SenoClaire

GE Breast Tomosynthesis

Pre-Installation Manual

OPERATING DOCUMENTATION

5415897-5-8EN
Revision 1

ATTENTION

LES APPAREILS A RAYONS X SONT DANGEREUX A LA FOIS POUR LE PATIENT ET POUR LE MANIPULATEUR SI LES MESURES DE PROTECTION NE SONT PAS STRICTEMENT APPLIQUEES

Bien que cet appareil soit construit selon les normes de sécurité les plus sévères, la source de rayonnement X représente un danger lorsque le manipulateur est non qualifié ou non averti.
Une exposition excessive au rayonnement X entraîne des dommages à l'organisme.
Par conséquent, toutes les précautions doivent être prises pour éviter que les personnes non autorisées ou non qualifiées utilisent cet appareil créant ainsi un danger pour les autres et pour elles-mêmes.
Avant chaque manipulation, les personnes qualifiées et autorisées à se servir de cet appareil doivent se renseigner sur les mesures de protection établies par la Commission Internationale de la Protection Radiologique, Annales 26 : Recommandations de la Commission Internationale sur la Protection Radiologique et les normes nationales en vigueur.

WARNING

X-RAY EQUIPMENT IS DANGEROUS TO BOTH PATIENT AND OPERATOR UNLESS MEASURES OF PROTECTION ARE STRICTLY OBSERVED

Though this equipment is built to the highest standards of electrical and mechanical safety, the useful x-ray beam becomes a source of danger in the hands of the unauthorized or unqualified operator.
Excessive exposure to x-radiation causes damage to human tissue.
Therefore, adequate precautions must be taken to prevent unauthorized or unqualified persons from operating this equipment or exposing themselves or others to its radiation.
Before operation, persons qualified and authorized to operate this equipment should be familiar with the Recommendations of the International Commission on Radiological Protection, contained in Annals Number 26 of the ICRP, and with applicable national standards.

ATENCION

LOS APARATOS DE RAYOS X SON PELIGROSOS PARA EL PACIENTE Y EL MANIPULADOR CUANDO LAS NORMAS DE PROTECCION NO ESTAN OBSERVADAS

Aunque este aparato está construido según las normas de seguridad más estrictas, la radiación X constituye un peligro al ser manipulado por personas no autorizadas o incompetentes. Una exposición excesiva a la radiación X puede causar daños al organismo.
Por consiguiente, se deberán tomar todas las precauciones necesarias para evitar que las personas incompetentes o no autorizadas utilicen este aparato, lo que sería un peligro para los demás y para sí mismas.
Antes de efectuar las manipulaciones, las personas habilitadas y competentes en el uso de este aparato, deberán informarse sobre las normas de protección fijadas por la Comisión Internacional de la Protección Radiológica, Anales No 26: Recomendaciónes de la Comisión Internacional sobre la Protección Radiológica y normas nacionales.

ACHTUNG

RÖNTGENAPPARATE SIND EINE GEFAHR FÜR PATIENTEN SOWIE BEDIENUNGSPERSONAL, WENN DIE GELTENDEN SICHERHEITSVORKEHRUNGEN NICHT GENAU BEACHTET WERDEN

Dieser Apparat entspricht in seiner Bauweise strengsten elektrischen und mechanischen Sichereitsnormen, doch in den Händen unbefugter oder unqualifizierter Personen wird er zu einer Gefahrenquelle.
Übermäßige Röntgenbestrahlung ist für den menschlichen Organismus schädlich.
Deswegen sind hinreichende Vorsichtsmaßnahmen erforderlich, um zu verhindern, daßunbefugte oder unqualifizierte Personen solche Geräte bedienen oder sich selbst und andere Personen deren Bestrahlung aussetzen können.
Vor Inbetriebnahme dieses Apparats sollte sich das qualifizierte und befugte Bedienungspersonal mit den geltenden Kriterien für den gefahrlosen Strahleneinsatz durch sorgfältiges Studium des Hefts Nr. 26 der Internationalen Kommission für Strahlenschutz (ICRP) vertraut machen: Empfehlungen der Internationalen Kommission für Strahlenschutz und anderer nationaler Normenbehörden.

Important Information

LANGUAGE

ПРЕДУПРЕЖДЕНИЕ (BG)

Това упътване за работа е налично само на английски език.

- Ако доставчикът на услугата на клиента изиска друг език, задължение на клиента е да осигури превод.
- Не използвайте оборудването, преди да сте се консултирали и разбрали упътването за работа.
- 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.

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。

警告 (ZH-HK)

本服務手冊僅提供英文版本。

- 倘若客戶的服務供應商需要英文以外之服務手冊，客戶有責任提供翻譯服務。
- 除非已參閱本服務手冊及明白其內容，否則切勿嘗試維修設備。
- 不遵從本警告或會令服務供應商、網絡供應商或病人受到觸電、機械性或其他的危險。

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)

Ovaj servisni priručnik dostupan je na engleskom jeziku.

- Ako davatelj usluge klijenta treba neki drugi jezik, klijent je dužan osigurati prijevod.
- Ne pokušavajte servisirati opremu ako niste u potpunosti pročitali i razumjeli ovaj servisni priručnik.
- Zanemarite li ovo upozorenje, može doći do ozljede davatelja usluge, operatera ili pacijenta uslijed strujnog udara, mehaničkih ili drugih rizika.

VÝSTRAHA (CS)

Tento provozní návod existuje pouze v anglickém jazyce.

- V případě, že externí služba zákazníkům potřebuje návod v jiném jazyce, je zajištění překladu do odpovídajícího jazyka úkolem zákazníka.
- Nesnažte se o údržbu tohoto zařízení, aniž byste si přečetli tento provozní návod a pochopili jeho obsah.
- 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.

ADVARSEL (DA)

Denne servicemanual findes kun på engelsk.

- Hvis en kundes tekniker har brug for et andet sprog end engelsk, er det kundens ansvar at sørge for oversættelse.
- Forsøg ikke at servicere udstyret uden at læse og forstå denne servicemanual.
- Manglende overholdelse af denne advarsel kan medføre skade på grund af elektrisk stød, mekanisk eller anden fare for teknikeren, operatøren eller patienten.

WAARSCHUWING (NL)

Deze onderhoudshandleiding is enkel in het Engels verkrijgbaar.

- Als het onderhoudspersoneel een andere taal vereist, dan is de klant verantwoordelijk voor de vertaling ervan.
- Probeer de apparatuur niet te onderhouden alvorens deze onderhoudshandleiding werd geraadpleegd en begrepen is.
- 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.

WARNING (EN)

This service manual is available in English only.

- If a customer's service provider requires a language other than English, it is the customer's responsibility to provide translation services.
- Do not attempt to service the equipment unless this service manual has been consulted and is understood.
- Failure to heed this warning may result in injury to the service provider, operator or patient from electric shock, mechanical or other hazards.

HOIATUS (ET)

See teenindusjuhend on saadaval ainult inglise keeles.

- Kui klienditeeninduse osutaja nõuab juhendit inglise keelest erinevas keeles, vastutab klient tõlketeenuse osutamise eest.
- Ärge üritage seadmeid teenindada enne eelnevalt käesoleva teenindusjuhendiga tutvumist ja sellest aru saamist.
- Käesoleva hoiatuse eiramine võib põhjustada teenuseosutaja, operaatori või patsiendi vigastamist elektrilöögi, mehaanilise või muu ohu tagajärjel.

VAROITUS (FI)

Tämä huolto-ohje on saatavilla vain englanniksi.

- Jos asiakkaan huoltohenkilöstö vaatii muuta kuin englanninkielistä materiaalia, tarvittavan käännöksen hankkiminen on asiakkaan vastuulla.
- Älä yritä korjata laitteistoa ennen kuin olet varmasti lukenut ja ymmärtänyt tämän huolto-ohjeen.
- Mikäli tätä varoitusta ei noudateta, seurauksena voi olla huoltohenkilöstön, laitteiston käyttäjän tai potilaan vahingoittuminen sähköiskun, mekaanisen vian tai muun vaaratilanteen vuoksi.

ATTENTION (FR)

Ce manuel d’installation et de maintenance est disponible uniquement en anglais.

- 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.
- Ne pas tenter d'intervenir sur les équipements tant que ce manuel d’installation et de maintenance n'a pas été consulté et compris.
- 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.

WARNUNG (DE)

Diese Serviceanleitung existiert nur in englischer Sprache.

- Falls ein fremder Kundendienst eine andere Sprache benötigt, ist es Aufgabe des Kunden für eine entsprechende Übersetzung zu sorgen.
- Versuchen Sie nicht diese Anlage zu warten, ohne diese Serviceanleitung gelesen und verstanden zu haben.
- Wird diese Warnung nicht beachtet, so kann es zu Verletzungen des Kundendiensttechnikers, des Bedieners oder des Patienten durch Stromschläge, mechanische oder sonstige Gefahren kommen.

ΠΡΟΕΙΔΟΠΟΙΗΣΗ (EL)

Το παρόν εγχειρίδιο σέρβις διατίθεται μόνο στα αγγλικά.

- Εάν ο τεχνικός σέρβις ενός πελάτη απαιτεί το παρόν εγχειρίδιο σε γλώσσα εκτός των αγγλικών, αποτελεί ευθύνη του πελάτη να παρέχει τις υπηρεσίες μετάφρασης.
- Μην επιχειρήσετε την εκτέλεση εργασιών σέρβις στον εξοπλισμό αν δεν έχετε συμβουλευτεί και κατανοήσει το παρόν εγχειρίδιο σέρβις.
- Αν δεν προσέξετε την προειδοποίηση αυτή, ενδέχεται να προκληθεί τραυματισμός στον τεχνικό σέρβις, στο χειριστή ή στον ασθενή από ηλεκτροπληξία, μηχανικούς ή άλλους κινδύνους.

FIGYELMEZTETÉS (HU)

Ezen karbantartási kézikönyv kizárólag angol nyelven érhető el.

- Ha a vevő szolgáltatója angoltól eltérő nyelvre tart igényt, akkor a vevő felelőssége a fordítás elkészíttetése.
- Ne próbálja elkezdeni használni a berendezést, amíg a karbantartási kézikönyvben leírtakat nem értelmezték.
- Ezen figyelmeztetés figyelmen kívül hagyása a szolgáltató, működtető vagy a beteg áramütés, mechanikai vagy egyéb veszélyhelyzet miatti sérülését eredményezheti.

AÐVÖRUN (IS)

Þessi þjónustuhandbók er aðeins fáanleg á ensku.

- Ef að þjónustuveitandi viðskiptamanns þarfnast annas tungumáls en ensku, er það skylda viðskiptamanns að skaffa tungumálaþjónustu.
- Reynið ekki að afgreiða tækið nema að þessi þjónustuhandbók hefur verið skoðuð og skilin.
- Brot á sinna þessari aðvörun getur leitt til meiðsla á þjónustuveitanda, stjórnanda eða sjúklings frá raflosti, vélrænu eða öðrum áhættum.

AVVERTENZA (IT)

Il presente manuale di manutenzione è disponibile soltanto in lingua inglese.

- Se un addetto alla manutenzione richiede il manuale in una lingua diversa, il cliente è tenuto a provvedere direttamente alla traduzione.
- Procedere alla manutenzione dell'apparecchiatura solo dopo aver consultato il presente manuale ed averne compreso il contenuto.
- 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.

警告 (JA)

このサービスマニュアルには英語版しかありません。

- 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。
- 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。
- 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。

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 서비스 제공자, 사용자 또는 환자에게 부상을 입힐 수 있습니다.

BRĪDINĀJUMS (LV)

Šī apkopes rokasgrāmata ir pieejama tikai angļu valodā.

- Ja klienta apkopes sniedzējam nepieciešama informācija citā valodā, klienta pienākums ir nodrošināt tulkojumu.
- Neveiciet aprīkojuma apkopi bez apkopes rokasgrāmatas izlasīšanas un saprašanas.
- Šī brīdinājuma neievērošanas rezultātā var rasties elektriskās strāvas trieciena, mehānisku vai citu faktoru izraisītu traumu risks apkopes sniedzējam, operatoram vai pacientam.

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)

Niniejszy podręcznik serwisowy dostępny jest jedynie w języku angielskim.

- Jeśli serwisant klienta wymaga języka innego niż angielski, zapewnienie usługi tłumaczenia jest obowiązkiem klienta.
- Nie próbować serwisować urządzenia bez zapoznania się z niniejszym podręcznikiem serwisowym i zrozumienia go.
- Niezastosowanie się do tego ostrzeżenia może doprowadzić do obrażeń serwisanta, operatora lub pacjenta w wyniku porażenia prądem elektrycznym, zagrożenia mechanicznego bądź innego.

ATENÇÃO (PT-BR)

Este manual de assistência técnica encontra-se disponível unicamente em inglês.

- Se outro serviço de assistência técnica solicitar a tradução deste manual, caberá ao cliente fornecer os serviços de tradução.
- Não tente reparar o equipamento sem ter consultado e compreendido este manual de assistência técnica.
- A não observância deste aviso pode ocasionar ferimentos no técnico, operador ou paciente decorrentes de choques elétricos, mecânicos ou outros.

ATENÇÃO (PT-PT)

Este manual de assistência técnica só se encontra disponível em inglês.

- Se qualquer outro serviço de assistência técnica solicitar este manual noutro idioma, é da responsabilidade do cliente fornecer os serviços de tradução.
- Não tente reparar o equipamento sem ter consultado e compreendido este manual de assistência técnica.
- 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.

ATENŢIE (RO)

Acest manual de service este disponibil doar în limba engleză.

- Dacă un furnizor de servicii pentru clienți necesită o altă limbă decât cea engleză, este de datoria clientului să furnizeze o traducere.
- Nu încercați să reparați echipamentul decât ulterior consultării și înțelegerii acestui manual de service.
- Ignorarea acestui avertisment ar putea duce la rănirea depanatorului, operatorului sau pacientului în urma pericolelor de electrocutare, mecanice sau de altă natură.

ОСТОРОЖНО! (RU)

Данное руководство по техническому обслуживанию представлено только на английском языке.

- Если сервисному персоналу клиента необходимо руководство не на английском, а на каком-то другом языке, клиенту следует самостоятельно обеспечить перевод.
- Перед техническим обслуживанием оборудования обязательно обратитесь к данному руководству и поймите изложенные в нем сведения.
- Несоблюдение требований данного предупреждения может привести к тому, что специалист по техобслуживанию, оператор или пациент получит удар электрическим током, механическую травму или другое повреждение.

UPOZORENJE (SR)

Ovo servisno uputstvo je dostupno samo na engleskom jeziku.

- Ako klijentov serviser zahteva neki drugi jezik, klijent je dužan da obezbedi prevodilačke usluge.
- Ne pokušavajte da opravite uređaj ako niste pročitali i razumeli ovo servisno uputstvo.
- Zanemarivanje ovog upozorenja može dovesti do povređivanja servisera, rukovaoca ili pacijenta usled strujnog udara ili mehaničkih i drugih opasnosti.

UPOZORNENIE (SK)

Tento návod na obsluhu je k dispozícii len v angličtine.

- Ak zákazníkov poskytovateľ služieb vyžaduje iný jazyk ako angličtinu, poskytnutie prekladateľských služieb je zodpovednosťou zákazníka.
- Nepokúšajte sa o obsluhu zariadenia, kým si neprečítate návod na obluhu a neporozumiete mu.
- Zanedbanie tohto upozornenia môže spôsobiť zranenie poskytovateľa služieb, obsluhujúcej osoby alebo pacienta elektrickým prúdom, mechanické alebo iné ohrozenie.

ATENCION (ES)

Este manual de servicio sólo existe en inglés.

- 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.
- No se deberá dar servicio técnico al equipo, sin haber consultado y comprendido este manual de servicio.
- 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.

VARNING (SV)

Den här servicehandboken finns bara tillgänglig på engelska.

- Om en kunds servicetekniker har behov av ett annat språk än engelska, ansvarar kunden för att tillhandahålla översättningstjänster.
- Försök inte utföra service på utrustningen om du inte har läst och förstår den här servicehandboken.
- Om du inte tar hänsyn till den här varningen kan det resultera i skador på servicetekniker, operatören eller patienten till följd av elektriska stötar, mekaniska faror eller andra faror.

OPOZORILO (SL)

Ta servisni priročnik je na voljo samo v angleškem jeziku.

- Če ponudnik storitve stranke potrebuje priročnik v drugem jeziku, mora stranka zagotoviti prevod.
- Ne poskušajte servisirati opreme, če tega priročnika niste v celoti prebrali in razumeli.
- Če tega opozorila ne upoštevate, se lahko zaradi električnega udara, mehanskih ali drugih nevarnosti poškoduje ponudnik storitev, operater ali bolnik.

DİKKAT (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.

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Revision History

Date	Reference	Revision	Main modification
2013–04	5415897-1-8EN	2	M3 Release.
2014–04	5415897-2-8EN	1	M4 Release.
2014–07	5415897-3-8EN	1	M4 FDA / Canada Release.
2014–11	5415897-4-8EN	1	Aurora Vitality Release.
2016–03	5415897-5-8EN	1	Pollux Release. Updated for Positioner Software upgrade, Image Position fix, Essential Upgrade kit for SenoClaire introduction and to resolve the following SPRs: • HCSDM00365157: FMI 12211 removal and Essential Upgrade Kit for SenoClaire introduction • HCSDM00380501: Recon Box Heat Output addition • HCSDM00376609: Gantry software release update (Pollux version) • HCSDM00391084: update of ADS and IDC versions to 56.21 (ADS) and 13.11-1.1 (IDC). • HCSDM00397247: minor corrections.

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Chapter 1 Safety

1 Introduction

This chapter contains safety information specific to the option.

For safety information regarding the System refer to the *Safety chapter* in the *Core SIP*.

⚠CAUTION

Connection of the system to a network/data coupling that includes other equipment could result in previously unidentified risks to patients, operators or third parties
The responsible organization should identify, analyze, evaluate and control these risks.

Subsequent changes to the network/data coupling could introduce new risks and require additional analysis.

Changes to the network/data coupling include:

- **changes in network/data coupling configuration,**
- **connection of additional items to the network/data coupling**
- **disconnecting items from the network/data coupling**
- **update of equipment connected to the network/data coupling**
- **upgrade of equipment connected to the network/data coupling.**

⚠WARNING

IF THIS EQUIPMENT IS MODIFIED, APPROPRIATE INSPECTION AND TESTING MUST BE CONDUCTED TO ENSURE CONTINUED SAFE USE OF THE EQUIPMENT.

