GE HealthCare

Senographe Pristina™
Senographe Pristina™ 3D
Pristina Serena™

Pre-Installation Manual

5729303-1-8EN
Revision 12

Language Policy

DOC0371395 - Global Language Procedure

PARALAJ-MËRIM (SQ-AL)	Ky manual është i disponueshëm në disa gjuhë. • Nëse një ofrues shërbimi klientësh kërkon një gjuhë të ndryshme nga ato që mundësohen në Portalin e dokumentacionit të klientit, është përgjegjësia e klientit që të ofrojë shërbime përkthimi. • Mos u përpiqni të kryeni shërbime në pajisje, pa lexuar dhe kuptuar paraprakisht manualin e shërbimit. • Mosrespektimi i këtij paralajmërimi mund të çojë në lëndim të ofruesit të shërbimit, operator-it ose pacientit si pasojë e goditjes elektrike, mekanike ose një rreziku tjetër.
تحذير (AR-SA)	هذا الدليل متوفر بعدة لغات • إذا كان مقدم الخدمة التابع للعميل يطلب لغة غير تلك المتوفرة في بوابة توثيق العميل، فإنه يقع على عاتق العميل مسؤولية تقديم خدمات الترجمة • لا تحاول صيانة الجهاز ما لم تتم استشارة دليل الخدمة هذا وفهمه • قد يؤدي عدم مراعاة هذا التحذير إلى إصابة مقدم الخدمة أو المشغل أو المريض من جراء الصدمات الكهربائية أو المخاطر الميكانيكية أو غيرها من المخاطر
ПРЕДУПРЕЖДЕНИЕ (BG)	Това ръководство е налично на няколко езика. • Ако доставчикът на услуги на даден клиент изисква език, който е различен от осигурените в портала с документация за клиенти, отговорност на клиента е да предостави преводачески услуги. • Не се опитвайте да обслужвате оборудването, освен ако не сте се консултирали с това сервизно ръководство и сте го разбрали. • Несъблюдаването на това предупреждение може да доведе до нараняване на предоставящия услугите, оператора или пациента вследствие на токов удар, механична или други опасности.
警告 (ZH-CN)	本手册有多种语言版本。 • 如果客户的服务提供商要求使用 Customer Documentation Portal（客户文档门户）未提供的其他语言，则客户有责任提供相应的翻译服务。 • 请勿尝试检修设备，除非已明确参考并理解本检修手册。 • 不遵循此警告可能会导致检修服务提供者、操作员或患者受到触电、机械或其他危害的损伤。
警告 (ZH-HK)	本手冊備有多個語言版本。 • 若客戶的服務提供者所需語言版本不在 Customer Documentation Portal（客戶文件入口網站）所列語言之中，客戶需自行負責提供翻譯服務。 • 除非已查閱並理解本檢修手冊，否則，請勿嘗試檢修設備。 • 不遵循此警告可能會導致服務提供者、操作員或患者因為觸電、機械或其他危險而受傷。
警告 (ZH-TW)	本手冊備有多個語言版本。 • 若客戶的服務提供者所需語言版本不在 Customer Documentation Portal（客戶文件入口網站）所列語言之中，客戶需自行負責提供翻譯服務。 • 除非已查閱並理解本檢修手冊，否則，請勿嘗試檢修設備。 • 不遵循此警告可能會導致服務提供者、操作員或患者因為觸電、機械或其他危險而受傷。
UPOZOR-ENJE (HR)	Ovaj je priručnik dostupan na nekoliko jezika. • Ako serviser klijenta zahtijeva jezik koji nije jedan od jezika dostupnih na portalu s korisničk-om dokumentacijom (Customer Documentation Portal), odgovornost je klijenta pružiti uslugu prevođenja. • Nemojte pokušavati servisirati opremu ako niste proučili i razumjeli ovaj servisni priručnik. • Nepoštovanje ovog upozorenja može izazvati ozljede servisera, rukovatelja ili pacijenta kao posljedicu strujnog udara, mehaničkih ili drugih opasnosti.

VÝSTRAHA (CS)	Tato příručka je k dispozici v několika jazycích. • Pokud zákazníkův poskytovatel služeb vyžaduje jiný jazyk než jazyky, které jsou k dispozici na portálu s uživatelskou dokumentací, je odpovědností zákazníka poskytnout překladatelské služby. • Nepokoušejte se provádět servis zařízení, aniž byste prostudovali tuto servisní příručku a porozuměli jí. • Nedodržení tohoto varování může vést ke zranění poskytovatele služeb, obsluhy nebo pacienta, způsobenému úrazem elektrickým proudem či mechanickým nebo jiným nebezpečím.
ADVARSEL (DA)	Denne vejledning fås på flere sprog. • Hvis en kundes tjenesteudbyder kræver et andet sprog end dem, der er til rådighed i Kundedokumentationsportalen, er det kundens ansvar at levere oversættelsestjenester. • Undgå at forsøge at udføre service på udstyret, medmindre du har læst og forstået denne servicevejledning. • Hvis du undlader at overholde denne advarsel, kan det føre til skader på servicemedarbejderen, operatøren eller patienten på grund af elektrisk stød, mekaniske eller andre farer.
WAAR-SCHUWING (NL)	Deze handleiding is in verschillende talen beschikbaar. • Als de serviceprovider van een klant een andere taal vereist dan de talen die beschikbaar worden gesteld in het Customer Documentation Portal (Klantdocumentatieportaal), is het de verantwoordelijkheid van de klant om vertaalservices te leveren. • Probeer geen service op de apparatuur uit te voeren zonder de servicehandleiding te hebben gelezen en begrepen. • Het negeren van deze waarschuwing kan leiden tot letsel bij de serviceprovider, de operator of de patiënt door elektrische schokken, mechanische of andere gevaren.
WARNING (EN)	This manual is available in several languages. • If a customer's service provider requires a language other than those provided in the Customer Documentation Portal, 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)	Käesolev juhend on saadaval mitmes keeles. • Kui kliendi teenusepakkuja vajab juhendit mõnes muus keeles, mida pole kliendidokumentatsiooni portaalis, on kliendi kohustuseks tõlketeenuste osutamine. • Ärge hakake seda seadet hooldama enne, kui olete käesolevat hooldusjuhendit lugenud ja selle sisu mõistnud. • Selle hoiatuse eiramine võib põhjustada hooldusteenuse pakkujale, operaatorile või patsiendile elektrilöögist, mehhaanilistest või muudest ohtudest tulenevaid vigastusi.
VAROITUS (FI)	Tämä opas on saatavilla useilla kielillä. • Jos asiakkaan palveluntarjoaja edellyttää muita kuin asiakkaan asiakirjaportaalissa saatavilla olevia kieliä, käännöspalveluiden tarjoaminen on asiakkaan vastuulla. • Lue huolto-opas huolellisesti ennen laitteen huoltotoimenpiteiden suorittamista. • Tämän varoituksen huomiotta jättäminen voi johtaa huollon suorittajan, laitteen käyttäjän tai potilaan loukkaantumiseen sähköiskun, mekaanisen vaaran tai muun vaaran vuoksi.
ATTENTION (FR)	Ce manuel est disponible en plusieurs langues. • Si le prestataire de services d'un client nécessite que le manuel soit rédigé dans une autre langue que celles fournies sur le Portail de Documentation Client, il incombe au client de le faire traduire. • Ne pas essayer d’assurer la maintenance de l’équipement sans avoir au préalable consulté et compris les informations contenues dans ce manuel. • 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)	Dieses Handbuch ist in mehreren Sprachen erhältlich. • Wenn ein Dienstleister des Kunden dieses in einer anderen Sprache als der im Kundendokumentationsportal verfügbaren benötigt, liegt es in der Verantwortung des Kunden, Übersetzungsdienstleistungen zu erbringen. • Wartungsarbeiten am Gerät dürfen nur durchgeführt werden, nachdem dieses Wartungshandbuch gelesen und verstanden wurde. • Andernfalls besteht Verletzungsgefahr für den Dienstleister, Bediener oder Patienten durch Stromschlag, mechanische Gefahren oder andere Gefahren.
ΠΡΟΕΙΔΟΠΟΙΗΣΗ (EL)	Αυτό το εγχειρίδιο διατίθεται σε διάφορες γλώσσες. • Εάν ο πάροχος υπηρεσιών συντήρησης ενός πελάτη χρειάζεται διαφορετική γλώσσα από αυτές που διατίθενται στο Customer Documentation Portal (Πύλη τεκμηριώσεων πελάτη), ο πελάτης είναι υπεύθυνος για την παροχή υπηρεσιών μετάφρασης. • Μην επιχειρήσετε να εκτελέσετε συντήρηση του εξοπλισμού, εάν δεν έχετε διαβάσει και κατανοήσει το παρόν εγχειρίδιο συντήρησης. • Εάν δεν τηρήσετε αυτήν την προειδοποίηση, μπορεί να προκληθεί τραυματισμός του παρόχου υπηρεσιών συντήρησης, του χειριστή ή του ασθενούς λόγω ηλεκτροπληξίας, μηχανικής βλάβης ή άλλου κινδύνου.
אזהרה (HE)	מדריך זה זמין במספר שפות • אם ספק שירות של לקוח זקוק לשפה שאינה מסופקת ב-Customer Documentation Portal (פורטל באחריות הלקוח לספק את שירותי התרגום, (תיעוד ללקוחות • אסור לנסות להעניק שירות לציוד לפני עיון במדריך שירות זה והבנת התוכן שלו • פעולה שלא בהתאם לאזהרה זו עלולה לגרום לפציעה של ספק השירות, המפעיל או המטופל כתוצאה מהתחשמלות, סיכונים מכניים או סיכונים אחרים
FIGYELMEZTETÉS (HU)	Ez a kézikönyv több nyelven is rendelkezésre áll. • Ha az ügyfél szervizszolgáltatója azoktól eltérő nyelvű kézikönyvet szeretne, mint amelyeket az Ügyféldokumentációs portálon biztosítunk, akkor az ügyfél feladata, hogy gondoskodjon a megfelelő fordításról. • Ne próbálkozzon a berendezés szervizelésével anélkül, hogy a jelen szervizkézikönyvet elolvasta és megértette volna. • Ennek a figyelmeztetésnek a figyelmen kívül hagyása áramütés, mechanikai vagy egyéb veszélyek következtében a szervizszolgáltató, a kezelő vagy a páciens sérülését okozhatja.
AÐVÖRUN (IS)	Þessi handbók er fáanleg á mörgum tungumálum. • Ef þjónustuaðili viðskiptavinar þarfnast annars tungumáls en þessara tungumála er það á ábyrgð viðskiptavinarins að veita þýðingarþjónustu. • Ekki reyna að þjónusta búnaðinn fyrr en búið er að lesa og skilja þessa þjónustuhandbók. • Sé ekki farið eftir þessari viðvörun getur það valdið meiðslum á þjónustuaðila, notanda eða sjúklingi af völdum raflosts, vélrænna áverka eða annarar hættu.
PERINGATAN (IN)	Manual ini tersedia dalam beberapa bahasa. • Jika penyedia layanan pelanggan membutuhkan bahasa selain dari yang disediakan dalam Portal Dokumentasi Pelanggan, merupakan tanggung jawab pelanggan untuk menyediakan layanan penerjemahan. • Jangan berupaya untuk melakukan servis pada peralatan sebelum menyimak manual servis dan memahami isinya. • Jika peringatan ini tidak ditaati, ini dapat menyebabkan cedera penyedia layanan, operator, atau pasien, akibat sengatan listrik, bahaya mekanis, atau bahaya lainnya.
AVVERTENZA (IT)	Il presente manuale è disponibile in varie lingue. • Qualora un fornitore di servizi del cliente richieda una lingua diversa da quelle fornite nel Portale con la documentazione per il cliente, sarà responsabilità del cliente fornire il servizio di traduzione corrispondente. • Non tentare di riparare l'apparecchiatura se non si è prima consultato e compreso il presente manuale di servizio. • Il mancato rispetto di questa avvertenza può provocare lesioni per il fornitore dei servizi, per l'operatore o per il paziente, a causa di scosse elettriche, meccaniche o altri pericoli.

警告 (JA)	本マニュアルは多言語で提供されています。 • お客様のサービスプロバイダが、お客様ドキュメントポータルページで使用されていない言語を必要とする場合は、お客様の責任で翻訳サービスを提供してください。 • 機器の保守を行う場合は、必ず本サービスマニュアルを読み理解した上で行ってください。 • この警告に従わない場合は、サービスプロバイダー、オペレータ、または患者が、感電、機械的異常、またはその他の有害要因によって負傷する恐れがあります。
경고 (KO)	이 설명서는 여러 언어로 제공됩니다. • 고객의 서비스 제공자가 고객 문서 포털에 제공된 언어가 아닌 다른 언어를 요구하는 경우 번역 서비스를 제공하는 것은 고객의 책임입니다. • 이 서비스 설명서를 참고했고 이해하지 않는 한은 해당 장비를 수리하려고 시도하지 마십시오. • 이 경고를 지키지 않으면 감전, 기계상의 위험 또는 다른 위험으로부터 서비스 제공자, 사용자 또는 환자가 다칠 수 있습니다.
BRĪDINĀJUMS (LV)	Šī rokasgrāmata ir pieejama vairākās valodās. • Ja klientu apkalpošanas speciālistam ir nepieciešama cita valoda, kas nav piedāvāta klientu dokumentācijas portālā, klienta pienākums ir nodrošināt tulkošanas pakalpojumus. • Nemēģiniet veikt aprīkojuma apkopi, kamēr nav izlasīta un izprasta apkopes rokasgrāmata. • Ja šis brīdinājums netiek ņemts vērā, pakalpojumu sniedzējs, operators vai pacients var tikt savainots elektriskās strāvas trieciena, mehāniskas vai citas bīstamības rezultātā.
ĮSPĖJIMAS (LT)	Šis vadovas yra išverstas į keletą kalbų. • Jei kliento paslaugų teikėjui reikalingas vertimas į kitą kalbą, kurios nėra kliento dokumentacijos portale, už vertimo paslaugų suteikimą atsako klientas. • Neatlikite įrangos techninės priežiūros, kol neperžiūrėjote ir neišsiaiškinote šio techninės priežiūros vadovo. • Nepaisant šio įspėjimo dėl elektros smūgio, mechaninio arba kitokio pavojaus gali būti sužalotas paslaugų teikėjas, operatorius arba pacientas.
TWISSIJA (MT)	Dan il-manwal huwa disponibbli f'diversi lingwi. • Jekk fornitur tas-servizz ta' klijent ikun jeħtieġ lingwa għajr dawk ipprovduti fil-Portal tad-Dokumentazzjoni tal-Klijent, hija r-responsabbiltà tal-klijent li jipprovdi servizzi ta' traduzzjoni. • Tippruvax tagħmel service fuq it-tagħmir sakemm ma jkunx ġie kkonsultat u mifhum dan il-manwal għas-service. • Jekk wieħed jonqos milli josserva din it-twissija, dan jista' jwassal f'korriment lill-fornitur tas-servizz, lill-operatur jew lill-pazjent minn xokk elettriku, mekkaniku, jew perikli oħra.
ADVARSEL (NO)	Denne håndboken er tilgjengelig på flere språk. • Hvis en kundes tjenesteleverandør krever et annet språk enn de som finnes i dokumentasjonsportalen for kunder, er det kundens ansvar å levere en oversettelsestjeneste. • Ikke prøv å utføre service på utstyret med mindre man har konsultert og forstått service-håndboken. • Om denne advarselen ikke følges kan det føre til skade på tjenesteleverandør, operatør eller pasient fra elektrisk støt, mekanisk eller annen fare.
OSTRZEŻENIE (PL)	Niniejszy podręcznik jest dostępny w kilku językach. • Jeżeli serwisant klienta wymaga języka, który nie został udostępniony w portalu dokumentacji klienta, obowiązkiem klienta jest zapewnienie usług tłumaczeniowych. • Nie podejmować prób serwisowania urządzenia bez uprzedniego zapoznania się z niniejszym podręcznikiem serwisowym i zrozumienia jego treści. • Nieprzestrzeganie tego ostrzeżenia może spowodować obrażenia u serwisanta, operatora lub pacjenta, spowodowane porażeniem prądem, zagrożeniami mechanicznymi lub innymi.

ATENÇÃO (PT-BR)	Este manual está disponível em vários idiomas. • Se o prestador de serviços de um cliente necessitar de um idioma diferente dos fornecidos no Portal da Documentação do Cliente, o fornecimento dos serviços de tradução é de responsabilidade do cliente. • Não tente realizar manutenção do equipamento a menos que o manual de serviço tenha sido consultado e seja entendido. • O não cumprimento deste aviso resultará em lesões ao provedor de serviço, operador ou paciente de choque elétrico, mecânico ou outros riscos.
ATENÇÃO (PT-PT)	Este manual está disponível em vários idiomas. • Se o fornecedor de serviços de um cliente necessitar de um idioma diferente dos fornecidos no Portal de Documentação do Cliente, é da responsabilidade do cliente assegurar os serviços de tradução. • Não experimente reparar o equipamento sem primeiro consultar, e compreender, o presente manual de assistência. • O incumprimento deste aviso pode resultar em ferimentos para o técnico de reparação, o operador ou o paciente decorrentes de perigos de eletrocussão, mecânicos ou outros.
ATENŢIE (RO)	Acest manual este disponibil în mai multe limbi. • Dacă furnizorul de servicii al unui client necesită o limbă diferită de cele furnizate în Customer Documentation Portal (Portalul cu documentaţie pentru clienţi), este responsabilitatea clientului să furnizeze servicii de traducere. • Nu încercaţi să efectuaţi întreţinerea echipamentului decât dacă aţi consultat şi aţi înţeles acest manual de service. • Nerespectarea acestei avertizări poate duce la rănirea furnizorului de servicii, a operatorului sau a pacientului din cauza şocurilor electrice, mecanice sau a altor pericole.
ПРЕДУПРЕЖДЕНИЕ (RU)	Это руководство доступно на нескольких языках. • Если поставщику услуг заказчика требуется языковая версия, отличная от предложенных на портале документации для заказчиков, перевод руководства на необходимый язык осуществляется стороной заказчика. • Не начинайте эксплуатацию оборудования без предварительного надлежащего ознакомления с этим руководством. • Если вы проигнорируете это предупреждение, поставщик услуг, оператор или пациент могут получить механические травмы, травмы вследствие поражения электрическим током или другие увечья.
UPOZORENJE (SR)	Ovaj priručnik je dostupan na nekoliko jezika. • Ako korisnikov serviser zahteva neki drugi jezik osim onih koji su dostupni na portalu sa korisničkom dokumentacijom (Customer Documentation Portal), klijent mora da obezbedi prevod. • Nemojte pokušavati da servisirate opremu ako niste proučili i razumeli ovaj priručnik za servisiranje. • Nepoštovanje ovog upozorenja može da izazove povrede servisera, operatera ili pacijenta kao posledicu strujnog udara, mehaničkih ili drugih opasnosti.
UPOZORNENIE (SK)	Táto príručka je k dispozícii v niekoľkých jazykoch. • Ak poskytovateľ služieb daného zákazníka požaduje jazyk odlišný od jazykov dostupných na portáli s dokumentáciou pre zákazníkov, za prekladateľské služby zodpovedá zákazník. • Nepokúšajte sa vykonávať servis na zariadení, pokiaľ ste si neprečítali a nepochopili pokyny v servisnej príručke. • Nedodržanie tohto varovania môže byť príčinou úrazu poskytovateľa servisu, obsluhy alebo pacienta v dôsledku zásahu elektrickým prúdom alebo v dôsledku mechanických alebo iných nebezpečenstiev.

OPOZORILO (SL)	Ta priročnik je na voljo v več jezikih. • Če ponudnik storitev stranke potrebuje priročnik v jeziku, ki ni na voljo na portalu z dokumentacijo stranke, mora stranka zagotoviti prevod. • Opreme ne poskušajte servisirati, če niste prebrali in razumeli tega servisnega priročnika. • V primeru neupoštevanja tega opozorila lahko pride do telesnih poškodb ponudnika storitev, upravljavca ali pacienta zaradi električnega udara, mehanskih ali drugih nevarnosti.
ADVERTEN-CIA (ES)	Este manual se encuentra disponible en varios idiomas. • Si el proveedor de servicios de un cliente requiere un idioma distinto de los proporcionados en el Customer Documentation Portal (Portal de documentación para clientes), es responsabilidad del cliente proporcionar los servicios de traducción. • No intente realizar el mantenimiento del sistema a menos que haya consultado y comprendido este manual de servicio. • El incumplimiento de esta advertencia puede causar lesiones al suministrador de servicios, el operador o el paciente debido a descarga eléctrica, mecánica u otros riesgos.
VARNING (SV)	Denna manual är tillgänglig på flera språk. • Om en kunds tjänsteleverantör behöver ett annat språk än de som tillgängliggjorts på portalen för kunddokumentation är det kundens ansvar att erbjuda översättningstjänster. • Försök inte att reparera utrustningen utan att först rådfråga och förstå denna servicehandbok. • Om denna varning inte beaktas kan det leda till skada för tjänsteleverantör, operatör eller patient genom elektrisk stöt, mekaniska eller andra faror.
DİKKAT (TR)	Bu kılavuz birden fazla dilde sunulmaktadır. • Bir müşterinin servis sağlayıcısı Müşteri Belgeleri Portalı'nda sağlananlardan farklı bir dil talep ederse çeviri hizmeti sağlamak müşterinin sorumluluğundadır. • Bu servis kılavuzuna başvurmadan ve içeriğini anlamadan ekipman üzerinde servis işlemi yapmayı denemeyin. • Bu uyarıya uyulmaması; elektrik çarpması, mekanik tehlikeler veya başka tehlikelerden ötürü servis sağlayıcı, operatör veya hastanın yaralanmasıyla sonuçlanabilir.
ПОПЕРЕДЖЕННЯ (UK)	Цей посібник доступний кількома мовами. • Якщо постачальник послуг замовника використовує мову, яку не вказано на порталі з документацією для замовників, послуги з перекладу має забезпечити замовник. • Не починайте роботу з обладнанням без попереднього належного ознайомлення з посібником із використання. • Якщо ви проігноруєте це попередження, постачальник послуг, оператор або пацієнт можуть зазнати механічних травм, ураження електричним струмом або інших тілесних ушкоджень.
CẢNH BAO (VI)	Tài liệu hướng dẫn này có sẵn ở một số ngôn ngữ. • Nếu nhà cung cấp dịch vụ của khách hàng yêu cầu ngôn ngữ khác với ngôn ngữ được cung cấp trong Cổng Thông Tin Tài Liệu Khách Hàng, khách hàng có trách nhiệm cung cấp dịch vụ dịch thuật. • Không cố bảo dưỡng thiết bị trừ khi đã tham khảo và hiểu rõ hướng dẫn sử dụng này. • Việc không chú ý đến cảnh báo này có thể dẫn đến thương tích cho nhà cung cấp dịch vụ, người vận hành hoặc bệnh nhân do điện giật, nguy hiểm cơ học hoặc các mối nguy hiểm khác.

Local GE HealthCare Representative

To contact your local GE HealthCare representative

To contact your local GE HealthCare representative:

Please go to: https://www.gehealthcare.com/about/contact-us

China Service Agent Address

Address details to contact the Service Agent in China

China Service Agent Address

通用电气医疗系统贸易发展（上海）有限公司

中国(上海) 自由贸易试验区意威路

96 号 1 幢

邮编 200131

售后服务热线：800-810-8188

Manufacturer Address Buc

Manufacturer

Manufacturer and Manufacturing Site

GE MEDICAL SYSTEMS SCS

283 RUE DE LA MINIERE

78530 BUC FRANCE

Revision History

This table is intentionally left in English.

Date	Reference	Main reason for change
2016-07	5729303-1-8EN Rev 1	Initial Release for Certification
2017-06	5729303-1-8EN Rev 2	Release for IB
2017-11	5729303-1-8EN Rev 3	Updates for IB release and Mag Stand becoming optional
2018-04	5729303-1-8EN Rev 4	Release for Pristina Serena™ Biopsy option introduction
2019-03	5729303-1-8EN Rev 5	M3-4 release: Introduction of options Wireless footswitch, With/ Without UPS configuration, RSVP (For M3-4 or after)
2019-09	5729303-1-8EN Rev 6	SPRs: • HCSDM00566547 (link to contact GEHC representative up-dated) • HCSDM00564534 Update to address new revisions of EMC/IEC standards
2020-06	5729303-1-8EN Rev 7	Release for Reborn including SPRs: HCSDM00603164: PRE A002 – Third-Party Review Workstation Compatibility HCSDM00547285: Core accessories crate packing information HCSDM00607040: Link update "http://www.gehealth-care.com/helpcenter.html" HCSDM00614432: New sections for webhelp

Date	Reference	Main reason for change
2021-01	5729303-1-8EN Rev 8	INFINITY • HCSDM00628435: WebHelp Responsive Presentation replaces WebHelp Classic • HCSDM00629062: Adds information on How to Navigate and use WebHelp Responsive Service Manuals • HCSDM00636416: changes to Environmental Requirements • HCSDM00636930: Pristina Mobile PIM environmental requirement change • HCSDM00639503: Non-operational conditions updated • HCSDM00642130: Incorrect and repetition of Copyright Dates
2022-05	5729303-1-8EN Rev 9	HCSDM00652069: Room Layout Planning HCSDM00658573: removes wireless footswitch HCSDM00680954: ISO 20417 date format HCSDM00692857: character set compatibility HCSDM00696305: gantry dimensions HCSDM00696942: removes translated X-ray warning
2024-10	5729303-1-8EN Rev 10	HCSDM00760565: RFID added HCSDM00781831: QHD monitor added HCSDM00744734: SA3 requirement added HCSDM00778497: merged 3D PIM + section Layout Constraints for Positioning Gantry and Control Station updated HCSDM00778821: Circuit Breaker Requirement updated HCSDM00768935: Essential Performance updated HCSDM00788025: IEC information updated
2025-03	5729303-1-8EN Rev 11	HCSDM00797740: Lean Control Station & configuration added HCSDM00801356: Adjustable Control station added HCSDM00801355: RSVP Modification, Installation checklist, Drilling Template removal, LG Diagnostic Monitor, 15m harness
2025-10	5729303-1-8EN Rev 12	• HCSDM00819756: IT10 scope 3D IQ and workflow • HCSDM00819766: IT10 Service scope • HCSDM00821053: PIM updates • HCSDM00827296: PIM updates

Contents

Chapter 1 Safety, general information and requirements

1.1 IMPORTANT...X-RAY PROTECTION

⚠ CAUTION

If not properly used, x-ray equipment may cause injury. Accordingly, it is your obligation to confirm that the instructions herein contained are thoroughly read and understood by everyone who will use the equipment before you attempt to place this equipment in operation. GE HealthCare will be glad to assist and cooperate in placing this equipment in use.

Although this apparatus incorporates a high degree of certain protections against x-radiation other than the useful beam, no feasible design of equipment can provide complete protection from all potential injury. Nor can any feasible design force the operator to take adequate precautions to prevent the possibility of any persons carelessly exposing themselves or others to radiation.

It is important that anyone having anything to do with x-radiation be properly trained and fully knowledgeable about the recommendations of the National Council on Radiation Protection and Measurements as published in NCRP Reports available from NCRP Publications, 7910 Woodmont Avenue, Room 1016, Bethesda, Maryland 20814, and of the International Commission on Radiation Protection. It is your obligation and responsibility to take adequate steps to protect against injury.

The equipment is sold with the understanding that GE HealthCare, its agents, and representatives have no responsibility for injury or damage, which may result from improper use of the equipment. Various protective materials and devices are available. It is urged that such materials or devices be used in accordance with your site's clinical practice.

1.2 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.

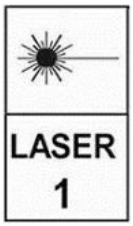
Use of Personal Protective Equipment

Throughout this Service Manual there are procedures that require you wear appropriate Personal Protective Equipment (PPE). When reading the procedures pay special attention to the risks quoted in the Danger, Warning, and Caution messages, and wear appropriate PPE (e.g. safety shoes, gloves, and goggles) according to the nature of the risk involved.

Meaning of Symbols

The following symbols may appear on parts of the Senographe Pristina system.

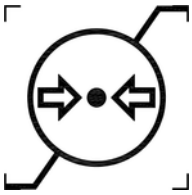
	Alternating current
	Protective Earth
	Functional Earth
	Dangerous voltage
	Type B equipment
	This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
	Name and address of manufacturer
	Date of manufacture
	Medical device catalogue number

	Medical device serial number
	Consult instructions for use -or- Attention, consult accompanying documents
	Caution
	Hot Surface
	Ionizing radiation Follow measures of protection to avoid exposure to ionizing radiation. For more information, see 1.1 IMPORTANT...X-RAY PROTECTION on page 13
	This symbol indicates the risk of entrapment between the system and a wall. Entrapment zones exist only in cases where the system is installed in a small room. Pay attention when performing tube head movements, and always ensure that there are no body parts that may become trapped by the movement.
	Laser label class 1 as per IEC 60825-1:2014

Meaning of Packaging Symbols

The following symbols may appear on the packaging for the parts of the Senographe Pristina system.

	This way up (indicates the correct upright position for the transportation package).
	Fragile, handle with care (indicates a medical device can be broken or damaged if not handled carefully)
	Recyclable packaging
	Corrugated board - recyclable packaging

	Keep dry (indicates a medical device that needs to be protected from moisture)
	Do not stack (indicates a medical device can be broken or damaged if it is stacked on other packaged items)
	Temperature limit (indicates the temperature limits to which the medical device can be safely exposed)
	Humidity limitations (indicates the range of humidity to which the medical device can be safely exposed)
	Atmospheric pressure limitation (indicates the range of atmospheric pressure to which the medical device can be safely exposed)
	Do not tip (indicates a medical device can be broken or damaged if it is tipped)
	Center of gravity

Unauthorized system modification hazards

DANGER

Any unauthorized modification of the system can result in personal or material damage and is strictly forbidden.

3D option

⚠ CAUTION

Senographe Pristina 3D uses a special high-precision anti-scatter grid in order to optimize the image quality when performing 2D and 3D exposures. When inserting or removing the Bucky, take care to protect it and the built-in anti-scatter grid from physical shocks that could damage it, or affect the grid positioning. A misaligned grid may cause image quality degradation. In case of doubt, perform the Texture Test to ensure that the image quality has not been affected. This test can also be performed monthly.

Classifications

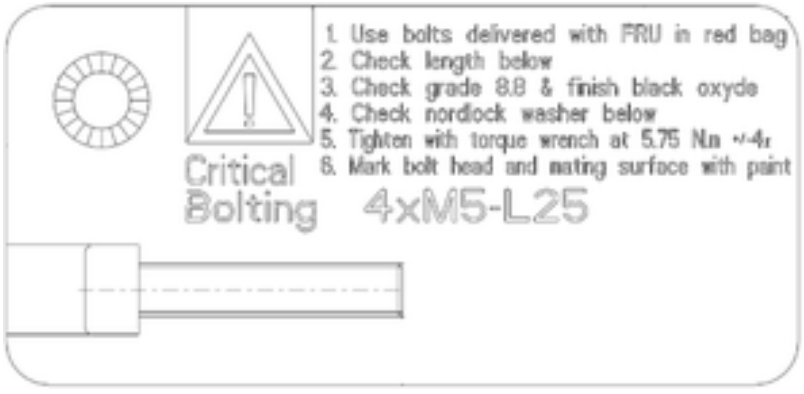
The Senographe Pristina system adheres to the following classifications:

Type of protection against electric shock	CLASS I
Degree of protection against electric shock	TYPE B applied parts
Protection against harmful ingress of water or particulate matter	IPX0 "Not protected", except footswitch: IPX5 "Protected against water jets"
Method of sterilization	No sterilization, cleaning only
Suitability for use in an Oxygen rich environment	Not suitable
Mode of operation	Continuous with intermittent loading

Critical Bolting Labeling

When applicable, to avoid risks associated with falling mass, various parts of the system are highlighted by a critical bolting label to indicate the following:

- that the bolts and washers provided in a red bag with the FRU **must** be used
- an illustration on a 1-to-1 scale is provided to assist you to verify that you use the correct bolts and washers
- the appropriate tightening torque to apply to the bolts
- when the appropriate torque is applied, the bolt head and mating surface must be marked with paint



Cable Ducting

⚠ CAUTION

To avoid creating trip hazards, run cable harnesses and cables through floor or wall ducting as appropriate.

