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Invenia ABUS System Setup and Basic Service Manual

Operating Documentation

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Regulatory Requirement

CE 0197

This product complies with regulatory requirements of the following European Directive 93/42/EEC concerning medical devices.

This manual is a reference for the Invenia ABUS. It applies to Version 1 Revision 0.0 software for the Invenia ABUS System Setup.

Change history

/Revision History

Revision	Date (YYYY-MM-DD)	Reason for change
Rev. 1	2013-11-4	Preliminary
Rev. 2	2014-01-16	Updated Version
Rev. 3	2014-02-08	Update Manual Name and Quality Assurance Personnel
Rev.4	2014-08-20	UDI Label Update
Rev. 5	2015/02/03	Workstation software only option update
Rev. 6	2015/07/09	CE Mark Labeling Update

Important precautions

Translation policy

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.**

AVERTISSEMENT (FR)

CE MANUEL DE MAINTENANCE N'EST DISPONIBLE QU'EN ANGLAIS.

- **SI LE TECHNICIEN DU CLIENT A BESOIN DE CE MANUEL DANS UNE AUTRE LANGUE QUE L'ANGLAIS, C'EST AU CLIENT QU'IL INCOMBE DE LE FAIRE TRADUIRE.**
- **NE PAS TENTER D'INTERVENTION SUR LES ÉQUIPEMENTS TANT QUE LE MANUEL SERVICE 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)

DIESES KUNDENDIENST-HANDBUCH 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, DAS GERÄT ZU REPARIEREN, BEVOR DIESES KUNDENDIENST-HANDBUCH NICHT ZU RATE GEZOGEN UND VERSTANDEN WURDE.**
- **WIRD DIESE WARNUNG NICHT BEACHTET, SO KANN ES ZU VERLETZUNGEN DES KUNDENDIENSTTECHNIKERS, DES BEDIENERS ODER DES PATIENTEN DURCH ELEKTRISCHE SCHLÄGE, MECHANISCHE ODER SONSTIGE GEFAHREN KOMMEN.**

AVISO (ES)

ESTE MANUAL DE SERVICIO SÓLO EXISTE EN INGLÉS.

- **SI ALGÚN PROVEEDOR DE SERVICIOS AJENO A GEHC SOLICITA UN IDIOMA QUE NO SEA EL INGLÉS, ES RESPONSABILIDAD DEL CLIENTE OFRECER UN SERVICIO DE TRADUCCIÓN.**
- **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.**

ATENÇÃO (PT-Br)

ESTE MANUAL DE ASSISTÊNCIA TÉCNICA SÓ SE ENCONTRA DISPONÍVEL EM INGLÊS.

- **SE QUALQUER OUTRO SERVIÇO DE ASSISTÊNCIA TÉCNICA, QUE NÃO A GEHC, SOLICITAR ESTES MANUAIS 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 POR EM PERIGO A SEGURANÇA DO TÉCNICO, OPERADOR OU PACIENTE DEVIDO A‘ CHOQUES ELÉTRICOS, MECÂNICOS OU OUTROS.**

AVISO (PT-pt)

ESTE MANUAL DE ASSISTÊNCIA ESTÁ DISPONÍVEL APENAS EM INGLÊS.

- **SE QUALQUER OUTRO SERVIÇO DE ASSISTÊNCIA TÉCNICA, QUE NÃO A GEHC, SOLICITAR ESTES MANUAIS NOUTRO IDIOMA, É DA RESPONSABILIDADE DO CLIENTE FORNECER OS SERVIÇOS DE TRADUÇÃO.**
- **NÃO TENTE EFECTUAR REPARAÇÕES NO EQUIPAMENTO SEM TER CONSULTADO E COMPREENDIDO PREVIAMENTE ESTE MANUAL.**
- **A INOBSERVÂNCIA DESTE AVISO PODE RESULTAR EM FERIMENTOS NO TÉCNICO DE ASSISTÊNCIA, OPERADOR OU PACIENTE EM CONSEQUÊNCIA DE CHOQUE ELÉCTRICO, PERIGOS DE ORIGEM MECÂNICA, BEM COMO DE OUTROS TIPOS.**

AVVERTENZA (IT)

IL PRESENTE MANUALE DI MANUTENZIONE È DISPONIBILE SOLTANTO IN INGLESE.

- **SE UN ADDETTO ALLA MANUTENZIONE ESTERNO ALLA GEHC RICHIEDE IL MANUALE IN UNA LINGUA DIVERSA, IL CLIENTE È TENUTO A PROVVEDERE DIRETTAMENTE ALLA TRADUZIONE.**
- **SI PROCEDA ALLA MANUTENZIONE DELL’APPARECCHIATURA SOLO DOPO AVER CONSULTATO IL PRESENTE MANUALE ED AVERNE COMPRESO IL CONTENUTO.**
- **NON TENERE CONTO DELLA PRESENTE AVVERTENZA POTREBBE FAR COMPIERE OPERAZIONI DA CUI DERIVINO LESIONI ALL’ADDETTO ALLA MANUTENZIONE, ALL’UTILIZZATORE ED AL PAZIENTE PER FOLGORAZIONE ELETTRICA, PER URTI MECCANICI OD ALTRI RISCHI.**

HOIATUS (ET)

KÄESOLEV 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 PALVELUNTARJOAJA 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 PALVELUNTARJOAJAN, LAITTEISTON KÄYTTÄJÄN TAI POTILAAN VAHINGOITTUMINEN SÄHKÖISKUN, MEKAANISEN VIAN TAI MUUN VAARATILANTEEN VUOKSI.

ΠΡΟΕΙΔΟΠΟΙΗΣΗ (EL)

ΤΟ ΠΑΡΟΝ ΕΓΧΕΙΡΙΔΙΟ ΣΕΡΒΙΣ ΔΙΑΤΙΘΕΤΑΙ ΣΤΑ ΑΓΓΛΙΚΑ ΜΟΝΟ.

- ΕΑΝ ΤΟ ΑΤΟΜΟ ΠΑΡΟΧΗΣ ΣΕΡΒΙΣ ΕΝΟΣ ΠΕΛΑΤΗ ΑΠΑΙΤΕΙ ΤΟ ΠΑΡΟΝ ΕΓΧΕΙΡΙΔΙΟ ΣΕ ΓΛΩΣΣΑ ΕΚΤΟΣ ΤΩΝ ΑΓΓΛΙΚΩΝ, ΑΠΟΤΕΛΕΙ ΕΥΘΥΝΗ ΤΟΥ ΠΕΛΑΤΗ ΝΑ ΠΑΡΕΧΕΙ ΥΠΗΡΕΣΙΕΣ ΜΕΤΑΦΡΑΣΗΣ.
- ΜΗΝ ΕΠΙΧΕΙΡΗΣΕΤΕ ΤΗΝ ΕΚΤΕΛΕΣΗ ΕΡΓΑΣΙΩΝ ΣΕΡΒΙΣ ΣΤΟΝ ΕΞΟΠΛΙΣΜΟ ΕΚΤΟΣ ΕΑΝ ΕΧΕΤΕ ΣΥΜΒΟΥΛΕΥΤΕΙ ΚΑΙ ΕΧΕΤΕ ΚΑΤΑΝΟΗΣΕΙ ΤΟ ΠΑΡΟΝ ΕΓΧΕΙΡΙΔΙΟ ΣΕΡΒΙΣ.
- ΕΑΝ ΔΕ ΛΑΒΕΤΕ ΥΠΟΨΗ ΤΗΝ ΠΡΟΕΙΔΟΠΟΙΗΣΗ ΑΥΤΗ, ΕΝΔΕΧΕΤΑΙ ΝΑ ΠΡΟΚΛΗΘΕΙ ΤΡΑΥΜΑΤΙΣΜΟΣ ΣΤΟ ΑΤΟΜΟ ΠΑΡΟΧΗΣ ΣΕΡΒΙΣ, ΣΤΟ ΧΕΙΡΙΣΤΗ Ή ΣΤΟΝ ΑΣΘΕΝΗ ΑΠΟ ΗΛΕΚΤΡΟΠΛΗΞΙΑ, ΜΗΧΑΝΙΚΟΥΣ Ή ΑΛΛΟΥΣ ΚΙΝΔΥΝΟΥΣ.

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.

VIÐVÖRUN (IS)

ÞESSI ÞJÓNUSTUHANDBÓK ER EINGÖNGU FÁANLEG Á ENSKU.

- **EF ÞJÓNUSTUAÐILI VIÐSKIPTAMANNS ÞARFNAST ANNARS TUNGUMÁLS EN ENSKU, ER ÞAÐ Á ÁBYRGÐ VIÐSKIPTAMANNS AÐ ÚTVEGA ÞÝÐINGU.**
- **REYNIÐ EKKI AÐ ÞJÓNUSTA TÆKIÐ NEMA EFTIR AÐ HAFA SKOÐAÐ OG SKILIÐ ÞESSA ÞJÓNUSTUHANDBÓK.**
- **EF EKKI ER FARIÐ AÐ ÞESSARI VIÐVÖRUN GETUR ÞAÐ VALDIÐ MEIÐSLUM ÞJÓNUSTUVEITANDA, STJÓRNANDA EÐA SJÚKLINGS VEGNA RAFLOSTS, VÉLRÆNNAR EÐA ANNARRAR HÆTTU.**

VÝSTRAHA (CS)

TENTO SERVISNÍ NÁVOD EXISTUJE POUZE V ANGLICKÉM JAZYCE.

- **V PŘÍPADĚ, ŽE POSKYTOVATEL SLUŽEB ZÁKAZNÍKŮM POTŘEBUJE NÁVOD V JINÉM JAZYCE, JE ZAJIŠTĚNÍ PŘEKLADU DO ODPOVÍDAJÍCÍHO JAZYKA ÚKOLEM ZÁKAZNÍKA.**
- **NEPROVÁDĚJTE ÚDRŽBU TOHOTO ZAŘÍZENÍ, ANIŽ BYSTE SI PŘEČETLI TENTO SERVISNÍ NÁVOD A POCHOPILI JEHO OBSAH.**
- **V PŘÍPADĚ NEDODRŽOVÁNÍ TÉTO VÝSTRAHY MŮŽE DOJÍT ÚRAZU ELEKTRICKÁM PROUDEM PRACOVNÍKA POSKYTOVATELE SLUŽEB, OBSLUŽNÉHO PERSONÁLU NEBO PACIENTŮ VLIVEM ELEKTRICKÉHOP PROUDU, RESPEKTIVE VLIVEM K RIZIKU MECHANICKÉHO POŠKOZENÍ NEBO JINÉMU RIZIKU.**

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 MEDMINDRE DENNE SERVICEMANUAL ER BLEVET LÆST OG FORSTÅET.**
- **MANGLENDE OVERHOLDELSE AF DENNE ADVARSEL KAN MEDFØRE SKADE PÅ GRUND AF ELEKTRISK, 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 VOORDAT 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.**

BRĪDINĀJUMS (LV)

ŠĪ APKALPES ROKASGRĀMATA IR PIEEJAMA TIKAI ANGĻU VALODĀ.

- **JA KLIENTA APKALPES SNIEDZĒJAM NEPIECIEŠAMA INFORMĀCIJA CITĀ VALODĀ, NEVIS ANGĻU, KLIENTA PIENĀKUMS IR NODROŠINĀT TULKOŠANU.**
- **NEVEICIET APRĪKOJUMA APKALPI BEZ APKALPES ROKASGRĀMATAS IZLASĪŠANAS UN SAPRAŠANAS.**
- **ŠĪ BRĪDINĀJUMA NEIEVĒROŠANA VAR RADĪT ELEKTRISKĀS STRĀVAS TRIECIENA, MEHĀNISKU VAI CITU RISKU IZRAISĪTU TRAUMU APKALPES SNIEDZĒJAM, OPERATORAM VAI PACIENTAM.**

ĮSPĖJIMAS (LT)

ŠIS EKSPLOATAVIMO VADOVAS YRA IŠLEISTAS TIK ANGLŲ KALBA.

- **JEI KLIENTO PASLAUGŲ TEIKĖJUI REIKIA VADOVO KITA KALBA – NE ANGLŲ, VERTIMU PASIRŪPINTI TURI KLIENTAS.**
- **NEMĖGINKITE ATLIKTI ĮRANGOS TECHNINĖS PRIEŽIŪROS DARBŲ, NEBENT VADOVAUTUMĖTĖS ŠIUO EKSPLOATAVIMO VADOVU IR JĮ SUPRASTUMĖTE**
- **NEPAISANT ŠIO PERSPĖJIMO, PASLAUGŲ TEIKĖJAS, OPERATORIUS AR PACIENTAS GALI BŪTI SUŽEISTAS DĖL ELEKTROS SMŪGIO, MECHANINIŲ AR KITŲ PAVOJŲ.**

ADVARSEL (NO)

DENNE SERVICEHÅNDBOKEN FINNES BARE PÅ ENGELSK.

- **HVIS KUNDENS SERVICELEVERANDØR TRENGER 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 FIRMA ŚWIADCZĄCA KLIENTOWI USŁUGI SERWISOWE WYMAGA UDOSTĘPNIENIA PODRĘCZNIKA W JĘZYKU INNYM NIŻ ANGIELSKI, OBOWIĄZEK ZAPEWNIENIA STOSOWNEGO TŁUMACZENIA SPOCZYWA NA KLIENCIE.**
- **NIE PRÓBOWAĆ SERWISOWAĆ NINIEJSZEGO SPRZĘTU BEZ UPRZEDNIEGO ZAPOZNANIA SIĘ Z PODRĘCZNIKIEM SERWISOWYM.**
- **NIEZASTOSOWANIE SIĘ DO TEGO OSTRZEŻENIA MOŻE GROZIĆ OBRAŻENIAMI CIAŁA SERWISANTA, OPERATORA LUB PACJENTA W WYNIKU PORAŻENIA PRĄDEM, URAZU MECHANICZNEGO LUB INNEGO RODZAJU ZAGROŻEŃ.**

ATENȚIE (RO)

ACEST MANUAL DE SERVICE ESTE DISPONIBIL NUMAI ÎN LIMBA ENGLEZĂ.

- **DACĂ UN FURNIZOR DE SERVICII PENTRU CLIENȚI NECESITĂ O ALTĂ LIMBĂ DECÂT CEA ENGLEZĂ, ESTE DE DATORIA CLIENTULUI SĂ FURNIZEZE O TRADUCERE.**
- **NU ÎNCERCAȚI SĂ REPARAȚI ECHIPAMENTUL DECÂT ULTERIOR CONSULTĂRII ŞI ÎNȚELEGERII ACESTUI MANUAL DE SERVICE.**
- **IGNORAREA ACESTUI AVERTISMENT AR PUTEA DUCE LA RĂNIREA DEPANATORULUI, OPERATORULUI SAU PACIENTULUI ÎN URMA PERICOLELOR DE ELECTROCUTARE, MECANICE SAU DE ALTĂ NATURĂ.**

ОСТОРОЖНО! (RU)

ДАННОЕ РУКОВОДСТВО ПО ОБСЛУЖИВАНИЮ ПРЕДОСТАВЛЯЕТСЯ ТОЛЬКО НА АНГЛИЙСКОМ ЯЗЫКЕ.

- **ЕСЛИ СЕРВИСНОМУ ПЕРСОНАЛУ КЛИЕНТА НЕОБХОДИМО РУКОВОДСТВО НЕ НА АНГЛИЙСКОМ ЯЗЫКЕ, КЛИЕНТУ СЛЕДУЕТ САМОСТОЯТЕЛЬНО ОБЕСПЕЧИТЬ ПЕРЕВОД.**
- **ПЕРЕД ОБСЛУЖИВАНИЕМ ОБОРУДОВАНИЯ ОБЯЗАТЕЛЬНО ОБРАТИТЕСЬ К ДАННОМУ РУКОВОДСТВУ И ПОЙМИТЕ ИЗЛОЖЕННЫЕ В НЕМ СВЕДЕНИЯ.**
- **НЕСОБЛЮДЕНИЕ УКАЗАННЫХ ТРЕБОВАНИЙ МОЖЕТ ПРИВЕСТИ К ТОМУ, ЧТО СПЕЦИАЛИСТ ПО ТЕХОБСЛУЖИВАНИЮ, ОПЕРАТОР ИЛИ ПАЦИЕНТ ПОЛУЧАТ УДАР ЭЛЕКТРИЧЕСКИМ ТОКОМ, МЕХАНИЧЕСКУЮ ТРАВМУ ИЛИ ДРУГОЕ ПОВРЕЖДЕНИЕ.**

ПРЕДУПРЕЖДЕНИЕ (BG)

ТОВА СЕРВИЗНО РЪКОВОДСТВО Е НАЛИЧНО САМО НА АНГЛИЙСКИ ЕЗИК.

- **АКО ДОСТАВЧИКЪТ НА СЕРВИЗНИ УСЛУГИ НА КЛИЕНТ СЕ НУЖДАЕ ОТ ЕЗИК, РАЗЛИЧЕН ОТ АНГЛИЙСКИ, ЗАДЪЛЖЕНИЕ НА КЛИЕНТА Е ДА ПРЕДОСТАВИ ПРЕВОДАЧЕСКА УСЛУГА.**
- **НЕ СЕ ОПИТВАЙТЕ ДА ИЗВЪРШВАТЕ СЕРВИЗНО ОБСЛУЖВАНЕ НА ТОВА ОБОРУДВАНЕ, ОСВЕН ВСЛУЧАЙ, ЧЕ СЕРВИЗНОТО РЪКОВОДСТВО Е ПРОЧЕТЕНО И СЕ РАЗБИРА.**
- **НЕСПАЗВАНЕТО НА ТОВА ПРЕДУПРЕЖДЕНИЕ МОЖЕ ДА ДОВЕДЕ ДО НАРАНЯВАНЕ НА ДОСТАВЧИКА НА СЕРВИЗНИ УСЛУГИ, НА ОПЕРАТОРА ИЛИ ПАЦИЕНТА ВСЛЕДСТВИЕНА ТОКОВ УДАР, МЕХАНИЧНИ ИЛИ ДРУГИ РИСКОВЕ.**

UPOZORENJE (SR)

OVAJ PRIRUČNIK ZA SERVISIRANJE DOSTUPAN JE SAMO NA ENGLESKOM JEZIKU.

- **AKO KLIJENTOV SERVISER ZAHTEVA JEZIK KOJI NIJE ENGLESKI, ODGOVORNOST JE NA KLIJENTU DA PRUŽI USLUGE PREVOĐENJA.**
- **NEMOJTE POKUŠAVATI DA SERVISIRATE OPREMU AKO NISTE PROČITALI I RAZUMELI PRIRUČNIK ZA SERVISIRANJE.**
- **AKO NE POŠTUJETE OVO UPOZORENJE, MOŽE DOĆI DO POVREĐIVANJA SERVISERA, OPERATERA ILI PACIJENTA UZROKOVANOG ELEKTRIČNIM UDAROM, MEHANIČKIM I DRUGIM OPASNOSTIMA.**

OPOZORILO (SL)

TA SERVISNI PRIROČNIK JE NA VOLJO SAMO V ANGLEŠČINI.

- ČE PONUDNIK SERVISNIH STORITEV ZA STRANKO POTREBUJE NAVODILA V DRUGEM JEZIKU, JE ZA PREVOD ODGOVORNA STRANKA SAMA.
- NE POSKUŠAJTE SERVISIRATI OPREME, NE DA BI PREJ PREBRALI IN RAZUMELI SERVISNI PRIROČNIK.
- ČE TEGA OPOZORILA NE UPOŠTEVATE, OBSTAJA NEVARNOST ELEKTRIČNEGA UDARA, MEHANSKIH ALI DRUGIH NEVARNOSTI IN POSLEDIČNIH POŠKODB PONUDNIKA SERVISNIH STORITEV, UPORABNIKA OPREME ALI PACIENTA.

UPOZORENJE (HR)

OVAJ SERVISNI PRIRUČNIK DOSTUPAN JE SAMO NA ENGLESKOM JEZIKU.

- AKO KLIJENTOV SERVISER ZAHTIJEVA JEZIK KOJI NIJE ENGLESKI, ODGOVORNOST KLIJENTA JE PRUŽITI USLUGE PREVOĐENJA.
- NEMOJTE POKUŠAVATI SERVISIRATI OPREMU AKO NISTE PROČITALI I RAZUMJELI SERVISNI PRIRUČNIK.
- AKO NE POŠTUJETE OVO UPOZORENJE, MOŽE DOĆI DO OZLJEDE SERVISERA, OPERATERA ILI PACIJENTA PROUZROČENE STRUJNIM UDAROM, MEHANIČKIM I DRUGIM OPASNOSTIMA.

UPOZORNENIE (SK)

TÁTO SERVISNÁ PRÍRUČKA JE K DISPOZÍCII LEN V ANGLIČTINE.

- AK ZÁKAZNÍKOV POSKYTOVATEĽ SLUŽIEB VYŽADUJE INÝ JAZYK AKO ANGLIČTINU, POSKYTNUTIE PREKLADATEĽSKÝCH SLUŽIEB JE ZODPOVEDNOSŤOU ZÁKAZNÍKA.
- NEPOKÚŠAJTE SA VYKONÁVAŤ SERVIS ZARIADENIA SKÔR, AKO SI NEPREČÍTATE SERVISNÚ PRÍRUČKU A NEPOROZUMIETE JEJ.
- ZANEDBANIE TOHTO UPOZORNENIA MÔŽE VYÚSTIŤ DO ZRANENIA POSKYTOVATEĽA SLUŽIEB, OBSLUHUJÚCEJ OSOBY ALEBO PACIENTA ELEKTRICKÝM PRÚDOM, PRÍPADNE DO MECHANICKÉHO ALEBO INÉHO NEBEZPEČENSTVA.

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.

DİKKAT
(TR)

BU SERVİS KILAVUZU YALNIZCA İNGİLİZCE OLARAK SAĞLANMIŞTIR.

- **EĞER MÜŞTERİ TEKNİSYENİ KILAVUZUN İNGİLİZCE DIŞINDAKİ BİR DİLDE OLMASINI İSTERSE, KILAVUZU TERCÜME ETTİRMEK MÜŞTERİNİN SORUMLULUĞUNDADIR.**
- **SERVİS KILAVUZUNU OKUYUP ANLAMADAN EKİPMANLARA MÜDAHALE ETMEYİNİZ.**
- **BU UYARININ GÖZ ARDI EDİLMESİ, ELEKTRİK ÇARPMASI YA DA MEKANİK VEYA DİĞER TÜRDEN KAZALAR SONUCUNDA TEKNİSYENİN, OPERATÖRÜN YA DA HASTANIN YARALANMASINA YOL AÇABİLİR.**

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(JA)

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(KO)

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All electrical Installations that are preliminary to positioning of the equipment at the site prepared for the equipment shall be performed by licensed electrical contractors. Other connections between pieces of electrical equipment, calibrations and testing shall be performed by qualified personnel. In performing all electrical work on these products, GE will use its own specially trained field engineers. All of GE’s electrical work on these products will comply with the requirements of the applicable electrical codes.

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Omission and errors

If there are any omissions, errors or suggestions for improving this documentation, contact the Global Documentation Group with specific information listing the system type, manual title, part number, revision number, page number and suggestion details.

Mail the information to:

Service Documentation
447 Indio Way
SUNNYVALE, CA 94085
USA
Tel: (408) 328-7924 Fax: (408) 738-9156

GE employees should use the complaint handling system to report service documentation issues.

These issues will then be in the internal problem reporting tool and communicated to the writer.

Service Safety Considerations

d DANGER

DANGEROUS VOLTAGES, CAPABLE OF CAUSING DEATH, ARE PRESENT IN THIS EQUIPMENT. USE EXTREME CAUTION WHEN HANDLING, TESTING AND ADJUSTING.

w WARNING

Use all Personal Protection Equipment (PPE) such as gloves, safety shoes, safety glasses, and kneeling pad, to reduce the risk of injury.

For a complete review of all safety requirements, refer to Chapter 1 in the Service Manual.

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Table of Contents

Chapter 1

Introduction

This chapter describes important issues related to safely servicing the Invenia ABUS Scan Station, Invenia ABUS Workstation, and Invenia ABUS Review Software. The service provider must read and understand all the information presented here before installing or servicing the Invenia ABUS Scan Station, Invenia ABUS Workstation, and Invenia ABUS Review Software.

Manual Overview

Contents in this manual

This manual provides installation and service information for the Invenia ABUS Scan Station, Invenia ABUS Workstation, and Invenia ABUS Review Software.

The manual is divided into ten chapters.

In the beginning of the manual, before Chapter 1, you will find the *Revision overview*, the *Important precautions* including *Translation policy*, *Damage in transportation*, *Certified electrical contractor statement*, *Omission & errors*, *Service safety considerations* and *Legal notes*, and the *Table of Contents*.

An Index has been included after Chapter 10.

