Senographe Crystal Nova

Pre-Installation Manual Class A

PIM-A

5673206-8EN
Revision 4

ABOUT THIS MANUAL

- Legal Manufacturer:
  GE ULTRASOUND KOREA, Ltd.
  9, Sunhwan-ro 214beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do Republic of Korea

- Manufacturing Site:
  GE ULTRASOUND KOREA, Ltd.
  9, Sunhwan-ro 214beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do Republic of Korea

The information in this document is subject to change without notice and does not represent a commitment on the part of the vendor.

If the device is not properly set causing it to malfunction or fail, we cannot guarantee any responsibility.

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CHAPTER1. SAFETY

1. Language Warning

ПРЕДУПРЕЖДЕНИЕ (BG)	Това упътване за работа е налично само на английски език. • Ако доставчикът на услугата на клиента изиска друг език, задължение на клиентае да осигури превод. • Не използвайте оборудването, преди да сте се консултирали и разбралиупътването за работа. • Неспазването на това предупреждение може да доведе до нараняване надоставчика на услугата, оператора или пациента в резултат на токов удар, механична или друга опасност.
警告 (ZH-CN)	本维修手册仅提供英文版本。 • 如果客户的维修服务人员需要非英文版本，则客户需自行提供翻译服务。 • 未详细阅读和完全理解本维修手册之前，不得进行维修。 • 忽略本警告可能对维修服务人员、操作人员或患者造成电击、机械伤害或其他形式的伤害。
警告 (ZH-HK)	本服務手冊僅提供英文版本。 • 倘若客戶的服務供應商需要英文以外之服務手冊，客戶有責任提供翻譯服務。 • 除非已參閱本服務手冊及明白其內容，否則切勿嘗試維修設備。 • 不遵從本警告或會令服務供應商、網絡供應商或病人受到觸電、機械性或其他的危險。
警告 (ZH-TW)	本維修手冊僅有英文版。 • 若客戶的維修廠商需要英文版以外的語言，應由客戶自行提供翻譯服務。 • 請勿試圖維修本設備，除非 您已查閱並瞭解本維修手冊。 • 若未留意本警告，可能導致維修廠商、操作員或病患因觸電、機械或其他危險而受傷。
UPOZORENJE (HR)	Ovaj servisni priručnik dostupan je na engleskom jeziku. • Ako davatelj usluge klijenta treba neki drugi jezik, klijent je dužan osigurati prijevod. • Ne pokušavajte servisirati opremu ako niste u potpunosti pročitali i razumjeli ovaj servisni priručnik. • Zanemarite li ovo upozorenje, može doći do ozljede davatelja usluge, operatera ili pacijenta uslijed strujnog udara, mehaničkih ili drugih rizika.
VaÝSTRAHA (CS)	Tento provozní návod existuje pouze v anglickém jazyce. • V případě, že externí služba zákazníkům potřebuje návod v jiném jazyce, je zajištění překladu do odpovídajícího jazyka úkolem zákazníka. • Nesnažte se o údržbu tohoto zařízení, aniž byste si přečetli tento provozní návod a pochopili jeho obsah.

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

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

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

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

	• Ne pokušavajte da opravite uređaj ako niste pročitali i razumeli ovo servisno uputstvo. • Zanemarivanje ovog upozorenja može dovesti do povređivanja servisera, rukovaoca ili pacijenta usled strujnog udara ili mehaničkih i drugih opasnosti.
UPOZORNENIE (SK)	Tento návod na obsluhu je k dispozícii len v angličtine. • Ak zákazníkov poskytovateľ služieb vyžaduje iný jazyk ako angličtinu, poskytnutie prekladateľských služieb je zodpovednosťou zákazníka. • Nepokúšajte sa o obsluhu zariadenia, kým si neprečítate návod na obluhu a neporozumiete mu. • Zanedbanie tohto upozornenia môže spôsobiť zranenie poskytovateľa služieb, obsluhujúcej osoby alebo pacienta elektrickým prúdom, mechanické alebo iné ohrozenie.
ATENCION (ES)	Este manual de servicio sólo existe en inglés. • Si el encargado de mantenimiento de un cliente necesita un idioma que no sea el inglés, el cliente deberá encargarse de la traducción del manual. • No se deberá dar servicio técnico al equipo, sin haber consultado y comprendido este manual de servicio. • La no observancia del presente aviso puede dar lugar a que el proveedor de servicios, el operador o el paciente sufran lesiones provocadas por causas eléctricas, mecánicas o de otra naturaleza.
VARNING (SV)	Den här servicehandboken finns bara tillgänglig på engelska. • Om en kunds servicetekniker har behov av ett annat språk än engelska, ansvarar kunden för att tillhandahålla översättningstjänster. • Försök inte utföra service på utrustningen om du inte har läst och förstår den här servicehandboken. • Om du inte tar hänsyn till den här varningen kan det resultera i skador på serviceteknikern, operatören eller patienten till följd av elektriska stötar, mekaniska faror eller andra faror.
OPOZORILO (SL)	Ta servisni priročnik je na voljo samo v angleškem jeziku. • Če ponudnik storitve stranke potrebuje priročnik v drugem jeziku, mora stranka zagotoviti prevod. • Ne poskušajte servisirati opreme, če tega priročnika niste v celoti prebrali in razumeli. • Če tega opozorila ne upoštevate, se lahko zaradi električnega udara, mehanskih ali drugih nevarnosti poškoduje ponudnik storitev, operater ali bolnik.
DİKKAT (TR)	Bu servis kılavuzunun sadece ingilizcesi mevcuttur. • Eğer müşteri teknisyeni bu kılavuzu ingilizce dışında bir başka lisandan talep ederse, bunu tercüme ettirmek müşteriye düşer. • Servis kılavuzunu okuyup anlamadan ekipmanlara müdahale etmeyiniz. • Bu uyarıya uyulmaması, elektrik, mekanik veya diğer tehlikelerden dolayı teknisyen, operatör veya hastanın yaralanmasına yol açabilir.

2. Important: X-ray Protection

ATTENTION

Les appareils à rayons X sont dangereux à la fois pour le patient et pour le manipulateur si les mesures de protection ne sont pas strictement appliquees

Bien que cet appareil soit construit selon les normes de sécurité les plus sévères, la source de rayonnement X représente un danger lorsque lemanipulateur est non qualifié ou non averti. Une exposition excessive au rayonnement X entraîne des dommages à l'organisme. Par conséquent, toutes les précautions doivent être prises pour éviter que les personnes non autorisées ou non qualifiées utilisent cet appareilcréant ainsi un danger pour les autres et pour elles-mêmes.

Avant chaque manipulation, les personnes qualifiées et autorisées à se servir de cet appareil doivent se renseigner sur les mesures deprotection établies par la Commission Internationale de la Protection Radiologique, Annales 60 : Recommandations de la CommissionInternationale sur la Protection Radiologique et les normes nationales en vigueur. Elles doivent également avoir reçu une formation surl'utilisation de ce matériel.

WARNING

X-ray equipment is dangerous to both patient and operator unless measures of protection are strictly observed

Though this equipment is built to the highest standards of electrical and mechanical safety, the useful X-ray beam becomes a source of dangerin the hands of the unauthorized or unqualified operator. Excessive exposure to x-radiation causes damage to human tissue.

Therefore, adequate precautions must be taken to prevent unauthorized or unqualified persons from operating this equipment or exposing themselves or others to its radiation.

Before operation, persons qualified and authorized to operate this equipment should be familiar with the Recommendations of the International Commission on Radiological Protection, contained in Annals Number 60 of the ICRP, and with applicable national standards and should have been trained in use of the equipment.

ATENCION

Los aparatos de rayos X son peligrosos para el paciente y el manipulador cuando las normas de proteccion no estan observadas

Aunque este aparato está construido según las normas de seguridad más estrictas, la radiación X constituye un peligro al ser manipulado por personas no autorizadas o incompetentes. Una exposición excesiva a la radiación X puede causar daños al organismo.

Por consiguiente, se deberán tomar todas las precauciones necesarias para evitar que las personas incompetentes o no autorizadas utilicen este aparato, lo que sería un peligro para los demás y para sí mismas.

Antes de efectuar las manipulaciones, las personas habilitadas y competentes en el uso de este aparato, deberán informarse sobre las normas de protección fijadas por la Comisión Internacional de la Protección Radiológica, Anales No 60: Recomendaciónes de la Comisión Internacional sobre la Protección Radiológica y normas nacionales y deben haber sido formatas en el uso de este equipo.

ACHTUNG

Röntgenapparate sind eine gefahr für patienten sowie bedienungspersonal, wenn die geltenden sicherheitsvorkehrungen nicht genau beachtet warden

Dieser Apparat entspricht in seiner Bauweise strengsten elektrischen und mechanischen Sichereitsnormen, doch in den Händen unbefugter oder unqualifizierter Personen wird er zu einer Gefahrenquelle. Übermäßige Röntgenbestrahlung ist für den menschlichen Organismus schädlich.

Deswegen sind hinreichende Vorsichtsmaßnahmen erforderlich, um zu verhindern, daßunbefugte oder unqualifizierte Personen solche Geräte bedienen oder sich selbst und andere Personen deren Bestrahlung aussetzen können.

Vor Inbetriebnahme dieses Apparats sollte sich das qualifizierte und befugte Bedienungspersonal mit den geltenden Kriterien für den gefahrlosen Strahleneinsatz durch sorgfältiges Studium des Hefts Nr. 60 der Internationalen Kommission für Strahlenschutz (ICRP) vertraut machen: Empfehlungen der Internationalen Kommission für Strahlenschutz und anderer nationaler Normenbehörden.

4. Definition of Warnings and Notes

Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.

Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.

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

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.

5. Safety Precautions

Always comply with the following precautions to avoid dangerous situations and ensure peak performance.

4-1. General Safety Information

GE Ultrasound Korea, LTD. is not responsible for any damages and injury caused by unauthorized modification or operation. Senographe Crystal Nova must be used by authorized personnel after an appropriate training. Senographe Crystal Nova should not be used by anyone, except by qualified personnel. The following skills are required for system usage:

Hold a certain level of knowledge and expertise of the general operations of the Windows® operating system and the concepts of PACS, RIS, DICOM, or server.

Perform the console operation, such as clicking, dragging, and/or select.

Perform the text input on the keyboard in English.

Select the menus and options on the screen.

This machine must be used only for mammography

No one, other than the patient and user of Senographe Crystal Nova, or any unnecessary equipment should be within the operating space of Senographe Crystal Nova, in order to prevent unintended problems or risks.

The patient should not have any unnecessary contact with the machine.

Images of a pregnant woman should only be taken under the direction and prescription of her attending physician.

Before each use, clean all parts that comes in contact with the patient. And clean again when any abnormal findings occur in a patient.

Take the image only after all metals such as necklace or other accessories unnecessary to the test are removed.

Frequently verify the wear of the compression paddle to prevent damages as cracks and tears, and consequent risks for the patients.

Pay attention to the LCD screen that is the most fragile part of the Control station.

If any abnormality with the machine or the patient is found, stop the operation, make sure the patient safe, and then take appropriate action. If repair is required, the device should be repaired by a professional engineer.

No modification of this equipment is allowed.

Do not modify this equipment without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

Assembly of systems and modifications during actual service life shall be evaluated based on the requirements of this standard.

Use only original accessories and spare parts.

The mammography is classified as permanently installed according to IEC 60601-1 international standard. This means that it must be electrically connected by means of permanent connections. In particular, for the maximum electrical safety, the protective earth conductor must be fixed and permanently installed.

Use this mammography, the control console and its software according to the instruction given in this manual. Do not tray to install unauthorized software, access to operating system configuration or perform other potentially dangerous operations.

Do not remove the steel cover and injection modeling cover after replacing the collimator lamp, as these covers block the heat produced by the collimator lamp during the image capturing.

The detector has a very strict range of temperature for correct operation. It must be operated between 10 and 35°C. Using the mammography outside this range can result in bad quality images.

Respect the storage conditions to avoid irreversible detector damage. Actually, this component is very sensitive to the sudden changes of temperature and it must be maintained between 0 and 60°C.

Check the pinch points on the equipment before the operation. Be careful not to catch the body parts to prevent injuries, and make sure that any dust or alien substance, leading to damage to the equipment, is not accumulated.

4-2. Radiation

Do not take unnecessary x-rays. Only those images required for the purpose of diagnosis should be taken.

Medical personnel, who work in the room, when necessary, should wear protective clothing, gloves, protective glasses, etc. containing lead to minimize exposure to X-rays.

During X-ray emission, operator must be behind the protective screen and in a position where it is possible to watch patient and unit.

Do not insert in the X-ray beam devices other than compression paddles or Magnification Stand.

X-ray units can only be operated inside dedicated room provided with X-ray protection that meets local standards and regulations.

4-3. Installation

The machine should be installed in a dry place.

Senogarphe Crystal Nova should be installed in a place which is not influenced by the adverse effects of atmospheric pressure, temperature, humidity, wind, direct sun light, salt, ion components, etc.

Install in a place without incline, vibration, impact, etc.

Do not install near chemicals or flammable gas.

Install only after operating conditions including indoor temperature, humidity or other environment issues have been checked.

4-4. Electricity

After the machine is installed, the device should be turned on to check whether it works normally or not.

Senogarphe Crystal Nova should only be used after it is grounded. Check whether the grounding terminal is at the installation location or if Senogarphe Crystal Nova is connected with the grounding line.

Be cautious of power, frequency, voltage, and permissible current, and carefully connect the grounding line.

Check whether all cords are connected correctly and safely.

Check the switch connection, polarity, dial setting, meters, etc. Then check the device to ensure it is operating properly.

When disconnecting the cables, do not use excessive force.

4-5. Maintenance

The machine should be kept clean and ready for the next use.

Accessories and cords should be kept clean and organized.

Cleaning is a physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use.

No heat or flowing water should be used on the parts that come in direct contact with patients.

Corrosive-solvents or detergents with abrasive particles should not be used.

During service, FE works on system or updates software. Unwanted motion occurs and hurts FE.

4-6. 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 Warning and Caution messages, and wear appropriate PPE (e.g. safety shoes, gloves, and goggles) per the nature of the risk involved.

4-7. Unauthorized System Modification Hazards

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

4-8. Cable Ducting

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

4-9. Handling System Cables

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

4-10. System Cleaning

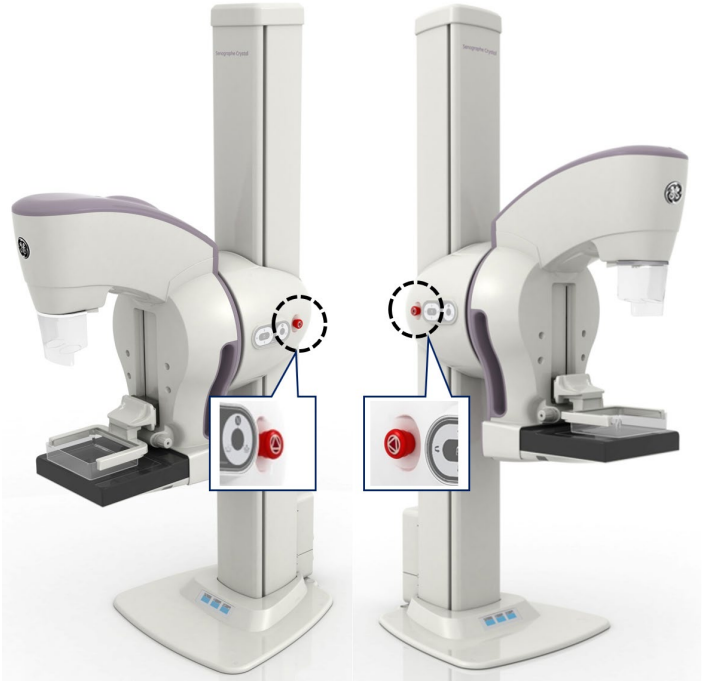
Medical device. Ensure that the system is cleaned according to system hygiene procedures before performing any service procedures.

4-11. Emergency Cutoff

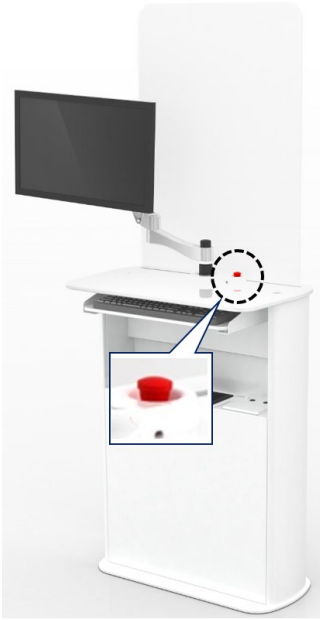
There are 3 Emergency switches that are located on the Gantry as well as the Control station.

- Both right and left sides on the C-arm of the Gantry
- On the table of the Control station

The positions of each Emergency switches are as below.

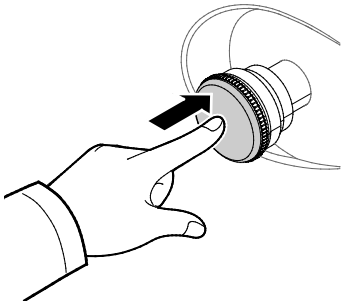


[Figure 1-1] Emergency Switches on the Gantry



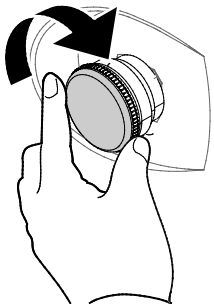
[Figure 1-2] Emergency Switch on the Control Station

Press the Emergency switch in case of an emergency to cut off the power supply. The equipment is totally disconnected from the main power, the X-ray emission is blocked, every motorized movement is blocked, and the compression paddle is automatically released to let the patient free.



[Figure 1-3] How to press the Emergency Switch

When the system check is complete, and it shows that the system is normal after an emergency stop, turn the Emergency switch 90 degrees clockwise to disengage the Emergency switch. Press system power ON switch to rerun the system.



[Figure 1-4] How to turn the Emergency Switch

NOTICE

If you cannot Switch ON the equipment on, inspect that all of the Emergency switches are unlocked.

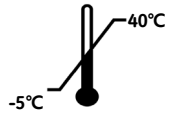
⚠CAUTION

Avoid using the Emergency switch other than in an emergency, as this could result in loss of data or damage to the equipment.

If you push the Emergency switch during acquiring image and then return the system, you should restart capture mode to recognize the current focus state.

6. Meaning of Symbols

Symbol	Description
	X-ray equipment. It is dangerous to both patient and operator unless measures of protection are strictly observed.
	Type B Equipment. This part comes into direct contact with the patient during the clinical procedure. It is designed not to present any electrical risks to the patient when Senographe Crystal Nova is used according to its intended function.
	Waste Electrical and Electronic Equipment Directive
	Alternating current
	Earth (ground)
	Protective earth (ground)
	Dangerous voltage
	Name and address of manufacturer
	Date of manufacture
	Medical device catalogue number
	Medical device serial number
	Attention, see instructions for use
	Caution -or- Attention, consult accompanying documents
	Keep away from rain

Symbol	Description
	Temperatures Limitation
	Fragile handle with care

CHAPTER 2. PUBLICATION PRESENTATION

1. Scope and Applicability of the publication

This Service publication provides all information required to understand, to plan installation, to install, and to maintain the Senogarphe Crystal Nova.

For information on associated equipment mentioned in this publication, such as the review workstation, refer to their specific publications.

This publication contains class A, and class M information. It is therefore restricted to use by GEMS Field Engineers only.

2. Content of this publication

2-1. Safety Information

The Safety chapter gives regulatory warnings which must be read and understood before reading the documentation and using the equipment.

2-2. Publication Presentation

The Publication Presentation chapter describes the content of the publication.

2-3. Proprietary Considerations

The Proprietary Considerations chapter describes proprietary aspects of installation and service of the Senographe system.