Handling System Cables

⚠ WARNING

Pay special attention to the safety information contained in this document when manipulating the system cables.

System Cleaning

⚠ CAUTION

MEDICAL DEVICE

Ensure that the system is cleaned according to system hygiene procedures before performing any service procedures.

1.3 Applicability

This publication provides information for planning and carrying out the installation of a Senographe Pristina system and the options Senographe Pristina 3D and Pristina Serena. Planning and installation of other equipment mentioned, such as the SenoIris™ Workstation, is described in other publications.

To maintain basic safety and essential performance, follow recommendations detailed in that publication.

The pictures and the screen captures in this manual are intended for demonstration purposes only and may not always be fully identical to the actual design or user interface.

1.4 Trademark Information

- Senographe Pristina, Senographe Pristina 3D, Pristina Serena and SenoIris are trademarks or registered trademarks of GE HealthCare. GE is a trademark of General Electric Company used under trademark license.
- DICOM is a trademark or registered trademark of the National Electrical Manufacturers Association
- Microsoft and Windows are trademarks or registered trademarks of Microsoft Corporation
- Adobe and Acrobat are trademarks or registered trademarks of Adobe Systems Incorporated
- All other trademarks, service marks, logos, company names and product names are the property of their respective owners.

1.5 How to access electronic versions of Technical Publications on a dedicated GE HealthCare website

Each System is shipped with User Technical Publications. These Technical Publications are available for download on a dedicated GE HealthCare website.

Consult the Release Letter related to your system to obtain a list of all Technical Publications and Software versions applicable to the System.

Release Letters contain all the Part Numbers for Technical Publications related to your System.

Always use the version of the Release Letter marked "New" or "Current" on the website.

The Technical Publications Release Letter for this system depends on the Pristina configuration:

For Lean configuration: 5972309-899

For standard configuration:

- for pre-M3-5 software: 5776077-899
- from M3-5 software: 5845675-899

This Service Manual and all other Technical Publications related to this Medical Device are available on the Internet at:

https://www.gehealthcare.com/support/manuals.

1. **Search for and download the Release Letter.**
   a. Go to https://www.gehealthcare.com/support/manuals.
   b. Enter the Release Letter Part Number in the search field and click the button  .
      The Release Letter appears in the search results.
   c. Click **Download**.
      Depending on your browser, either the file is automatically downloaded or a pop-up enabling to download the file appears.
   d. In the **Copyright** window, click **ACCEPT**.
   e. Follow the instructions on the website to open or save the file.
   f. In the Release Letter, search for the required Technical Publication (For example, Service Manual).
   g. Copy the Part Number from the relevant cell. (For example, 5729303-1-8EN)
2. **Search for and download the Technical Publication.**
   a. Operate the same way as the Release Letter to search and to download the required Technical Publication.

1.6 Scenario PRE A001 - Pre-installation Procedures

1.6.1 CONTEXT

This scenario provides a check list for use in planning and carrying out pre-installation work.

1.6.2 STEERING GUIDE

#	Requirement	Reference	Who?	Done?
Pre-purchase site visit				
1	Visit the proposed site to check for any potential problems associated with installation.	1.7 Scenario PRE A002 - Pre-purchase Site Visit on page 20	GE HealthCare sales representative	
Purchase Senographe Pristina **system**				
2	Order Senographe Pristina system with all appropriate options from the Price Book.	N/A	GE HealthCare sales representative	
Installation planning visit				
3	Visit site to assess installation requirements and specify the preparatory work required before delivery and installation.	1.8 Scenario PRE A003 - Installation Planning Visit on page 21	GE HealthCare site planner	
Preparatory work				
4	Hospital or third-party contractors carry out preparatory work.	N/A	Hospital	
Pre-delivery check				
5	Visit site to confirm that the preparatory work is satisfactory and the site is ready for delivery and installation.	1.10 Scenario PRE A004 - Pre-Delivery Check on page 23	GE HealthCare site planner	
Delivery and storage				
6	System delivery to designated storage.	Section 1.12 Planning for storage on page 27	Delivery personnel and hospital	
Installation				
7	System installation.	Senographe Pristina Service Manual	GE HealthCare installation engineers	

1.7 Scenario PRE A002 - Pre-purchase Site Visit

1.7.1 CONTEXT

This scenario provides a check list for use in planning and carrying out a pre-purchase site visit.

1.7.2 STEERING GUIDE

#	Requirement	Reference	Who?	Done?
Altitude				
1	Check that product specifications are compatible with the altitude of the site.	Chapter 4 Environmental Requirements on page 73	Hospital engineer	
Operating conditions				
2	Check that operating the temperature and humidity requirements can be met.	Chapter 4 Environmental Requirements on page 73	Heating engineer	
Room layout				

#	Requirement	Reference	Who?	Done?
3	Check that an adequate room is available, with suitable floor and access.	Section 2.2 Room layout planning on page 37	Site planner	
Electrical supply				
4	Check availability of suitable supply.	Chapter 5 Electrical Requirements on page 75	Hospital engineer, GE HealthCare personnel	
Networking				
5	Check possibility of connection to hospital network.	Chapter 6 Communication Requirements on page 83	Hospital engineer, GE HealthCare HMS representative	
Insite connection				
6	Check availability and type of broadband connection.	Section 6.1 Insite connection on page 83	Hospital engineer	
Third Party Review Stations				
7	Check compatibility with customer third party review workstations.	6.6.1 Job Card PRE A002 - Third-Party Review Workstation Compatibility Checks on page 93	Hospital engineer, GE HealthCare HMS representative	
RIS compatibility				
8	Check RIS for character set compatibility.	Section 6.2 Networking connections and broadband access on page 83	Hospital engineer	

1.8 Scenario PRE A003 - Installation Planning Visit

1.8.1 CONTEXT

This scenario provides a check list for use in planning and carrying out an installation planning visit.

1.8.2 STEERING GUIDE

#	Action	Reference	Who?	Done?
Storage conditions				
1	Check the dimensions and environment of the pre-installation storage room.	Section 1.12 Planning for storage on page 27	Hospital engineer	
Room layout				
2	Plan and specify layout with adequate spacing between the Gantry and control station components.	Section 2.2 Room layout planning on page 37	Site planner	
Operating conditions				
3	Check that operating the temperature and humidity requirements will be met.	Chapter 4 Environmental Requirements on page 73	Heating engineer	
Radiation protection (wall, ceiling, floor, doors)				
4	Consult the Radiation Physicist for advice on radiation protection.	Section 3.1 Planning for radiation protection on page 62	Radiation protection specialist	

#	Action	Reference	Who?	Done?
Structural requirements				
5	Check access door width and height.	Section 1.12.2 Packing Information on page 27	Hospital engineer	
6	Check floor requirements (strength, flatness).	Section 2.3.3 Floor Requirements on page 60	Flooring specialist	
Room Layout Planing				
7	Make the underfloor plan localizing the water and electrical ducts.		Hospital engineer	
8	Plan the location of the main components.	Section 2.2.1 Dimensions and Masses on page 37	Hospital engineer + GE HealthCare Site planner	
9	Specify the installation of anchorage bolts. In seismic areas, anchors must be provided for the various equipment (additional radiation screen, etc.).	Section 2.2.3 Anchoring to the Floor on page 53	Flooring specialist	
10	Plan cable runs; specify ducting, etc.	Section 2.2.4 Interconnecting Cables Path and Length on page 57	Site planner	
Electrical requirements				
11	Check that room power supply requirements will be met.	Chapter 5 Electrical Requirements on page 75	Electrician	
12	Check the line voltage specification.	Section 5.3 Line Voltage Specifications on page 79	Electrician	
13	Check the line frequency specification.	Section 5.4 Line Frequency Specifications on page 80	Electrician	
14	Check the kVA load characteristics.	Section 5.5 kVA Load Characteristics on page 80	Electrician	
15	Check the line impedance.	Section 5.6 Line Impedance on page 80	Electrician	
16	Check the main circuit breaker characteristics.	Section 5.8 Circuit Breaker and Circuit Isolator on page 80	Electrician	
Door protection switches				
17	Specify the requirement for provision and connection of the door X-ray protection switches.	Section 5.9 Door lights and safety switch on page 81	Electrician	
Insite connection				
18	Specify requirements for Insite broadband connection.	Section 6.1 Insite connection on page 83	Hospital Network Administrator	
Networking				
19	Specify network connections and cable runs.	Section 2.2 Room layout planning on page 37	Site planner	
20	Allocate IP, Gateway, and Subnet mask addresses.	Section 6.2 Networking connections and broadband access on page 83	Hospital Network Administrator	
Lighting				
21	Specify requirements for dimmer switches, drapes, etc.	Section 4.5 Lighting on page 74	Lighting specialist	

1.9 Shipping and Storage Environmental Requirements (in packaging)

The shipping and storage environment must adhere to the parameters listed below.

Relative humidity (non-condensing)		Temperature		Atmospheric pressure*	
Min.	Max.	Min	Max.	Min	Max
10%	95%	-40°C (-40°F)	70°C (158°F)	500hPa	1060hPa

***** During shipping a pressurized environment must be used to maintain the atmospheric pressure limits.

- The system includes a detector assembly in its casing, which is sensitive to changes in temperature and humidity.
- The specified storage requirements assume that all the equipment remains in its packaging, including the protection for the detector.

⚠ WARNING

During transportation and storage, the different system components must remain in their original transportation packaging in order for the values in the table above to apply.

1.10 Scenario PRE A004 - Pre-Delivery Check

1.10.1 CONTEXT

This scenario provides a check list for use in planning and carrying out a pre-delivery check visit.

For more information, see 1.8 Scenario PRE A003 - Installation Planning Visit on page 21.

1.10.2 STEERING GUIDE

#	Requirement	Who?	Done?
Storage conditions			
1	Check preparation of pre-installation storage room.	Hospital engineer	
Room preparation			
2	Check the proposed layout and preparations for cable runs.	Site planner	
3	Check floor and anchorage preparation.	Flooring specialist	
4	Check access requirements.	Hospital engineer	
Radiation protection (wall, ceiling, floor, doors)			
5	Check preparation for radiation protection (wall, ceiling, doors).	Radiation protection specialist	
Insite connection			
6	Check preparations for Insite broadband connection.	Hospital Network Administrator	
Lighting			
7	Check room lighting conditions.	Lighting specialist	

1.11 Job Card PRE A001 - Checking for Damage

The Senographe Pristina system is inspected for proper operation and appearance before shipment. However, it is necessary to inspect the product after the shipment is received.

The Senographe Pristina system is supplied in different pallets as summarized in 1.12.2 Packing Information on page 27.

Pallets for overseas shipment are protected by a wood and cardboard cover with shock and tilt indicators. Pallets for road shipment do not have this cover.

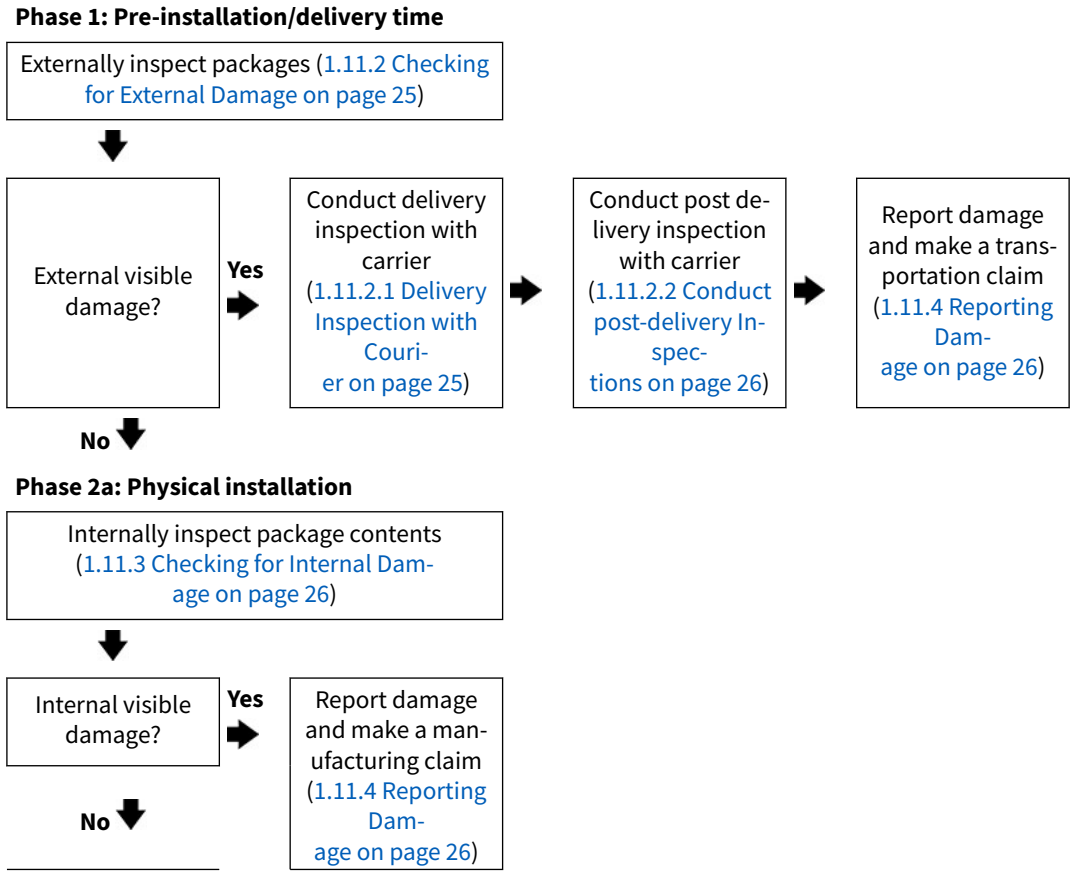
1.11.1 POSSIBLE TYPES OF DAMAGE

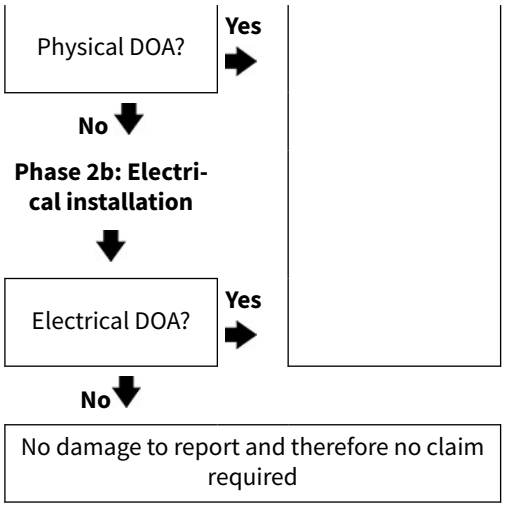
Two types of possible damage can exist:

- **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 following steps summarizes the general process to determine:

- whether any of the Senographe Pristina 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 physical and electrical installation of the Senographe Pristina system. Any damage found during this phase is considered as either physical DOA or electrical DOA, which is the responsibility of GE HealthCare manufacturing.

1.11.2 Checking for External Damage

1.11.2.1 Delivery Inspection with Courier

When the shipment of the Senographe Pristina system arrives, a GE HealthCare representative or a hospital receiving agent must proceed as follows for each of the three pallets.

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 pallets 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 1.11.4 Reporting Damage on page 26.

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.

1.11.2.2 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 inspection, report the details of the damage to GE HealthCare and the carrier according to 1.11.4 Reporting Damage on page 26.

1.11.3 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 1.11.4 Reporting Damage on page 26.

1.11.4 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 is 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.

1.12 Planning for storage

1.12.1 Temporary Storage in the Hospital

⚠ WARNING

Usage, storage and transport outside the defined environmental conditions, may compromise the safety of the system. If the delay between delivery and installation exceeds 2 days, ensure that a suitable storage room is available to store the equipment in its crates.

Refer to section Environmental requirements for storage environment conditions.

1.12.2 Packing Information

The table below lists the main dimensions and masses of shipping crates.

Table 1-1 Shipping dimensions and masses

Item	Dimensions in mm *(inches)*			Mass in kg *(lbs)*
	Depth	Width	Height	
Crate 1	1530 *(60.2)*	825 *(32.5)*	2210 *(87)*	525 *(1157.43)*
Crate 1 includes the Gantry, its packaging, the ramp to remove it from its packaging and the Gantry column front covers.				
Crate 2 (x 2)	720 *(28.3)*	580 *(22.8)*	640 *(25.2)*	120 *(264.55)*
Crate 2 (two crates) include the Core system accessories, Digital Detector, Monitor Arm, Control Station Back and Side Covers, and their packaging. For the list of Core system accessories, see 2.1.3 Accessories on page 35.				
Crate **3a**, **3b1**, **3b2** or **3c** delivered depending on the control station: • Crate **3a** for Lean Control Station • Crate **3b1** for Fixed Control Station before Q2 2025 • Crate **3b2** for Fixed Control Station packaged from Q2 2025 • Crate **3c** for Adjustable Control Station				
Crate 3a	584 *(23.0)*	1040 *(40.9)*	1372 *(54.0)*	108.7 *(239.6)*
Crate 3a includes the Lean Control Station and its packaging.				
Crate 3b1	695 *(27.4)*	1074 *(42.3)*	1510 *(59.4)*	129.2 *(284.8)*
Crate 3b1 includes the Control Station packaged before Q2 2025, its packaging and the ramp to remove it from its packaging.				
Crate 3b2	674 *(26.5)*	1059 *(41.7)*	1362 *(53.6)*	129 *(284.4)*
Crate 3b2 includes the Fixed Control Station packaged from Q2 2025 and its packaging.				

Table 1-1 Shipping dimensions and masses (Table continued)

Item	Dimensions in mm *(inches)*			Mass in kg *(lbs)*
	Depth	Width	Height	
Crate 3c	700 *(27.6)*	1070 *(42.1)*	1400 *(55.1)*	140 *(308.6)*
Crate 3c includes the Adjustable Control Station and its packaging.				
Crate 4	1010 *(39.7)*	670 *(26.4)*	160 *(6.3)*	8 *(17.6)*
Crate 4 includes the Front cover of the Control Station and its packaging.				
Crates 5 and 6	Vary	Vary	Vary	Vary
One or two accessories crates (i.e. crate 5 and 6) may exist, depending on the optional accessories ordered by the customer. These crates include the Keyboard, Radiation Screen (if ordered), and options chosen by the customer and their packaging. For the list of optional accessories, see 2.1.3 Accessories on page 35. ***Note:*** *The dimensions and mass of these crates can vary according to the options chosen by the customer. The values quoted above are maximum storage requirements assuming that all options have been ordered.*				

Table 1-2 Shipping dimensions and masses of Biopsy option

Item	Dimensions in mm *(inches)*			Mass in kg *(lbs)*
	Depth	Width	Height	
Biopsy Positioner box	1010 *(39.77)*	760 *(29.93)*	738 *(29.06)*	25 *(55.11)*
Accessory Boxes	400 *(15.75)*	600 *(23.63)*	400 *(15.75)*	4.5 *(9.92)*
	400 *(15.75)*	600 *(23.63)*	400 *(15.75)*	9 *(19.84)*
	500 *(19.69)*	600 *(23.63)*	400 *(15.75)*	6.5 *(14.33)*

1.12.3 Constraints for Moving the Equipment Into the Room

The Gantry is delivered with its front column covers off, and only the rear column covers on. The minimum dimension of the entry door to move in the (un-crated) Gantry on its transport tool are:

- door opening at least 700 mm (27.6 inches) wide.
- without Gantry column front covers: a total height of 1958 mm (i.e. height of 1928 mm + 30 mm space between the transport tool and the floor).
- without Gantry rear column covers: a total height of 1908 mm (i.e. height of 1878 mm + 30 mm space between the transport tool and the floor.
- In case you need to move the gantry with Gantry column front covers: a total height of 2002 mm (i.e. height of 1972 mm + 30 mm space between the transport tool and the floor).

NOTE
If the hospital doors are less than 1958 mm (77.09 inches) high, prepare time to remove the Gantry column rear covers during the delivery of the Senographe Pristina. You will need to remove the Gantry column rear covers so that you can move the Gantry under the doors.

NOTE
The door height restriction values above assume that there is a space of 30 mm between the base of the Gantry and the floor when the Gantry is mounted on the transport tool. The transport tool is adjustable, and this overhead space of 30 mm can be reduced if there are no objects on the floor (such a plinths) inside the opening of the door.

NOTE

In cases where a Senographe Pristina is not installed on the ground floor of a building, you must consider the size of the hospital elevators. The minimum depth of hospital elevators must be slightly larger than 1312 mm (51.65 inches) to be able to move the Gantry.

Chapter 2 Equipment Requirement

2.1 System Components

Senographe Pristina Acquisition System:

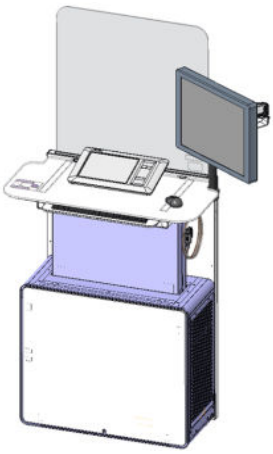
Fixed control station

Lean control station

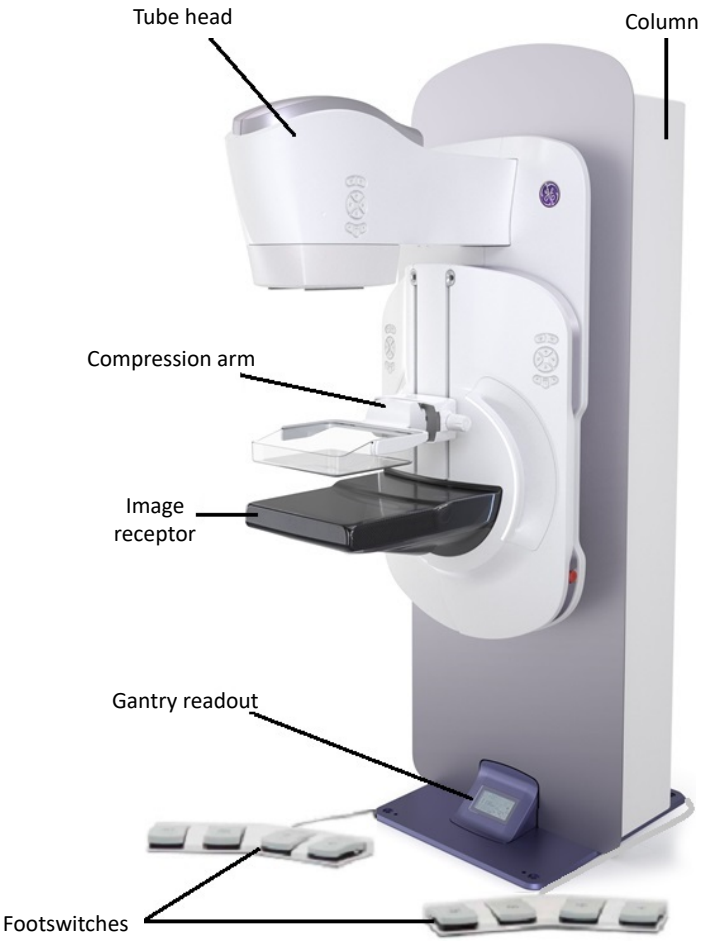
OR

Adjustable control station

OR



Gantry



Definitions:

Gantry = Arm + Column + Image Receptor

Arm = Tube Head + Compression Arm

Image Receptor = Digital Detector + Bucky (or Mag Stand)

Review options:

SenoIris Review Workstation

2.1.1 System Features

Senographe Pristina is the latest Digital Mammography System from GE HealthCare. It has been designed to perform Screening examinations as well as Diagnostic Views (including Spot compression, Magnified and/or Coned views). It takes advantage of digital technology, including on-screen image display, Networking, Filming, and Archiving.

The Senographe Pristina system is equipped with a double track X-ray tube (molybdenum/rhodium) and a Digital Detector. The Digital Detector is a flat panel of amorphous silicon on which cesium iodide is deposited to maximize detection of X-rays. The X-ray Console controls the X-ray exposure parameters and controls the power to all parts of the Senographe Pristina system. The Arm control keypads control the positioning operations of the Tube Head.

- It offers the capability to acquire images in near real time, process images, and manipulate images with the ability to vary brightness and contrast levels.
- It also offers high examination productivity as compared with screen film, and introduces new applications such as Networking and Archiving.
- It is built on a new platform, designed for superior Image Quality. The Rhodium spectrum of the X-ray tube is adapted to Digital Imaging.

The Control Station includes an Acquisition Workstation (AWS) with monitor, keyboard, and mouse, computer, electronics, and an Uninterruptible Power Supply (UPS, optional). The AWS is used for image acquisition, processing, and display. The AWS can also be used for database management, and can send images to archive, review, or filming.

- The Acquisition Workstation displays acquired images in the room, allowing immediate evaluation of breast positioning and possible motion blur, or adjustment of brightness and contrast.
  Archiving, Networking, and Filming are all possible from the Acquisition Workstation, which can produce any number of equally high quality film copies as needed.

  A hardcopy laser-film printer can be used for image interpretation. Printer window width and window level are set automatically, based on the image content. Images are displayed per film 1 on 1.

  The Acquisition Workstation can also display and print SCPT (Secondary Capture) images (if they have the modality MG). This allows the Operator to view images which have been reviewed and annotated on a review workstation (such as the SenoIris Review Workstation).

Several options are available for use with the Senographe Pristina system. These options include a SenoIris Review Workstation, a mass archiving system, a laser camera, and networking capabilities.

- The optional SenoIris Review Workstation is a stand-alone workstation, with its own dedicated computer and image database. It is connected to the Acquisition Workstation (AWS) by a high speed link. It supports image display and manipulation.
  This powerful computer is equipped with three dedicated, two high resolution monochrome monitors and a dedicated keypad. Networking is possible from this workstation, as well as printing and receiving images from an archive device.

2.1.2 System Component Description

2.1.2.1 Overview

The following pages describe the main system components:

1. The Gantry is equipped with a Digital Detector for efficient creation of X-ray images. The X-ray Console controls Gantry operations, X-ray exposures, and power to all parts of the Senographe Pristina system.

   The X-ray Console is always mounted on the Control Station.

2. The Control Station includes the Acquisition Workstation (AWS) Cabinet, an LCD monitor, a keyboard and mouse, and a radiation screen. The AWS Cabinet houses the workstation electronics and potentially a UPS (Uninterruptible Power Supply, see 2.1.2.5.2 UPS (optional) on page 35).

3. Accessories (standard and optional).

Mandatory marking labels such as CE marking, UL Listing labels, and FDA labels are located on the bottom left-hand side and rear of the Gantry.

All of the characteristics of the Senographe Pristina system including range(s), accuracy, and precision of displayed values can be found in the *Specifications* chapter of the *Operator Manual*.

2.1.2.2 X-ray System

The Senographe Pristina is equipped with a double track X-ray tube (molybdenum/rhodium) and a Digital Detector. Mammographic examinations can be made with standing, sitting, or recumbent patients; both contact and magnification views are available (if the optional Mag Stands are present).

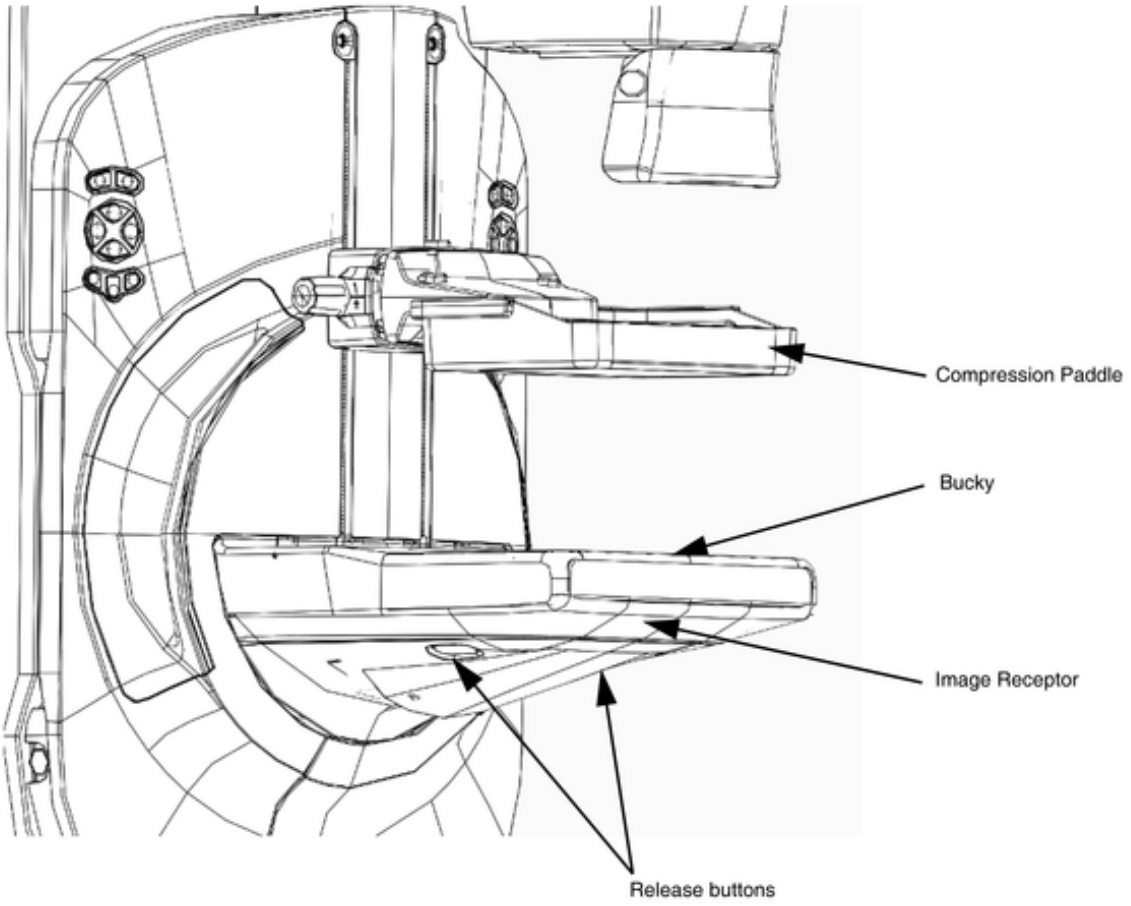
Images are acquired by direct digitization; they are displayed immediately on the LCD monitor and are stored for later diagnostic review. They can be processed and/or filmed.

AOP (Automatic Optimization of Parameters) and manual setting modes are provided for control of the X-ray parameters; the system provides auto-collimation.

2.1.2.3 Digital Detector and Image Receptor

The Digital Detector is built into the Image Receptor, shown below. It is a flat panel of amorphous silicon on which cesium iodide is deposited to maximize detection of X-Rays and transmission of light photons. The high definition digital images produced are sent to the Acquisition Workstation for visualization and processing.