Table 1-1: Contents in this manual

Chapter Number	ChapterTtitle	Description
1.	Introduction	Contains a content summary and warnings.
2.	Site preparations	Contains pre-setup requirements for the Invenia ABUS.
3.	System Setup	Contains setup procedure with procedure checklist.
4.	General Procedures and Functional Checks	Contains functional checks that must be performed as part of the installation, or as required during servicing and periodic maintenance.
5.	Components and Functions (Theory)	Contains and functional explanations of the electronics.
6.	Service Adjustments	Contains instructions on how to make any available adjustments to the Invenia ABUS.
7.	Diagnostics/ Troubleshooting	Provides procedures for running diagnostic or related routines for the Invenia ABUS.
8.	Replacement procedures	Provides disassembly procedures and reassembly procedures for all changeable FRU.
9.	Renewal Parts	Contains a list of replacement parts for Invenia ABUS.
10.	Care & Maintenance	Provides maintenance procedures for Invenia ABUS.
Index	Index	A quick way to the topic you’re looking for.

Typical users of the System Setup and Basic Service Manual

- GE Service Personnel (setup, maintenance, etc.)
- Invenia ABUS User
- Licensed Hospitals' Service Providers
- Technical Trainers

Invenia ABUS models covered by this manual

Table 1-2: Invenia ABUS Models and Hardware/Software Compatibility

Model Number	Description	System SW	Appl. SW
H5014SS	Invenia ABUS Scan Station	Windows 7 Professional	Version 1 Revision x.x
H5014WS	Invenia ABUS Workstation	Windows 7 Professional	Version 2 Revision x.x
H5014SW	Invenia ABUS Review Software	Windows 7 Professional	Version 2 Revision x.x

The Invenia™ Automated Breast Ultrasound System (ABUS) comes with a review workstation available as software only (Invenia ABUS Review Software) or with dedicated hardware (Invenia ABUS Workstation).

NOTE: When not otherwise specified, the contents of this manual applies to all Invenia ABUS models.

Product Overview

Invenia ABUS Scan Station and System

The Invenia ABUS is composed of the following components:

- Invenia ABUS Scan Station
- Invenia ABUS Workstation or Invenia ABUS Review Software

Figure 1-1. Invenia ABUS Scan Station, Invenia ABUS Workstation, or Invenia ABUS Review Software

After performing the exam study on the Scan Station, the exam study is transferred to the Invenia ABUS over the DICOM network. After reviewing the patient's study on the workstation, the study is sent to PACS for archiving, or to some other form of manual archive.

Invenia ABUS Scan Station and System (continued)

For more information on the Invenia ABUS Scan Station, please refer to the Invenia ABUS Scan Station Basic User Manual, Part Number 4700-0014-00.

For more information on the Workstation, please refer to the Invenia ABUS Workstation and Invenia ABUS Review Software Basic User Manual, Part Number 4700-0015-00.

Invenia ABUS Scan Station and System (continued)

The Invenia™ Automated Breast Ultrasound System (ABUS) comes with a review workstation available as software only (Invenia ABUS Review Software) or with dedicated hardware (Invenia ABUS Workstation).

There are three (3) distinctions to note with regard to the naming conventions used in this manual:

- **Workstation**. A generic name for computer hardware, provided by GE or by a 3rd party, running the Invenia ABUS Review Software.
- **3rd Party Workstation**. Computer hardware, provided by a 3rd party, running the Invenia ABUS Review Software.
- **Invenia ABUS Workstation**. Computer hardware, provided by GE, running the Invenia ABUS Review Software.

Figure 1-2. Invenia ABUS Scan Station and Invenia ABUS Workstation

Invenia ABUS Scan Station

The Invenia ABUS is intended to be used in medical practices and in clinical departments and serves the purposes as a review station for the radiologist's interpretation of images, electronic documentation of examinations in the form of text and images and generation of medical reports.

- Ultrasound engine with articulating arm
- Scanner Assembly with C15-6XW Reverse Curve™ transducer
- Rotating Touch Screen monitor
- Workstation (please refer to the Workstation User Manual)

Figure 1-3. Invenia ABUS Overview

Table 1-3: Main System Components

1. Rotating Touch Screen Monitor 2. Ultrasound Coupling Lotion Holders 3. Power Cord, Mains Power Switch, and Network Connector (not shown, on back of system)	4. System Standby Button (On/ Off) 5. Articulating Arm 6. Scanner Assembly with C15-6XW Reverse Curve™ transducer

This section will walk you through how to use the Touch Screen monitor and scanner assembly to perform the ABUS scan. In addition, this section will discuss how to move the system and set the front and rear brakes.

NOTE: The Invenia ABUS Scan Station is ideally positioned with the articulating arm adjacent to the top right or left corner of the bed.

Invenia ABUS Workstation and Review Software

The Invenia ABUS Review Software will typically be used in a mammography reading room environment, normally with low ambient light levels next to a mammography reading station and a DICOM workstation.

The Invenia ABUS Review Software is designed to accept, transfer, display, store and process medical images and data. Invenia ABUS Review Software enables the user to optimize, measure and annotate the images. The Invenia ABUS Review Software provides images to enable Physicians to differentiate normal and abnormal breast tissue and is intended for use by Health Care Professionals only.

The Invenia ABUS Review Software displays three-dimensional data sets for viewing in three orthogonal planes and standard Ultrasound images, permitting Interpreting Physicians to quickly rerview, locate, and mark regions of interest.

The Invenia ABUS Workstation, if provided, includes the following components:

1. Monitor and Computer, with proprietary GE software
2. Keyboard
3. Mouse

Direct Network Connection Between the Invenia ABUS Scan Station and Workstation to PACS (typical configuration)

Exam studies are sent from the Invenia ABUS Scan Station to the Invenia ABUS Review Software directly and reviewed by the Interpreting Physician before they are archived.

Figure 1-4. Review Prior to Archival

Connection Through a Storage system, such as PACS

Exams are archived first to Storage and then reviewed by an Interpreting Physician at any Invenia ABUS connected to the network.

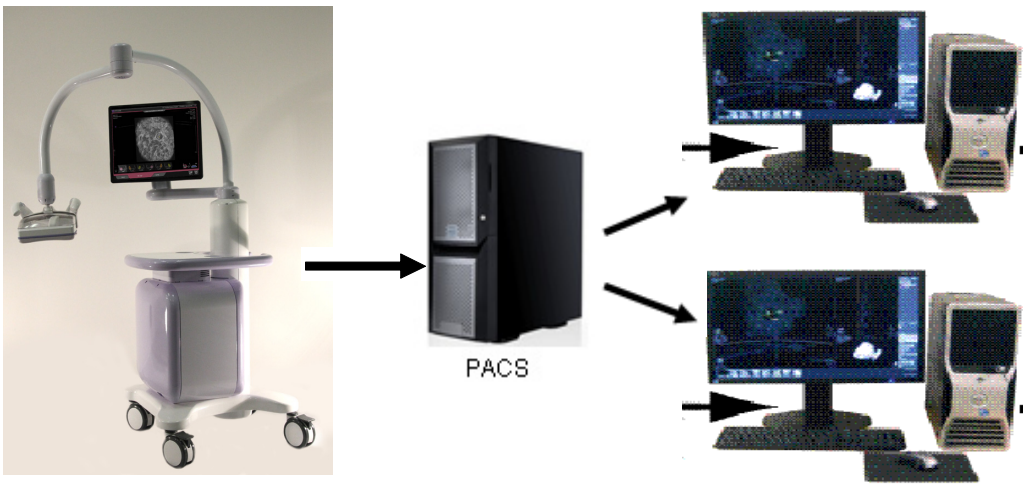


Figure 1-5. Connection through a PACS

Storage and Archive

The Workstation provides temporary storage for approximately 200 patient studies. The workstation can be configured to maintain 10, 20, 30, 40, or 50 percent of the available disk space free to ensure good workstation performance. If free space reaches a percentage under the configured limit specified by the user, a warning appears when logging into the Invenia ABUS application. Old reviewed studies are then deleted (oldest first) overnight or when the workstation is powered up the next time. Transfers from the Invenia ABUS Scan Station are rejected if free disk space falls below 5%. Scans will not transfer to the Workstation if there is not enough disk space. Suspended or un-reviewed studies are never automatically deleted in this manner. Deleted studies can only be re-displayed if the whole study was stored to PACS or external storage and re-imported.

Product description in this Manual

Overview of the Invenia ABUS Scan Station and Workstation

This Invenia ABUS is a high performance digital ultrasound imaging system with total data management via the Workstation.

Signal flows from the Probe Connector Panel through the Invenia ABUS Scan Station and finally to the monitor.

System configuration is stored on the Scan Station and Workstation. Each have their configuration locally.

All necessary software is loaded from the hard drive on power up.

History - hardware/software versions

Please refer to Chapter 9 in this manual.

Field Replaceable Units (FRUs)

Please refer to Chapter 8 in this manual.

How to turn the Invenia ABUS Scan Station and Workstation ON and OFF

Please refer to Chapter 4 in this manual.

How to check for hardware/software version

To verify the hardware versions on the boards, please refer to Chapter 4 in this manual.

Purpose of the operator manual(s)

The operator manuals should be fully read and understood before operating the Invenia ABUS.

The online versions of the operator manuals are available via the Help function on Invenia ABUS's operator panel.

Important conventions

Conventions used in book

Important conventions, used in this document, are described next.

Model designations

This manual covers the Invenia ABUS Scan Station and Workstation (Invenia ABUS Workstation and Invenia ABUS Review Software).

‘Invenia ABUS models covered by this manual’ on *page 1-3*.

Icons

Pictures, or icons, are used wherever they will reinforce the printed message. The icons, labels, and conventions used on the product and in the service information are described in this chapter.

Safety precaution messages

Various levels of safety precaution messages may be found on the equipment and in the service information. The different levels of concern are identified by a flag word that precedes the precautionary message. Known or potential hazards to personnel are labeled in one of three ways:

- DANGER
- WARNING
- CAUTION

d  DANGER

Danger is used to indicate the presence of a hazard that will cause severe personal injury or death if the instructions are ignored.

w  WARNING

Warning is used to indicate the presence of a hazard that can cause severe personal injury and property damage if instructions are ignored.

c  CAUTION

Caution is used to indicate the presence of a hazard that will or can cause minor personal injury and property damage if instructions are ignored. Equipment damage possible.

NOTE: Notes are used to provide important information about an item or a procedure.

NOTE: Be sure to read the notes; the information contained in a note can often save you time or effort.

Standard hazard icons

Important information will always be preceded by either the exclamation point (!) contained within a triangle, or the symbols for “Danger”, “Warning” or “Caution”, as seen throughout this chapter. In addition to text, several different graphical icons (symbols) may be used to make you aware of specific types of hazards that could possibly cause harm. Even if a symbol isn’t used in this manual, it may be included for your reference.

Table 1-4: Standard hazard icons

	ELECTRICAL
	MECHANICAL
	HEAT
	PINCH
	MAGNET PACEMAKER

Standard Icons that indicate that a special procedure is to be used

Some others icons make you aware of specific procedures that should be followed.

Table 1-5: Standard Icons that indicates that a special procedure is to be used

Avoid Static Electricity	Tag and Lockout	Wear Eye Protection
		
Hand Protection	**Foot Protection**	**Wear Eye Protection**
		

Be sure to read the notes; the information contained in a note can often save you time or effort.

Product icons

Always refer to the product's User Manual for a full list of labels used on the Invenia ABUS Scan Station and Workstation.

Labels locations

It is important to refer to the current revision of the Invenia ABUS Scan Station and Workstation User Manuals for a full list of product labels prior to servicing the system.

Safety considerations

Introduction

The following safety precautions must be observed during all phases of operation, service and repair of this equipment. Failure to comply with these precautions or with specific warnings elsewhere in this manual, violates safety standards of design, manufacture and intended use of the equipment.

Human Safety

- Operating personnel must not remove the system covers.
- Servicing should be performed by authorized personnel only.

This equipment contains dangerous voltages that are capable of serious injury or death.

If any defects are observed or malfunctions occur, stop operating the equipment and perform the proper action for the patient. Inform a qualified service person and contact a Service Representative for information.

There are no user serviceable components inside the console. Refer all servicing to qualified service personnel only.

Ensure that unauthorized personnel do not tamper with the unit.

The warranty is void if covers have been removed.

Only personnel who have participated in an Invenia ABUS Scan Station and Workstation Training Seminar are authorized to service the internal components of this equipment.

Human Safety (continued)

d DANGER

DANGEROUS VOLTAGES, CAPABLE OF CAUSING DEATH, ARE PRESENT IN THIS EQUIPMENT. USE EXTREME CAUTION WHEN HANDLING, TESTING AND ADJUSTING.

d DANGER

WHERE APPLICABLE, THERE ARE SEVERAL PLACES ON THE IMAGING ENGINE CHASSIS, THE AC DISTRIBUTION, DC DISTRIBUTION, AND TIP BOARD THAT ARE DANGEROUS. BE SURE TO POWER DOWN THE SYSTEM, TURN OFF THE MAINS POWER SWITCH AND DISCONNECT THE MAINS POWER CABLE FROM THE WALL OUTLET BEFORE YOU REMOVE ANY PARTS. BE CAUTIOUS WHENEVER POWER IS STILL ON AND COVERS ARE REMOVED.

w WARNING

If the covers are removed from an operating Invenia ABUS Scan Station, some metal surfaces may be warm enough to pose a potential heat hazard if touched, even while in shutdown mode.

w WARNING

Because of the limited access to cabinets and equipment in the field, placing people in awkward positions, GE has limited the lifting weight for one person in the field to 16 KG (35 LBS). Anything over 16 KG (35 LBS) requires 2 people.

w WARNING

Attempts to move the Invenia ABUS Scan Station considerable distances or on an incline by one person could result in injury or damage or both.

Human Safety (continued)

Explosion Warning

DO NOT operate the equipment in an explosive atmosphere. Operation of any electrical equipment in such an environment constitutes a definite safety hazard.

DO NOT substitute parts or modify equipment

Because of the danger of introducing additional hazards, ONLY install GE approved parts. DO NOT perform any unauthorized modification of the equipment.

Ensure that the Invenia ABUS Scan Station is turned off and unplugged

Wait for at least 20 seconds for capacitors to discharge as there are no test points to verify isolation.

Invenia ABUS Scan Station components may be energized. Always refer to LOTO warnings and cautions

Risk of electrical shock, Invenia ABUS Scan Station must be turned off and disconnected from power source. Cord must be controlled at all times.

Wait for at least 20 seconds for capacitors to discharge as there are no test points to verify isolation.

Invenia ABUS Scan Station components may be energized. Always refer to LOTO warnings and cautions

Tilting the console requires two people in order to avoid injury to service personnel and damage to the equipment.

Human Safety (continued)

Use all Personal Protection Equipment (PPE) such as gloves, safety shoes, safety glasses, and kneeling pad, to reduce the risk of injury.

Beware of possible sharp edges on all mechanical parts. If sharp edges are encountered, the appropriate PPE should be used to reduce the risk of injury.

Wear all PPE including gloves as indicated in the chemical MSDS.

Lockout/Tagout (LOTO) requirements

Lockout/Tagout

Follow Lockout/Tagout requirements by ensuring you are in total control of the AC power plug at all times during the service process.

To apply Lockout/Tagout (LOTO):

1. Plan and prepare for shutdown.
2. Shutdown the equipment.
3. Isolate the equipment.
4. Apply Lockout/Tagout Devices.
5. Control all stored and residual energy.
6. Verify isolation.

All potentially hazardous stored or residual energy is relieved.

Energy Control and Power Lockout

Energy Control and Power Lockout for Invenia ABUS.

When servicing parts of the Invenia ABUS Scan Station where there is exposure to voltage greater than 30 volts:

1. Follow LOCKOUT/TAGOUT procedures.
2. Turn off the Power Mains Switch.
3. Unplug the Invenia ABUS Scan Station.
4. Maintain control of the Invenia ABUS Scan Station power plug.
5. Wait for at least 20 seconds for capacitors to discharge as there are no test points to verify isolation.

Invenia ABUS Scan Station components may be energized.

Dangerous procedure warnings

Warnings, such as the example below, precede potentially dangerous procedures throughout this manual. Instructions contained in the warnings must be followed.

d DANGER

DANGEROUS VOLTAGES, CAPABLE OF CAUSING DEATH, ARE PRESENT IN THIS EQUIPMENT. USE EXTREME CAUTION WHEN HANDLING, TESTING AND ADJUSTING.

w WARNING

If the covers are removed from an operating Invenia ABUS, some metal surfaces may be warm enough to pose a potential heat hazard if touched, even while in shutdown mode.

w WARNING

Explosion Warning

DO NOT operate the equipment in an explosive atmosphere. Operation of any electrical equipment in such an environment constitutes a definite safety hazard.

w WARNING

DO NOT substitute parts or modify equipment

Because of the danger of introducing additional hazards, ONLY install GE approved parts. DO NOT perform any unauthorized modification of the equipment.

Electrical safety

Safe practices

Follow these guidelines to minimize shock hazards whenever you are using the Invenia ABUS Scan Station:

- To minimize shock hazard, the equipment chassis must be connected to an electrical ground.
- The Invenia ABUS Scan Station is equipped with a three-conductor AC power cable. This must be plugged into an approved electrical outlet with safety ground.
- The power outlet used for this equipment should not be shared with other types of equipment.
- Both the system power cable and the power connector must meet international electrical standards

Connecting a Invenia ABUS to the wrong voltage level will most likely destroy it.

Transducer

Follow these guidelines before connecting the transducer to the Invenia ABUS:

- Inspect the probe prior to each use for damage or degradation to the:
  - housing
  - lens
  - seal
  - connector pins
- Do not use a damaged or defective probe.
- Never immerse the probe connector or adapter into any liquid.

Mechanical safety

WARNING

While the software install procedure is designed to preserve data, ensure that all patient exams have transferred to the Workstation or PACS.

WARNING

Ultrasound probes are highly sensitive medical instruments that can easily be damaged by improper handling. Use care when handling and protect from damage when not in use. do not use a damaged or defective probe. Failure to follow these precautions can result in serious injury and equipment damage.

WARNING

Never use a probe that has fallen to the floor. Even if it looks OK, it may be damaged.

WARNING

When the Invenia ABUS Scan Station is raised for a repair or moved along any incline, use extreme caution since it may become unstable and tip over.

CAUTION

Invenia ABUS weighs 123 kg (271 lbs.) when ready for use. Care must be used when moving it or replacing its parts.

Failure to follow the precautions listed below could result in injury, uncontrolled motion and costly damage.

ALWAYS:

- be sure the pathway is clear
- use slow, careful motions
- use two people when moving on inclines or lifting more than 16 kg (35 lbs)

Mechanical safety (continued)

CAUTION

Before you move or transport the Invenia ABUS Scan Station, make sure to lock the Touch Screen monitor and Articulating Arm to prevent damage to the Invenia ABUS Scan Station.

CAUTION

To avoid injury when you move the Touch Screen monitor and the Articulating Arm, do not put your finger, hand, or object on the joint of the monitor or the monitor arm.

CAUTION

Keep the heat venting holes on the Touch Screen monitor unobstructed to avoid overheating of the monitor.

CAUTION

Do not transport Invenia ABUS in a vehicle without locking the casters (wheels) and securing it as described in the User Manual.

CAUTION

Use protective glasses during drilling, filing smooth surfaces, and during all other work where eyes need protection.

CAUTION

Practice good ESD prevention. Wear an anti–static strap when handling electronic parts and even when disconnecting/ connecting cables.

CAUTION

Do not pull out or insert circuit boards while power is on.

Mechanical safety (continued)

CAUTION

Do not operate this Invenia ABUS Scan Station unless all board covers and frame panels are securely in place. System performance and cooling require this.

CAUTION

Use safety shoes when doing work where there is any chance of foot injury.

CAUTION

Use protective gloves when working with sharp edges or when directed to wear PPE during a removal/replacement procedure.

CAUTION

Be careful not to pinch any of the cables.

NOTE: Special care should be taken when transporting the Invenia ABUS in a vehicle:

- Before transporting, place the system in its special storage container.
- Ensure that the system is firmly secured while inside the vehicle.
- Secure system with straps or as directed otherwise to prevent motion during transport.
- Prevent vibration damage by driving cautiously. Avoid unpaved roads, excessive speeds, and erratic stops or starts.

Electromagnetic compatibility (EMC)

What is EMC?

Electromagnetic compatibility describes a level of performance of a device within its electromagnetic environment. This environment consists of the device itself and its surroundings including other equipment, power sources and persons with which the device must interface. Inadequate compatibility results when a susceptible device fails to perform as intended due interference from its environment or when the device produces unacceptable levels of emission to its environment. This interference is often referred to as radio–frequency or electromagnetic interference (RFI/EMI) and can be radiated through space or conducted over interconnecting power of signal cables. In addition to electromagnetic energy, EMC also includes possible effects from electrical fields, magnetic fields, electrostatic discharge and disturbances in the electrical power supply.

Compliance

Invenia ABUS conforms to all applicable conducted and radiated emission limits and to immunity from electrostatic discharge, radiated and conducted RF fields, magnetic fields and power line transient requirements.

For applicable standards, refer to the Safety Chapter of the Invenia ABUS Scan Station and Invenia ABUS Workstation and Invenia ABUS Review Software User's Manuals.

NOTE: It is critical that all covers, screws, shielding, gaskets, mesh, clamps, are in good condition, installed tightly without skew or stress. Proper installation following all comments noted in this service manual is required in order to achieve full EMC performance.

Electrostatic discharge (ESD) prevention

WARNING

DO NOT touch any boards with integrated circuits prior to taking the necessary ESD precautions.

Always connect yourself, via an arm-wrist strap, to the advised ESD connection point located on the rear of the Invenia ABUS Scan Station (near the power connector).

Follow general guidelines for handling of electrostatic sensitive equipment.

WARNING

Risk of electrical shock, Invenia ABUS Scan Station must be turned off. Avoid all contact with electrical contacts, conductors and components. Always use non-conductive handles designed for the removal and replacement of ESD sensitive parts. All parts that have the potential for storing energy must be discharged or isolated before making contact.

Customer assistance

Contact information

If this equipment does not work as indicated in this service manual or in the user manual, or if you require additional assistance, please contact the GE Service or appropriate support resource. Note the following:

1. System ID serial number.
2. Software version.
3. Date and time of occurrence.
4. Sequence of events leading to issue.
5. Is the issue repeatable?

Refer to Figure 3-1 to locate the System ID Serial Number on the Invenia ABUS Scan Station and Invenia ABUS Workstation. Specific label descriptions can be found in the user manuals.

Phone numbers for Customer Assistance

Table 1-6: Phone numbers for Customer Assistance

LOCATION	PHONE NUMBER	
USA/Canada GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC 9900 Innovation Drive Wauwatosa, WI 53226	Service: On-site	1-800-321-7937
	Service Parts	1-800-558-2040
	Application Support	1-800-682-5327 or 1-262-524-5698
Latin America	Service Application Support	1-262-524-5300 1-262-524-5698
EMEA GE Ultraschall Deutschland Gmbh & Co. KG Beethovenstrasse 239 Postfach 11 05 60, D-42655 Solingen Germany	Phone:	+49 (0) 212-2802-652
	Fax:	+49 (0) 2122-8024-31
EAGM Egypt Service Center UAE Service Center	Service Tel	 00202 2322 1252 00971 8003646
Asia (Singapore) GE Ultrasound Asia Service Department - Ultrasound 298 Tiong Bahru Road #15-01/06 Central Placa Singapore 168730	Tel:	+65 6291-8528
	Fax:	+65-6291-7006
Japan Support Center	Phone: Fax:	81-426-48-2940 81-426-48-2905
Australlia/New Zealand China India South Korea	Online Services Ultrasound Asia	+(61) 1-800-647-855 +(86) 800-810-8188 +(91) 1800-425-8025 +(91) 1800-102-7750 +(91) 1800-425-7255 +(82) 2-1544--6119

System manufacturer

Table 1-7: System manufacturer

MANUFACTURER
U-Systems, Inc. 447 Indio Way Sunnyvale, CA 94085 USA

Returning parts

Returning the probe and repair parts

Equipment being returned must be clean and free of blood and other infectious substances. Policy states that body fluids must be properly removed from any part or equipment prior to shipment. Employees, as well as customers, are responsible for ensuring that parts/equipment have been properly decontaminated prior to shipment. Under no circumstance should a part or equipment with visible body fluids be taken or shipped from a clinic or site (for example, body coils or an ultrasound probe).

The purpose of the regulation is to protect employees in the transportation industry, as well as the people who will receive or open this package.

NOTE: The US Department of Transportation (DOT) has ruled that "items that were saturated and/or dripping with human blood that are now caked with dried blood; or which were used or intended for use in patient care" are "regulated medical waste" for transportation purposes and must be transported as a hazardous material.

NOTE: The USER/SERVICE staff should dispose of all the waste properly, per federal, state, and local waste disposal regulations.

The Invenia ABUS is not meant to be used for long-term storage of patient data or images. The user is responsible for the data on the system.