⚠WARNING

THE USE OF ACCESSORIES, TRANSDUCERS AND CABLES OTHER THAN THOSE SPECIFIED, WITH THE EXCEPTION OF TRANSDUCERS AND CABLES SOLD BY THE MANUFACTURER OF THE SYSTEM AS REPLACEMENT PARTS FOR INTERNAL COMPONENTS, MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE SYSTEM.

2 Definition of Warnings and Notes

⚠DANGER

INDICATES AN IMMINENTLY HAZARDOUS SITUATION THAT, IF NOT AVOIDED, WILL RESULT IN DEATH OR SERIOUS INJURY.

⚠WARNING

INDICATES A POTENTIALLY HAZARDOUS SITUATION THAT, IF NOT AVOIDED, COULD RESULT IN DEATH OR SERIOUS INJURY.

⚠CAUTION

Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.

NOTICE

Used for instructions to the Operator to prevent damage to property.

NOTE: Used to draw attention to information that is important for the Operator to know.

Chapter 2 General Description

1 Scope and Applicability of the Publication

1.1 Applicability

This publication provides information for planning and carrying out the installation of the GE Breast Tomosynthesis option on a Senographe Essential system.

1.2 How to Read This Publication

The contents fall into two main categories Descriptive and Procedural.

- Descriptive content

  About the GE Breast Tomosynthesis Option provides a high level description of the GE Breast Tomosynthesis option.

  Chapter 3, Pre Installation Requirements describes the main physical characteristics of system components, environmental and other requirements which must be taken into account when planning and carrying out an installation of the GE Breast Tomosynthesis option.

- Procedural content:

  Chapter 3, Pre Installation Procedures includes the planning and pre-installation information that must be followed before performing the installation of the GE Breast Tomosynthesis option.

2 Content of this Publication

This Service Manual contains the following chapters:

- Pre Installation

  Specifies the site planning requirements and pre-installation planning procedures required for the GE Breast Tomosynthesis option.

- System Description

  Describes the high-level technical aspects of the GE Breast Tomosynthesis option.

3 Acronyms Glossary

Acronym	Meaning
A	
ACR	American College of Radiology
ADS	Apollo Digital System
ADU	Analog to Digital Unit (or "count")
AGD	Average Glandular Dose
AOP	Automatic Optimization of Parameters
ARC	Analog Readout Chip
B	
BNU	Brightness Non Uniformity
BPA	Bisphenol A
C	
CC	CranioCaudal
CESM	Contrasted Enhanced Spectral Mammography
CF	Conversion Factor
CNR	Contrast
CsI	Cesium Iodide
CTQ	Critical to Quality
D	
DBT	Digital Breast Tomosynthesis
DEHP	Di Ethylhexyl Phtalate
DICOM	Digital Imaging and Communications in Medicine
DMR	Dual Molybdenium
DQE	Detective Quantum Efficiency
DRS	Design Requirement Specification
E	
ESAK	Entrance Skin Air Kerma
ESE	Entrance Skin Exposure
EUREF	European Reference Organization for Quality Assured Breast Screening and Diagnostic Services
F	
FE	Field Engineer
FFDM	Full Field Digital Mammography
FOV	Field of view
FRU	Field Replaceable Unit
G	
GEN	Generator
GUI	Graphical User Interface
H	
HFM	High Frequency Modulation

Acronym	Meaning
HVL	Half
I	
IDC	Image Detection Controller
IEC	International Electrotechnical Commission
IFF	Image Feedback Function
IM	Installation Manual
IQ	Image Quality
IQST	Image Quality Signature Test
K	
kV	kiloVolt
kVp	kiloVolt peak
L	
LF	Large Focal Spot
LFOV	Large Field Of View
LRS	Long Range Scatter
LSB	Least significant bit
LSL	Lower Specification Limit
LUT	Look Up Table
M	
mA	milliAmpere
mAs	milliAmpere per second
MG	DICOM code for Mammography Modality
MLO	MedioLateral Oblique
Mo	Molybdenum
MPC	Medical Procedure Card
MQSA	Mammography Quality Standard Acts
MTD	Motorized Tomosynthesis Device
MTF	Modulation Transfer Function
N	
N/A	Not Applicable
NPS	Noise Power Spectrum
O	
OLC	On Line Center
OM	Operator Manual
OME	Operator Manual Extract
OPET	Overall Pre-Exposure Time
OS	Operating System
P	
PIM	Pre-Installation Manual
PMMA	PolyMethyl MethAcrylate

Acronym	Meaning
PN	Part Number
PPS	Performed Procedure Step
Q	
QAP	Quality Assurance Procedure
QC	Quality Control
QG	Quick Guide
QIF	Quantum Improvement Factor
R	
RAC	Risk Assessment and Control
Rh	Rhodium
RoHS	Restriction of Use of Hazardous Substances
ROI	Region Of Interest
RRA	Repeat and Reject Analysis
RWS	Review WorkStation
S	
SDNR	Signal Difference to Noise Ratio
SF	Small Focal Spot
SID	Source to Image Distance
SIP	Service Information Procedures
SM	Service Manual
SNR	Signal to Noise Ratio
SPS	Scheduled Procedure Step
T	
Tp	Transmission of Primary Radiation
Ts	Transmission of Secondary Radiation
U	
UID	Unique IDentifier
USL	Upper Specification Limit

4 About the GE Breast Tomosynthesis Option

The GE Breast Tomosynthesis option allows a Senographe Essential system to be upgraded so that Digital Breast Tomosynthesis (DBT) mammographic techniques can be performed. The kit for the GE Breast Tomosynthesis option contains the following components:

- **Motorized Tomosynthesis Device (MTD) and Dedicated MTD Compression Paddles**

  The MTD is plugged into the Breast Support connectors on the Gantry instead of the Bucky or Mag Stand. The MTD is the specific breast support designed for GE Breast Tomosynthesis, with anti-scatter grid, compression carriage and paddle holder assembly, which is attached directly to the digital detector. It allows fixed compression of the breast independent of the X-ray tube movements needed for DBT view acquisitions. Dedicated MTD Compression Paddles are used for compression with the MTD.

- **MTD compatible Detector Rails**

  The MTD requires either the more robust metal or plastic Detector Rails. If the existing system contains resin Detector Rails, they must be changed with the plastic Detector Rails supplied with the GE Breast Tomosynthesis Kit.

- **Precise 50N Rotation Clutch**

  The anglulation required by the GE Breast Tomosynthesis option requires a more precise 50N Rotation Clutch with less play in the clutch movement. The precise 50N Rotation Clutch supplied with the GE Breast Tomosynthesis Kit provides the necessary precision in the clutch movement to ensure that the system cannot get stuck in either angulation or rotation mode when switching between modes.

- **Reconstruction Computer**

  Reconstruction Computer housed in a separate Reconstruction Station housing located either close behind or far away from the Control Station. The Reconstruction Computer manages the generation of 3D DICOM objects. The Reconstruction Computer reconstructs DBT images from the acquired nine projection views. It reads nine projection views from the ADS Computer and processes them to generate DBT images parallel to the detector plane.

- **A Multiplug with UPS Supply Cable**

  A multiplug with UPS supply cable in the Control Station, which shares the original AC power source from the Gantry between the components in the Control Station and the Reconstruction Computer in the Reconstruction Station.

- **Gigabit Ethernet Switch**

  A Gigabit Ethernet Switch in the Control Station is required so that the data going between the Reconstruction Computer, ADS Computer and IDC Computer is fast enough to allow the reconstruction volumes on the Reconstruction Computer to be created in a timely manner.

- **Additional ADS Computer Memory**

  Additional memory in the ADS Computer to support the extra processing power required when acquiring each of the nine projection images in a 3D exam.

- **3D Foot Pedal**

A specific pedal, called the “3D foot pedal” has been designed for the GE Breast Tomosynthesis option. This pedal is installed close to the Control Station; it is pressed by the operator to enable tube motion during a DBT X-ray exposure. The 3D foot pedal requires a compatible DBT Lift Board in the Gantry, which has an additional connector for the 3D foot pedal.

- **Short or Long Harness**

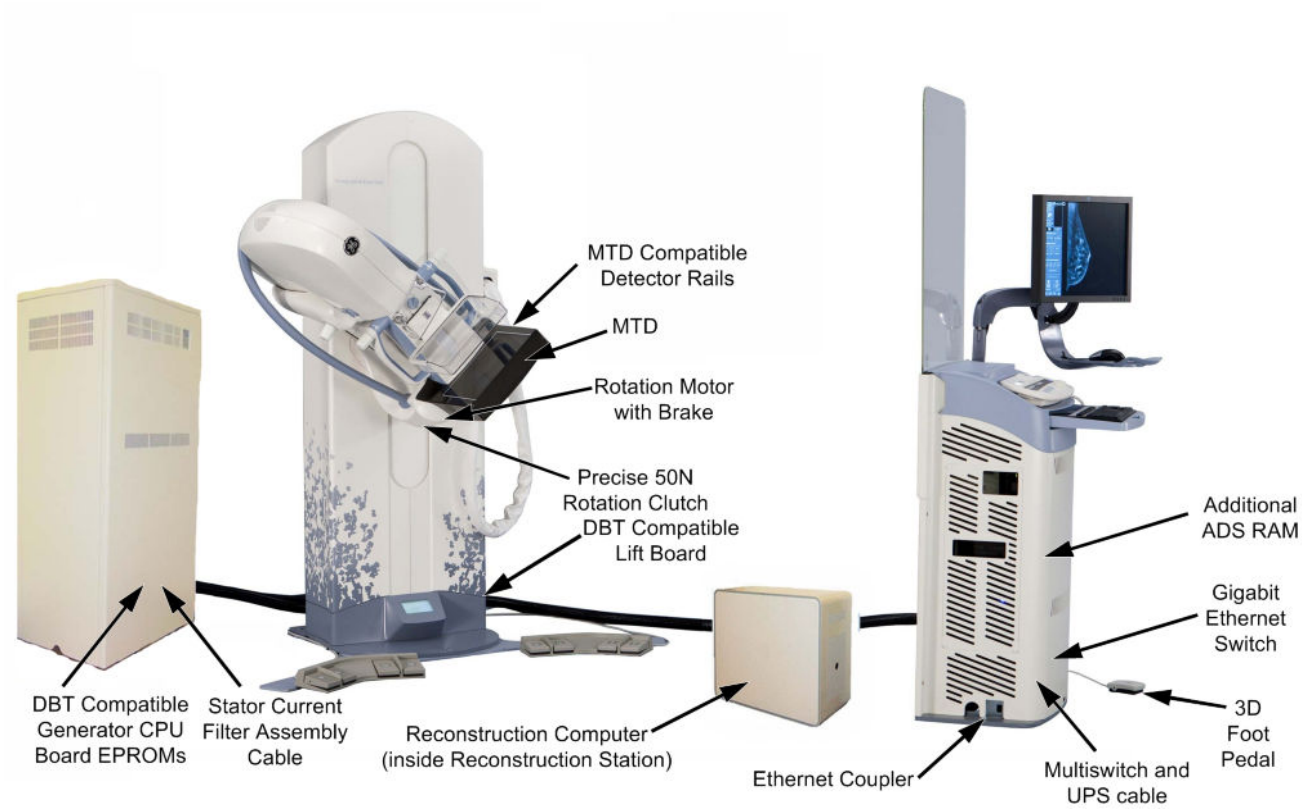
  A short or long harness (depending on the location of the Reconstruction Station) containing all the necessary power, ground and network cables for connecting the ADS Computer to the Reconstruction Computer.

- **DBT Compatible Software**

  Software to support the DBT functionality on the Generator (DBT Compatible Generator CPU Board EPROMs), Gantry, ADS Computer, IDC Computer, and Reconstruction Computer.

Illustration 2-1 summarizes the majority of the physical components required to enable DBT functionality on a Senographe Essential system.

Illustration 2-1: Summary of physical components required to enable DBT



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Chapter 3 Pre Installation

1 Pre Installation Requirements

1.1 About this Chapter

The following pre installation requirements are specific to the option:

- Environmental Requirements
- IEC60601-1-2 Electromagnetic Standards Compliance
- Planning for Storage
- Room Layout Planning
- Networking connections
- Associated review workstations

The following requirements are common between the option and the core system, they can be found in the *Pre-Installation System Requirements* chapter in the *Service Information and Procedures* of the system:

- Noise
- Structural requirements
- Electrical requirements.
- Door lights and safety switch
- Planning for radiation protection
- Insite connection

1.2 Environmental Requirements

Environmental requirement for the system remain the same as for the Senographe Essential. For more information, refer to the *Pre-Installation System Requirements* chapter in the *Service Information and Procedures* of the system.

1.2.1 GE Breast Tomosynthesis kit working environment

Table 3-1: GE Breast Tomosynthesis kit working environment

Relative humidity (non-condensing)		Temperature		Atmospheric pressure		Altitude	
Min.	Max.	Min.	Max.	Min.	Max.	Min.	Max.
10%	80%	15°C	35°C	700hPa	1060hPa	0 m	3000 m
		59°F	95°F			0 ft	9840 ft

1.2.2 GE Breast Tomosynthesis kit transport and short term (<5 days) storage conditions

Table 3-2: GE Breast Tomosynthesis kit transport and short term (<5 days) storage conditions - temperature and humidity

Relative humidity (non-condensing)		Temperature		Atmospheric pressure	
Min.	Max.	Min.	Max.	Min.	Max.
10%	85%	–20°C	70°C	500hPa	1060hPa
		-4°F	158°F		

1.2.3 Long term storage

Contact your Field Engineer prior to placing the GE Breast Tomosynthesis in long term storage.

1.2.4 Heat Output

Component	kW	BTU/h
Reconstruction Computer Heat Output (in standby)	0.650	2217

1.3 IEC60601-1-2 Electromagnetic Standards Compliance

1.3.1 General

This option complies with the IEC60601-1-2 Edition 2 and 3 EMC standard for medical devices. It has been tested on a Senographe Essential system. The option is suitable for use in electromagnetic environments as defined in the limits and recommendations given in the following tables:

- Emission Compliance level and limits (Table 3-3).
- Immunity Compliance levels and recommendations for ensuring that the equipment retains its clinical utility (Table 3-4).

This equipment complies with the above EMC standard when used with cables supplied by the manufacturer up to the maximum lengths permitted by the system design specifications.

1.3.2 Electromagnetic Emission

⚠CAUTION

The GE Breast Tomosynthesis option is intended for use in the electromagnetic environment specified below. The customer or the user of the GE Breast Tomosynthesis option should assure that it is used in such an electromagnetic environment.

Table 3-3: Electromagnetic emission

Emissions Test	Compliance	Electromagnetic Environment
RF emissions CISPR11	Group 1	The GE Breast Tomosynthesis option 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 CISPR11	Class A	The GE Breast Tomosynthesis option is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

1.3.3 Electromagnetic Immunity

The Senographe system is suitable for use in the specified electromagnetic environment. The purchaser or Operator of a Senographe system must ensure that it is used in an electromagnetic environment as described below:

⚠CAUTION

The GE Breast Tomosynthesis option is intended for use in the electromagnetic environment specified below. The customer or the user of the GE Breast Tomosynthesis option should assure that it is used in such an electromagnetic environment.

Table 3-4: Electromagnetic immunity

Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	For 240 Vac / 50Hz ±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	For 240 Vac / 50Hz and 200 Vac / 50Hz ±2 kV for power supply lines ±1 kV for input/output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	For 240 Vac / 50Hz and 200 Vac / 50Hz ±1 kV mode differential ±2 kV mode common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 5 s	For 240 Vac / 50Hz 0 Vac during 5 s And for 200 Vac / 50Hz 0 Vac during 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the GE Breast Tomosynthesis option requires continued operation during power mains interruptions, it is recommended that the GE Breast Tomosynthesis option be powered from an uninterruptible power supply or a battery. As the GE Breast Tomosynthesis option is part of a system which rated input current exceeds 16 A per phase, it is exempt from voltage dips tests.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m for 50Hz And 3 A/m for 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

⚠CAUTION

The GE Breast Tomosynthesis option is intended for use in the electromagnetic environment specified below. The customer or the user of the GE Breast Tomosynthesis option should assure that it is used in such an electromagnetic environment.

Table 3-5: Electromagnetic immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the GE Breast Tomosynthesis option, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

			Recommended separation distance $d = 1.17\sqrt{P}$ 150 kHz to 80 MHz $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (1) should be less than the compliance level in each frequency range (2). Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated radio-frequency IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	[E1] = 3 V/m	

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

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

1. 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, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GE Breast Tomosynthesis option is used exceeds the applicable RF compliance level above, the GE Breast Tomosynthesis option should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the GE Breast Tomosynthesis option.
2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

1.3.4 Recommended Separation Distances for Portable and Mobile Radio Frequency Communications Equipment IEC 60601-1-2

⚠CAUTION

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

Table 3-6: RECOMMENDED SEPARATION DISTANCES

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.16	1.16	2.33
10	3.69	3.69	7.37

100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

1.3.5 Use Limitation

External components:

⚠CAUTION

The use of accessories, transducers, and cables other than those specified by GEMS can result in the degraded Electromagnetic compatibility of the Senographe.
Refer to the Component Index in the Parts section of the Service Manual for a list.

1.3.6 Installation Requirements and Environmental Control

In order to minimize interference risks, the following requirements apply.

1.3.6.1 Cable Shielding & Grounding

All interconnecting cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded can result in the equipment causing radio frequency interference.

1.3.6.2 Separated Power Supply Distribution Panel & Line

⚠CAUTION

This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the GE Breast Tomosynthesis equipment or shielding the location.

This product complies with the radiated emission limits of the CISPR11 Group1 Class A standard.

The Senographe is primarily intended for use in non-domestic environments, and not connected directly to the public mains supply network. It is primarily intended for use in environments (such as hospitals) with a dedicated supply system, and in an X-ray shielded room.

To avoid interference in the event that the Senographe is used in a domestic environment (in a doctors office, for example), it is recommended that it must be connected to a separate AC power distribution panel and line, and it must be installed in an X-ray shielded room.