A removable grid (Bucky) plugs into the Arm above the Image Receptor. For magnification views, optional Mag Stands providing magnifications of 1.5 or 1.8 are used instead of the Bucky. The presence of the Bucky or the optional Mag Stand is recognized automatically.



The removable Bucky automatically locks itself into position when it is positioned in close proximity to the back of the Digital Detector. The automatic release of the Bucky is achieved by simultaneously pressing both of the two release buttons located underneath the Digital Detector.

The sliding compression paddle can be set to centered, left or right, corresponding to the three different FOV positions (centered, left, and right) that are available.

2.1.2.4 Bad Pixels or Bad ROI Test Fails

⚠ WARNING

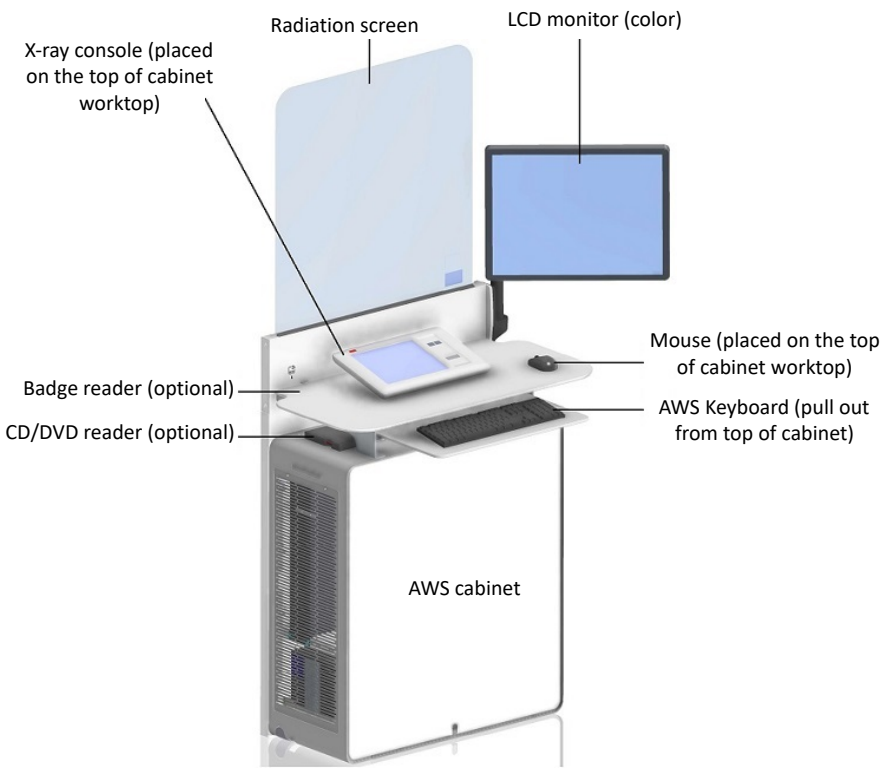
To avoid the risk of loss of information in clinical images, the detector must have fewer bad pixels than the specification allows. One fail in the defect category means that the detector has more bad pixels than the GE Bad Pixel specification allows. The root cause of the failure must be found before any clinical use of the system.

For more information, see Job Cards CHK A010 to A013.

2.1.2.5 Control Station

Three Control Stations are available depending on system configuration:

Fixed control station



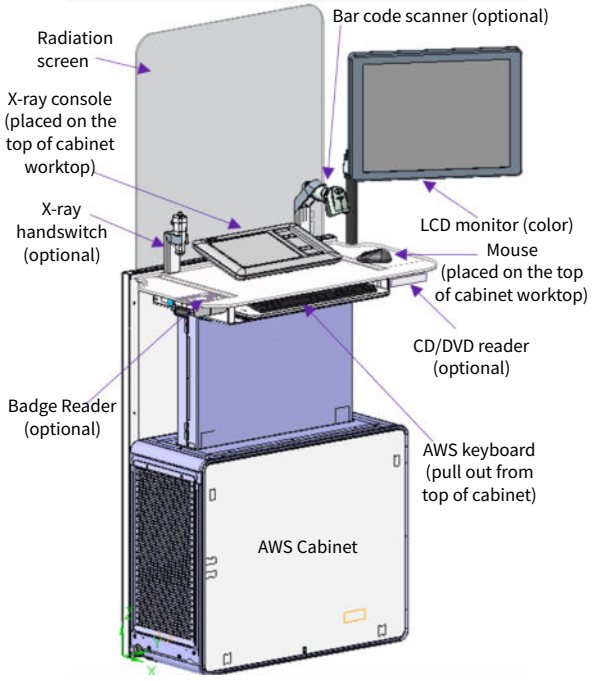
Options (not shown):

Bar code scanner

X-ray handswitch

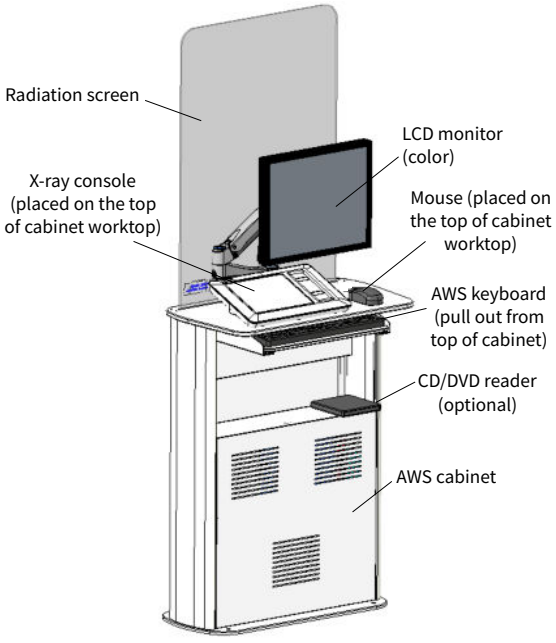
X-ray footswitch

Adjustable control station



Option (not shown): X-ray footswitch

Lean control station



No additional option

2.1.2.5.1 Overview

The Control Station is used for image acquisition and display, database management, and to send images to archive, review or filming.

It includes the Acquisition Workstation (AWS) Cabinet, which accommodates:

- the workstation electronics (acquisition computer).
- an optional CD-R unit for interchange purposes.

The AWS Cabinet supports the LCD monitor used for control and display, a pointing device (mouse), and a radiation screen.

2.1.2.5.2 UPS (optional)

To assure system safety in the event of disturbances in the mains power supply, some Senographe Pristina systems incorporate a UPS, housed in the Control Station cabinet.

During power fluctuations or brief interruptions, the UPS assures a continuous supply to the workstation and the acquisition system. The UPS prevents mains disturbances from being transmitted to the system. When a power failure occurs the UPS continues to supply power to the workstation until it has shut down safely.

After M3-4, the UPS does not communicate with the system for graceful shutdown That will be handled by Prisitina system software; it only prevents from power fluctuations.

From Pristina 8.4, no UPS is available as an option with Senographe Pristina.

2.1.2.5.3 External Connections

One CAT 5 Ethernet cable connection to the local hospital network is connected at the rear of the cabinet for external communications (such as Insite connection).

2.1.2.6 3D Option Components

For 3D option to be possible, an existing Senographe Pristina system with an AXIS Computer must be upgraded with the following components:

- Reconstruction Computer housed in the Control Station next to the AXIS Computer or Pristina 2D/3D PC.
- A set of cables necessary to connect the Reconstruction Computer to ground and power, and a cable to connect the AXIS Computer to the Reconstruction Computer. (Not applicable to Pristina 2D/3D PC).
- Reconstruction Software (OS and application) to be installed on the Reconstruction Computer
- Universal face shield to replace the Standard face shield.

In case of a Senographe Pristina system equipped with a Pristina 2D/3D PC, you will need the Universal face shield to replace the Standard face shield.

Refer to Senographe Pristina 3D or Senographe Pristina Operator Manual to adjust 3D user parameters.

2.1.3 Accessories

2.1.3.1 Senographe Pristina Accessories

⚠ CAUTION

Only Senographe Pristina recommended accessories must be used with this equipment. Failure to heed this warning can cause unexpected results and possible data loss.

The Senographe Pristina is delivered with the following standard accessories:

Standard configuration

- 24x29 Standard Paddle OR 24x29 Flexible Paddle
- Standard or Universal Face Shield
- Calibration Plates Suitcase containing six 10 mm acrylic plates, one 5 mm acyclic plate and a Flat Field Phantom (385 mm x 305 mm x 25 mm)
- IQST Phantom with Adaptor for Mag Stand
- Dosimeter Support

The following accessories are optional:

- 1.5 Mag Stand
- 1.8 Mag Stand
- Sliding 19x23 Standard Paddle
- Sliding 19x23 Flexible Paddle
- Sliding Round Spot Paddle
- Sliding Square Spot Paddle
- Sliding 10x23 Implant Paddle
- Pre-surgical localization sliding 19x23 paddle
- Pre-surgical localization sliding 19x23 perforated paddle
- Small pre-surgical localization sliding paddle (from Pristina 9)
- ACR Breast Phantom - RMI 156
- Independent Radiation Shield

Optional accessories available for the Gantry include:

- Patient self-compression solution (software license and remote control)
- Mechanical cross-hair
- Laser cross-hair (from Pristina 9)
- Non-mirrorred footswitch (from Pristina 9)
- Hydraulic examination chair

Optional accessories available for the Control Station include:

- Adjustable control station
- Bar code scanner
- X-ray handswitch
- X-ray footswitch
- external CD/DVD reader (from Pristina 8.4)
- RFID badge reader (from Pristina 9): a list of compatible RFID badges can be found in Senographe Pristina Operator Manual.

Lean configuration

- 24x29 Standard Paddle
- Sliding 19x23 Standard Paddle
- Standard or Universal Face Shield
- Calibration Plates Suitcase containing six 10 mm acrylic plates, one 5 mm acyclic plate and a Flat Field Phantom (385 mm x 305 mm x 25 mm)
- IQST Phantom with Adaptor for Mag Stand
- Dosimeter Support

The following accessories are optional:

- 1.5 Mag Stand
- 1.8 Mag Stand
- 24x29 Flexible Paddle
- Sliding 19x23 Flexible Paddle
- Sliding Round Spot Paddle
- Sliding Square Spot Paddle
- Sliding 10x23 Implant Paddle
- Pre-surgical localization sliding 19x23 paddle

Optional accessories available for the Gantry include:

- Mechanical cross-hair
- Hydraulic examination chair

Optional accessories available for the Control Station include:

- external CD/DVD reader

NOTE

Due to regulatory or legal restrictions, not all options are available in all countries or locations. To find out if a particular option or accessory is available in your country, contact your local GE HealthCare Sales representative.

2.1.3.2 System Options

System options available include:

- **Review Workstation.** SenoIris Review Workstation.
- **Mass Archiving System.** When installed and connected to the Senographe Pristina system, acquired images can be sent to the mass archiving device for permanent storage, either

automatically or on request. A list of all patients ever imaged on the Senographe Pristina system can be kept on the mass archiving device, making future retrievals fast and easy.

- **Laser Camera.** To provide “hard copies” of images, the Senographe Pristina system can be connected to a high resolution DICOM MG compatible laser camera for film printing.

⚠ WARNING

To avoid the risk of mis-diagnosis due to poor image quality, only images produced by GE Healthcare recommended laser cameras should be used for final interpretation of examinations. For a list of compatible printers, see the latest product data sheets for this system, obtainable from local GE Healthcare sales representatives.

- **Networking.** The Senographe Pristina is DICOM compliant, allowing it to be connected in a network with other compliant devices for the exchange of images. Networking allows transmission of images acquired with the Senographe Pristina system to other DICOM-compatible review workstations, using the “Network Push” function of the Application Desktop. In some cases, detailed evaluations are needed for the implementation of customized connections. DICOM conformance statements can be accessed at *www.gehealthcare.com/products/interoperability*.
  IHE integration statements can be accessed at *www.gehealthcare.com/products/interoperability*

See your GE HealthCare Representative for more information on accessories and options.

2.2 Room layout planning

2.2.1 Dimensions and Masses

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

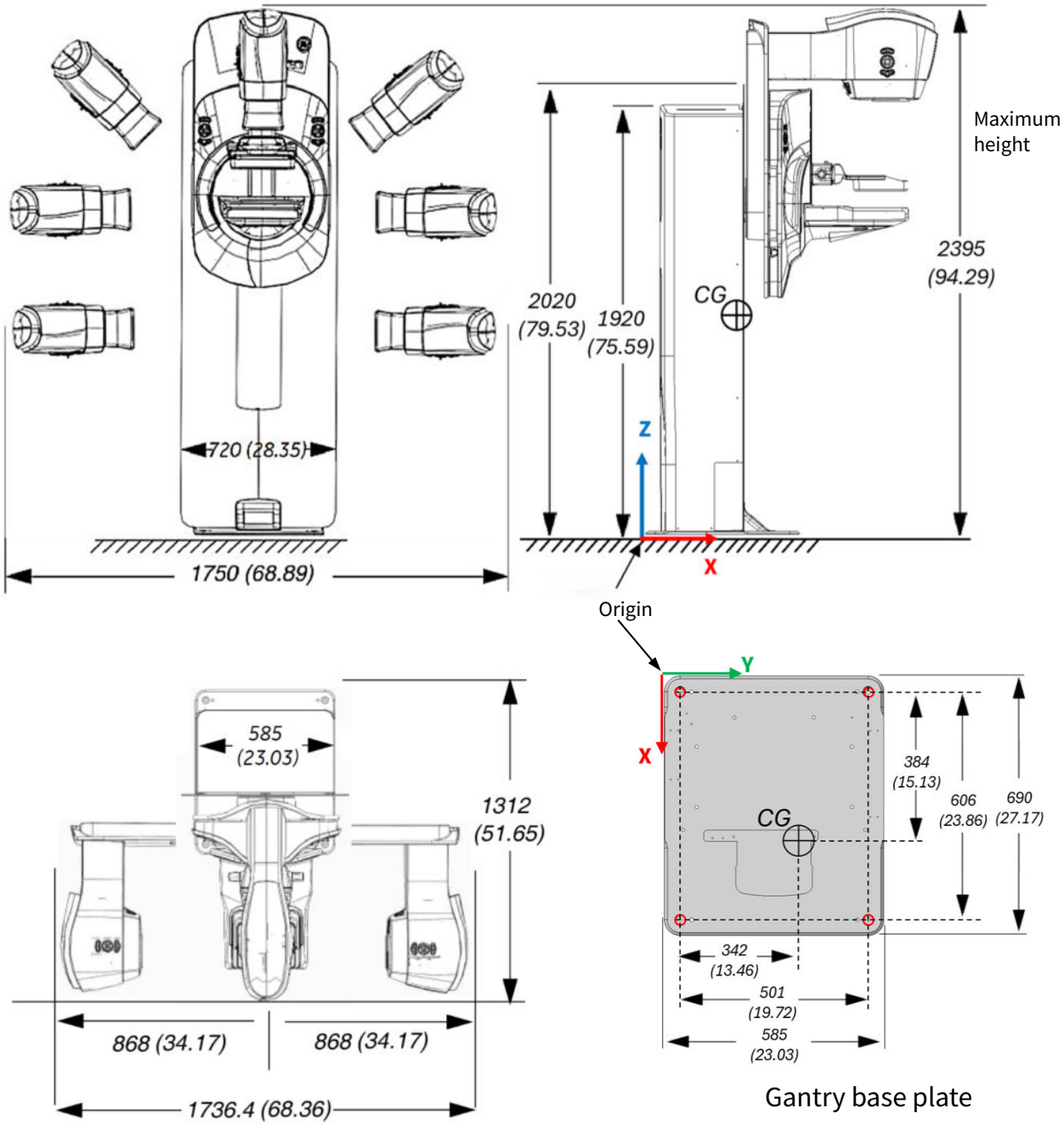
Table 2-1 System component dimensions and masses.

Component	Depth mm *(inches)*	Width mm *(inches)*	Height mm *(inches)*	Mass kg *(lbs)*
1 MP 19" color monitor (Eizo RadiForce MX191)	61.5 *(2.42)*	405 *(15.94)*	334 *(13.15)*	5.2 *(11.46)*
3 MP 21.2" color monitor (option)	97 *(3.82)*	500 *(19.69)*	376 *(14.80)*	7.4 *(16.31)*
3 MP 21"3 RX370 color monitor	78 *(3.07)*	463 *(18.23)*	341.3 *(13.425)*	5.2 *(11.46)*
QHD monitor	41.9 *(1.65)*	540.1 *(21.26)*	321.1 *(12.64)*	3.4 *(7.50)*
3 MP 21"3 21HQ513D IPS monitor for Lean Control Station	72.4 *(2.85)*	484 *(19.05)*	343.1 *(13.51)*	5.0 *(11.0)*
X-ray Console	240 *(9.45)*	390 *(15.35)*	90 *(3.54)*	1.6 *(3.53)*
Radiation Shield for fixed or adjustable Control Station	6 *(0.24)*	700 *(27.56)*	1150 *(45.28)*	16.5 *(36.38)*
Radiation Shield for Lean Control Station	6 *(0.24)*	600 *(23.62)*	950 *(37.40)*	11.7 *(24.25)*

For Gantry and Control Station, refer to illustrations Figure 2-1 Gantry dimensions - mm (inches) of systems manufactured before 2024-09 on page 38 or Figure 2-2 Gantry dimensions - mm (inches) of systems manufactured after 2024-08 on page 39, and Figure 2-3 Fixed Control

Station dimensions - mm (inches) on page 40 or Figure 2-5 Lean Control Station dimensions - mm on page 42.

Figure 2-1 Gantry dimensions - mm (inches) of systems manufactured before 2024-09



Center of Gravity (CG):

X = 426 *(16.8)*

Y_{max} = 384 *(15.1)*

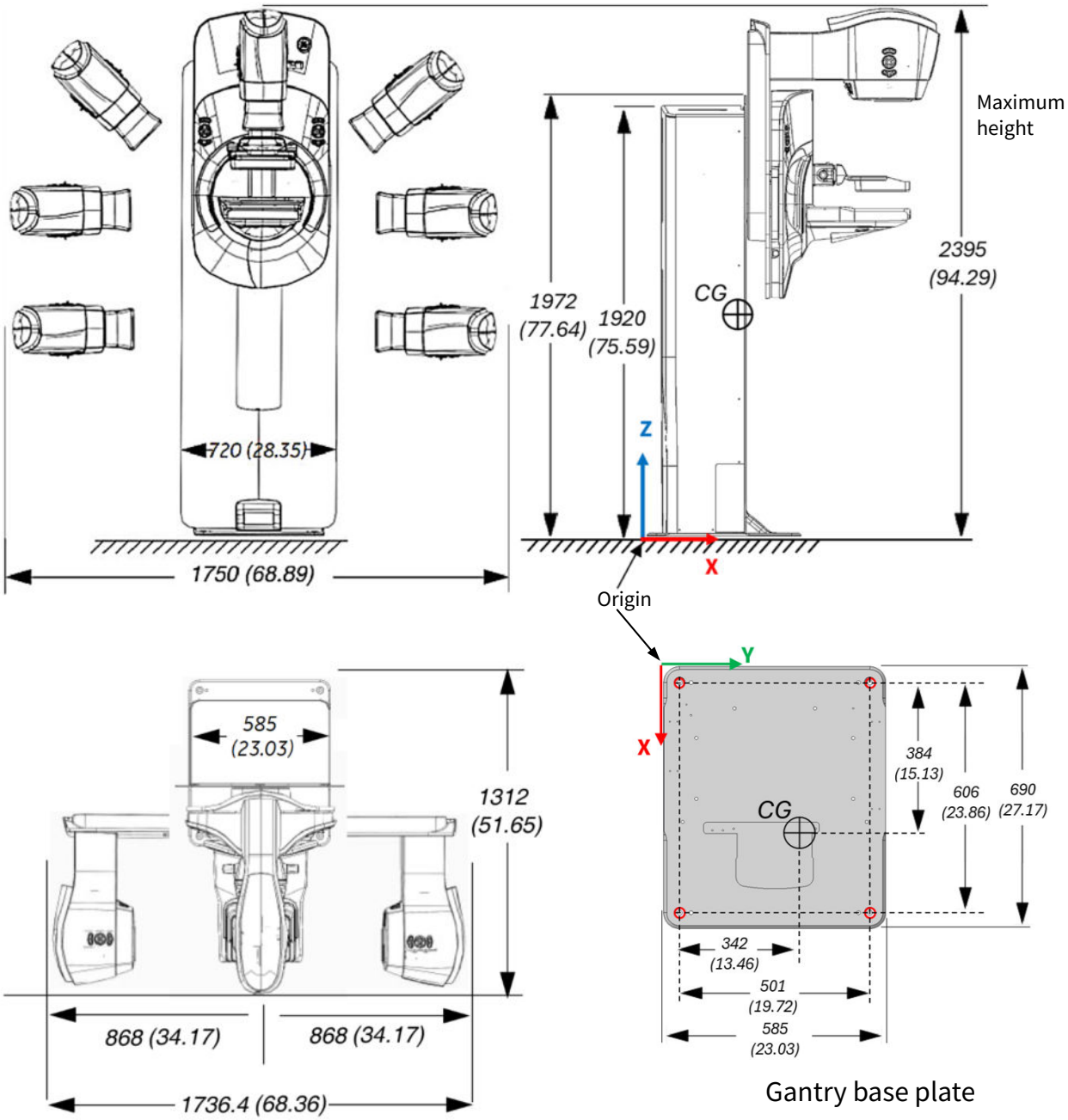
Z_{max} = 1001 *(39.4)*

All measurements shown as: mm *(inches)*

Mass of Gantry: Refer to 2.3.3 Floor Requirements on page 60.

OR

Figure 2-2 Gantry dimensions - mm (inches) of systems manufactured after 2024-08



Center of Gravity (CG):

X = 426 *(16.8)*

Y_{max} = 384 *(15.1)*

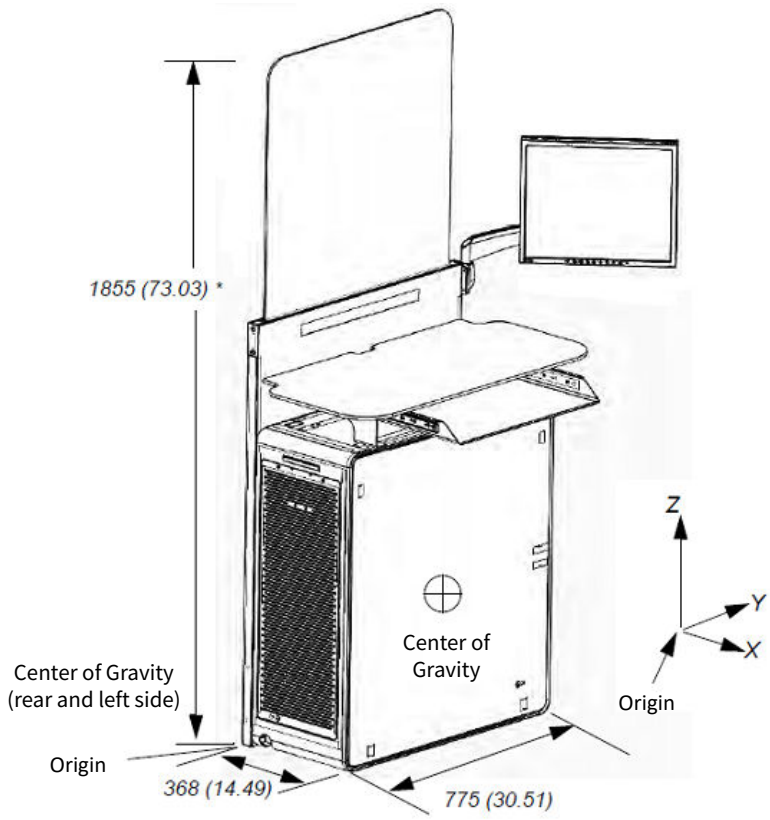
Z_{max} = 1001 *(39.4)*

All measurements shown as: mm *(inches)*

Mass of Gantry: Refer to 2.3.3 Floor Requirements on page 60.

Anchor Points for the Gantry: Refer to 2.2.3.2 Anchoring Inserts on page 53.

Figure 2-3 Fixed Control Station dimensions - mm (inches)



Center of Gravity with Radiation Shield (origin as shown):

Prior to Pristina 8.4 full configuration

X = 157.70 *(5.45)*

Y = 377.13 *(14.859)*

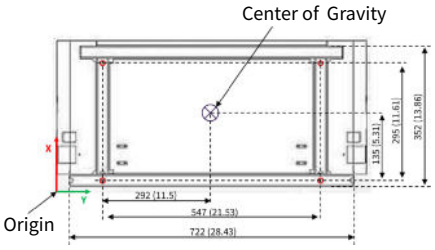
Z = 577.23 *(26.21)*

From Pristina 8.4 with Lenovo PC (worst case)

X = 151.37 *(5.96)*

Y = 404.67 *(15.93)*

Z = 610.27 *(24.03)*



* Control Station height with Radiation Shield is 1855 *(73.03)*

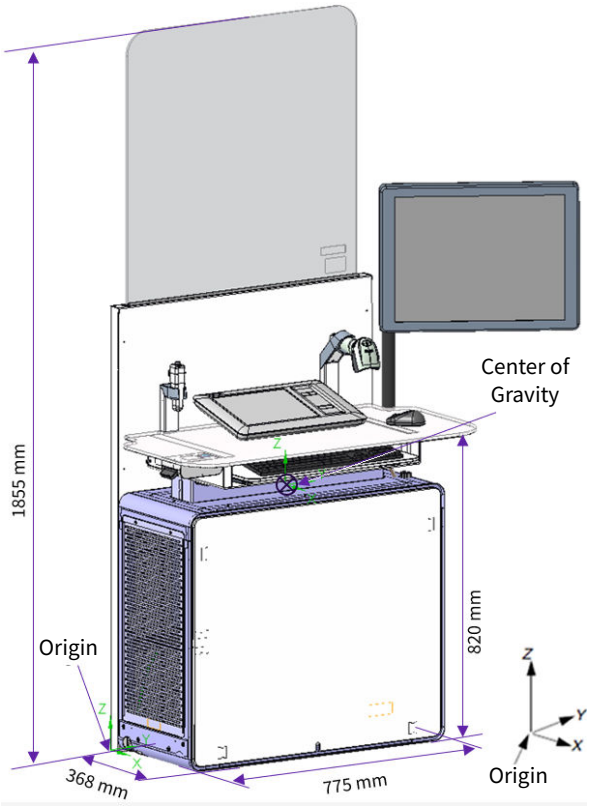
All measurements shown as: mm *(inches)*

Mass of Fixed Control Station: Refer to 2.3.3 Floor Requirements on page 60.

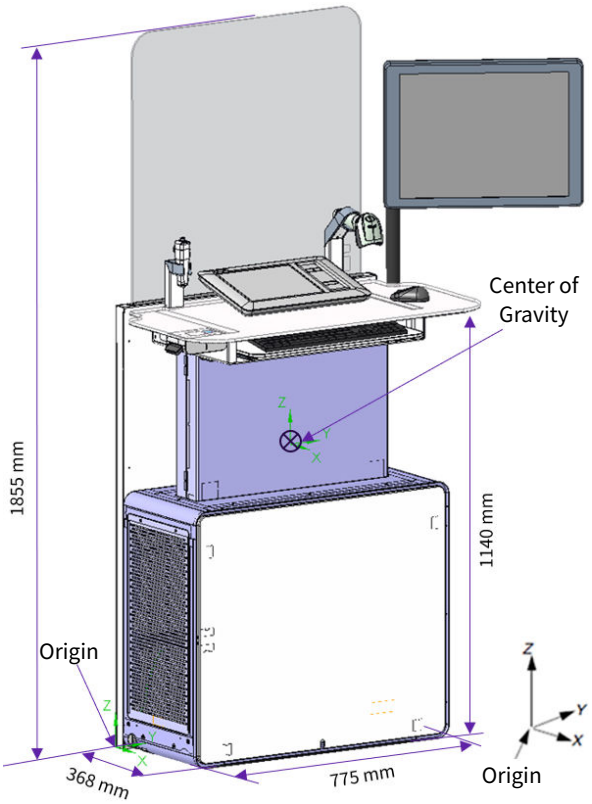
Anchor Points for the Control Station: Refer to 2.2.3.2 Anchoring Inserts on page 53.

Figure 2-4 Adjustable Control Station dimensions - mm (inches)

Working plan at bottom-most location



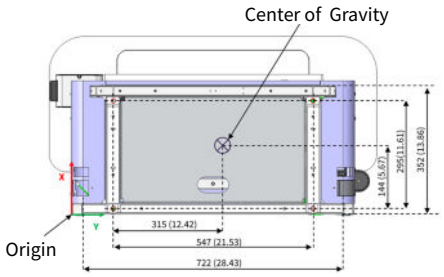
Working plan at top-most location



Center of Gravity with Radiation Shield and monitor (origin as shown):

X = 160 *(6.30)*
Y = 428 *(16.85)*
Z = 666 *(26.22)*

X = 160 *(6.30)*
Y = 428 *(16.85)*
Z = 768 *(30.24)*



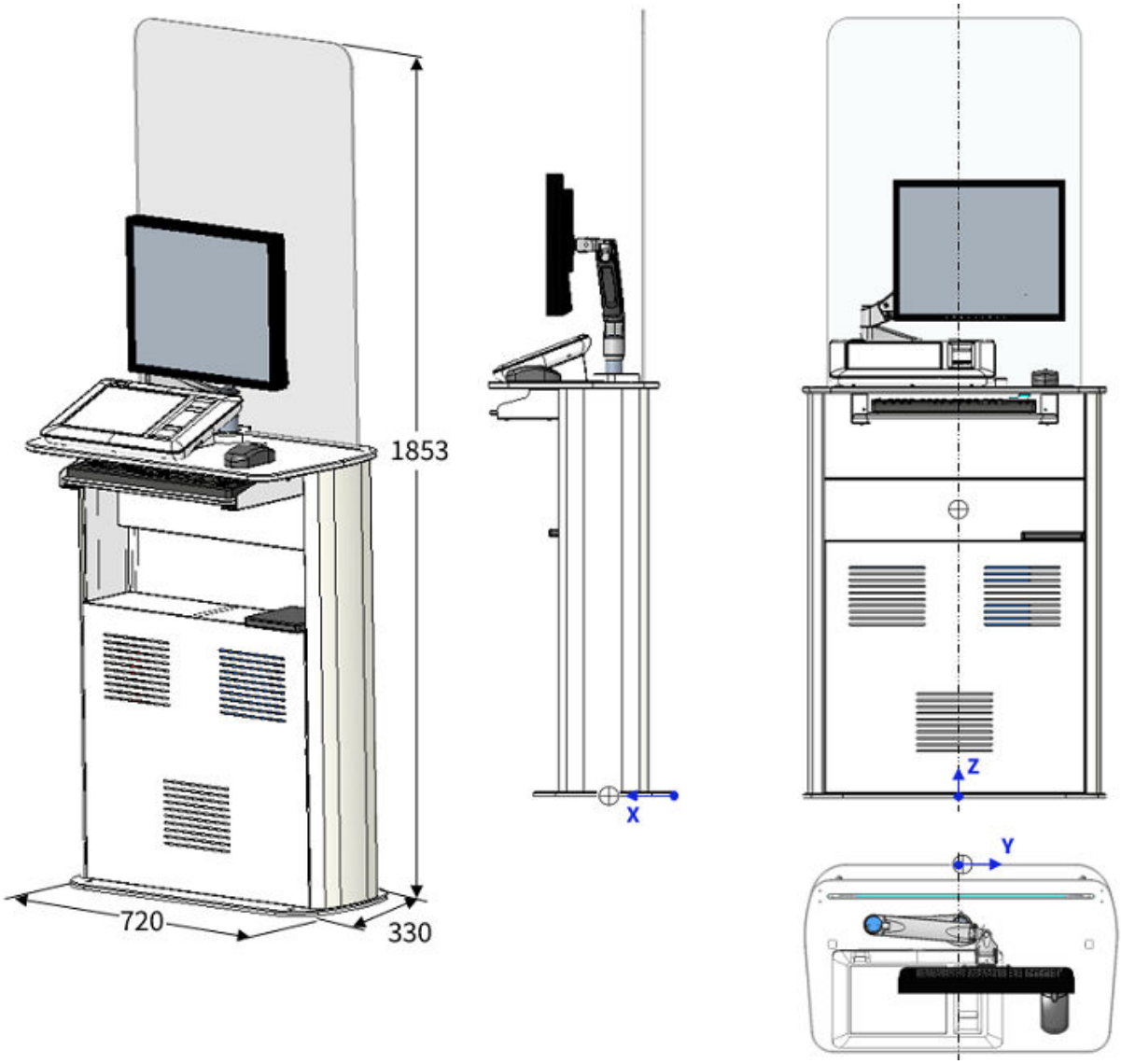
* Control Station height with Radiation Shield is 1855 *(73.03)*

All measurements shown as: mm *(inches)*

Mass of Adjustable Control Station: Refer to 2.3.3 Floor Requirements on page 60.