If the system is sent for repair, please ensure that any patient information is backed up and erased from the system before shipping. It is always possible during system failure and repair to lose patient data. GE is not responsible for the loss of this data.

Returning the probe and repair parts (continued)

If PHI (Patient Healthcare Information) data needs to be sent to GE employees for service purposes, GE will ascertain agreement from the customer. Patient information shall only be transferred by approved service processes, tools and devices restricting access, protecting or encrypting data where required, and providing traceability in the form of paper or electronic documents at each stage of the procedure while maintaining compliance with cross-border restrictions of patient information transfers.

Chapter 2

Site Preparations

This chapter provides the information required to plan and prepare for the setup of an Invenia ABUS Scan Station, Invenia ABUS Workstation, and Invenia ABUS Review Software. Included are descriptions of the facility and electrical needs to be met by the purchaser of the Invenia ABUS Scan Station, Invenia ABUS Workstation, and Invenia ABUS Review Software.

General Invenia ABUS requirements

Invenia ABUS Scan Station environmental requirements

If the Invenia ABUS Scan Station is very cold or hot

When unpacking the Invenia ABUS Scan Station, allow the temperature of the Invenia ABUS Scan Station to stabilize before powering up. The following table describes guidelines for reaching operational temperatures from storage or transport temperatures.

CAUTION

If the Invenia ABUS Scan Station is very cold or hot, do not turn on its power until it has had a chance to acclimate to its operating environment.

Table 2-1: Invenia ABUS Scan Station acclimate time

°C	-40	-35	-30	-25	-20	-15	-10	-5	0	5	10	15	20	25	30	35	40	45	50	55	60	65	70
°F	-40	-31	-22	-13	-4	5	14	23	32	41	50	59	68	77	86	95	104	113	122	131	140	149	158
Hrs	20	18	16	14	12	10	8	6	4	2	0	0	0	0	0	0	0	2	4	6	8	10	12

Cooling

The cooling requirement for a typical console Ultrasound system with monitor and on board peripherals, is up to 3800 BTU/h. This figure does not include cooling needed for lights, people, or other equipment in the room.

NOTE: Each person in the room places an additional 300 BTU/h demand on the cooling system.

Lighting

Bright light is needed for Invenia ABUS Scan Station setup, updates, and repairs. However, operator and patient comfort may be optimized if the room light is subdued and indirect. Therefore a combination lighting system (dim/bright) is recommended. Keep in mind that lighting controls and dimmers can be a source of Electromagnetic Interference (EMI) which could degrade image quality. These controls should be selected to minimize possible interference.

Electrical requirements

General requirements

The Invenia ABUS Scan Station requires a dedicated power and ground for the proper operation of its Ultrasound equipment. A separate power outlet with a minimum 10 amp circuit breaker for 100-240 VAC.

NOTE: Please note that image artifacts can occur, if at any time within the facility, the ground from the main facility's incoming power source to the Invenia ABUS Scan Station is only a conduit.

Power outage may occur. The Invenia ABUS requires a dedicated single branch circuit. To avoid circuit overload and possible loss of critical care equipment, make sure you do not have any other equipment operating on the same circuit.

Site power outlets

A dedicated AC power outlet must be within reach of the Invenia ABUS Scan Station without extension cords. Other outlets adequate for the external peripherals, medical and test equipment needed to support this Invenia ABUS Scan Station must also be present within 1 m (3.2 ft.) of the Invenia ABUS Scan Station. Electrical installation must meet all current local, state, and national electrical codes.

Unit power plug

Refer to Chapter 9 for Power Plug part numbers. If the Invenia ABUS Scan Station and Workstation arrives without a power plug, or with the wrong plug, you must contact your GE dealer or the installation engineer must supply what is locally required.

Power stability requirements

Voltage drop-out:

Max 10 ms.

Power transients (all applications):

Less than 25% of nominal peak voltage for less than 1 millisecond for any time of transient, including line frequency, synchronous, asynchronous, or aperiodic transients.

Power stability requirement

Table 2-2: Power Stability Requirement

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle	<5% UT (>95% dip in UT) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment.
	40% UT (60% dip in UT) for 5 cycles	40% UT (60% dip in UT) for 5 cycles	
	70% UT (30% dip in UT) for 25 cycles	70% UT (30% dip in UT) for 25 cycles	
	<5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 5 s	

EMI limitations

Ultrasound systems are susceptible to Electromagnetic Interference (EMI) from radio frequencies, magnetic fields, and transients in the air or wiring. They also generate EMI. The Invenia ABUS Scan Station and Invenia ABUS Workstation complies with limits as stated on the EMC label. However there is no guarantee that interference will not occur in a particular installation.

Possible EMI sources should be identified before the Invenia ABUS Scan Station and Workstation are set up.

EMI limitations (continued)

Electrical and electronic equipment may produce EMI unintentionally as the result of a defect. Some of these sources include:

- medical lasers
- scanners
- cauterizing guns
- computers
- monitors
- fans
- gel warmers
- microwave ovens
- light dimmers
- mobile phones
- in-house wireless phones (DECT phones)
- wireless computer keyboard and mouse
- air conditioning system
- High Frequency (HF) surgery equipment
- general AC/DC adapters

The presence of a broadcast station or broadcast van may also cause interference.

See: ‘EMI prevention/abatement’ on *page 2-7* for EMI prevention tips.

EMI prevention/abatement

Table 2-3: EMI prevention/abatement

EMI RULE	DETAILS
Be aware of Radio Frequency sources	• Keep the Invenia ABUS Scan Station at least 5 meters (15 feet) away from other EMI sources. • Special shielding may be required to eliminate interference problems caused by high frequency, high powered radio or video broadcast signals.
Ground the Ultrasound system	Poor grounding is the most likely reason an Ultrasound system will have noisy images. Check grounding of the power cord and power outlet.
Replace all screws, Radio Frequency gaskets, covers, cores	• After you finish repairing or updating the Ultrasound system, replace all covers and tighten all screws. • Any cable with an external connection requires a magnet wrap at each end. • Install all covers. Loose or missing covers or Radio Frequency gaskets allow radio frequencies to interfere with the ultrasound signals.
Replace broken Radio Frequency gaskets	If more than 20% or a pair of the fingers on an Radio Frequency gasket are broken, replace the gasket. Do not turn on the Ultrasound system until any loose metallic part is removed.
Do not place labels where Radio Frequency gaskets touch metal	Where applicable, never place a label where Radio Frequency gaskets meet the Ultrasound system. Otherwise, the gap created will permit Radio Frequency leakage. Or, if a label has been found in such a position, move the label.
Take care with cellular phones	Cellular phones may transmit a 5 V/m signal; that could cause image artifacts.

Facility needs

Purchaser responsibilities

The work and materials needed to prepare the site is the responsibility of the purchaser. Delay, confusion, and waste of manpower can be avoided by completing pre-installation work before delivery. Purchaser responsibility includes:

- Procuring the materials required
- Completing the preparations before delivery of the Ultrasound system (See Site Survey Planner below).
- Paying the costs for any alterations and modifications not specifically provided in the sales contract

NOTE: All electrical installations that are preliminary to the positioning of the equipment at the site prepared for the equipment must be performed by licensed electrical contractors. Other connections between pieces of electrical equipment, calibrations, and testing must also be performed by qualified personnel. The products involved (and the accompanying electrical installations) are highly sophisticated and special engineering competence is required. All electrical work on these products must comply with the requirements of applicable electrical codes. The purchaser of GE equipment must only utilize qualified personnel to perform electrical servicing on the equipment.

The desire to use a non–listed or customer provided product or to place an approved product further from the Ultrasound system than the interface kit allows, presents challenges to the installation team. To avoid delays during installation, such variances should be made known to the individuals or group performing the installation at the earliest possible date (preferably prior to the purchase).

The ultrasound suite must be clean prior to delivery of the Ultrasound system. Carpet is not recommended because it collects dust and creates static. Potential sources of EMI (electromagnetic interference) should also be investigated before delivery. Dirt, static, and EMI can negatively impact Ultrasound system reliability.

Site Survey Planner

Use the Site Survey Planner on the next two pages to help with your planning activities.

You can also download this form (part number 9000-0014-01) from the Common Documentation Library (http://www3.gehealthcare.com/en/Support/Support_Documentation_Library).

U SYSTEMS
A GE Healthcare Company

Pre-Installation Site Survey Worksheet

SITE INFORMATION & CONTACT PERSONNEL

Facility Name: _____ Clinic Hours: _____ AM until _____ PM ☐ M-F ☐ Other_____

Physical Address: _____

Primary ABUS Contact:	_____	Phone:	_____	E-Mail:	_____
Delivery/Install Contact:	_____	Phone:	_____	E-Mail:	_____
IT/Network Admin Contact:	_____	Phone:	_____	E-Mail:	_____
PACS or ABUS Image Data Storage Contact:	_____	Phone:	_____	E-Mail:	_____
Secondary IT, Network Admin or PACS Contact:	_____	Phone:	_____	E-Mail:	_____

☐ To optimize the efficient implementation of your ABUS scanning prog ram, please consider purchase of a service contract.

INSTALLATION SCHEDULING INFORMATION

Scheduled Installation Date: _____-_____-_____ PO Number: _____ SO Number: _____

ABUS Delivery Date: _____-_____-_____ Applications Date: _____-_____-_____ ABUS "Go-Live" Date: _____-_____-_____

Comments: _____

SITE LAYOUT & MINIMUM REQUIREMENTS

Does the ABUS scan room meet the minimum size requirements of 96 Inches X 120 Inches? ☐ Yes ☐ No, size: _____ X _____ Ft

ABUS Scan Station Cat 5 LAN Connection: ☐ Direct (wall plate) ☐ Switch or Hub

ABUS Workstation Cat 5 LAN Connection: ☐ Direct (wall plate) ☐ Switch or Hub

ABUS Workstation Table Size: (30"W X 24"D Recommended) _____ X _____ In

Placement of CPU: ☐ On Table with Monitor ☐ Under Table ☐ N/A (iMac) ☐ Other

Comments regarding the size and layout of the ABUS exam room, ABUS reading room and/or ABUS Workstation Setup:

_____

NETWORKING INFORMATION

The ABUS System (Scan Station + Workstation) must be networked to operate outside of any domain: ☐ OK

Network Speed: ☐ 1G ☐ 100BaseT

Duplex Settings: ☐ Half ☐ Full ☐ Auto

If multiple Scan Stations and/or Workst ations will be networked, please supply additional information on the next page.

SCAN STATION 1		WORKSTATION 1			
AE Title:	_____	_____		Workstation Port:	_____
IP Address:	_____._____._____._____	_____._____._____._____		Workstation DNS:	_____._____._____._____
Subnet Mask:	_____._____._____._____	_____._____._____._____		Workstation Alt DNS:	_____._____._____._____
Gateway:	_____._____._____._____	_____._____._____._____		Workstation Internet Access:	☐ Yes ☐ No

Will the facility's mail server be accessible to the Scan Station for sending system lo gs for remote diagnostics? ☐ Yes ☐ No

If Yes, Host Name: _____ Port: _____ Auth Type: ☐ None ☐ SMTP ☐ POP3 DNS: _____._____._____._____

P/N: 9000-0014-01 Rev03 Date: 05/03/2013 Confidential Page 2 of 3

Figure 2-1. Site Survey

U SYSTEMS

Pre-Installation Site Survey Worksheet

DICOM MODALITY WORKLIST

Does your facility intend to utilize a DICOM modality worklist to su pply patient a ppointment data to ABUS? ☐ Yes ☐ No If Yes, where does your DICOM worklist reside? ☐ HIS/RIS ☐ PACS ☐ Other

If yes, please provide the DICOM modality worklist information: AE Title: _____ Port: _____ IP Address: ____.____.____.____

Comments: _____

STORAGE of PATIENT IMAGE DATA

The 3D image data for a typical bilateral ABUS exam (6 views) is approximately 600MB. How will patient image data be managed long-term?

☐ 3D ABUS exams will be stored (600MB) ☐ Only select 2D images will be stored
☐ Storage on PACS ☐ Storage on facility's network attached storage (NAS)
☐ No image data will be stored ☐ Other _____

PACS STORAGE MODEL: _____

AE Title: _____ Port: _____

IP Address: ____.____.____.____ Gateway: ____.____.____.____

☐ Store ☐ Print ☐ Query/Retrieve

OTHER STORAGE MODEL: _____

AE Title: _____ Port: _____

IP Address: ____.____.____.____ Gateway: ____.____.____.____

☐ Store ☐ Print ☐ Query/Retrieve

☐ Please Note: The ABUS workstation does not accept compressed image data files. So, while compressed when it is pushed to PACS or an alternative NAS, it must be uncompressed before it is ABUS 3D image data may be pulled back to the workstation .

How many complete 3D ABUS exams do you plan to push to storage during a typical week? _____

Do you plan to utilize a secondary PACS or other long-term archival system for 3D ABUS exams? ☐ Yes ☐ No

If Yes, please describe: _____

ABUS DELIVERY INSTRUCTIONS

Is a loading dock available at the facility? ☐ Yes ☐ No If Yes, what are the hours? _____ AM to _____ PM ☐ M-F ☐ Other_____

Will a delivery truck with a lift gate be required? ☐ Yes ☐ No How many drivers will be needed for unloading? ☐ One ☐ Two

What will happen to the ABUS crate after delivery? ☐ Return to U-Systems ☐ Disposal by Customer ☐ Storage by Customer

Site specified delivery time: _____ ☐ AM ☐ PM Special notes: _____

ADDITIONAL SCAN STATIONS and/or WORKSTATIONS

Will multiple scan stations an d/or workstations be installed? ☐ No or ☐ Yes and ☐ Now / ☐ Later If Yes & Now, please supply the information below for each item

Scan Station 2 Room Number: _____ Room Size: _____ X _____ Ft Room Usage: ☐ ABUS Only ☐ Other Procedures

Scan Station 2 Location Relative to Scan Station 1: ☐ Same Building ☐ Same Department ☐ Same Floor ☐ Same Room ☐ Off Site

Workstation 2 Room Number: _____ Table Size: _____ X _____ In Room Usage: ☐ Multiple Readers ☐ Single Reader

Workstation 2 Location Relative to Workstation 1: ☐ Same Building ☐ Same Department ☐ Same Floor ☐ Same Room ☐ Off Site

SCAN STATION 2		WORKSTATION 2	
AE Title:	_____	_____	Workstation Port: _____
IP Address:	____.____.____.____	____.____.____.____	Workstation DNS: ____.____.____.____
Subnet Mask:	____.____.____.____	____.____.____.____	Workstation Alt DNS: ____.____.____.____
Gateway:	____.____.____.____	____.____.____.____	Workstation Internet Access: ☐ Yes ☐ No

SIGN OFF: Facility Representative Name: _____ Date: _____ Signature: _____

P/N: 9000-0014-01 Rev03 Date: 05/03/2013 Confidential Page 3 of 3

Figure 2-2. Site Survey

Time and manpower requirements

Site preparation takes time. Begin site preparation checks as soon as possible, if possible, six weeks before delivery, to allow enough time to make any changes.

Facility needs

The following are required:

- Dedicated single branch power outlet of adequate amperage, meeting all local and national codes, which is located less than 2.5 m (8 ft.) from the Ultrasound system's proposed location
- Door opening is at least 76 cm (30 in) wide
- Proposed location for Ultrasound system is at least 0.5 m (1.5 ft.) from the wall for cooling
- Power outlet and place for any external peripheral are within 2 m (6.5 ft.) of each other with peripheral within 1 m of the Ultrasound system to connect cables.
- Power outlets for other medical equipment
- Power outlets for test equipment within 1 m (3.2 ft.) of Ultrasound system
- Material to safely clean probes (done with a plastic container, never metal)

The following are desired:

- Door is at least 92 cm (3 ft.) wide
- Circuit breaker for dedicated power outlet is easily accessible
- Sink with hot and cold water
- Receptacle for bio–hazardous waste, for Single Use Stabilization Membrane
- Storage for linens and equipment
- Nearby waiting room, lavatory, and dressing room
- Dual level lighting (bright and dim)
- Storage area for Single Use Stabilization Membranes and Ultrasound Coupling Lotion

Important Notices

General Electric, Affiliate, or Distributor Field Engineers and Application Specialists will setup the system.

NOTICE

This medical equipment is approved, in terms of the prevention of radio wave interference, to be used in hospitals, clinics and other institutions which are environmentally qualified. The use of this equipment in an inappropriate environment may cause some electronic interference to radios and televisions around the equipment.

Ensure that the following is provided for the new system:

- A separate power outlet with a minimum of a minimum 10 amp circuit breaker for 100-240 VAC.
- Take precautions to ensure that the console is protected from electromagnetic interference.

  Precautions include:

  - Operate the console at least 5 meters (15 feet) away from motors, typewriters, elevators, and other sources of strong electromagnetic radiation (non-medical grade UPS must be at least 2 meters (6 feet) away from console).
  - Operation in an enclosed area (wood, plaster or concrete walls, floors and ceilings) helps prevent electromagnetic interference.
  - Special shielding may be required if the console is to be operated in the vicinity of radio broadcast equipment.

Important Notices (continued)

WARNING

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

To avoid risk of fire, the system power must be supplied from a separate, properly rated outlet.

Under no circumstances should the AC power plug be altered, changed, or adapted to a configuration rated less than specified. Never use an extension cord or adapter plug.

To help assure grounding reliability, connect to a “hospital grade” or “hospital only” grounded power outlet.

CAUTION

Use caution to ensure that the power cable does not disconnect during system use.

If the system is accidentally unplugged, data may be lost.

CAUTION

To avoid leakage current above safety limits as prescribed by IEC 60601-1 and to ensure continuity of protective earth. DO NOT connect Invenia ABUS Scan Station or Workstation and mains-operated accessories to a single or multiple socket extension cord or power strip.

The Invenia ABUS requires a dedicated power and ground for the proper operation of its Ultrasound equipment. A separate power outlet with a minimum 10 amp circuit breaker for 100-240 VAC.

Invenia ABUS Scan Station

Figure 2-3. Typical Room Layout for the Invenia ABUS Scan Station

Invenia ABUS Scan Station (continued)

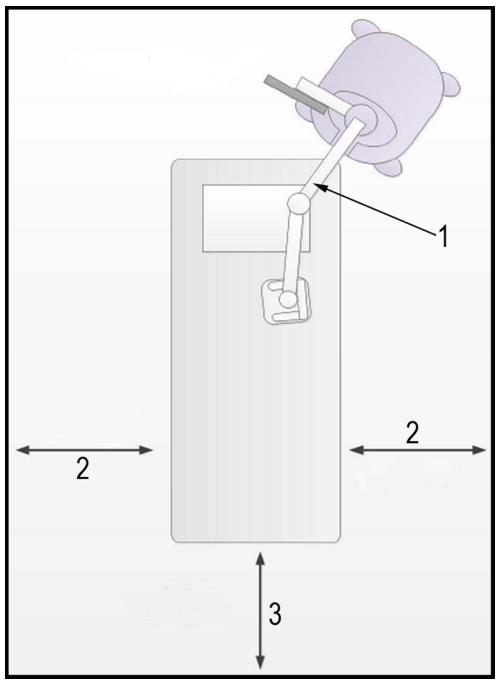


Figure 2-4. Desired Footprint

1. Maximum arm reach is ~1 m, or 39”
2. ~0.76 m, or 30” clear space recommended
3. ~0.61 m, or 24” clear space recommended

Invenia ABUS Scan Station (continued)

Figure 2-5. Invenia ABUS Scan Station

Invenia ABUS Scan Station System Specifications

System Features

- Multi-slice B-Mode image acquisition with frame-by-frame 3D position registration
- User-customizable workflow protocols
- Image Processing Algorithms
  - Tissue Equalization Algorithm (TEA)
  - Speckle Reduction
  - Nipple Shadow Compensation (NSC)
  - Breast Border Detection
  - Chest Wall Detection
- Acquisition Scout Images
  - Transverse Plane (Real-time)
  - Coronal Plane (Static, for Nipple Placement)
- DICOM 3.0 Compliant
  - Worklist (DMWL)
  - Modality Performed Procedure Step (MPPS)
  - Store (SCU)
- 10/100/1000 Base-T Ethernet
- User-Replaceable Fan Filter
- Remote Service Diagnostics
- Embedded User Manual

Invenia ABUS Scan Station System Specifications (continued)

Scanner Assembly Features

- Compression Assist
  - Increase/Decrease Compression
  - Start Scan (one-touch volume acquisition)
  - Abort Scan
- Ergonomic Arm with 3 Operator-selectable Levels of Compression between 5-20 lbs (2.25-9.7 kg)
- Integrated, extra-wide transducer:
  - C15-6XW Reverse Curve™
  - Frequency Range: 6-15 MHz
  - Aperture Length: 15.3 cm
  - Transducer Travel Distance: 16.9 cm
  - Number of Elements: 768
  - Element Pitch: 0.20 mm
  - Out-of-plane Aperture: 3.5 mm
  - Transducer Bandwidth: 85%
  - Imaging Depth: Up to 5.0 cm
- Single-Use Stabilization Membrane
- Single Volume Acquisition in less than 60 Seconds
- Multi-Row LED Task Lighting
- Removeable Scanner View Window, for easier clean-up

Invenia ABUS Scan Station System Specifications (continued)

Specifications

- Width: 23 inches (59 cm)
- Length: 26 inches (66 cm)
- Height (Arm):
  Lowest Position 65 inches (165 cm)
  Highest Position 85 inches (216 cm)
- Footprint: 4.2 sq. ft. (0.39 sq. m)
- Weight: 271 lbs (123 kg)
- Articulating Arm Reach (max): 39 inches (100 cm)
- Main Voltage: 100-240 VAC
- Maximum Current: 10 amps
- Mains Frequency: 50/60 Hz
- HDD Data Capacity: 200 GB (approximately 200 Studies), with Storage Status Indicator
- Study Transfer: Auto and Manual
- Display: 17” High Resolution LCD Touch Screen
- Cart: Mobile platform with 4-wheel steering and braking
- Operating System: MS Windows 7 Professional, 64 bit

Invenia ABUS Review Software

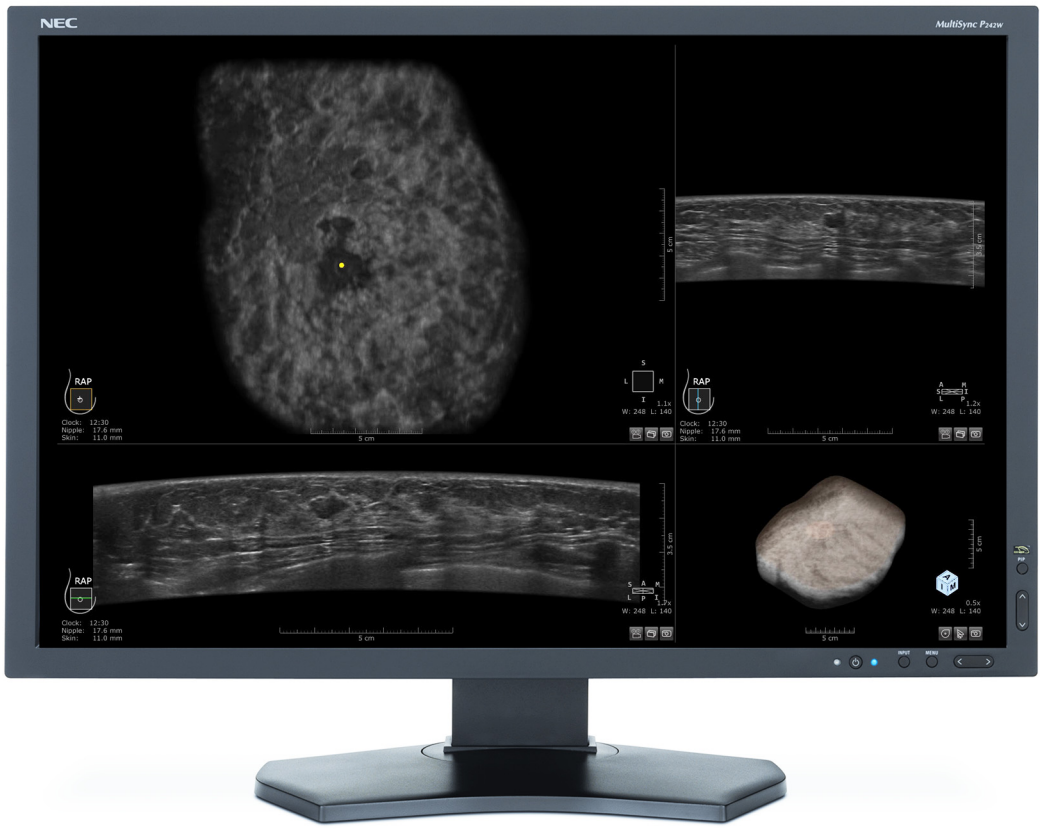


Figure 2-6. Invenia ABUS Review Software

Invenia ABUS Workstation System Specifications

NOTE: Workstation Specifications are only applicable for the Invenia ABUS Workstation Option.