2-4. Descriptive Chapters

Descriptive chapters give information required to understand the equipment, together with reference information:

- System Description gives a physical and operational description of the system. It includes theory of operation, functional diagrams, FE operations, component and FRU location, and a component index.

- System Identification and Follow-up gives system configuration and service history information.

- Pre-Installation System Requirements specifies site planning requirements.

2-5. Procedural Chapters

- **Service Contexts**

Procedural chapters describe procedures required in specific service contexts:

- Physical Installation

- Electrical Installation.

- Corrective Maintenance.

- Planned Maintenance

- Verification Checks

- FRU List

Installation and Planned Maintenance procedures assume that no equipment failure occurs. If an equipment failure occurs, the FE must refer to Corrective Maintenance procedures.

- **Procedural Instructions**

Procedural instructions are given in three types of document: Error message lists, Scenarios, and Job Cards:

- **Error Message Lists**

Error message lists document messages intended for the FE. These messages can be displayed on screen, on dedicated display panels, or stored in an error log Specified or suggested corrective actions are listed. These can include hypertext links to relevant Job Cards.

- **Scenarios**

A scenario is a high-level description of the steps required to carry out a defined Service action, such that:

The context is perfectly known.

The initial state and the final state are perfectly known.

All the steps are identified, including preparation steps (pre-requisites) and finalization steps (post - requisites). The steps are defined in Job Cards.

The sequencing (order) of the steps is exactly defined. However, there can be alternative (conditional) paths in the sequence.

Scenarios contain two sections:

Context: explains the circumstances in which the scenario must be performed.

Steering guide: gives the exact sequence of jobs to be performed, in a tabular format.

- **Job Cards**

Job Cards are used to describe specified independent tasks (e.g., the installation of a specific component, a calibration procedure, etc.).

Job Cards include all instructions required to carry out the specified task. These can include instructions to perform other Job Cards.

The same Job Card can be used in different contexts. For example, a Job Card specifying a calibration procedure can be carried out during installation, or after changing a component.

2-5-1. Job Card and Scenario Categories

[Table2-1] Job Card Code Categories

Category definition	Scope	JC Code
Pre-Installation	Includes wall, ceiling, and floor preparation, electrical cabling, etc	**PRE**
System Physical Installation	First installation on Customer site – Physical installation step	**PHY**
System Electric Installation	First installation on Customer site - Starts with powering on the Senographe Crystal Nova	**ELE**
Upgrade	Describes installation of an option or application of an FMI on an existing functional system, i.e., a change to the configuration of the system.	**UPG**
Corrective maintenance:		
Configuration (HW & SW)	Describes Procedures for configuration of hardware and/or software. Restore procedures are considered as configuration.	**CFG**
Calibrations and adjustments	Describes calibration procedures.	**CAL**
Diagnostics	Used when a problem has been identified, and it is required to locate the root cause or to choose between different root causes. May also be used to describe the use of diagnostic software tools.	**DIAG**
Trouble shooting	Gives general guidance for a diagnostic and repair strategy in a certain context (i.e., a certain combination of symptoms). Describes adjustment procedures.	**TSG**
Disassembly/Reassembly	Describes removal and reinstallation of a component or assembly. Does not usually include calibration procedure, but points to them.	**D/R**
Planned Maintenance	Specifies planned maintenance procedures and their frequency.	**PM**

3. Acronyms Glossary

This manual uses the following terminology:

ACR: American College Radiology

AEC: Automatic Exposure Control

Collimator: Device at the X-ray tube to control the area of the receptor that is exposed

DICOM: Digital Imaging and Communications in Medicine

FFDM: Full Field Digital Mammography

Grid: Element within the Digital Image Receptor that reduces scatter Radiation during the exposure

GUI: Graphic User Interface

PACS: Picture Archiving and Communications System

4. Revision History

Release	Date (dd/mmm/yyyy)	Description
5673206-8EN Rev 1	26/Jun/2017	DOC1979646 Senographe Crystal Nova Service Manual M Initial Release
5673206-8EN Rev 1	04/Jul/2017	DOC1979646 Senographe Crystal Nova Service Manual M Rev3 Release
5673206-8EN Rev 1	04/Aug/2017	Part Initial Release
5673206-8EN Rev 2	17/Nov/2017	Update information for/from: - the sliding collimation plate design changes - the anchoring templete - the reflection on service improvement opportunity feedbacks (for more details, please refer to SPR# HCSDM00487292)
5673206-8EN Rev 3	15/May/2018	Update information for: - the accessories storage option - the reflaction on monitor spec (3MP 24” diagonal) (for more details, please refer to SPR# HCSDM00501318)
5673206-8EN Rev 4	27/Feb/2019	Update information for: - packing information - safety (SA1) and servicability (SE1) for layout constraints - compression scale part - Legal manufacturer - DICOM URL (for more details, please refer to SPR#HCSDM00544409 and HCSDM00544275)

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CHAPTER 3. SYSTEM DESCRIPTION

1. System Component Description

Senographe Crystal Nova is delivered with a packing box that contains the following components:

Component	Accessory
Gantry with C-arm	▪ Standard 24x29 Paddle ▪ Standard Collimation Plate ▪ Sliding Paddle Kit (includes a Sliding 18x24 paddle and Sliding Collimation Plate) **– Option** ▪ 2D Localization Kit (includes a Sliding 2D Localization Perforated 18x24 Paddle, 2D Cross Hair and Sliding Collimation Plate) **– Option** ▪ Spot Paddle Kit (includes a Spot Paddle and Spot Collimation Plate) **– Option** ▪ Magnification Kit (includes a Magnification Paddle, Magnification Collimation Plate and Magnification Stand) **– Option** ▪ Sliding Small Breast and Implant 10x24 Paddle Kit (includes Sliding Small Breast and Implant 10x24 Paddle and Sliding Collimation Plate) **– Option** ▪ Additional Standard 24x29 Paddle **- Option** ▪ Face Shield ▪ Footswitches ▪ Flat Field Phantom ▪ IQST Phantom **- Option** ▪ ACR Mammography Phantom**- Option** ▪ Hydraulic Chair**- Option**
Control Station	▪ 2MP Monitor 23” Color LCD or 3MP Monitor 24” Color LCD ▪ Keyboard ▪ Mouse ▪ PC ▪ Software CD ▪ Emergency Stop Button and X-ray Exposure Button ▪ Lead Glass **- Option**
Detector	▪ Digital Detector 24x29 VXFOV
Generator	▪ Main Power Switch ▪ Exposure Switch
Miscellaneous	▪ Power Cable ▪ Connection Cables ▪ Manuals (IM in English, OM Exract in all required languages, User Publication CDs that contain SM/IM/PIM/OM/QCM)

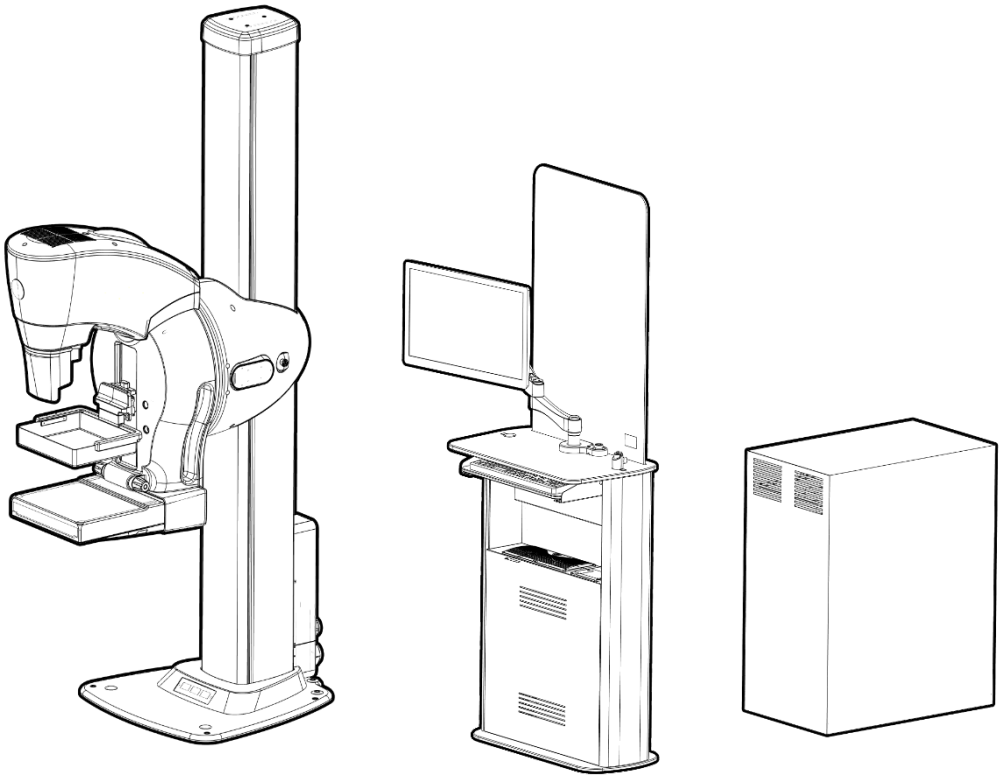
Component	Accessory
	▪ Parts for Installation

1-1. System Overview

Digital mammography Senographe Crystal Nova is a complete mammography solution optimized for digital imaging.

It consists of:

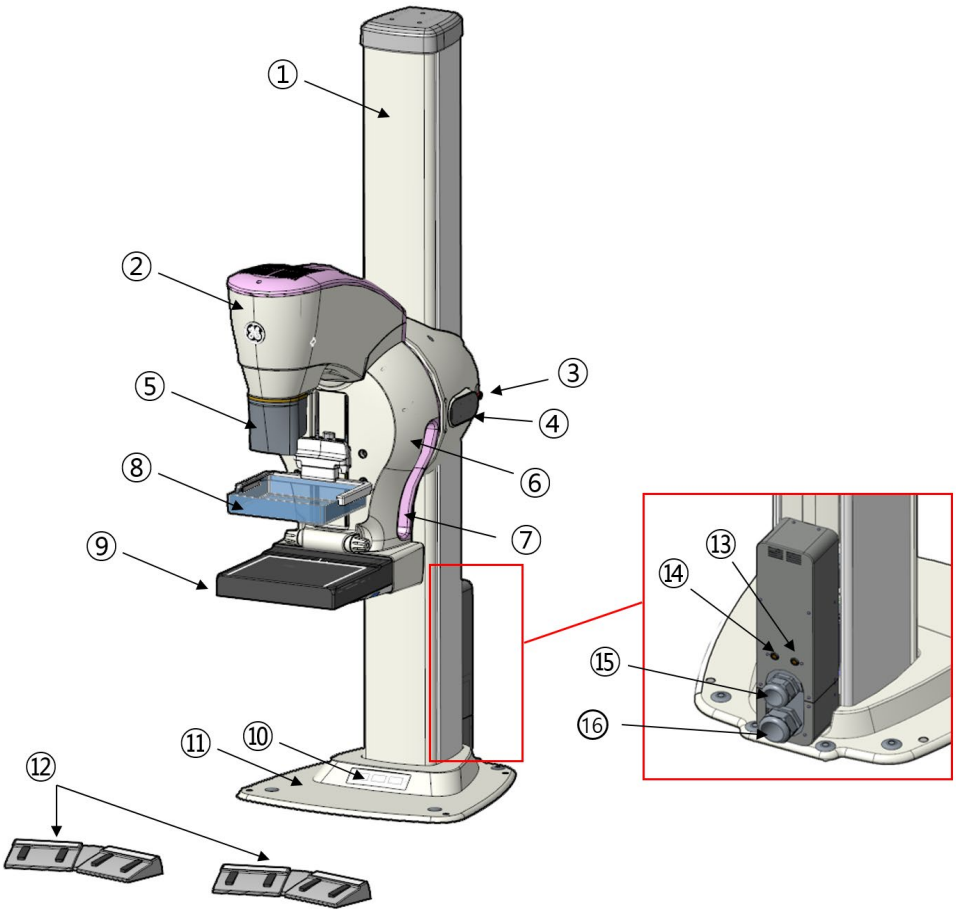
- Gantry with X-ray tube and digital detector
- Integrated X-ray control and image acquisition Control Station
- Generator to produce high voltage power for capturing X-ray images



[Figure 3-5] Gantry, Control Station and Generator

1-2. Gantry

The Gantry is equipment that houses the following parts for capturing images.



[Figure 3-6] Gantry Component

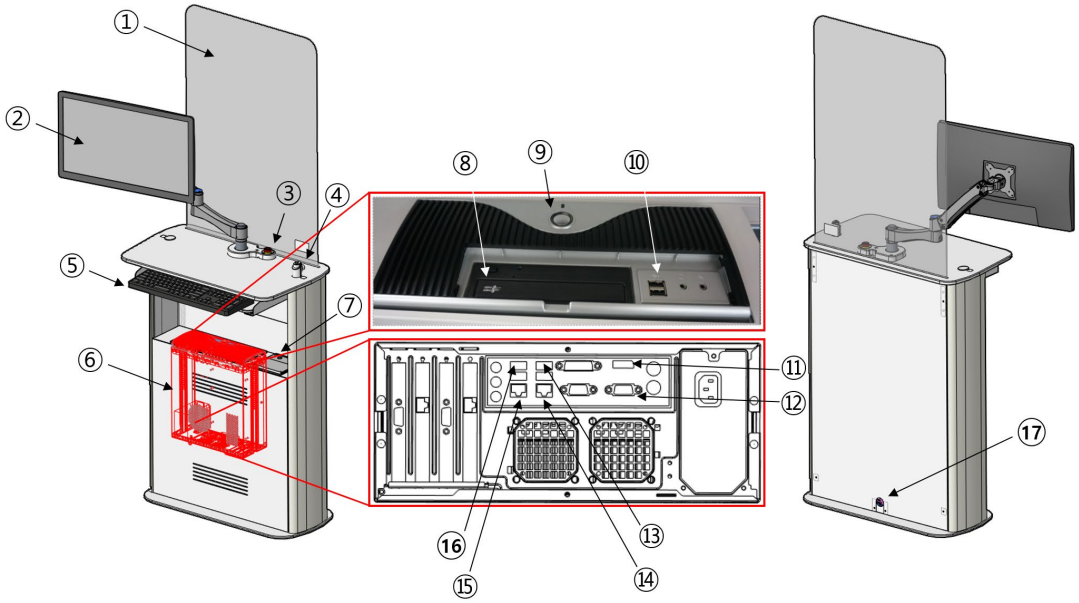
[Table 3-2] Gantry Component Description

No.	Designation	Description
1	Column	An exterior part of the system
2	X-ray Tube	Located on the inside of the case, this device generates the X-ray and includes the collimator
3	Emergency Switch	Emergency Swithces which are used to stop equipment in emergencies
4	Keypad	Keypads which are used to up, down or rotate the C-arm and control the compression paddle auto release and optical field ON
5	Face Shield	A screen to protect the rest of the non-injected part of the patient from X-ray
6	C-arm	A C-arm which is equipped with an X-ray tube and digital detector and it moves to the location of the breast to be imaged using a motor

No.	Designation	Description
7	C-arm Handles	Two pairs of hand rests are available on each side of the column to position the patient's hands for greater comfort and to optimize access to the breast, especially for lateral and oblique views.
8	Compression Paddle	A paddle that compresses a breast when the image is captured
9	Digital X-ray Detector	A digital X-ray sensor (inside the Bucky)
10	Base Display	Displays the angle of the C-arm, compressed thickness and compression force
11	Baseplate	A device base
12	Footswitches	Use the footswitches to apply / release compression and to move the lift up/down
13	Footswitch Cable Connector Insert	An insertion point to connect the foot switch cable
14		
15	Control Station Connection Cable	A cable for connecting the communication cable and Frame Grabber cable
16	Generator Connection Cable	A cable for connecting the Generator high voltage cable, filament/stator cable, and communication cable

1-3. Control Station

The Control station is a Control station that houses the following parts to control the system.



[Figure 3-7] Control Station Component

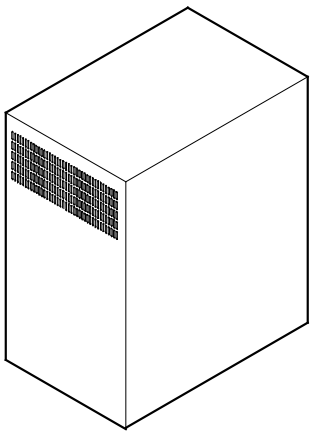
[Table 3] Control Station Component Description

No.	Designation	Description
1	Lead glass	A transparent protective barrier made of leaded glass, to prevent the exposure of X-rays (Option)
2	Monitor	A unit in a desk computer that contains the screen used to confirm software operation and patient's image
3	Emergency Switch	Emergency Switches which are used to stop equipment in emergencies
4	X-ray Exposure Switch	Press and hold this Switch to perform a X-ray exposure
5	Keyboard	An Input device to control software operation
6	PC	The CPU installed with necessary software and used to store images and to send images to PACS
7	Main Power button(ON/OFF)	A button for switching the main power ON/OFF
8	DVD/CD Drive	A device for storing image files and data in and out of CD/DVD media
9	PC Power Button	A button for turning the Control station ON/OFF
10	USB Port	A port for USB devices
11	Display Cable	Display Cable from AWS Monitor to be connected

No.	Designation	Description
12	PC-Main RS232 Communication Cable	RS232 Communication Cable from Gantry to be connected
13	Mouse Cable	USB Cable from AWS Mouse to be connected
14	Network LAN Cable	Ethernet cable to hospital network to be connected
15	PC-Detector Gigabit LAN Cable (246C)	Gigabit Ethernet cable to Detector in the Gantry
16	Keyboard Cable	USB Cable from AWS Keyboard to be connected
17	Power Cable	AC Power input
18	Cable Guard Insert	An insertion point to arrange and keep cables

1-4. Generator

The generator is a device for generating a high voltage to irradiate X-rays for capturing images.