Anchor Points for the Control Station: Refer to 2.2.3.2 Anchoring Inserts on page 53.

Figure 2-5 Lean Control Station dimensions - mm

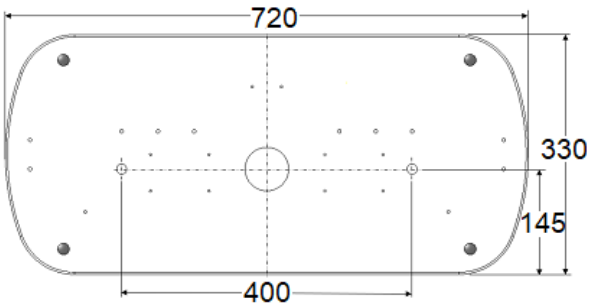


Center of Gravity with Radiation Shield (origin as shown):

X = 158.66 mm

Y = 3.84 mm

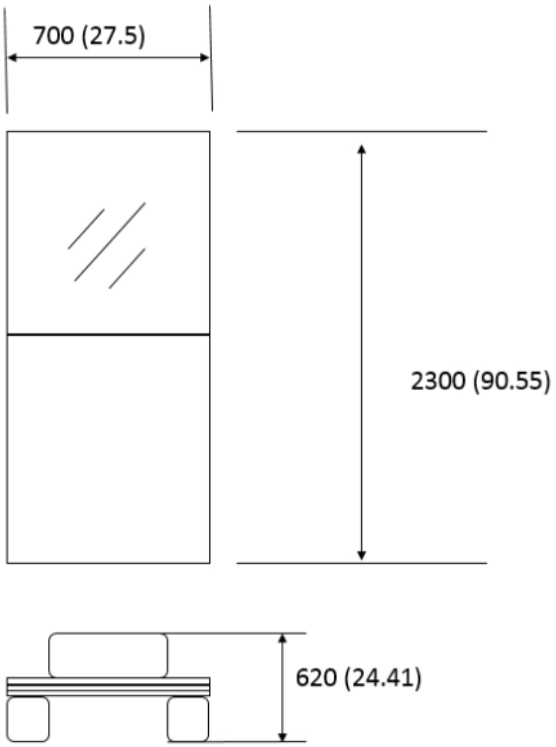
Z = 663 mm



All measurements shown are in mm

Anchor Points for the Control Station: Refer to 2.2.3.2 Anchoring Inserts on page 53.

Figure 2-6 Dimensions of optional radiation shields - mm (inches)



Single configuration:

Optional radiation shield plus one optional radiation screen extension to put at one side of the control station.

Ordering:

Optional radiation shield: S30321MM (2234536)

Optional radiation shield extension (never ordered alone): S30311CW (2166641)

All measurements shown as: mm *(inches)*

NOTE

The optional separate radiation shield does not support the fixation of the X-ray Console, which is always installed the Control Station.

The optional separate radiation shield must be located between the Gantry and Control Station in such a way to always protect the Operator from X-rays when using the X-ray Console.

2.2.2 Layout Constraints for Positioning Gantry and Control Station

The layout and positioning of the Gantry and Control Station depend on various factors summarized below:

- **Safety**
  - **SA1:** Minimum "trapping zone" safety clearance around the motorized moving parts of the Gantry is 500 mm. Therefore, the minimum distance between the extreme positions of the Tube Head and any objects (e.g. wall) must be a minimum of 500 mm.
    If room size does not allow 500 mm, the following text must be added on the room layout proposal reviewed and approved by customer (translated in customer local language):

    Note that your Senographe Pristina *installation in the selected room does not meet the following minimal requirement: 500 mm required distance between the Tube Head and any stationary object.*

    Therefore we must apply a warning label on both Tube Head sides to remind the Operator about entrapment hazard during Gantry motions.
  - **SA2:** The Stop motion buttons are located on both sides of the Gantry, relatively far away from the Control Station. Access to these buttons from the Control Station must be easy going around the Control Station by the left or by the right.

- **SA3:** Both visual and voice contact of operator with the patient shall be maintained throughout the examination, either through physical proximity or through window or CCTV and intercom.

- **Serviceability**
  All sides of the three components need access for servicing.
  - **SE1:** Gantry: 370 mm between the rear edge of the Gantry baseplate and the wall.
    If the recommended 370 mm cannot be applied to the room layout, this distance can be reduced to 170 mm but the following text must be added on the room layout proposal reviewed and approved by customer (translated in customer local language):

    Note that your Senographe Pristina *installation in the selected room does not meet the following minimal requirement: 370mm recommended distance of rear clearance,*

    This might lead to more than one day downtime in case of parts replacement requiring rear accessibility.
  - **SE2:** Fixed or adjustable Control Station only: A clearance of 300 mm from both edges of the Control Station baseplate to enable access to the computer and other parts.
  - **SE3:** Lean Control Station only: A clearance of 450 mm from the back of the Control Station baseplate to enable access to the computer.

- **System Use**
  - **SU1:** Control Station: The path of the Rotative Arm must be such that the LCD Monitor does not come into contact with the Tube Head, wall, or other objects.

- **Clinical Use**
  - **CU1:** Control Station: A clearance of 780 mm from the Control Station baseplate front edge, so that the Operator has a clearance of 500 mm with a fully expanded keyboard.
  - **CU2:** Fixed or adjustable Control Station only: A clearance of 150 mm from the Control Station baseplate left and right edge, so that the Operator can open the optional DVD-ROM drive.
  - **CU3:** Easy access to the patient area. Stretchers and other mobile hospital equipment must be able to reach the table quickly.
  - **CU4:** Clinicians in the patient area must be able to communicate easily with operators and others in the control area.
  - **CU5:** Operators must have easy access to the X-ray Console. However, the X-ray Console must be positioned so that the Operator can only take exposures while behind the radiation shield.
  - **CU6:** Recommend 1.5 m diameter space in front of chest wall edge of the detector for patient access (including wheelchair). If this is not possible, the following layout message will be included:
    Note that your Senographe Pristina installation in the selected room does not meet the minimal requirement, and may prevent accessibility for patients experiencing disabilities.

    NOTE
    The distances given above correspond to a minimum, but it remains the responsibility of the local installation services team to ensure that the country regulations are followed. For example, in the United States the Labor Occupational Safety and Health Administration (OSHA) regulations must be taken into account, such that an Egress of 28" (711 mm) is respected.

2.2.2.1 Ancillary Equipment

Consult hospital personnel regarding additional space requirements for hospital equipment such as storage cabinets, sinks, and crash cart.

2.2.2.2 Positioning of the LCD Monitor on the Control Station

For the Fixed and Adjustable Control Stations

Typically the FE will install the rotative arm that supports the AWS monitor on the right-hand side of the Control Station. This is because, for most Operators (who are right-handed), it is more convenient to have the mouse on the right-hand side.

However, the following situations require the rotative arm that supports the AWS monitor to be installed on the left-hand side of the Control Station:

- the rare occasion where all or the majority of operators at the customer site are left handed, and the layout of the room allows the rotative arm to be installed on the left-hand side of the Control Station.
- the room that hosts the Senographe Pristina does not permit the Control Station to have the AWS monitor on the right-hand side of the Control Station, due to either limited space or intrusive objects such as doors or pillars.

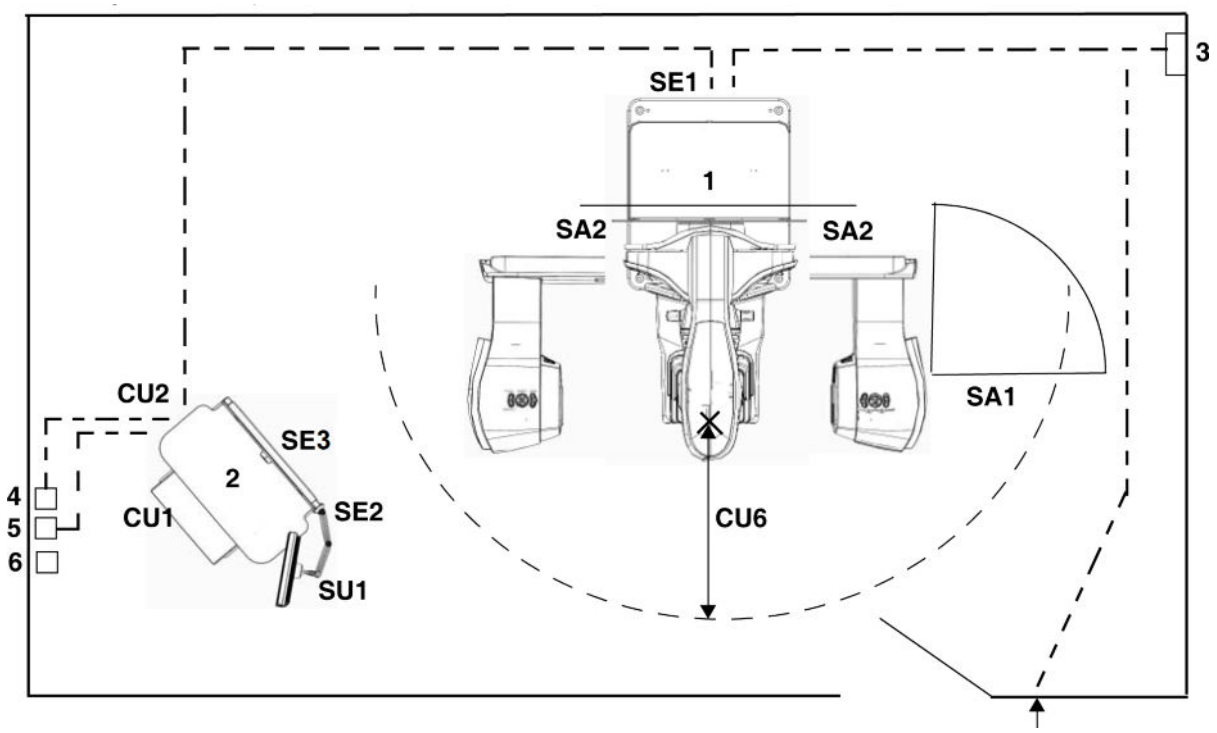
When reviewing the room that will host the Senographe Pristina, you must determine whether the AWS monitor must be installed on the left-hand side of the Control Station.

For the Lean Control Station

On this control station, the monitor arm is installed in the middle, but the monitor can be on the left or right side.
Generally, the FE installs the monitor on the right-hand side of the Control Station. This is because it is more convenient for most operators, who are right-handed, to have the mouse on the right-hand side.

2.2.2.3 Generic Constraints Overview

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



SE2, CU2: Fixed or Adjustable Control Station only

SE3: Lean Control Station only

1. Gantry.
2. Control Station with Radiation Shield.
3. AC power input through power distribution box (supplied by customer).
4. Broadband connection for Insite and OnWatch (supplied by customer).
5. Hospital network connection (supplied by customer).
6. Telephone connection for operators.

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

2.2.2.4 Minimum Room Size Layout Example

Figure 2-7 Minimum room size layout with Fixed Control Station on page 47 provides an example layout which adheres to the constraints listed above.

NOTE
Your local regulations may impose different constraints to those listed above, which can result in larger room requirements to that shown below. Check with your local GE Healthcare Pre-Installation team to confirm the minimum room dimensions if your local requirement impose different constraints to those listed above.

NOTE
Ensure that the room layout is adapted to the cable length constraints as listed in the table below and as summarized in section 2.2.4 Interconnecting Cables Path and Length on page 57.

Cable/Harness	Length	Diameter
Gantry to Control Station cables in Harness	8 m (*26' 2"*)*	43 mm (*1.7"*)

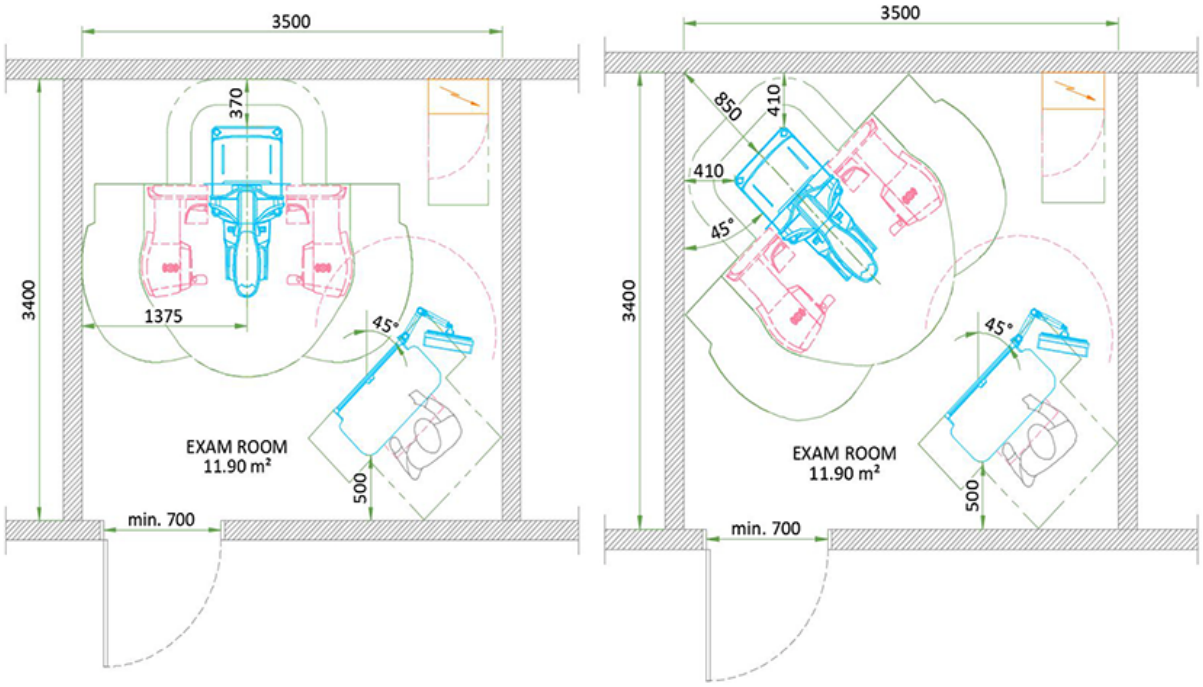
Cable/Harness	Length	Diameter
Gantry to Control Station: X-ray Console Cable	The X-ray Console cable is integrated within the harnesses.	-

*Optional 15 m *(49.2 ft)* harness available

NOTE
If a separate radiation screen is used instead of the integrated radiation screen, the Control Station must positioned so that the LCD Monitor cannot collide with the integrated radiation screen.

NOTE
If the room size is small such that it restricts the positioning of the Control Station so that it is close to a wall or separate radiation screen, the Rotative Arm securing the LCD Monitor can be adjusted so that it does not move.

Figure 2-7 Minimum room size layout with Fixed Control Station



In the minimum room size layout, the orientation of the Control Station and Gantry are all positioned in a way, such that:

- all the cable groups are along one wall and kept out of the way, preventing damage to them or having them become a trip hazard
- full use of the Rotative Arm for LCD monitor is permitted

2.2.2.5 Room size layout for interventional procedures (biopsy)

This section summarizes the three layout types for interventional procedures (biopsy).

Figure 2-8 INTERVENTIONAL (BIOPSY) MINIMUM ROOM SIZE WITH A CHAIR on page 48 shows the minimum room size layout with a chair.

Limitation:

- The limited room dimensions do not allow biopsy table usage.

Figure 2-8 INTERVENTIONAL (BIOPSY) MINIMUM ROOM SIZE WITH A CHAIR

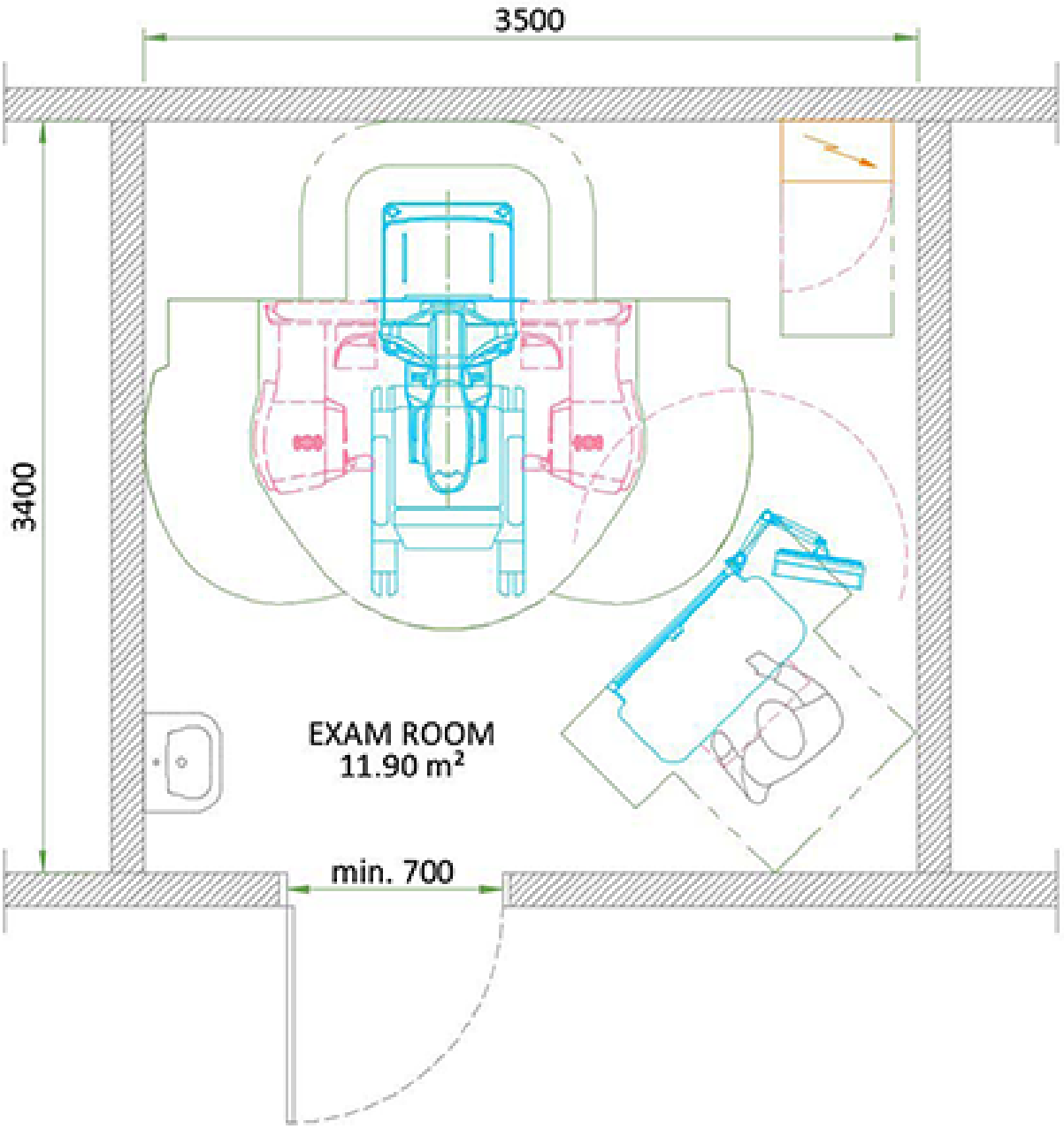


Figure 2-9 INTERVENTIONAL (BIOPSY) MINIMUM ROOM SIZE WITH A TABLE on page 49 shows the minimum room size layout with a table.

Such layout with limited clearance around the table degrades the maneuverability in room and has sub-optimal user workflow during biopsy procedure.

Limitations:

- Room dimensions do not allow optimum usage of the table.
- Limited physicist/technician circulation around the table.
- No parking place for the table during the procedure.
- Limited cart maneuvering

Figure 2-9 INTERVENTIONAL (BIOPSY) MINIMUM ROOM SIZE WITH A TABLE

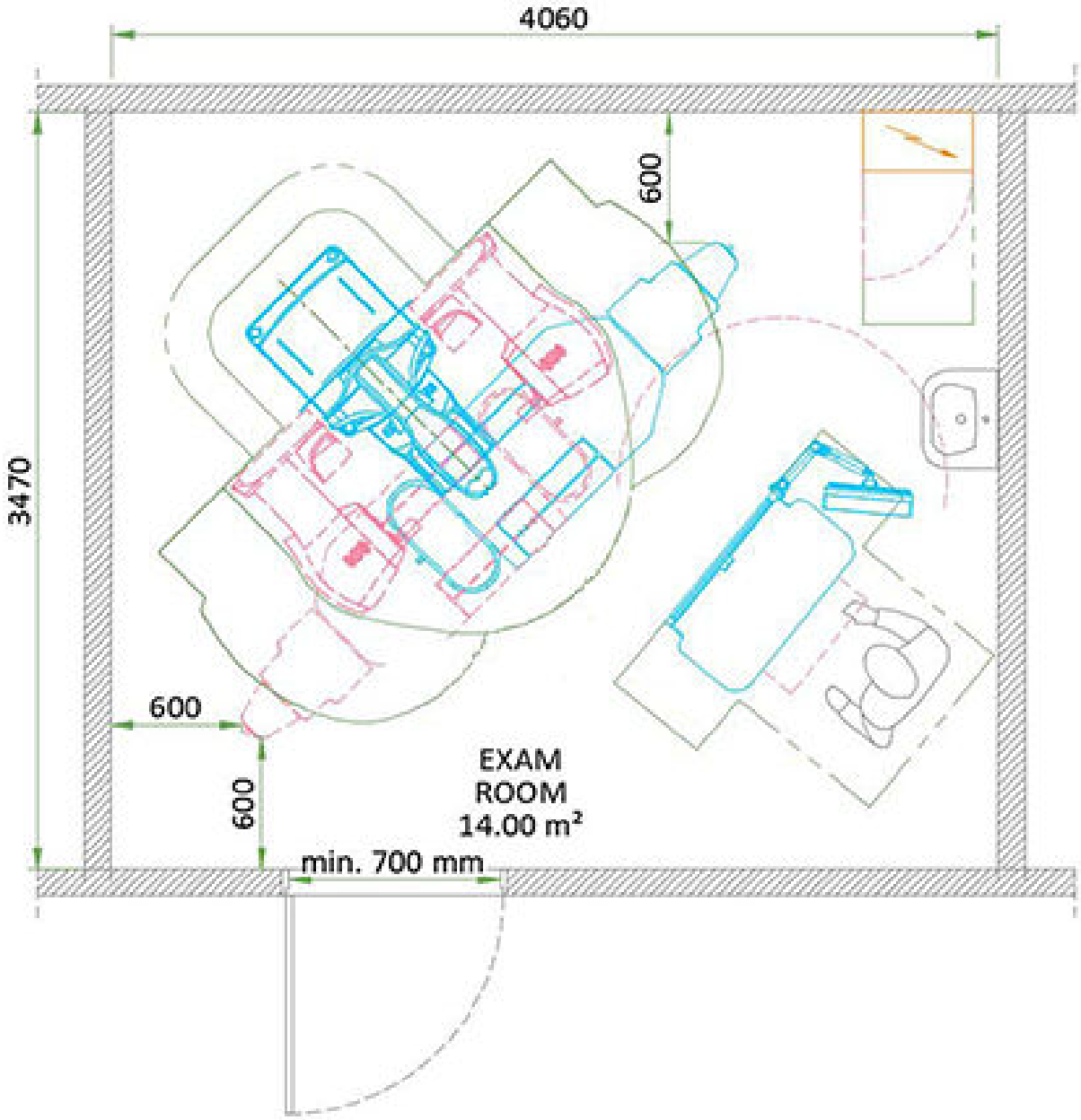
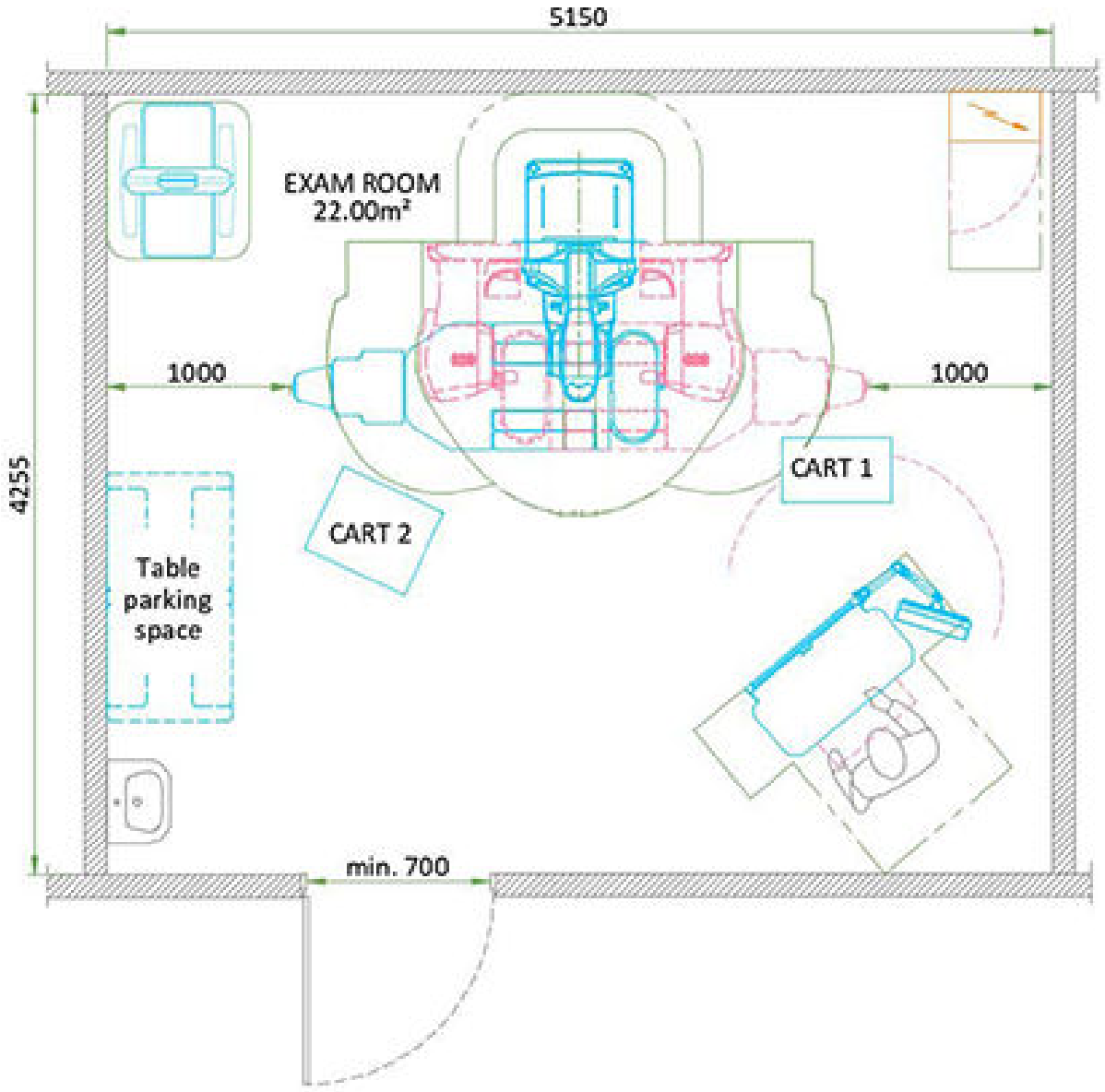


Figure 2-10 INTERVENTIONAL (BIOPSY) OPTIMAL ROOM SIZE WITH A TABLE on page 50 shows the optimal room size layout with a table, which has no limitations.

- Circulation (no restricted maneuvering) around the table with a cart (1000 mm) + table rotation movement
- Reserved space to park the table
- Reserved space for Breast Support Stand

Figure 2-10 INTERVENTIONAL (BIOPSY) OPTIMAL ROOM SIZE WITH A TABLE



2.2.2.6 Gantry in the Wall

In order for the Gantry to be installed flush to the wall, the following points must be obeyed.

1. General : Installing Senographe Pristina with a partition wall is possible as long as all the Pre-Installation requirements are followed.
2. The wall must be mounted without physical interference with the system, and must consider the following:
   - Spacing between the wall and the sides of the Gantry must be sufficient (40 mm clearance around Gantry Column covers) as indicated in illustration Figure 2-11 WALL SPACING TO GANTRY SIDES FOR COVER ACCESS on page 51, to allow the removal of the Gantry covers.
   - So that the Gantry can be easily positioned, the width and height of the wall space to accommodate the Gantry (see illustration Figure 2-12 WALL SPACE TO ACCOMMODATE GANTRY AND GTT on page 52) must also be sufficient to support the Gantry Transport Tool (GTT).

3. Need to ensure the same environmental requirement (temperature/humidity) as for systems without a wall (15-30°C) so to avoid over-heating of equipment located behind the wall. The wall must be mounted to allow an air flow between both rooms to keep the temperature as per the system specification (see 4.1 Operating and non-operating requirements on page 73).
4. For regulatory reason access to system information located on the left side of the bottom of the Gantry column must be easy for anybody without the need of a tool. The system information is located on the label panel, which has the dimensions 125 x 300 mm (see illustration Figure 2-13 LOCATION AND DIMENSIONS OF LABELS PANEL on page 52).
5. The minimum space for the Field Engineer on both sides of the Gantry must be 710x900 mm. In the case of only one opening, a space of 500 mm must be set between the covers and the wall. These spaces must not be used as storage (no cabinet or shelves).
6. Proper lighting must be provided in the space behind the wall.
7. The door in the open position must not interfere with the Tube Head motion.
8. The access to the space behind the wall must be possible with all Arm positions.
9. The Senographe Pristina is sensitive to dust. Therefore the wall must be built before installing the Senographe Pristina system.

NOTE
Installation of the Gantry in the wall might not be compatible with some future options.