Image Display and Navigation

- Individual user-defined Hanging and Viewing Protocols
- Multi-Slice Viewing: 4-12 Images
- Streamlined Review Protocols
- Standardized View Orientations: Thick-slice Coronal, Transverse, Sagittal, Radial, Anti-radial, and ROI Views
- Variable Slice Thickness: 0.5 to 10.00 mm (increments of 0.5 mm)
- Grayscale Windowing and Leveling
- Pan and Zoom Feature
- 4X Magnifying Tool
- CINE Review with Adjustable Playback Speed
- 360 Degree Any Point of Compass Display
- Side-by-Side Display for Coronal View Comparison
- Right-Click Graphical Navigational Tools

Networking/Storage/Archiving

- User Login Authentication
- DICOM 3.0 Compliant:
  - Query/Retrieval SCU
  - Store SCP/SCU
  - Print SCU
- 10/100/1000 Base-T Ethernet
- Compatible Media Storage
  - USB Media Stick
  - DVD +/- RW

Invenia ABUS Workstation System Specifications (continued)

Annotation and Reporting

- 3-Dimensional Position Referencing By:
  - Clock Position
  - Distance from Nipploe
  - Depth from Skin Surface
- Measurement Toolbox
- Standardized Labeling for Scan Positions
- Graphic Labels for Scan Position and Clock Position
- Customizable auto Report Function with User-Selectable Images
- Patient Study Browser
- Patient List Filtering Based on User's Setting

Hardware Specifications

- Tower: Workstation Class Hardware
- Operating System: Windows 7 Professional, 64 bit
- Display: 24-inch (diagonal) Display

Workstation Hardware Specifications for ABUS Review Software

Operating System (O.S.)

- Windows 7 Professional 64 Bit

Monitor

Minimum Requirements:

- Dedicated 24" Color Monitor
- Minimum resolution 1920x1200

Recommended Monitor Specs:

- 24” or greater diagonal size
- 1920 x 1200 resolution or higher
- LED backlit, Color Panel
- Brightness 250 cd/m or greater
- Contrast Ratio 1000:1 or higher

Input Devices

- Standard Keyboard
- Mouse with 3 Buttons and Scroll Wheel with individually distinct detents

Available Disk Space

Hard Drive with 400MB reserved for application and separate Hard Drive/disk space for Exams (1GB per exam, recommend 300 exams cache)

Minimum requirements at installation:

- 300 GB of available space

Video Card

- Support for OpenGL 3.3 or Higher
- 2 GB GDDR5 Dedicated Video Memory or more
- Memory Bandwidth 100GB/s or higher
- Support Resolution of at least 1920 x 1200 at 60Hz

NOTE: On-board GPU (e.g Intel HD graphics) is not supported.

Workstation Hardware Specifications for ABUS Review Software (continued)

Processor, Memory

- Xeon E5-1620 3.6GHz or better
- 8.0GB RAM or better

Minimum requirements at installation:

- 8.0 GB of RAM

Database

The Invenia ABUS software uses MySQL database. The database is installed and configure automatically during the installation process.

No other instances of MySQL database are supported on the same computer.

Networking/Storage/Archiving

- 10/100/1000 Base-T Ethernet
- Compatible Media Storage
  - USB Media Stick
  - DVD +/- RW

I/O ports

- One or more USB 2.0 port

Environmental Requirements

The system should be operated, stored, or transported within the parameters outlined below. Either its operational environment must be constantly maintained or the unit must be turned off.

NOTE: You may get an overheating message with regard to fan speed. Ensure adequate system/room ventilation.

Table 2-4: System Environmental Requirements

	Operational	Storage	Transport (<16hrs.)
Temperature	5° - 35°C 41° - 95°F	-10° - 60°C 14° - 140°F	-10° - 60°C 14° - 140°F
Humidity	30% to 75% non-condensing	10% to 85% non-condensing	10% to 85% non-condensing
Altitude	0-3,000 m (9,800 feet)	0-5,000 m (16,400 feet)	0-5,000 m (16,400 feet)

Packaging Information

The shipping crate size is 55”L x 34”W x 73”H (1.4m L x 0.86m W x 1.85m H).

Networking setup requirements

Scanner connected to hospital's network

Supported networks:

10/100/1000 Base-T Ethernet

InSite Requirements

InSite ExC allows GE to remotely assist users, Biomedical Technicians, and Field Service personnel by using a secure remote connection across the network.

Internet access is needed to be able to connect to InSite ExC.

The following is needed to configure InSite:

- System IP Address
- Default Gateway
    - Proxy Server, if necessary, and Port
- Proxy Authentication, if necessary
    - User Name and Password
- System ID (SID) Number

Purpose of the DICOM network function

DICOM services provide the operator with clinically useful features for moving images and patient information over a hospital network.

Examples of DICOM services include the transfer of images to workstations for viewing or transferring images to remote printers.

As an added benefit, transferring images in this manner frees up the on-board monitor and peripherals, enabling viewing to be done while scanning continues.

With DICOM, images can be archived, stored, and retrieved faster, easier, and at a lower cost.

DICOM setup requirements

To configure the Ultrasound system to work with other network connections, the site's network administrator must provide information to complete the form "Worksheet for DICOM Network Information". Ensure that there are no spaces in any field of the form.

Entries must include:

- A host name, local port number, AE Title, IP address and Net Mask for the Ultrasound system.
- The IP addresses for the default gateway and other routers at the site for ROUTING INFORMATION.
- The host name, IP address, port and AE Title for each device the site wants connected to the Ultrasound system for DICOM APPLICATION INFORMATION. A field for the make (manufacturer) and the revision of the device, is also included. This information may be useful for error solving.

Refer to the Site Planning worksheet on the Figure 2-1 *on page 2-10*.

Environmental Dangers

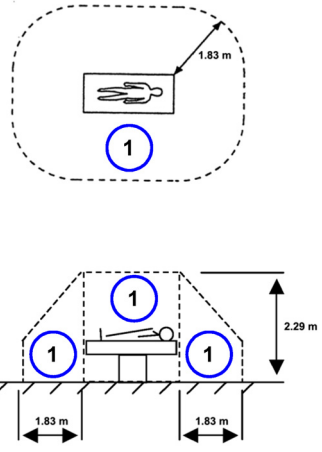
Commercial devices such as laser cameras, printers, VCRs and external monitors, usually exceed allowable leakage current limits and, when plugged into separate AC outlets, are in violation of patient safety standards. Suitable electrical isolation of such external AC outlets, or providing the device with extra protective earth, will be required in order to meet UL60601-1 and IEC60601-1 / IEC60601-1-1 standards for electrical leakage.

Patient Vicinity UL60601-1 (USA)

NOTE: This section is only applicable if the Workstation is provided by GE (Invenia ABUS Option).

2.12.20DV (UL60601-1:2003)

In area in which patients are normally cared for, the patient vicinity is the space with surfaces likely to be contacted by the patient or attendant who can touch the patient. This encloses a space within the room 1.83 m (6 ft.) beyond the perimeter of the bed (examination table, dental chair, treatment booth, and the like) in its intended location, and extending vertically 2.29 m (7.5 ft.) above the floor.



1. Patient environment

Chapter 3

System Setup

This chapter contains information needed to install Invenia ABUS.

Included is a procedure that describes how to receive and unpack the equipment and how to file a damage or loss claim.

How to set up the system and how to check and test the unit, probes, and external peripherals for electrical safety are also included in this procedure.

Setup reminders

Average setup time

- Unpacking the Invenia ABUS: 0.5 hour
- Set up Scan Station and Workstation: 3 hours or more, depending on the configuration
- DICOM Network Configuration: 3 hours or more, depending on the configuration
- Install InSite: 0.5 hour

Setup warnings

WHEN USING ANY TEST INSTRUMENT THAT IS CAPABLE OF OPENING THE AC GROUND LINE (I.E., METER'S GROUND SWITCH IS OPEN), DON'T TOUCH THE ULTRASOUND SYSTEM!

To prevent electrical shock, connect the unit to a properly grounded power outlet. Do not use a three to two prong adapter. This defeats safety grounding.

Do not wear the ESD wrist strap when you work on live circuits and more than 30 V peak is present.

Do not operate this unit unless all board covers and frame panels are securely in place. System performance and cooling require this.

The system must be supplied by an adequately rated electrical circuit. The capacity of the supply circuit must be as specified.

Setup warnings (continued)

CAUTION

If the Ultrasound system is very cold or hot, do not turn on its power until it has had a chance to acclimate to its operating environment.

The following table describes guidelines for reaching operational temperatures from storage or transport temperatures.

°C	-40	-35	-30	-25	-20	-15	-10	-5	0	5	10	15	20	25	30	35	40	45	50	55	60	65	70
°F	-40	-31	-22	-13	-4	5	14	23	32	41	50	59	68	77	86	95	104	113	122	131	140	149	158
Hrs	20	18	16	14	12	10	8	6	4	2	0	0	0	0	0	0	0	2	4	6	8	10	12

CAUTION

Operator Manual(s)

The User Manual(s) should be fully read and understood before operating the Invenia ABUS and kept near the Ultrasound system for quick reference.

Receiving and unpacking the equipment

Warnings for receiving and unpacking

CAUTION

Attempts to move the Ultrasound system considerable distances or on an incline by one person could result in injury or damage or both.

Two people are required whenever a part weighing 16 KG (35 LBS) or more must be lifted.

CAUTION

Remember to use relevant personal protecting equipment (PPE) during packing and unpacking. Check with your local EHS representative.

The Tilt & Shock indicators

Overview

Improper handling during transportation may harm the equipment inside the package even if the package itself is undamaged.

To make it easier to detect if the handling during transportation has been improper, a set of Tilt & Shock indicators have been attached to the transportation box.

Table 3-1: Shock and Tilt Watch

Description	Illustration
ShockWatch	
Tilt Watch	

Receiving the Invenia ABUS

Overview

Improper handling during transportation may harm the equipment inside the package even if the package itself is undamaged.

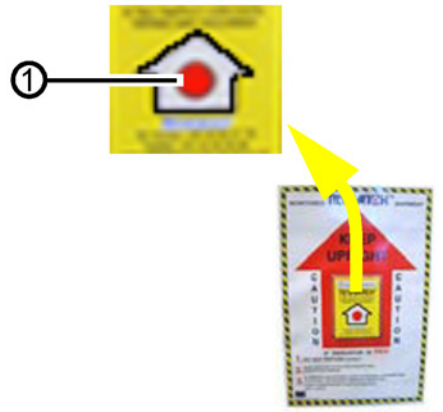
Examine all packages

Examine package closely at time of delivery, as described in the procedure below.

Table 3-2: Examine all packages

Step	Task	Illustrations
1.	Is damage apparent? • If **YES**; continue with the instructions in 'Damage in transportation' on *page 3-10*. • If **NO**; continue with the next step.	
2.	Is the Shock Indicator red colored inside the middle of the indicator? • If **YES**: The Shock Indicator has been activated. Continue with the instructions in 'Damage in transportation' on *page 3-10*, then continue with the next step. • If **NO**: continue with the next step.	 1 - Red Color

Table 3-2: Examine all packages (Continued)

Step	Task	Illustrations
3.	Is the Tilt Indicator red colored inside the middle of the indicator? • If **YES**: The Tilt Indicator has been activated. Continue with the instructions in 'Damage in transportation' on *page 3-10* before you continue with the next step. • If **NO**: continue with the next step.	 1 - Red Color
4.	Continue with the instructions in 'Unpacking the Invenia ABUS' on *page 3-11*.	

Position of the Tilt & Shock indicators

The Tilt & Shock indicators have been attached to the transportation crate.

NOTE: Before cutting the straps, check Shock and Tilt Tags to make sure they have not been triggered. If damaged, report it to the carrier. If not, then cut the straps around the crate.

If Shock Indicator has triggered or is missing

The purpose of a shock indicator label is NOT to tell if a product has been damaged during shipment. The purpose of these labels are to alert people handling a package that the product contained is very sensitive to shock damage and that it should be handled carefully. It is basically an active "Fragile" label that turns red if a predetermined shock does occur. Because the labels can receive false activation due to an impact shock directly on the label, an activated label must not be interpreted to mean product damage. It simply means that the receiver should note on the shipping papers at the time of receipt that the label was activated and the product should be inspected for possible concealed damage. Conversely, a high level, product-damaging shock could occur to the package in a way that does not activate the label, so a non activated label does not insure that the product is not damaged. Some degree of inspection is still required.

Table 3-3: Shock Indicator has triggered or is missing

Step	Task
1.	**If the Shock Indicator is missing:** Note on the shipping papers at the time of receipt that the Shock Indicator label is missing. **If the Shock Indicator has triggered:** Note on the shipping papers at the time of receipt that the Shock Indicator label was activated.
2.	Inspect the product for possible concealed damage.

If Tilt Indicator has triggered or is missing

The purpose of the tilt indicator label is to alert people handling a product that it is sensitive to tipping and it must remain upright at all times. It is basically an active "Up Arrow" that changes color if the package is tipped 89 degrees or more from horizontal. These labels can be false activated if tipped less than 89 degrees, and shocked or vibrated at the same time. This event does occur, but is considered uncommon. If a package is received with an activated tilt indicator label, there is high degree of certainty it tipped 89 degrees or more from horizontal during shipment.

An activated tilt indicator label does not indicate if the package was simply “Tipped” (laid down with no impact shock) or “Tipped Over” (free fall, with an impact shock). Using both shock indicator labels and tilt indicator labels will help identify if a Tip Over impact shock occurred.

Table 3-4: Tilt Indicator has triggered or is missing

Step	Task
1.	**If the Tilt Indicator is missing:** Note on the shipping papers at the time of receipt that the Tilt Indicator label is missing. **If the Tilt Indicator has triggered:** Note on the shipping papers at the time of receipt that the Tilt Indicator label was activated.
2.	Inspect the product for possible concealed damage.

Damage in transportation

Follow this procedure if damage is apparent:

1. Write “Damage In Shipment” on ALL copies of the freight or express bill **BEFORE** delivery is accepted or “signed for“ by a GE representative or hospital receiving agent.
2. Report the damage to the carrier.
   - Whether noted or concealed, damage **MUST** be reported to the carrier immediately upon discovery, or in any event, within 14 days after receipt, and the contents and containers held for inspection by the carrier.
   - A transportation company will not pay a claim for damage if an inspection is not requested within this 14 day period.

Invenia ABUS transportation box label

The Invenia ABUS transportation crate label is located at the front of the transportation crate.

Table 3-5: transportation box label

Symbols	Definition/Comments
	1. TOP,. UPRIGHT - Transportation and Storage 2. FRAGILE, Handle with Care 3. RECYCLING 4. KEEP DRY (protect from moisture)

Unpacking the Invenia ABUS

Instructions are provided in the materials attached to the Shipping Crate.

Table 3-6: Unpacking the Invenia ABUS Scan Station and Workstation

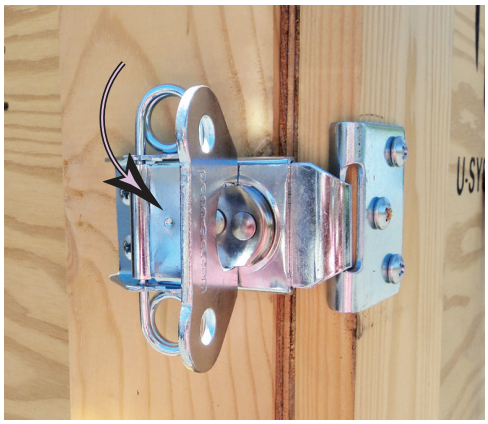
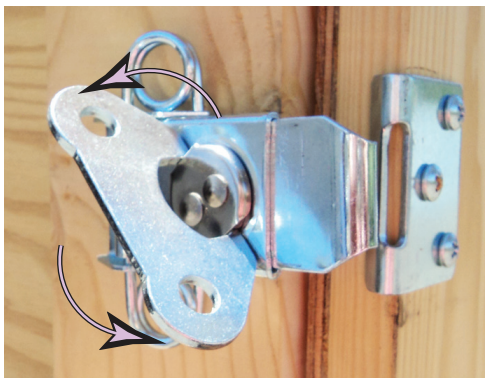
Steps	Illustration
1. Carefully remove any shipping straps that secure the front door/ramp and back door.	
2. Lift the hasp handles away from the crate. Repeat for the step for the other three hasps.	
3. Rotate the hasp handles counterclockwise to release.	

Table 3-6: Unpacking the Invenia ABUS Scan Station and Workstation

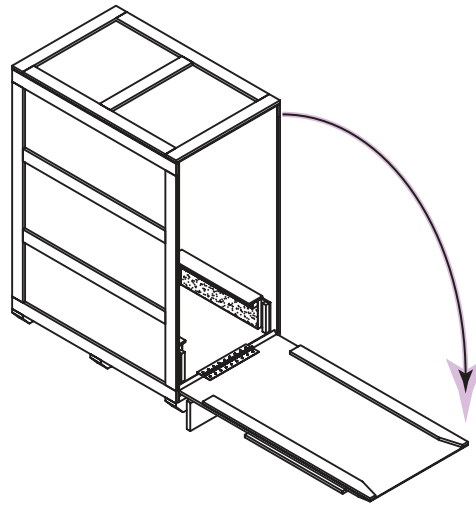
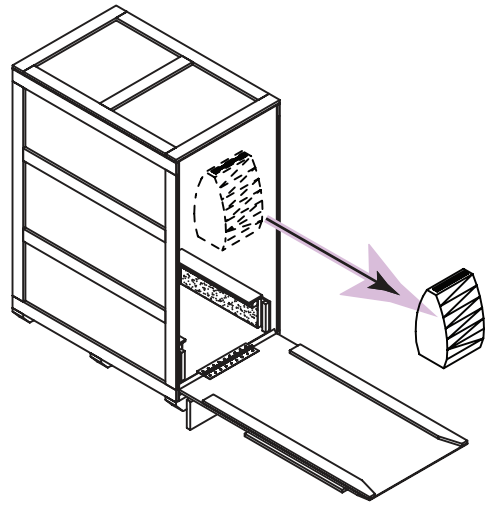
Steps	Illustration
4. Slowly lower the front door/ramp until it rests on the floor.	
5. Remove any loose packaging, if present.	

Table 3-6: Unpacking the Invenia ABUS Scan Station and Workstation

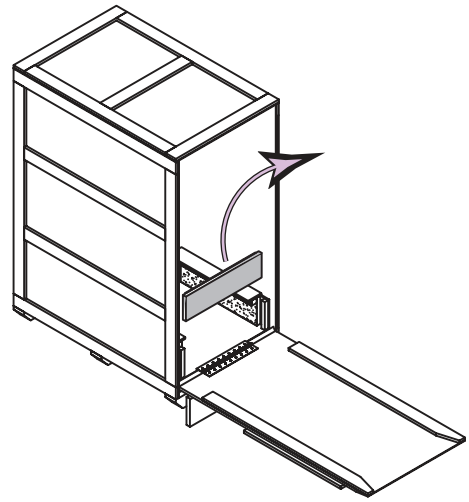
Steps	Illustration
6. Lift the front blocking plate up and out of the crate.	
7. If the wheel locks are locked, release the brakes. Slowly roll/remove the Invenia ABUS Scan Station straight out of the crate.	
8. Repeat the steps for opening the hasps, on the crate back door.	

Table 3-6: Unpacking the Invenia ABUS Scan Station and Workstation

Steps	Illustration
9. Slowly swing the door open and remove the Workstation (if ordered) and any other supplies.	
10. Remove all of the packaging and place the removed packaging back into the crate to store for possible future use.	

Packing materials - recycling information

Packing materials

The packing materials for Invenia ABUS are recyclable:

- The Transportation Box is made of spruce or similar material. (“PHYTOSANITARY CERTIFICATE” included in all shipments to The People's Republic of China.)
- Lever lockings (hinges) are made of zinc plated steel.
- The inner reinforcements are made of Ethafoam (Polyethylene foam).
- The plastic foil is made of LDPE (Low Density Polyethylene).

Preparing for setup

Verify customer order

Compare items received by the customer to that which is listed on the delivery order. Report any items that are missing, back ordered, or damaged.

Physical inspection

Verify that the system arrived intact (visual inspection).

If the system has been damaged, please refer to ‘Damage in transportation’ on *page i-11* in the beginning of this manual.

EMI protection

The Invenia ABUS has been designed to minimize the effects of Electro-Magnetic Interference (EMI). Many of the covers, shields, and screws are provided primarily to protect the system from image artifacts caused by this interference. For this reason, it is imperative that all covers and hardware are installed and secured before the unit is put into operation.

See ‘EMI limitations’ on *page 2-5* for more information about EMI protection.

The Invenia ABUS has been designed to minimize the effects of Electro-Magnetic Interference (EMI). Many of the covers, shields, and screws are provided primarily to protect the system from image artifacts caused by this interference. For this reason, it is imperative that all covers and hardware are installed and secured before the unit is put into operation.

Product Labels and Descriptions

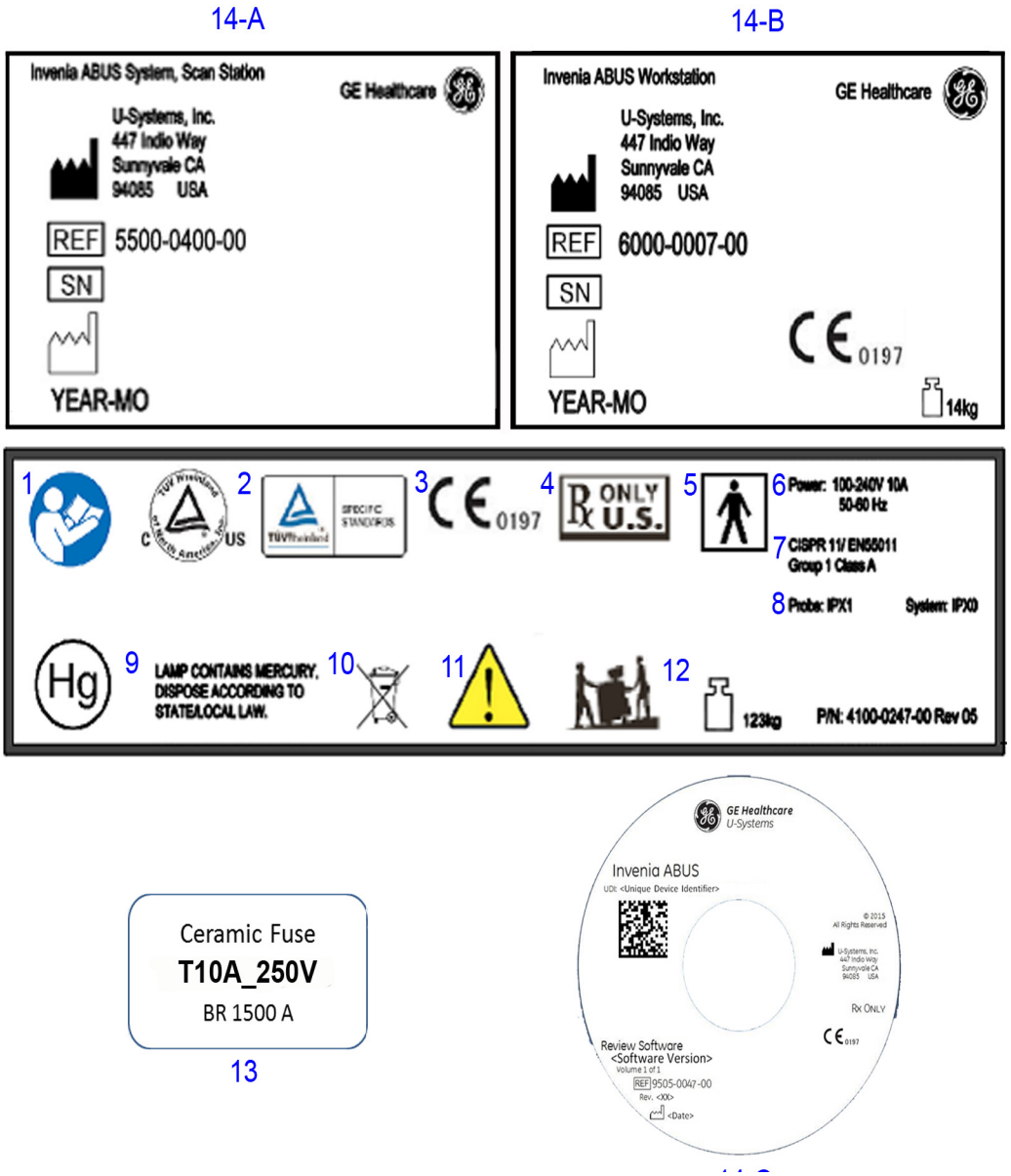


Figure 3-1. Product Labels

Product Labels and Descriptions (continued)

Table 3-7: Rear Panel Label Explanations

1. “ATTENTION” - Consult accompanying documents” is intended to alert the user to refer to the operator manual or other instructions when complete information cannot be provided on the label.
2. TUV Rhineland Label: NRTL Listing and Certification Mark is used to designate conformance to nationally recognized product safety standards. The Mark bears the name and/or logo of the testing laboratory, product category, safety standard to which conformity is assessed, and a control number.
3. The CE Mark of Conformity indicates this equipment conforms with the Council Directive 93/42/EEC.
4. Prescription Device (For U.S.A. Only)
5. BF Applied Part
6. Identification and Rating Plate–USA/Asia 120V console
7. CISPR Emissions Label
8. System and Probe IP Code
9. Mercury Warning Label
10. WEEE Symbol
11. Possible shock hazard. Do not remove covers or panels. No user serviceable parts are inside. Refer servicing to qualified service personnel.
12. The equipment weighs approximately 123 kg (271 lbs). To avoid possible injury and equipment damage when transporting from one area of use to another:
    - Be sure the pathway is clear.
    - Limit movement to a slow careful walk.
    - Use two or more persons to move the equipment on inclines or long distance.
13. Fuse Label
14. Invenia ABUS Scan Station (A), Workstation Rating Plate (B) and Invenia ABUS Review Software CD Label (C)
    - Manufacturer’s name and address
    - Part Number
    - Model/Serial Number/Date of Manufacturer

Unique Device Identification (UDI) Label and Location

Invenia ABUS Option

Figure 3-2. Invenia ABUS Scan Station

Figure 3-3. Invenia ABUS Workstation

Unique Device Identification (UDI) Label and Location (continued)

Invenia ABUS Review Software Option

You can view UDI Label information via the System Configuration page.