2. Specification

2-1. Technical Specifications

Power Supply	
Line voltage	220-230V (±10%) 50 or 60 Hz
Power input	6.9 kVA
Current absorption	28A
Number of phases	Single phase
Connection	Permanently installed (IEC 60601-1)
Wall connection	32A (type D) Thermal-magnetic circuit breaker
Non-continuous Mode	Max output/5min
Maximum impedance of supply mains	The maximum impedance of supply mains must be lower than the value indicated below:

Supply Mains	Max. Impedance (ohm)
Distribution Transformer	0.339
Every Feeder Cable	0.095
Generator Input Terminal	0.625

Environmental Conditions	
Storage and delivery conditions	Temperature -5°C to +40°C Barometric Pressure 500 hPa to 1060 hPa Humidity 10% to 95%
Operating conditions	Temperature +15°C to +30°C (24 hours) Barometric Pressure 700 hPa/1060 hPa (24 hours) Humidity 10% to 80%(24 hours)

2-2. System Specification

System Information (IEC 60601-2-45)	
Nominal X-ray tube voltage and highest X-ray tube current available at that voltage.	30kV; 100mA
Highest X-ray tube current and highest X-ray tube voltage available at that current.	125 mA at 50 kV (Generator only)
Corresponding combination of X-ray tube voltage and X-ray tube current which results in the highest electrical output power.	33 kV; 100 mA
Nominal electric power given as the highest constant electric power (in KW) which the X-ray generator can deliver, for a loading time 0.1 s at an X-ray tube voltage of 30kV.	125 W at 30 kV, 100 mA
kV Range	25 to 35 kV in 1 kV increments
kV Accuracy	± 1 kV, over range 25 to 35 kV
mA Range	Small focal spot : 22 to 40 mA from 25 to 35 kV Large focal spot: 50 to 100mA from 25 to 33kV 50 to 80 mA from 34 to 35 kV
mAs Range	Large Focal spot : 1 to 320 mAs Small Focal spot : 1 to 125 mAs
mAs Accuracy	± 5%
Irradiation in AEC mode	Nominal shortest irradiation time : 500 ms at 40 mAs Range of X-ray tube voltage during irradiation : 25 through 35 kV Range of X-ray tube current during irradiation : 27.5 through 100 mA

Generator	
High Frequency, 25kHz	
Single phase 220Vac	
Microprocessor controlled with auto diagnostic and error indication for easy maintenance	
X-ray tube overload protection	
X-ray tube HU available indication and continuous monitoring for X-ray tube protection	
Automatic line compensation	±10% VAC
Maximum power kW	5 kW
kV Range	20 to 50 kV (0.5 kV step)
kV Resolution (Manual & Auto mode)	0.5 kV
mA Range	5 - 125 mA
Exposure Time Range	1 ms - 12.5 sec
mAs Range	0.1 - 500 mAs

X-Ray Tube	Varex (Insert: M-103T, Housing: B-121)
Anode rotation speed	2800 - 3000 rpm 50 Hz 3400 - 3600 rpm 60 Hz
Target material	Rhenium tungsten molybdenum target
Maximum anode heat content	222 kJ (300 kHU)
Anode Heat Dissipation	714W
X-ray Tube Assembly Permanent Filteration	0.63 mm Be
Housing Heat Sotrage Capacity	370 kJ (500 kHU)
Cooling method	With Fans
Anode disc target angle	10°/16°
Anode disc diameter	77 mm
Nominal Anode Input Power	Small focus: 2500 W Large focus : 9900 W
Nominal X-ray tube voltage	49 kV
Polarity of high-voltage connector	Only the positive pole(Anode)
Max. Tube Current (at 50 Hz)	Small: 46 mA Large: 165mA
Focal spots	2
Focal spot size according to IEC 60336	Small focal spot : 0.1 Large focal spot : 0.3
HVL measured at 28 kV	>0.3 mm Al equiv.
Total filtration	>0.5 mm Al

Filter Properties	
50µm Rhodium	0.05 mm Rh

Digital Image Detector	
Field of View (FOV) of the Digital Detector	24 cm x 29 cm
Digiter Detector Technology	GEMS Amorphos Silicon Matrix with CsI Scintillator
Detector Elements Pitch	100 µm
Image Size (in pixels)	X=2394, Y=2850

Image	
Depth	14bits
Imaging Area (H x W)	239.4 x 285 mm (For Contact View) 178 x 234 mm (For Magnification View) 178 x 234 mm (For Sliding View) 178 x 234 mm (For Spot View)
Pixel Matrix	2394 x 2850 pixels (For Contact View) 1780 x 2340 pixels (For Magnification View) 1780 x 2340 pixels (For Sliding View) 1780 x 2340 pixels (For Spot View)

Grid	
Ratio	3.5:1
Lines/cm	41
Bucky factor	1.68
Focal Distance	662 mm
Material	Carbon Fiber
Attenuation	Primary Transmission: 75 % Secondary Transmission: 25.5 %

C-arm	
S.I.D. (Source-to-Image Distance)	662 mm
Motorized rotation	± 180°
Display of angle rotation	On Base display
Motorized vertical movement with respect to breast support (C-arm in vertical position)	684 mm to 1334 mm
Protection of examination field	Detachable face shield

Collimator	
Light radiation	Automatic timer operated when the Push button is pressed, or compression is manipulated
Precision in optical spectroscopy	Conformed to IEC 60601-1-3
Mirror	-
Collimation plate type	Manual (by Collimation Plate)

Compression System	
Compression plate movement	Motor driven
Compression paddles	Standard 24x29 Paddle Sliding 18x24 Paddle (Optional) Sliding 2D Localization Perforated 18x24 Paddle (Optional) Sliding Small Breast and Implant 10x24 Paddle (Optional) Magnification Paddle (Optional) Spot Paddle (Optional)
Maximum available between compression paddle and surface of bucky	257mm (for Standard Paddle)
Compression thickness display	Displayed in mm
Compression force	Motor driven compression up to 20 (daN). User defined motorized compression force limit 3 to 20(daN)

Compression System	
Compression force display	Effective applied force with a sensitivity limit of 1 (daN)
Compression holder	Fast mechanical unlock
Compression plate release after exposure	Selectable from keypad on Gantry and AWS

Magnification Stand	
Maaterial	Polly carbonate
Magnification rate (Variable)	x1.5 / x1.8

Footswitch	
Function	C-arm Up/Down Compression paddle Up/Down

Emergency switch/Shutdown Switches	
Emergency switch	On both sides on the Gantry and on the table of Control Station.

Dose Calculator	
Calculated dose	AGD (Average Glandular Dose) That complies with the following by “D. R. Dance et al.”
Data observation	Display and Control station

Key pad	
Function	C-arm UP C-arm Down C-arm CW rotation C-arm CCW rotation Lamp turn-on Next Function Automatic Compression Release

Base	
Display	3-digit display (7 segment)
Information	C-arm rotation angle Compression thickness Compression force

2-3. Control Station Specifications

Control Station	
DICOM interfaces	3.0 MG modality
Lead glass Lead (Pb) equivalent	Compliant to IEC60601-2-45

High Resolution LCD Color Display	2MP	3MP
Display type	LCD	LCD
Viewable size	2MP 23” diagonal	3MP 24” diagonal
Display resolution	1920 x 1080 Full-HD	2560 x 1440 Quad HD
Pixel pitch	0.2652 mm	0.20535 mm
Contrast ratio	1000 :1	1000 : 1
Brightness	250 cd/m2	30 cd/m2
Viewing angle	Horizontal: 178 °/ Vertical: 178 °	Horizontal: 178 °/ Vertical: 178 °
Response time	5 ms (typical)	8 ms (typical) 5 ms (fast mode)
Palette	16.7 million colors	16.7 million colors
Refresh rate	56 to 85 Hz	50 to 76 Hz

2-4. Tube Specifications

X-Ray Tube	Varian M-103T
Maximum Potential Difference ● Cathode to Ground ● Anode to Ground	0 kV 39 - 49 kV
Target material	W (Tungsten)
Typical Bias Voltage for Focals	-5 to -100 Vdc
Housing Heat Storage Capacity	370 kJ (500 kHU)
Nominal Continuous Input Power	300 Watts (405 HU/sec) IEC 60613:2010
Maximum Housing Temperature	78°C
X-Ray Tube Assembly Permanent Filtration	0.63 mm Be IEC 60522/1999
Leakage Technique Factors	49 kV, 6.0 mA
Thermal Switch	Normally Closed Rating - 10 A @ 240Vac 79.4°C ±3.9°C (175°F ±7°F) : Open
Anode disc target angle	10°/16°
Anode disc diameter	80 mm
Ambient Air Temperature Limits for Operation	5°C to 40°C
Temperature Limits for Storage and Transportation	-10°C to 75°C
Humidity	+10% to +90%
Atmospheric Pressure Range	70 kPa to 106 kPa
Loading Factor for Resolution:	Small - 25 kV, 30 mA Large - 25 kV, 100 mA
Nominal Anode Input Power:	Small - 2.5 kW IEC 60613 Large - 9.9 kW IEC 60613 For the equivalent anode input power of 60 Watts

3. Suggested Manual Exposure Condition

3-1. for General Patient

Compressed breast thickness (mm)	With Bucky (contact view):			With MagStand (magnification view):		
	Target/Filter	kVp	mAs	Target/Filter	kVp	mAs
< 20	W/Rh	26	28	W/Rh	27	40
21-30	W/Rh	27	32	W/Rh	28	45
31-40	W/Rh	28	50	W/Rh	29	63
41-50	W/Rh	28	63	W/Rh	30	71
51-60	W/Rh	28	90	W/Rh	31	80
61-70	W/Rh	28	125	W/Rh	32	90
71-80	W/Rh	28	180	W/Rh	32	110
81-90	W/Rh	28	220	W/Rh	33	110
91-100	W/Rh	29	220			
>100	W/Rh	30	220			

3-2. for Patient with Breast Implants

Compressed breast thickness (mm)	With Bucky (contact view):			With MagStand (magnification view):		
	Track / Filter	kV	mAs	Target/Filter	kVp	mAs
<30	W/Rh	27	36	W/Rh	28	45
31-40	W/Rh	28	60	W/Rh	29	71
41-50	W/Rh	28	90	W/Rh	30	90
51-60	W/Rh	28	140	W/Rh	32	90
61-70	W/Rh	28	200	W/Rh	33	100
71-80	W/Rh	29	220	W/Rh	34	100
81-90	W/Rh	30	250	W/Rh	35	100
91-100	W/Rh	31	250			
>100	W/Rh	31	320			

4. Dimension and Masses

⚠CAUTION

The equipment must be installed by authorized personnel only.

The detector has a very strict range of temperature and must be removed from its original packing only after unpacking and placement of the unit and after installation room has reached operating temperature between 20 and 30°C.

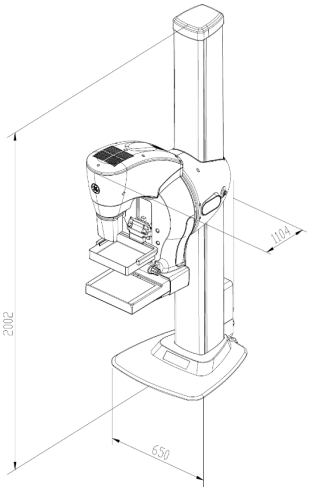
Extreme care must be taken during detector unpacking to prevent damage.

Handle the detector with care to reduce hazards of ESD (Electrostatic Discharge). (ESD is the sudden flow of electricity between two electrically charged objects caused by contact, an electrical short or dielectric breakdown.)

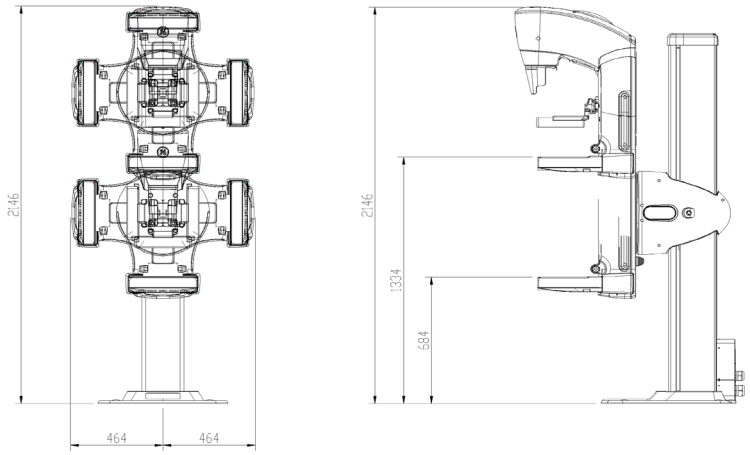
4-1. Gantry

4-1-1. Gantry (without dolly)

- Dimension (Tolerance ±7%):
  - Depth: 1104 mm
  - Width (depending on the angle of C-arm): 650 mm or 928 mm
  - Height (depending on the C-arm position): 2002 mm or 2146 mm
- Weight (including all cables and foot switches): 308.6 kg



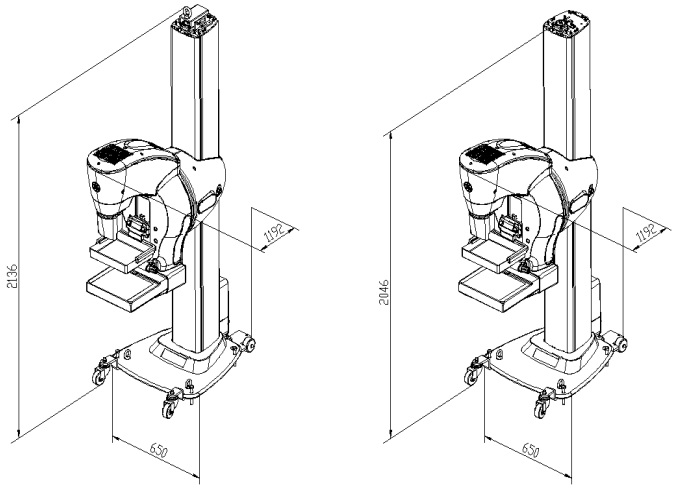
[Figure 3-8] Gantry (without dolly)



[Figure 3-9] L: Maximum height of detector, R: Hight of tube head and detector

4-1-2. Gantry with dolly

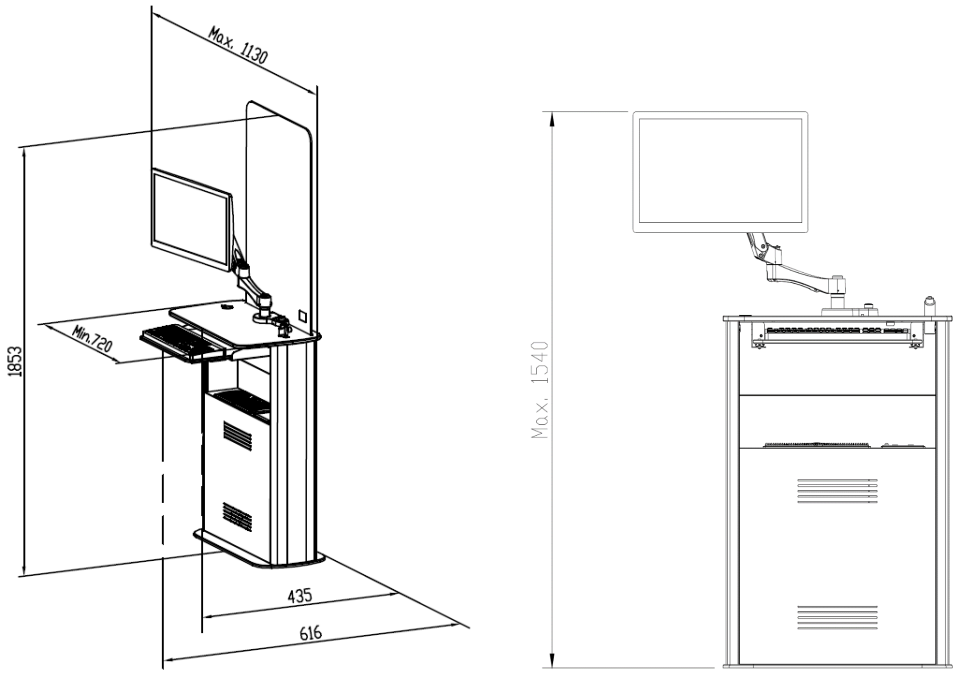
- Dimension (Tolerance ±7%):
  - Depth: 1192 mm
  - Width (depending on the angle of C-arm): 650 mm
  - Height (depending on the C-arm position): 2136 mm (without lift bracket and eyebolt: 2046 mm)
- Weight (including all cables and foot switches): 308.6 kg



[Figure 3-10] Gantry with dolly

4-2. Control Station

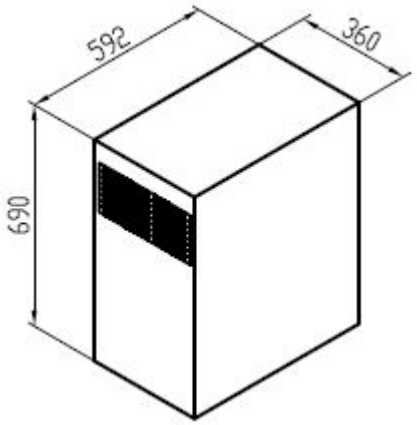
- Dimension (Tolerance ±7%):
  - Depth (depending on keyboard tray position): 435 mm, 616 mm
  - Width (depending on the monitor arm position): 720 mm or 1130 mm
  - Height (depending on the existence of Lead glass): 1540 mm or 1853 mm
- Weight: 97.2 kg (with lead glass)



[Figure 3-11] L: Control Station with lead glass, R: Control Station without lead glass

4-3. Generator

- Dimension (Tolerance ±7%):
  - Depth: 592 mm
  - Width: 360 mm
  - Height: 690 mm
- Weight: 91.8 (with cable)



[Figure3- 12] Generator

5. Accessories

5-1. Senographe Crystal Nova Accessories

The Senographe Crystal Nova is delivered with a standard paddle for use with the Bucky. The following accessories may be standard or optional according to country:

- Standard:	Compression Paddle 24 x 29 (Standard) Collimation Plate 24 x 29 (Standard)
- Sliding Option (SCAT# S30332DH):	Compression Paddle 18 x 24 (Sliding) Collimation Plate 18 x 24 (Sliding)
- Sliding Localization Perforated Option (SCAT# S30332DJ):	Compression Paddle 18 x 24 (Sliding Localization) Collimation Plate 18 x 24 (Sliding) Cross Hair
- Sliding Small Breast/Implant Option (SCAT# S30332DM):	Compression Paddle 10 x 24 (Sliding Small Breast/Implant) Collimation Plate 10 x 24 (Sliding Small Breast/Implant)
- Magnification Option (SCAT# S30332DL):	Compression Paddle (Mag) Collimation Plate (Mag) Magnification Stand
- Spot Option (SCAT# S30332DK):	Compression Paddle (Spot) Collimation Plate (Spot)
- Accessories storage Option	
- Flat Field Phantom	
- IQST Phantom Option	
- ACR Mammography Phantom Option	

⚠CAUTION

Only the paddles and accessories recommended for your Senographe model should be used with this equipment. Failure to heed this warning may cause unexpected results.

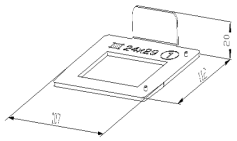
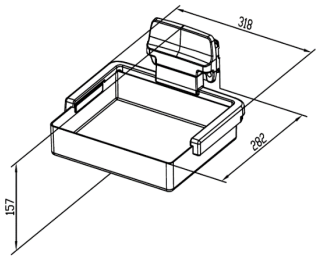
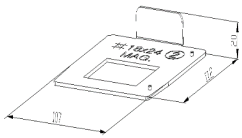
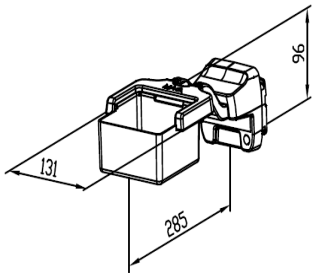
All accessories must be checked regularly to ensure that their surfaces do not contain cracks and that they have no sharp edges or corners that might cut, pinch, or otherwise hurt a patient.

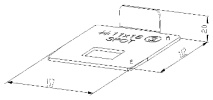
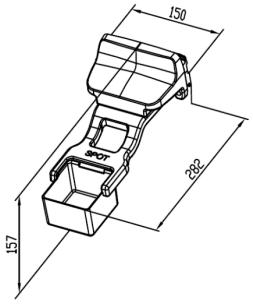
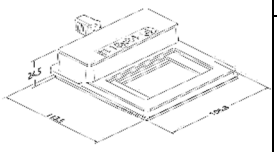
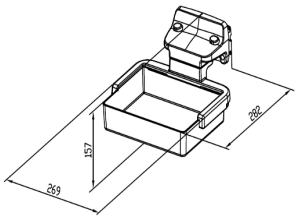
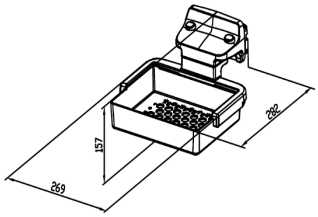
⚠CAUTION

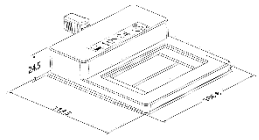
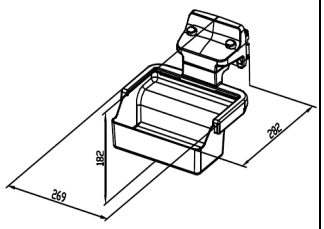
Handle all system parts and accessories with care. To avoid risk of injuries from falling parts and accessories, use appropriate handles and procedures.