Figure 2-11 WALL SPACING TO GANTRY SIDES FOR COVER ACCESS

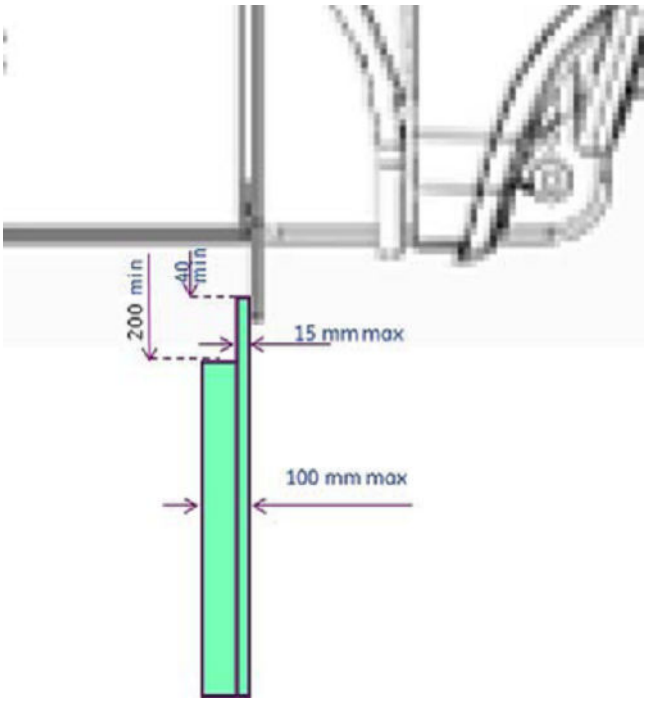


Figure 2-12 WALL SPACE TO ACCOMMODATE GANTRY AND GTT

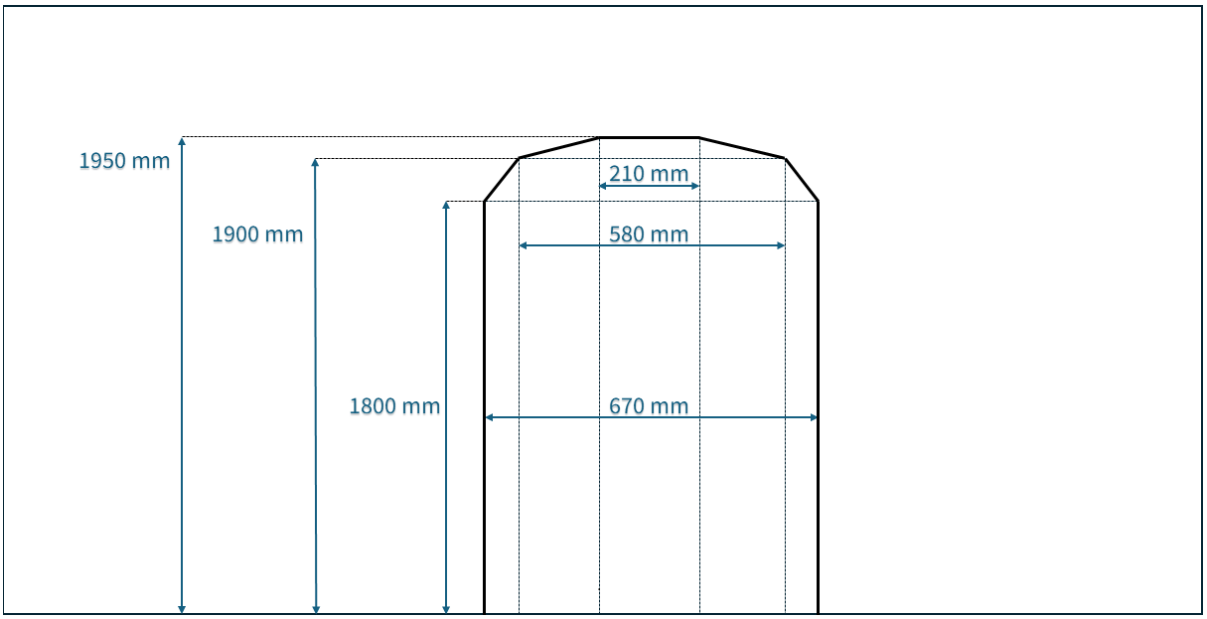


Figure 2-13 LOCATION AND DIMENSIONS OF LABELS PANEL

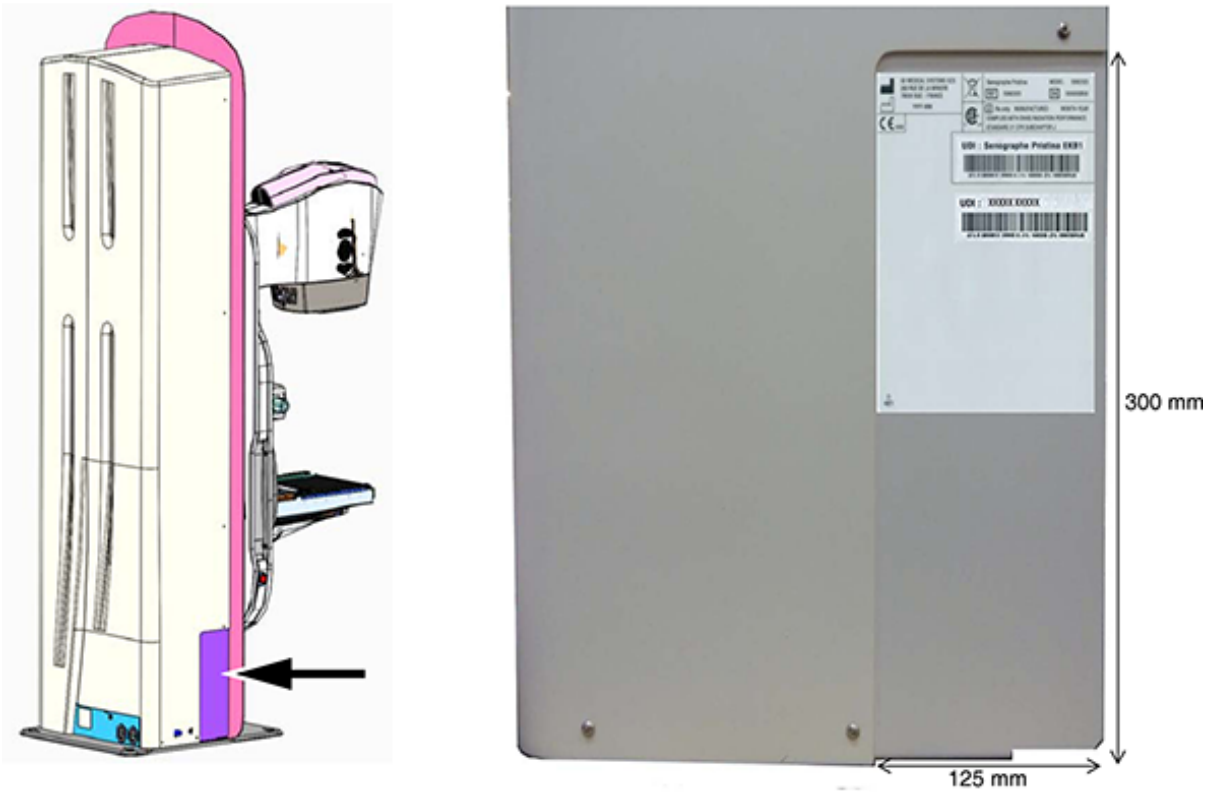
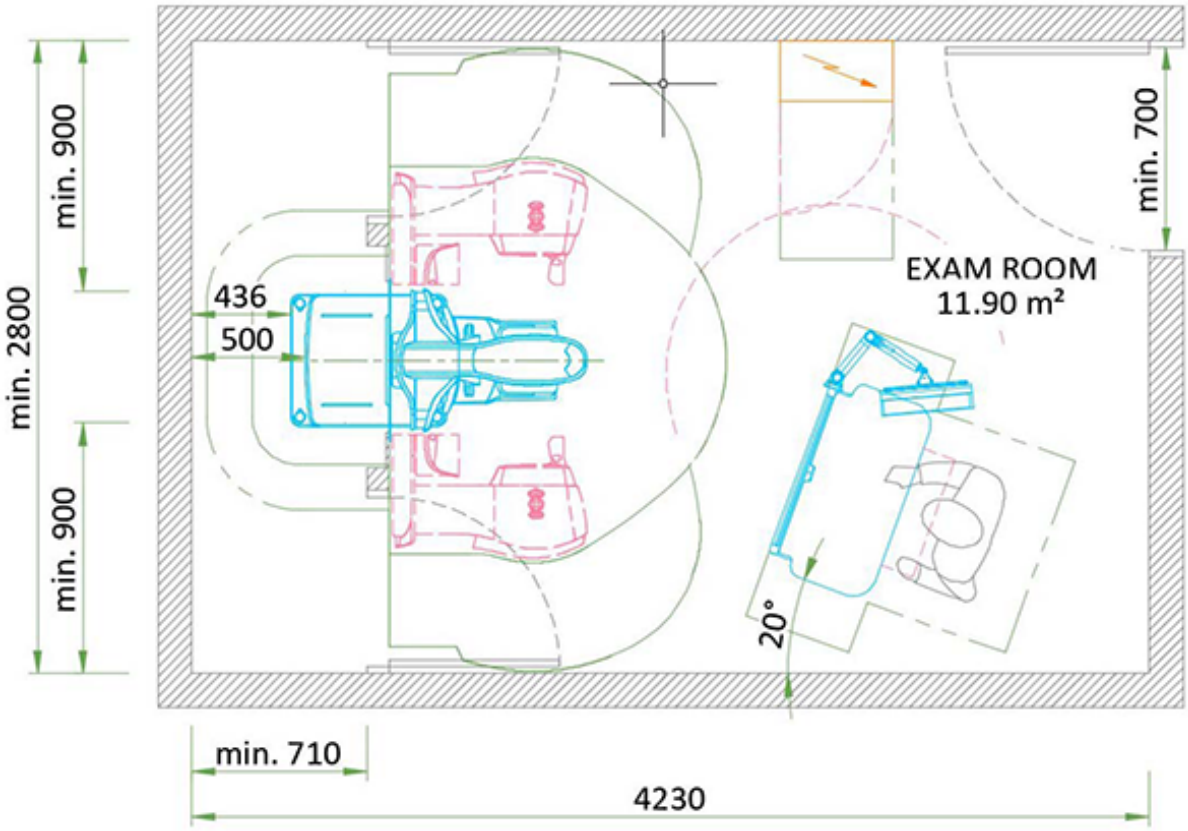


Figure 2-14 EXAMPLE GANTRY IN WALL LAYOUT



2.2.3 Anchoring to the Floor

2.2.3.1 The Positioning Template

To anchor the Gantry and Control Station, position them and use a felt-tip pen or marker to mark the ground. Ensure the baseplate (Gantry and Control Station) is in direct contact with the floor, preferably concrete. Avoid fixing it on soft materials such as carpet, rugs, mats, or similar surfaces.

A drilling template for the Gantry and Fixed or Adjustable Control Station is not included with the system but is available as a Field Replaceable Unit (FRU) (see Figure 2-15 **Gantry and Fixed or Adjustable Control Station drilling template** on page 57). This metal sheet drilling template provides the layout for the anchor drill holes for both the Gantry and the Fixed or Adjustable Control Station.

The floor bolting installation kit also contains five 1 mm thick shims for leveling the metal sheet drilling template if the floor is not completely flat. If the floor is uneven, use the set of five shims to compensate, and catch up the floor flatness before drilling.

There is no drilling template available for the Lean Control Station.

2.2.3.2 Anchoring Inserts

Ensure that the load rating for the floor is enough to withstand the mass of the Gantry and the Control Station: refer to 2.3.3 Floor Requirements on page 60.

2.2.3.2.1 Anchoring Inserts (only for non-seismic areas)

NOTE
If the installation is in an area subject to seismic events, section 2.2.3.2.2 Seismic Anchoring Methods on page 55 below specifies the anchoring requirements.

The inserts provided with the Senographe Pristina system work only in non-seismic areas.

Table 2-2 Anchoring Inserts (Provided) and Alternate Non-Metric Anchors (Not Provided) for Non-Seismic Areas

	PROVIDED ANCHORS			Alternate NON-METRIC ANCHORS (not provided, to be purchased locally)	
Anchoring holes in the floor	**Gantry baseplate** (see Figure 2-15 Gantry and Fixed or Adjustable Control Station drilling template on page 57)	**Fixed or Adjustable Control Station baseplate** (see Figure 2-15 Gantry and Fixed or Adjustable Control Station drilling template on page 57)	**Lean Control Station baseplate**	**Gantry baseplate** (see Figure 2-15 Gantry and Fixed or Adjustable Control Station drilling template on page 57)	**Fixed or Adjustable Control Station baseplate** (see Figure 2-15 Gantry and Fixed or Adjustable Control Station drilling template on page 57)
Provider	FRU: P/N 5983817 Gantry + Lean Control Station FRU: P/N 5599095 Old branding Gantry + Fixed and adjustable Control Station FRU: P/N 5582308-2 New Branding Gantry (Pristina 9.1 and above) + Fixed and adjustable Control Station			Heavy Duty Tapcon+ alternate non-metric	
Concrete compression (min)	3000 psi				
Anchor characteristics	M10 x 60	M10 x 110	HILTI HSL4 M8 d12x97	3/8” x 4”	3/8” x 4”
Number of holes in the metal sheet template	4	4	2	4	4
Diameter of the hole in the metal sheet plate	13 mm	12 mm	N/A	13 mm (0.51”)	12 mm (0.47”)
Hole diameter in the floor	10 mm	10 mm	12 mm	3/8”	3/8”
Hole depth in the floor	Nominal: 80 mm	Nominal: 80 mm	Min: 80 mm	4.3” (109.2 mm)	4” (101.6 mm)
Provided inserts	PN 5611363	PN 5747343	PN 5791005	Not provided	
Minimum floor thickness	120 mm	120 mm	120 mm	4.5” (114.3 mm)	4.5” (114.3 mm)
Recommended tightening torque	30 N.m	30 N.m	15 N.m	30 N.m (22 ft.lbf) Max Torque 67 N.m (50 ft.lbf)	30 N.m (22 ft.lbf) Max Torque 67 N.m (50 ft.lbf)

NOTICE

The Heavy Duty Tapcon+ alternate non-metric anchor may be loosened by a maximum of one turn and retightened with a manual torque wrench to facilitate fixture attachment or realignment.

Complete removal and reinstallation of the anchor is not allowed.

In case of complete removal of Heavy Duty Tapcon+ alternate non-metric anchor, the same floor holes cannot be reused. The only solution is to relocate the gantry.

In installations where the floor thickness is:

- less than required for provided anchors (i.e. less than 120 mm), or
- less than required for Heavy Duty Tapcon+ alternate non-metric anchors solution (i.e. less than 4.5”), or
- the floor is not concrete.

You must substitute different anchoring fasteners. Each fastener must be able to withstand a minimum tensile force of 1000 N. Substitute fasteners must be installed in accordance with installation instructions provided by the fastener supplier.

You are responsible to seek the approval of a substitute anchoring method by a structural engineer, qualified and authorized in accordance with local building regulations.

Visit Tapcon website to get a list of supplier for Heavy Duty Tapcon+ alternate non-metric concrete anchors 3/8” x 4” suppliers location.

2.2.3.2.2 Seismic Anchoring Methods

For a seismic installation, the customer shall refer to all applicable state/local laws and building codes.

Customer shall consult with structural engineer, site contractor, or architect for seismic installation requirements pertaining to all device components/sub-systems.

Seismic anchoring is an alternate anchoring method.

An alternative installation plan that meets all required seismic codes for the region the product is located in, should be developed for sites requiring seismic installations.

Development of this plan is the responsibility of the customer.

Generally, this requires the customer to contract the services of a Structural Engineering firm to develop the seismic anchoring plan prior to install.

The alternative seismic installation plan should be executed at time of installation in place of the existing anchoring method defined in the service manual.

This plan must be retained by the customer since it must be reviewed by service personnel at time of de-installation.

GE HealthCare does not supply anchors for seismic installation.

It is the responsibility of the customers to have qualified structural engineers to determine and supply the correct seismic anchors and anchor torques.

The type and length of the anchor must be defined in the alternative seismic anchoring plan and purchased separately by the customer.

The existing 2.2.3.2.1 Anchoring Inserts (only for non-seismic areas) on page 53 provided by GE HealthCare shall be discarded and NOT used for seismic installations.

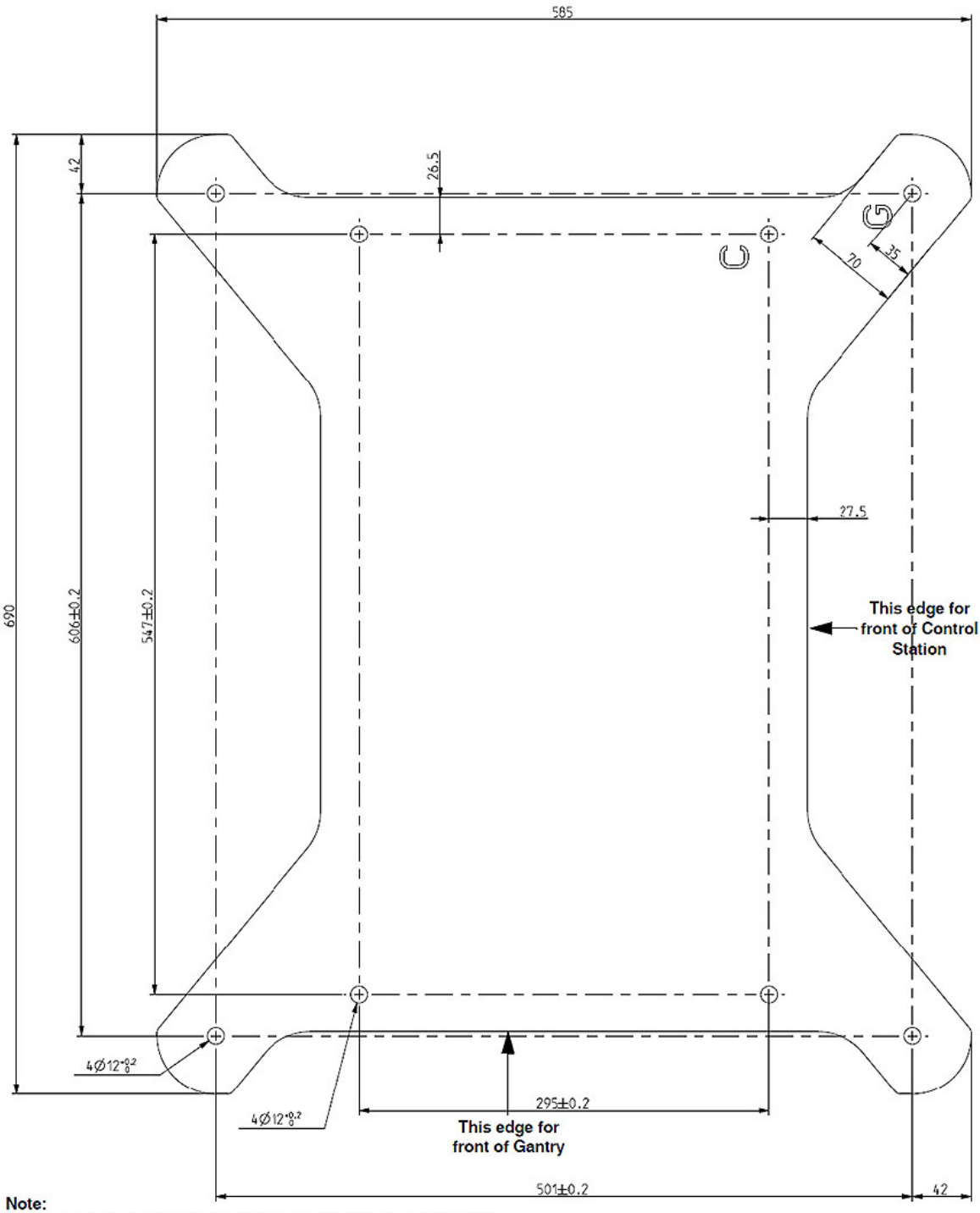
2.2.3.2.3 Kit Bolting on Floor

A drilling template (Figure 2-15 **Gantry and Fixed or Adjustable Control Station drilling template** on page 57) with the position of holes to drill on the floor to fix the Gantry and Fixed or Adjustable Control Station is not included with the system but is available as a Field Replaceable Unit (FRU).

- The outer set of four holes, marked with a G and a separation distance of 606 mm x 501 mm correspond to the drilling holes for the Gantry fixations.
- The inner set of four holes, marked with a C and a separation distance of 547 mm x 295 mm correspond to the drilling holes for the Fixed or Adjustable Control Station fixations.

NOTE
The drilling template doesn't provide drill hole position for Lean Control Station.

Figure 2-15 Gantry and Fixed or Adjustable Control Station drilling template



Note:
Gantry drill holes marked by the box labelled G (606 mm x 501 mm)
Control Station drill holes marked by the box labelled C (547 mm x 295 mm)

2.2.4 Interconnecting Cables Path and Length

The diagram below is provided to help planning cable runs between subsystems.

Codification color on the illustration:

Black = Harness, Shipped with the system

Red = Power AC supply Line Supply Cable supplied by customer

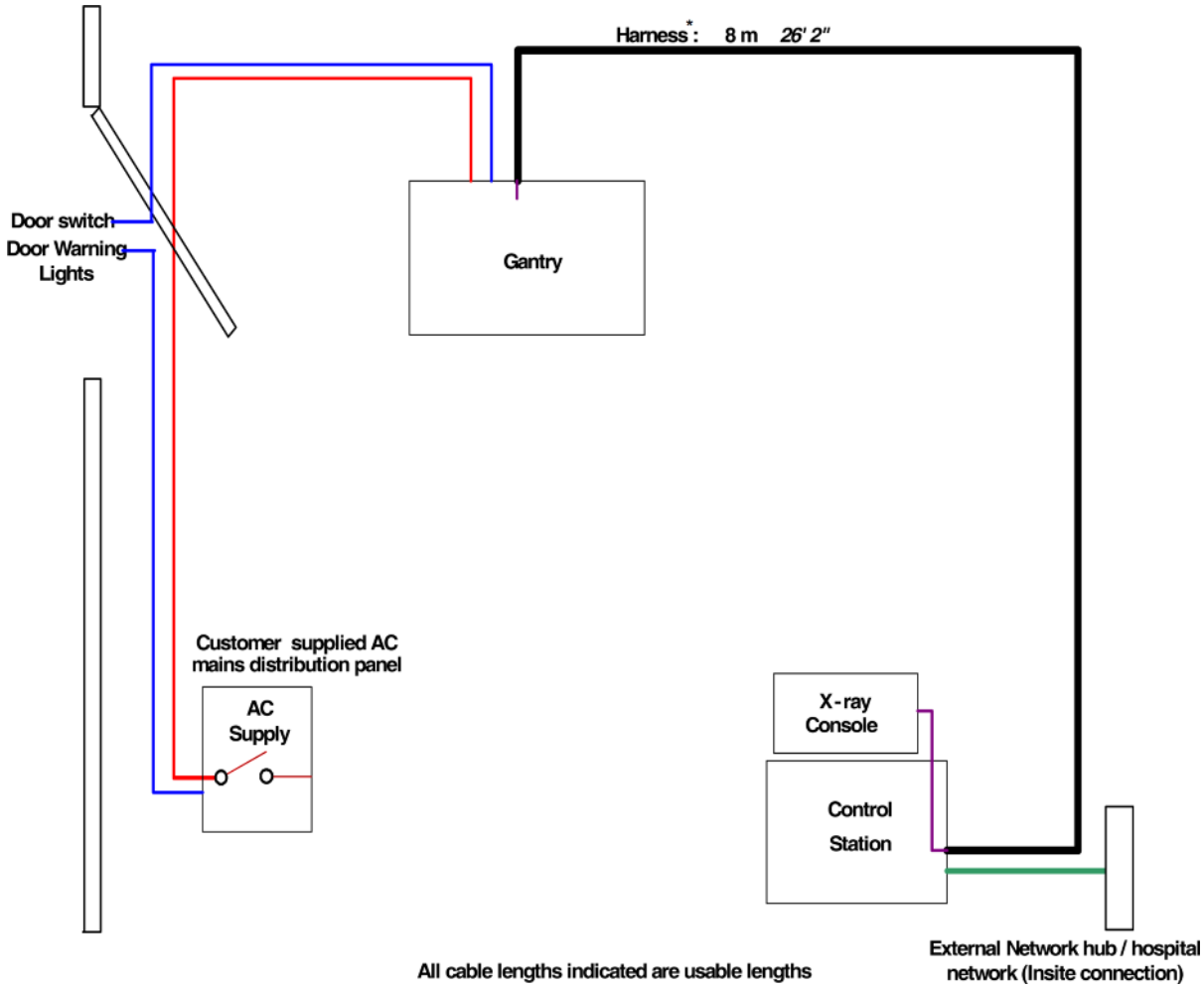
Blue = Door light and switch (local adaptation)

Green = Insite and OnWatch connection

Purple = X-ray Console Cable

NOTICE

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



*Optional 15 m *(49.2 ft)* harness available

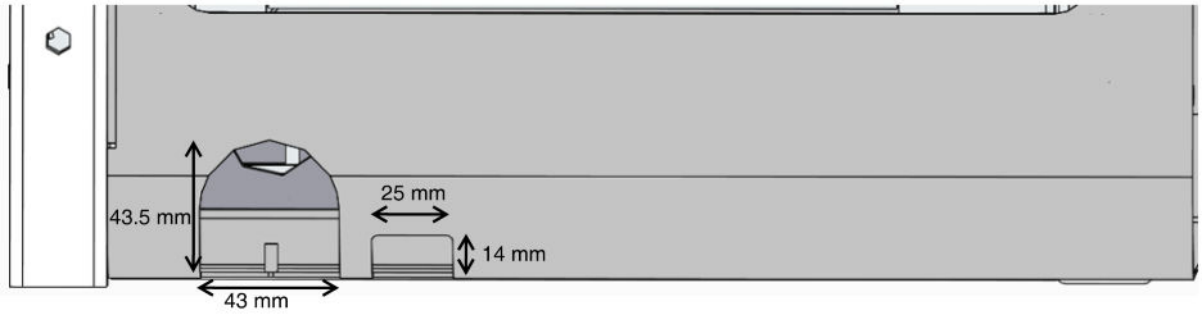
NOTE

Regardless of the control station, only 3 meters of the gantry harness can be stored within it. Order the appropriate harness to meet this requirement.

The Control Station cable opening dimensions are shown on the pictures below.

Figure 2-16 Fixed or Adjustable Control Station cable opening dimensions

Left hand side



Right hand side

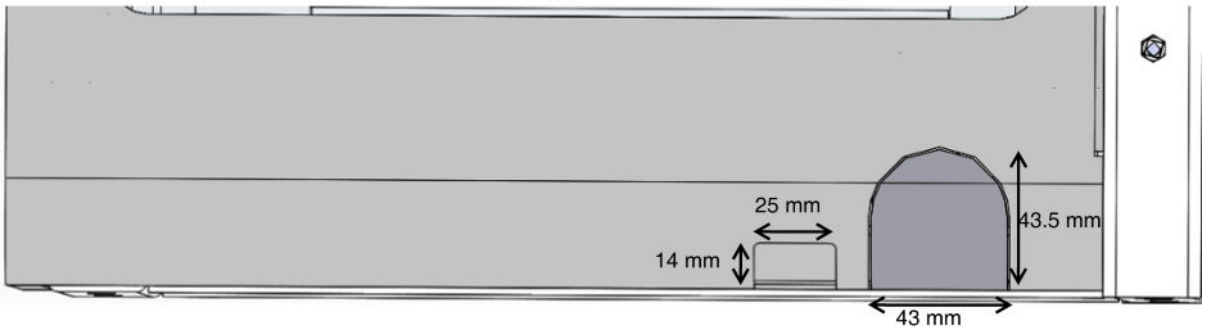
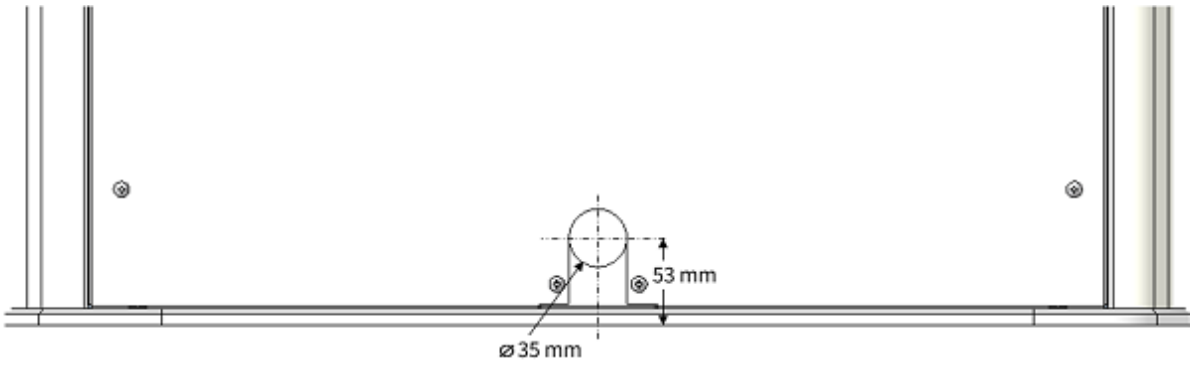


Figure 2-17 Lean Control Station cable opening dimensions

Back side



2.3 Structural requirements

2.3.1 Ceiling Requirements

The top of the Senographe Pristina Tube Head can travel up to 3 different discrete maximum heights. The Tube Head maximum height is determined by setting one of the 3 discrete *Lift Travel Limit Ranges* on the Senographe Pristina. Table 2-3 MINIMUM CEILING HEIGHT on page 60 below summarizes the minimum ceiling height required corresponding to the 3 different Lift Travel Limit Ranges. Figure 2-1 Gantry dimensions - mm (inches) of systems manufactured before 2024-09 on page 38 shows the dimensions of the Gantry.

Table 2-3 MINIMUM CEILING HEIGHT

Lift Upper Limit Position Software Limit	Corresponding Tube Head Height	Minimum Ceiling Height *	Corresponding Bucky Plane Maximum Height
Bottom	2235 mm (87.99")	2300 mm (90.55")	1340 mm (52.76")
Middle	2335 mm (91.93")	2400 mm (94.49")	1440 mm (56.69")
Top (default setting)	2395 mm (94.29")	2500 mm (98.43")	1500 mm (58.86")
* - The minimum ceiling height assumes that there is a marginal gap of 65 mm between the top of the Tube Head and the ceiling for the bottom and middle Software limit, and 105 mm for the Software limit position.			

The distance between the plane of the Bucky and the top of the Tube Head is fixed at 895 mm (35.24 inches). Table 2-3 MINIMUM CEILING HEIGHT on page 60 also shows the corresponding maximum Bucky plane height for each of the three different Lift Travel Limit Ranges. You must determine:

- whether the maximum Bucky plane height corresponding to your ceiling height is acceptable for your customer base
- if you have to make appropriate allowances such as the use of chairs for tall patients

2.3.2 Wall Requirements

The hospital must take special precautions regarding X-ray protection in the examination room walls. See 3.1 Planning for radiation protection on page 62.