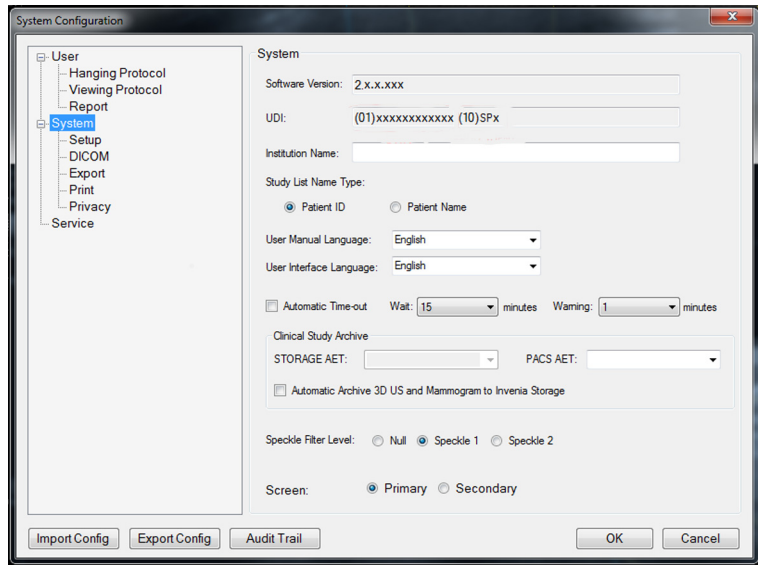


Figure 3-4. System Configuration

MHLW Label Location

Figure 3-5. MHLW Label Location

1. MHLW Scan Station Label Location
2. MHLW Monitor Label Location
3. MHLW Workstation Label Location

Note: Other country specific labels may be added in these areas of the Scan Station and Workstation.

Completing the setup

Electrical specifications

Connecting a Invenia ABUS to the wrong voltage level will most likely damage it.

Verification of the system's voltage setting

Verify that the mains voltage specified for the Invenia ABUS is available on-site.

The voltage setting for the unit is found on a label near the Mains Power Switrch on the rear of the system.

Refer to Figure 3-1 to locate the label.

Connections on the Rear Panel

NOTE: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC60950 for data processing equipment and IEC60601-1 for medical equipment). Furthermore, all complete configurations shall comply with the valid version of the system standard IEC60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part of Invenia ABUS, configures a medical system, and is therefore responsible that the Ultrasound system complies with the requirements of the valid version of IEC60601-1-1. If in doubt, consult the technical service department or your local representative for GE.

Connect Ethernet

Connect the network cable to the Ethernet connector on th Rear Panel.

The connector is located on the rear side of Invenia ABUS.

Setting up the Invenia ABUS Review Software

For Setup of the Invenia ABUS Review Software, refer to the documentation provided with the Workstation.

NOTE: Invenia ABUS Review Software should only be installed by a trained GE Service Representative.

Anti-Virus Software

All unused ports will be locked down; no anti-virus software is required. Anti-virus software is not recommended to be placed on the Invenia ABUS Scan Station, Invenia ABUS Review Software, or 3rd Party Workstation. .

This equipment contains dangerous voltages that are capable of serious injury or death.

If any defects are observed or malfunctions occur, stop operating the equipment and perform the proper action for the patient. Inform a qualified service person and contact a Service Representative for information.

There are no user serviceable components inside the console. Refer all servicing to qualified service personnel only.

Ensure that unauthorized personnel do not tamper with the unit.

Switch ON the AC Power to Invenia ABUS

The System Standby button is used to turn the system On and Off. The System Standby button is located on the upper, left-hand portion of the console, below the left-hand gel holder.

1. Switch ON the Power Mains Switch at the rear of the unit.
2. Press once on the **On/Off** button on the Invenia ABUS to boot the unit.

DO NOT unplug the power cord until after the complete shutdown procedure has been performed.

Power shut down

When you switch off the unit, the system performs an automatic shutdown sequence. Press the On/Off/Standby button to initiate the shutdown sequence.

Logging In

Touch the Touch Screen Monitor to open up the Login Screen. Select your User Name and type your Password. Or type your User Name and Password. Then touch the Login icon.

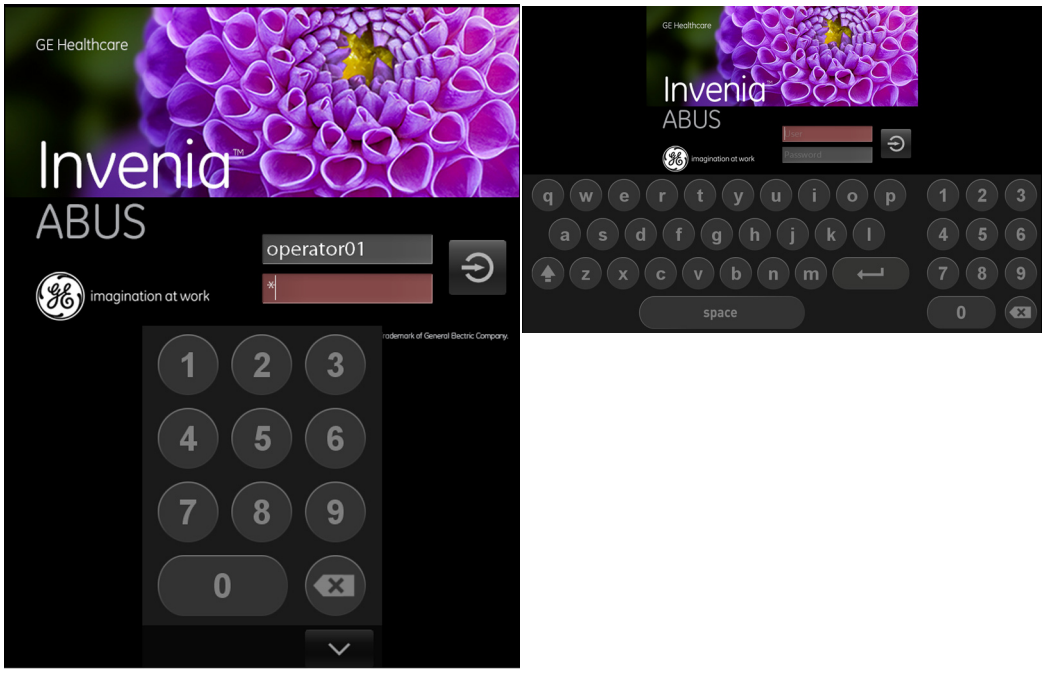


Figure 3-6. Login Screen

System Customization

To access system customization, tap the gear icon in the lower, right-hand corner of the screen. You then select the desired Configuration Menu by touching one of the following buttons on the left-side of the menu:

- General
- Scanning Protocols
- Worklist
- Storage
- System
- About

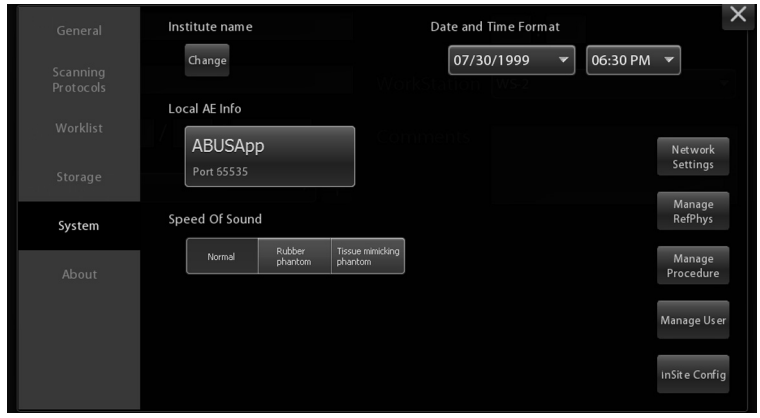


Figure 3-7. Configuration Menu

General Configuration

From the General Configuration menu, you can configure the following:

- DICOM Worklist server location
- MPPS Server location
- Workstation destination location
- User Interface operating language
- User Manual Language
- Acoustic Power (%)
- Manage System Storage. The Status gauge displays the Invenia ABUS hard disk capacity (200GB)
- Scan depth default (3.5cm, 4.0cm, or 5.0cm)

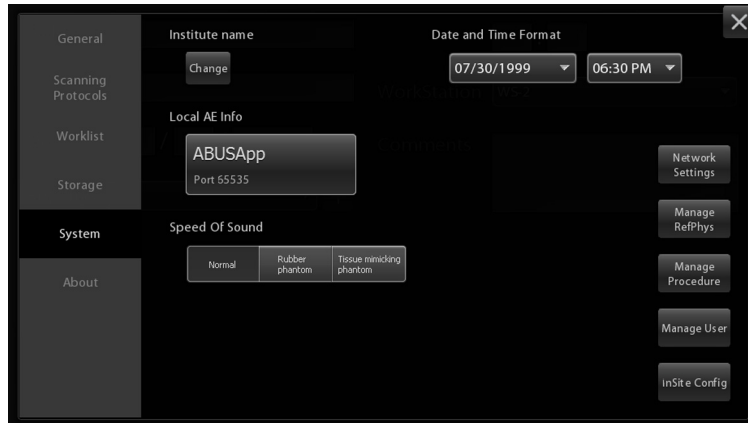


Figure 3-8. General Configuration Menu

Scanning Protocols

The Scanning Protocol menu allows you to select from one of the four (4) preset workflow protocols:

- Perform Exam Starting on the patient's right
- Perform Exam Starting on the patient's left
- Perform complete exam from only the patient's right side (right side of the bed only)
- Perform complete exam from only the patient's left side (left side of the bed only)
- Specify location of the transducer's start position.

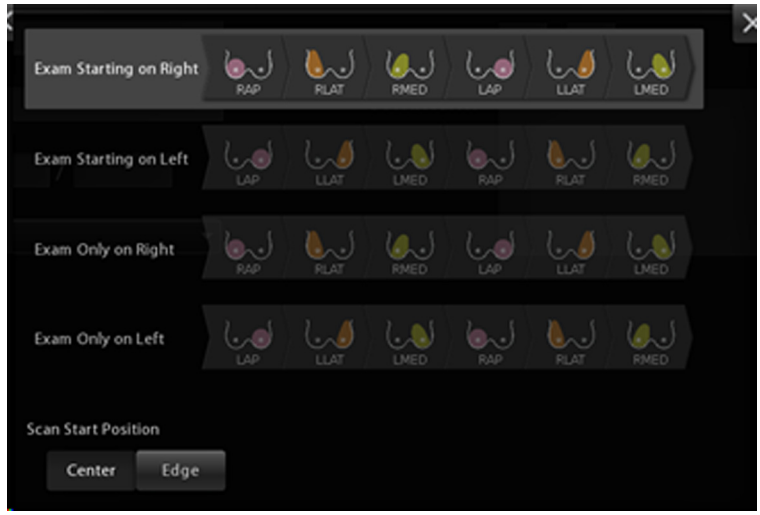


Figure 3-9. Scanning Protocol Configuration Menu

Worklist Configuration

The Worklist Configuration menu allows you to specify how the DICOM Worklist is displayed.

- Date Filter (Today, This Week, This Month)
- Modality Filter (Ultrasound, All)
- Optional Worklist Columns. Select two (2) from the following:
  - Procedure
  - Referring Physician
  - Accession Number
- Default Select Page (Worklist, Work Item Input)
- Procedure DICOM Tag (Administrator)

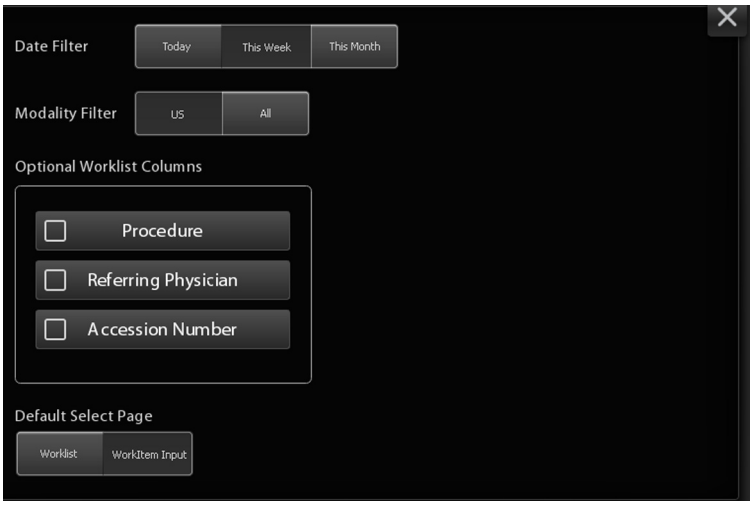


Figure 3-10. Worklist Configuration (User)

Worklist Configuration (continued)

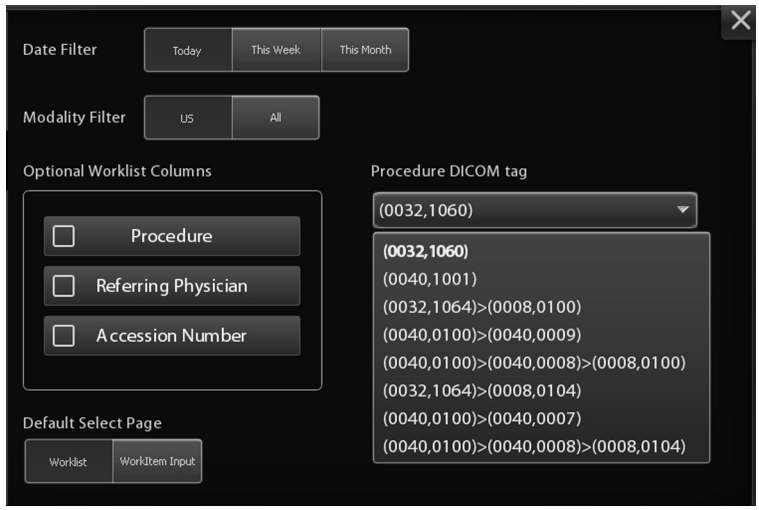


Figure 3-11. Worklist Configuration (Administrator)

The Procedure DICOM Tag (also known as the Modality Performed Procedure Step) is received from the Modality Worklist. A complementary service to Modality Worklist, Modality Performed Procedure Step (MPPS) enables a modality to send a report about a performed study, including data about the acquired images (begin/end time, duration, type of study, etc.). This facilitates better coordination of image storage servers by providing the server with a list of objects to send prior to or while actually sending such object.

Storage Configuration

The Storage Configuration menu allows you to configure how exam data is stored and deleted from the Invenia ABUS hard drive. The Storage Forced Manual Cleanup lets you specify when the Invenia ABUS will require exam data to be removed from the hard disk. The Auto Delete Shipped Data lets you specify the frequency to have exam data deleted from the Invenia ABUS hard disk after it has already been successfully transfer to the Workstation. The following information is displayed:

- Storage Status
- Storage Forced Manual Cleanup (80%, 85%, 90%)
- Auto Delete Shipped Data (Never, After 3 months (90 days), After 1 month (30 days), or After 1 Week (7 days)
- Storage Warning

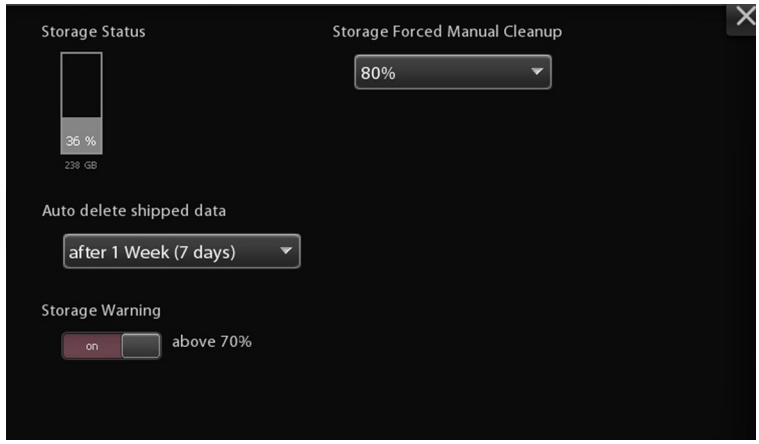


Figure 3-12. Storage Configuration Menu

System Configuration

From the System Configuration screen, the User can configure the following:

- Institute name. Press Change to type in the Institute's name.
- Network Settings

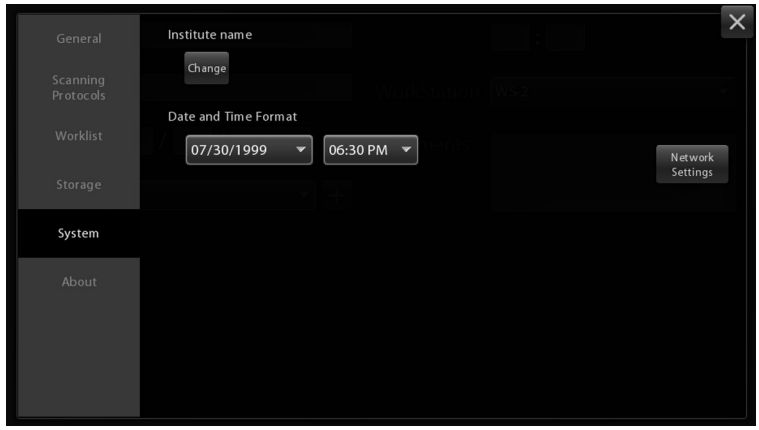


Figure 3-13. System Configuration (User)

Changing the IP Address on the Invenia ABUS

To change the IP Address,

1. From the System Configuration page, select the “Network Settings” button.

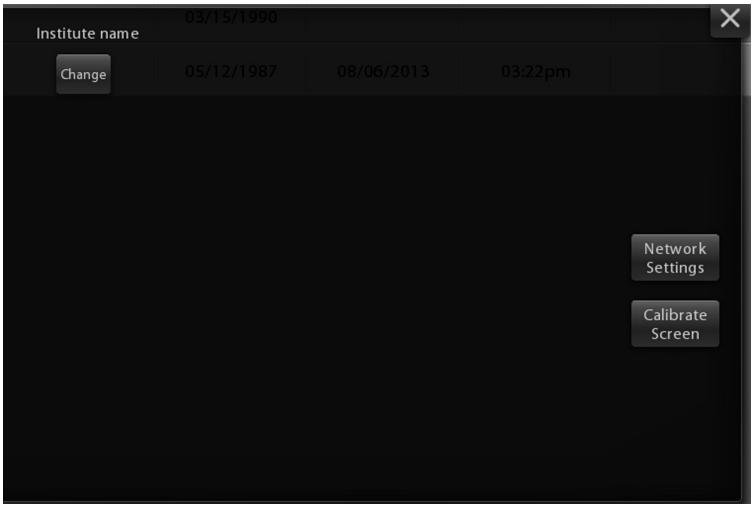


Figure 3-14. System Configuration (User)

The Windows Connectivity screen appears.

Changing the IP Address on the Invenia ABUS (continued)

2. From the Windows Connectivity screen, double click (press twice quickly with your finger) the “Local Area Connection” box.

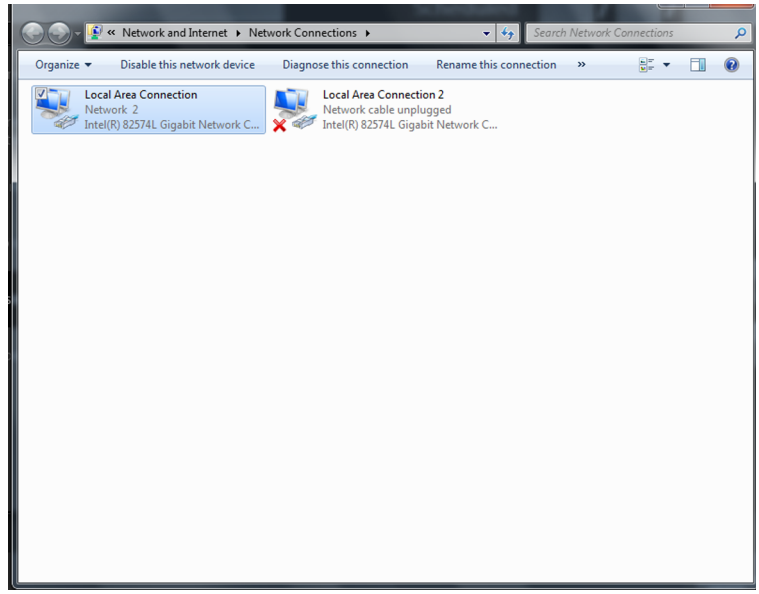


Figure 3-15. Windows Connectivity Screen

The Local Area Connection Status pop-up appears.

Changing the IP Address on the Invenia ABUS (continued)

3. On the Local Area Connection Status pop-up, select “Properties” from the lower, left-hand corner of the pop-up.

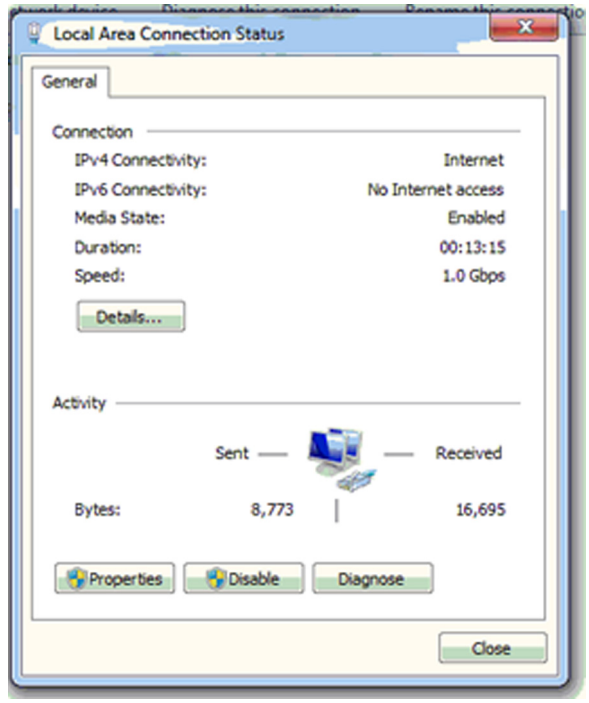


Figure 3-16. Local Area Connection Status Pop-Up

The Local Area Network Properties pop-up appears.

Changing the IP Address on the Invenia ABUS (continued)

4. From the Local Area Network Properties pop-up, select “Internet Protocol Version 4/6 (TCP/IPv4/6)”. The Internet Protocol Version 4/6 (TCP/IPv4/6) Properties pop-up appears.