To avoid the risk of mis-diagnosis and poor image quality, always handle Compression Paddle with care. When not in use, store the Bucky and Mag Stand in a place where it is protected from physical shock and vibration.

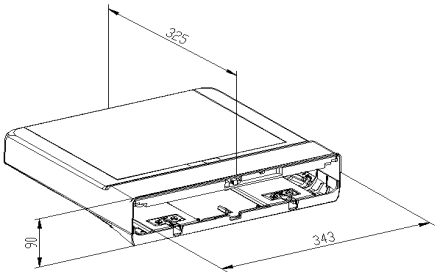
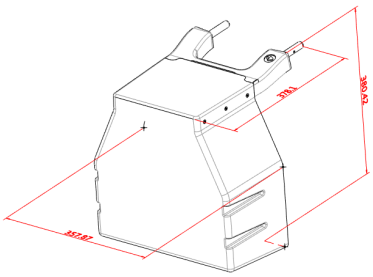
1. Compression Paddle and Collimation Plate

#	Collimation Plate	Compression Paddle	Weight (Kg) [Tolerance ±7%]	Basic or Optional	Breast support compatibility		Applied Part
					Bucky	Magnification Stand	
1	Standard collimation plate PN: 5773145 	Standard 24x29 paddle PN: 5773144 	Paddle: 1.4 Plate: 0.36	Basic	Yes	No	Type B (only for the paddle plate)
2	Magnification collimation plate PN: 5773132 	Magnification paddle PN: 5773130 	Paddle: 1.1 Plate: 0.15	Optional	No	Yes	Type B (only for the paddle plate)

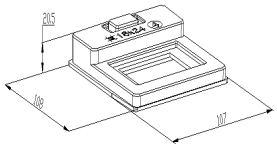
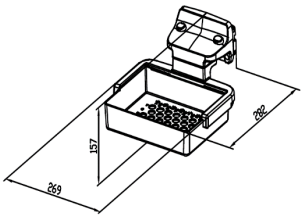
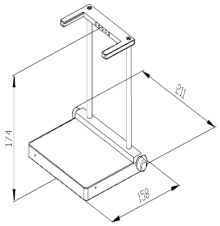
#	Collimation Plate	Compression Paddle	Weight (Kg) [Tolerance ±7%]	Basic or Optional	Breast support compatibility		Applied Part
					Bucky	Magnification Stand	
3	Spot collimation plate PN: 5773142 	Spot paddle PN: 5773135 	Paddle: 1.1 Plate: 0.18	Optional	Yes	No	Type B (Only for the paddle plate)
4	Sliding collimation plate PN: 5773150-2 	Sliding 18.x24 paddle PN: 5773147 	Paddle: 1.4 Plate: 0.35	Optional	Yes	No	Type B (Only for the paddle plate)
		Sliding localization perforated 18.x24 paddle PN: 5773151 	Paddle: 1.4 Plate: 0.35	Optional	Yes	No	Type B (Only for the paddle plate)
5	Sliding small breast & implant collimation plate	Sliding small breast & implant 10x24 paddle	Paddle: 1.4	Optional	Yes	No	Type B (Only

#	Collimation Plate	Compression Paddle	Weight (Kg) [Tolerance ±7%]	Basic or Optional	Breast support compatibility		Applied Part
					Bucky	Magnification Stand	
	PN: 5773155-2 	PN: 5773153 	Plate: 0.35				for the paddle plate)

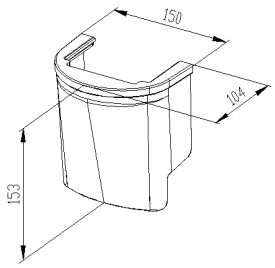
2. Breast Support

#	Name	Illustration	Weight (Kg) [Tolerance ±7%]	Context	Basic or Optional	Applied Part
1	Bucky PN: 5773126		2.1	Contact view	Basic	Type B
2	Magnification stand (x1.5 / x1.8) PN: 5773129		2.4	Magnification view	Optional	Type B (Only for the Mag.Stand plate)

3. 2D Localization Accessories

#	Name	Illustration	Weight (Kg) [Tolerance ±7%]	Basic or Optional	Breast Support Compatibility		Applied Part
					Bucky	Magnification Stand	
1	Standard collimation plate PN: 5773145		0.35	Optional	Yes	No	No
2	2D localization Sliding Perforated 18x24 Paddle PN: 5773151		1.4	Optional	Yes	No	Type B (Only for the paddle plate)
3	Cross hair PN: 5773156		0.67	Optional	Yes	No	No

4. Patient Positioning Accessories

#	Name	Illustration	Weight (Kg) [Tolerance ±7%]	Basic or Optional	Applied Part
1	Face Shield PN: 5773124		0.25	Basic	Type B (Only for the face shield cover)

5. Accessories storage

6. Flat Field Phantom

7. IQST Phantom Option

8. ACR Mammography Phantom Option

5-2. System Options

System options available include:

- **Review Workstation** – SenoIris Review Workstation
- **Mass Archiving System** – When installed and connected to the Senographe Crystal Nova System, acquired images can be sent to mass archiving device for permanent storage, either automatically or on request. A list of all patients ever imaged on the Senographe Crystal Nova system can be kept on the mass archiving device, making future retrievals fast and easy.
- **Networking** – The Senographe Crystal Nova 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 Crystal Nova 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 via below link https://www.gehealthcare.com/en/products/interoperability/dicom.

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

6. Labeling

6-1. System Labeling

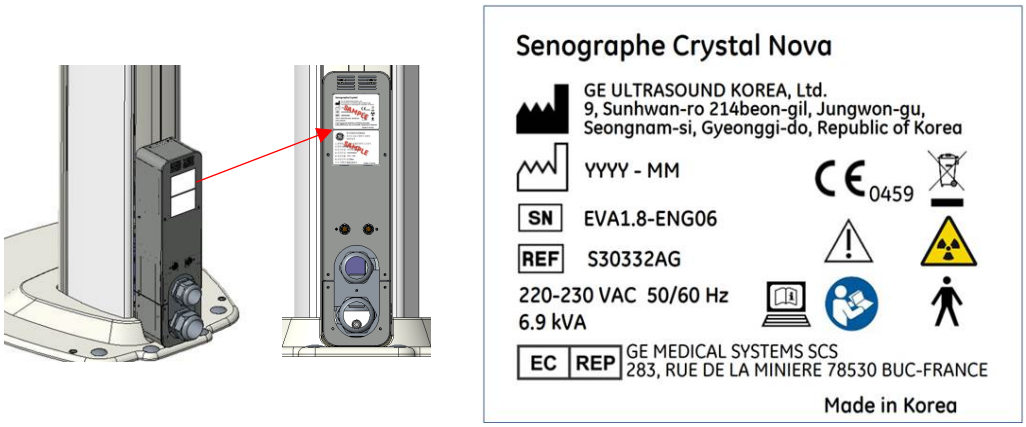


Figure 3-13 System Label (Sample)

6-2. Sub-System Labeling

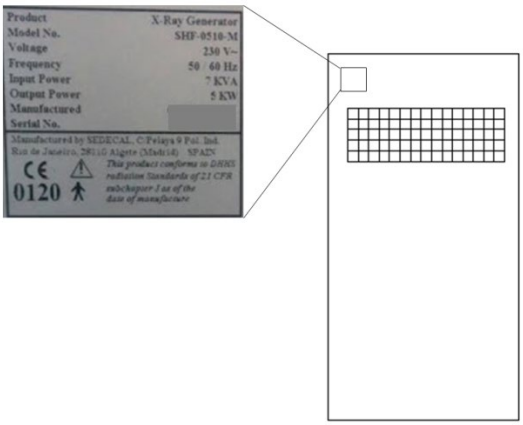
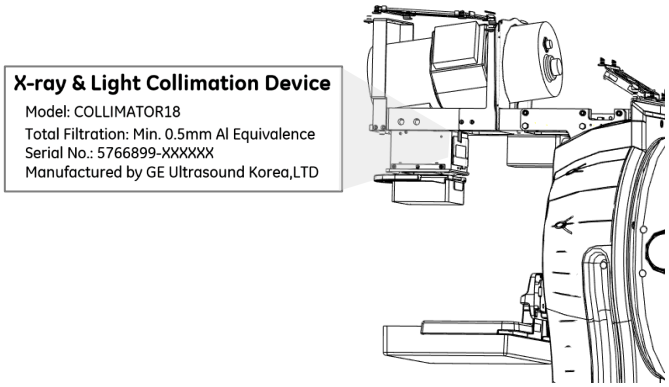
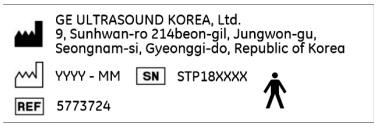
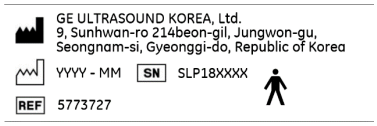
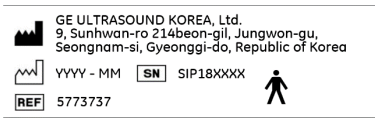
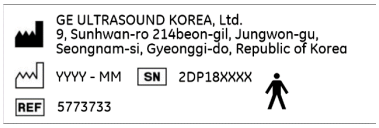
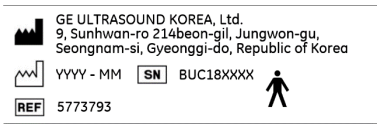
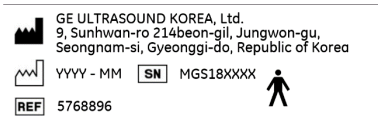


Figure 3-14 Generator Label Sample



[Figure 3-15] Location of Collimator Label (Sample)

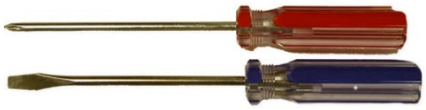
6-3. Accessories Labeling

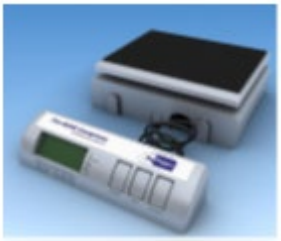
No	Accessories	Label Image (Sample)
1	STANDARD 24X29 PADDLE	
2	SLIDING 18X24 PADDLE	
3	SPOT PADDLE	
4	MAGNIFICATION PADDLE	
5	SLIDING SMALL BREAST AND IMPLANT 10X24 PADDLE	
6	SLIDING 2D LOCALIZATION PERFORATED 18 X 24 PADDLE	
7	VXFOV BUCKY	
8	FACE SHIELD MODULE	
9	CROSS HAIR MODULE	
10	Magnification Stand	

7. Tools Glossary

NOTICE

The specific tools should be used for assembling and de-assembling all cover parts.

Tool	Part No	Image
Set of Allen metric wrenches: 1.5 mm - 2 mm - 2.5 mm - 3 mm - 4 mm -5 mm - 5.5 mm - 6 mm- 8 mm- 10 mm		
(+) and (-) Screwdrivers		
Nipper pliers		
Long Nose Pliers		
Spanner		
Watch driver set		
Ratchet (+) Driver		
Digital Multimeter		

Tool	Part No	Image
Torque wrench (1-30 N·m)		
3 m measuring tape		
Ratchet handle (1/4" Square Drive)		
10 Piece Metric Standard Hex Socket Set (1/4" Square Drive): 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm)		
Digital Spirit level		
Mammography compression scale with digital Display	5796978 or 46-194427P407	
W/Rh compatible dosimeter		

Tool	Part No	Image
Grease		

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CHAPTER 4. PRE-INSTALLATION SYSTEM REQUIREMENTS

1. General Requirements

1-1. Objectives and Overview

This document helps planning the installation of the Senographe Crystal Novaby providing the various requirements and pre-conditions induced by the system.

In order that the installation goes smoothly, it is important that the site is prepared correctly. This pre-inspection will be requested before the delivery of the equipment to check whether the examination room is ready for the installation. Before installation, fill out the below Site Checklist.

Note:

All changes to the examination room have to be done before the installation.

If the room is NOT properly cleaned and all requirements are NOT met, the installation will be postponed.

1-2. Customer Responsibilities

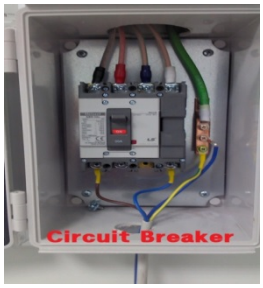
Before installing the equipment, know the following conditions:

- The customer should appoint a person who is responsible for the examination room and has knowledge about how the equipment will be used.
- Network information, PACS information, and system configuration should be addressed to the local General Electric Field Engineer before the mammography system arrives at the location.

Before installation, Installation specialist should fill out the following Site checklist.

Check Point	Detail		
A. Site Information			
Name of Imaging center/hospital			
Address			
Phone / FAX Number			
Name of Director			
Phone Number / E-mail Address			
Name of Radiological Technician			
Phone Number / E-mail Address			
Number of radiological technicians for the operation training			
B. Information for the Delivery			
Desired Date for Installation			
Examination Room Ready?	YES □ NO □	Completion date	
Entrance	**Access to the site for the transport company**		

Check Point	Detail	
	Loading Dock □ Main Entrance □ etc. ( )	
Carriage	Elevator □ Stairs □ Forklift □ etc. ( )	
Which floor?	Ground □ 1F □ 2F □ 3F □ 4F □ 5F □ etc. ( )	
Please fill in general information: • When do you want the Senographe Crystal Novato be installed? • Whether the examination room ready? (Interior work, electric work, floor, etc…), if NOT when it will be completed? • Please fill in information for carrying Mammography Unit from Main entrance to the examination room. • Please take photos and attach them when you reply. **Checkpoint**: Design the building access plan for the boxes based on their dimensions.		
C. Measurements for Installation		
Dimensions of the Room	Width: mm / Depth: mm / Height: mm	
Examination Room Door Size	Width: mm / Height: mm	
Dimensions of Elevator	Width: mm / Depth: mm / Height: mm	
Elevator Door Size	Width: mm / Height: mm	
Dimension of Hall Way	Width: mm / Height: mm	
D. Electrical Requirements		
Voltage Frequency	220V □ 230V □ 240V □ etc. ( )	
Circuit Breaker Capacity	**50 A (Recommended)**	A
Electric Capacity	**6.9 KVA (Recommended)**	KVA
Power Connection Type	Circuit Breaker □ Socket Outlet □	
Outlet with Ground	YES □ NO □	
Number of Phases	Single-phase □ Two-phase □ Three-phase □	



<Circuit Breaker>

<Socket Outlet>

<Circuit Breaker Capacity>

Check Point	Detail		
▪ Please check the voltage and frequency. Senographe Crystal Novais working in Single phase 220 Vac, ±10% 27A, 60Hz. ▪ Make sure that the circuit breaker capacity is over 30A (50A is recommended). ▪ Make sure that the capacity of power is over 6.6kW (220V X 30A = 6,600VA). ▪ Make sure that ground line must be ready. ▪ Please check the type of power cable connection. ▪ Please check the type of input voltage phase. Senographe Crystal Novais working in 1 or 2 phases. ▪ Please take photos and attach them when you reply.			
E. NETWORK Information (For Mammography System)			
IP Address		Network Speed	100Mbps □ 1Gbps □ etc.( )
Subnet Mask		Anti-virus from Hospital	YES □ NO □
Default Gateway		Product Name	
DNS Server			
F. PACS (Picture Archiving Communications System) Information			
Manufacturer		Manager Name	
Product Name		Manager Contact	
Server Information	**Worklist Server**	**Storage Server**	
AE Title			
IP Address			
Port Number			
Location of Main Server	In the Hospital □ Out of Hospital □ etc.( )		
Dose hospital's SCP (PACS or RIS) need a **Static Port Number** from the SCU (Modality-Senographe Crystal NOVA)? AE Title ■ (Must) IP Address ■ (Must) **Static Port Number** (YES □ NO □)			
▪ Please fill in all information of PACS. ▪ Please check YES or NO about the Static Port Number.			
G. DICOM Printer Information			
DICOM Printer	YES □ NO □	AE Title	
Manufacturer		IP Address	
Product Name		Port Number	
Film Size		Layout Option	1x1 □ 1x2 □ etc.( )
H. DICOM CD Burner Information			
DICOM CD Burner	YES □ NO □	AE Title	
Manufacturer		IP Address	
Product Name		Port Number	
I. Extra Device			
Device Type		AE Title	
Manufacturer		IP Address	
Product Name		Port Number	

Check Point	Detail		
J. Circumstances			
Air Conditioner in Room	YES □ NO □	Controlled Separately?	YES □ NO □
Room Temperature	20°C - 30°C (Recommended)		°C
Room Humidity	30 % - 75 % (Recommended)		%
A number of Expected case a day	Under 15 □ 16 - 30 □ 31 - 45 □ 46 - 60 □ Over 60 □		
Medical Monitor	YES □ NO □	Monitor Resolution	3M □ 5M □ etc( )
Former Mammo Unit	YES □ NO □	Manufacturer	
Which type	Film □ CR □ DR □	Product Name	
▪ Is there an air conditioning system in the examination room? If yes, is it possible to control the temperature only for the examination room? ▪ Please check the room temperature and humidity. ▪ Please check an expected patient number a day. Is there a medical monitor? If yes, please check the resolution of the medical monitor. ▪ Have you used any other mammo unit in this hospital? If yes, please check the type of mammo system and write down the manufacturer & product name.			
K. Special Instructions or Requirements to Installation Team			
L. Local Regulation for Mammography System and DCS			
▪ If there are local regulations for using Mammography system, you MUST inform to GE Ultrasound sales or SVC Field engineer about regulations and compliance test list. ▪ You MUST inform GE Ultrasound sales or SVC Filed engineer about DCS of PACS, DICOM Printer, etc.			
M. Inspected by			
Name		Company	
Tel		E-mail	

2. Environmental Requirements

2-1. Atmospheric Pressure Limits

Atmospheric pressure				Altitude (from sea level)	
Min			Max	Min	Max
Operational	Storage	Transportations			
700hPa	500hPa	500hPa	1060hPa	0 m	3000m
				0ft	*9840ft*

NOTICE

During transportation, a pressurized environment must be used to maintain the atmospheric pressure limits.

2-2. Storage Requirements – Temperature and Humidity

2-2-1. General Requirements

The system includes a detector assembly in its casing, which is sensitive to changes in temperature and humidity.

The specified storage requirements assume that the all the equipment remains in its packaging, including the protection for the detector.

2-2-2. Before Installation - Short Term

For short-term storage (less than 5 days), refer to the storage requirements table below.

Relative humidity (non-condensing)		Temperature	
Min	Max	Min	Max
10%	95%	-5°C	40°C
		23*°F*	104*°F*

2-2-3. Before Installation - Long Term

For long-term storage (more than 5 days), it is recommended that the detector assembly is kept in an area with relatively dry and low temperature, or area with air condit~ioning. For example, relative humidity is less than 80%.

2-3. Operating Requirements – Temperature and Humidity

Relative humidity (non-condensing)		Temperature	
Min	**Max**	**Min**	**Max**
10%	80%	15°C	30°C
		59*°F*	*86°F*

2-3-1. Air Conditioning

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

For patient comfort, ambient temperatures of 23°C ± 3°C (73ºF ± 5ºF) are recommended.

2-4. Storage of Detector after Removal

If the detector is removed from the system and stored again in its original packaging, it is recommended that the detector is stored between 0°C (32ºF) and 40°C (140ºF).

2-5. Heat Output

The average heat output of the system (Gantry and Generator and Control Station combined) is 440 W / 1507 BTU/h (for an 8-hour working day with 50 patients examined).

3. IEC60601-1-2 ELECTOMAGNETIC STANDARDS COMPLIANCE

3-1. General

This equipment complies with the IEC60601-1-2 Edition 2 and 3 EMC standard for medical devices.

The Senographe Crystal NovaEquipment or System 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 1).

