrical Clearance: 29 CFR 1910 Subpart S (OSHA) and NFPA 70E (Standard for Electrical Safety in the Workplace) define minimum clearance requirements for the workspace around electrical equipment. Under both OSHA 1910.303(g)(1) and NFPA 70E (2004 edition) 400.15, a minimum clear space of 36" depth (with minimum 30" width and 78" height) must be provided in front of electrical equipment with parts operating at 600 volts or below and likely to require examination, adjustment, servicing, or maintenance while energized.

This safety clearance requirement applies to all GEHC equipment. Although 36 in. is the minimum clearance for most installations, the standards require an increased minimum clearance distance where parts operate above 150 volts (but still below 600 volts) under the following circumstances:

- If the wall or surface directly facing the electrical equipment is grounded (e.g. brick, concrete, or tile) or includes grounded protrusions (such as medical gas ports, metal door or window frames, water sources and metallic sink structures, metallic cabinetry, electrical disconnects or emergency off panels, air conditioners or vents), then a 42" clearance depth is required.
- If the possibility exists of exposed and unguarded live parts on both sides of the workspace (for example if a power distribution unit were positioned on the wall directly facing the GEHC equipment), then a 48" clearance depth is required.











### **C.1.2 Regulated Minimum Working Clearance by Major Subsystem**

Requirements apply to equipment operating at 600V or less, where examination, adjustment, servicing, or maintenance is likely to be performed while live parts are exposed.

Direction of Service Access is defined as perpendicular to the surface of the equipment being serviced. Required regulatory clearance distances must be maintained and may not be used for storage. This includes normal system operation as well as service inspection or maintenance.

For the gantry and table, distances are measured from the enclosure, not the finish covers.

**Table C-1: Gantry Subsystem** 

Work Space Requirement	Minimum Clear Space	Additional Conditions
Direction of service access (all sides)	914 mm (36 in.)	If exposed live parts of 151 - 600 volts are present, 1219 mm (48 in.) on both sides of workspace with the operator between is required.
		If the opposite wall is grounded and exposed live parts of 151 - 600 volts are present, 1067 mm (42 in.) is required.
Service access width (left-right of workspace)	762 mm (30 in.)	This is the width of the working space in front of the equipment. A minimum of 762 mm (30 in.) or the width of the equipment, whichever is greater, is required.









**Table C-2: Table Subsystem** 

Work Space Requirement	Minimum Clear Space	Additional Conditions
Direction of service access	914 mm (36 in.)	There are no exposed live parts hazards with the cover in place.
(table head or foot)		This component is typically serviced from all four sides.
		This is the width of the workspace on each side of the equipment. A minimum of 914.4 mm (36 in.), or the width of the equipment, whichever is greater, is required.
Direction of service access (table sides)	914 mm (36 in.)*	*This distance can be reduced to 711 mm (28 in.) provided a written and signed approval is obtained by the local team from the local AHJ (Authority Having Jurisdiction). The signed document must be on file with GE.
Direction of Service access (table foot)	711 mm (28 in.)	For the front gantry cover removal, a minimum of 457 mm (18 in.) is allowed only if an unobstructed egress space of 711 mm (28 in.) is maintained around the equipment for room exit. This also means no trip hazards exist along the path of egress.
Service access width (left-right of workspace)	762 mm (30 in.)	This is the width of the working space in front of the equipment. A minimum of 762 mm (30 in.) or the width of the equipment, whichever is greater, is required.









#### **Table C-3: Console Subsystem**

Work Space Requirement	Minimum Clear Space	Additional Conditions
Direction of service access: front of console	914 mm (36 in.)	There are no exposed live part hazards with the cover in place. If the console is placed under a counter, the front edge of the console must be even with the vertical edge of the console workspace.
		Note: This component is typically serviced from the front with access to the rear.
Service access width: Front of console	762 mm (30 in.)	This is the width of the workspace in front of the equipment. A minimum of 762 mm (30 in.) or the width of the equipment, whichever is greater, is required.
Head clearance	1981.2 mm (78 in.)	This is the height of the workspace measured from the floor at the front edge of the equipment to the ceiling or overhead obstruction(s).
		A minimum of 1981.2 mm (78 in.) or the height of the equipment, whichever is greater, is required.