1.3.6.3 Subsystem & Accessories Power Supply Distribution

All components, accessories, subsystems, and systems which are electrically connected to the Senographe must have AC power supplied by the same power distribution panel and line.

NOTE: You can not connect together different electrical devices and supply them by different AC power distribution lines.

In order to avoid interference, all components and accessories connected to the Senographe must be connected to the same AC power distribution panel. This AC power distribution panel which is itself supplied by a single power line.

1.3.6.4 Stacked Components & Equipment

The Senographe must not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Senographe must be monitored to ensure that normal operation occurs in the configuration in which it is used.

1.3.6.5 Static Magnetic Field Limits

In order to avoid interference on the Senographe system, static field limits from the surrounding environment are specified.

Static field is specified as less than 1 Gauss in the Examination room (Gantry room), and in the Control Area (for all Subsystems).

Static field is specified as less than 3 Gauss in the Technical Room.

1.3.6.6 Electrostatic Discharge Environment & Recommendations

In order to reduce electrostatic discharge interference, a charge dissipative floor must be installed to prevent charge accumulation.

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

Relative humidity must be maintained above 30 percent.

1.4 Electrical Requirements

1.4.1 Introduction

The option's electrical requirements are identical to the Core system's requirements, except for the *kVA Load Characteristics*.

1.4.2 kVA Load Characteristics

- Maximum power in standby: 1.5 kVA.
- Maximum instantaneous power (during exposures, up to 6 seconds) 9 kVA.
- Power factor: 0.6.
- Line current crest factor: 1.7 at 200 V.

1.5 Planning for Storage

1.5.1 Temporary Storage in the Hospital

There is normally a short delay (e.g., overnight) between the delivery of the equipment and its installation.

If this delay lasts for more than two days, it is essential that a suitable storage room is available to receive the equipment in its crates.

Refer to the *Environmental Requirements* section in the *Pre-Installation Manual* section of the *Core SIP* for information on the environmental requirement.

1.5.2 Packing Information

Table 3-7 lists the main dimensions and masses of shipping crate for the GE Breast Tomosynthesis option.

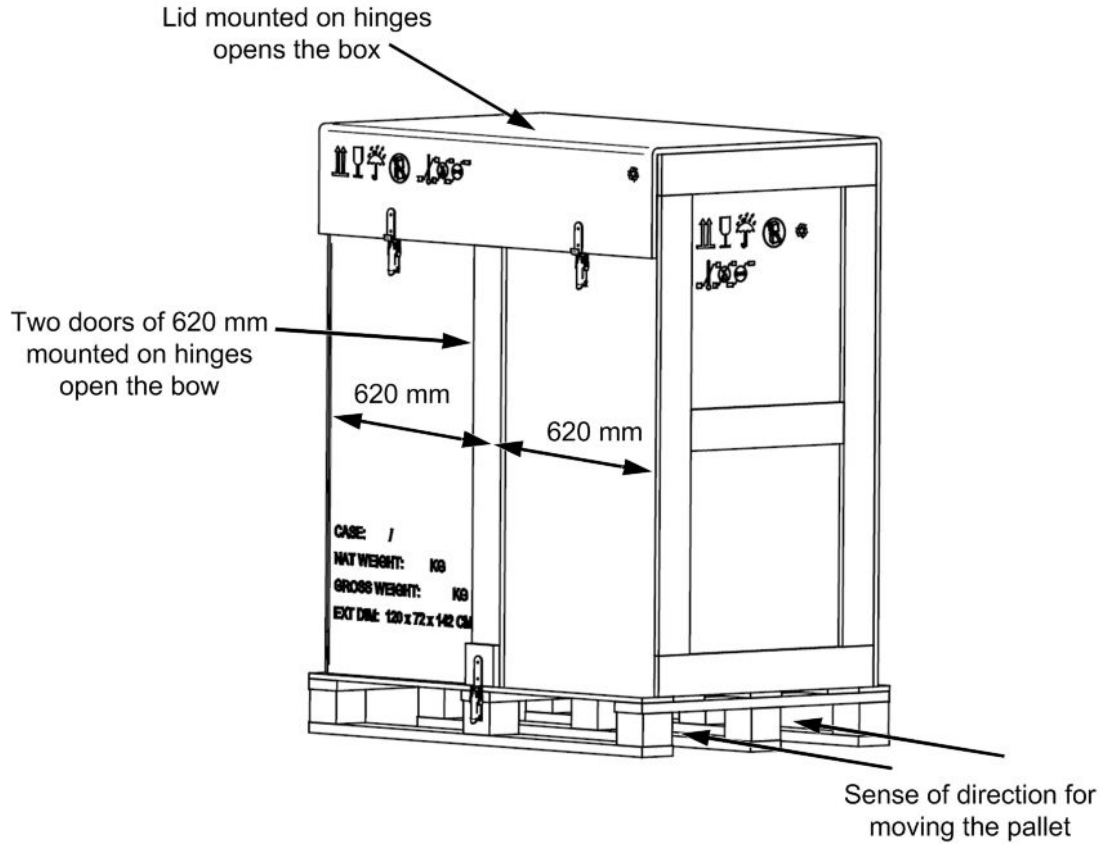
Table 3-7: SHIPPING DIMENSIONS AND MASSES.

Item	Dimensions in mm (*inches*)			Mass in kg (*lbs*)
	Depth	Width	Height	
Pallet	1200 (*47.3*)	800 (*31.5*)	1420 (*55.9*)	137 kg (*301.4 lbs*)

1.5.3 Constraints for Moving the Equipment Into the Room

Illustration 3-1shows the constraints of moving the equipment into the room in terms of the shipping crate.

Illustration 3-1: Constraints for Moving the Equipment Into the Room



- the sense of direction is dictated by the pallet lift entry points of the pallet
- the lid and two doors must be closed when moving the crate on a pallet lift

1.6 Room Layout Planning

1.6.1 Dimensions and Masses

Refer to the following pages for more information on major components provided by the option.

For more information on the core system major components, refer to the *Room layout planning* section of the *Core SIP*.

Table 3-8: Dimensions and Masses

Component	**Depth** mm (*inches*)	**Width** mm (*inches*)	**Height** mm (*inches*)	**Mass** kg (*lbs*)
Gantry (with MTD)	1273 (*50.1*)	616 (*245.25*) *Required space:* 1842 (*72.5*)	1930 (*76*) to 2430 (*95.67*) ()	418 (*922*)
Reconstruction housing	278 (*10.95*)	590 (*23.23*)	520 (*20.48*)	Empty: 19 (*42*) With the reconstruction station: 36 (*80*)

1.6.2 Layout Constraints for Positioning the Reconstruction Station

The Reconstruction Station can either be placed behind the Control Station or away from the Control Station. In most situations the Reconstruction Station is placed behind the Control Station.

- By default (for situations where the Reconstruction Station is directly behind the Control Station), a cable harness of 600 mm (23.62”) is provided in the GE Breast Tomosynthesis kit. At the Control Station end, approximately 50 mm (1.97”) of the cable harness is inside the Control Station. At the Reconstruction Station end, approximately 135 mm (5.31”) of the cable harness is inside the Reconstruction Station. The remaining 415 mm (16.34”) of cable harness is external, and facilitates the close proximity curving of the cable harness between the Control Station and the Reconstruction station. For more information about the cables supplied within the 600 mm cable harness, see Section 1.9.2.1, Short Harness Cables.
- For situations where the Reconstruction Station cannot be placed directly behind the Control Station, a cable harness of 8200 mm (322.83”) (5434153) can be ordered. At the Control Station end, approximately 50 mm (1.97”) of the cable harness is inside the Control Station. At the Reconstruction Station end, approximately 135 mm (5.31”) of the cable harness is inside the Reconstruction Station. The remaining 8015 mm (312.55”) of cable harness is external, and facilitates the cable connection between the Control Station and the Reconstruction station. In this case, suitable provision (plinths, under-floor conduits, etc.) must be made for passing cable harness between the Control Station and Reconstruction Station. For more information about the cables supplied within the 8200 mm (322.83”) cable harness, see Section 1.9.2.2, Long Harness Cables.

1.6.2.1 Floor and Wall Spacing

The footprint of the Reconstruction Station housing is 590 mm x 278 mm (23.23” x 10.94”) (Illustration 3-2). For serviceability reasons, the front side of the Reconstruction Station needs

1000 mm of space to allow the opening of the front side panel and accessing the inside of the Reconstruction Station.

Illustration 3-2: Floor space requirement when Reconstruction Station is on its own (Reconstruction Station footprint)

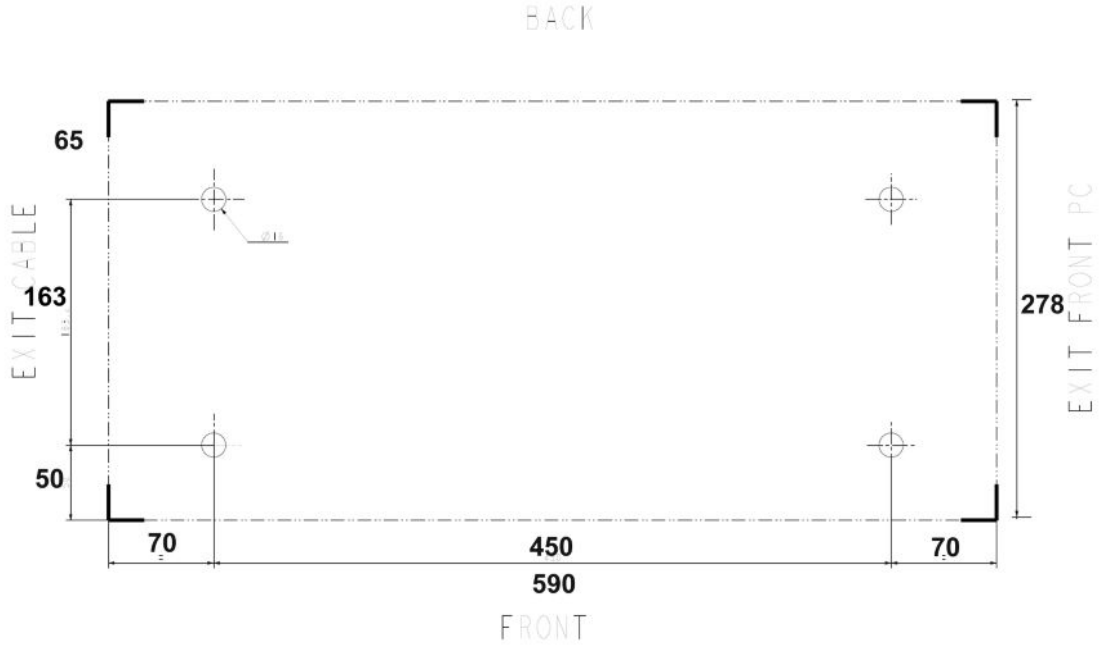


Illustration 3-3 and Illustration 3-4 show the floor space requirements when the Reconstruction Station housing can be placed directly behind the Control Station.

Illustration 3-3: Floor space requirement when Reconstruction Station is behind the Control Station with the monitor arm on the right

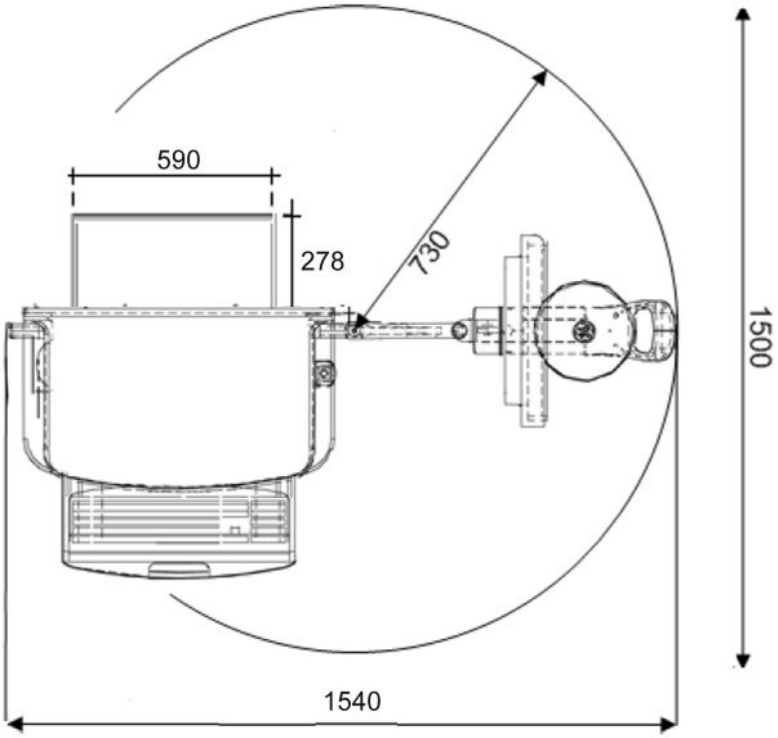
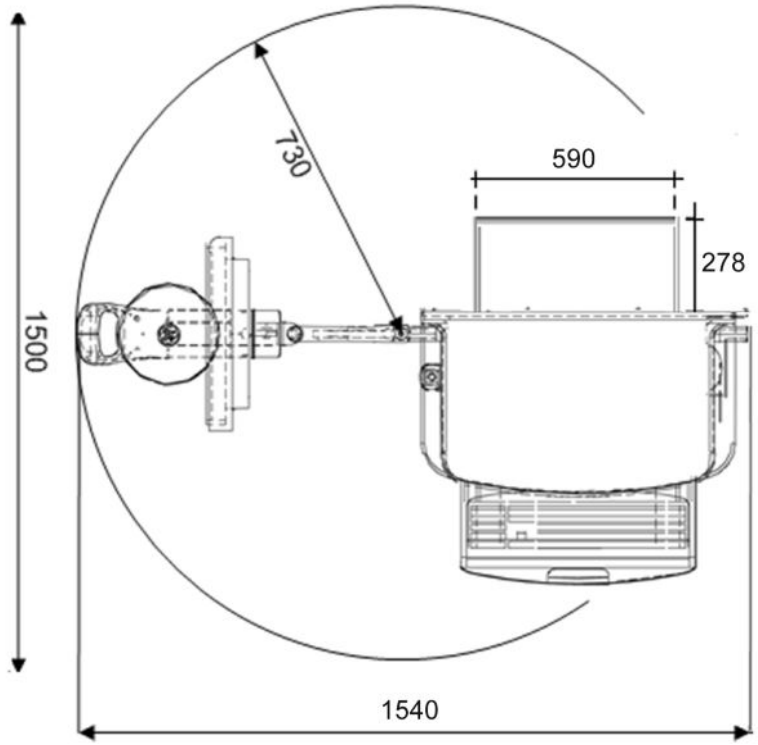


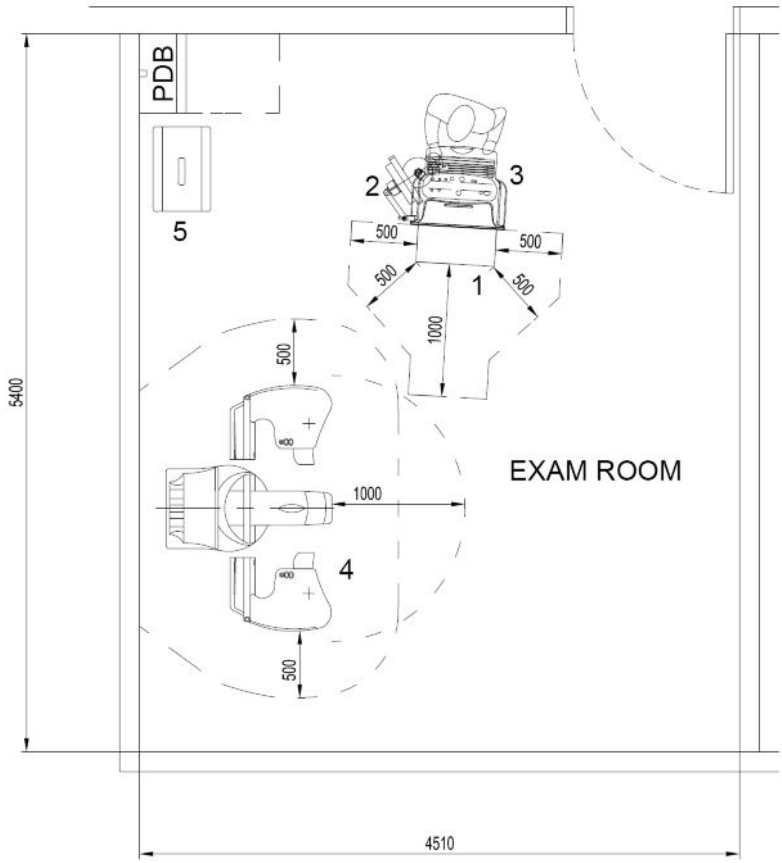
Illustration 3-4: Floor space requirement when Reconstruction Station is behind the Control Station with the monitor arm on the left



1.6.2.2 General Layout

Illustration 3-5 shows the general layout recommendations when the Reconstruction Station housing can be placed directly behind the Control Station.

Illustration 3-5: General layout suggestion when Reconstruction Station is behind the Control Station with the monitor arm on the right



The diagram below generically highlights the constraints mentioned above, which you must consider when planning a room layout.

1. Reconstruction Computer Housing
2. Monitor Arm
3. Control Station
4. Gantry
5. Generator

Apply the following distances between the Control Station equipped with Reconstruction Station located directly behind it, and the Gantry:

- minimum distance of 500 mm allowed for free movement around the Gantry and the Reconstruction Station housing

  NOTE: If an existing install base system has a space of less than 500 mm and more than 150 mm between the Tube Head the wall of the room, the GE Breast Tomosynthesis option can be installed.

- minimum distance of 1000 mm at the back of the Reconstruction Station housing for serviceability
- minimum distance of 1000 mm from the X-ray Source in the Tube Head and the Radiation Screen on the Control Station
- maximum distance depending on Gantry cables length : see the *Pre-Installation System Requirements* chapter in the *Core System SIP/PIM*.

After the room layout is decided, suitable provision (plinths, under-floor conduits, etc.) must be made for passing cables and conduits.