• Immunity Compliance levels and recommendations for ensuring that the equipment retains its clinical utility (Tables 2, 3, and 4).

⚠CAUTION

No explanation is provided on fixed devices or system cabling which users cannot remove. The cabling is a part of the system used to measure all EMC. Without the cabling, the system will not work.

⚠WARNING

If accessories, convertors and cables other than those designated are used or such convertor and cable are not purchased as substitute parts through the device or system manufacturer, the amount of emission may increase, or the immunity of the device or system may malfunction.

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

Requirement	Sub-clause
Accuracy of LOADING FACTORS Accuracy and reproducibility of X-RAY TUBE BOLTAGE Accuracy of CURRENT TIME PRODUCT	203.6.4.3.102
AUTOMATIC CONTROL SYSTEM AEC reproducibility AEC thickness response	203. 6.5
Imaging performance NOMINAL FOCAL SPOT VALUE DEFECTIVE DETECTOR ELEMENTS of the integrated X-RAY IMAGE RECEPTOR Replacement of data originating from DEFECTIVE DETECTOR ELEMENTS Image homogeneity Homogeneity of intercepting layers in the X-RAY SOURCE ASSEMBLY Motion of the ANTI-SCATTER GRID under maximum compression force ARTEFACTS from grid lines Maximum LOADING TIME	203.6.7
Missed tissue at chest wall side	2038.5.4.101
BREAST COMPRESSION DEVICE	203.8.5.4.102

Requirement	Sub-clause
Control of compression movements Range of movement Design of compression plates Strength of compression plates Compression force	
Linearity of AIR KERMA over limited intervals of LOADING FACTORS	203.6.3.1.2
Reproducibility of the X-RADIATION output	203.6.3.2

3-2. Electromagnetic Emission

⚠CAUTION

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

[Table 4-4] ELECTROMAGNETIC EMISSION

Instruction and Announcement from the Manufacturer - Electromagnetic Emission		
The Senographe system is suitable for use in the specified electromagnetic environment. The purchaser or Operator of a Senographe system must ensure that it is used in an electromagnetic environment as described below:		
Emission Inspection	**Compliance**	**Electromagnetic Environment**
RF emission CISPR 11	Group 1	The Senographe is primarily intended for use in non-domestic Environments, and not connected directly to the public mains supply network. It is primarily intended for use in environments (such as hospitals) with a dedicated supply system, and in an X-ray shielded room.
RF emission CISPR 11	Class A	The Senographe uses RF energy only for its internal function. The RF emission is therefore very low, and not likely to cause any interference in nearby electronic equipment.
Harmonic emission IEC 61000-3-2	N/A	The Senographe is primarily intended for use in non-domestic Environments, and not connected directly to the public mains supply network.
Voltage Variation/ Flicker emission IEC 61000-3-3	N/A	The Senographe is primarily intended for use in non-domestic Environments, and not connected directly to the public mains supply network.

⚠WARNING

This device or system should not be placed near other devices and other devices should not be placed on this device or system. If it is necessary to place it near with other devices, the device or system must be observed before confirming its working order.

3-3. Electromagnetic Immunity

⚠CAUTION

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

[Table 4-5] ELECTROMAGNETIC IMMUNITY - PART 1

Instruction and Announcement from the Manufacturer – Electromagnetic Immunity			
Senographe Crystal Novais designed to be use under the designated electromagnetic environment as shown below. Customers or users of Senographe Crystal Novamust be aware that they must use the equipment under the following environment.			
Immunity	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment**
ESD (electrostatic discharge) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	The floor must be wood, concrete, or ceramic tiles. If the floor is covered by a synthetic material, the relative humidity must be at least 30 %.
EFT (Electrical fast Transient)/burst IEC 61000-4-4	In case of the power supply line, ±2 kV In case of the input/output line, ±1 kV	In case of the power supply line, ±2 kV In case of the input/output line, ±1 kV	The quality of the main power must be as high as that in a typical commercial environment or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV contact mode	±1 kV differential mode ±2 kV contact mode	The quality of the main power must be as high as that in a typical commercial environment or hospital environment.

In the power supply input line, voltage drop, short-duration interruption, and voltage variation IEC 61000-4-11	<5% *U*T (>95% dip in *U*T) in case of 0.5 cycle 40 % *U*T (60 % dip in *U*T) in case of 5 cycles 70 % *U*T (30 % dip in *U*T) in case of 25 cycles	N/A	The quality of the main power must be as high as that in a typical commercial environment or hospital environment. If it is necessary to continuously operate even during a main outage, Senographe Crystal Novausers are recommended to run it on an uninterruptable power supply unit. Senographe Crystal Novahas the rated input current of more than 16 A per phase.
	<5 % *U*T (>95 % dip in *U*T) in case of 5 secs	<5 % *U*T (>95 % dip in *U*T) in case of 5 secs	
Power frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	The magnetic field of the power frequency must reach the level shown for a typical place in a normal commercial environment or hospital environment.

Note:

UT is the main voltage of a.c. before the test level is applied.

[Table 4-6] ELECTROMAGNETIC IMMUNITY - PART 2

Instruction and Announcement from the Manufacturer – Electromagnetic Immunity			
Senographe Crystal Novais designed to be used under the designated electromagnetic environment as shown below. Customers or users of Senographe Crystal Novamust be aware that they must use the equipment under the following environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz - 80 MHz 3 V/m 80 MHz - 2.5 GHz	3 Vrms 10 V/m	Portable and mobile RF communication devices should not be used close to any parts of Senographe Crystal Nova (including its cables) and the distance should not be closer than the recommended separation distance calculated in accordance with the formula applied to the transmitter frequency. Recommended separation distance d = 1.2 P \ d = 1.2 P \ 80 MHz - 800 MHz d = 2.3 P \ 800 MHz - 2.5 GHz Where P is the maximum rated output power of the transmitter displayed in wattage (W) by the transmitter manufacturer; and d is the recommended separation distance displayed in meters (m). As shown in the electromagnetic site investigation a, the field force of the fixed RF transmitter must be smaller than the compliance level in the scope of each frequency b.  Near the devices marked with the following symbol, interruption may occur:
The field force of a fixed transmitter – e.g., wireless (mobile phone/wireless) base station, land mobile radio, amateur radio, AM/FM radio broadcasting, TV broadcasting, etc. – cannot be precisely predicted. To evaluate the electromagnetic environment created by such fixed RF transmitter, the electromagnetic site investigation must be considered. If the force of the field measured at the location where Senographe Crystal Novais used exceeds the RF compliance level, it must be confirmed through observation whether Senographe Crystal Novaworks normally or not. If abnormal operation is identified, additional actions such as change to the position or direction of Senographe Crystal Novamay be required. Within the frequency scope of 150 kHz - 80 MHz, the field force must be lower than 3 V/m.			

Note:

Between 80 MHz and 800 MHz, the higher frequency scope will be applied.

The guidelines are not applied to all situations. The electromagnetic waves can be influenced by absorption and reflection of a structure, an object or a person.

3-4. Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2

⚠CAUTION

The Senographe Crystal Novais intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Senographe Crystal Novacan help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Senographe Crystal Novaas recommended in this document, per the maximum output power of the communications equipment.

[Table 3-7] RECOMMENDED SEPARATION DISTANCES

Portable and Mobile RF Communication Device and the Recommended Separation Distance with the Device/System			
Senographe Crystal Novais designed to be used in the electromagnetic environment where RF disturbance emissions are controlled. Senographe Crystal Novacustomers or users may prevent electromagnetic interruption by maintaining the minimum distance between the portable and mobile RF communication device (transmitter) and Senographe Crystal Novaas recommended below in accordance with the maximum output power of the communication device.			
Rated maximum output power of a transmitter (W)	**Separation distance in accordance with transmitter frequency (m)**		
	150 kHz - 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz - 800 MHz** $d = 0{,}35\sqrt{P}$	**800 MHz - 2.5 GHz** $d = 0{,}7\sqrt{P}$
0.01	0.12	0.035	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.1	2.2
100	12	3.5	7
In case of a transmitter whose maximum output power is not mentioned above, the recommended separation distance displayed in meter (m) may be predicted by using the formula applied to the transmitter frequency, where P is the maximum rated output power of the transmitter displayed in wattage (W) by the transmitter manufacturer.			

Note:

Between 80 MHz and 800 MHz, the higher frequency scope will be applied.

The guidelines are not applied to all situations. The electromagnetic waves can be influenced by absorption and reflection of a structure, an object or a person.

3-5. Use Limitation

External components:

WARNING

The use of accessories, transducers, and cables other than those specified by GE Healthcare can result in the degraded Electromagnetic compatibility of the Senographe Crystal NOVA. Refer to the FRU Parts section Chapter 11. FRU List.

3-6. Installation Requirements and Environmental Control

To minimize interference risks, the following requirements apply.

3-6-1. Cable Shielding & Grounding

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

3-6-2. Separated Power Supply Distribution Panel & Line

WARNING

This Senographe Crystal Novais 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.

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

The Senographe Crystal Novais 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 Crystal Novais used in a domestic environment (in a doctor's office, for example), it is recommended that it must be connected to a separate AC power distribution panel and line, and it must be installed in an X-ray shielded room.

3-6-3. Subsystem & Accessories Power Supply Distribution

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

NOTICE

You cannot connect different electrical devices and supply them by different AC power distribution lines.

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

3-6-4. Stacked Components & Equipment

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

3-6-5. Static Magnetic Field Limits

To avoid interference on the Senographe Crystal NOVA, static field limits from the surrounding environment are specified.

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

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

3-6-6. Electrostatic Discharge Environment & Recommendations

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

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

Relative humidity must be maintained above 30 percent.

4. Structural Requirements

4-1. Ceiling Requirements

Table below summarizes the minimum ceiling height (See Dimensions and Masses, 9-1-1 Gantry).

[Table 4-8] RECOMMENDED MINIMUM CEILING HEIGHTS

Tube Head Maximum Height	Rotated C-arm Maximum Height	Maximum Height for Service Ability	Recommended Minimum Ceiling Height
2146mm	2146mm	2262mm	2400mm

4-2. Wall Requirements

The hospital must take special precautions regarding X-ray protection in the examination room walls (See section7. Planning for Radiation Protection).

4-3. 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:

1. Gantry:

- The worst-case mass of the complete Gantry is 308.6 ± 10% kg (680.3lbs)
- The bearing surface of the base plate is 0.35 m²
- The Gantry is provided with 6 anchoring points (refer to Anchoring Inserts)

2. Control Station:

- The worst-case mass of the complete Control Station is 97.2± 10% kg (214.3lbs)
- The bearing surface of the base plate is 0.222667 m²
- The Control Station is provided with 2 anchoring points (refer to Anchoring Inserts)

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 Anchoring Inserts the customer must inform GE Healthcare. Flooring consists of all materials above the structural floor support including subflooring and equipment support/mounting. The flooring requirements and recommendations are as follows:

- Flooring materials must support the Senographe Crystal Novaequipment mass (See 9-1. Dimensions and Masses).
- 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.

4-4. Seismic Requirements

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

Sites that require seismic anchoring must have a site architect and engineer review the response spectra and/or Uniform Builders Code (UBC) for their location.

4-4-1. 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 Anchoring Inserts.
- Anchors installed to the required minimum floor thickness (See 9-4-2. Anchoring Inserts).

4-4-2. 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.

4-4-3. Generator Cabinet

In seismic areas, provision must be made for securing the Generator 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.

4-4-4. 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.

5. Electrical Requirements

Note:

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 additions, 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 Medical 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 will use its own specially trained Field Engineers. All of GE electrical work on these products will comply with the requirements of the applicable electrical codes.

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

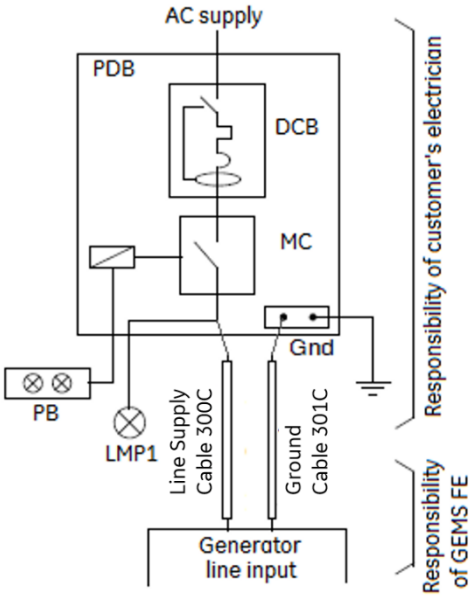
5-1. Room Power Supply

NOTICE

Line power to the Senographe Crystal Novamust be supplied through a suitable circuit breaker (See section Main Circuit Breaker Specifications).

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 diagram given here outlines a suitable supply system and indicates items to be provided and installed by the customer electrician. Refer to the following sections for more information.



Legend:

- **PDB**: Power Distribution Box supplying AC power to the Senographe Crystal Novaequipment.
- **DCB**: Differential Circuit Breaker (thermomagnetic).
- **MC**: Main Contractor. Manual switch to be accessible for emergency use.
- **PB:** Push Button. Remote control for main contactor; ON/OFF impulse push-buttons, lockable ON/OFF, with indicator lights (Red = ON, Green = OFF). To be located near access door, 1.5 m (59 inches) above the floor.
- **LMP1**: Red power presence indicator light (continuous glow or flashing), located above access door; bulb 30 V, 25 W max.
- **Line Supply Cable**: Comprises of two supply wires – 2x4 mm².
- **Ground Cable**: Ground cable (Gnd) - 5.26 mm².

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.

5-1-1. Lockable LOTO Enabled Power Sources

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

- the Line Supply Cable going from the room Mains Distribution Panel and the Generator
- the Status Lamps power cables going from the room door to the Generator

Examples of LOTO enabled lockable power sources include those with lockable disconnecting switches (See example 1 and example 2 in Illustration 1), or lockable breakers (see example 3 in Illustration 1).

[Figure 4-16] EXAMPLES OF LOCKABLE LOTO ENABLED POWER SOURCES

5-2. Line Voltage Specifications

- Single phase input voltages (phase/neutral or phase/phase): 220 or 230Vac, ±10%
- Maximum line current of the system: 32.71A at 198 VAC, based on maximum input voltage (35 kV) and output current (100 mA) of the tube housing assembly.
- The maximum line current corresponds to the use of the technique factors 35kV, large focal spot and 320mAs.

5-3. Line Frequency Specifications

- 50 Hz or 60 Hz (±1 Hz).

5-4. kVA Load Characteristics

- Maximum power in standby: 0.5 kVA.
- Maximum instantaneous power (during exposures, up to 3.2 seconds) 6.9 kVA.

5-5. Line Impedance

The maximum impedance of supply mains must be lower than the value indicated below:

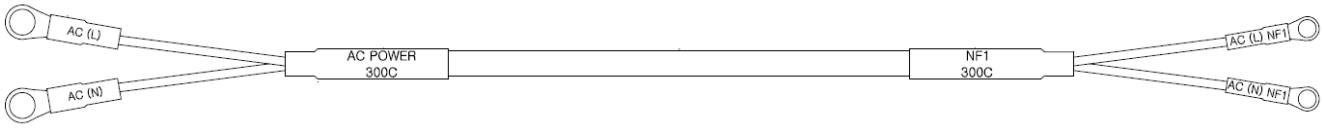
Supply Mains	Max. Impedance (ohm)
Distribution Transformer	0.339
Every Feeder Cable	0.095
Generator Input Terminal	0.625

5-6. Line Supply Cable

The Line Supply Cable provides AC power from the hospital Mains Distribution Panel to the Generator.

The Line Supply Cable comprises of two supply wires.

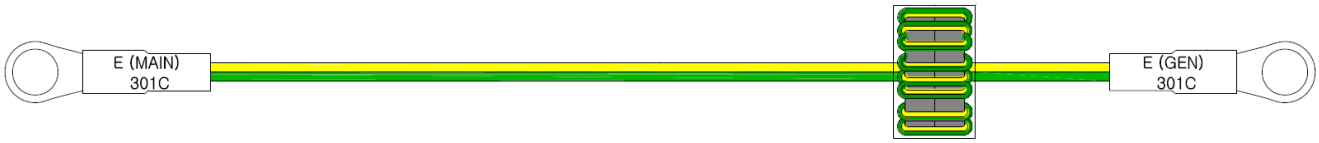
- Total length =10m (393.7inches)
- Usable length =9.5m (374.01inches)



The ground cable with the following actual/usable lengths:

- Total length =10m (393.7inches)
- Usable length =9m (354.33inches)
- Cable gauge:

- Phase and neutral wires: 10 AWG
- Ground wire: 10 AWG



5-7. Main Circuit Breaker Specifications and Circuit Isolator Requirements

5-7-1. Circuit Breaker Sizes for Europe:

From 200 V up to 240 V:

- Rate current (I_n): 32 A (type D)
- Instantaneous tripping current: 12 I_n ±20%
- Leakage current trip sensitivity: 30 mA (waveform pulsed)

5-7-2. Circuit Breaker Sizes and Supply Conductors for the US Market

- The branch circuit used must be rated 30 A or less.
- The current capacity of supply branch circuit conductors and the current rating of overcurrent protective devices must not be less than 50% of the momentary rating or 100% of the long-time rating, whichever is greater (NEC 1993 Section 517-73 (a) Item 1).
- The current capacity of supply feeders and the current rating of overcurrent protective devices supplying two or more branch circuits supplying X-ray units must not be less than 50% of the momentary demand rating of the largest unit plus 25% of the momentary demand rating of the next largest unit plus 10% of the momentary demand rating of each additional unit. Where the X-ray units are used for simultaneous biplane examinations, the supply conductors and overcurrent protective devices must be 100% of the momentary demand rating of each X-ray unit (NEC 1993 Section 517-73 (a) Item 2).

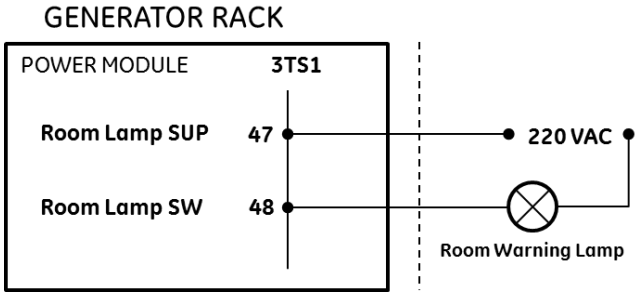
5-7-3. Circuit Isolator Requirements

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

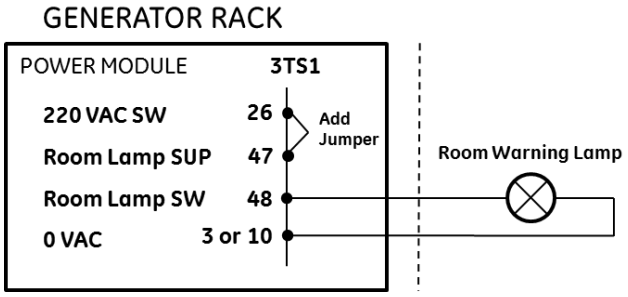
- Circuit Isolator must have rated Impulse Withstand Voltage (Uimp): 4 kV
- Circuit Isolator must have control switch (S1) on PDB door to operate).
- Control Switch (S1) must have provision for lockout/tagout(LOTO)
- Circuit Isolator must open all poles simultaneously when control switch (S1) is turned 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).

6. Room Warning Lamp and Room Door Interlock Switch Configuration

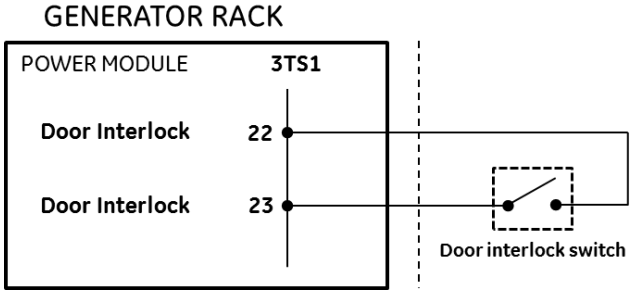
To meet safety and regulatory requirements, access to rooms in which X-ray equipment is installed must be controlled by controlled by warning lamps and safety door interlock switches. The Generator provides facilities to met these requirements. The diagram below shows the circuits used, and indicates itiems required for supply by the customer.