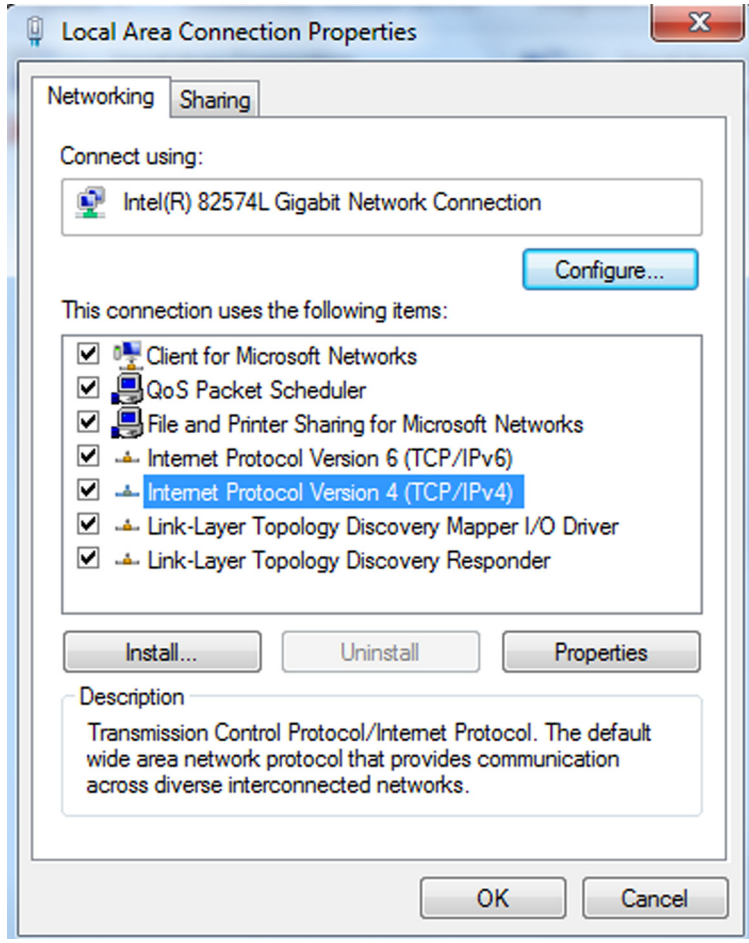


Figure 3-17. Local Area Network Properties Pop-Up

The Internet Protocol Version 4 (TCP/IPv4) Properties pop-up appears.

Changing the IP Address on the Invenia ABUS (continued)

5. From the Internet Protocol Version 4 (TCP/IPv6) Properties pop-up, select the “Use the following IPv4 address:” radial button.

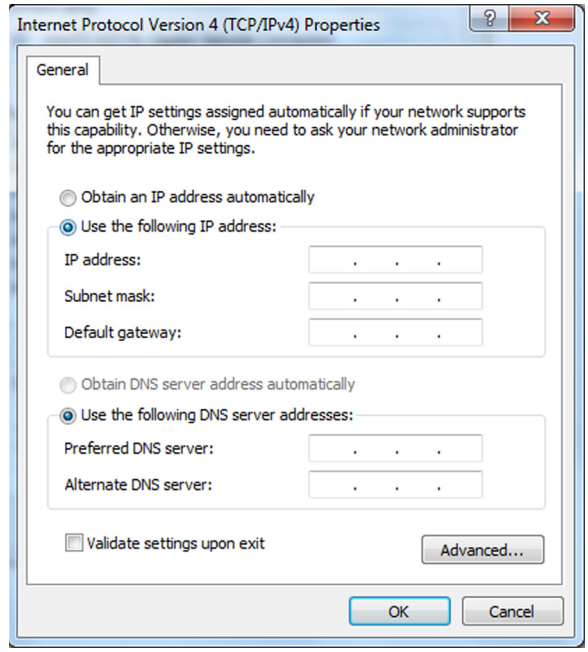


Figure 3-18. Protocol Version 4 (TCP/IPv4) Properties Pop-Up

Changing the IP Address on the Invenia ABUS (continued)

6. Type in the following information:

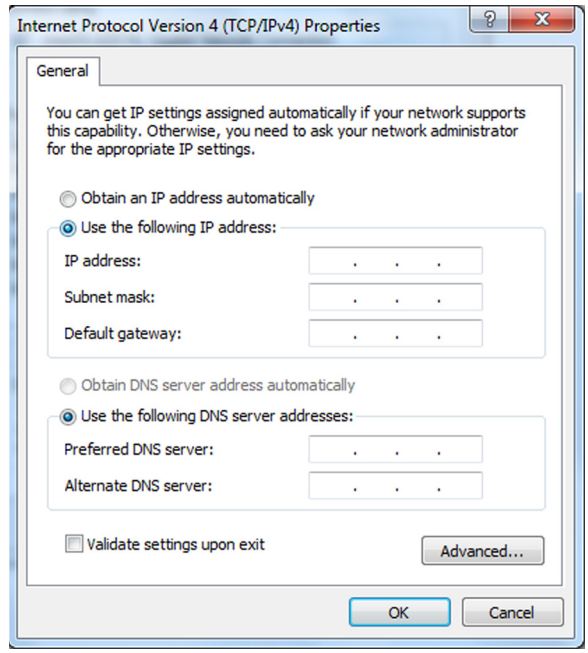


Figure 3-19. Protocol Version 4 (TCP/IPv4) Properties Pop-Up

- IP address (IPv4 address)
- Subnet prefix length
- Default gateway

For information on how to change the AE Title, see
Figure 3-20 *on page 3-39*

System Configuration (Administrator)

From the System Configuration screen, the Administrator can configure the following:

- Institute name. Press Change to type in the Institute's name.
- Network Settings
- Callibrate Screen
- Manage Referring Physician
- Manage Procedure
- Manage User
- InSite Configuration

Figure 3-20. System Configuration (Administrator)

Press the Local AE Info button to change the AE Title on the Invenia ABUS Scan Station, then type in the AE Tile and press the Enter Icon.

Adding Users

To add users, press Manage User-->Add, then type in the User's information.

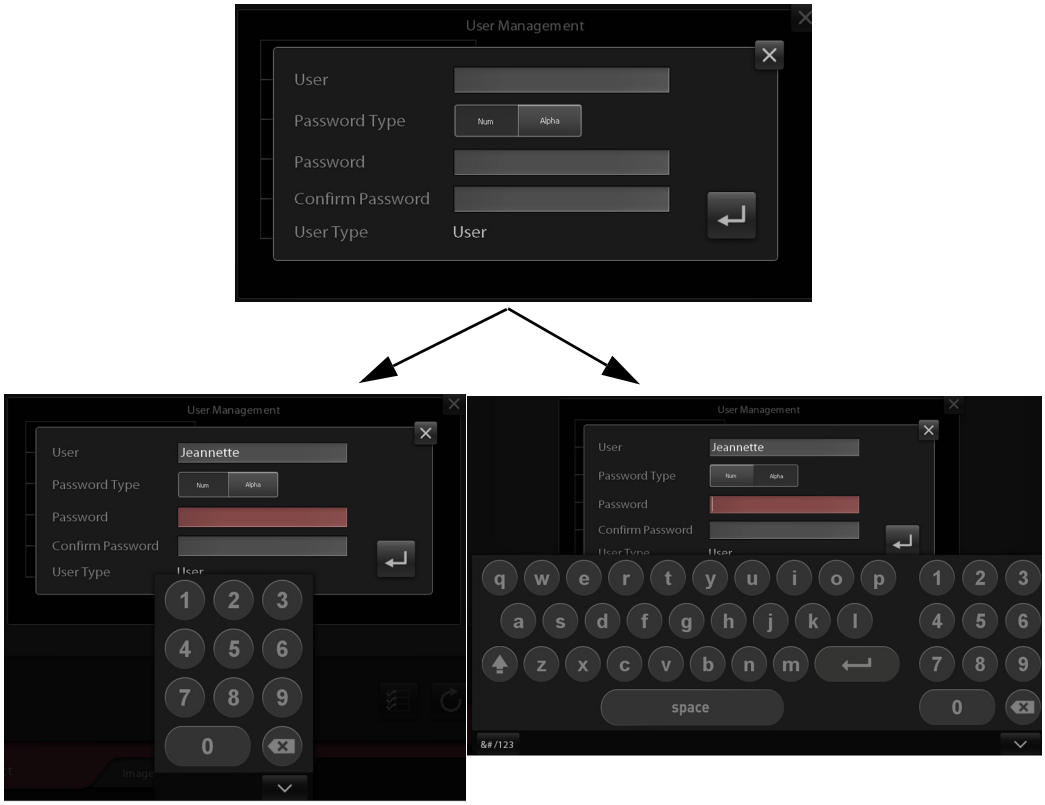


Figure 3-21. Adding a User's Login

Adding Referring Physicians

To add a Referring Physician manually (DICOM Worklist automatically provides Referring Physician information), press Manage RefPhys-->Add, then type in the Physician's information.

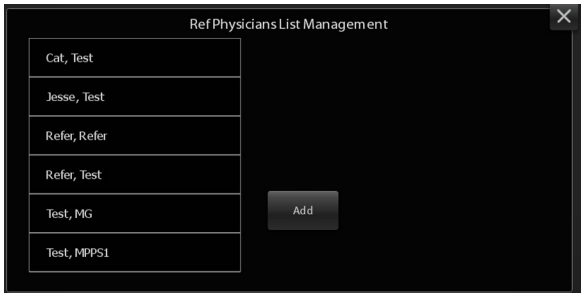


Figure 3-22. Adding a Referring Physician

Adding Procedures

To add a procedure, press Manage Procedure-->Add, then type in the name of the procedure.

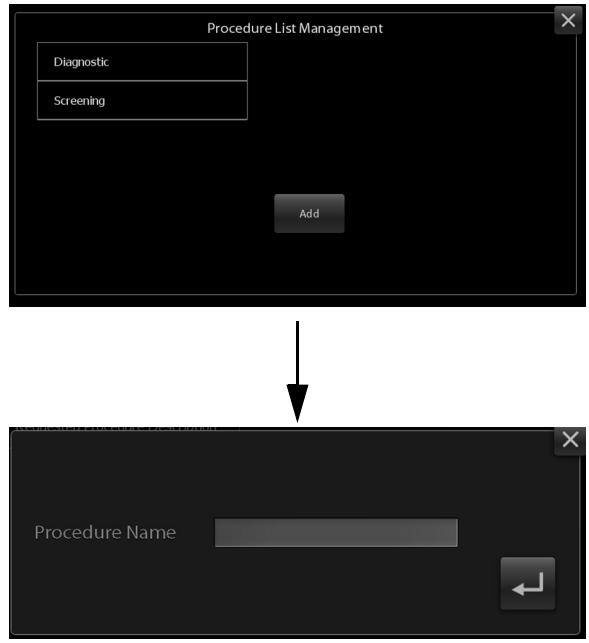


Figure 3-23. Adding a Procedure

About Configuration

The About Page lists the 3rd Party Software used on the Invenia ABUS.

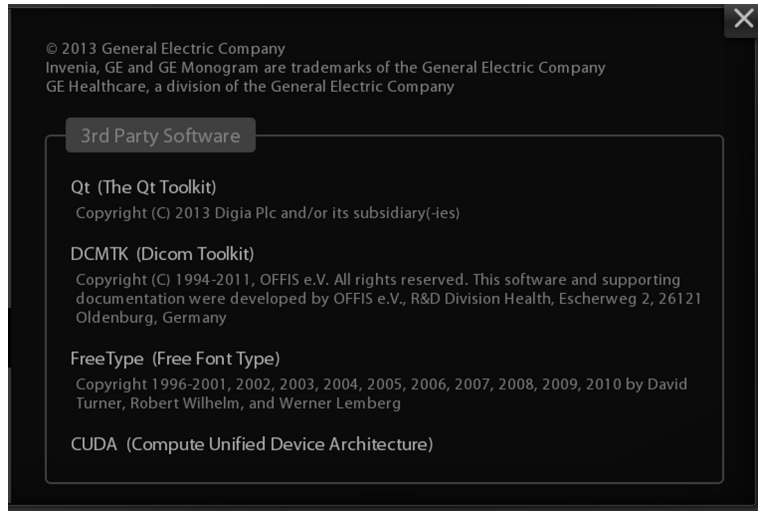


Figure 3-24. About Page

InSite Setup (Administrative User)

If the Invenia ABUS has not been configured for InSite, please contact GE Service for assistance. They will direct you to the following screens (you must be logged in as Administrator to access these screens).

You access the InSite Configuration screen via Utility Gear Icon--> System --> InSite Config:

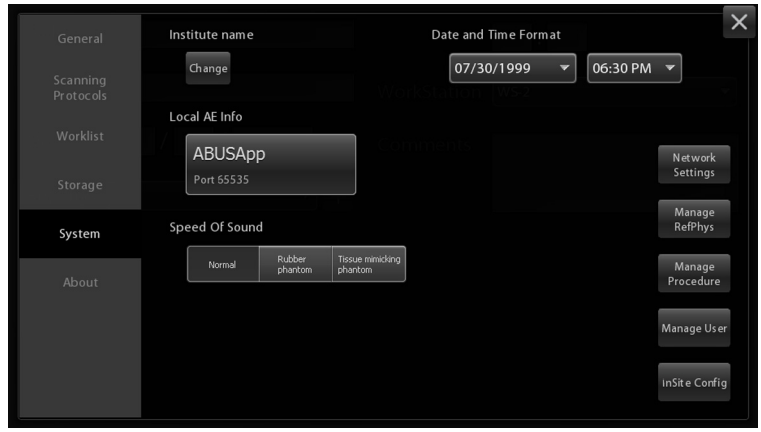


Figure 3-25. System Configuration (Administrator)

InSite Setup (Administrative User) (continued)

The InSite Configuration screen appears. GE Service will help you fill in this information.

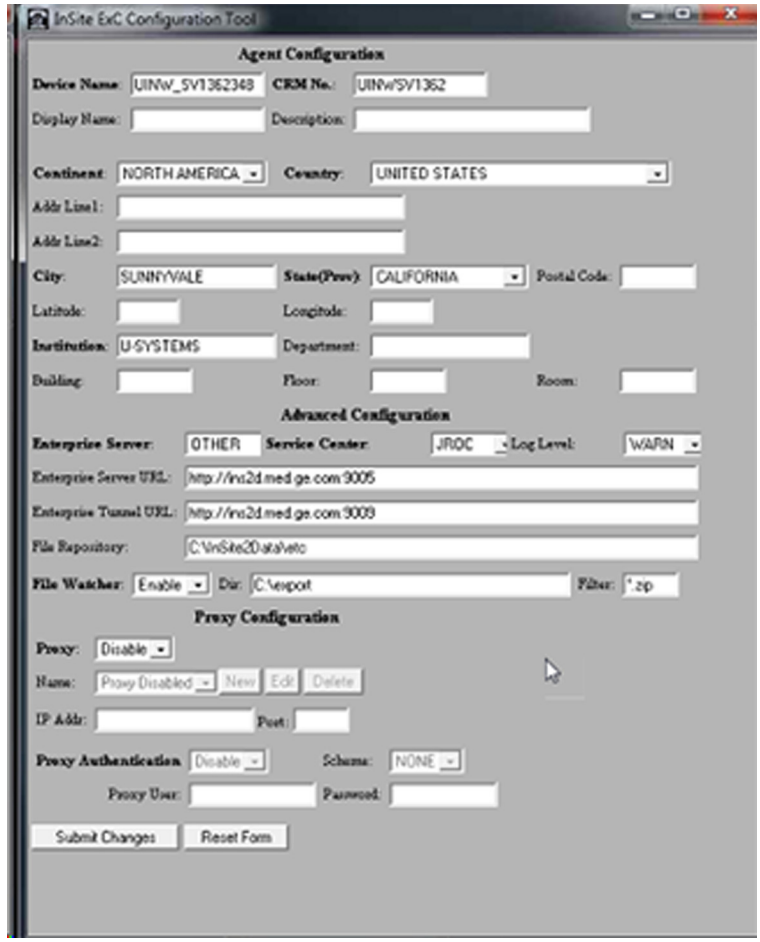


Figure 3-26. InSite Configuration

InSite Setup (Administrative User) (continued)

Configuring InSite

InSite is set up by GE Field Service during installation. S/he will set the folliowing parameters per the instructions below:

Table 3-8: DICOM Agent Configuration

Field	Setting
CRM No.	Must match System ID.
Display Name	Enter the „Device Name“ followed by some descriptive name indicating location in the facility e.g. VINW-W140033 (Reading Room 1).
Desciption	Create a unique description for the system. For example, “St. Mary’s Hospital”

Table 3-9: DICOM Advanced Configuration

Field	Setting
Enterprise Servers	Select PILOT2 or PRODUCTION. The Pilot Server is used for initial production. Please confirm with the Online Center to verify which server should be used.
Service Center	Configure settings as RPROC
File Watcher Field	Set at “Enable”. File Watcher monitors d:\service.
Dir:	Do not change the Directory field.
Filter	Set the Filter to *.zip so that the system will only uploiad zip files to the back office.

Configuring InSite (continued)

Table 3-10: DICOM Proxy Configuration

Field	Setting
Proxy	Set to “Enable”.
IP Addr	Set the IP Address.
Port:	Set the Port.
Proxy Authentication	Set at “Disable”, unless needed. In that case, “Enable” and enter the Scheme. Note: MUST BE SET AT “DISABLE”, unless a proxy server is provided by the hospital/clinic.
Scheme	Set at “None”, unless needed. In that case, enter the user information and password in the Proxy User and Password fields below.

NOTE: The Proxy Configuration should ONLY be performed if necessary.

Press “Submit Changes” to complete the InSite configuration. It may take approximately 10 seconds to 2 minutes to get confirmation.

Connectivity overview

Physical connection

Wired Ethernet from Invenia ABUS to a workstation

- Connection via Hospital Network.

  You will need one network cable to connect the Invenia ABUS to a wall outlet on the hospital's network.

Connection from Invenia ABUS to a DICOM Server on a network

You will need one network cable.

1. Connect one end of the cable to the Ethernet connector on Invenia ABUS.
2. Connect the other end of the cable to the wall outlet.

Configuration

Invenia ABUS Connectivity Configuration

Setting up connectivity is fully explained in the user manual for both the Invenia ABUS Scan Station and Workstation.

Refer to the Invenia ABUS Scan Station and Workstation Basic User Manual.

Paperwork after setup

NOTE: During and after setup, the documentation (i.e. CDs with documentation, User Manuals, Installation Manuals, etc.) for the Invenia ABUS and the peripherals must be kept as part of the original Ultrasound system documentation. This ensures that all relevant safety and user information is available during the operation and service of the complete Ultrasound system.

User's Manual(s)

Check that the correct User Manual(s) or CD with User Manuals, per software (SW) revision and language, for the system is included.

For a complete list of User's Manuals for Invenia ABUS, refer to Chapter 9 in this manual.

Chapter 4

Functional Checks

This chapter is designed to give the reader the ability to test the majority Invenia ABUS functions. During new installations and Update Installations this chapter can be a great asset in determining if the Invenia ABUS is working as it should.

General procedures

General Precautions

CAUTION

Invenia ABUS Scan Station requires all covers.

Operate this Ultrasound system only when all board covers and frame panels are securely in place. The covers are required for safe operation, good Ultrasound system performance and cooling purposes.

WARNING

Energy Control and Power Lockout for Invenia ABUS.

When servicing parts of the Invenia ABUS Scan Station where there is exposure to voltage greater than 30 volts:

1. Follow LOCKOUT/TAGOUT procedures.
2. Turn off the Power Mains Switch.
3. Unplug the Invenia ABUS Scan Station.
4. Maintain control of the Invenia ABUS Scan Station power plug.
5. Wait for at least 30 seconds for capacitors to discharge as there are no test points to verify isolation.
6. Remove/disconnect the battery, if present.

Invenia ABUS Scan Station components may be energized.

Overview

Some procedures are used more often than others. The intention with this section is to keep the most used procedures in one place.

Checking the Software Version

To check the version of software on the Invenia ABUS Scan Station, look in the lower, left-hand corner of the display just after the system starts up, prior to opening up a Login screen:

Figure 4-1. Invenia ABUS Scan Station Software Version

Checking the Software Version (continued)

To check the software version on the Workstation, select the Gear--> System--> Software Version:

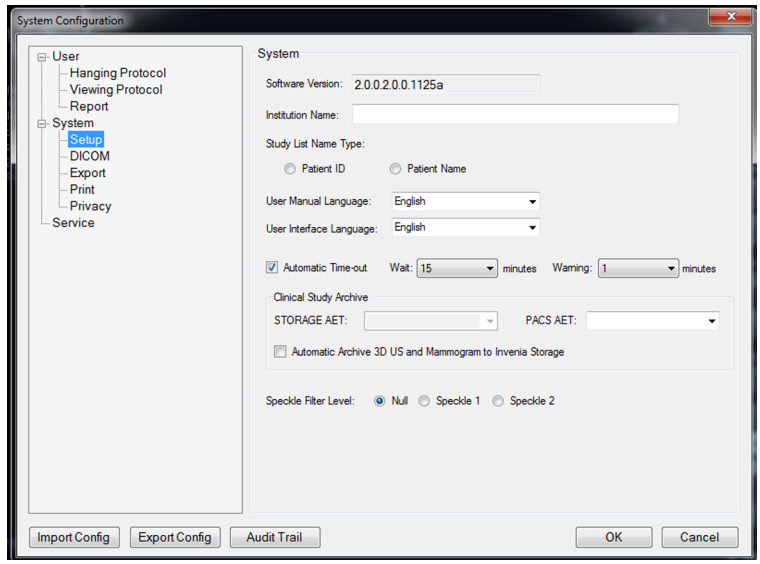


Figure 4-2. System Configuration

Power ON/Boot Up

Warnings


DANGER

ALWAYS CONNECT THE Invenia ABUS Scan Station TO A FIXED POWER SOCKET WHICH HAS THE PROTECTIVE GROUNDING CONNECTOR.


DANGER

NEVER USE A THREE-TO-TWO PRONG ADAPTER; THIS DEFEATS THE SAFETY GROUND.


DANGER

ENSURE THAT THE POWER CORD AND PLUG ARE INTACT AND THAT THE POWER PLUG IS THE PROPER HOSPITAL-GRADE TYPE (WHERE REQUIRED).


CAUTION

Invenia ABUS Scan Station requires all covers.

Operate this Ultrasound system only when all board covers and frame panels are securely in place. The covers are required for safe operation, good Ultrasound system performance and cooling purposes.


CAUTION

Use only power supply cords, cables and plugs provided by or designated by GE.

NOTE: Do not cycle the Mains Power Switch ON-OFF-ON in less than five (5) seconds. When turning OFF the Mains Power Switch, the Invenia ABUS Scan Station should de-energize completely before turning the Mains Power Switch ON.

Connect AC (mains) Power to the Invenia ABUS

Connecting AC Power to the Invenia ABUS ultrasound unit, involves preliminary checks of the power cord, voltage level and compliance with electrical safety requirements.

1. Ensure that the wall outlet is of appropriate type, and that the Power Mains Switch is turned off.
2. Uncoil the power cable, allowing sufficient slack so that the unit can be moved slightly.
3. Verify that the power cable is without any visible scratches or any sign of damage.
4. Verify that the on-site mains voltage is within the limits indicated on the rating label near the Power Mains Switch on the rear of the unit.
5. Connect the Power Cable's female plug to the Power Inlet at the rear of the unit.
6. Verify that the Power Mains Switch is in OFF position, if not, switch it OFF.
7. Connect the Power Cable's other end (male plug) to a hospital grade mains power outlet with the proper rated voltage, and the unit is ready for Power ON/Boot Up.

Switch ON the AC Power to Invenia ABUS

The System Standby button is used to turn the system On and Off. The System Standby button is located on the upper, left-hand portion of the console, below the left-hand gel holder.

1. Switch ON the Power Mains Switch at the rear of the unit.
2. Press once on the **On/Off** button on the Invenia ABUS to boot the unit.

DO NOT unplug the power cord until after the complete shutdown procedure has been performed.

Power shut down

When you switch off the unit, the system performs an automatic shutdown sequence. Press the On/Off/Standby button to initiate the shutdown sequence.

Moving and Transporting the Invenia ABUS

Moving the System

To move the system,

1. Position the articulating arm, Scanner Assembly, and monitor and then lock into position.

Figure 4-3. Touch Screen and Articulating Arm Lock

2. Unlock the front and rear brakes.
3. Disconnect the power cord from the wall and from its connector on the rear of the system.
4. Disconnect the Ethernet cable from the wall and from its connector on the rear of the system.

NOTE: The system weighs 123 kg (271 lbs).

CAUTION

Secure the articulating arm and monitor prior to moving the system. Failure to secure the articulating arm and monitor could cause damage to the arm and/or monitor, other equipment, or other personnel.

Disconnect the power cord prior to moving the system. Failure to do so could cause you to run over the power cord or cause a tripping hazard.

Preparation before moving the system is important to minimize potential damage to sensitive components and to avoid safety hazards. Review the moving instructions prior to moving the system.

DO NOT park or leave the system unattended on a slope. Even if the rear brakes are locked, the system may slide down a ramp.

Transporting the System

Use extra care when transporting the system using vehicles. In addition to the instructions used when moving the system (see ‘Moving the System’ on *page 4-7* for more information), also perform the following:

1. Only use vehicles that are designed for transport of the Invenia ABUS.
2. Load and unload the system to a vehicle parked on a level surface.
3. Ensure that the transporting vehicle can handle the weight of the system plus the passengers.
4. Ensure that the load capacity of the lift (a minimum of 123 kg [271 lbs] is recommended) is capable of handling the weight of the system.
5. Ensure that the lift is in good working order.
6. Secure the system while it is on the lift so that it cannot roll. Use either wood chocks, restraining straps, or other similar types of constraints. Do not attempt to hold it in place by hand.