In the following situations it is not possible to place the Reconstruction Station behind the Control Station:

- if the customer has the TechInsight option (the MDS will be already positioned behind the Control Station)
- if below the floor behind the Control Station there is under floor cabling or piping that inhibits the fixation of the Reconstruction Station
- if the monitor arm is on the left side of the Control Station and the right edge, top edge, or top right corner (looking down) of the Reconstruction Station are closer than a 1000 mm to the Gantry Tube Head
- the Control Station is in a separate room, close to the wall, such that a gap of at least 1278 mm is not present between the rear of the Control Station and the wall making the serviceability of the Reconstruction Station impossible (i.e. less than 1000 mm gap is present from the rear of the Reconstruction Station housing)

1.6.3 Anchoring to the Floor

1.6.3.1 The Positioning Template

The installation kit supplied with the equipment includes one template printed on white paper. This template assists with the layout of the Reconstruction housing and positioning the anchors. The template is provided in the Reconstruction housing itself.

1.6.3.2 Gantry Floor Requirements

The Senographe Essential equipped with the MTD may vibrate during Tomosynthesis Acquisition and cause IQ issues if the Gantry is not installed on a flat floor surface as specified in *Floor Requirements* section of the *Core SIP*. The floor surface must remain horizontal and flat within ±2.5 mm per meter (*±1/10 inch in 39 inches*) after installation of the Gantry.

⚠WARNING

FAILURE TO RESPECT THE FLOOR REQUIREMENTS FOR THE GANTRY CAN RESULT IN VIBRATION OF THE MTD CAUSING IQ ISSUES.

1.6.3.3 Anchoring Inserts

The recommendations listed in the table below correspond to the anchoring inserts that are supplied in the same box as the Reconstruction Station Housing. You must choose to use

different anchoring inserts if your floor thickness is less than 120 mm and/or if you are installing the option in a seismic area.

Anchoring holes in the floor	4
Number of holes in the plate	4
Diameter of the hole in the plate	12 mm
Hole diameter in the floor	16 mm
Minimum Hole depth in the floor	90 mm
Provided inserts	Hilti HAM M10x80 Universal Expanding Raw Plug External diameter of 16 mm for a screw with 10 mm diameter
Maximum bolt load pull tension (at each bolt)	580 daN
Minimum floor thickness	120 mm
Recommended tightening torque	45 Nm on concrete 20 Nm on masonry (brick)

If you use different anchoring inserts to those supplied, you must use the recommendations corresponding with those anchoring inserts and not those listed in this table. Your local structural engineer is responsible for evaluating the recommendations of third-party anchoring inserts.

1.6.4 Interconnecting Cables Path and Length

Illustration 3-6 and Illustration 3-7 are provided to help planning cable runs between subsystems with the short and long Reconstruction Station cable harness, respectively.

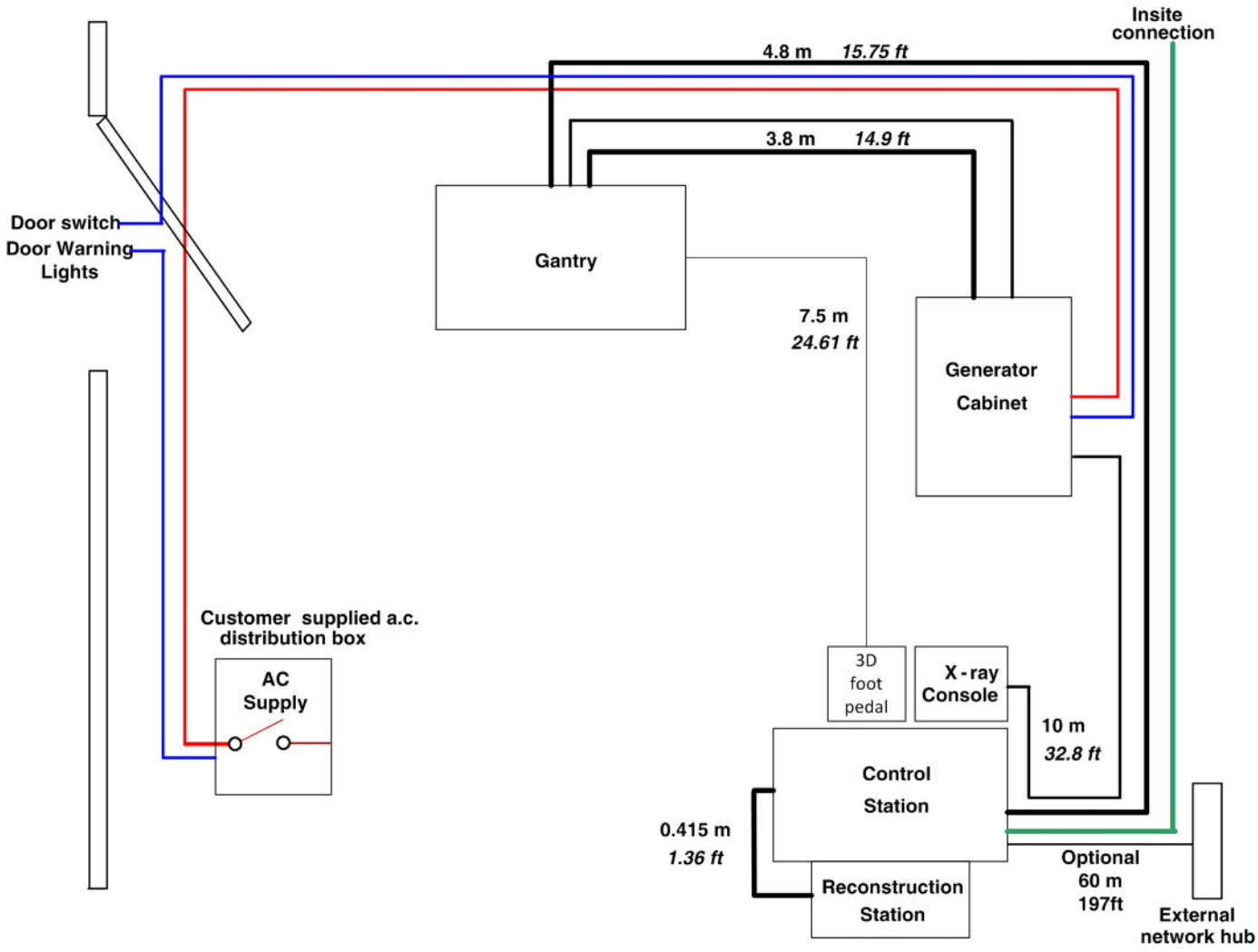
Codification color on the illustration:

- Black = Harness, Shipped with the system and the GE Breast Tomosynthesis option (short harness by default, and a long harness can be ordered if necessary)
- Red = Power AC supply (Line Supply Cable) (GEMS supplies a usable length = 6.5 m (21’-4”) cable)
- Blue = Door light and switch (local adaptation)
- Green = Insite connection
- Purple = X-ray Console Cable

⚠CAUTION

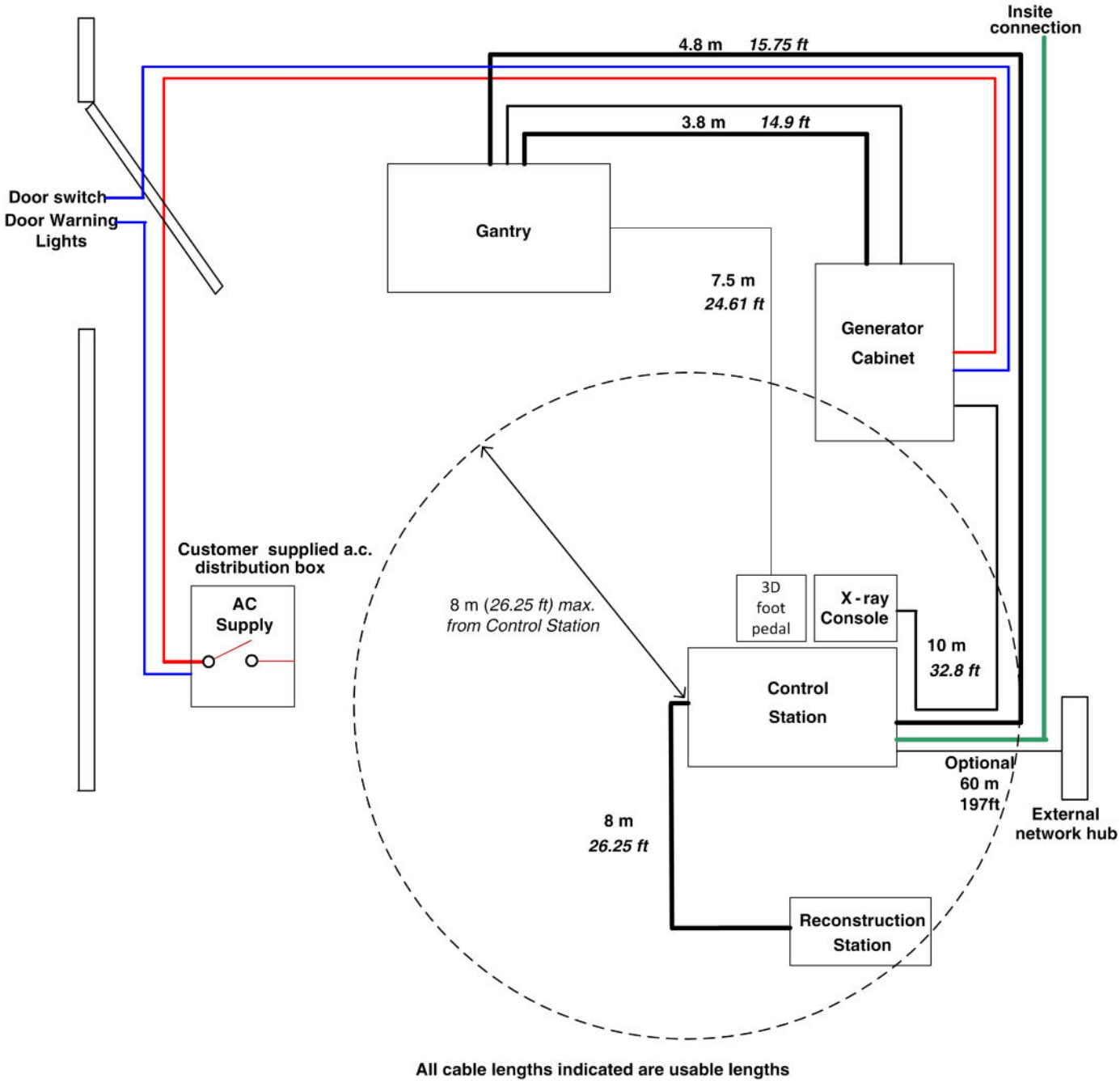
Cables between Generator and Gantry and X-ray Console are fragile:
Protect these cables in a cable housing or ensure that the cable path is safe.

Illustration 3-6: Interconnecting Cables Path and Length – Short Reconstruction Station Cable Harness



All cable lengths indicated are usable lengths

Illustration 3-7: Interconnecting Cables Path and Length – Long Reconstruction Station Cable Harness



1.7 Interoperability and Networking Connections

The DICOM committee has defined a dedicated DICOM standard format, called DICOM Breast Tomosynthesis Object (BTO), to store the breast 3D volume data. GE Breast Tomosynthesis option implements this new format.

As Tomosynthesis generates more data for each exam than conventional mammography, a larger archiving capacity is required.

Therefore, integrating the GE Breast Tomosynthesis option to an existing workflow implies to check:

- the **DICOM compatibility** of other systems (PACs) (see Section 1.7.1)
- the **storage capacity** corresponds to the Tomosynthesis intended use (see Section 1.7.2)
- the **networking** on site corresponds to the Tomosynthesis intended use (see Section 1.7.3)

The customer needs to be aware of these needs and can contact a GE representative for further information and guidance on DICOM object generated and its storage.

1.7.1 DICOM Compatibility

All workflow actors (such as PACS, archiver…) that will receive the Tomosynthesis images must support : **DICOM Storage as SCP for :** Breast Tomosynthesis Image 1.2.840.10008.5.1.4.1.1.13.1.3 (SOP class UID) with at least one of the following proposed transfer syntax:

- Explicit VR Big Endian - 1.2.840.10008.1.2.2
- Implicit VR Little Endian - 1.2.840.10008.1.2
- Explicit VR Little Endian - 1.2.840.10008.1.2.1
- Lossless JPEG Compression - 1.2.840.10008.1.2.4.70
- Lossy JPEG Compression - 1.2.840.10008.1.2.4.51 (when authorized on site)

1.7.2 Storage Capacity

A GE representative can support the customer to evaluate the storage capacity needed for the intended use of Tomosynthesis. The customer might plan to upgrade the storage capacity available to meet the storage need.

The GE Breast Tomosynthesis option installation shall be synchronized to the data storage capacity upgrade when applicable.

1.7.3 Networking Connections

In order to benefit from the optimal performance of the option, the client should provide a Gigabit Ethernet compatible connection to the network.

Other networking requirements remain the same as those described in the *Core SIP*.

NOTE: From ADS 56.10 delivered with the GE Breast Tomosynthesis option, the AE title used for worklist no longer includes WL_ and keeps letter case.

No other change in DICOM declaration is required.

1.8 Associated Review Workstations

The GE Breast Tomosynthesis option requires a Review Workstation compatible with DICOM *Digital Breast Tomosynthesis* images to display the reconstructed 3D objects.

The *IDI mammography Workflow solution 4.7.0 V-Preview (named MR3 or Build 382) and above releases* are compatible with this DICOM format.

NOTE: Before installing the GE Breast Tomosynthesis option, ensure that customer's IDI Mammography Workflow Solutions system is already at version 4.7.0 V-Preview (named MR3 or Build 382) or above. If the customer's IDI Mammography Workflow Solutions system needs upgrading to version 4.7.0 V-Preview (named MR3 or Build 382) or above, it can take several weeks to receive the upgrade software.

In scenarios where the customer's IDI Mammography Workflow Solutions system needs upgrading to version 4.7.0 V-Preview (named MR3 or Build 382) or above, ensure that you plan enough time so that the GE Breast Tomosynthesis option can be installed after the upgrade of the IDI Mammography Workflow Solutions system.

1.9 Cable Lay-out and Pin-out

Cables that are visible from a serviceability perspective are those within the Reconstruction Station (see Section 1.9.1) or those within the harness going from the Reconstruction Station to the Control Station (see Section 1.9.2).

1.9.1 Internal Reconstruction Station Cabling

The internal Reconstruction Station cabling consists of only ground cables, as described in the sub-sections below.

1.9.1.1 Ground Cable – C5-C5 AWG12 LG450 (5365831)

Two 0.45 m ground cables with C5 connectors at each end exists, going from the Reconstruction Station housing Ground Bar to the following:

- rear panel Ground connection on the Reconstruction Computer
- Reconstruction Station housing fixed side cover

Illustration 3-8: Ground Cable – C5-C5 AWG12 LG450

1.9.1.2 Ground Cable – FAS C5 AWG12 LG420 (5365830)

Two 0.42 m ground cables with a C5 connector at one end and a FAS connector at the other end exists, going from the Reconstruction Station housing Ground Bar to the following:

- Reconstruction Station housing rear (left) trap door
- Reconstruction Station housing removable side cover

Illustration 3-9: Ground Cable – FAS C5 AWG12 LG420

1.9.1.3 Ground Cable – FAS C5 AWG12 LG1000 (5366584)

A 1 m ground cable with a C5 connector at one end and a FAS connector at the other end, going from the Reconstruction Station housing Ground Bar to the Reconstruction Station housing front (right) trap door.

Illustration 3-10: Ground Cable – FAS C5 AWG12 LG1000

1.9.2 Reconstruction Station to Control Station Cabling

The set of cables going between the Reconstruction Station and the Control Station vary according to whether the short or long harness is installed.

1.9.2.1 Short Harness Cables

This section describes the cables in the short harness going from Reconstruction Station to Control Station.

1.9.2.1.1 W801 Cable — Short Gigabit Ethernet Cable for the Reconstruction Computer to ADS Computer (5434079)

2.5 m TIA certified CAT 6E gigabit Ethernet cable going from the Reconstruction Computer bottom RJ45 connector (eth0) to the ADS Computer lower RJ45 connector (e1000g0).

The pairing and pinout of the W801 cable are summarized in Illustration 3-11 and Table 3-9.

Illustration 3-11: W801 Cable Pinouts

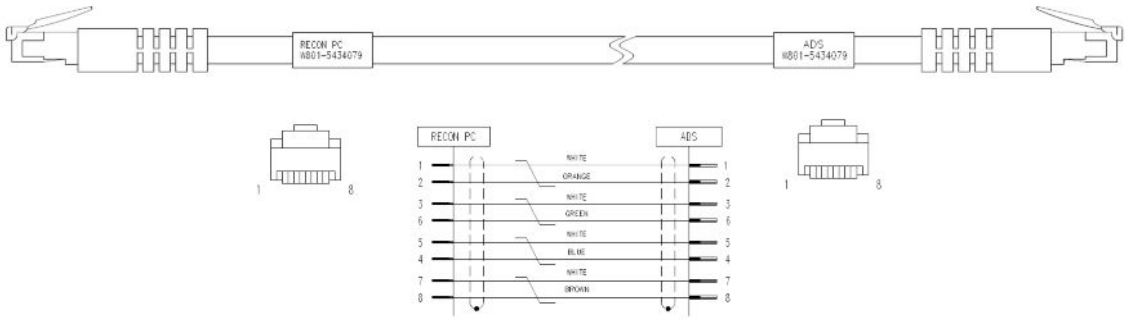


Table 3-9: W801 Cable Pinouts

Pin Number Reconstruction Computer end	Color	Function	Pin Number on ADS Computer end
1	White	Tx+	1
2	Orange	Tx-	2
3	White	Rx+	3
6	Green	Rx-	6
5	White	Not Used	5
4	Blue	Not Used	4
7	White	Not Used	7
8	Brown	Not Used	8

1.9.2.1.2 W802 Cable – Short Gigabit Ethernet Cable for the Hospital Network (5434078)

2.5 m TIA certified CAT 6E gigabit Ethernet cable going from the Reconstruction Computer upper RJ45 connector (eth1) to the CAT6 Ethernet Junction in the base of the Control Station.

The pairing and pinout of the W802 cable are summarized in Illustration 3-12 and Table 3-10.