[Figure 6-1] Room Warning Lamp connection (Externally powered lamp)



[Figure 6-2] Room Warning Lamp connection (Internally powered lamp)



[Figure 6-3] Room door interlock switch connection

6-1. Room Lighting

In order to obtain a room brightness value of 160 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.

7. Planning for Radiation Protection

7-1. Radiation Protection – General

⚠CAUTION

Respect the minimum distances required between the Gantry and the Control Station or Lead glass to allow for X-ray attenuation.

Because the X-ray equipment produces radiation, the purchaser must take special precautions or make special site modifications. The General Electric Company 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.

7-2. 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 20mSv per year. For other non-European countries, consult your local regulations for the dose limit value.

The X-ray Console must be mounted behind either an integrated Lead glass or behind a free-standing Radiation shield.

- Lead glass lead (Pb) equivalent is compliant to IEC60601-2-45.

8. Planning for Storage

8-1. Temporary Storage in the Hospital

Note:

There is normally a short delay between the delivery of the equipment and its installation. If this delay is not short (more than two days), it is essential that a suitable storage room is available to receive the equipment in its crates. See 2. Environmental Requirements **for information on the environment required.**

8-2. Packing Information

The Senographe Crystal Nova 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 Crystal Nova is supplied in a pallet which includes the Gantry, Control Station, Generator and Accessories and a box includes detector.

- Crate 1:
  - Gantry
  - Control Station
  - Generator
  - Accessories
- Crate 2 (Supplier Box):
  - Detector

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

Item	Dimensions in mm			Weight
	Depth	Width	Height	
Crate1	2280	1400	1550	About 765 kg±10%
Crate 1 includes the Gantry, Control Station, Generator and the Crystal Nova Accessories				

Item	Dimensions in mm			Weight
	Depth	Width	Height	
Crate 2	698.5	622.3	428.6	19.575 kg±10%
Crate 2 includes the Detector (Supplier Box)				

8-3. Constraints for Moving the Equipment into the Room

The minimum dimension of the entry door to move in the (uncrated) Gantry on its wheels with a 75mm (2.95 inches) are:

- Door opening at least 750 mm (29.52 inches) wide.
- Height of 2136 mm (84.09inches) with Gantry's dolly and eyebolt.
- Height of 2046 mm (80.55 inches) with Gantry's dolly.
- Height of 2002 mm (78.81 inches) with Gantry's top cover.

Note:

If the hospital doors are less than height of 2136 mm (84.09inches) high, prepare time to remove the eyebolt during the delivery of the Senographe Crystal NOVA. You will need to remove the eye bolt so that you can move the Gantry under the doors.

In cases where a Senographe Crystal Novais 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 1205 mm (47.44 inches) and the minimum width must be slightly larger than 650 mm (25.59 inches) and the minimum height must be slightly larger than 2046 mm (80.55 inches) to be able to move the Gantry.

9. Room Layout Planning

Before installing the equipment, check the following conditions:

- A network socket must be available
- The network-related information must be available
  - The IP address and subnet mask that the system will be using
  - The gateway address (if applicable)
  - The DNS server address
- Wall painting and floor preparation must be complete
- The room must be clean
- All electric work must be complete

9-1. Dimensions and Masses

⚠CAUTION

The equipment must be installed by authorized personnel only.

The detector has a very strict range of temperature and must be removed from its original packing only after unpacking and placement of the unit and after installation room has reached operating temperature between 20 and 30°C.

Extreme care must be taken during detector unpacking to prevent damage.

Handle the detector with care to reduce hazards of ESD (Electrostatic Discharge, it is the sudden flow of electricity between two electrically charged objects caused by contact, an electrical short or dielectric breakdown)

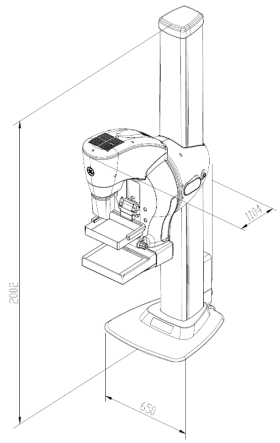
[Table 4-9] System Dimensions and Masses

Component	Depth in mm (Tolerance ±7%)	Width in mm (Tolerance ±7%)	Height in mm (Tolerance ±7%)	Mass in kg
Gantry	1104	650 (C-arm angle 0°) 928 (C-arm angle 90°)	2002 (Column Height) 2146 (C-arm Max Height)	308.6
Control Station	435 (key board tray - opened) 616 (key board tray- closed)	720 (Monitor arm - closed) 1130 (Monitor arm – opened)	1540 (without lead glass) 1853 (with lead glass)	97.2
Generator	592	360	690	91.8

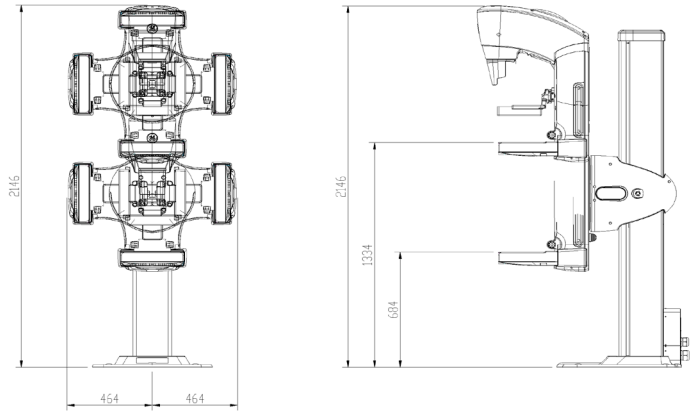
9-1-1. Gantry

9-1-1-1. Gantry (without dolly)

- Dimension (Tolerance ±7%):
  - Depth: 1104 mm
  - Width (depending on the angle of C-arm): 650 mm or 928 mm
  - Height (depending on the C-arm position): 2002 mm or 2146 mm
- Weight (including all cables and foot switches): 308.6 kg



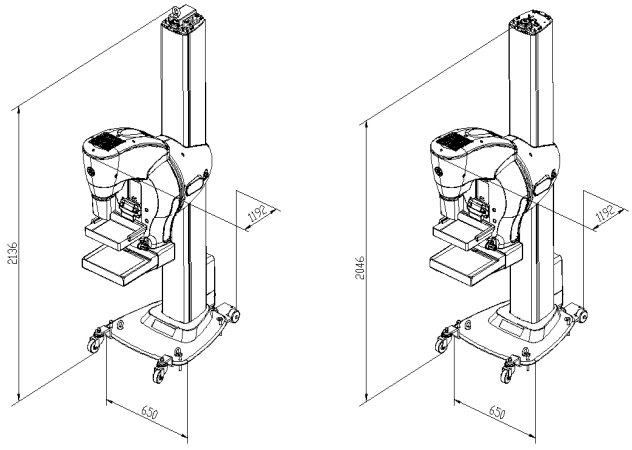
[Figure 4-17] Gantry (without dolly)



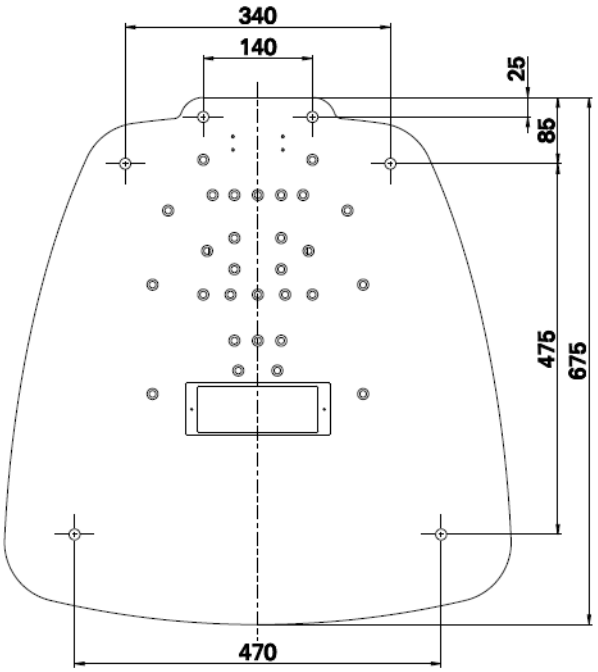
[Figure 4-18] L: Maximum height of detector, R: Hight of tube head and detector

9-1-1-2. Gantry with dolly

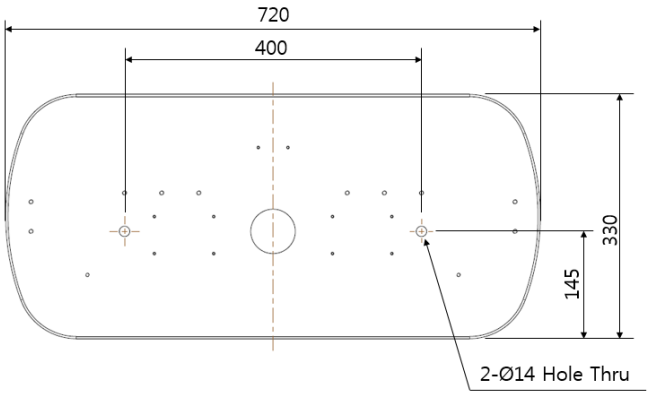
- Dimension (Tolerance ±7%):
  - Depth: 1192 mm
  - Width (depending on the angle of C-arm): 650 mm
  - Height (depending on the C-arm position): 2136 mm (without lift bracket and eyebolt: 2046 mm)
- Weight (including all cables and foot switches): 308.6 kg



[Figure 4-19] Gantry with dolly



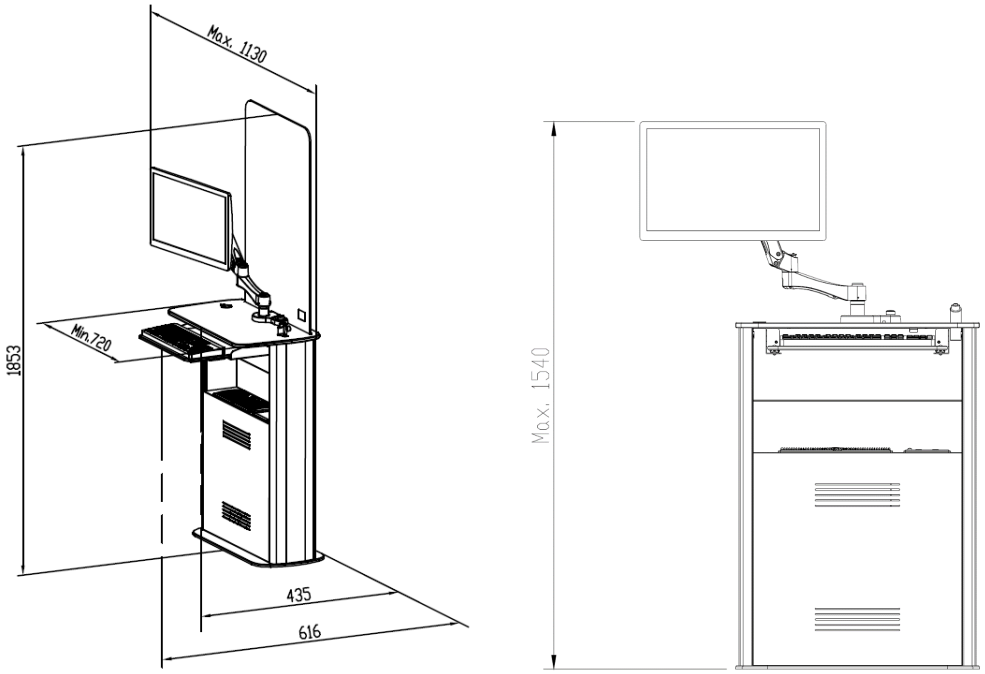
[Figure 4-20] Gantry Base Plate



[Figure 4-21] Control Station Base Plate

9-1-2. Control Station

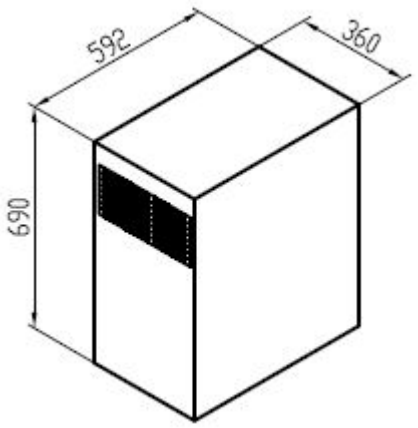
- Dimension (Tolerance ±7%):
  - Depth (depending on keyboard tray position): 435 mm , 616 mm
  - Width (depending on the monitor arm position): 720 mm or 1130 mm
  - Height (depending on the existence of Lead glass): 1540 mm or 1853 mm
- Weight: 97.2 kg (with lead glass)



[Figure 4-22] L: Control Station with lead glass, R: Control Station without lead glass

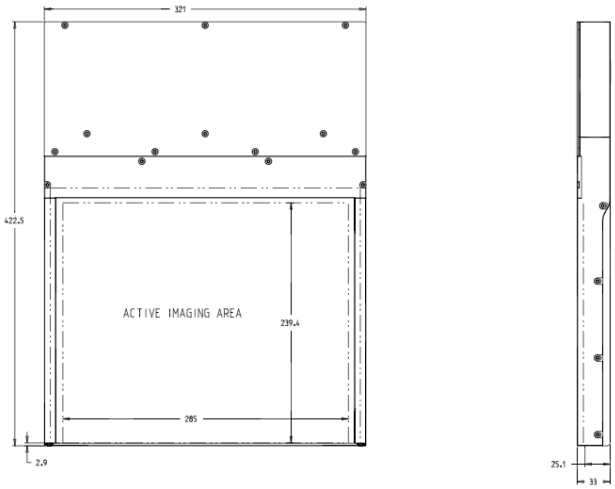
9-1-3. Generator

- Dimension (Tolerance ±7%):
  - Depth: 592 mm
  - Width: 360 mm
  - Height: 690 mm
- Weight: 91.8 (with cable)



[Figure 4-23] Generator

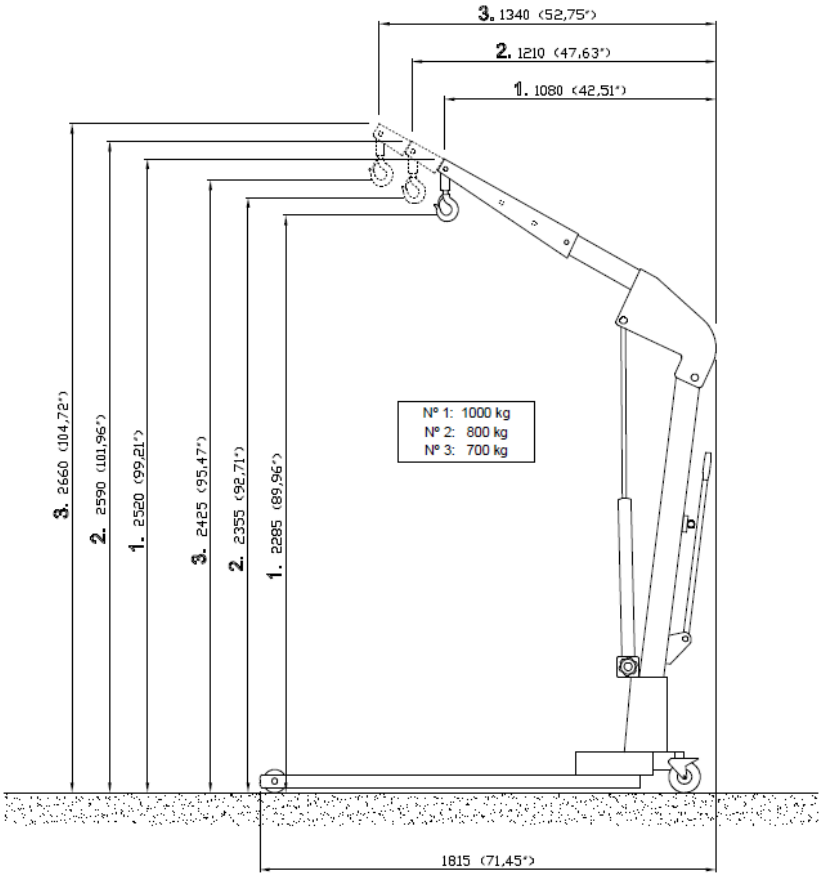
9-1-4. Detector (24 x 29 cm)



[Figure 4-24] VXFOV Detector (24 x 29)

9-1-5. Crane

- Dimension:
  1. 1815 x 1080 x 2520 mm
  2. 1815 x 1210 x 2590 mm
  3. 1815 x 1340 x 2660 mm
- Weight: 118 kg

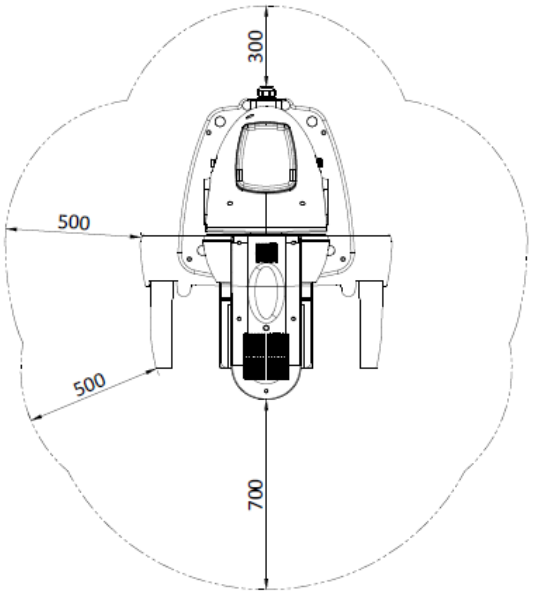


[Figure 4-25] Crane

9-2. Clearance Distances

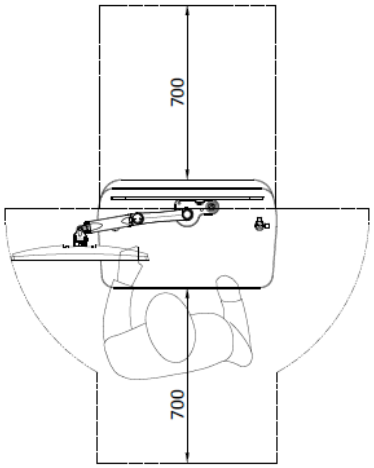
For usability and serviceability, observe the following clearance distances around the components:

9-2-1. Gantry



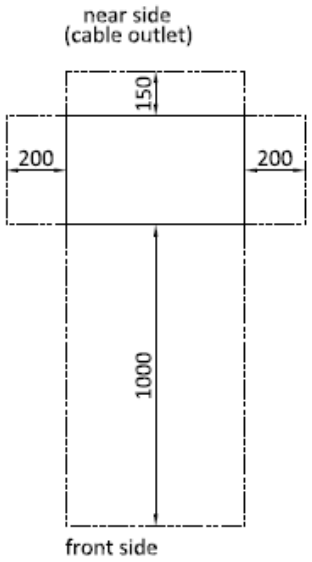
[Figure 4-26] Gantry Clearance Distance

9-2-2. Control Station



[Figure 4-27] Control Station Clearance Distance

9-2-3. Generator



[Figure 4-28] Generator Clearance Distance

⚠WARNING

Do not install or operate any non-patient device except the Control station console within 1.5meter distance from the patient.

According to the local regulation for radiological protection, the access to the equipment and to the controlled area must be restricted to the authorized personnel only.