2.3.3 Floor Requirements

The Gantry and Control Station must be anchored to the floor. The floor must be stable and flat, and sufficiently strong to accept masses as defined below without distortion beyond the tolerance given:

	Gantry	Fixed Control Station	Adjustable Control Station	Lean Control Station
Worst-case mass	420 kg *(926 lbs)*	160 kg *(352.8 lbs)*	140 kg *(308.6 lbs)*	100 Kgs *(220.5 lbs)*
The bearing surface of the base plate	0.40 m^2 *(4.30 sq. ft.)*	0.27 m^2 *(2.9 sq. ft.)*	0.27 m^2 *(2.9 sq. ft.)*	0.23 m^2 *(2.48 sq.ft.)*
Number of anchoring point (refer to 2.2.3.2 Anchoring Inserts on page 53)	4 anchoring points	4 anchoring points	4 anchoring points	2 anchoring points
Floor surface condition after installation	The floor surface must remain horizontal and flat within ±2.5 mm per meter (*±1/10 inch in 39 inches*) after installation.			

Anchoring inserts provided with the Senographe Pristina only apply for concrete slab floor with a thickness greater than 12 cm. If the customer floor is different (for example, raised technical flooring, timber etc.), then the customer is responsible for the structural analysis of the floor and the proposed mounting method. The customer must hire a structural engineer to design and approve the mounting method, and provide GE HealthCare with an engineering report. If the results of the structural analysis require stronger anchoring inserts the defaults supplied in 2.2.3.2 Anchoring Inserts on page 53, the customer must supply this anchoring hardware.

Flooring consists of all materials above the structural floor support including sub-flooring and equipment support/mounting. The flooring requirements and recommendations are as follows:

- Flooring materials must support the Senographe Pristina equipment mass, refer to 2.2.1 Dimensions and Masses on page 37.
- Floors must support the equipment and any transport device used to move the equipment.

- Flooring throughout the system including X-ray Room must be in accordance with local and national codes.

2.4 Seismic Requirements

For each unit, the unit mass and the position of the center of gravity is provided in 2.2.1 Dimensions and Masses on page 37, to allow compliance with local codes or regulations.

2.4.1 X-Floor Requirements When Using provided Floor Anchors

The maximum load pull tension per provided anchor was calculated assuming:

- Maximum bolt load pull tension at each bolt, refer to 2.2.3.2 Anchoring Inserts on page 53.
- Anchors installed to the required minimum floor thickness, refer to 2.2.3.2 Anchoring Inserts on page 53.

2.4.2 X-Pan Type Floor Construction Requirement

For Pan type floor construction, steel channels must be designed by a local structural engineer or architect to span floor joists.

2.4.3 Independent Radiation Shield

In seismic areas, if the optional independent radiation shield is present, it must be anchored to the floor, or provision must be made to secure it in place. For example, encircle the unit with a nylon belt secured to wall anchors.

Chapter 3 Special Construction Requirements

3.1 Planning for radiation protection

3.1.1 Radiation Protection - General

⚠ CAUTION

Respect the minimum distances required between the Gantry and the Control Station with its associated radiation screen(s) to allow for X-ray attenuation.

Because the X-ray equipment produces radiation, the purchaser must take special precautions or make special site modifications. GE HealthCare does not make specific recommendations regarding radiation protection. It is the purchaser's responsibility to consult a radiation physicist for advice on radiation protection in X-ray rooms.

3.1.2 Radiation Shielding - Operators

Operators must remain in an area protected against radiation when X-ray exposures are made. This means that X-ray controls (X-ray Console) must be mounted in such a way that they can only be used while the Operator remains in a protected area.

To meet European Regulations (*Directive Euratom 96 29*), the limit value for the whole-body equivalent dose must not exceed 20 mSv per year. For other non-European countries, consult your local regulations for the dose limit value.

There are two types of radiation shields:

- The integrated radiation shield for Lean Control Station, supplied with the Senographe Pristina is 600 mm wide, and attached directly to the Control Station. The integrated radiation shield is 6 mm (0.24") thick and has a lead thickness equivalence of 0.5 mm (0.020") at 35 kV.
- The integrated radiation shield for Fixed or Adjustable Control Station, supplied with the Senographe Pristina is 700 mm wide, and attached directly to the Control Station. The integrated radiation shield is 6 mm (0.24") thick and has a lead thickness equivalence of 0.5 mm (0.020") at 35 kV.
  In the case of the integrated radiation shield, the X-ray Console must be mounted on the Control Station, behind the integrated radiation shield.
- For installations that require wider shields or shields with a greater lead thickness equivalence than that provided by the integrated radiation shield, GE HealthCare provides free-standing radiation shields with widths of 705, 1440, or 2175 mm (27.76, 56.7, or 85.6 inches). These optional radiation shields have a lead thickness equivalence of 1 mm (0.04") (see Figure 2-6 Dimensions of optional radiation shields - mm (inches) on page 43). In this case, the free-standing radiation shield (and it(s) extension(s) if applicable) must be placed so as to protect the operator from X-rays when they use the X-ray console.

Other forms of protection can be used, in particular structural or custom-made shielding.

NOTE
If other forms of protection are used, the Senographe Pristina is still delivered with either an integrated or free-standing radiation screen.

NOTE
Radiation Shields supplied by GE HealthCare have toughened glass. If the customer requires a separate free-standing Radiation Shield, it must be made with toughened glass.

3.2 IEC60601-1-2 electromagnetic standards compliance

3.2.1 General

The Senographe Pristina systems manufactured before 2024 comply with the IEC60601-1-2 Edition 2.1, 3 and 4 EMC standard for medical devices.

The Senographe Pristina systems manufactured from 2024 comply with the IEC60601-1-2 Edition 4 and IEC60601-1-2 Edition 4.1 EMC standard for medical devices. They were also tested according to the recommendations of IEC TR 60601-4-2 Edition 1: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

The Senographe Pristina is intended to be used in a PROFESSIONAL HEALTHCARE facility environment.

The Senographe Pristina 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 3-2 ELECTROMAGNETIC EMISSION on page 66).
- Immunity Compliance levels and recommendations for ensuring that the equipment retains its clinical utility (Table 3-3 ELECTROMAGNETIC IMMUNITY - PART 1 on page 67, Table 3-4 ELECTROMAGNETIC IMMUNITY - PART 2 on page 69 and Table 3-6 RECOMMENDED SEPARATION DISTANCES on page 71).

The Senographe Pristina system 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 (see Table 3-1 SUPPLY CABLES on page 64). The Senographe Pristina can be affected by radio-frequencies from portable and mobile communication devices.

Figure 3-1 ANNOTATION OF SUPPLY CABLES

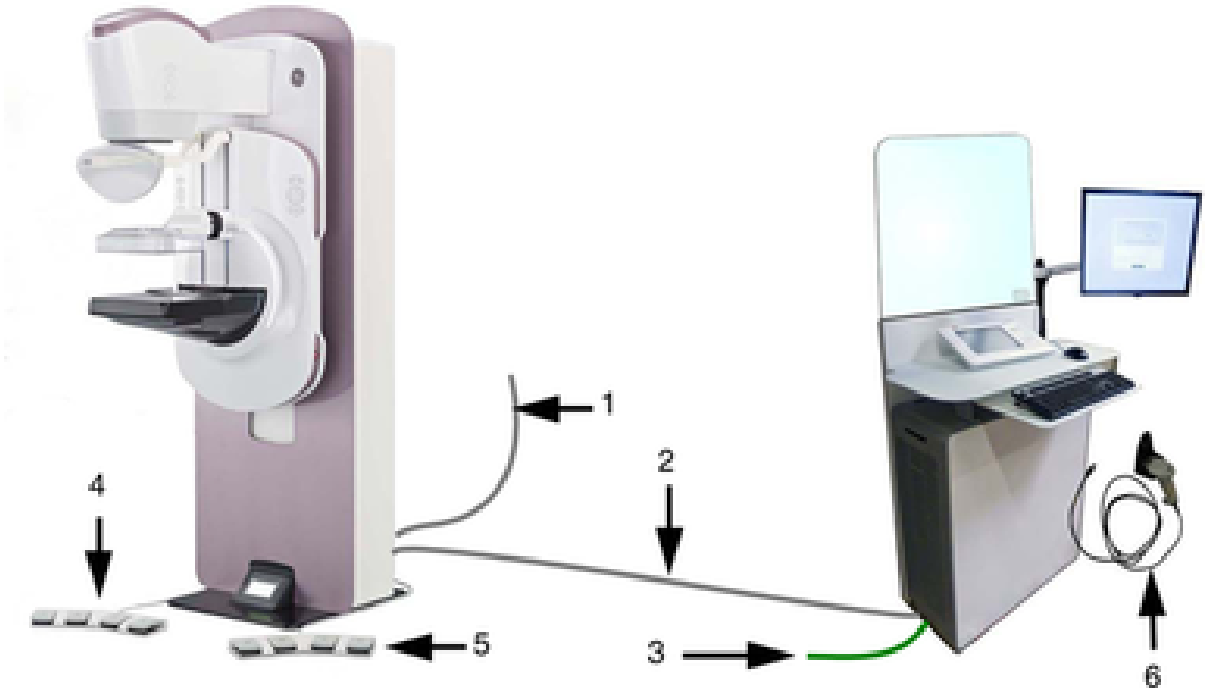


Table 3-1 SUPPLY CABLES

#	Designation	Description with minimal available length
1	AC-supply	Line supply cable provided by customer, which can vary in length. For more information, see 5.7 Line Supply Cable on page 80.
2	Gantry - Control Station Harness	Gantry to Control Station harness: 8 m (*26' 2"*)*
3	Network (supplied by customer)	External Ethernet CAT 5 cable type RJ45 shielded
4	Left Footswitch or Right Footswitch in non-mirrored configuration	Shielded cable: 3.5 m (*11' 6"*) or shielded cable: 3.5 m + 0.3 m adaptor (*11' 6"+12"*) in non-mirrored configuration
5	Right Footswitch	Shielded cable: 3.5 m (*11' 6"*) and NA
6	Bar code reader	Optional scanner with USB shielded cable: 1.5 m (*4' 11"*)
See Figure 3-1 ANNOTATION OF SUPPLY CABLES on page 64 for the location of the numbered cable within the Senographe Pristina system.		

*Optional 15 m *(49.2 ft)* harness available

The Senographe Pristina adheres to the following list of Essential Performance requirements and sub-clauses, according to IEC 60601-2-45 (2015):

Requirement	Sub-clause	Associated job cards
Accuracy of LOADING FACTORS	203.6.4.3.102	
Accuracy and reproducibility of X-RAY TUBE VOLTAGE		*Job Card ELE A012 - Measure the X-ray Tube Peak Voltage kVp* is performed at installation and after a component of generator replacement. kV accuracy is controlled by design, no check during service life.

Requirement	Sub-clause	Associated job cards
Accuracy of CURRENT TIME PRODUCT		*Job Card ELE A011 - Measure the X-ray Tube Anode Current* is performed at installation and after a component of generator replacement. mA accuracy is controlled by design, no check during service life.
AUTOMATIC CONTROL SYSTEM	203.6.5	
AEC reproducibility		Tube loading and air kerma are indirectly controlled by mAs and kV accuracy. Averaged pixel value is checked in flatfield QC test (*Job Cards CHK A010 to A013*), done in planned maintenance.
AEC thickness response		
Imaging performance	203.6.7	*Job Card ELE A032 - IQST Test* *TEST MED PHY 04 - Sub-system MTF measurement*
NOMINAL FOCAL SPOT VALUE		In case of focal spot degradation over time this would be detected through IQST and ACR score test (*Job Cards ELE A032 and A034*) during planned maintenance.
DEFECTIVE DETECTOR ELEMENTS of the Integrated X-RAY IMAGE RECEPTOR		*Job Card CAL A007 - Bad pixel calibration*
Replacement of data originating from DEFECTIVE DETECTOR ELEMENTS		This essential performance is not influenced by fatigue, wear, aging and degradation.
Image homogeneity		This essential performance is checked during planned maintenance and through QC testing, *Job Cards CHK A010 to A013*
Homogeneity of intercepting layers in the X-RAY SOURCE ASSEMBLY		This essential performance is checked during planned maintenance and through Quality control testing,*Job Cards CHK A010 to A013*
Motion of the ANTI-SCATTER GRID under maximum compression force		Carbon cover above the grid is not subject to fatigue or wear over time that would impede the grid motion. In case of part damaged, Bucky is a FRU.
ARTEFACTS from grid lines		This essential performance is checked during Quality control procedure, *Job Cards CHK A010 to A013*
Maximum LOADING TIME		This essential performance is not influenced by fatigue, wear, aging and degradation.
Missed tissue at chest wall side	203.8.5.4.101	Paddle test in manufacturing If ever plate is visible, adjustment procedure exists. *Job Card ELE A015 – Paddle Border Test*
BREAST COMPRESSION DEVICE	203.8.5.4.102	
Control of compression movements		This essential performance is not influenced by fatigue, wear, aging and degradation.
Range of movement		This essential performance is not influenced by fatigue, wear, aging and degradation.
Design of compression plates		This essential performance is not influenced by fatigue, wear, aging and degradation.
Strength of compression plates		This essential performance is not influenced by fatigue, wear, aging and degradation.
Compression force		*Job Card CAL A011 - Compression Force Sensor Calibrations*

Requirement	Sub-clause	Associated job cards
Linearity of AIR KERMA over limited intervals of LOADING FACTORS	203.6.3.1.2	Air Kerma reproducibility is a consequence of high voltage and mAs accuracy, therefore this is indirectly controlled through kV and mAs accuracy.
Reproducibility of the X-RADIATION output	203.6.3.2	Tube loading and air kerma are indirectly controlled by mAs and kV accuracy. Averaged pixel value is checked in flatfield Quality Control test (*Job Cards CHK A010 to A013*), done in planned maintenance.

In case of electromagnetic field conditions different than the one tested according to the standard, obvious artefacts in the image could be observed. No impact on other essential performance has been observed in case of electromagnetic disturbances.

3.2.2 Immunity performance criteria list

(applicable for systems manufactured from 2024)

Immunity performance criteria (IEC TR 60601-4-2)	What happens if the performance is lost due to electromagnetic disturbance (refer to below Note)
System initialization at power ON	Pristina functions are not available.
Display and entry of information	Information related to system status is not available. Operator cannot use keyboard or mouse.
Data import/export	Operator cannot import/export data from/to USB key or CD/DVD.
Gantry and console reinitialization	Pristina patient positioning and X-ray image acquisition are not available.
Patient positioning	Pristina functions to position patient are not available.
Bar code scanner option	Operator cannot use barcode reader.

NOTE
If any immunity performance criterion is degraded or lost due to transient electromagnetic disturbances, the Senographe Pristina has to be shut down and then powered-up. The performance criterion will be recovered and available after the shutdown / power-up sequence.

3.2.3 Electromagnetic Emission

⚠ CAUTION

The Senographe Pristina is intended for use in the electromagnetic environment defined in this document. It is the customer's responsibility to ensure that Senographe Pristina is used in the predetermined environment.

Table 3-2 ELECTROMAGNETIC EMISSION

Emissions Test	Compliance	Electromagnetic Environment
RF emissions CISPR11	Group1	The Senographe Pristina 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 Senographe Pristina 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.

Table 3-2 ELECTROMAGNETIC EMISSION (Table continued)

Emissions Test	Compliance	Electromagnetic Environment
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

3.2.4 Electromagnetic Immunity

To maintain basic safety and essential performance regarding electromagnetic disturbances for the Expected Service Life, follow recommendations detailed in that section.

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

⚠ CAUTION

The Senographe Pristina is intended for use in the electromagnetic environment defined in this document. It is the customer's responsibility to ensure that Senographe Pristina is used in the predetermined environment.

Table 3-3 ELECTROMAGNETIC IMMUNITY - PART 1

Immunity Test	IEC 60601-1-2 Ed2.1 & 3 Test level (not LIFE-SUPPORTING)	IEC 60601-1-2 Ed 4 Test Level (professional healthcare environment)	IEC 60601-1-2 Ed 4.1 Test Level (professional healthcare environment)	IEC TR 60601-4-2 Ed 1 Test Level (professional healthcare environment)	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	±4 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be concrete. 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 at 5 kHz or 100 kHz (input power port) ±1 kV at 5 kHz or 100 kHz (Sip/sop port)	±2 kV at 100 kHz (input power port) ±1 kV at 100 kHz (Sip/sop port)	±2 kV at 100 kHz (input power port) ±1 kV at 100 kHz (Sip/sop port)	±1 kV at 5 or 100 kHz (input power port) ±.5 kV at 5 or 100 kHz (Sip/sop port)	*For systems before 2024:* ±2 kV at 5 kHz and 100 kHz (input power port) ±1 kV at 5 kHz and 100 kHz (Sip/sop port) *For systems from 2024:* ±2 kV at 100 kHz (input power port) ±1 kV at 100 kHz (Sip/sop port)	Mains power quality should be that of a typical commercial or hospital environment.

Table 3-3 ELECTROMAGNETIC IMMUNITY - PART 1 (Table continued)

Immunity Test	IEC 60601-1-2 Ed2.1 & 3 Test level (not LIFE-SUPPORTING)	IEC 60601-1-2 Ed 4 Test Level (professional healthcare environment)	IEC 60601-1-2 Ed 4.1 Test Level (professional healthcare environment)	IEC TR 60601-4-2 Ed 1 Test Level (professional healthcare environment)	Compliance Level	Electromagnetic Environment Guidance
Surge IEC 61000-4-5	±1 kV line(s) to line(s) for 0° or 180° and 90°, 270° under 2Ω ±2 kV line(s) to earth for 0° or 180° and 90°, 270° under 12Ω	±1 kV line(s) to line(s) for 0°, 90°, 180° and 270° under 2Ω ±2 kV line(s) to earth for 0°, 90°, 180° and 270° under 12Ω	±1 kV line(s) to line(s) for 0°, 90°, 180° and 270° under 2Ω ±2 kV line(s) to earth for 0°, 90°, 180° and 270° under 12Ω	±1 kV line(s) to line(s) for 0°, 90°, 180° and 270° under 2Ω ±2 kV line(s) to earth for 0°, 90°, 180° and 270° under 12Ω	±1 kV differential mode for 0°, 90°, 180° and 270° under 2Ω ±2 kV common mode for 0°, 90°, 180° and 270° under 12Ω	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 5s	<5% U_T (>95% dip in U_T) for 5s	<5% U_T (>95% dip in U_T) for 5s	<5% U_T (>95% dip in U_T) for 5s	0 Vac during 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Senographe Pristina requires continued operation during power mains interruptions, it is recommended that the Senographe Pristina be powered from an uninterruptible power supply or a battery. As the Senographe Pristina has a rated input current that exceeds 16 A per phase, it is exempt from voltage dips tests.
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	3 A/m for 50 Hz and 60 Hz	30 A/m for 50 Hz and 60 Hz	30 A/m for 50 Hz and 60 Hz	3 A/m for 50 Hz and 60 Hz	3 A/m and 30 A/m for 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-39	Not applicable	Not applicable	134.2 kHz at 65 A/m (PM 2.1kHz) 13.56MHz at 7.5 A/m (PM 50kHz)	Not applicable	*Only applicable from 2024:* 134.2 kHz at 65 A/m (PM 2.1kHz) 13.56MHz at 7.5 A/m (PM 50kHz)	Magnetic field sources such as RFID readers shall kept at least 1m from the Gantry.

NOTE
U_T is the a.c. mains voltage prior to application of the test level.

Table 3-4 ELECTROMAGNETIC IMMUNITY - PART 2

<table>
<tr><th>Immunity Test</th><th>IEC 60601-1-2 Ed2.1 & 3 Test level (not LIFE-SUPPORTING)</th><th>IEC 60601-1-2 Ed 4 and 4.1 Test Level (professional healthcare environment)</th><th>IEC TR 60601-4-2 Ed 1 Test Level (professional healthcare environment)</th><th>Compliance Level</th><th>Electromagnetic Environment Guidance</th></tr>
<tr><td rowspan="2">Conducted RF
IEC 61000-4-6</td><td>3 Vrms 150 kHz to 80 MHz</td><td>3 Vrms 150 kHz to 80 MHz</td><td rowspan="2">3 Vrms 150 kHz to 80 MHz</td><td>3 Vrms</td><td rowspan="4">Portable and mobile RF communications equipment should be used no closer to any part of the Senographe Pristina, 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 2.7 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 meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.
Interference may occur in the vicinity of equipment marked with the following symbol:
((•))</td></tr>
<tr><td>Not applicable</td><td>And 6 Vrms for the ISM bands a)</td><td>6 Vrms for ISM bands</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz - 2.5 GHz</td><td>3 V/m
80 MHz - 2.7 GHz
and refer to Test specifications for enclosure port immunity to RF wireless communications equipment (Table 3-5)</td><td>3 V/m
80 MHz - 2.7 GHz
and refer to Test specifications for enclosure port immunity to RF wireless communications equipment (Table 3-5)</td><td>[$E_{1=}$] 3 V/m
and refer to Test specifications for enclosure port immunity to RF wireless communications equipment (Table 3-5)</td></tr>
<tr><td colspan="5">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.</td></tr>
<tr><td colspan="5">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 Senographe Pristina is used exceeds the applicable RF compliance level above, the Senographe Pristina should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Senographe Pristina.</td></tr>
</table>

a) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Table 3-5 Test specifications for enclosures port immunity to RF wireless communications equipment

Test frequency (MHz)	IEC TR 60601-4-2 Ed 1 Field level (V/m)	IEC 60601-1-2 Ed 4 & 4.1 Field level (V/m)	Compliance Level (V/m)	Modulation [b]
385	6	27	27	Pulse modulation [b] 18 Hz
450	9	28	28	FM [c] ± 5 kHz deviation 1 kHz sine
710 745 780	3	9	9	Pulse modulation [b] 217 Hz
810 870 930	9	28	28	Pulse modulation [b] 18 Hz
1 720 1 845 1 970	9	28	28	Pulse modulation [b] 217 Hz
2 450	9	28	28	Pulse modulation [b] 217 Hz
5 240 5 500 5 785	6	9	9	Pulse modulation [b] 217 Hz
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.				
[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.				

3.2.5 Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2

⚠ WARNING

EMC HAZARD

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Senographe Pristina System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

This includes devices which intentionally transmit RF signals, such as cellular phones, transceivers or radio controlled products.

Table 3-6 RECOMMENDED SEPARATION DISTANCES

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150KHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 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 meters (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.

3.2.6 Use Limitation

External components:

⚠ WARNING

EMC HAZARD

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Refer to the Component Index in the Parts section of the Service Manual for a list.

This does not apply to transducers and cables sold by the manufacturer of the equipment or system as replacement parts for internal components.

3.2.7 Installation Requirements and Environmental Control

To minimize interference risks, the following requirements apply.

3.2.7.1 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.

3.2.7.2 Separated Power Supply Distribution Panel & Line

⚠ CAUTION

This Senographe Pristina system is intended for use by healthcare professionals only. The system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the system or shielding the location.

NOTE

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The Senographe Pristina 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 Pristina is used in a domestic environment (in a doctors office, for example), it must be connected to a separate AC power distribution panel and line, and it must be installed in an X-ray shielded room.

3.2.7.3 Subsystem & Accessories Power Supply Distribution

All components, accessories, subsystems, and systems which are electrically connected to the Senographe Pristina 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.To avoid interference, all components and accessories connected to the Senographe Pristina must be connected to the same AC power distribution panel. This AC power distribution panel which is itself supplied by a single power line.

3.2.7.4 Stacked Components & Equipment

⚠ WARNING

EMC HAZARD

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Chapter 4 Environmental Requirements

4.1 Operating and non-operating requirements

The Operating and non-operating environment must adhere to the parameters listed below:

NOTE
Non-operating is when the system is switched off in the examination room.

	Atmospheric pressure		Altitude (from sea level)	
	Min.	Max.	Min.	Max.
	700 hPa	1060 hPa	0 m (0 ft)	3000 m (9840 ft)
	Relative humidity (non-condensing)		Temperature	
	Min.	Max.	Min.	Max.
Operating	10%	80%	15°C (59°F)	30°C (86°F)
Non-operating	10%	95%	-5°C (-23°F)	40°C (104°F)

Air conditioning must be provided where necessary to ensure that no part of the equipment operates in an ambient temperature exceeding 30°C (86°F).

NOTE
The digital detector is a very fragile and highly sensitive piece of equipment. Take care never to leave the detector without the Bucky or the detector protective cover installed.

4.2 Preventing Thermal Shock to the Detector

To prevent thermal shock to the detector, the ambient temperature must remain between -5 °C (23 °F) and 40 °C (104 °F), at a max rate of 15 °C (59 °F) per hour between a pressure range of 500-1060 hPa.

The temperature and humidity ranges for the detector when not in use are as follows:

- ambient temperature must remain between -5°C to 40°C (23°F to 104°F), at a max rate of 15 °C (59 °F) per hour between a pressure range of 500-1060 hPa.
- relative humidity 10% to 95%, non-condensing.

4.3 Heat Output

The heat output of the system (including all options) is at most 814W (2777 BTU/hr) (Control Station 210 W (716 BTU/hr) + Gantry 604 W (2061 BTU/hr)).

The heat dissipation of the system in standby mode is 360 W (1228 BTU/hr) (Control Station 200 W (682 BTU/hr) + Gantry 160 W (546 BTU/hr)).

4.4 Noise

Gantry: 46 dBA at 1m

Control Station: 30.1 dBA at 1m

4.5 Lighting

To obtain a room brightness value of 100 lux or less for correct viewing of monitor images, the room lights must be equipped with a dimmer switch. Shades and/or drapes must be fitted to windows.

Chapter 5 Electrical Requirements

5.1 Certified Electrical Contractor Statement

NOTICE

All electrical installations that are preliminary to positioning of the equipment at the site prepared for the equipment must be performed by licensed electrical contractors. In addition, electrical feeds into the Power Distribution Unit must be performed by licensed electrical contractors. Other connections between pieces of electrical equipment, calibrations, and testing must be performed by qualified GE HealthCare personnel. The products involved (and the accompanying electrical installations) are highly sophisticated, and special engineering competence is required. In performing all electrical work on these products, GE HealthCare will use its own specially trained Field Engineers. All of GE HealthCare electrical work on these products will comply with the requirements of the applicable electrical codes.

The purchaser of GE HealthCare equipment must only utilize qualified personnel to perform electrical servicing on the equipment. That is GE HealthCare Field Engineers, personnel of third-party service companies with equivalent training, or licensed electricians.

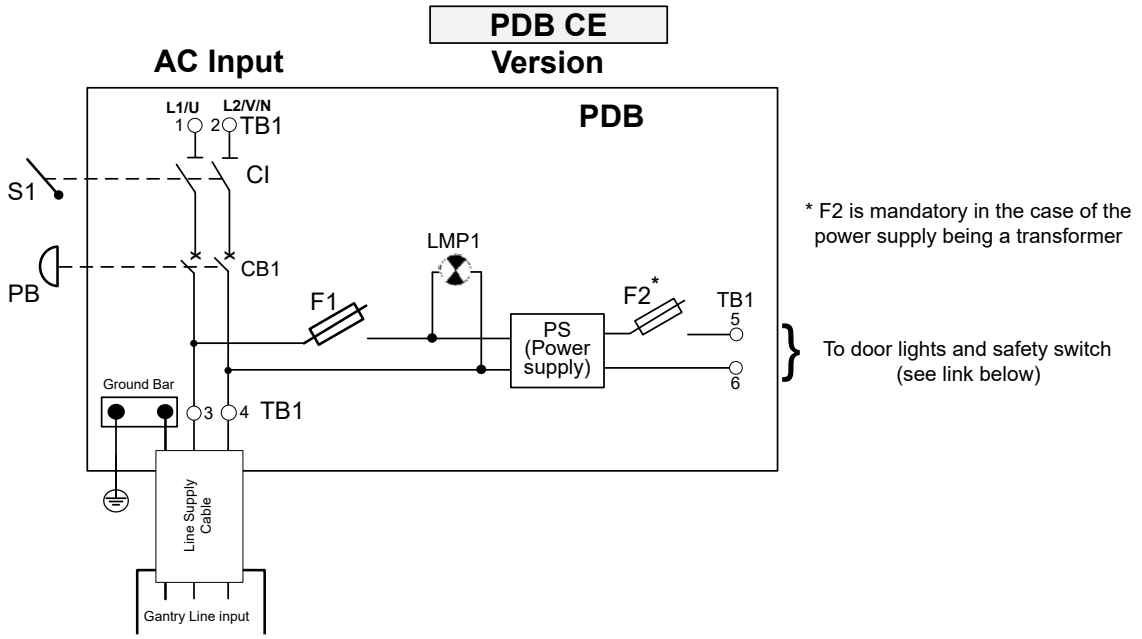
5.2 Room Power Supply

NOTICE

Line power to the Senographe Pristina must be supplied through a suitable circuit breaker (see section 5.8 Circuit Breaker and Circuit Isolator on page 80). The circuit breaker must be accessible to allow it to be opened rapidly in case of emergency. An indicator light must be provided to indicate that power is present.

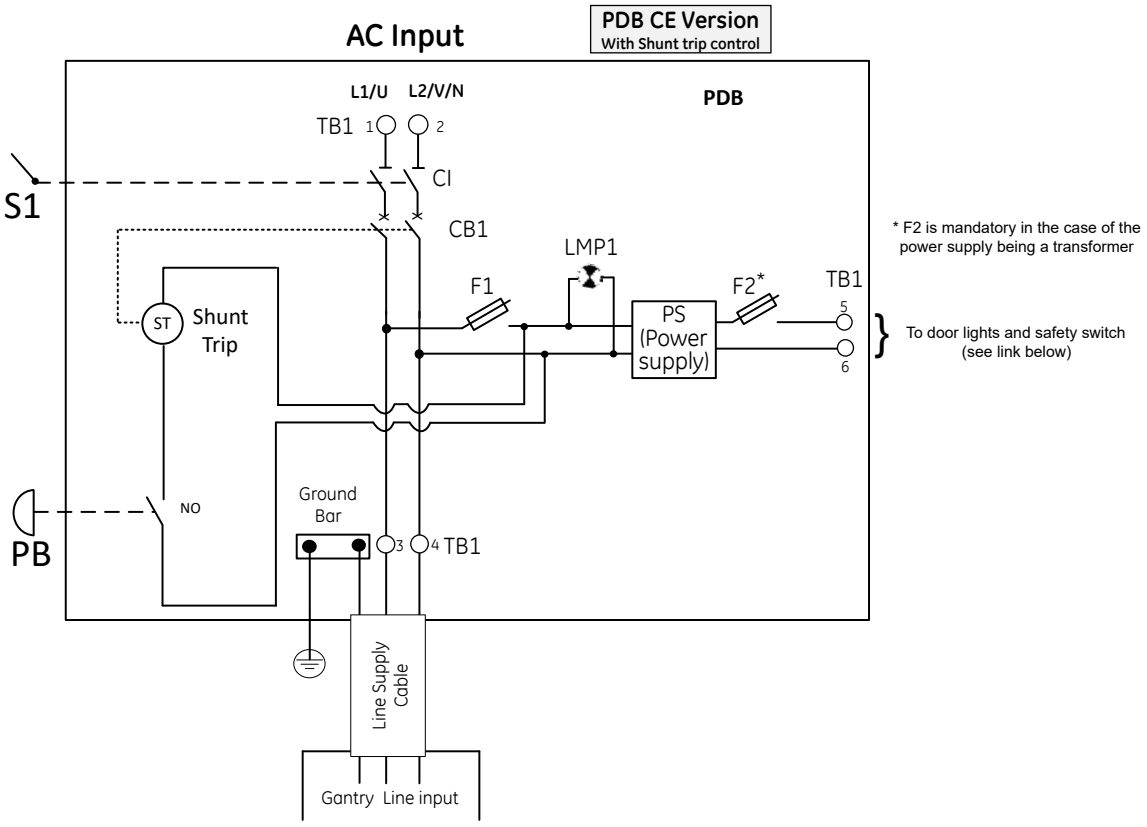
The diagrams (Figure 5-1 PREFERRED ROOM POWER SUPPLY SCHEMATICS FOR CE VERSION on page 76 to Figure 5-4 PREFERRED ROOM POWER SUPPLY WITH SHUNT TRIP CONTROL SCHEMATICS FOR UL VERSION on page 77) given here outline a suitable supply system and indicate items to be provided and installed by the customer electrician. These diagrams are separated by region (CE or UL) and whether or not shunt trip control is present. Refer to the following sections for more information.