Illustration 3-12: W802 Pinouts

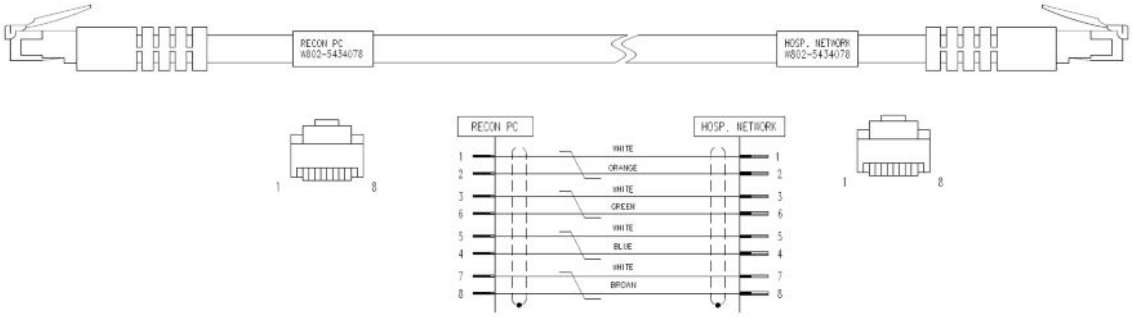


Table 3-10: W802 Cable Pinouts

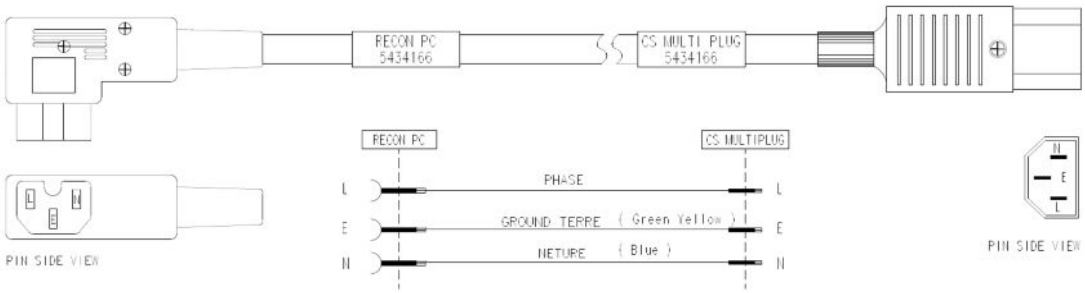
Pin Number Reconstruction Computer end	Color	Function	Pin Number on hospital end
1	White	Tx+	1
2	Orange	Tx-	2
3	White	Rx+	3
6	Green	Rx-	6
5	White	Not Used	5
4	Blue	Not Used	4
7	White	Not Used	7
8	Brown	Not Used	8

1.9.2.1.3 Short Reconstruction Computer AC Supply Cable (5434166)

2.0 m AC supply cable going from the Reconstruction Computer rear panel AC connector to the AC multi-connector in the base of the Control Station.

Illustration 3-13 shows the parings and pinouts of the Live (L), Earth (E), and Neutral (N) cables in the Short Reconstruction Computer AC Supply Cable.

Illustration 3-13: Short Reconstruction Computer AC Supply Cable Pinouts



1.9.2.1.4 W805 Cable – Short Reconstruction Station Housing Earth Cable

2.5 m ground cable going from the Ground Bar in the Reconstruction Station housing to the Ground Bar in the Control Station housing.

Illustration 3-14: W805 Cable – Short Reconstruction Station Housing Earth Cable

1.9.2.2 Long Harness Cables

This section describes the cables in the long harness going from Reconstruction Station to Control Station.

1.9.2.2.1 W803 Cable — Long Gigabit Ethernet Cable for the Reconstruction Computer to ADS Computer (5434175)

10.2 m TIA certified CAT 6E gigabit Ethernet cable going from the Reconstruction Computer bottom RJ45 connector (eth0) to the ADS Computer lower RJ45 connector (e1000g0).

The pairing and pinout of the W803 cable are summarized in Illustration 3-15 and Table 3-11.

Illustration 3-15: W803 Cable Pinouts

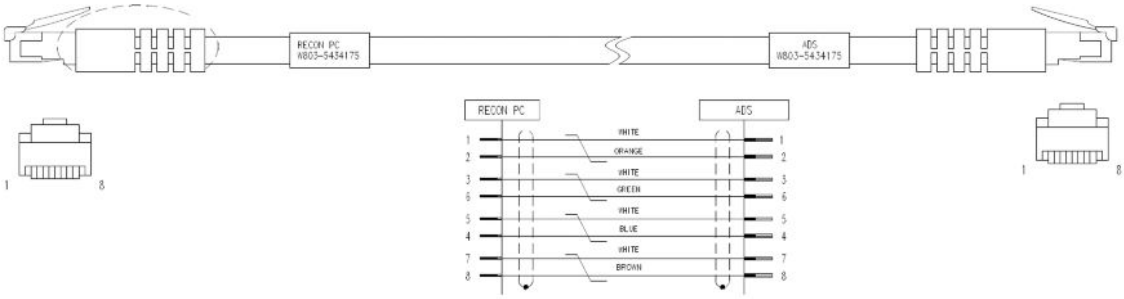


Table 3-11: W803 Cable Pinouts

Pin Number Reconstruction Computer end	Color	Function	Pin Number on ADS Computer end
1	White	Tx+	1
2	Orange	Tx-	2
3	White	Rx+	3
6	Green	Rx-	6
5	White	Not Used	5
4	Blue	Not Used	4
7	White	Not Used	7
8	Brown	Not Used	8

1.9.2.2.2 W804 Cable – Long Gigabit Ethernet Cable for the Hospital Network (5434176)

10.2 m TIA certified CAT 6E gigabit Ethernet cable going from the Reconstruction Computer upper RJ45 connector (eth1) to the CAT6 Ethernet Junction in the base of the Control Station.

The pairing and pinout of the W804 cable are summarized in Illustration 3-16 and Table 3-12.

Illustration 3-16: W804 Cable Pinouts

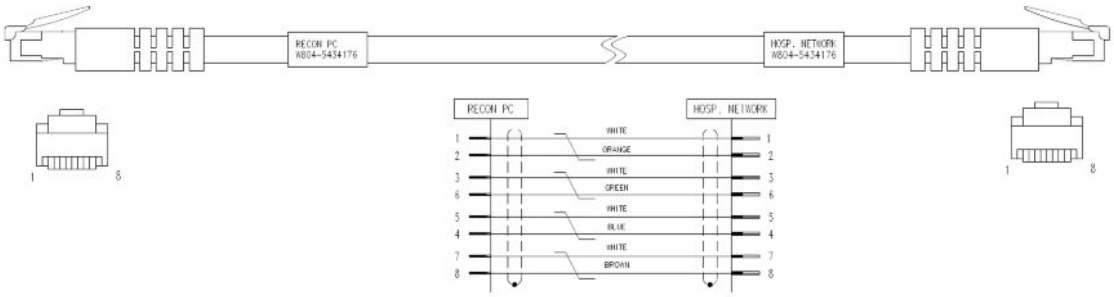


Table 3-12: W804 Cable Pinouts

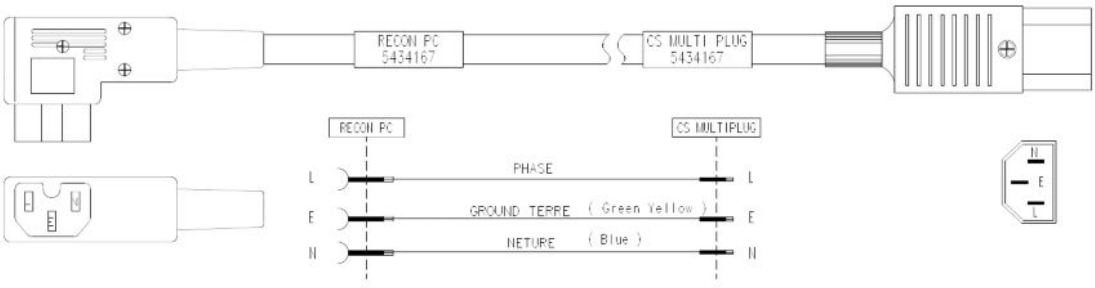
Pin Number Reconstruction Computer end	Color	Function	Pin Number on hospital end
1	White	Tx+	1
2	Orange	Tx-	2
3	White	Rx+	3
6	Green	Rx-	6
5	White	Not Used	5
4	Blue	Not Used	4
7	White	Not Used	7
8	Brown	Not Used	8

1.9.2.2.3 Long Reconstruction Computer AC Supply Cable (5434167)

9.85 m AC supply cable going from the Reconstruction Computer rear panel AC connector to the AC multi-connector in the base of the Control Station.

Illustration 3-17 shows the parings and pinouts of the Live (L), Earth (E), and Neutral (N) cables in the Long Reconstruction Computer AC Supply Cable.

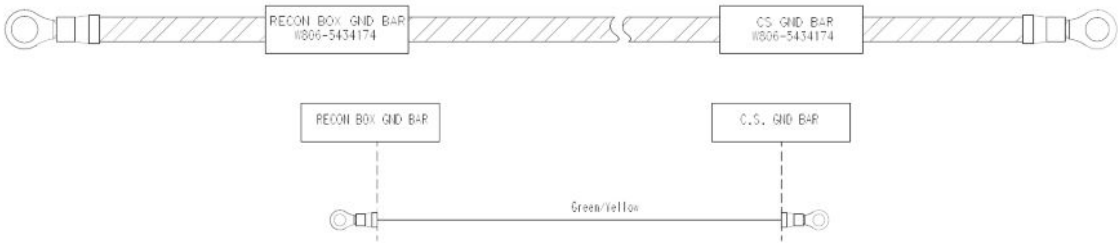
Illustration 3-17: Long Reconstruction Computer AC Supply Cable Pinouts



1.9.2.2.4 W806 Cable – Long Reconstruction Station Housing Earth Cable

10.2 m ground cable going from the Ground Bar in the Reconstruction Station housing to the Ground Bar in the Control Station housing.

Illustration 3-18: W806 Cable – Long Reconstruction Station Housing Earth Cable



1.10 Specifications

1.10.1 Maximum tolerance of displayed constants in DBT mode

1.10.1.1 Manual mode exposure accuracy selected on the X-ray console

mAs accuracy is within ± (10% +0.2 mAs) of the technical parameters selected on the X-ray console.

Measurement Conditions:

Connect an HV voltage divider (Machlett Dynalizer IIIA; ratio 10 kV/1 V) in series with the x-ray tube. Connect a waveform analyzer (Tektronix 7854) to the output of the divider; the analyzer receives a signal proportional to the voltage applied to the tube. The mAs values are given by:

$$mAs = \int_{T1}^{T2} i\,dt$$

where T1 is the time at which the high voltage reaches 75% of its maximum value, and T2 is the time at which the high voltage returns to 75% of the maximum value.

1.10.1.2 AOP mode exposure accuracy displayed on the acquisition workstation

mAs accuracy per projection in GE Breast Tomosynthesis AOP Mode is within ± (10% +0.2 mAs) annotated in the image displayed on the acquisition workstation.

1.10.1.3 Compression force and breast thickness displayed on the Gantry Readout

Compression Force: ± 10 newton

Breast Thickness: ± 10 mm

1.10.1.4 Tube angulation displayed on the Gantry Readout

Angulation value: ± 0.2°

1.10.2 X-ray tube head movement

The X-ray tube head during rotation or angulation moves at a constant speed of 10° per second.

1.10.3 Radiation and filter information

1.10.3.1 Source to Image Distance (SID)

Fixed SID: 660 mm

1.10.3.2 Radiation reference axis

Conforming to standard mammography practice, the radiation reference axis is directed at the chest wall edge of the digital detector; radiation is shielded so that there is no radiation directed behind the chest wall.

1.10.3.3 Nominal X-ray tube voltages and currents

1.10.3.3.1 Irradiation in AOP mode

- Nominal shortest irradiation time in AOP mode: 40 ms.
- Range of X-ray tube voltage during irradiation in AOP mode: 24 through 35 kVp.
- Range of X-ray tube current during irradiation in AOP mode: 30 through 100 mA.

1.10.3.3.2 Irradiation in Manual mode

- Nominal shortest irradiation time in Manual mode: 40 ms.
- Range of X-ray tube voltage during irradiation in Manual mode: 22 through 49 kVp.
- Range of X-ray tube current during irradiation in Manual mode: 21.4 through 100 mA.

1.10.3.4 Nominal focal spot size with the MTD

Large focal spot: 0.3 mm.

1.10.3.5 Dimensions and locations of all available effective image receptive areas

The field of view (FOV) is the area that is irradiated by X-rays during an exposure. Prior to exposure, its size (e.g. 9 x 9, 9 x 19, 13 x 21, 13 x 18, 19 x 23 and 24 x 31) and position (left, right, centered) are set by pressing the Collimator light and FOV control buttons.

1.10.3.5.1 FOV for 2D acquisitions with MTD

FOV settings for 2D acquisitions with the MTD inserted are the same as on the Senographe Essential with the Bucky. Table 3-13 below gives the initial FOV size and position automatically taken by the system depending on the Arm angle and compression paddle type inserted for 2D acquisitions (and 3D acquisitions).

Table 3-13: Initial FOV Sizes and Positions for 2D and 3D acquisitions

MTD Dedicated Paddle Type	Arm Rotation Angle	Initial FOV size, and position at paddle insertion	
		Size	Position
Standard 24 x 31 Paddle for MTD Elevated 24 x 31 Paddle for MTD	-90° ≤ angle ≤ +90°	24 x 31	Centered
Sliding 19 x 23 Paddle for MTD	-10° ≤ angle ≤ +10°	19 x 23	Centered
Sliding 19 x 23 Paddle for MTD	+11° ≤ angle ≤ +90°	19 x 23	Off-centered Right
Sliding 19 x 23 Paddle for MTD	-90° ≤ angle ≤ -11°	19 x 23	Off-centered Left

For 2D acquisitions, the 9 x 9, 9 x 19, 13 x 21, 13 x 18, 19 x 23 and 24 x 31 FOVs are available, as summarized in Table 3-14.

Table 3-14: FOV Sizes and Positions According Paddle Types and Positions

Mode	MTD Dedicated Paddle Type	Paddle Position	FOV Size & Position

Contact	Sliding 19 x 23 Paddle for MTD	Centered	• 24 x 31 • 19 x 23 • 13 x 18 • 9 x 9
		Left	• 19 x 23 Left • 13 x 21 Left • 9 x 19 Left
		Right	• 19 x 23 Right • 13 x 21 Right • 9 x 19 Right
	Standard 24 x 31 Paddle for MTD Elevated 24 x 31 Paddle for MTD	Centered	• 24 x 31 • 19 x 23 • 19 x 23 Left • 19 x 23 Right • 13 x 18 • 13 x 21 Left • 13 x 21 Right • 9 x 9 • 9 x 19 Left • 9 x 19 Right

1.10.3.5.2 FOV for 3D acquisitions

For 3D acquisitions, only 19 x 23, 24 x 31 FOV are available. Table 3-13 above gives the initial FOV size and position automatically taken by the system depending on the Arm angle and compression paddle type inserted for 3D acquisitions (and 2D acquisitions). For 3D acquisition, the FOV Size cannot be modified. However for 2D acquisitions, it is possible to modify the FOV size (see Table 3-14 above).

1.10.3.6 Attenuation equivalence

1.10.3.6.1 Attenuation equivalence at 100 kVp

Attenuation equivalence for components in the X-ray beam, in accordance with FDA HHS 21 CFR, § 1020.30, for measurements made at a potential of 100 kVp, using an X-ray beam with an HVL of 3.6 mm of aluminum.

Component	Al equivalence (mm)
Image receptor support on the MTD	less than 0.2

1.10.3.6.2 Attenuation equivalence at 30 kVp

Attenuation equivalence for components in the X-ray beam for measurements made at a potential of 30 kVp, using an X-ray beam with an HVL of 0.3 mm of aluminum.

Component	Al equivalence (mm)
Image receptor support on the MTD	less than 0.3

1.10.4 Dose Display and Dose Display Accuracy for AGD

1.10.4.1 Dose Display

The displayed estimates of the dose to the patient are calculated as follows:

- Entrance Skin Exposure (ESE) for the entire sequence of exposures in 3D mode, or per exposure in 2D mode.

  This quantity, also known as Entrance Skin Air Kerma (ESAK), corresponds to the free-in-air airkerma, in the plane of the compression paddle in contact with the breast, with no back-scatter contribution from the breast. It is calculated using a calibrated model taking into account the attenuation of the X-ray beam by the compression paddle.

- Average Glandular Dose (AGD) for the entire sequence of exposures in 3D mode, or per exposure in 2D mode.

  This conventional quantity (AGD) is obtained by multiplying the above-mentioned ESE and the Normalized glandular Dose (DgN) for the technique factors used. The DgN values are interpolated from the tables contained in "*Spectral dependence of glandular tissue dose in screen-film mammography*" (Xieng Wu, Gary T. Barnes, Douglas M. Tucker, Radiology 1991; 179:143-148), and "*Molybdenum target-Rhodium filter and Rhodium target-Rhodium filter mammography*" - Xieng Wu, Gary T. Barnes, Douglas M. Tucker, Radiology 1994; 193:83-89.

  The interpolated DgN values, for each interpolation point chosen, are accurate within 9% compared with the values in the tables.

  Average glandular dose for 3D is computed with the same formulas as for 2D mode. Given the tomo sequence parameters, the error made on that calculation is approximately 1%. Based on "*Computation of the glandular radiation dose in digital tomosynthesis of the breast*" - Ioannis Sechopoulos, Sankararaman Suryanarayanan, Srinivasan Vedantham, Carl D'Orsi, Andrew Karellas, Med. Phys. 2007; 34 (1):221-232.

1.10.4.2 Dose Display Accuracy for AGD

The values calculated for ESE are accurate within 30%.

The values calculated for AGD, (DgN * ESE), are accurate within 40%.

NOTE: When using a compression device that does not completely cover the breast, the entrance surface of the breast may no longer be a plane, and the distance from focal spot to skin is not clearly defined. In addition, the ESE value is not uniform between parts covered and not covered by the paddle, because of the attenuation caused by the paddle. In such cases, a single accurate value cannot be provided. However, the displayed ESE value continues to be calculated using the same convention as in the regular exam.