⚠CAUTION

Install the wires along the walls and attach the wires on the walls' surface, so that it should not cause interference to the flow of human traffic.

9-3. Layout Constraints for Positioning Gantry, Generator, and Control Station

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

- **Safety**

- SA1: Minimum "trapping zone" safety clearance (as defined by IC 60601-1 3rd Edition Trapping Zone) 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 or Generator) 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):
  Please note that your Senographe Crystal Nova installation in the selected room does not meet the following minimal requirement: 500 mm required distance between the C-arm 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: Protection of the Operator, such that the X-ray dose level they receive is within a safe level (as defined by Directive Euratom 96 29). X-rays emitted from the Tube Head are attenuated to a safe level when the default radiation screen supplied with the system is at least 700 mm from the Tube Head at an angle of 0°.

- **Serviceability**

All sides of the three components need access for servicing.

- SE1: Gantry: 300 mm between the rear edge of the Gantry baseplate and the wall.

  If the recommended 300 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).
  Please note that your Senographe Crystal Nova installation in the selected room does not meet the following minimal requirement: 300 mm recommended distance of rear clearance.
  This might lead to more than one day downtime in case of parts replacement requiring rear accessibility.
- SE2: Generator: 200 mm on either left/right side of the Generator where the cables can exit. The two power control buttons on the front side must be facing outwards away from the wall.

- **System Use**

- SU1: Generator: 150 mm at the rear side to allow uninhibited air Flows.

- **Clinical Use**

- CU1: Control Station: A clearance of 700 mm from the Control Station baseplate front edge, so that the Operator has a clearance of 500 mm with a fully expanded keyboard.

Note:

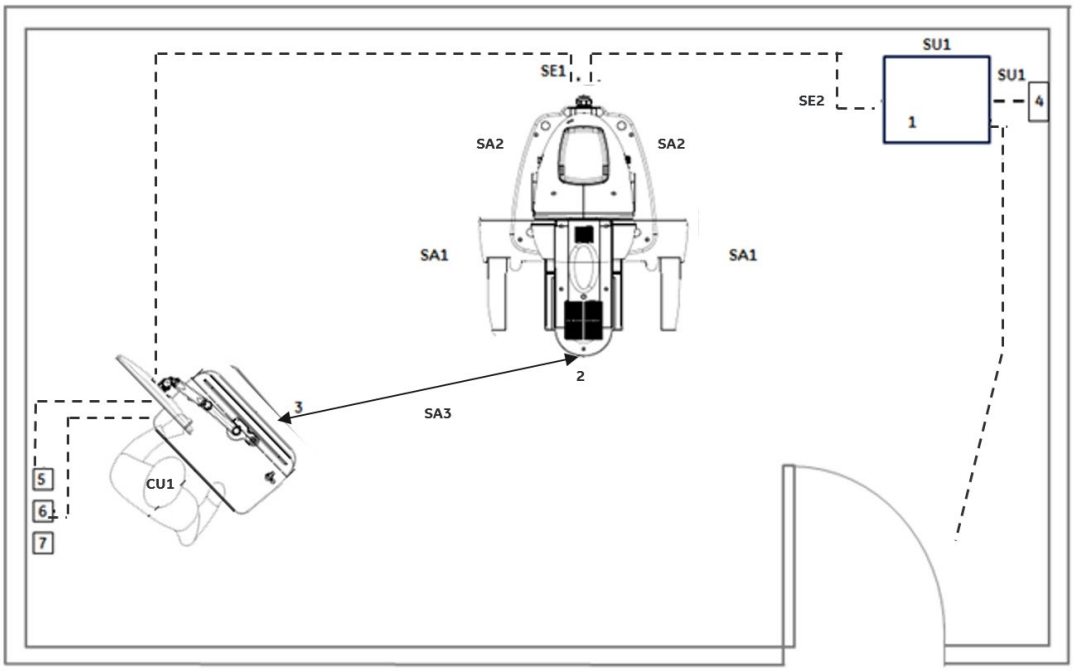
The distances given above correspond to the minimum, but it remains the responsibility of the local installation services team to ensure that the country regulations are followed. For example, in the United States the Labor Occupational Safety and Health Administration (OSHA) regulations must be considered,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

9-3-1. Ancillary Equipment

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

9-3-2. Generic Constraints Overview

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



1. Generator
2. Gantry
3. Control Station with Lead glass
4. AC power input through power distribution box (supplied by customer).
5. Insite Connection (supplied by customer).
6. Networking Connection (supplied by customer).
7. 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.

9-3-3. Layout Examples

The following illustrations provide some example layouts which adhere to constraints listed above.

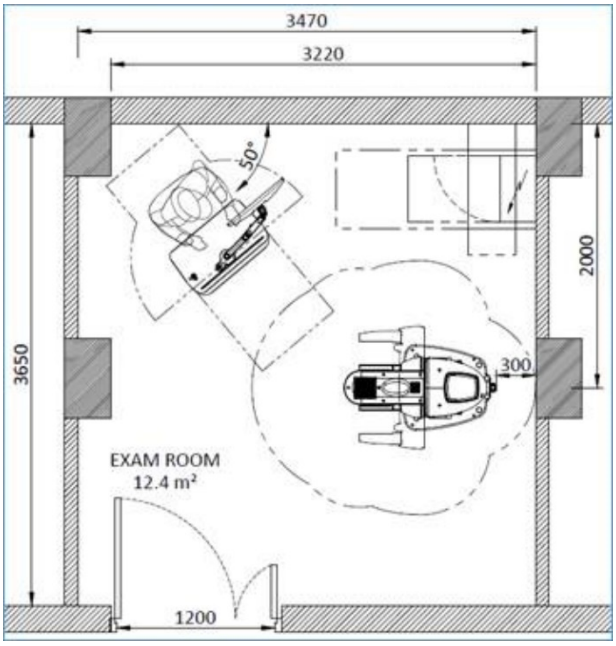
Note:

Ensure that the room layout is adapted to the cable length constraints as listed in the table below and as summarized in section 9-5. Interconnecting Cables Path and Length.

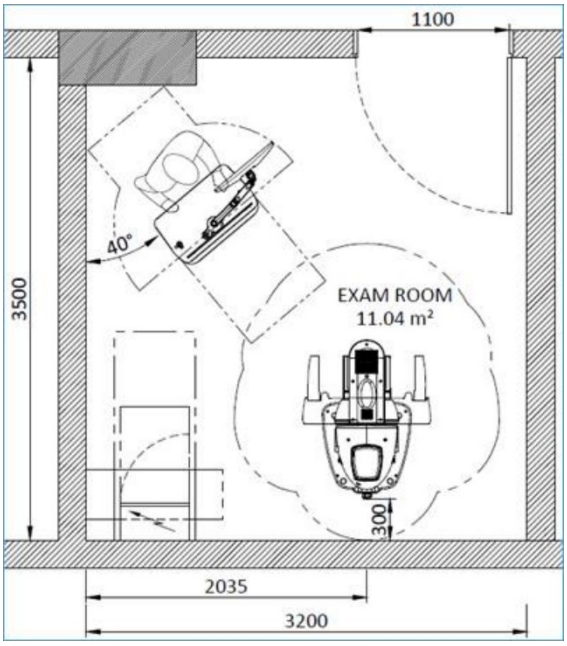
If the room is smaller than the minimum room size, a risk of entrapment label (PN: 5763422) should be applied.

[Table 4-10] Cable Harness and Length

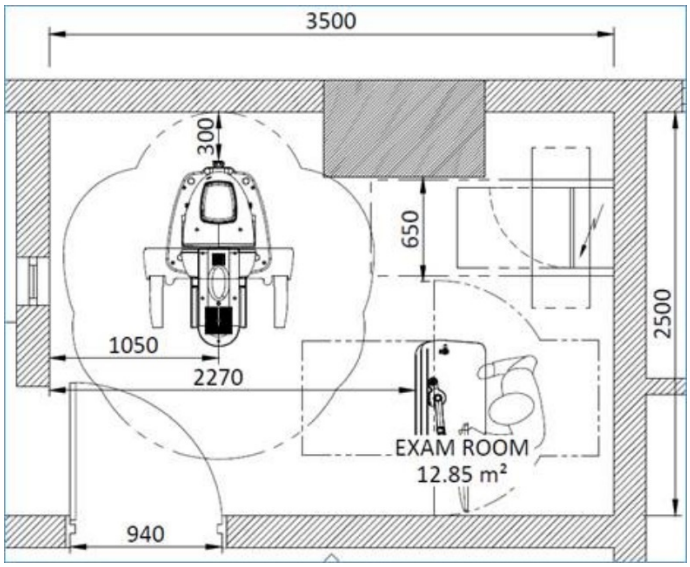
Cable/Harness	Length
Gantry to Control Station cables in Harness 1	6.5 m (255.9")
Gantry to Generator cables in Harness 2	3.5 m (137.8")



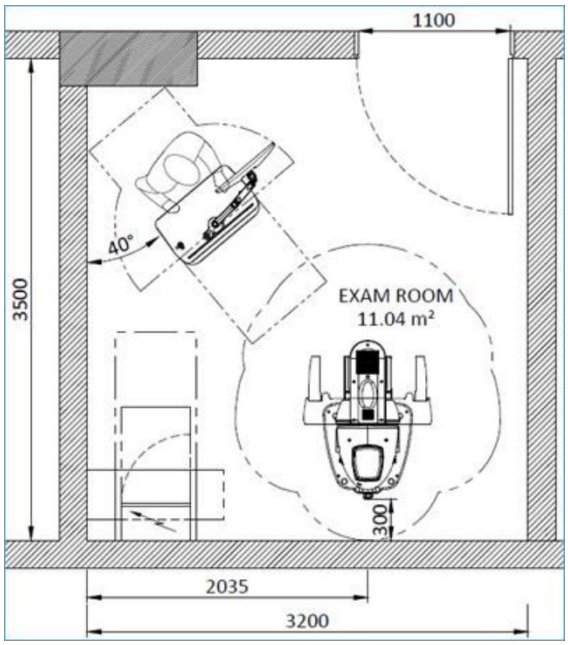
[Figure 4-29] Room Layout Example 1



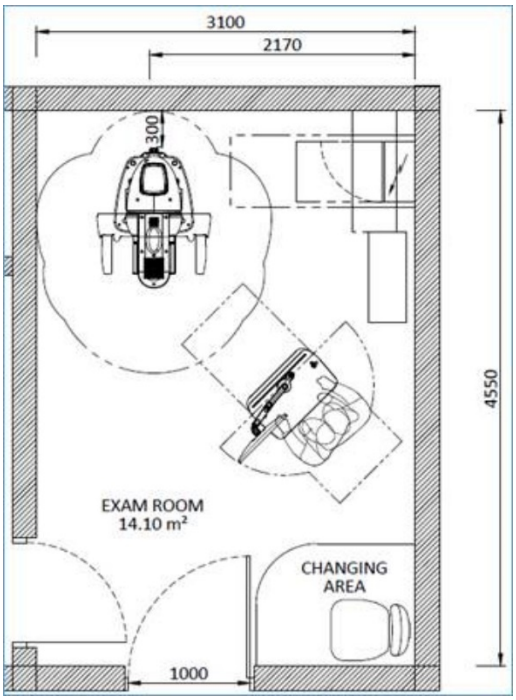
[Figure 4-30] Room Layout Example 2



[Figure 4-31] Room Layout Example 3



[Figure 4-32] Room Layout Example 4



[Figure 4-33] Room Layout Example 5

9-4. Anchoring to the Floor

Note:

Remember to respect the minimum distances required between the Gantry and the Control Station or Lead glass to allow access to the Emergency Switches.

9-4-1. Anchoring Inserts

Please ensure that the load rating for the floor is enough to withstand the mass of the Gantry, the Control Station, and the Generator: (See 4-3. Floor Requirements)

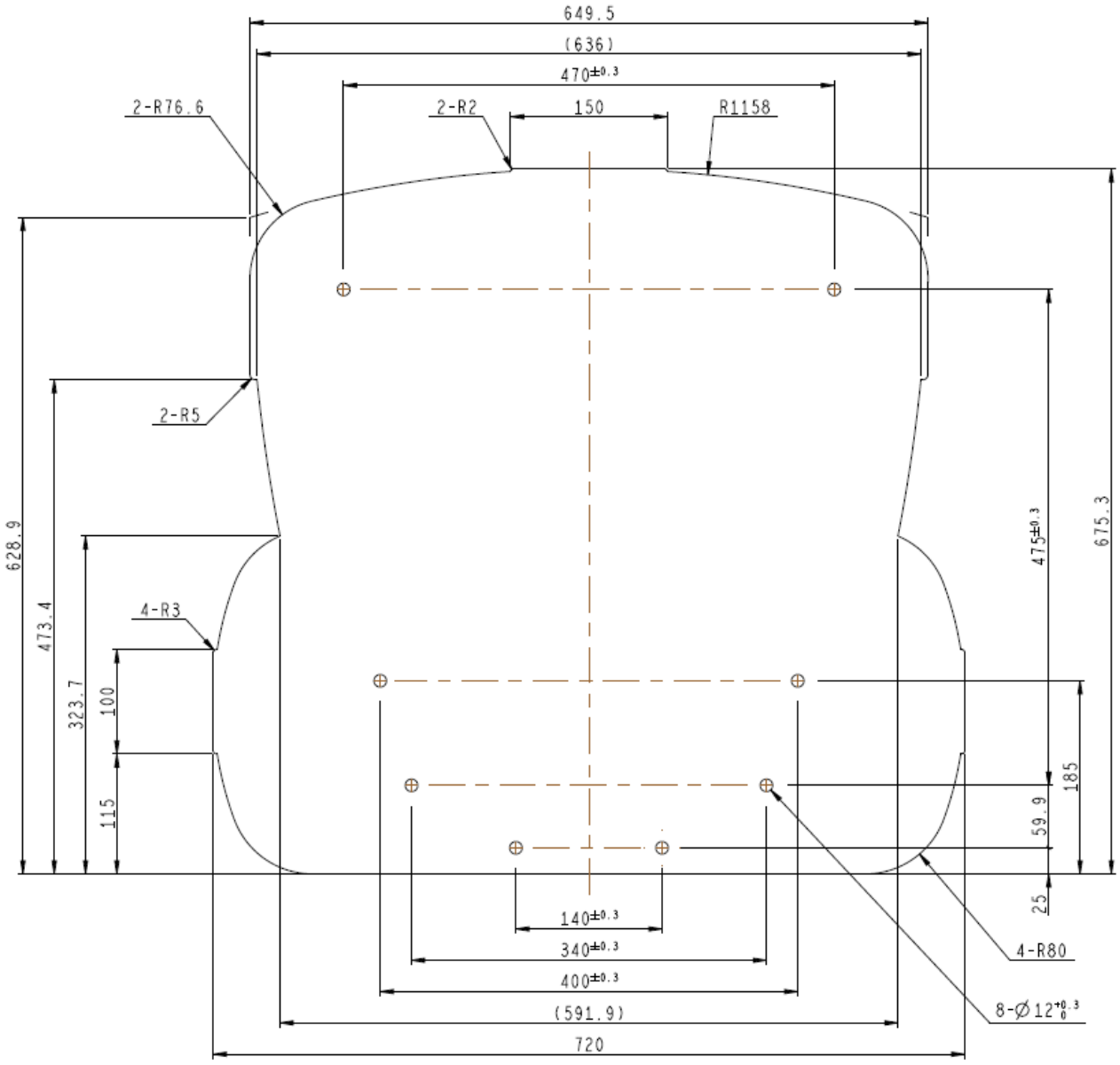
- **Anchoring Inserts Not Provided with the Senographe Crystal Nova**

It is strongly recommended that Gantry and Control Station are anchored by Hilti HSL-3 M8 / 20.

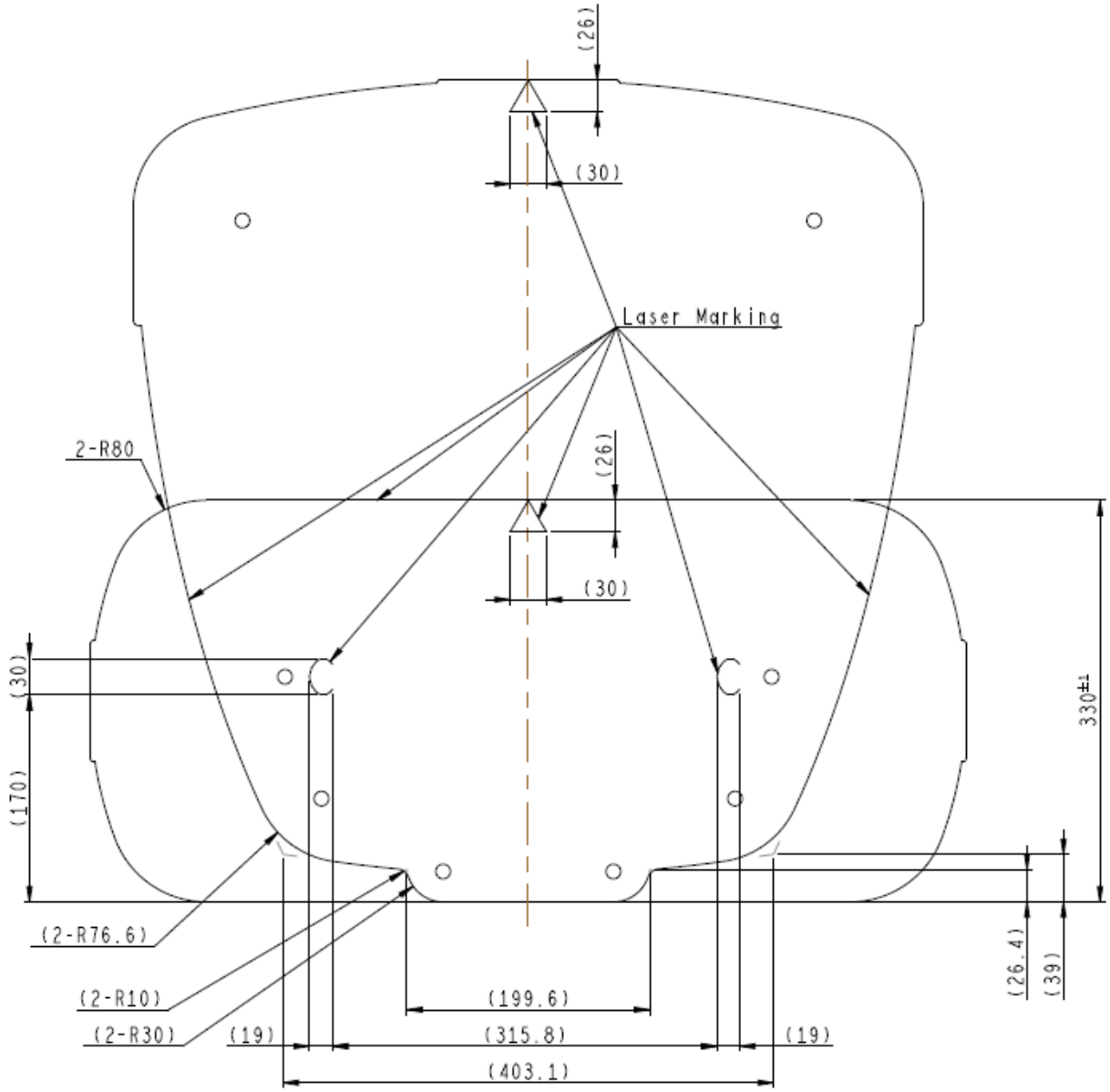
Anchoring holes in the floor	Gantry baseplate	Control Station baseplate
Number of holes in the plate	6	2
Diameter of the hole in the plate	14 mm	14 mm
Hole diameter in the floor	12 mm	12 mm
Hole depth in the floor	Min: 80 mm	Min: 80 mm
inserts to be used	HILTI M8/20 HSL-3	HILTI M8/20 HSL-3
Minimum floor thickness	100 mm	100 mm
Recommended tightening torque	25 Nm	25 m

9-4-2. Anchoring Template

The anchoring metal sheet template with the position of holes to drill on the floor to fix the Gantry and the Control Staion is provided with the Senographe Crystal Nova.