Figure 5-1 PREFERRED ROOM POWER SUPPLY SCHEMATICS FOR CE VERSION



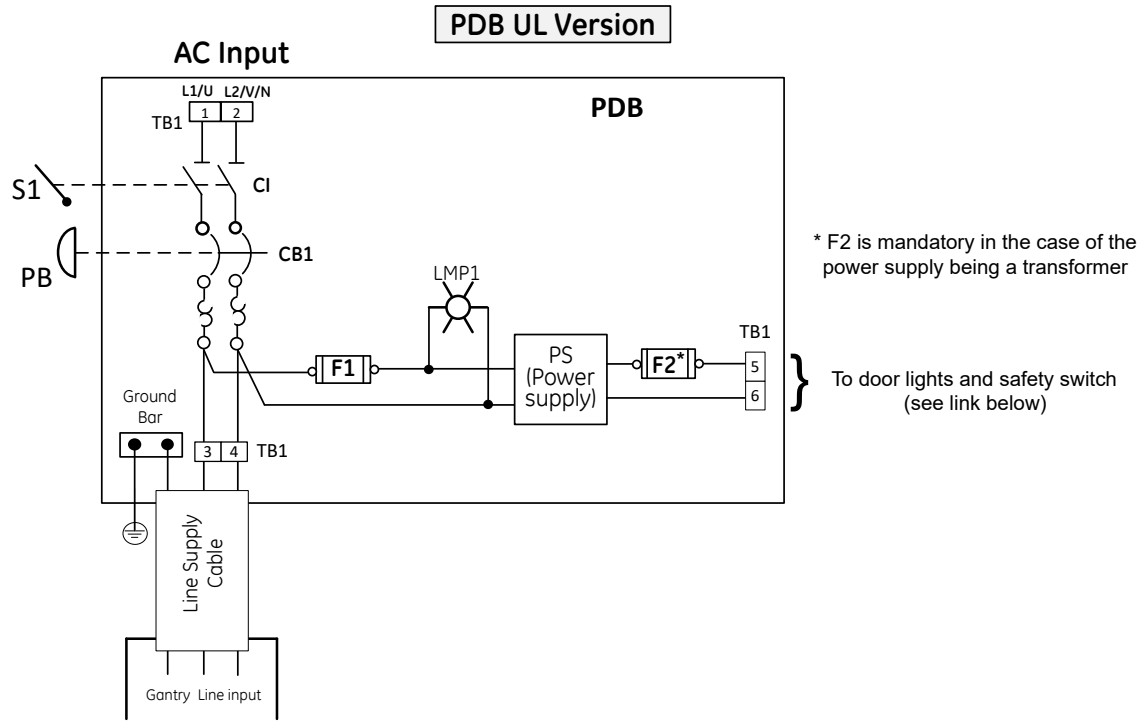
For door lights and safety switch, see section 5.9 Door lights and safety switch on page 81

Figure 5-2 PREFERRED ROOM POWER SUPPLY WITH SHUNT TRIP CONTROL SCHEMATICS FOR CE VERSION



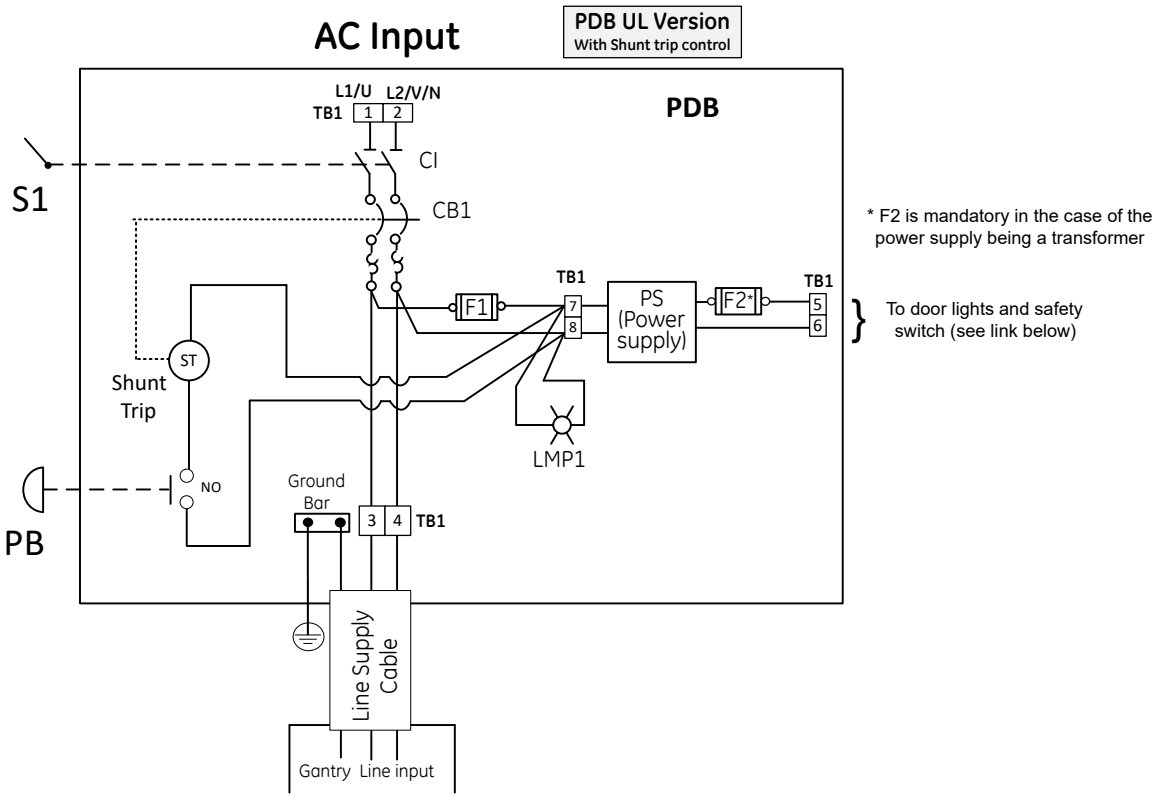
For door lights and safety switch, see section 5.9 Door lights and safety switch on page 81

Figure 5-3 PREFERRED ROOM POWER SUPPLY SCHEMATICS FOR UL VERSION



For door lights and safety switch, see section 5.9 Door lights and safety switch on page 81

Figure 5-4 PREFERRED ROOM POWER SUPPLY WITH SHUNT TRIP CONTROL SCHEMATICS FOR UL VERSION



For door lights and safety switch, see section 5.9 Door lights and safety switch on page 81

Legend for diagrams:

- PDB: Power distribution box:
  The PDB supplies AC power to the Senographe Pristina equipment, and must be functional within the following input ranges depending on the any of the input voltage / frequency availability at hospital mains as given below:
  - Voltage range: 200-240V AC ±10% (Line to Line or Line to Neutral).
  - Frequency range: 50 Hz or 60 Hz (±3 Hz).
    The PDB must have a power presence indicator light L1 per local regulation, and the voltage rating must be adapted to the input main supply voltage.
- CB1: Circuit Breaker 1
- CI: Circuit Isolator
- S1: Switch 1: Control switch to operate the circuit isolator.
- ST: Shunt Trip.
- TB1: Terminal Block 1.
- PB: Push Button: ON/OFF impulse push button.
- L1: Line 1
- L2: Line 2
- LMP1: power presence indicator light.
- PS: Power supply:
  - If room lamps and a door switch are used:
    Isolated 24V AC transformer compliant with local electrical regulations, protected from downstream over-current (5A max, to protect PDU board relays K1, K2 and K3). The protection can come as a separate fuse or as built-in over-current protection.
  - If only room lamps are used:
    Power supply with max. output voltage 30V AC or DC, protected from downstream over-current (5A max, to protect PDU board relays K1, K2 and K3). The protection can come as a separate fuse or as built-in over-current protection.
- F: Fuse. - There are 2 fuses, F1 and F2, with the following requirements:
  Fuse F1 requirements:
  - Fuse current rating must be based on the current drawn Power presence indicator light L1 and power supply PS.
  - Fuse voltage rating must be adapted to input the mains supply voltage.

  Fuse F2 requirements (mandatory if the power supply is a transformer):
  - Fuse current rating must be 5A max.
  - Fuse voltage rating must be:
    - 24V AC if room lamps and a door switch are used.
    - 30V AC or DC if only room lamps are used.
- Line Supply Cable (see 5.7 Line Supply Cable on page 80).

⚠ WARNING

The Line Supply Cable from the Gantry must be internally and permanently connected to the hospital power distribution box, and cannot be externally connected to the power distribution box via a plug. The internal and permanent connection must be made in such a way that the Line Supply Cable can only be disconnected by use of a tool.

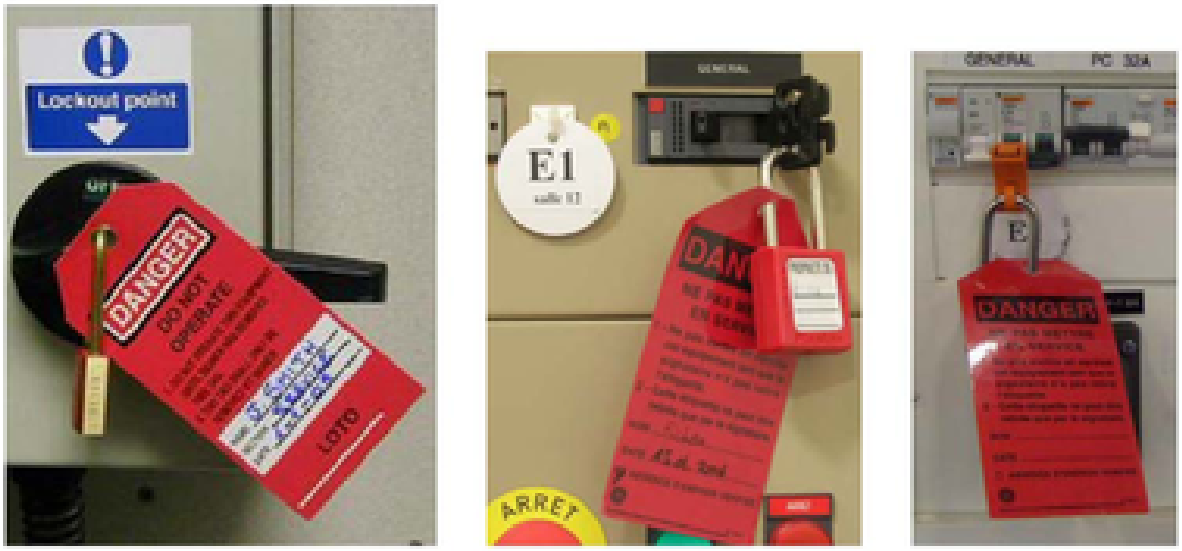
5.2.1 Lockable LOTO Enabled Power Sources

Lockable LOTO enabled power sources must be made available to the following:

- the S1 switch.
- the Status Lamps power cables going from the room door to the Gantry.

Examples of LOTO enabled lockable power sources include those with lockable disconnecting switches (see example 1 and example 2 in Figure 5-5 EXAMPLES OF LOCKABLE LOTO ENABLED POWER SOURCES on page 79), or lockable breakers (see example 3 in Figure 5-5 EXAMPLES OF LOCKABLE LOTO ENABLED POWER SOURCES on page 79).

Figure 5-5 EXAMPLES OF LOCKABLE LOTO ENABLED POWER SOURCES



Example 1 Example 2 Example 3

NOTE
If the customer cannot provide lockable breakers that use padlocks as shown in Figure 5-5 EXAMPLES OF LOCKABLE LOTO ENABLED POWER SOURCES on page 79, they must provide a lockable breaker using another type of locking device, and make that locking device available to the Field Engineer when they service the system.

5.3 Line Voltage Specifications

- Single phase input voltages (phase/neutral or phase/phase): 200-240 VAC (±10%).
- Maximum momentary line current of the system: 27 A at 170V AC, based on maximum tube peak power (3 kW).
  The maximum line current corresponds to the use of the technique factors 30 kV, Mo track, large focal spot and 100 mAs or more (up to 560 mAs).

- Long time line current rating (considering the mean current consumption during the period of an exam): 7 A at 170V AC, based on the following worse case exam conditions:
  - 10% time in acquisition at max tube power (equivalent to 300 W mean tube power over the exam).
  - 40% time in standby mode (system ready for acquisition).
  - 50% time in patient positioning (Gantry motions).

5.4 Line Frequency Specifications

- 50 Hz or 60 Hz (± 3 Hz).

5.5 kVA Load Characteristics

- Maximum power in standby: 1.2 kVA.
- Maximum instantaneous power (during exposures) 4.6 kVA.
- Power factor: greater than 0.9 during an exposure at maximum power.

5.6 Line Impedance

The apparent resistance of the mains supply R_L must be less than that which would cause a voltage drop of 6% at the maximum power load of 4.6 kVA. Refer to the table below for relevant values:

Assigned voltage	200	208	220	230	240
Allowed ± 10% voltage range	180 - 220	187 - 229	198 - 242	207 - 253	216 - 264
Maximum resistance R_L (ohms) (6% drop for 4.6 kVA)	0.40	0.43	0.48	0.53	0.57

5.7 Line Supply Cable

The electrical cables going from the power distribution box to the system (phase, neutral and protective earth) must have a cross-sectional area between 4 mm^2 (AWG10) and 16 mm^2 (AWG6), and comply with local regulations. Protecting the system's connection to the electrical network is the hospital's responsibility.

The replacement of this cable is not the responsibility of GE HealthCare Service personnel.

5.8 Circuit Breaker and Circuit Isolator

NOTE
One device can serve as circuit breaker and circuit isolator provided it meets all the requirements below in 5.8.1 Circuit Breaker Requirements on page 80 and 5.8.2 Circuit Isolator Requirements on page 81.

5.8.1 Circuit Breaker Requirements

A circuit breaker must be fitted to protect the Senographe Pristina (and no other equipment), and must meet the following requirements:

- Current Rating of circuit breaker must be 30 A or 32 A.
- Voltage rating of circuit breaker must be adapted to input main supply voltage.

- Frequency rating of circuit breaker must be adapted to input line frequency i.e., 50 Hz or 60 Hz (±3 Hz).
- Breaking capacity of circuit breaker must be adapted to upstream input line breaking capacity.
- Circuit breaker must be compliant to local regulation.
- Type of circuit breaker must be curve C or D.
- Circuit breaker must have ground fault circuit interrupter of 30 mA unless local regulation is in contradiction with the requirement.
- Circuit breaker must open all poles simultaneously when tripped / opened.

Emergency Power Off (EPO) requirements for the circuit breaker:

- Circuit breaker must have shunt trip capability for emergency power-off.
- PDB door must have an emergency power-off push button (PB).
- When the emergency power-off push button (PB) is pressed, the shunt trip must open all contacts of the Circuit breaker.
- The emergency power-off push button (PB) shall have an indicator light complying with local regulations.
- The ON/OFF switch (S1) and emergency power-off button (PB) can be relocated to a nearby wall as per local regulations.

5.8.2 Circuit Isolator Requirements

A circuit isolator must be fitted to protect the Senographe Pristina (and no other equipment), and must meet the following requirements:

- Circuit Isolator must have rated Impulse Withstand Voltage (Uimp): 4 kV.
- Circuit Isolator must have control switch (S1) on PDB door to operate.
- Control switch (S1) must have provision for lockout / tagout (LOTO) (see 5.2.1 Lockable LOTO Enabled Power Sources on page 79).
- Circuit Isolator must open all poles simultaneously when control switch (S1) is turned OFF.
- The direction of movement of the actuator (S1) shall comply with IEC 60447 (The OFF to ON direction must be left to right, bottom to top or clockwise).

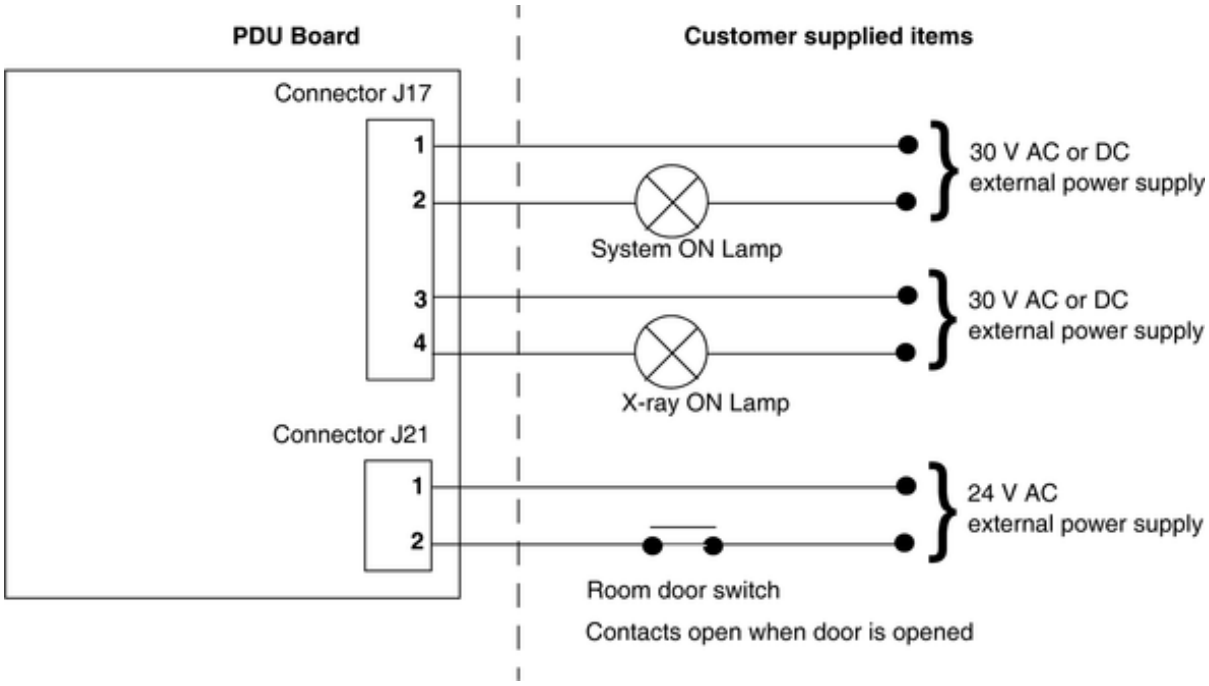
5.9 Door lights and safety switch

To meet safety and regulatory requirements, access to rooms in which X-ray equipment is installed may be controlled by warning lights (System ON and X-ray ON) and by safety switches (room door switch).

The Gantry PDU Board provides facilities to meet these requirements. The diagram below shows the circuits used, and indicates items required for supply by the customer.

If room door switch is not used on site, it is recommended to use 24V DC to power the warning lights.

If using AC with timed relay, take into account leakage current from the PDU which may activate permanently the timed relay controlling the X-ray ON lamp.



For more information about the room door and light supply, see 5.2 Room Power Supply on page 75.

Chapter 6 Communication Requirements

6.1 Insite connection

For Remote Service Connectivity, Senographe Pristina system must be allowed to send data via the customer network, through the customer firewall to the GE HealthCare Remote Server via the Internet.

To make the system Remote Service Connectivity operational before the system installation is finished, ensure the connectivity solution is defined as early as possible during the pre-installation process and proper information are exchanged between the customer Network Administrators and GEHC Sales and/or Service representatives.

- The customer needs to allow outbound TCP traffic on Port 443 (https protocol) to the internet and to provide a DNS IP.
- If a proxy is required to reach the Internet, customer IT shall provide Proxy IP and port + proxy username and password if Proxy requires authentication.
- Customer security network environment (firewall) configuration should allow SSL/TSL (HTTPS) Protocol and whitelist GE HealthCare Server URLs:
  For Global (US):
  - https://insite.gehealthcare.com:443
  - https://as1-insite.gehealthcare.com:443
  - https://as2-insite.gehealthcare.com:443
  - https://download.flexnetoperations.com:443
  - https://gehealthcare-ns.flexnetoperations.com:443

  For Europe:
  - https://insite-eu.gehealthcare.com:443
  - https://as1-insite-eu.gehealthcare.com:443
  - https://download.flexnetoperations.com:443
  - https://gehealthcare-ns.flexnetoperations.com:443

  For China:
  - https://insite.gehealthcare.cn:443
  - https://as1-insite-cn.health.ge.com:443
  - https://as2-insite-cn.health.ge.com:443
  - https://download.flexnetoperations.com:443
  - https://gehealthcare-ns.flexnetoperations.com:443

6.2 Networking connections and broadband access

- The Senographe Pristina system must be connected to the hospital Ethernet network via the acquisition computer within the Control Station to exchange data with other medical

equipment (network hosts) on the hospital network. Typical medical equipment (network hosts) usually connected to the Senographe Pristina system include:

- Worklist providers (HIS or RIS).
- Mass archiver (Storage or PACS).
- Review stations (i.e. GE SenoIris).
- CAD (Computer Aided Detection).
- Network transfer systems (i.e. DICOM Shuttle).
- Printers.

- Before installation, the following information must be obtained for each network host so that it can be declared in the acquisition computer:
  - IP address for the network host.
  - Host name.
  - Port Number.
  - Application Entity Title (AET).
  - Subnet mask.

  The hospital network administrator usually supplies this information.
- The customer must provide an RJ-45 Ethernet cable (CAT 5 or higher) of a sufficient length so that it can be easily run from the acquisition computer within the Control Station to the Ethernet wall outlet connected to the hospital network.
- Before installation, so that the acquisition computer within the Control Station can communicate with the hospital network, the following information must be obtained:
  - An IP address assigned to the acquisition computer.
  - A IP address of the hospital Gateway.
  - A Subnet mask.
  - If additional routers and/or static routes are used by the hospital, those must also be provided.

  The hospital network administrator usually supplies this information.

Attention is drawn to the following:

- connection of Senographe Pristina to the hospital network that includes other equipment could result in previously unidentified risks to patients, operators or third parties.
- the Customer must identify, analyze, evaluate and control these risks.
- subsequent changes to the hospital network could introduce new risks and require additional analysis.
- changes to the hospital network, including:
  - changes in hospital network configuration.
  - connection of additional items to the hospital network.
  - disconnecting items from the hospital network.
  - update of equipment connected to the hospital network.
  - upgrade of equipment connected to the hospital network.
- character decoding compatibility:
  The Senographe Pristina is supporting only the specific character set ISO_IR 100 (Latin alphabet No. 1). Any information received from a remote system will be decoded with this character set, even if the remote system is using a different one. As such it is recommended

for a RIS providing a worklist to the Senographe Pristina to be configured to use the ISO_IR 100 (Latin alphabet No. 1) character set. If the RIS is using a different character set, then the received worklist information may be either incorrectly decoded or refused by the Senographe Pristina.

In case of error in network/data coupling, risks are the following:

- Measurement errors.
- Patient mismatch.
- Annotations error
- Image quality degraded

6.2.1 Specific networking connections

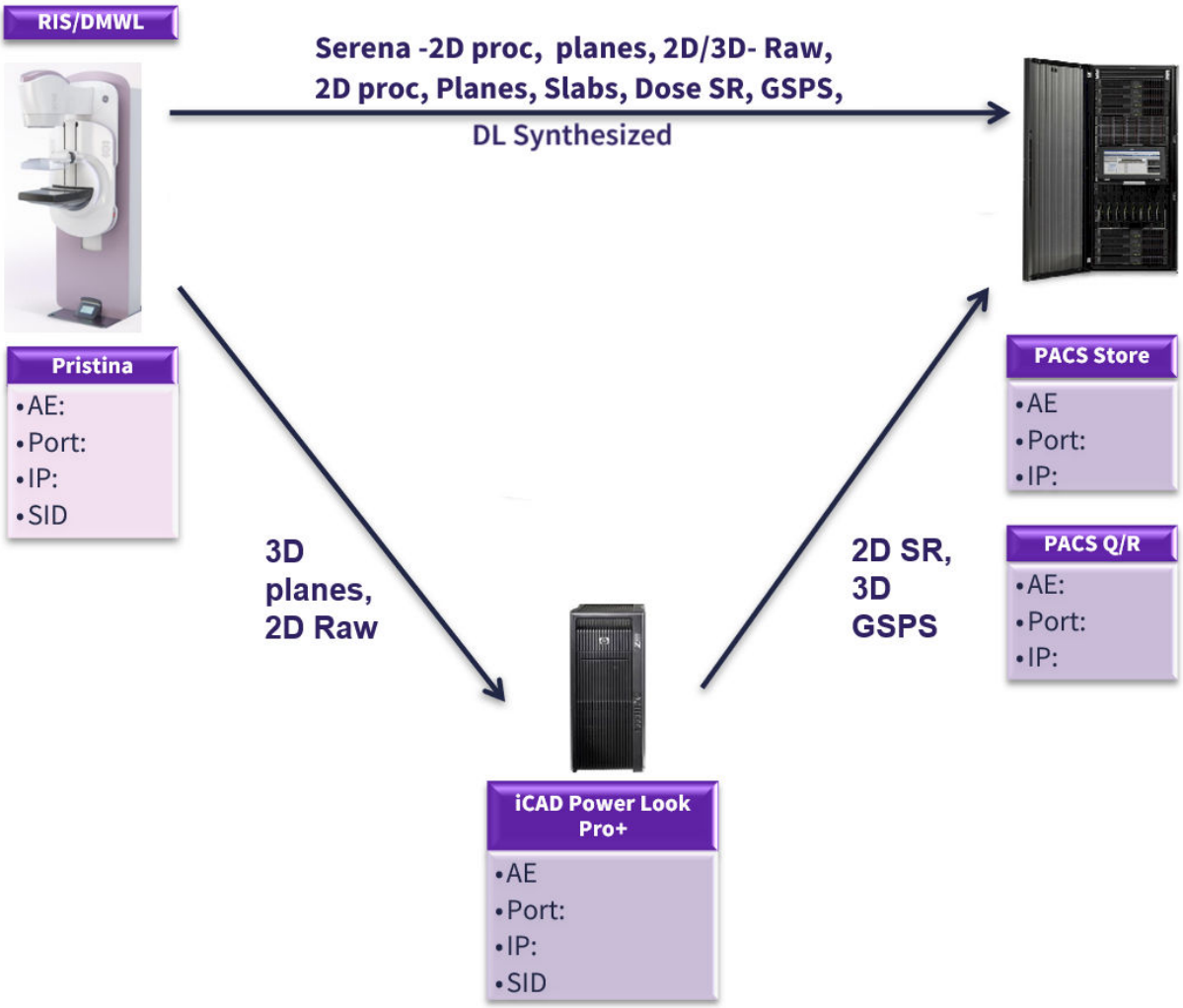
The client should provide a Gigabit Ethernet compatible connection to the network in order to benefit from the optimal performance of:

- the Senographe Pristina 3D option
- the priors feature (from Pristina 9)

Other networking requirements remain the same as those described in 6.2 Networking connections and broadband access on page 83.

6.2.2 Workflow map

Figure 6-1 Example of workflow map



NOTE
Minimum recommendation for LAN/WAN speed is 1G for DBT.

6.2.3 Installation checklist

FACILITY INFORMATION						
DESCRIPTION	SITE NAME	STREET ADDRESS	CITY	STATE	ZIP CODE	
MAIN FACILITY						
SATELLITE FACILITY 1 (IF APPLICABLE)						
SATELLITE FACILITY 2 (IF APPLICABLE)						

WORKFLOW END TO END TESTING CONTACTS						
ROLE	NAME	PHONE	EMAIL			
MAMMO DEPT CONTACT						
IT & NETWORKING						
PACS ADMIN						
LEAD TECH or RIS ADMIN						
HANGING PROTOCOLS (RADIOLOGIST or PACS ADMIN)						
ICAD						
THIRD PARTY INTEGRATION (IF NEEDED)						
GON#	FIELD ENGINEER			PHONE #		

NETWORK INFRASTRUCTURE							
DEVICE	DESCRIPTION	PHYSICAL LOCATION	SYSTEM ID (IF APPLICABLE)	AE TITLE	IP ADDRESS	PORT	SUB NET MASK
PACS - DICOM STORE (PACS)							
PACS - DICOM QUERY / RETRIEVE							
WORKLIST PROVIDER							
PRINTER (IF NEEDED)							
CAD							
OTHER							
DEFAULT NETWORK GATEWAY IP							
NTP SERVER IP							

MAMMO IMAGING EQUIPMENT							
DEVICE	DESCRIPTION	PHYSICAL LOCATION	CRM Number / System ID	IP ADDRESS	AE TITLE	PORT	SUB NET MASK
MAMMO SYSTEM 1	Seno Pristina		GEHC TO PROVIDE			4006	
SENOIRIS CONNECT 1	Senolris Connect		GEHC TO PROVIDE			104	
SENOIRIS REVIEW	Senolris Review		GEHC TO PROVIDE			104	

Remote Service Connectivity			
DNS	DNS 1 IP:	DNS 2 IP:	
Proxy (if applicable)	Proxy IP:		
	Proxy Port:		
	Proxy Username:		
	Proxy password:		
GE HealthCare URL to be white-listed	(Global) https://insite.gehealthcare.com:443 https://as1-insite.gehealthcare.com:443 https://as2-insite.gehealthcare.com:443 https://download.flexnetoperations.com:443 https://gehealthcare-ns.flexnetoperations.com:443	(Europe) https://insite-eu.gehealthcare.com:443 https://as1-insite-eu.gehealthcare.com:443 https://download.flexnetoperations.com:443 https://gehealthcare-ns.flexnetoperations.com:443	
TCP PORTS TO KEEP OPEN			
1. 104 DICOM storage			
2. 4005 DICOM worklist			
3. 8080 Support interface			
4. 5900 VNC, Remote Desktop Tool			
5. 3389 RDP, Remote Desktop Protocol			
6. 9090 Internal remote control server (not configurable)			
7. 59717 Internal cache message server (not configurable)			
8. 27778 Postgres SQL			
9. 27777 Remote Control Registry			

6.3 Malicious software protection

The Senographe Pristina system needs to be configured and maintained in a way that continually protects Privacy & Security.

The computing environment is increasingly hostile, and threats continue to grow from malicious software, including computer viruses, worms, Trojan horses, denial of service attacks, and other malware. Vigilant defense on many levels is required to keep systems free from compromise by malicious software. In most cases, effective protection requires cooperation and partnership between GE HealthCare and our customers.

Commercial AntiVirus software is commonly used on general-purpose computers to detect the presence of malicious software (virus, Trojan horse, worm, etc.). AntiVirus software is useful on general-purpose computers as they typically cannot be sufficiently hardened against the attack vectors used by malicious software. Medical Devices however are single purpose (dedicated) devices that have controlled intended use, and thus often can be well hardened. For medical devices, the patient safety risk introduced by using commercial AntiVirus software need to be carefully considered. Such risks include:

- Real-time scanning affecting system performance.
- Introducing false positives.
- Quarantining of clinical data that randomly appear to match a virus signature.
- The AntiVirus software itself is another popular attack vector.
- Support of the AntiVirus software throughout the life cycle of the medical device (Operating System support and virus signatures/libraries).

The Senographe Pristina system comes pre-configured with the latest virus definition files available at the time of product packaging. However, new updates to the virus definition files are made available daily or even more frequently. It is highly recommended that the system is updated to include the latest virus definition files. The hospital should have McAfee® ePolicy Orchestrator installed on their network that can be used to update the system to the latest virus definition files.