NOTE: When the ESE is not accurate because of the conditions described above, or when the breast is partially irradiated (e.g., due to the collimation being smaller than the breast), the AGD definition is no longer directly applicable. In such cases, the displayed AGD value should be used as an indication only.

1.10.5 Applicable Classifications

The following classifications are the same as the Core Senographe Essential system (for more information, refer to the *Pre-Installation System Requirements* chapter of the *Service Information and Procedures* of the Core Senographe Essential system):

- Type of protection against electric shock : CLASS 1
- Degree of protection against electric shock : TYPE B
- Method(s) of sterilization or disinfection recommended by the manufacturer : refer to the *System Hygiene* chapter of the *Operator Manual*
- Degree of safety of application in the presence of a FLAMMABLE AN-AESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE : must not be used in the presence of flammable gases
- Mode of operation : Continuous operation with intermittent loading

The degree of protection against harmful ingress of water for the parts in the GE Breast Tomosynthesis Service are, as follows:

- MTD : IPX0
- 3D footswitch : IPX5

2 Pre Installation Procedures

2.1 About this chapter

This chapter contains the Job Cards describing the verification procedure necessary to ensure compatibility of the system with the option.

2.2 Job Card PRE A001 - Image Backup and RRA Analysis

2.2.1 Objective

Image backup:

For security reasons, the images existing on AWS must be archived on CD ROM or PACS (Radstore). The customer must do this task before the arrival of the FE. This could represent a large amount of time.

RRA analysis:

The data for the automated repeat reject analysis (RRA) is stored in a computer in the acquisition workstation (AWS). In the event of an AWS hardware failure, there is some risk that this data will be lost. That is why periodic data backup is included in the automated repeat analysis procedure.

For customers using RRA, the repeat and reject analysis must be done before the upgrade is performed. The customer must do this task before the arrival of the FE. For more information, refer to the Operator to the QC Manual. This could represent a large amount of time.

2.2.2 Procedure

Contact the customer before coming onsite to ensure that they have performed the images backup, and RRA analysis backup.

2.3 Job Card PRE A002 - Ensure Minimum System Level is Met

2.3.1 Introduction

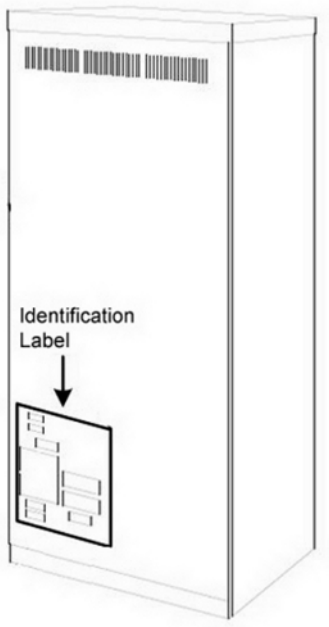
Before you apply the kit, you must ensure that the Senographe System has had FMI12075 applied and that it is equipped with the necessary hardware. Also, if the Senographe System is a pre-Sunburst system or non-CESM system, you must ensure that the Senographe System has had FMI12166 applied. This Job Card gives you the procedure to follow to define what are the necessary actions to ensure compatibility of the system with the kit.

2.3.2 Define the necessary checks

To define the necessary checks, follow these steps:

1. Define the model number by looking on the system identification label. It is on the cover of the Generator Cabinet. Illustration 3-19 below shows an example of the system identification labelling.
2. Check which options have been added to the system by checking which Upgrade Labels have been stuck next to the system identification label:
   - Stereotaxy: 5123686
   - CESM: 5392184

Illustration 3-19: Location of system identification label



3. Record the model number and the upgrades applied to the system in the *form* in Section 2.3.6
4. Consult Table 3-15 below to define the necessary checks.

NOTE: For any system with the **Stereotaxy option** installed, the rotation board and the rotation gas spring are at the necessary level.

If the Stereotaxy option is installed on the system, do not check for FMI12075, but check the Control Station version, and only check the rotation clutch when you are asked to check the Rotation-related hardware.

NOTE: If the **CESM option** is installed on the system, do not check for FMI12075, but check the Control Station version.

Table 3-15: System level - Necessary checks

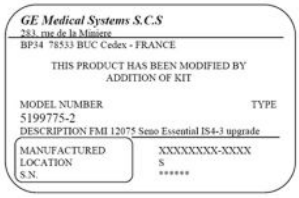
Technical Release	Manufacturing Version(ADS Version)	Model Number	Next actions
Sirius M3	M3 (40.11)	5144816	1. Check if FMI12075 is already applied following the procedure described in Section 2.3.3 2. Check Control Station version following the procedure described in Section 2.3.4
Sirius M3A Plus	M3A Plus Standard (41.00)	5144816	
	M3A Plus International (41.00)	5144816-1-1	
Sirius M3A FB	M3A FB Standard (41.02)	5144816	
	M3A FB International (41.02)	5144816-1-1	
Sirius M3A Bucky	M3A Bucky Standard (41.02)	5144816	
	M3A Bucky International (41.02)	5144816-1-1	
Sirius M4	M4 Standard (41.02)	5144816	
	M4 International (41.02)	5144816-1-1	
Sirius M41	M41 Standard (41.02)	5144816	
	M41 International (41.02)	5144816-1-1	
Sirius M42 (IS4-2 Madras)	M42 International (V1/V2 CS : 43.00) (V3 CS : 53.00)	5144816-2-1	
Sirius M44 (IS4-3 Fwd Prod)	M44 International (V1/V2 CS : 43.10.1) (V3 CS : 53.10.1)	5144816-3	Check Control Station version following the procedure described in Section 2.3.4
Sirius M45 (Orion 1)	M45 International (V3 CS : 53.10.10)	5144816-4	

Technical Release	Manufacturing Version(ADS Version)	Model Number	Next actions
Sirius M46 (Slave)	M46 International (V3 CS : 53.10.10)	5144816-5	
Sirius M47 (*) (KiwiM3s1)	M47 International (V3 CS : 53.30)	5144816-5	
Sirius M48 (Litchi2K)	M48 International (V3 CS : 53.30)	5144816-6	
Sirius M49 (Zodiac)	M49 International (V3 CS : 53.30)	5144816-7 and 5144816-7-LE	
Sirius M410 (Penduick)	M410 International (V3 CS : 53.40)	5144816-8 and 5144816-8-LE	
Sirius M411 (LFOV2 + Z400)	M411 International (V4 CS : 54.10)	5144816-9 and 5144816-9-LE	No check required. Go to Section 2.3.5
Sirius M412 (Sunburst)	M412 International (V4 CS : 54.20)	5144816-10 and 5144816-10-LE	
Sirius M413 (eIFU)	M413 International (V4 CS : 54.20)	5144816-11 and 5144816-11-LE	
Sirius M414 (SFDA)	M414 International (V4 CS : 54.20)	5144816-12 and 5144816-12-LE	
Sirius M415 (CE removal)	M415 International (V4 CS : 54.20)	5144816-13 and 5144816-13-LE	
Sirius M416 (Vitality)	M416 International (V5 CS : 55.40)	5144816-14 and 5144816-14-LE or higher	
IB system upgraded with CESM option	N/A (55.10 or 55.20)	N/A	Check Control Station version following the procedure described in Section 2.3.4.
If the Senographe system is not listed in this table proceed to Job Card PRE A003 - Pre Installation Planning - Ensure compatibility with the GE Breast Tomosynthesis option * — System upgraded with Stereotaxy Kit (ADS SW 53.30, 3000N Rotation Gas Spring (5154719) and Rotation Board with V2 Rotation Clutch Connector (2375488–12))			

2.3.3 Perform FMI12075 checks

2.3.3.1 Physical checks

1. Check the log books to see if there is an entry suggesting that the Senographe system has been updated to FMI12075.
2. Check the presence of the FMI12075 identification label that should have been stuck on the bottom of the Gantry column front cover.



2.3.3.2 Service desktop checks

1. Use one of the following two methods to access the Service Desktop.
   - In the Browser, click the **Tools menu** button  then click *Service Desktop* in the context menu.
   - Use the right mouse button to click in the background of the Browser screen, then select *Service Tools*|*Service Desktop* from the pop-up menu.
2. From the SITE INFORMATION page of the Service Desktop, ensure that the firmware and software versions listed are equal to or greater than the values listed in Table 3-16.

Table 3-16: Required FW and SW versions

Board	Component	FW/SW versions after FMI 12075 - Seno Essential
Gantry CPU	Poseidon	NSC1.1.7
Bucky	Bucky HC12	13.6.6
	Bucky CPLD	5.0.3 [1]
Rotation	Rotation HC12	5.9.4
	Rotation DSP	5.13.5
	Rotation CPLD	5.1.2[1]
Lift	Lift HC12	5.10.2
	Lift DSP	5.6.3
	Lift CPLD	10.0.1/5.0.1 [1][2]
Compression	Compression HC12	5.7.1
	Compression CPLD	5.1.4 [1]

Board	Component	FW/SW versions after FMI 12075 - Seno Essential
Tilt	Tilt HC12	5.4.0
	Tilt CPLD	5.1.5 [1]
ADS	Workstation	53.10.1
IDC	IDC	9.3-1
DMR Generator	DMR	V1.10 CMN
PDU	PDU HC12	4.0.7 (will be displayed V12334.12630.7)/ 5.0.7 [3]

Notes:
[1]: means these are not supplied on the FMI 12075 CD-ROM and are not needed.
[2]: means that both versions 5.0.1 and 10.0.1 are acceptable. The previous version of Lift CPLD will work with this configuration. The new lift CPLD is only needed if lift brake option is included.
[3]: means that both versions 4.0.7 and 5.0.7 are acceptable.

2.3.4 Check the Control Station version

To be compatible with the kit, the Control Station must be at least a V4.

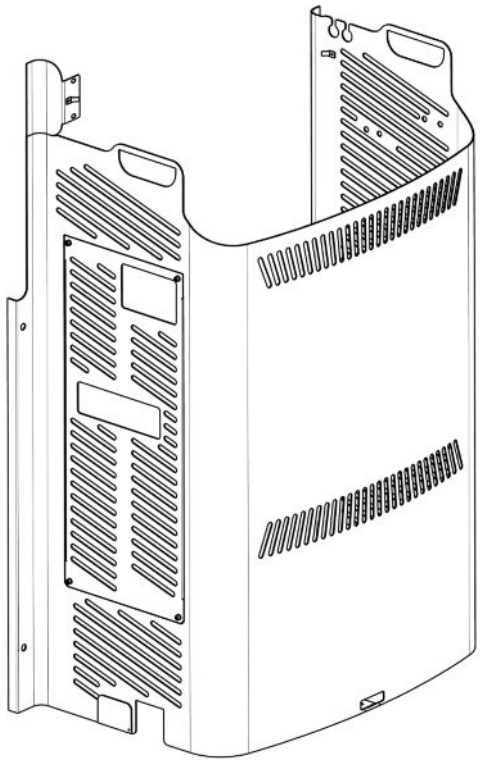
To check the Control Station version, follow these steps:

1. Use one of the following two methods to access the Service Desktop:
   - In the Browser, click the [Tools menu] button  then click Service Desktop in the drop-down menu.

   OR

   - Right-click in the background of the Browser screen, then select Service Tools/Service Desktop from the context menu.
2. On the SITE INFORMATION page of the Service Desktop check the AWS application version.
   - If the version number starts with a **4**, e.g. *43.00*, the Control Station is a V1 or V2.
   - If the version number starts with a **5**, e.g. *53.00*, the Control Station is a V3, V4 or V5.
3. If the Control Station is a V3, V4 or V5 follow these steps:
   - If the Omega cover has no vents, it is a V3 Control Station.
   - If the Omega cover has vents, it is a V4 or a V5 Control Station. See Illustration 3-20.

Illustration 3-20: Example of the Omega cover of the V4 Control Station



4. Record this information in the *form* in Section 2.3.6.

2.3.5 Next Actions

2.3.5.1 FMI12075 is not applied

Define a time with the customer to perform FMI12075 before you proceed to Job Card PRE A003 - Pre Installation Planning - Ensure compatibility with the GE Breast Tomosynthesis option.

2.3.5.2 The Control Station is a V1/V2/V3

Define a time with the customer to perform the **hardware** upgrades of *Accelera V1/V2/V3 to V5* before you proceed to Job Card PRE A003 - Pre Installation Planning - Ensure compatibility with the GE Breast Tomosynthesis option.

Since the option upgrades the software of the different subsystems to new versions, the software upgrades contained in *Accelera V1/V2/V3 to V5* are not necessary.

2.3.5.3 The appropriate FMIs are applied and the Control Station is a V4 or higher

Proceed directly to Job Card PRE A003 - Pre Installation Planning - Ensure compatibility with the GE Breast Tomosynthesis option.

2.3.6 Record Form

Copy or print out this form to record the information collected with this Job Card.

Table 3-17: Record Form

Checks	Check results
System level	
Upgrades	
FMI 12075	
Control Station Version	

2.4 Job Card PRE A003 - Pre Installation Planning - Ensure compatibility with the GE Breast Tomosynthesis option

2.4.1 Ordering Kits

Before going on-site to install the Kit, order the following kits based on the existing system configuration. Use the recorded results of the checks performed in the JC PRE A002 Ensure Minimum System Level is Met. See the situations detailed below to know which kits to order.

- The system is at IS43 (FMI12075) level
- The system contains at least a V4 Control Station
- The Gantry contains following Rotation-related Gantry parts at the level as specified below:
  - Rotation Board with V2 Rotation Clutch Connector (2375488–12 or above)
  - 3000N Rotation Gas Spring (5154719)
  - Precise 50N Rotation Clutch (5481350)

Therefore, before going on-site to install the GE Breast Tomosynthesis Kit, check the existing configuration and then order the following kits based on the existing system configuration.

Table 3-18: Kits to order depending on the installation scenario

Scenario	System Level (Model Number)	Order:
Scenario A	Senographe Essential - LFOV2 - V4 Control Station (5144816-9) Senographe Essential - Sunburst - V4 Control Station (5144816-10) Senographe Essential - eIFU – V4 Control Station (5144816-11) Senographe Essential - SFDA – V4 Control Station (5144816-12) Senographe Essential - CE removal – V4 Control Station (5144816-13) (system already installed) Senographe Essential - Vitality – V5 Control Station (5144816-14) (system already installed)	• GE Breast Tomosynthesis Kit (5434135-5) • Execute Job Card PM A001, section *2.2 Check for Rotation Slippage Issues* and decide if you need to install Rotation Motor Brake Upgrade kit. • Potentially a Breast Support Locking Mechanism (BSLM) board (see Section 2.4.6)
Scenario B	Senographe Essential - Penduick - V3 Control Station (5144816-8)	The following kits: • GE Breast Tomosynthesis Kit (5434135-5) • Accelera 2 Kit for Senographe Essential (S30331YW) • Essential Hardware Upgrade Kit for SenoClaire (S30361AV) • Potentially a BSLM board (see Section 2.4.6)

Scenario	System Level (Model Number)	Order:
Scenario C	Senographe Essential - Pre-Penduick - V1 Control Station (5144816) and Senographe Essential - Pre-Penduick - V2 Control Station (5144816, 5144816-1-1)	The following kits: • GE Breast Tomosynthesis Kit (5434135-5) • Accelera 2 Kit for Senographe Essential (S30331YW) • Essential Hardware Upgrade Kit for SenoClaire (S30361AV) • Potential need for a new monitor with DVI connection (see Section 2.4.7) • Potentially a BSLM board (see Section 2.4.6)
Scenario D	Senographe Essential - Pre-Penduick - V3 Control Station (5144816-2-1, 5144816-3, 5144816-4, 5144816-5, 5144816-6, 5144816-7)	The following kits: • GE Breast Tomosynthesis Kit (5434135-5) • Accelera 2 Kit for Senographe Essential (S30331YW) • Essential Hardware Upgrade Kit for SenoClaire (S30361AV) • Potentially a BSLM board (see Section 2.4.6)
Scenario E	Senographe Essential - LFOV2 - V3 Control Station (5144816-2-1, 5144816-3, 5144816-4, 5144816-5, 5144816-6, 5144816-7, 5144816-8) – systems that have been upgraded using the Nautilus Kit.	The following kits: • GE Breast Tomosynthesis Kit (5434135-5) • Accelera 2 Kit for Senographe Essential (S30331YW) • Essential Hardware Upgrade Kit for SenoClaire (S30361AV) • Potentially a BSLM board (see Section 2.4.6)
Scenario F	Senographe Essential - CE removal – V4 Control Station (5144816-13) (not yet installed) Senographe Essential Systems - V5 Control Station (5144816-14) (not yet installed)	• GE Breast Tomosynthesis Kit (5434135-5) • Execute Job Card PM A001, section *2.2 Check for Rotation Slippage Issues* and decide if you need to install Rotation Motor Brake Upgrade kit. • Potentially a BSLM board (see Section 2.4.6)

2.4.2 MANPOWER REQUIREMENTS

The following manpower is required:

- 1 Field Engineer for about 16.5 hours in total, including procedure reading, material unpacking, software/hardware upgrade, verification and IQ tests.
- If the Stereotaxy option is present, 1 Field Engineer for an additional 2 hours in total to configure the Stereotaxy Positioner.

2.4.3 Special Tools and Equipment

- Tools and phantom for IQ tests:
  - Flat Field Phantom

- ACR standard Phantom
- IQST standard Phantom with adapter for Mag Stand
- Set of acrylic plates

- Tools for lift calibration, rotation calibration (standard toolbox)
- Optional Male DVI to Female VGA adaptor for temporarily connecting the ADS monitor to the IDC.
- Ensure that you still have the LFOV Mammo Detector Manufacturing Data CD-ROM to reload the detector data onto the Essential IDC. The LFOV Mammo Detector Manufacturing Data CD-ROM is unique to the detector installed with the Senographe system. If you need another LFOV Mammo Detector Manufacturing Data CD-ROM, contact the Online Center in the appropriate Pole for Detector Data, quoting the detector ID of the system.
- If you are upgrading a Pre-Penduick Senographe Essential with a V1/V2 Control Station (scenario C) then the existing LFOV Mammo Detector Manufacturing Data will be on a floppy diskette which cannot be read by Z400/ R2 Computers that replaces the SB-150 Computer. In these scenarios you need to order LFOV Mammo Detector Manufacturing Data CD-ROM to use instead of the diskette. To do this, contact the Online Center in the appropriate Pole for Detector Data, quoting the detector ID of the system.