[Figure 34] Gantry and Control Station Anchoring Metal Sheet Template



[Figure 35] Gantry and Control Station Anchoring Metal Sheet Template with laser marking

9-5. 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

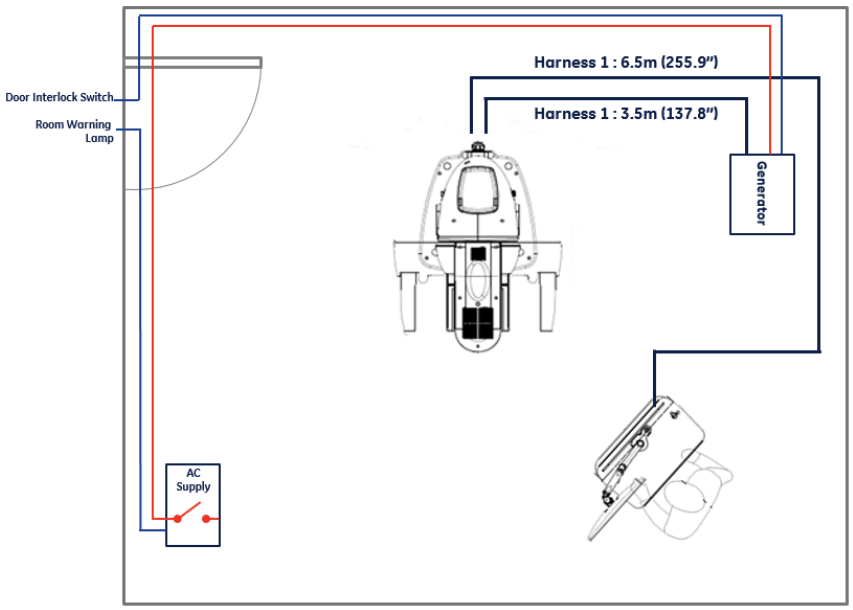
Red = Power AC supply (Line Supply Cable) (GE Healthcare supplies a usable length = 9.5m (374.01inches) cable)

Blue = Door light and switch (local adaptation)

⚠CAUTION

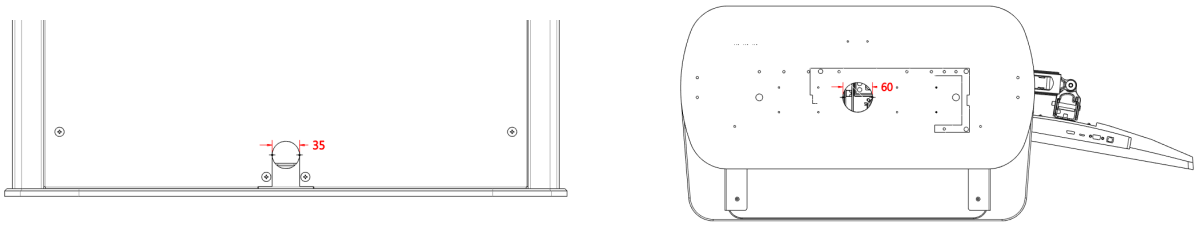
Cables between Generator and Gantry and X-ray Console are fragile:

Protect these cables in cable housing or ensure that the cable path is safe.



[Figure 4-36] Interconnecting cables path and length

The Control Station cable entrance dimension is shown in [Figure 4-22].



[Figure 4-22] Control Station Cable Entrance Dimension

9-6. Cable Ducts

Ensure the cable ducts meet or exceed the following dimensions: 130 mm (H) x 80 mm (W).

10. Insite Connection

A broadband Internet connection or a Dedicated Service Network must be provided for access to Insite services.

There are currently three main methods of providing this connection. Either Virtual Private Network (VPN) tunneling on a broadband Internet connection, or a Dedicated Service Network as follows:

- Site to Site VPN (GE Solution): using an analog or digital broadband router supplied by GE.
- Site to Site VPN (Customer Solution): using an analog or digital broadband router and infrastructure supplied by the customer.
- Dedicated Service Network provided by the country local health service (if available) (e.g. NHSnet/N2/N3 in the UK, SJUnet in Sweden, and Sescam in Spain).

More information can be found in the Broad Band (BB) Solutions Catalogue. You can download this from the OTR & Sales section at http://supportcentral.ge.com/products/sup_products.asp?prod_id=24026 (GE HEALTHCARE SSO login credentials required).

Note:

The BB Solutions Catalogue are only available via the GE Healthcare Intranet. If a customer requires this document, then GE Healthcare personnel can provide the customer with this document at request. In the Americas region, only the Site to Site VPN (Customer Solution) is possible.

11. Networking Connections

- The Control Station and any optional equipment provided are to be connected together as a hospital network.
- Before installation, the following information must be obtained for each network host so that it can be addressed by the AWS:

- IP address; Gateway address; Subnet mask.

- The hospital network administrator usually supplies this information.
- Provision must be made for Ethernet cables to be easily run from the Control Station to the hospital network.

Typical equipment options which can be connected to the hospital network include: review workstation,

Mass Archiver, Laser Printer, HIS/RIS network kit, CAD (Computer Aided Detection).

12. Telephone Connection

It is recommended that a telephone is provided close to the X-ray Console (normally mounted on the Control Station), to allow convenient dialog with teleservice technicians.

CHAPTER 5. PRE-INSTALLATION PROCEDURES

Scenario PRE 001A – Pre-installation Procedures

1. Context

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

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.	Scenario PRE 002A – Pre-purchase Site Visit	GEHC sales representative	
Purchase Senographe system				
2	If the floor thickness is less than 120 mm and/or the installation is in a seismic area, order different anchoring bolts.	9-4. Anchoring to the Floor	-	
Installation planning visit				
3	Visit site to assess installation requirements and specify the preparatory work required before delivery and installation.	Scenario PRE 003A – Installation Planning Visit	GEHC site planner	
Preparatory work				
4	Hospital or third-party contractors carry out preparatory work.	-	Hospital	
Pre-delivery check				
5	Visit site to confirm that the preparatory work is satisfactory, and the site is ready for delivery and installation.	Scenario PRE 004A – Pre-Delivery Check	GEHC site planner	
Delivery and storage				
6	System delivery to designated storage.	Chapter 4. Pre-Installation System Requirements 8. Planning for Storage	Delivery personnel and hospital	
Installation				
7	System installation.	-	GEHC installation engineers	

Scenario PRE 002A – Pre-purchase Site Visit

1. Context

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

2. Steering Guide

Step	Requirement	Reference	Who	Done
Altitude				
1	Check that product specifications are compatible with the altitude of the site	Chapter 4. Pre-Installation System Requirements, 2. Environmental Requirements	Hospital engineer	
Operating conditions				
2	Check that operating the temperature and humidity requirements can be met	Chapter 4. Pre-Installation System Requirements, 2. Environmental Requirements	Heating engineer	
Room layout				
3	Check that an adequate room is available, with suitable floor and access	Chapter 4. Pre-Installation System Requirements	Site planner	
Electrical supply				
4	Check availability of suitable supply	Chapter 4. Pre-Installation System Requirements, 5. Electrical Requirements	Hospital engineer	
Networking				
5	Check possibility of connection to hospital network	Chapter 4. Pre-Installation System Requirements, 11. Networking Connections	Hospital engineer, GEHC representative	
Insite connection				
6	Check availability and type of broad band connection	Chapter 4. Pre-Installation System Requirements, 10. Insite Connection	Hospital engineer	

Scenario PRE 003A – Installation Planning Visit

1. Context

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

2. Steering Guide

Step	Action	Reference	Who	Done
Storage conditions				
1	Check the dimensions and environment of the pre-installation storage room.	Chapter 4 Pre-Installation System Requirements, 8. Planning for Storage	Hospital engineer	
Room layout				
2	Plan and specify layout with adequate spacing between the Gantry and control station components.	Chapter 4 Pre-Installation System Requirements, 9. Room Layout Planning	Site planner	
Operating conditions				
3	Check that operating the temperature and humidity requirements will be met.	Chapter 4 Pre-Installation System Requirements, 2. Environmental Requirements	Heating engineer	
Radiation protection (wall, ceiling, floor, doors)				
4	Consult the Radiation Physicist for advice on radiation protection	Chapter 4 Pre-Installation System Requirements, 7. Planning for Radiation Protection	Radiation protection specialist	
Structural requirements				
5	Check access door width and height.	Chapter 4 Pre-Installation System Requirements, 4. Structural Requirements	Hospital engineer	
6	Check floor requirements (Strength, flatness)	Chapter 4 Pre-Installation System Requirements, 4. Structural Requirements	Flooring specialist	
Room Layout Planning				
7	Make the underfloor plan localizing the water and electrical ducts	-	Hospital engineer	

Step	Action	Reference	Who	Done
8	Plan the location of the main components	Chapter 4 Pre-Installation System Requirements, 9-4. Anchoring to the Floor	Hospital engineer, GEHC Site planner	
9	Specify the installation of anchorage bolts. In seismic areas. Anchors must be provided for the generator and ancillary equipment (additional Lead glass, etc.).	Chapter 4 Pre-Installation System Requirements, 9-4. Anchoring to the Floor	Flooring specialist	
10	Plan cable runs; specify ducting, etc.	Chapter 4 Pre-Installation System Requirements, 9-5 Inter Connecting Cables Path and Length	Site planner	
Electrical requirements				
11	Check that room power supply requirements will be met.	Chapter 4. Pre-Installation System Requirements, 5. Electrical Requirements	Electrician	
12	Check the line voltage specification	Chapter 4. Pre-Installation System Requirements, 5. Electrical Requirements	Electrician	
13	Check the line frequency specification	Chapter 4. Pre-Installation System Requirements, 5. Electrical Requirements	Electrician	
14	Check the kVA load characteristics	Chapter 4. Pre-Installation System Requirements, 5. Electrical Requirements	Electrician	
15	Check the line impedance	Chapter 4. Pre-Installation System Requirements, 5. Electrical Requirements	Electrician	
16	Check the main circuit breaker characteristics.	Chapter 4. Pre-Installation System Requirements, 5. Electrical Requirements	Electrician	
Door protection switches				
17	Specify the requirement for provision and connection of the door X-ray protection switches.	Chapter 4. Pre-Installation System Requirements, 5. Electrical Requirements	Electrician	
Insite connection				
18	Specify requirements for Insite broadband connection	Chapter 4. Pre-Installation System Requirements, 10. Insite Connection	Hospital Network Administrator	

Step	Action	Reference	Who	Done
Networking				
19	Specify network connections and cable runs	Chapter 4. Pre-Installation System Requirements, 11. Networking Connections	Site planner	
20	Allocate IP, Gateway, and Subnet mask addresses	Chapter 4. Pre-Installation System Requirements, 11. Networking Connections	Hospital Network Administrator	
Lighting				
21	Specify requirements for dimmer switches, drapes, etc.	Chapter 4. Pre-Installation System Requirements, 6-1. Room Lighting	Lighting specialist	

Scenario PRE 004A – Pre-Delivery Check

1. Context

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

2. Steering Guide

Step	Requirement	Reference	Who	
Storage conditions				
1	Check preparation of Pre-Installation storage room	Chapter 4 Pre-Installation System Requirements, 8. Planning for Storage	Hospital engineer	
Room preparation				
2	Check the proposed layout and preparations for cable runs.	Chapter 4 Pre-Installation System Requirements, 9. Room Layout Planning	Site planner	
3	Check floor and anchorage preparation	Chapter 4 Pre-Installation System Requirements, 9. Room Layout Planning	Flooring specialist	
4	Check access requirements	Chapter 4. Pre-Installation System Requirements, 4. Structural Requirements	Hospital engineer	
Radiation protection (wall, ceiling, floor, doors)				
5	Check preparation for radiation protection (wall, ceiling, doors)	Chapter 4. Pre-Installation System Requirements, 7. Planning for Radiation Protection	Radiation protection specialist	
Insite connection				
6	Check preparations for Insite broadband connection	Chapter 4. Pre-Installation System Requirements, 10. Insite Connection	Hospital Network Administrator	
Lighting				
7	Check room lighting conditions	Chapter 4. Pre-Installation System Requirements, 6-1. Room Lighting	Lighting specialist	

Scenario PRE 005A – Receiving and storing a Senographe Crystal Nova

1. Context

This scenario provides a check list to receive and store a Senographe Crystal Nova, before the system is installed.

2. Steering Guide

Step	Requirement	Reference	Who	Done
1	Receive the equipment and check for external damage.	Job Card PRE 001A – Checking for Damage	GEHC representative and hospital staff	
2	Store the Senographe Crystal Nova.	Chapter 4 Pre-Installation System Requirements, 8. Planning for Storage	Hospital staff	

Job Card PRE 001A – Checking for Damage

The Senographe Crystal Nova is inspected for proper operation and appearance before shipment.

However, it is necessary to inspect the product after the shipment is received.

The Senographe Crystal Nova is supplied in a pallet.

Pallets	Contents
1	Gantry Control Station Generator Accessories
2	Detector

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

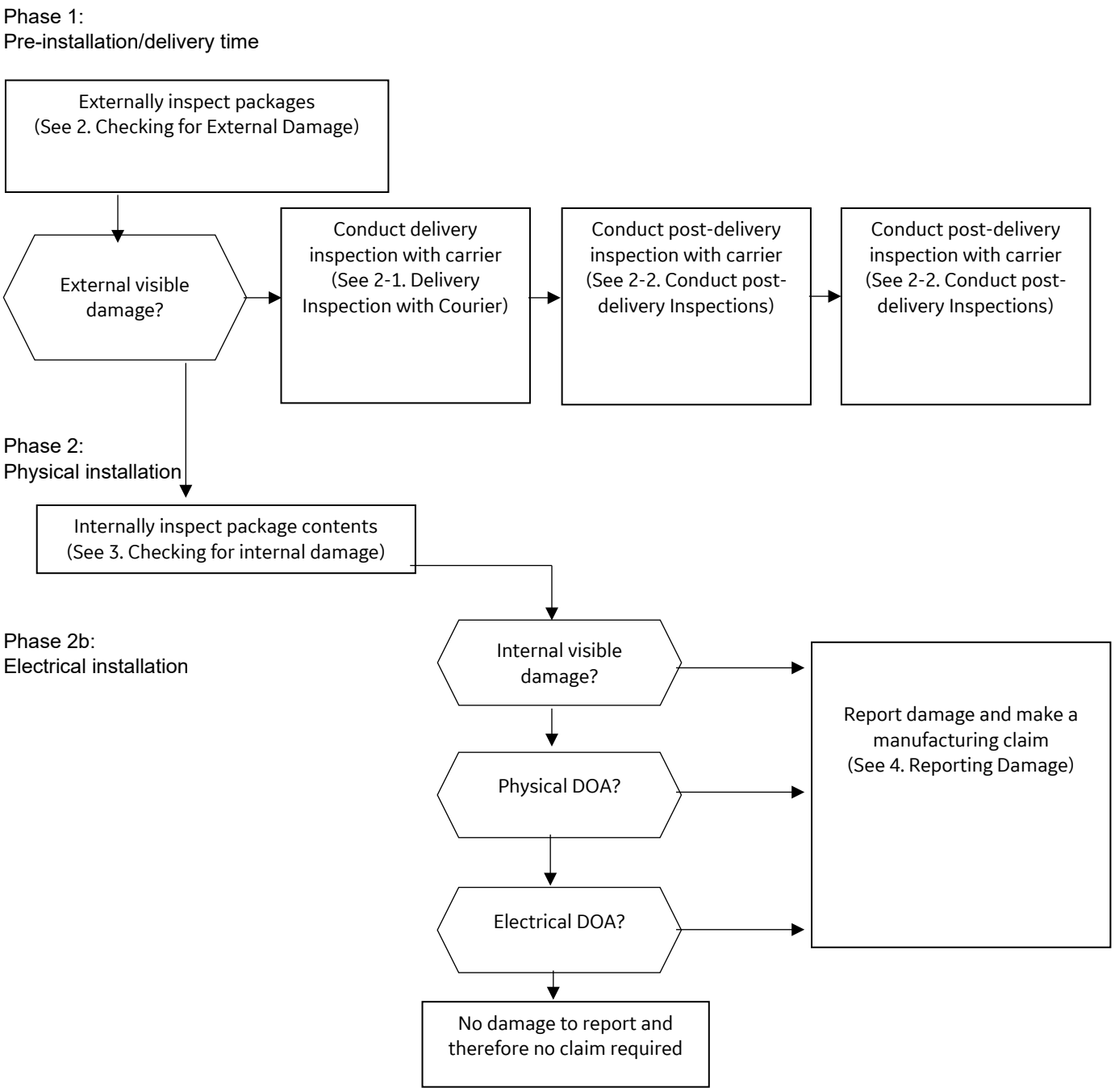
1. Possible Types of Damage

Two types of possible damage can exist, as follows:

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

The illustration on the below summarizes the general process to determine:

- whether any of the Senographe 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.

Note:

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 Crystal Nova. Any damage found during this phase is considered as either physical DOA or electrical DOA, which is the responsibility of GE Healthcare manufacturing.

2. Checking for External Damage

2-1. Delivery Inspection with Courier

When the shipment of the Senographe Crystal Nova arrives, a General Electric representative or a hospital receiving agent must proceed as follows for each of the two pallets.

1. Closely examine each pallet for visible damage and check any shock and tilt indicators present.
   A. If the pallets in the shipment show visible signs of damage, excessive shock, etc. you must perform a delivery inspection as follows:
   B. Open the pallets immediately to check the contents and ask the driver to inspect the contents with you.
   C. Write a precise description of the damage on your copy and carrier’s copy of the delivery receipt, along with the notation "damage in shipment".
   D. Sign for the shipment and arrange a post-delivery inspection within delivery complaint period defined by your country consumer laws.
   E. Contact GE Healthcare to report the initial damage according to section 4, Reporting Damage.
   F. If the pallets in the shipment do not show visible signs of damage or excessive shock, no action is required other than to sign for the shipment.
2. Move the pallet into or close to the x-ray room, ready for unpacking.

2-2. Conduct Post-delivery Inspections

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

Once you have completed a post-delivery the details of the damage to GE Healthcare and the carrier according to section 4, Reporting Damage.

3. Checking for internal damage

As soon as possible after delivery, unpack, and inspect your shipment. If you discover internal (concealed) damage, report it to GE Healthcare immediately according to section 4, Reporting Damage.

4. Reporting Damage

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

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

2. The GE Healthcare Distributor and/or GE Healthcare Account Manager will contact the factory of origin to determine the most cost-effective way to repair the damage.

    - If damage deemed to warrant a factory repair, a Return Merchandise Authorization (RMA) will be issued to return damaged product to factory. Factory will provide quote to repair damaged equipment after inspection of damage upon receipt of damaged equipment. Do not ship any damaged product back to factory without an RMA.
    - If damage is deemed minimal and can be repaired in the field with replacement parts, the factory will provide a quote to the consignee to purchase those parts.
    - If damage is deemed catastrophic and requires complete replacement of damaged equipment, GE Healthcare will provide a quote to the consignee with quote to replace damaged equipment.

3. Discuss how to proceed with your GE Healthcare Distributor and/or GE Healthcare Account Manager:

    - If you determined that the bad transportation was to blame for the damage, then your GE Healthcare Distributor and/or GE Healthcare Account Manager will advise you how to file a transportation claim and how to proceed with the transportation claim process.
    - If you determined that the transportation was not to blame for the damage, then your GE Healthcare Distributor and/or GE Healthcare Account Manager will advise you how to file a manufacturing claim and how to proceed with the manufacturing claim process.