NOTE: *Strap the system below its handle so that the system does not break loose.*

Never ride on the lift with the system. A person's weight coupled with the weight of the system may exceed the load capacity of the lift.

7. Employ two to three persons to load and unload safely from a vehicle.

Transporting the System (continued)

8. Load the unit aboard the vehicle carefully and over its center of gravity. Keep the unit still and upright.

NOTE: Do not lay the unit down on its side.

9. Ensure that the system is firmly secured while inside the vehicle. Any movement, coupled with the weight of the system, could cause it to break loose.
10. Secure system with straps or as directed otherwise to prevent motion during transport.
11. Prevent vibration damage by driving cautiously. Avoid unpaved roads, excessive speeds, and erratic stops or starts.

At the new location

When the unit is in place at a new location:

1. Lock the wheel brakes.
2. Position the Monitor Arm, and Scanner Arm and Scanner Assembly away from a walking or work area.
3. Position the Scanner Arm and Scanner Assembly at the lowest position.

Where are the User Manuals and the Service Manual?

Both the User Manuals and the Service Manual are delivered on paper. Additional paper copies may be ordered from GE. In addition, manuals may be downloaded from the Common Documentation Library.

You can download manuals from the Common Documentation Library (http://www3.gehealthcare.com/en/Support/Support_Documentation_Library).

Functional checks

Overview

This section describes the functional checks used with the Invenia ABUS. Functional checks are used to verify that the product works as specified after performing maintenance procedures. Functional checks may also be used during troubleshooting.

Performance Functional Checks

Power On/Boot Up Functional Check

Confirm that the system:

- Powers on when you press the On/Off/Standby control.
- That the transducer moves across the Scanner Assembly.
- That the software runs through its initialization.
- And that each user type (User or Admin) can successfully login to the system.

Power Shut Down Functional Check

Confirm that the system exits the application and powers down.

Probe Functional Check

Ensure that the probe:

- Upon Power Up moves across the Scanner Assembly.
- That the lights on the Scanner Assembly light up.
- That the Probe images as a scan is being performed.
- That the Probe generates a 3D Volume.

Performance Functional Checks (continued)

B-Mode Functional Checks

Confirm that the system:

- Performs a B-Mode scan.
- Places B-Mode imaging parameters on the Touch Screen Monitor.
- Images evenly across the entire Touch Screen.

3D Volume Functional Checks

Confirm that the 3D Volume:

- Gets generated after each Scan View performed.

Performing the Exam

Confirm that the system can:

- Login the User.
- Access the Worklist and/or Enter Patient information manually.
- Perform the exam.
- Verify the exam.
- Send the exam to the Workstation / PACS.
- Perform Query/Retrieve process to PACS

Mechanical Functions Checks

Scanner Assembly Functional Checks

Ensure that the Scanner Assembly:

- Adjusts the Image Orientation to the Scan View being performed.
- Compression buttons work as specified.
- Start button initiates the scan.
- Stop button stops the scan.
- Rotates 360 degrees.
- Arm locks into position after compression has been applied.

Articulating Arm Functional Checks

Ensure that the Articulating Arm:

- Can be repositioned easily.
- Can be moved up/down with ease.
- Can be locked into position for transport.
- Can support the Scanner Assembly.

Touch Screen Monitor Functional Checks

Ensure that the Touch Screen Monitor:

- Can be used to adjust the Scan View workflow.
- Can be used to specify Scan Depth.
- Can be used to type in Patient information.
- Doesn’t drop any pixels.

Casters (Wheels) and Brakes Functional Checks

Examine the wheels frequently for defects to avoid breaking or jamming and the brakes lock.

Connectivity Functional Checks

Confirm the following:

- Exams transfer successfully to the Workstation
- InSite is active
- DICOM Worklist functions
- DICOM MPPS functions

Chapter 5

Components and Functions (Theory)

This chapter explains Invenia ABUS' system concepts, component arrangement, and subsystem functions.

Invenia ABUS Components and Functions (Theory)

Invenia ABUS General Description

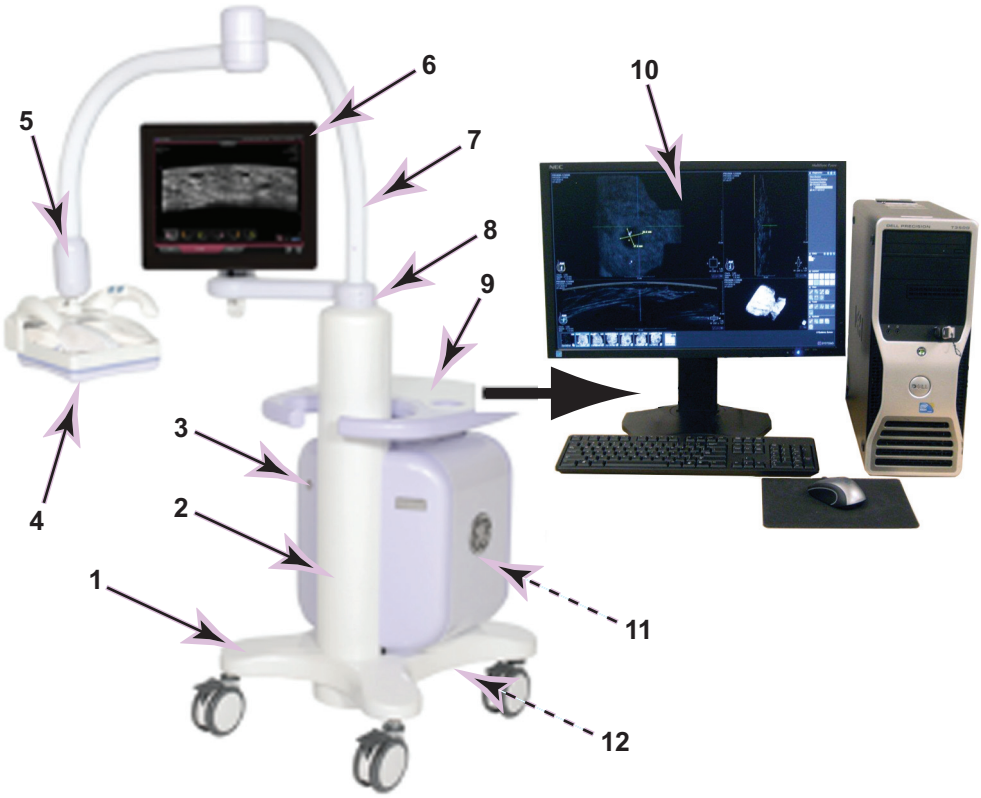


Figure 5-1. Invenia ABUS System

1. Base and Casters
2. Weight Tower
3. ON/OFF Power Switch
4. Scanner Head Assembly
5. Ball Joint
6. Monitor (Touch Screen)
7. Articulating Arm Assembly
8. Monitor Arm Assembly
9. Service Table
10. Workstation (Preloaded with Invenia ABUS Review Software or purchased as a Software Only Option)
11. IEC (Imaging Engine Chassis)
12. Fan Assembly

Invenia ABUS General Description (continued)

The Invenia ABUS Scan Station is an ultrasound system designed for volume imaging of the breast.

The system consists of a cart, an arm, and a scanner with an integrated ultrasound probe.

At the heart of the system is the IEC (Imaging Engine Chassis) which contains:

- an ATX Power Supply and Power Sequencer Board
- two Acquisition Boards (Master and Slave)
- TIP (Transducer Interface and Power) Board
- a compatible Motherboard and GPU which acquires and processes 128 channels of ultrasound data. The GPU performs the ultrasound data processing.
    - interfaces to all system peripherals,
    - distributes power to all system components,
    - communicates with two peripheral controllers:
    - the Scanner Head Controller
    - the Weight Controller

Located in the Scanner Head is the Scanner Head Controller which moves a probe across the breast under command of the IEC, while the chassis acquires a sequence of 2D images that represents an ultrasound volume. This controller also monitors and reports User Interface activity at the Scanner Head and controls a locking Ball Joint to implement the system workflow.

A USB 2.0 connection serves as the physical link for communications between the IEC and the Scanner Head Controller.

Located within the Arm Base (Weight Tower), the Weight Controller manages an electro-mechanical vertical arm locking mechanism and an automatic Scanner weighting mechanism under control of the IEC. A second USB 2.0 connection to the IEC provides these communications.

Air Filter

In the chassis base, there are two features to facilitate removal of the air filter. The walls above and below the Air Filter Compartment have recessed areas to enable a user to pinch the air filter with thumb and fore finger and pull on the air filter.

Scanner Assembly

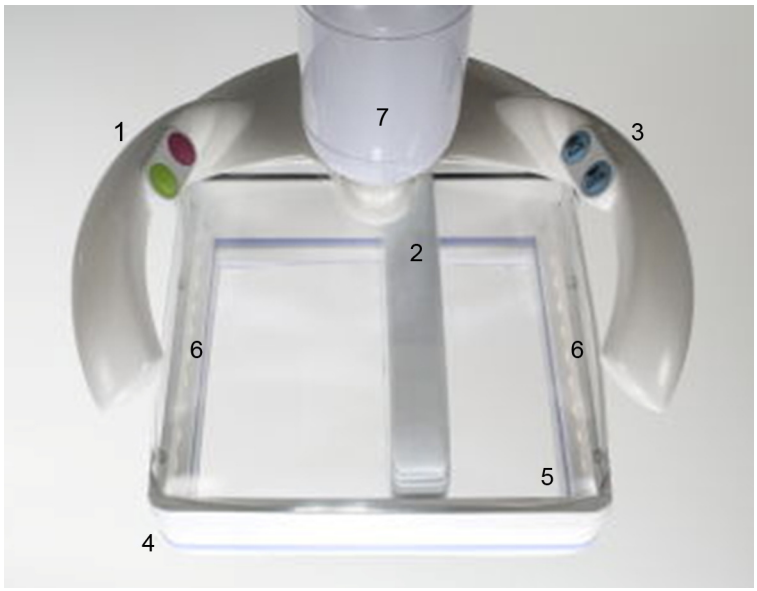


Figure 5-2. Scanner Assembly

1. Begin/Abort Scan
2. C15-6XW Reverse Curve transducer
3. Increase/Decrease compression
4. Single Use Stabilization Membrane
5. Scanner Assembly Cover
6. Lights
7. Multi-AXIS Lock

The Scanner Assembly houses the C15-6XW Reverse Curve transducer (shielded by a Single Use Stabilization Membrane. The transducer moves across the Disposable, Single Use Stabilization Membrane and the surface of the breast. Buttons for controlling the scan are also found on the Scanner Assembly. The Scanner Assembly is attached to the articulated arm which allows the Scanner Assembly to be easily positioned for all scan views.

Scanner Assembly (continued)

Figure 5-3. Transducer with Positioning Arrows

1. Anterior/Posterior
2. Lateral and Medial
3. Not Used

Arrows on the sides of the transducer indicate where to position the breast nipple on the transducer for different View Types (Lateral, Anterior/Posterior, and Medial).

The Single Use Stabilization Membrane covers the bottom of the Scanner Assembly. During the scan it stabilizes the breast tissue and enables better image quality. If a Single Use Stabilization Membrane is not positioned or not in place, an error message “No membrane is detected,” and cannot begin the scan until the Single Use Stabilization Membrane has been properly positioned or placed on the Scanner Assembly.

When the Scanner Assembly and Transducer, is ready to begin the scan, the Transducer will position itself 2 cm from the center (in either direction) of the Scanner Assembly. This is so Scanner Assembly can be centered on the patient’s breast nipple.

Chapter 6

Service Adjustments

This chapter describes how to test and make adjustments to the Invenia ABUS. You can use these to test the system for errors.

Service Adjustments

This Chapter only covers the components or assemblies that require adjustments for the Invenia ABUS. Currently no components or assemblies require adjustments.

System adjustments need to be performed by trained, qualified personnel. Contact GE for training.

Chapter 7

Diagnostics/Troubleshooting

This chapter describes how to setup and run the tools and software that help maintain image quality and system operation. Very basic host, system and board level diagnostics are run whenever power is applied. Some Service Tools may be run at the application level.

Noise troubleshooting

Introduction

Before you start troubleshooting electronic noise, you should read the following subsections:

- ‘General recommendations’ on *page 7-3*
- ‘EMI prevention/abatement’ on *page 2-7*
- ‘Overview of types of noise’ on *page 7-6*

When talking to the customer, try to gather as much information as possible about the conditions when the noise appear:

Is the noise present...

… all the time?

… after some time of use? (After how long time?)

… at special times of the day (or night)? When?

… at all locations in the hospital, or only in one room/area?

… from time to time, no special pattern of time is observed?

General recommendations

Ultrasound systems are susceptible to Electromagnetic Interference (EMI) from radio frequencies, magnetic fields, and transients in the air or wiring. They also generate EMI. The Invenia ABUS Scan Station complies with limits as stated on the EMC label. However there is no guarantee that interference will not occur in a particular installation.

Possible EMI sources should be identified before the Invenia ABUS Scan Station is installed.

Electrical and electronic equipment may produce EMI unintentionally as the result of a defect. Some of these sources include:

- medical lasers
- scanners
- cauterizing guns
- computers
- monitors
- fans
- microwave ovens
- light dimmers
- mobile phones
- in-house wireless phones (DECT phones)
- wireless computer keyboard and mouse
- air conditioning system
- High Frequency (HF) surgery equipment
- general AC/DC adapters

The presence of a broadcast station or broadcast van may also cause interference.

EMI prevention/abatement

Table 7-1: EMI prevention/abatement

EMI RULE	DETAILS
Be aware of Radio Frequency sources	• Keep the Invenia ABUS Scan Station at least 5 meters (15 feet) away from other EMI sources. • Special shielding may be required to eliminate interference problems caused by high frequency, high powered radio or video broadcast signals.
Ground the Ultrasound system	Poor grounding is the most likely reason an Ultrasound system will have noisy images. Check grounding of the power cord and power outlet.
Replace all screws, Radio Frequency gaskets, covers, cores	• After you finish repairing or updating the Invenia ABUS Scan Station, replace all covers and tighten all screws. • Any cable with an external connection requires a magnet wrap at each end. • Install all covers. Loose or missing covers or Radio Frequency gaskets allow radio frequencies to interfere with the ultrasound signals.
Replace broken Radio Frequency gaskets	If more than 20% or a pair of the fingers on an Radio Frequency gasket are broken, replace the gasket. Do not turn on the Invenia ABUS Scan Station until any loose metallic part is removed.
Do not place labels where Radio Frequency gaskets touch metal	Where applicable, never place a label where Radio Frequency gaskets meet the Ultrasound system. Otherwise, the gap created will permit Radio Frequency leakage. Or, if a label has been found in such a position, move the label.
Use GE specified harnesses and peripherals	The interconnect cables are grounded and require ferrite beads and other shielding. Also, cable length, material, and routing are all important; do not change from what is specified.
Take care with cellular phones	Cellular phones may transmit a 5 V/m signal; that could cause image artifacts.
Properly route peripheral cables	Where applicable, do not allow cables to lie across the top of the Card Rack or hang out of the peripheral bays. Loop the excess length for peripheral cables inside the peripheral bays. Attach the monitor cables to the frame.
System won’t shut down	Press and hold down the power button until the system shuts down. ONLY do this if the system does not shut down normally (light press of the power button).

Different Power Outlet

Connect the unit to another power outlet and verify if the noise changes or disappear.

NOTE: Invenia ABUS requires a dedicated power and ground for the proper operation of its Ultrasound equipment. This dedicated power shall originate at the last distribution panel before the Ultrasound system.

The Invenia ABUS will function on voltages from 100-240 Volts and 50 or 60 Hz. However, if using 220 volt power in North America, then a center tapped power source is required.

Sites with a mains power system with defined Neutral and Live:

The dedicated line shall consist of one phase, a neutral (not shared with any other circuit), and a full size ground wire from the distribution panel to the Ultrasound outlet.

Sites with a mains power system without a defined Neutral:

The dedicated line shall consist of one phase (two lines), not shared with any other circuit, and a full size ground wire from the distribution panel to the Ultrasound outlet.

Different system

Try another Invenia ABUS at the same location and look for the same noise. If the noise is present on the new system too, the noise is most likely from an external source/equipment.

Different location

Move the scanner to another location and verify if the noise changes or disappear. This may help you to locate an external noise source.

Try to move the scanner to:

- another location inside the room
- another room
- another floor

Disconnect external cables

Disconnect network cable to verify if the noise disappears.

Overview of types of noise

There are different types of noise. Use the information next to classify the noise and possible cause.

Noise picked up from the air

Electromagnetic Interference (EMI) from radio frequencies, magnetic fields, and transients in the air.

If picked up by a probe cable, the noise will be coherent -“penlight noise” pointing down in the picture - due to the fact that the noise is received on all channels.

- Is it a problem on the probe?

  Remove probe, reverse (flip it), and replace probe.
- Is it a problem on one of the probe connectors only?

  Move the scanner to another location and verify any changes.

Noise Received via the External Cables

Electromagnetic Interference (EMI) from radio frequencies, magnetic fields, and transients in the wiring. The noise can enter the system via the mains power cable, probe cable(s) or any other external connected cable(s).

To troubleshoot this type of noise, disconnect cables that are not needed for the basic use of the scanner. Check for any change in the noise each time a cable has been disconnected from the Invenia ABUS.

- Network cable

Verify if the noise change or disappear when the cables are removed.

Often, this type of noise is due to grounding problems in the mains power system or that the scanner is sharing a power line with other equipment.

Intermittent noise

- Is there any equipment that is turned on and off near the scanner?
- Is the noise present all around the clock or only at special occasions?

Self generated noise (noise generated inside the unit)

- Self generated noise may be due to either:
  - heat problems
  - hardware problems
  - software problems

Heat problems

Heat problems are usually starting when Invenia ABUS has been ON for some time.

If Invenia ABUS has been used for scanning for some time before the noise appears, it may be due to either heat problems or some software related issues. By doing a restart you may learn some more about the cause.

Restart the system.

- If the noise is present after the restart, the cause is most likely due to heat problems.
- If the noise is gone after the restart, it may be due to either the setup/adjustments of the or a software failure.

Some possible causes for heat problems:

- Fan filters need to be cleaned or replaced.
- Room temperatures outside the allowed temperature limits.
- Fans are worn-out.
- Hardware problems.

Hardware problems

A hardware is an error/malfunction in either the probe or the main unit.

A hardware issue may be an error/malfunction on a card.

Software problems

Check if a newer software version is available. A software update may include noise fixes. If needed, update the software.

InSite

InSite is your direct link with a GE Online Service Engineer or a direct request for service.

InSite on the Invenia ABUS Scan Station

Press on the Network Indicator located in the upper, right-hand corner of the Touch Screen to invoke the InSite icons.

Figure 7-1. Invoking InSite

InSite is your direct link with a GE Online Service Engineer or a direct request for service.

Figure 7-2. InSite Icons

InSite on the Invenia ABUS Scan Station (continued)

Table 7-2: InSite Icons

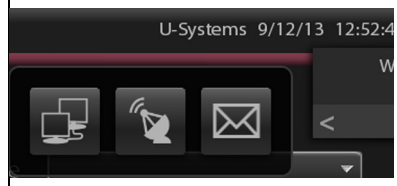
Item	Icon	Description
1.		Network and InSite Indicators. Press to get the current status or to invoke InSite. Network Indicators. Provides Network Status and DICOM Send status (lets you know the status of sending the just-completed exam to the Workstation). • Green=Network Active • Red=Network Inactive InSite Indicators • Green=Connected. InSite Services are running. • Red=Remote Desktop (Console Observation) is active. • Black=Service is Installed
2.		Press the left arrow (<) to bring up the InSite Services Menu (Remote Desktop, Connect to GE, and Contact GE).
3.		**Remote Desktop - Touch Screen Share** • Shares the Scan Station Desktop with a GE Online Service Engineer. • Allows Technical Support to control Invenia ABUS functionality remotely. • Allows Technical Support to run system diagnostics remotely and to collect system logs.
4.		**Connect to GE** • Direct contact with GE Technical Support. • Stays on fast polling for 15 minutes • System returns to normal polling after 15 minutes or after the system is restarted.
5.		**Contact GE - Request for Service** • Opens a Serevice Dispatch with GE Service. See Details below.

InSite on the Invenia ABUS Review Software

On the Workstation, access to InSite can be found on the System Pane:

Figure 7-3. System Pane

Table 7-3: System Pane

Icon	Name	Example	Description
	InSite		Activates InSite. Refer to Chapter 8 for more information.

InSite Functionality

Activate Remote Desktop

Allows Technical Support to control Invenia ABUS functionality remotely.

Connect to GE

Selecting this ICON changes the polling time from 15 minutes to 15 seconds so that your call can be answered as quickly as possible, as well as allowing disruptive mode. InSite ExC icons appear differently, depending on their state

Table 7-4: InSite Icons

InSite Icon	Description
	Remote desktop is active. Service may connect to and interact with the system using screen sharing.
	InSite is connected to GE, but screen sharing is not activated. User can send requests for service, but service cannot connect directly to device for screen sharing.
	InSite installation is corrupt or missing. This is an error condition and user should call service if this icon persists.
	InSite is installed properly, but is not connected to GE. User cannot connect to GE or send service requests. GE cannot connect to the system. This is an error condition, as InSite should always be connected. If this icon persists, user should call service.

InSite Functionality (continued)

Contact GE

To open a Service Dispatch (request for Field Service Engineer),

1. Press the Network/InSite Icon located in the upper, right-hand corner of the Touch Screen.
2. Ensure that the InSite Icon is Green. Then press the left arrow (<).
3. Select the Contact GE Icon (envelope). The Contact GE form appears.
4. Fill in the Contact GE Form.
   - Items with a red asterisk
   - Problem type
   - Problem area
   - Problem description
   - Send

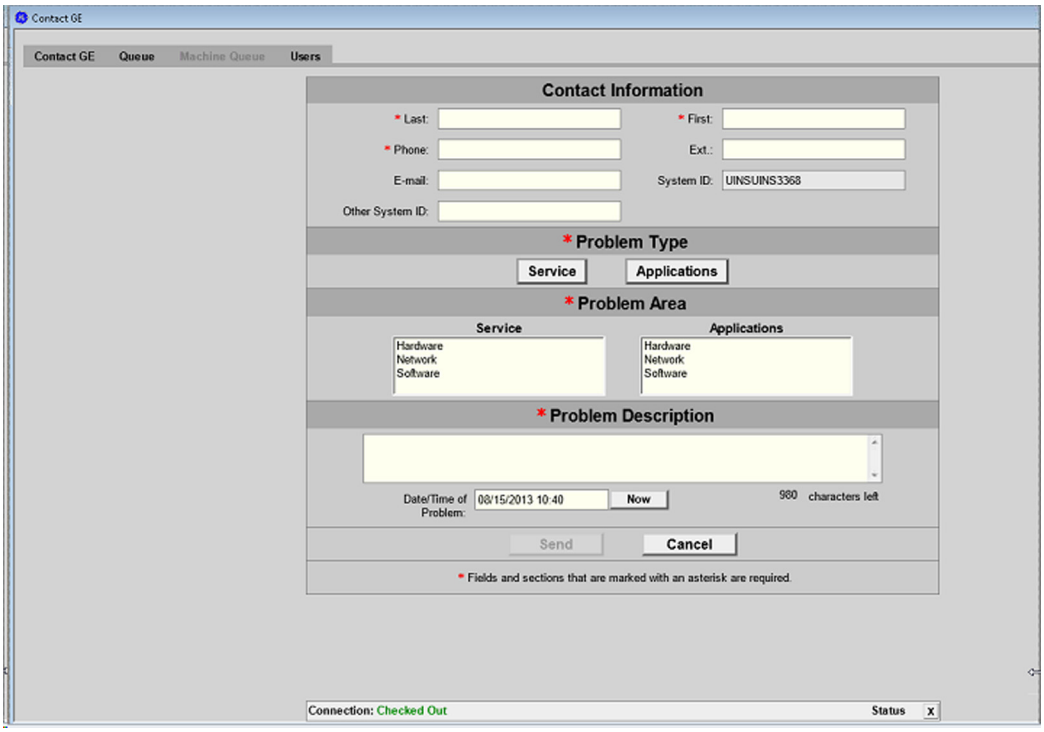


Figure 7-4. Contact GE

InSite Functionality (continued)

After you press Send, the following pop-up appears:

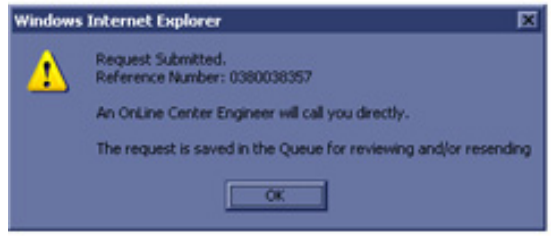


Figure 7-5. Request for Service Confirmation

Troubleshooting and System Messages

Invenia ABUS Scan Station Troubleshooting and System Messages

Troubleshooting

Table 7-5: Scan Station Messages

Symptom	Action to Take
Blank Screen	Troubleshoot the following: • Is the system plugged in? • Is the system turned on and the power button lit (green)? • Does the probe initialize (move across the face of the Scanner Head Assembly)?
If the system powers on with an error on the screen.	Reboot the system, up to three (3) times. If the error still appears, contact GE Service.
Mechanical Noise / Thumping	Contact GE Service. DO NOT spray any spray or oil, or apply any grease to any part of the system.
Multi-Axis Lock Stops Working	Contact GE Service.
System Overheating	Clean the filter. CAUTION: DO NOT operate the system without an air filter.
Image doesn't transfer from the Invenia ABUS Scan Station to the Workstation	Confirm that the Workstation Network Indicator light is green. Shut down both the Invenia ABUS Scan Station and Workstation; then 1st reboot the Workstation, and 2nd reboot the Scan Station. Note: If the Scan Station/Workstation is full, files will not transfer.