2.4.4 Pre-GE Breast Tomosynthesis Upgrade Scheduling Tasks

Before going on-site to perform the GE Breast Tomosynthesis upgrade, ensure that you have scheduled the availability of the following people during the day of the visit:

- GST Team to perform InSite checkout.
- Hospital Physicist to perform the related post-upgrade tests according to their local requirements
- If the Stereotaxy option is present, the Medical Applications Specialist so appropriate Stereotaxy related training can be given to the Operator.

2.4.5 Potential Need For Rotation-Related Gantry Hardware

In order for the GE Breast Tomosynthesis option to work, the Gantry needs to contain the following Rotation-related Gantry parts at the level as specified below.

- 3000N Rotation Gas Spring (5154719)
- Precise 50N Rotation Clutch (5481350)
- Rotation Board with V2 Rotation Clutch Connector (2375488–12 or above)

For system older than 5144816-8 included, Essential Upgrade Kit for SenoClaire must be installed. It contains among others gantry related parts:

- 3000N Rotation Gas Spring (5154719)
- Rotation Board with V2 Rotation Clutch Connector (2375488–13)

Table 3-19 summarizes the forward production systems that were already manufactured with these parts, and which do not need to be upgraded with that particular part.

Table 3-19: Forward production systems manufactured with GE Breast Tomosynthesis compatible Rotation-related Gantry parts

Minimum Rotation-related Gantry part required for GE Breast Tomosynthesis	Forward Production System (Model Number)
Rotation Board with V2 Rotation Clutch Connector (2375488-12)	IS4–3 (5144816-3)
3000N Rotation Gas Spring (5154719)	Litchi (5144816–6)
Precise 50N Rotation Clutch (5481350)	CE removal (5144816-13)

NOTE: Systems upgraded with the Stereotaxy Kit will contain the necessary 3000N Rotation Gas Spring (5154719) and Rotation Board with V2 Rotation Clutch Connector (2375488-12), but will contain the non-50N V2 Rotation Clutch (2345968–3), which will need upgrading with the 50N V2 Rotation Clutch (5481350).

2.4.5.1 Deciding What Rotation-Related Gantry Parts to Take Onsite

Table 3-20 describes which Rotation-related Gantry parts you need to order and take on-site. Once on-site, you will perform the necessary physical checks, and if necessary upgrade those parts.

Table 3-20: Rotation-related Gantry Parts that need changing as a function of Model Number

Technical Release	Manufacturing Version(ADS Version)	Model Number	Rotation-related Gantry Parts to order (assuming they have never been changed during the system lifetime)
Sirius M3	M3 (40.11)	5144816	Essential Hardware Upgrade Kit for SenoClaire (S30361AV)
Sirius M3A Plus	M3A Plus Standard (41.00)	5144816	
	M3A Plus International (41.00)	5144816-1-1	
Sirius M3A FB	M3A FB Standard (41.02)	5144816	
	M3A FB International (41.02)	5144816-1-1	
Sirius M3A Bucky	M3A Bucky Standard (41.02)	5144816	
	M3A Bucky International (41.02)	5144816-1-1	
Sirius M4	M4 Standard (41.02)	5144816	
	M4 International (41.02)	5144816-1-1	

Technical Release	Manufacturing Version(ADS Version)	Model Number	Rotation-related Gantry Parts to order (assuming they have never been changed during the system lifetime)
Sirius M41	M41 Standard (41.02)	5144816	
	M41 International (41.02)	5144816-1-1	
Sirius M42 (IS4-2 Madras)	M42 International (V1/V2 CS : 43.00) (V3 CS : 53.00)	5144816-2-1	
Sirius M44 (IS4-3 Fwd Prod)	M44 International (V1/V2 CS : 43.10.1) (V3 CS : 53.10.1)	5144816-3	
Sirius M45 (Orion 1)	M45 International (V3 CS : 53.10.10)	5144816-4	
Sirius M46 (*) (Slave)	M46 International (V3 CS : 53.10.10)	5144816-5	
Sirius M47 (**) (KiwiM3s1)	M47 International (V3 CS : 53.30)	5144816-5	
Sirius M48 (Litchi2K)	M48 International (V3 CS : 53.30)	5144816-6	
Sirius M49 (Zodiac)	M49 International (V3 CS : 53.30)	5144816-7 and 5144816-7-LE	
Sirius M410 (Penduick)	M410 International (V3 CS : 53.40)	5144816-8 and 5144816-8-LE	
Sirius M411 (LFOV2 + Z400)	M411 International (V4 CS : 54.10)	5144816-9 and 5144816-9-LE	Execute Job Card PM A001 , section *2.2 Check for Rotation Slippage Issues* and decide if you need to install Rotation Motor Brake Upgrade kit.
Sirius M412 (Sunburst)	M412 International (V4 CS : 54.20)	5144816-10 and 5144816-10-LE	
Sirius M413 (eIFU)	M413 International (V4 CS : 54.20)	5144816-11 and 5144816-11-LE	
Sirius M414 (SFDA)	M414 International (V4 CS : 54.20)	5144816-12 and 5144816-12-LE	
Sirius M415 (CE removal)	M415 International (V4 CS : 54.20)	5144816-13 and 5144816-13-LE	

Technical Release	Manufacturing Version(ADS Version)	Model Number	Rotation-related Gantry Parts to order (assuming they have never been changed during the system lifetime)
Sirius M416 (Vitality)	M415 International (V5 CS : 55.40)	5144816-14 and 5144816-14-LE or higher	
IB system upgraded with CESM option	N/A (55.10 or 55.20)	N/A	Depends on the Model Number of the IB System as listed above.
* — Some Q1 2009 Essential Systems (5144816-5) not upgraded with the Stereotaxy Upgrade Kit were already manufactured with the 3000N Rotation Gas Spring. For more information, see Section 2.4.5.2. ** — System upgraded with Stereotaxy Kit (ADS SW 53.30, 3000N Rotation Gas Spring (5154719) and Rotation Board with V2 Rotation Clutch Connector (2375488–12)), but will contain the non-50N V2 Rotation Clutch (2345968–3), which will need upgrading with the 50N V2 Rotation Clutch (5481350).			

2.4.5.2 Q1 2009 Essential Systems (5144816-5) Manufactured With the 3000N Rotation Gas Spring

Some Essential Systems with model number 5144816-5 that were never upgraded with the Stereotaxy Kit may already have 3000 N Rotation Gas Spring (5154719) required by the GE Breast Tomosynthesis option.

- All Senographe Essential systems manufactured after April 1st 2009 have the 3000 N Rotation Gas Spring (5154719), which is compatible with the GE Breast Tomosynthesis option. In this case, you do not need to change the Rotation Gas Spring.
- Senographe Essential systems manufactured before April 1st 2009 may have the 2600 N Rotation Gas Spring (2412202) or 3000 N Rotation Gas Spring (5154719). The 2600 N Rotation Gas Spring (2412202) is not compatible with the GE Breast Tomosynthesis option, whereas the 3000 N Rotation Gas Spring (5154719) is compatible with the GE Breast Tomosynthesis option.

Table 3-21 summarizes the Senographe Essential systems manufactured before April 1st 2009 that have the new 3000 N Rotation Gas Spring (5154719), which is compatible with the GE Breast Tomosynthesis option. To identify your system, check the labels on the base of the Gantry and on the Generator covers.

Table 3-21: Q1 2009 Essential Systems manufactured with the 3000 N Rotation Gas Spring

Manufacturing date	Gantry S/N	System S/N
2009–01–21	4590MC6	574095BU6
2009–01–21	4592MC2	574102BU0
2009–01–26	4591MC4	574449BU5
2009–01–29	4611MC0	574451BU1
2009–01–29	4609MC4	574452BU9
2009–01–29	4612MC8	574920BU5
2009–01–30	4610MC2	574454BU5
2009–01–30	4613MC6	574453BU7

Manufacturing date	Gantry S/N	System S/N
2009–02–02	4616MC9	574918BU9
2009–02–04	4614MC4	574919BU7
2009–02–02	4615MC1	574914BU8
2009–02–04	4617MC7	574913BU0
2009–02–05	4622MC7	574916BU3
2009–02–09	4621MC9	575260BU5
2009–02–10	4624MC3	575261BU3
2009–02–11	4618MC5	575263BU9
2009–02–13	4623MC5	574912BU2
2009–02–19	4629MC2	575450BU2
2009–02–19	4628MC4	575446BU0
2009–02–23	4626MC8	575442BU9
2009–02–25	4630MC0	575262BU1
2009–03–02	4625MC0	575264BU7
2009–03–03	4619MC3	575443BU7
2009–03–09	4634MC2	576017BU8
2009–03–09	4631MC8	576018BU6
2009–03–10	4627MC6	576005BU3
2009–03–10	4633MC4	576004BU6
2009–03–12	4632MC6	575449BU4
2009–03–16	4635MC9	576007BU9
2009–03–16	4639MC1	576008BU7
2009–03–17	4656MC5	576003BU8
2009–03–18	4654MC0	576010BU3
2009–03–18	4643MC3	576012BU9
2009–03–18	4657MC3	576009BU5
2009–03–24	4640MC9	575981BU6
2009–03–24	4636MC7	575983BU2
2009–03–25	4667MC2	575984BU0
2009–03–26	4642MC5	576011BU1

2.4.6 Potential Need to Change BSLM Board

In older Gantries, there may be a need to change the Breast Support Locking Mechanism board. Some BSLM Boards in the install base are not compatible with the MTD because they store excessive charge from the Gantry CAN bus, which the MTD is sensitive to. When a BSLM Board is not compatible with the MTD, there is a lapse of CAN communication between the MTD and the Gantry, and the MTD will not boot up when plugged into the Gantry. Order a BSLM Board (5137301-3) and take it on-site in case it needs changing during the GE Breast Tomosynthesis upgrade.

2.4.7 Potential Need For New Monitor on Systems Upgraded by Accelera Kit

If you are upgrading a system with a V1/V2 Control Station with the Accelera Kit (scenario C), and if the customer has a monitor without a DVI connection, you must order a monitor with a DVI connection (19" LCD Monitor PN: 51487020-4).

2.4.8 Potential Need For Long Reconstruction Cable Harness

If during the pre-installation planning phase (see Section 1.6.2, Layout Constraints for Positioning the Reconstruction Station) it was decided that the Reconstruction Station cannot be positioned directly behind the Control Station, order the Long Reconstruction Station Cable Harness (5434153).

2.4.9 Planning Upgrades of IDI Mammography Workflow Solutions

Before installing the GE Breast Tomosynthesis option, ensure that customer's IDI Mammography Workflow Solutions system is already at version 4.7.0 V-Preview (named MR3 or Build 382) or above has a Tomo license. If the customer's IDI Mammography Workflow Solutions system needs upgrading to version 4.7.0 V-Preview (named MR3 or Build 382) or above, it can take several weeks to receive the upgrade software. In scenarios where the customer's IDI Mammography Workflow Solutions system needs upgrading to version 4.7.0 V-Preview (named MR3 or Build 382) or above, ensure that you plan enough time so that the GE Breast Tomosynthesis option can be installed after the upgrade of the IDI Mammography Workflow Solutions system.

NOTE: If the customer's IDI 4.7.0 version is not at build 382 (also named MR3) or above, Breast Tomosynthesis Objects will not be supported.

2.4.10 Obtaining Test BTO Images to Check PACS Compatibility

Before going on site, you should obtain test BTO images so that they can be used to check PACs compatibility.

1. On a USB flash memory device, copy the folder **e6** from the following FTP server address: **ftp://medical.nema.org/MEDICAL/Dicom/DataSets/WG15/BreastTomoImage/GE_BreastTomo_2012_10/**

   To establish this FTP connection, you must configure your FTP client as follows:

   - FTP host : medical.nema.org
   - Username : anonymous
   - Password : your e-mail address
   - Remote Start Folder : MEDICAL/Dicom/DataSets/WG15/BreastTomoImage/GE_BreastTomo_2012_10/

   If you are within the GE network when connecting to the remote FTP server, you will need to configure the advanced settings in your FTP client so it can traverse the GE proxy.

   - Proxy host : ftp-proxy.med.ge.com
   - Port : 21

- User Id : blank (nothing)
- Password : blank (nothing)
- FTP Proxy : UserId = user@hostname

NOTE: The images from the link indicated above were generated for connectivity testing purposes only. They are not representatives for the display nor for any other functionality

NOTE: Depending on your Internet connection speed. The folders may take some time (order of minutes) to update within your FTP client.

2. Once the **e6** folder from the FTP server have finished downloading (could take up to 2 hours depending on your Internet connection), verify that the folder structure and file structure/size is as follows within the **e6** folder:
   - s36
     - i150.MGDC.2 — 171,241 KB
     - i151.MGDC.1 — 18,159 KB
   - s43
     - i164.MGDC.1 — 18,466 KB
     - i165.MGDC.2 — 170,751 KB
   - s44
     - i166.MGDC.2 — 163,213 KB
     - i167.MGDC.1 — 18,659 KB
   - s46
     - i170.MGDC.2 — 163,212 KB
     - i171.MGDC.1 — 18,659 KB

   If any of the files are missing or not the file sizes quoted above, download the contents of the **e6** folder from the FTP server.
3. Copy the **e6** folder from the FTP server to a USB flash memory device.

2.5 Job Card PRE A004 - Checking for Damage

The option kit is inspected for proper operation and appearance before shipment. However, it is necessary to inspect the product after the shipment is received. The option kit is supplied in one pallet that contains the following elements:

- Motorized Tomosynthesis Device,
- Reconstruction Housing,
- Reconstruction Computer,
- Technical publication,
- Accessory kit, which includes:
  - Short Reconstruction Station Cable Harness
  - CAT6 Ethernet Coupler
  - 3D Foot Pedal
  - Lift Board
  - Multi-plug
  - UPS Power Cable
  - Ethernet Switch
  - 20 x Tie Wraps
  - Z400 RAM Modules
  - Generator EPROMs
- Standard 24x31 Paddle for MTD,
- Elevated 24x31 Paddle for MTD,
- Sliding 19x23 Paddle for MTD,
- Software upgrade kit,
- Detector Rails,
- 50N V2 Rotation Clutch,
- Gas Spring for Rotation Worm Gear.

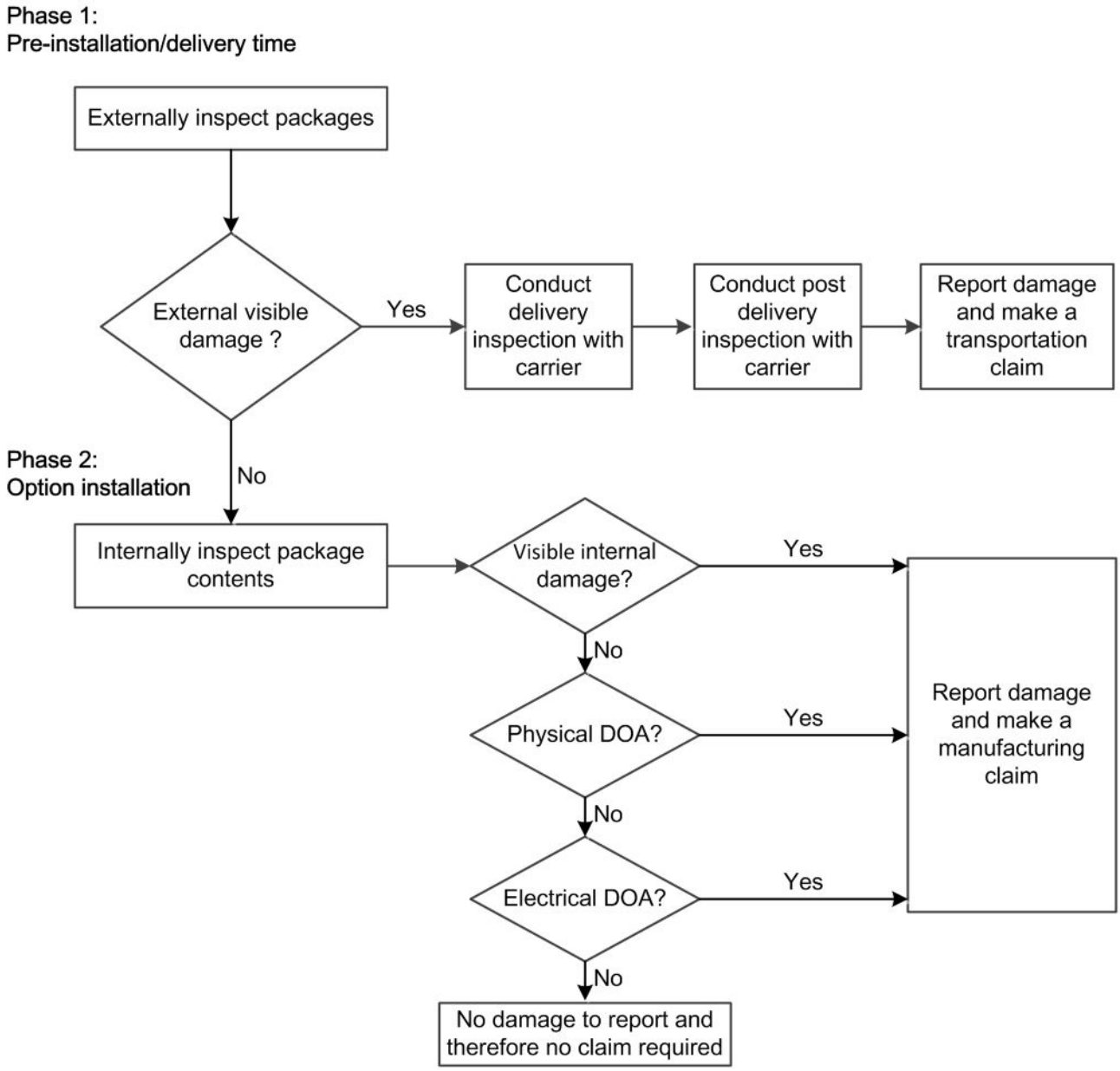
2.5.1 POSSIBLE TYPES OF DAMAGE

Two types of possible damage can exist, as follows:

- External (noted) damage: damage is visible on the packages and there may or may not be actual damage to the contents of the packages. This type of damage is a consequence of bad transportation.
- Internal (concealed) damage: no damage is visible on the packages however there is actual damage to the contents of the packages. This type of damage is a consequence of bad manufacturing.