NOTICE

Senographe Pristina comes pre-installed with McAfee® VirusScan Enterprise for Linux. This is the only supported AntiVirus software that has been validated for use with this system. The system has been validated for correct operation with the pre-installed version of McAfee® VirusScan Enterprise for Linux. McAfee® ePolicy Orchestrator should be configured to not update the VirusScan software on the system.

The procedure for configuring the McAfee® ePolicy Orchestrator on the system is described in the Service Manual.

Configuration of the McAfee® ePolicy Orchestrator is performed at installation time, before installation of Senographe Pristina options. Confirm with customer:

- the McAfee® ePolicy Orchestrator server availability.
- hospital IT representative allowing configuring Senographe Pristina system at installation time availability.

6.4 Specific network requirements for Senographe Pristina 3D

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

The Senographe Pristina 3D option implements this format.

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

Therefore, integrating the Senographe Pristina 3D option to an existing workflow implies to check:

- the **DICOM compatibility** of other systems (PACs) (See section 6.5 PACS Compatibility on page 91)
- the **storage capacity** corresponds to the Tomosynthesis intended use (See section 6.4.1 Storage Capacity on page 91)
- the **networking** on site corresponds to the Tomosynthesis intended use (See section 6.2.1 Specific networking connections on page 85)

Contact a GE HealthCare representative for further information and guidance on DICOM object generation and its storage.

6.4.1 Storage Capacity

A GE HealthCare 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.

Synchronize the Senographe Pristina 3D option installation to the data storage capacity upgrade when applicable.

6.5 PACS Compatibility

PACS Compatibility with Senographe Pristina 3D

Before the Senographe Pristina 3D installation, make sure that the PACS (and/or other storage devices on site) are able to store DICOM Breast Tomosynthesis Objects (BTO).

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 syntaxes:

Up to M3-3 UP1:

- 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)

From M3-3 UP2:

- Lossless JPEG-LS 1.2.840.10008.1.2.4.80 (new)
- Lossless JPEG2000 1.2.840.10008.1.2.4.90 (new)
- Lossless JPEG Compression - 1.2.840.10008.1.2.4.70

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

The PACS (and/or other storage devices on site) BTO compatibility can be tested from the GESenoIris workstation, by loading BTO test objects to the workstation and then pushing them from it to the PACS (and/or other storage devices on site).

Typical compressions ratio for DBT volumes are:

- between 2 and 2.5 for JPEG standard
- between 3.5 and 4 for JPEG-LS and JPEG2000
- about 0.1 better for JPEG-LS than JPEG2000

DICOM Storage as SCP for Senographe Pristina (only from Pristina 9)

If priors query/retrieve is expected to be used on Senographe Pristina, check the PACS will allow query/retrieve.

All workflow actors (such as PACS, archiver, review stations…) that will send prior images to Senographe Pristina must comply with at least one of the following proposed transfer syntaxes:

- Lossless JPEG Compression - 1.2.840.10008.1.2.4.70
- Explicit VR Little Endian - 1.2.840.10008.1.2.1
- Explicit VR Big Endian - 1.2.840.10008.1.2.2
- Implicit VR Little Endian - 1.2.840.10008.1.2

6.6 Associated Review Workstations

The GE SenoIris release is the only review workstation that is compatible with the Senographe Pristina system.

The Senographe Pristina 3D option requires a review workstation compatible with DICOM Digital Breast Tomosynthesis images to display the reconstructed 3D objects.

The GE SenoIris release is compatible with this DICOM format.

> **NOTE**
> Before installing Senographe Pristina and the Senographe Pristina 3D option, ensure that customer's workstation SenoIris is installed. The review workstation at version 4.7.0 and lower is not compatible with Senographe Pristina nor with the Senographe Pristina 3D option. If the customer's review workstation system needs upgrading to SenoIris, it can take several weeks to receive the upgrade software. In scenarios where the customer's review workstation needs upgrading to SenoIris, ensure that you plan enough time to install SenoIris on the review workstation and if needed the Senographe Pristina 3D option after the upgrade of the review workstation system.

Planning information for the SenoIris review workstation can be found in the SenoIris Pre-Installation Manual.

SenoIris is compatible with DICOM Digital Breast Tomosynthesis images coming from the previous GE Breast Tomosynthesis system SenoClaire.

6.6.1 Job Card PRE A002 - Third-Party Review Workstation Compatibility Checks

Table 6-1 SUPPLIES

Two or three USB flash memory devices formatted with FAT32 filing system and with at least 380 MBytes of free space or two blank CD-Rs.

Table 6-2 REQUIRED EFFORT

Personnel: 1 Field Engineer or Pre-Installation Specialist

Time: 30 minutes offsite, and 1 hour on customer site

Table 6-3 SAFETY PRECAUTIONS

None.

6.6.1.1 Overview

Due to their incompatibility with DICOM standards, some third-party review stations are not able to properly display the images created by the Senographe Pristina system or Senographe Pristina 3D option. These incompatibilities are categorized as follows:

- Sigmoid LUT related images
  Third party review workstations that are used to review images from the Senographe Pristina system or Senographe Pristina 3D option must be able to support the Sigmoid look up table (LUT) on their display. If they do not support the Sigmoid LUT, then the Linear LUT mode shall be activated on the Senographe Pristina system (see *Job Card ELE A054 - Linear LUT Configuration on the Senographe Pristina Service Manual*).
- Orientation and annotations
  Third-party review workstations that are used to review images from the Senographe Pristina system or Senographe Pristina 3D option must be able to correctly show the annotations and portray the correct orientation on their display. Images from the Senographe Pristina system or Senographe Pristina 3D option must not be reviewed on review stations that do not correctly show the annotations and/or portray the correct orientation.

Before performing a Senographe Pristina system or Senographe Pristina 3D option installation on-site, it is recommended to obtain the test images used for both the categories of incompatibility, and run a compatibility test on-site with the customer's third-party review workstation.

First, you must obtain the test images and put them on an appropriate media that is compatible with the customer's third-party review workstation (see 6.6.1.2 Obtaining the Test Images and Creating Test Media on page 93). Then, you must use those test images on the customer site to run the compatibility test (see 6.6.1.3 Running the Third-Party Review Station Compatibility Tests on page 96).

6.6.1.2 Obtaining the Test Images and Creating Test Media

Depending on the media capability customer's review workstation, use either 6.6.1.2.1 Create USB Test Media on page 94 or 6.6.1.2.2 Create CD-R Test Media on page 95 to create appropriate test media.

NOTE
For flexibility when going on customer site, it is recommended to create both a USB based and CD-R based test media. That way you have both test media types available, and can use the appropriate test media on review workstations without the prior knowledge of their media capabilities.

6.6.1.2.1 Create USB Test Media

NOTE
Use two separate USB flash memory devices for each test type (or three if 3D option is enabled). If you only have one USB flash memory device available, then you must erase its content each time before creating the Sigmoid LUT test media or Annotations and Orientation test media. If you attempt to create both the Sigmoid LUT test media or Annotations and Orientation test media on the same USB flash memory device, the test will fail.

1. Obtain the Test Images:
   a. Contact your service representative to get the test pattern images.
   b. Download **Pristina_Sigmoid.zip**, **2D_Pristina_annotations.zip** and 3D images (**3D_Pristina_annotations.zip** or **3D_ReconDL_It10_Pristina_Annotations.zip** depending on the system version tested/installed) if 3D option is enabled on your system, onto your laptop.

      The **Pristina_Sigmoid.zip** file size is approximately 990 kBytes (It contains both 2D and 3D sigmoid images).

      The **2D_Pristina_annotations.zip** file size is approximately 10 MBytes.

      The **3D_Pristina_annotations.zip** file size is approximately 126 MBytes.

      The **3D_ReconDL_It10_Pristina_Annotations.zip** file size is approximately 712 MBytes.
2. Decompress the **Pristina_Sigmoid.zip** file on your laptop.

   The decompressed files from the **Pristina_Sigmoid.zip** file will be used to create the Sigmoid LUT test media. It contains both 2D and 3D sigmoid images.
3. Decompress the **2D_Pristina_annotations.zip** file on your laptop.

   The decompressed files from the **2D_Pristina_annotations.zip** file will be used to create the Annotations and Orientation test media.
4. If needed, decompress the **3D_Pristina_annotations.zip** or **3D_ReconDL_It10_Pristina_Annotations.zip** file on your laptop.

   The decompressed files from the 3D images file will be used to create the Annotations and Orientation test media.
5. Use the following steps to create a Sigmoid LUT test media on a USB flash memory device:
   a. Label the USB flash memory device assigned for the Sigmoid LUT tests with "Sigmoid".
   b. Insert the USB flash memory device assigned for the Sigmoid test images in your laptop.
   c. If necessary, format the USB flash memory device with a FAT32 file system.
   d. Copy all the files from the decompressed **Pristina_Sigmoid.zip** file to the root of a USB flash memory device.
   e. Once the copy has completed, safely eject the USB flash memory device.
6. Use the following steps to create a 2D Annotations and Orientation test media on a USB flash memory device:
   a. Label the USB flash memory device assigned for the Annotations and Orientations tests with "A and O".
   b. Insert the USB flash memory device assigned for the Annotations and Orientations test images in your laptop.
   c. If necessary, format the USB flash memory device with a FAT32 file system.

d. Copy all the files from the decompressed **2D_Pristina_annotations.zip** file to the root of a USB flash memory device.

e. Once the copy has completed, safely eject the USB flash memory device.

7. If needed, use the following steps to create a 3D Annotations and Orientation test media on a USB flash memory device:

a. Label the USB flash memory device assigned for the Annotations and Orientations tests with "A and O".

b. Insert the USB flash memory device assigned for the Annotations and Orientations test images in your laptop.

c. If necessary, format the USB flash memory device with a FAT32 file system.

d. Copy all the files from the decompressed 3D images (**3D_Pristina_annotations.zip** or **3D_ReconDL_It10_Pristina_Annotations.zip**) file to the root of a USB flash memory device.

e. Once the copy has completed, safely eject the USB flash memory device.

6.6.1.2.2 Create CD-R Test Media

1. Obtain the Test Images:

a. Contact your service representative to get the test pattern images.

b. Download **Pristina_Sigmoid.iso**, **2D_Pristina_annotations.iso** and 3D images (**3D_Pristina_annotations.iso** or **3D_ReconDL_It10_Pristina_Annotations.iso**) if 3D option is enabled on your system, onto your laptop.

The **Pristina_Sigmoid.iso** file size is approximately 218 MBytes (It contains both 2D and 3D sigmoid images).

The **2D_Pristina_annotations.iso** file size is approximately 52 MBytes.

The **3D_Pristina_annotations.iso** file size is approximately 383 MBytes.

The **3D_ReconDL_It10_Pristina_Annotations.iso** file size is approximately 712 MBytes.

2. Use the following steps to create a Sigmoid LUT test media on a CD-R:

a. Label the blank CD-R assigned for the Sigmoid LUT tests with "Sigmoid LUT".

b. Insert the blank CD-R assigned for the Sigmoid test images in your laptop.

c. Use your preferred CD/DVD Authoring Tool to burn the **Pristina_Sigmoid.iso** file on a CD-R. It contains both 2D and 3D sigmoid images.

d. Once the CD-R burning process has completed, eject the CD-R and store it in its protective cover.

3. Use the following steps to create a 2D Annotations and Orientations test media on a CD-R:

a. Label the blank CD-R assigned for the Annotations and Orientations tests with “Annotations and Orientation”.

b. Insert the blank CD-R assigned for the Annotations and Orientations test images in your laptop.

c. Use your preferred CD/DVD Authoring Tool to burn the **2D_Pristina_annotations.iso** file to a CD-R.

d. Once the CD-R burning process has completed, eject the CD-R and store it in its protective cover.

4. If needed, use the following steps to create a 3D Annotations and Orientations test media on a CD-R:
   a. Label the blank CD-R assigned for the Annotations and Orientations tests with “Annotations and Orientation”.
   b. Insert the blank CD-R assigned for the Annotations and Orientations test images in your laptop.
   c. Use your preferred CD/DVD Authoring Tool to burn the 3D images (**3D_Pristina_annotations.iso** or **3D_ReconDL_It10_Pristina_Annotations.iso**) file to a CD-R.
   d. Once the CD-R burning process has completed, eject the CD-R and store it in its protective cover.

6.6.1.3 Running the Third-Party Review Station Compatibility Tests

6.6.1.3.1 Sigmoid LUT Test on 2D images

1. Refer to third-party workstation Service Manual to import images from the USB flash memory device or CD-R media to the third-party workstation.

   The path of the NoVOI and VOI sigmoid test images are as follows:

   - `STORE\PA1\ST1\SE1\IM1` - NoVOI
   - `STORE\PA1\ST1\SE1\IM2` - VOI

   The two sigmoid test images (NoVOI and VOI) are now on the third party review workstation.
2. On the third party review workstation, do the following for the NoVOI sigmoid test image:
   a. Locate and open the NoVOI sigmoid test image that you previously pushed to the review workstation and has the following Patient ID, Patient name and processing description:

      Patient ID: **GE**

      Patient name: **Sigmoid Test Pattern**

      Processing description: **NoVOI**
   b. Check if the Window Width (WW) is 2900 and the Window Level (WL) is 2048.
   c. If not, set the WW to 2900 and WL to 2048.
   d. Check the image to see if you can see the text SIGMOID appear in both the light gray box and dark gray box.

3. On the third party review workstation, do the following for the VOI sigmoid test image:
   a. Locate and open the VOI sigmoid test image that you previously pushed to the review workstation and has the following Patient ID, Patient name and processing description:

      Patient ID: **GE**

Patient name: **Sigmoid Test Pattern**

Processing description: **VOI**

b. Without changing the WW and WL, check the image to see if you can see the text SIGMOID appears in both the light gray box and dark gray box.

4. Determine your next step for the VOI Sigmoid test image:
   - If the text SIGMOID appears in both VOI and NoVOI images, and the WW/WL values displayed on the review workstation are correct, the test is passed. Inform the customer that no further action is necessary.
   - If the text SIGMOID does not appear in any of VOI nor NoVOI images, the test is failed.
     - Inform the customer that the review station needs to be configured to apply the sigmoid LUT, so that the images are displayed correctly and the windowing can be modified.
     - If the sigmoid LUT is not available on the review workstation set the system to linear LUT and inform the customer that the autowindowing presets won't be available.
   - If the text SIGMOID only appears in one of VOI or NoVOI images:
     - Inform the customer that the review station needs to be configured to apply the sigmoid LUT, to get smoother transition when changing the windowing.
     - If the sigmoid LUT is not available on the review workstation,
       - if 3D option is not available on the system, leave it as is.
       - if 3D option is installed on the system, follow 6.6.1.3.2 Sigmoid LUT Test on 3D images on page 97.

NOTE
If the sigmoid LUT is not available on the review workstation, inform the customer that their review workstation is not DICOM compliant because it is not able to apply the sigmoid presentation LUT.

6.6.1.3.2 Sigmoid LUT Test on 3D images

1. Refer to third-party workstation Service Manual to import images from the USB flash memory device or CD-R media to the third-party workstation.

   The path of the NoVOI and VOI sigmoid test images are as follows:

   - `STORE\PA1\ST1\SE2\IM1` - Slabs
   - `STORE\PA1\ST1\SE2\IM2` - Planes
   - `STORE\PA1\ST1\SE3\IM1` - V-Preview (VP)

   The three sigmoid test images are now on the third party review workstation.

2. On the third party review workstation, locate and open the sigmoid test **planes** image that you previously loaded to the review workstation and has the following Patient ID and Patient name:

   Patient ID: **GE**

   Patient name: **Sigmoid Test Pattern**

3. On the third party review workstation, do the following:

   a. Set the Window Width (WW) to 2900 and the Window Level (WL) to 2048.

   b. Check the image to see if you can see the text SIGMOID appears in both the light gray box and dark gray box.

4. Determine your next step:

   - If the text SIGMOID appears in both the light gray box and dark gray box, the test is passed. Inform the customer that no further action is necessary.
   - If the text SIGMOID does not appear in both the light gray box and dark gray box, the test is failed. In this case inform the customer that the review station may need to be configured so that the images is displayed correctly. Tell the customer that the images from the Senographe Pristina 3D system images follow the DICOM standard, and to they should refer to the *DICOM Conformance Statement* (which is publicly available on the GE HealthCare website) for more details.

5. On the third party review workstation, locate and open the sigmoid test **slabs** image that you previously loaded to the review workstation and has the following Patient ID and Patient name:

   Patient ID: **GE**

   Patient name: **Sigmoid Test Pattern**

6. Repeat Step 3. If the test fails, perform *Job Card ELE A054 – Linear LUT Configuration* in Senographe Pristina Service Manual.

7. On the third party review workstation, locate and open the sigmoid test **VP** image that you previously loaded to the review workstation and has the following Patient ID and Patient name:

   Patient ID: **GE**

Patient name: **Sigmoid Test Pattern**

8. Repeat Step 3. If the test fails, perform the VP LUT Linear – in SenoIris Service Manual (for SenoIris review station).

6.6.1.3.3 Annotation and Orientation Tests on 2D images

The purpose of this test is to aid the detection of incompatibilities between image orientation and the annotations generated by the Senographe Pristina and the client third-party review workstations.

1. Refer to third-party workstation Service Manual to import images from the USB flash memory device or CD-R media to the third-party workstation.

   The four test images (R MLO, L MLO, R CC and L CC) are now on the third party review workstation.

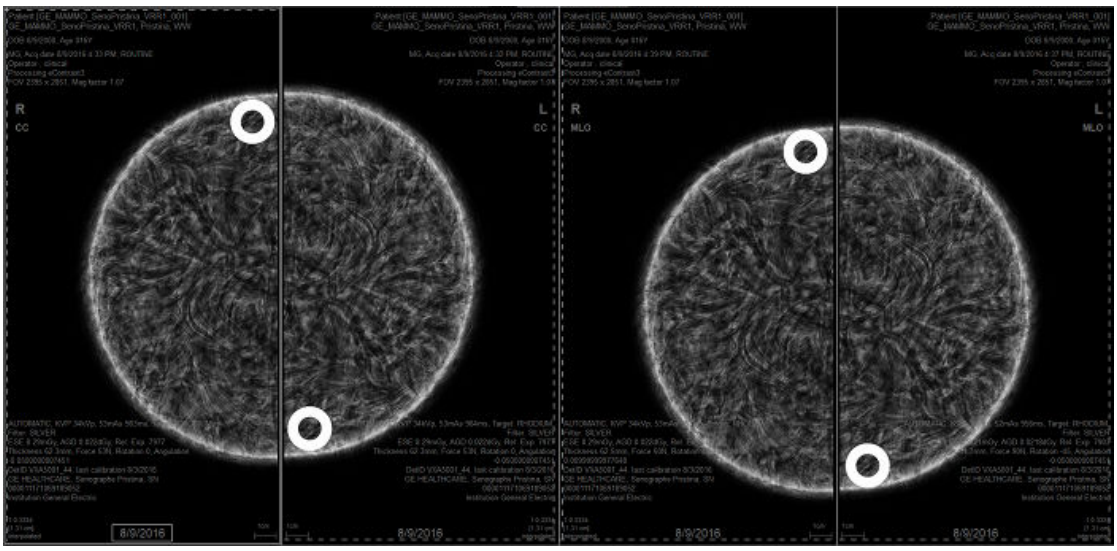
2. On the third party review workstation, do the following for each of the four test images (R MLO, L MLO, R CC and L CC):

   a. Locate, and open the annotation test image that you previously imported into the third-party review workstation and has the following Patient ID and Patient name:

      Patient ID = **GE_MAMMO_SenoPristina_VRR1_001**

      Patient name = **Ge_Mammo_Senopristina_Vrr1**

   b. Perform the orientation check (verify if the position of the coin is as shown below) and annotation check (the R CC/L CC/R MLO/L MLO highlighted annotations must be readable in the four different images as shown below).



3. Determine your next step for each of the four test images:

   - If the orientation is correct in all the images and the annotations appear in all the images, no further action is required.
   - If the orientation test fails once or the annotations test fails once, inform the customer that the third-party review station may need to be configured so that the images are displayed correctly. Tell the customer that the images from the Senographe Pristina system follow the DICOM standard, and that they should refer to the *DICOM Conformance Statement* (which is publicly available on the GE HealthCare website) for more details.

6.6.1.3.4 Annotation and Orientation Tests on 3D images

The purpose of this test is to aid the detection of incompatibilities between image orientation and the annotations generated by the Senographe Pristina and the client third-party review workstations.

1. Refer to third-party workstation Service Manual to import images from the USB flash memory device or CD-R media to the third-party workstation.

   The eight following test images are now on the third party review workstation:

Table 6-4 3D_ Pristina_annotations

Image type	Image name
VPreview	R MLO
	L MLO
	R CC
	L CC
Slabs	ROUTINE_3D_VOL_R MLO
	ROUTINE_3D_VOL_ L MLO
	ROUTINE_3D_VOL_ R CC
	ROUTINE_3D_VOL_ L CC

Table 6-5 3D_ ReconDL_It10_Pristina_Annotations

Image type	Image name
Slabs	RMLO 3D Slabs
	LMLO 3D Slabs
	RCC 3D Slabs
	LCC 3D Slabs
Generated 2D (DL Synthesized)	RMLO DL Synthesized
	LMLO DL Synthesized
	RCC DL Synthesized
	LCC DL Synthesized

2. On the third party review workstation, do the following for each of the eight test images:

   a. Locate, and open the annotation test image that you previously imported into the third-party review workstation and has the following Patient ID and Patient name:

      - For 3D_Pristina_annotations:
        Patient ID = **GE_MAMMO_SenoPristina_VRR1_001**

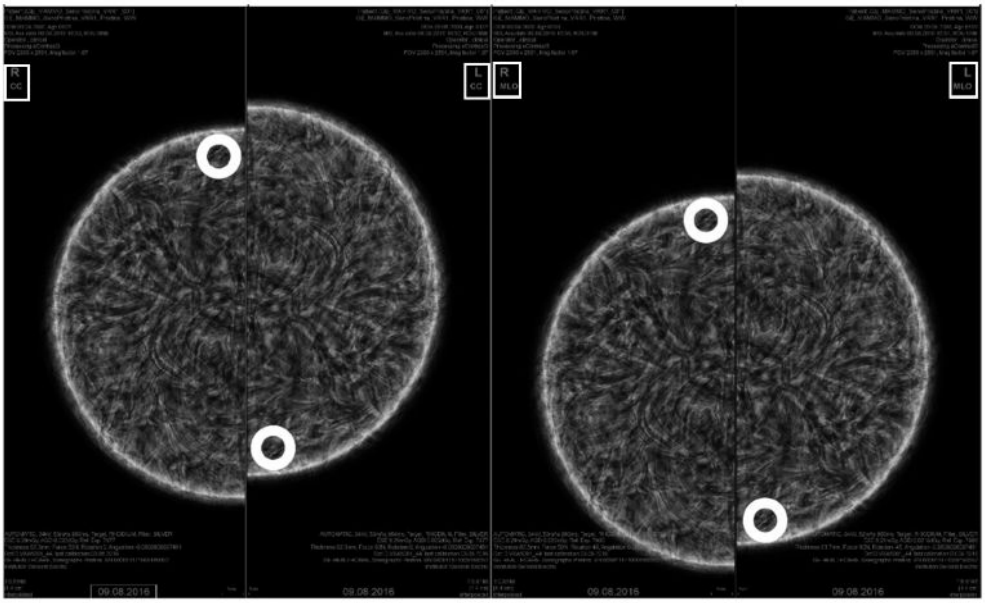
        Patient name = **Ge_Mammo_Senopristina_Vrr1**

      - For 3D_ReconDL_It10_Pristina_Annotations:
        Patient ID = **GEHC_MAMMO_It10**

        Patient name = **Pristina_Iteration10_ReconDL**

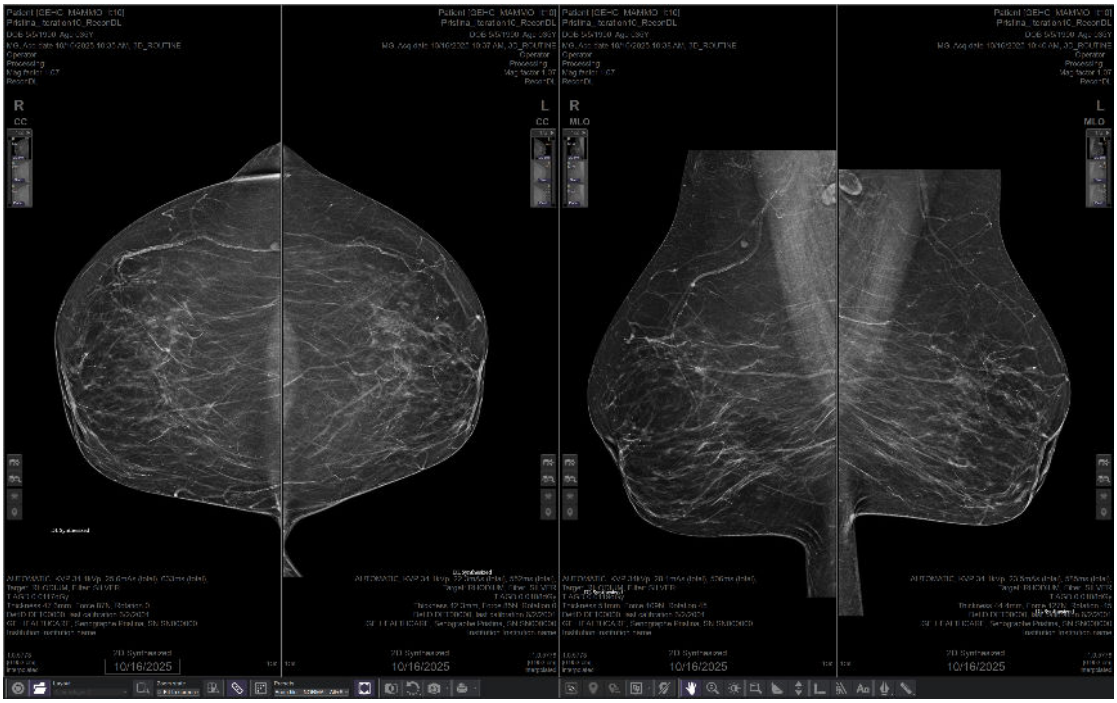
b. Perform the orientation check (verify if the position of the coin or the breast laterality is as shown below) and annotation check (laterality RCC LCC RMLO LMLO are readable in the eight different images).

Figure 6-2 3D_Pristina_annotations:



NOTE
You may need to scroll on the images to find the coin.

Figure 6-3 3D_ReconDL_It10_Pristina_annotations:



3. Determine your next step for each of the eight test images:
   - If the orientation is correct in all the images and the annotations appear in all the images, no further action is required.
   - If the orientation test fails once or the annotations test fails once, inform the customer that the third-party review station may need to be configured so that the images are displayed correctly. Tell the customer that the images from the Senographe Pristina

system follow the DICOM standard, and that they should refer to the *DICOM Conformance Statement* (which is publicly available on the GE HealthCare website) for more details.

Appendix A Acronyms Glossary

A

AC

Alternating Current

AET

Application Entity Title

AOP

Automatic Optimization of Parameters

ARC

Analog Readout Chip

ASIS

Application Specific Integrated Circuit

AWS

Acquisition Workstation

A/D

Analog to Digital

B

BCR

Bar Code Reader

BSLM

Breast Support Locking Mechanism

C

CAD

Computer-Aided Diagnosis

CAN

Controller Area Network

CF

Conversion Factor

CL

Central Listing

CM

Corrective Maintenance

CPLD

Complex Programmable Logic Device

CPU

Central Processing Unit

D

DC

Direct Current

DCB

Differential Circuit Breaker

DICOM

Digital Imaging and Communications in Medicine

DJINN

Name given to the Generator Hardware and Software Platform

DLC

Data Length Code (CANopen protocol)

DMPU

Digital Mammography Processing Unit

DQE

Defective Quantum Efficiency

DSP

Digital Signal Processor

DRC

Digital Readout Chip

DPS

Detector Power Supply

D/R

Disassemble and Reassemble

E

EMC

Electromagnetic Compatibility

ESD

ElectroStatic Discharge

F

FAU

Field Adjustable Unit

FD

Functional Diagram

FDA

Food and Drug Administration

FE

Field Engineer

FET

Field Effect Transistor

FFDM

Full Field Digital Mammography

FMI

Field Modification Instruction

FOV

Field Of View

FPGA

Field Programmable Gate Array

FRU

Field Replaceable Unit

FQDN

Fully Qualified Domain Name

FSB

Front System Bus

FW

Firmware or Feeder Wire

G

GLI

Grid Line Interference

Gnd

Ground

GPS

Gantry Power Supply

GTT

Gantry Transport Tool

H

HCI

Harness-Cable Interconnection

HIS

Hospital Information System

HNS

Hospital Network Service OR Health Net Services

HP

High Power

HV

High Voltage

HVL

Half Value Layer

HT

High Tension

I

IHE

Integrating the Healthcare Enterprise

IPMS

Isis Positioner Motion Software (old definition that covers the whole Gantry) or Interrupt Pipes Management System (low-level processor activity)

IP

Internet Protocol

IIP

Insite Interactive Platform

IOD

Information Object Definition

IDC

Image Detection Controller

I/F

Interface

J

JC

Job Card

L

LFOV

Large Field Of View

LMP

Lamp

LP

Low Power

LSL

Lower Specification Limit

LUT

Look Up Table

LV

Low Voltage

M

MC

Main Contactor

MCU

Micro Controller Unit (usually refers to the HC12 chip on the Gantry nodes)

MCM

MulitChip Module

MDR

Main Distribution Rack

MDS

Mammography Documentation Station

MFU

Main Functional Unit

MQSA

Mammography Quality Standards Act

MTF

Modulation Transfer Function

N

NPS

Noise Power Spectrum

O

OLC

OnLine Center

P

PACS

Picture Archiving and Communication System

PB

Push Button

PDB

Power Distribution Board

PDI

Product Delivery Instructions

PDO

Process Data object (CANOpen protocol)

PDU

Power Distribution Unit

PI

Part Identity

PPP

Point-to-Point Protocol

PPS

Performed Procedure Step

PWA

Printed Wiring Assembly

PM

Planned Maintenance

PTB

Positioner Tracking Board (main Gantry control board called Roadrunner that has Poseidon SW on it)

Q

QAP

Quality Assurance Procedures OR Quality Assurance Program

Q/R

Query Retrieve

R

RF

Radio Frequency

r.h.

Relative Humidity

RIS

Radiology Information System

RNU

Resolution Non-Uniformity

ROI

Region Of Interest

RWS

Review Workstation

RT

Real Time

S

SBC

Single Board Computer

SC

Scenario Categories

SCP

Service Class Provider

SCU

Service Class User

SDD

Source to Dosimeter Distance

SEL

Select

SID

Source to Image Distance

SIP

Service Information and Procedures

SLDU

Second Look Digital Unit

SM

Service Manual

SMART

Self Monitoring And Reporting Technology

SNA

Systems Network Architecture

SOP

Service Object Pair

T

TBx

Terminal Block (for fuses)

TEC

ThermoElectric Cooler

TFT

Thin Film Transistor

TP

Twisted Pair

U

UBC

Universal Builders Code

UPS

Interruptible Power Supply

USL

Upper Specification Limit

V

VOI

Volume Of Interest

W

WL

Window Level

WW

Window Width

GE HealthCare

www.gehealthcare.com