#### **Table C-4: UPS Subsystem**

Work Space Requirement	Minimum Clear Space	Additional Conditions
Direction of service access (front of UPS)	914.4 mm (36 in.)*	There are no exposed live part hazards with the cover in place. This component is typically serviced from the front with access to the rear.
		$^{st}$ If exposed live parts of 151 - 600 volts are present, 1219 mm (48 in.) is required on both sides of the workspace with the opera-tor between.
		* If the opposite wall is grounded and exposed live parts of 151 - 600 volts are present, 1067 mm (42 in.) is required.
Service access width (right side and length of UPS)	762 mm (30 in.)	This is the width of the working space in front of the equipment. A minimum of 762 mm (30 in.) or the width of the equipment, whichever is greater, is required
Head clearance	1981 mm (78 in.)	This is the height of the workspace measured from the floor at the front edge of the equipment to the ceiling or overhead obstruction(s). A minimum of 1981 mm (78 in.) or the height of the equipment, whichever is greater, is required.











**Table C-5: MDP Disconnect Subsystem** 

Work Space Requirement	Minimum Clear Space	Additional Conditions
Direction of service access (front of MDP)	914.4 mm (36 in.)*	There are no exposed live part hazards with the cover in place. This component is typically serviced from the front with access to the rear.
		$^{st}$ If exposed live parts of 151 - 600 volts are present, 1219 mm (48 in.) is required on both sides of the workspace with the opera-tor between.
		* If the opposite wall is grounded and exposed live parts of 151 - 600 volts are present, 1067 mm (42 in.) is required.
Service access width (right side and length of MDP)	762 mm (30 in.)	This is the width of the working space in front of the equipment. A minimum of 762 mm (30 in.) or the width of the equipment, whichever is greater, is required.
Head clearance	1981 mm (78 in.)	This is the height of the workspace measured from the floor at the front edge of the equipment to the ceiling or overhead obstruction(s). A minimum of 1981 mm (78 in.) or the height of the equipment, whichever is greater, is required.









#### C.1.3 Terms and Definitions

**Egress**: The path of exit from within any room. U.S. regulations require a minimum of 28" (711.2 mm) of continuous and unobstructed space, including trip hazards along the path of exit.

**Workspace**: The dimensional box required for safe inspection or service of energized equipment. It consists of depth, width, and height. The depth dimension is measured perpendicular to the direction of access. The U.S. regulation minimum is 36" (914.4 mm), but additional conditions can increase the minimum dimension requirement. GEHC defines this as the envelope of the component superstructure with the external covers in place.

**Service Access Width**: The width of the workspace in front of the equipment. A minimum of 30" (762 mm), or the width of the equipment, whichever is greater.

**Head Clearance**: The height dimension of the workspace. The height of the workspace measured from the floor at the front edge of the equipment to the ceiling or overhead obstruction(s). 78" (1981.2 mm), or the height of the equipment, whichever is greater.

**Grounded Wall**: Any wall that can be electrically conductive to earth ground. Masonry, concrete, and tile are considered conductive. Additional commonly found aspects of a wall should also be considered grounded.











#### The following is not an all-inclusive list:

- Medical gas ports and plates
- Metal doors and window frames
- Water sources and metallic sink structures
- Metallic wall-mounted cabinetry
- MDP
- Equipment Emergency OFF panels
- Industrial equipment (such as air conditioners and vents)
- Expansion joints
- Surface raceway
- Exposed wall conduits
- Floor outlets boxes

The following are not considered as grounded elements of a common wall:

- Standard wall outlet
- Light switches
- Telephones
- Communication wall jacks
- Ceiling tile grids











### **C.1.4 Additional Regulatory Clearance Information**

### **C.1.4.1 Regulatory Caution**

Site prints are required for all system installations including relocation and moves. The room layout, as shown on your site print, shall meet all regulatory requirements as described in the installation manual. Additional room components, such as cabinets, reduce room size. Equipment not shown on the site print may void the caution statement, making the room non-compliant. Actual site measurements before installation will be taken to determine room size and compliance.

### **C.1.4.2 Egress Clearance**

Egress requires a clear, unobstructed route out of the room, either around the back of the gantry or around the back of the table. If your egress route is not around the back of the table, maintain 457 mm (18") of clearance between the back of the table, with a continuous width of 3200 mm (126"), 1600 mm (63") on each side of the table center line, on each side to any obstruction so that the front cover can be removed. Refer to the Pre-Installation manual for more details on service clearances.

#### **Exceptions**

Rooms smaller than 512 cm  $\times$  374 cm (17 ft.  $\times$  12 ft.), require construction to meet the minimum requirements. The design center or your GE PMI may have additional recommendations for your room size.











Regulatory Clearances C.2 Service Clearances

#### C.2 Service Clearances

Servicing of the system can be safely performed within the regulatory envelopes defined in C.1 Regulatory Clearances; however sufficient space must be maintained to remove the covers from the system.

To achieve this clearance for the gantry, clear space must be available to maneuver the gantry covers. One Service Engineer can accomplish this.