The illustration below summarizes the general process to determine:

- whether any of the option components are damaged
- the cause (and liability) of possible damage
- whether you have to make a claim for damage with the carrier company
- whether you have to make a manufacturing claim for damage or components considered dead on arrival (DOA) with GE Healthcare



The damage checking process is split into two main phases:

- The first phase must be undertaken during the delivery complaint period defined by your country consumer laws (usually 14 days). So that in the event that external damage has occurred, the liability of the damage can be attributed to the carrier company.

NOTICE

External (noted) damage must be reported to the carrier immediately upon discovery, or in any event within the delivery complaint period (defined by your local consumer laws) after receiving the delivery (e.g.14 days in the USA). A transportation company will not pay a claim for damage if a post-delivery inspection is not requested within the delivery complaint period defined by your country consumer laws (usually 14 days).

- The second phase can be undertaken later during the installation of the option. Any damage found during this phase is considered as either physical DOA or electrical DOA, which is the responsibility of GE Healthcare manufacturing.

2.5.2 CHECKING FOR EXTERNAL DAMAGE

2.5.2.1 Delivery Inspection with Courier

When the shipment of the option kit arrives, a General Electric representative or a hospital receiving agent must proceed as follows for each of the pallet.

1. Closely examine each pallet for visible damage, and check any shock and tilt indicators present.

   If the pallets in the shipment show visible signs of damage, excessive shock, etc. you must perform a delivery inspection as follows:

   a. Open the pallet immediately to check the contents, and ask the driver to inspect the contents with you.

   b. Write a precise description of the damage on your copy and carriers copy of the delivery receipt, along with the notation "damage in shipment".

   c. Sign for the shipment and arrange a post-delivery inspection within delivery complaint period defined by your country consumer laws.

   d. Contact GE Healthcare to report the initial damage according to Section 2.5.4 Reporting Damage.

      If the pallets in the shipment do not show visible signs of damage or excessive shock, no action is required other than to sign for the shipment.

2. Move the pallet into or close to the x-ray room, ready for unpacking.

2.5.2.2 Conduct post-delivery Inspections

Contact the Customer Service Department at phone number provided on the carriers bill to help you determine whether a post-delivery inspection and formal written report is required. Occasionally, the carrier may not have an inspector examine the damaged freight. Instead, they may request that you do the post-delivery inspection yourself and keep a written description. This written description can be used if a transportation claim is filed later. Note, that a post-delivery inspection report is not a transportation claim.

Once you have completed a post-delivery the details of the damage to GE Healthcare and the carrier according to Section 2.5.4 Reporting Damage.

2.5.3 CHECKING FOR INTERNAL DAMAGE

As soon as possible after delivery, unpack, and inspect your shipment. If you discover internal (concealed) damage, report it to GE Healthcare immediately according to Section 2.5.4 Reporting Damage.

2.5.4 REPORTING DAMAGE

1. Contact the GE Healthcare Distributor and/or GE Healthcare Account Manager from which the product was purchased to inform them of the damage. Be ready to supply the following information:

- name of carrier,
- delivery date,
- consignee name,
- freight or express bill number,
- item damaged,
- extent of damage.

2. The GE Healthcare Distributor and/or GE Healthcare Account Manager will contact the factory of origin to determine the most cost effective way to repair the damage.
   - If damage deemed to warrant a factory repair, a Return Merchandise Authorization (RMA) will be issued to return damaged product to factory. Factory will provide quote to repair damaged equipment after inspection of damage upon receipt of damaged equipment. Do not ship any damaged product back to factory without an RMA.
   - If damage is deemed minimal and can be repaired in the field with replacement parts, the factory will provide a quote to the consignee to purchase those parts.
   - If damage is deemed catastrophic and requires complete replacement of damaged equipment, GE Healthcare will provide a quote to the consignee with quote to replace damaged equipment.
3. Discuss how to proceed with your GE Healthcare Distributor and/or GE Healthcare Account Manager:
   - If you determined that the bad transportation was to blame for the damage then your GE Healthcare Distributor and/or GE Healthcare Account Manager will advise you how to file a transportation claim and how to proceed with the transportation claim process.
   - If you determined that the transportation was not to blame for the damage then your GE Healthcare Distributor and/or GE Healthcare Account Manager will advise you how to file a manufacturing claim and how to proceed with the manufacturing claim process.

2.6 Job Card PRE A005 - Unpacking the kit

2.6.1 Personnel Requirements

Personnel Requirements	Preliminary Reqs	Procedure	Finalization
1 Field Engineer	Not Applicable	45 mins	Not Applicable

2.6.2 Overview

The GE Breast Tomosynthesis Kit is delivered on only one pallet.

The objective of this Job Card is to unpack the MTD, the upgrade kit, the accessories, the Reconstruction housing and computer to check them for damage and move them to the mammography room.

In addition to the GE Breast Tomosynthesis Kit, the Essential Upgrade Kit for Senoclaire may have been ordered and delivered at the same time. The content and unpacking instructions of the Essential Upgrade Kit for Senoclaire are beyond the scope of this Job Card. However, if it was ordered, you must ensure that the Essential Upgrade Kit for Senoclaire has also been delivered.

2.6.3 Preliminary Requirements

2.6.3.1 Tools and Test Equipment

Item	Qty	Effectivity	Part#	Manufacturer
Standard Tool Box	1	-	-	-
Safety gloves	1	-	-	-

2.6.3.2 Safety

⚠WARNING

RISKS OF CRUSHING INJURIES.
THE MOTORIZED TOMOSYNTHESIS DEVICE (MTD) WEIGHS OVER 12 KG. ALWAYS USE BOTH HANDS TO MANIPULATE THE MTD WHEN MANIPULATING THE DEVICE. BE CAREFUL DURING THE MANIPULATION OF THE MTD.

⚠WARNING

RISKS OF CRUSHING INJURIES.
THE RECONSTRUCTION HOUSING AND THE RECONSTRUCTION COMPUTER ARE HEAVY.
NEVER LIFT THE HOUSING OR COMPUTER. TO MOVE THEM, TILT THE EQUIPMENT 15° AND USE YOUR LEG TO PUSH IT TO DESTINATION. ALWAYS USE BOTH HANDS TO MANIPULATE THE RECONSTRUCTION HOUSING AND COMPUTER.

⚠CAUTION
Risks of bruising injuries during manipulation of paddles.
Handle the paddles with care.

⚠CAUTION
Risk of cut when opening the kit and handling the packaging.
Wear protective gloves.

2.6.3.3 Required Conditions

Condition	Reference	Effectivity
The pallet is on flat, level ground.	-	-

2.6.4 Procedure

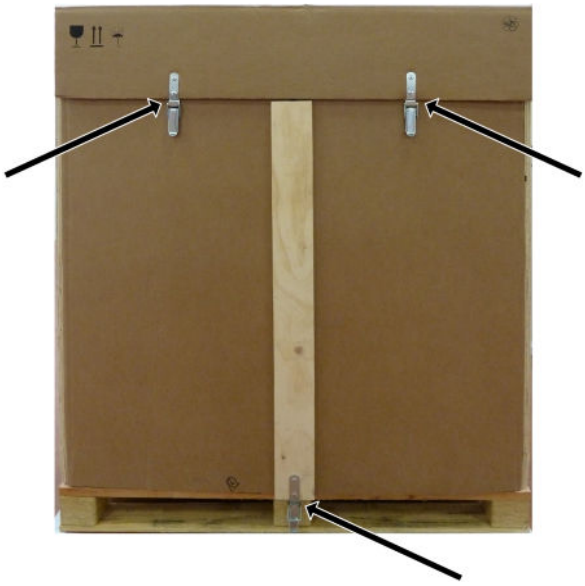
2.6.4.1 Reception

The kit is delivered on a single pallet. At reception check the entire consignment for damage according to Job Card PRE A004 - Checking for damage

2.6.4.2 Packaging description

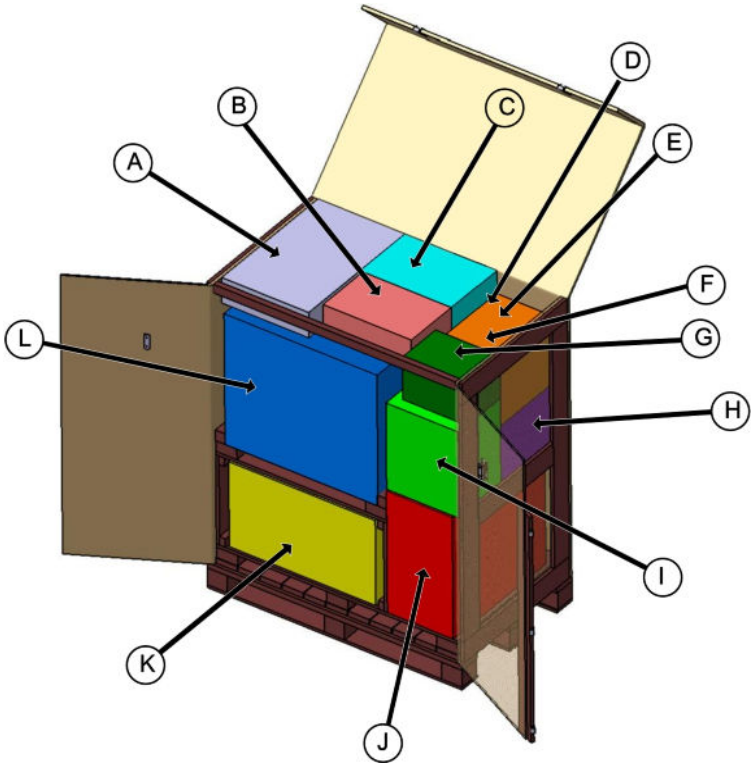
1. Open the three latches (see Illustration 3-21) to release the top cover and the doors of the package.

Illustration 3-21: Package closed



2. Push the top cover and open the doors.

   Refer to Table 3-22 for a description of the pallet content.



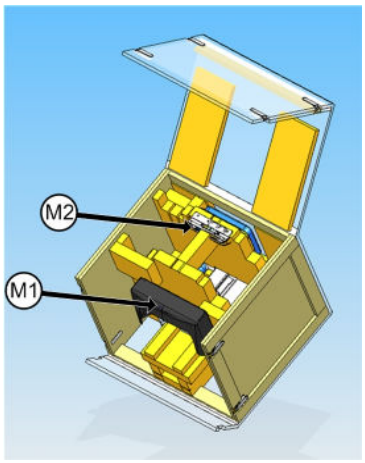


Table 3-22: Pallet content

Identification	Content
A	Protective Foam
B	Software kit
C	Technical Publications (Operator Manual, Installation Manual)
D	Plastic Detector Rails and Stator Current Filter Assembly Cable
E	Precise 50N Clutch
F	Standard 24x31 Paddle for MTD
G	Deflector set

Identification	Content
H	Elevated 24x31 Paddle for MTD
I	Accessory kit
J	Reconstruction Computer
K	Reconstruction Housing
L	Motorized Tomosynthesis Device (M1) and Sliding 19x23 Paddle for MTD (M2)

2.6.4.3 Unpacking the kit

1. Open each box that you remove the package and check the items for damage such as scratches or visible impacts.
2. Remove the following:
    a. foam (A in Table 3-22),
    b. Software kit (B in Table 3-22),
    c. Technical Publications (C in Table 3-22),
    d. Plastic Detector Rails and Stator Current Filter Assembly Cable (D in Table 3-22)
    e. Precise 50N Clutch (E in Table 3-22)
    f. Standard 24x31 Paddle for MTD (F in Table 3-22),
    g. Deflector set (G in Table 3-22),
    h. Elevated 24x31 Paddle for MTD (H in Table 3-22),
    i. Accessory kit (I in Table 3-22).
    j. Reconstruction Computer (J in Table 3-22)
    k. Reconstruction Housing (K in Table 3-22)
    l. Motorized Tomosynthesis Device and Sliding 19x23 Paddle for MTD (L in Table 3-22)

2.6.4.3.1 Reconstruction computer

⚠WARNING

RISKS OF CRUSHING INJURIES.
THE RECONSTRUCTION HOUSING AND THE RECONSTRUCTION COMPUTER ARE HEAVY.
NEVER LIFT THE HOUSING OR COMPUTER. TO MOVE THEM, TILT THE EQUIPMENT 15° AND USE YOUR LEG TO PUSH IT TO DESTINATION.
ALWAYS USE BOTH HANDS TO MANIPULATE THE RECONSTRUCTION HOUSING AND COMPUTER.

⚠CAUTION

Risk of cut when opening the kit and handling the packaging.
Wear protective gloves.

NOTICE

Make sure the computer is on an even non-slippery surface at all time.

Leave the computer on the ground, do not lift it to put it on a table.

1. Remove the Reconstruction computer box from the package.

   Use the handle that is cut in the box, as indicated in Illustration 3-22.

Illustration 3-22: Reconstruction computer box in pallet

2. Check that the inscription **open here** is present in the top left corner of the box.

   If the **open here** inscription is not in the top left corner, turn the box before you open it.

3. Open the box on the side of the **open here** inscription.
4. The computer is protected by two protective foams and a black plastic bag, see Illustration 3-23

Illustration 3-23: Reconstruction computer in box

⚠WARNING

RISKS OF CRUSHING INJURIES.
THE RECONSTRUCTION HOUSING AND THE RECONSTRUCTION COMPUTER ARE HEAVY.
NEVER LIFT THE HOUSING OR COMPUTER.

5. Remove the computer from the box:
    a. Slide your hands on the sides of the computer.
    b. Pull the computer on each side alternatively to take it out of the box.
6. Remove the foam and plastic bag.
    a. Remove the foam on top.
    b. Open the top of the plastic bag and slide it down.

NOTICE

Hold the computer to prevent it from falling when you remove the protective foam.

    c. Put the computer on its side.
    d. Put the computer on its top.
    e. Remove the protective foam and the plastic bag.
    f. Put the computer on its side then put it back on its base.
7. Remove and discard the front protection of the computer.

2.6.4.3.2 Reconstruction housing

1. Remove the Reconstruction housing box from the package.
    Use the handles attached to the side of the box, as indicated in Illustration 3-24.

Illustration 3-24: Reconstruction housing box in pallet

2. Put the box on its base as indicated by the position of the handles.

⚠WARNING
RISKS OF CRUSHING INJURIES.
THE RECONSTRUCTION HOUSING AND THE RECONSTRUCTION COMPUTER ARE HEAVY.
NEVER LIFT THE HOUSING OR COMPUTER.

3. Open the side of the box.
4. Remove the housing from the box:
    a. Slide your hands on the sides of the housing.
    b. Pull the housing on each side alternatively to take it out of the box.

5. Remove the protective foams.
    a. Put the housing on its side.
    b. Put the housing on its top.
    c. Remove the protective foam.
    d. Put the housing on its side.
    e. Put the housing on its base.
    f. Remove the protective foam.

2.6.4.3.3 Motorized Tomosynthesis Device (MTD)

1. Pull on the MTD box to access the latches on each side.
2. Open the latches, see Illustration 3-25

Illustration 3-25: MTD box in pallet

3. Push the MTD box back into the pallet.
4. Push the front cover of the box up and position it so it stays in place on top of the box, see Illustration 3-26.

Illustration 3-26: Open the MTD box

5. Pull the MTD box so it is one tenth out of he pallet.
6. Push the top cover so the box stays open.
7. Remove the two parts of the MTD table stand from the box and assemble them.
8. Remove the protective foams indicated in Illustration 3-27.

Illustration 3-27: MTD protective foams

9. Remove the plastic sheet protecting the MTD grid.

⚠WARNING

RISKS OF CRUSHING INJURIES.
THE MOTORIZED TOMOSYNTHESIS DEVICE (MTD) WEIGHS OVER 12 KG. ALWAYS USE BOTH HANDS TO MANIPULATE THE MTD WHEN MANIPULATING THE DEVICE. BE CAREFUL DURING THE MANIPULATION OF THE MTD.

10. Remove the MTD from its packaging.
    a. Pivot the MTD to position it vertically.
    b. Lift the MTD using the handles and put the MTD on its table stand.

2.6.5 Finalization

Unless the customer asks otherwise, dispose of the packaging following the hospital guidelines for waste management. Ensure you do not throw away important items such as the TRA sheet as it is needed later on when sending the localization card.

2.7 Job Card PRE A006 - Overall system behavior check

The objective of the procedures described in this Job Card is to check the system for problems that could critically interfere with the intended use of the option.

2.7.1 Check the system for Gantry related errors

In the **Error Log** section of the Service Desktop (see *How to use the Error Log* in the *Core SIP*), check the presence of any Gantry related errors.

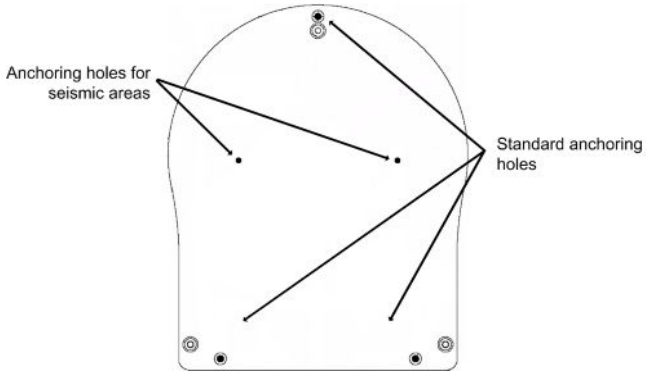
If any Gantry related errors are present, follow the recommended actions described in the *Error Messages* chapter of the *Core SIP*.

2.7.2 Check the anchoring of the system

Given the specificities of the option, the system anchoring needs to be checked to ensure its optimal performance.

Check the three or five (for seismic areas) inserts of the Gantry, indicated in Illustration 3-28:

Illustration 3-28: Gantry anchoring



If the inserts are loose, tighten them accordingly. If the inserts remain loose, contact your OLC as further corrective actions need to be performed before performing more exams.

2.7.3 Perform an acquisition

Perform an acquisition using AOP mode with a Flat Field Phantom and check the following:

- AOP mode is working as expected
- Collimator blades are not visible in the image
- Grey level is correct (image is not black or white)
- No visible artifacts, dust or bad pixels present

If there are any of the issues listed above, resolve them before performing the upgrade of the system.

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