Table 7-5: Scan Station Messages

Symptom	Action to Take
Lines in the Image	Remove the probe, then reverse it 180 degrees and plug it back in. If you still see lines on the image, but on the opposite side of the screen, then the probe is defective. If the lines are still on the same side of the screen, then the issue is on the adcquisition board or the TIP board. In either case, contact GE Service.
Intermittent Operation, System Lock-Ups, System Slow-Downs, Overheating, Poor Image Quality	Clean the system filter and let the system cool down for 30 minutes to 1 hour. Keep the system a distance of 18 inches (~0.46 m) from curtains. CAUTION: DO NOT operate the system without a filter.

System Messages

The following messages may appear during the scan. Please refer to the cause/action information provided when trying to resolve the issue.

Table 7-6: Scan Station Messages

System Message	Cause/Action to Take
[Patient Name] is already selected for this scan	You have already selected a patient for this scan.
Abort fininshed. Ready for next scan.	You can start the next scan; the previous scan was aborted.
Aborted	The scan has been aborted.
Aborting	The current scan is being ended.
Are you sure you want to logout?	Prompts the user to confirm that they intended to stop using the system.
Dataset is not available	The selected patient's dataset is no longer available. It cannot be re-sent to the workstation.
Imaging Engine Initializing....	The system is in the process of starting up.
Please check the scantype	The user must select a scan type before scanning can begin.
Please input patient information.	Prompts the user to fill in all patient information fields prior to starting the scan.
Please mark all nipple positions	The nipple positions on the scan must be set before proceeding with further action on the system.
Please select a new patient	You need to select a new patient in order to begin the scan.
Please unlock scanner first	Login to begin scanning.
Please wait until processing is finished	The system is still processing the current task; please wait to start the next tast.
Press compression button	Apply compression before starting the scan.
Press Compression button or Start button	Apply compression, then press Start to begin the scan.
Press Scan Button on Scan Head to Start Scanning	Press Start on the Scanner Assembly to begin the scan.
Press Start button to start scan	Press Start on the Scanner Assembly to begin the scan.
Processing...	The acquired image data is being processed for display. Wait until the acquisition is complete before performing any further actions.

Table 7-6: Scan Station Messages

System Message	Cause/Action to Take
Scan finished	The system has completed scanning for this View Type.
Scan limit reached	Confirm system Storage Status via the General Configuration page.
Scan order for this patient already selected	The scan order has already been specified for this patient. You can select additional View Types for this patient via the Select Tab.
Scan started	Allow the scan to complete, or Abort the scan.
Scan Station Initializing...	The system is in the process of starting up.
Scanning	The system is performing the scan.
Select scan order	Specify the workflow.
Select scan type	Specify the View Types you want to use for this patient.
The user name or password you entered is incorrect.	A valid user name and password must be entered to use the system.
There are scans missing for this patient. Are you sure you want to finish?	Informs the user that there are scans that have been selected to be completed for the patient and these scans have not yet been completed. Prompts user to select whether or not they would like to finish the session before completing all scheduled scans.
There are scans missing for this patient. Are you sure you want to logout?	Informs the user that there are scans that have been selected to be completed for the patient and these scans have not yet been completed. Prompts the user to select whether or not they would like to finish the exam before logging off and allowing another user to use the system.
Transducer is moving. Please wait.	Please allow the transducer to complete the scan.
You must first select a patient	A patient must be selected from the Worklist before scanning can begin.

Workstation Troubleshooting and System Messages

Troubleshooting

Table 7-7: Workstation Messages

Symptom	Action to Take
No Communication Between Scan Station and Workstation	Power down both the Workstation and the Scan Station. Then power both back on, first the Workstation and then the Scan Station.
Confirm DICOM Send	Open up the DICOM Status from the DICOM Indicator. You will be able to see which studies were sent and which studies failed.

System Messages

The following messages may appear during the review. Please refer to the cause/action information provided when trying to resolve the issue.

Table 7-8: Workstation Messages

System Message	Cause/Action to Take
An application entity can only be set to Print or Store, not both.	Select Print or Store.
Are you sure you want to delete all these series/ images?	Confirm selection.
Are you sure you want to delete these studies?	Confirm selection.
Are you sure you want to delete this study?	Confirm selection.
Are you sure you want to delete this series/image?	Confirm selection.
Are you sure you want to log off?	Confirm selection.
Are you sure you want to remove all calipers?	Confirm selection.
Automatic export items can’t be deleted.	Informational message.
Can’t load report data.	Informational message.
Delete confirmation	Confirm selection.
DICOM connection test failed.	Informational message.
DICOM connection test passed.	Informational message.
Do you want to resume the last saved session?	Confirm selection.
Export from DICOM server is not supported.	Informational message.

Table 7-8: Workstation Messages

System Message	Cause/Action to Take
Failed to export users.	Informational message. Please try the operation again.
Failed to retrieve images from the DICOM server.	Informational message. Please try the operation again.
Invalid port number. Port number can only have four digits.	Confirm the port number.
Invalid printer, or no printer, is installed.	Check printer installation.
No DICOM images found at the folder <folder>.	Informational message.
No images are retrieved.	This message appears when a non-service user tries to change the local Port or AE Title.
Only Service users can change the local settings.	This message appears when a n on-service user tries to change the Local Port or AE Title.
Only three lines of text are allowed for Institute Address.	Informational message. Please try the operation again.
Please enter a User name.	Informational message. Please try the operation again.
Please retrieve the study before you load it.	Informational message. Please try the operation again.
Unable to restore study. Please load it from the study pane.	Informational message. Please try the operation again.
Please restart DICOM receive application to make the changes effective.	Informational message. Please try the operation again.
Please select a location to export the study(s) to.	Informational message. Please try the operation again.
Printer error.	Informational message. Please try the operation again.
Please select another study.	Informational message. Please try the operation again.
Please select either Export To Disk or Export to DICOM Servers for exporting.	Informational message. Please try the operation again.
Printer error.	Check the printer and try the operation again.
Report file [file name] already exists.	Change export filename.
Retrieve completed	Informational message.
Retrieving study <id>.	Informational message.
Study doesn’t exist.	Informational message. Please try the operation again.

Table 7-8: Workstation Messages

System Message	Cause/Action to Take
The Invenia ABUS application has encountered a problem.	Please restart the application.
The Invenia ABUS disk space is below [configured free space]%. Reviewed studies will automatically be deleted to free space.	Informational message. Please manage disk space.
The Study doesn't exist.	Informational message. Please try the operation again.
The study <id> of the patient <id> already exists. Do you want to overwrite?	Confirm selection.
The user name already exists. Please choose a different user name.	Informational message. Please try the operation again.
The view type of the image stored in the Invenia ABUS Storage can't be changed.	Informational message.
Unauthorized to access the printer.	Informational message.
UsysDcmReceiveApp is missing in the installation directory ... Failed to start.	Contact service for re-installation
You have images in the data pane.	Informational message.
You have images in the data pane. Are you sure you want to open a new study?	Confirm selection.
You have images pending int he DICOM queue.	Informational message.
You must restart Invenia ABUS for the configuration changes to take effect.	Please restart the application.

Chapter 8

Replacement Procedures

This chapter describes how to remove and replace the system's filter and transducer.

Warnings and important information

Warnings

WARNING

Energy Control and Power Lockout for Invenia ABUS.

When servicing parts of the Invenia ABUS Scan Station where there is exposure to voltage greater than 30 volts:

1. Follow LOCKOUT/TAGOUT procedures.
2. Turn off the Power Mains Switch.
3. Unplug the Invenia ABUS Scan Station.
4. Maintain control of the Invenia ABUS Scan Station power plug.
5. Wait for at least 30 seconds for capacitors to discharge as there are no test points to verify isolation.
6. Remove/disconnect the battery, if present.

Invenia ABUS Scan Station components may be energized.

WARNING

Because of the limited access to cabinets and equipment in the field, placing people in awkward positions, GE has limited the lifting weight for one person in the field to 35 LBS (16 KG). Anything over 35 LBS (16 KG) requires 2 people.

WARNING

At least two people are needed when replacing casters (wheels) or adjusting brakes.

WARNING

Avoid contacting used parts before disinfecting.

Warnings (continued)

WARNING

DO NOT touch any boards with integrated circuits prior to taking the necessary ESD precautions.

Always connect yourself, via an arm-wrist strap, to the advised ESD connection point located on the rear of the Invenia ABUS Scan Station (near the power connector).

Follow general guidelines for handling of electrostatic sensitive equipment.

NOTE: Use an ESD compatible work space or the ESD-kit during parts replacement.

WARNING

The waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately.

Please contact the manufacturer or other authorized disposal company to decommission your equipment.

Manpower

Two people are required for:

- Anything over 35 LBS (16 KG)

Returning/shipping probes and repair parts

Equipment being returned must be clean and free of blood and other infectious substances.

GE policy states that body fluids must be properly removed from any part or equipment prior to shipment. GE employees, as well as customers, are responsible for ensuring that parts/equipment have been properly decontaminated prior to shipment. Under no circumstance should a part or equipment with visible body fluids be taken or shipped from a clinic or site (for example, body coils or an ultrasound probe). The purpose of the regulation is to protect employees in the transportation industry, as well as the people who will receive or open this package.

NOTE: The US Department of Transportation (DOT) has ruled that "items that were saturated and/or dripping with human blood that are now caked with dried blood; or which were used or intended for use in patient care" are "regulated medical waste" for transportation purposes and must be transported as a hazardous material.

Parts Disposal

Used Media and Used Parts Disposal

The waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately.

Please contact the manufacturer or other authorized disposal company to decommission your equipment.

Properly dispose of all old or used parts and media according to current policies and procedures. Never keep old software or leave old software at the customer site.

Cleaning the Filter / Replacement

Clean the filter on a monthly basis. This will also be performed by the Service Engineer during their normal PM process. To clean or replace the Filter,

Table 8-1: Cleaning the Filter

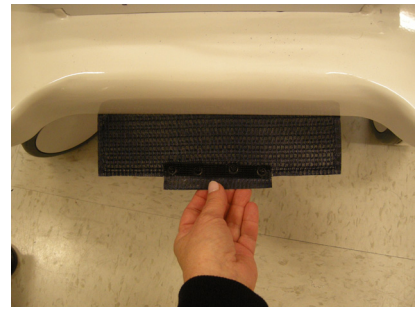
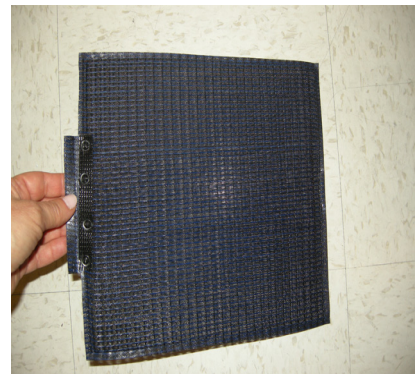
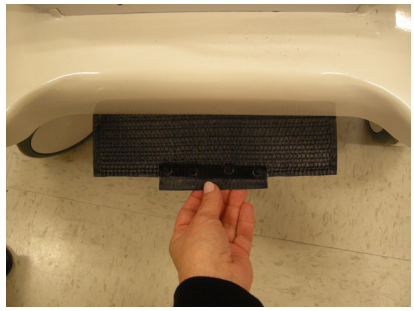
Steps	Illustrations
1. Power down the system.	
2. Remove the filter which is located on the bottom of the Scan Station. The filter is attached using Velcro.	
3. Vacuum the filter.	

Table 8-1: Cleaning the Filter

Steps	Illustrations
4. Replace the filter, velcro side up.	

Filter Replacement Functional Check

Confirm that the system:

- Powers on when you press the On/Off/Standby control.
- That the transducer moves across the Scanner Assembly.
- That the software runs through its initialization.
- That each user type (User, Admin) can successfully login to the system.
- And that the system images the patient successfully.

Replacing the Transducer

To remove the transducer,

1. Power down the system.
2. Remove the Scanner Assembly View Window and Single Use Stabilization Membrane.
3. Clean and Disinfect the transducer.
4. You will be separating the transducer (2) from the transducer connector (1). Please refer to the image below.

Figure 8-1. Transducer and Transducer Connector

Replacing the Transducer (continued)

5. Gently grab and firmly hold on to the transducer with one hand and hold the top of the transducer connector with the other hand.

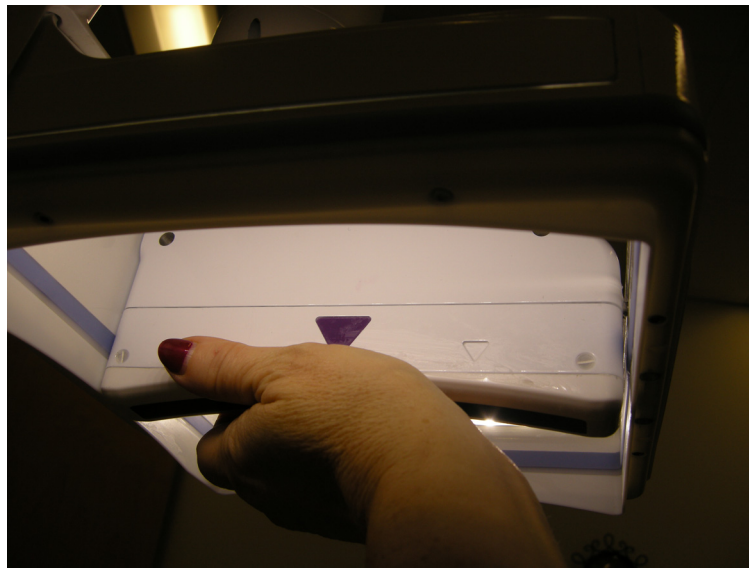


Figure 8-2. Removing the Transducer

6. Gently rock the transducer back and forth until you have released it from the Scanner Assembly.

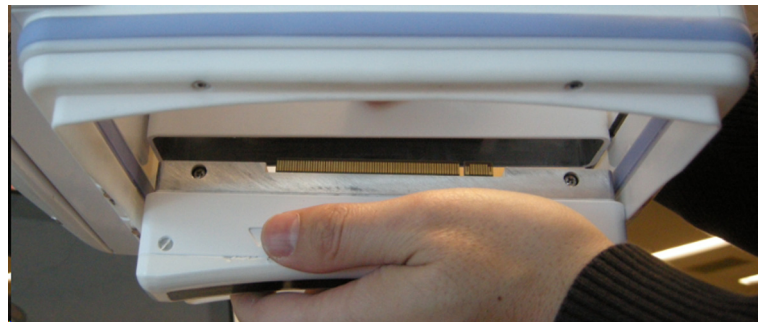


Figure 8-3. Transducer Removed from Connector

Replacing the Transducer (continued)

To replace the transducer,

1. Remove the Scanner Assembly View Window and Single Use Stabilization Membrane.
2. Firmly holding the transducer with one hand and the top of the transducer holder with the other hand, gently push the transducer into the transducer holder until it is completly seated.

Transducer Functional Check

Ensure that the transducer:

- Upon Power Up moves across the Scanner Assembly.
- That the lights on the Scanner Assembly light up.
- That the transducer images as a scan is being performed.
- That the transducer generates a 3D Volume.

B-Mode Functional Checks

Confirm that the system:

- Performs a B-Mode scan.
- Places B-Mode imaging parameters on the Touch Screen Monitor.
- Images evenly across the entire Touch Screen.

3D Volume Functional Checks

Confirm that the 3D Volume:

- Gets generated after each Scan View performed.

Performing the Exam

Confirm that the system can:

- Login the User.
- Access the Worklist and/or Enter Patient information manually.
- Perform the exam.
- Verify the exam.
- Send the exam to the Workstation / PACS.
- Perform Query/Retrieve process to PACS

Replacing the Power Cord

To remove the power cord,

1. Locate the power cord receptacle on the back of the system.

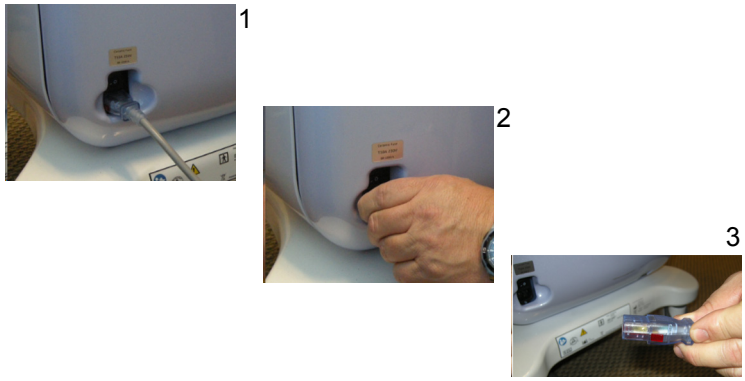


Figure 8-4.

2. Disconnect the power cord from its receptical by sliding the red tabs back and pulling the power cord straight out.

CAUTION

Removing the power cord without sliding back the red tabs may damage the system.

To replace the power cord,

1. Locate the power cord receptacle on the back of the system.
2. Align the power cord prongs to match the receptacle, then securely push the cord straight back into the receptacle.

Monitor (Touch Screen)

Replacing the Monitor

Table 8-2: Removing the Monitor

Steps	Illustrations
1. Tilt the Monitor and remove the screw securing the cover for the cable, using a #2 Phillips screwdriver.	
2. Squeeze the rear cover for the cables, as shown and slide the cover from the monitor.	
3. Disconnect the three cables from the Monitor.	

Table 8-2: Removing the Monitor (Continued)

Steps	Illustrations
4. Remove the four screws securing the Monitor to the Monitor Arm Assembly, using a #2 Phillips screwdriver. Remove the bottom screws first, then support the Monitor and remove the top two screws.	

Table 8-3: Replacing the Monitor

Steps	Illustrations
1. Install the four screws to secure the Monitor to the Monitor Arm Assembly, using a #2 Phillips screwdriver. Install the top bottom screws first to support the Monitor, then the bottom screws. Tighten securely.	
2. Reconnect the three cables to the Monitor.	

Table 8-3: Replacing the Monitor (Continued)

Steps	Illustrations
3. Squeeze the rear cover for the cables, as shown and slide the cover onto the monitor.	
4. Install the screw to secure the cover for the cable, using a #2 Phillips screwdriver.	

Functional Checks

Calibration and adjustments

Perform Touch Screen Adjustments. See Chapter 6, Touch Screen Adjustments.

Verification

Perform the following steps to verify that the product is functioning as intended after this replacement:

1. Verify that all screws that you removed earlier have been installed.
2. If finished, connect cables and Probe removed earlier.
3. Power up the system to verify that it operates as intended.

Functional Checks

Perform the following functional checks to confirm the system is operational before returning the system to the customer.

If all are successful, include the following debrief script: Invenia ABUS System Setup and Basic Service Manual, Direction 4700-0021-00, Rev. 6. Equipment passed all required checks and is ready for use.

Table 8-4: Monitor Replacement Functional Checks

See Chapter	Functional Check	Debrief Script
4	Power ON/Boot Up	Invenia ABUS System Setup and Basic Service Manual, Direction 4700-0021-00, Rev. 6. Equipment passed all required checks and is ready for use.
4	Power shut down	
4	Probe/Connectors Checks	
4	B-Mode Checks	
4	Mechanical Function Checks	

System Backup and Software Load

System Backup and Software reloading needs to be performed by trained, qualified personnel. Contact GE for training.

Notice against user modification

Never modify this product, including system components, software, cables, and so on. User modification may cause safety hazards and degradation in system performance. All modification must be done by a GE qualified person.

This equipment contains dangerous voltages that are capable of serious injury or death.

If any defects are observed or malfunctions occur, stop operating the equipment and perform the proper action for the patient. Inform a qualified service person and contact a Service Representative for information.

There are no user serviceable components inside the console. Refer all servicing to qualified service personnel only.

Ensure that unauthorized personnel do not tamper with the unit.

Internal Component Replacement

Internal System components **MUST ONLY** be serviced by trained, qualified personnel.

Contact GE for training.

- Covers and Service Table
- Scanner Assembly
- Articulating Arm and Tower
- Monitor Display
- Internal Imaging Components
- Caster Wheels

WARNING

This equipment contains dangerous voltages that are capable of serious injury or death.

If any defects are observed or malfunctions occur, stop operating the equipment and perform the proper action for the patient. Inform a qualified service person and contact a Service Representative for information.

There are no user serviceable components inside the console. Refer all servicing to qualified service personnel only.

Ensure that unauthorized personnel do not tamper with the unit.

Chapter 9

Renewal Parts

This chapter lists the renewal parts available for the Invenia ABUS. It also gives you an overview of the available Spare Parts for Invenia ABUS. In addition, probe that may be used on Invenia ABUS, are listed.

Expected Service Life

The expected service life for the Invenia ABUS is at least seven (7) years from the manufacturing date under the provision of regular maintenance by authorized service personnel.

Expected Service Life - The maximum period of useful life of the equipment in which GE guarantees repair and part's supply to keep the equipment's performance and safe for use. Beyond that period, GE may not be able to guarantee technical support and/or repair on eventual failures due to obsolescence of subcomponents or because it is no longer feasible to acquire the technology and/or parts necessary to maintain the equipment. Similarly, the expected service life of the ABUS Review Software is at least seven (7) years from the manufacturing date.

Reordering Supplies

Table 9-1: Replacement Part Numbers

Part Number/ ECAT	Description
3787-0006-00	Filter
3787-0044-00	Transducer
 3787-0013-00 3787-0017-00 3787-0014-00 3787-0021-00 3787-0015-00 3787-0022-00 3787-0023-00 3787-0011-00 3787-0012-00 3787-0019-00 3787-0020-00 3787-0018-00 3787-0016-00	Power Cords: A.C. Power Cable Switzerland A.C. Power Cable UK/Ireland A.C. Power Cable Australia A.C. Power Cable Denmark A.C. Power Cable Italy A.C. Power Cable Argentina A.C. Power Cable Israel A.C. Power Cable N.America A.C. Power Cable Europe A.C. Power Cable China A.C. Power Cable Brazil A.C. Power Cable Japan A.C. Power Cable S. Africa/India
3787-0008-00	Planar Touch Screen 17” Monitor

Table 9-2: Accessory Part Numbers

Part Number/ ECAT	Description
5486351 E8365EC	PolySonic Ultrasound Lotion (Non-Sterile) -- 8.5oz dispenser bottles
5489491 E8365EF	PolySonic Ultrasound Lotion (Non-Sterile) -- 1 US gallon with refillable dispenser
5486348 E8340AB	ABUS Single-Use Stabilization Membrane - non-Sterile, (50 pack)
2102-0121-00	Monster Cable Screen Clean LCD Touch Screen Cleaner (not available in all markets)

Table 9-2: Accessory Part Numbers

Part Number/ ECAT	Description
	• ProteX Ultra Disinfectant Wipes - 60 ct Soft-pack w/ stay-put adhesive backing (not available in all markets) • ProteX Ultra Disinfectant Wipes -- 120 ct Canister pack (not available in all markets)
	Dispatch Hospital Cleaner Disinfectant Towels with Bleach – Clorox
	Clinell Universal Wipes - GAMA Healthcare Ltd
3500-0684-00	Invenia ABUS Starter Kit:, contains: • Lotion, Ultrasound Coupling Pack, non-sterile (12 pack) • Invenia ABUS Single Use Stabilization Membrane (50 pack) • Country-specific power cords (see below)

Chapter 10

Care & Maintenance

*This chapter describes **Care and Maintenance** on the Invenia ABUS* Scan Station *and peripherals. These procedures are intended to **maintain the quality** of the Ultrasound **system's performance**. Read this chapter completely and familiarize yourself with the procedures before performing a task.*

System Care and Maintenance

Tools and Maintenance Schedule

You use the following tools and materials when performing the PM on the Invenia ABUS Scan Station and View Station:

- Digital Volt Meter
- Electrical Safety Analyzer
- Phantom with Targets
- PolySonic Ultrasound Lotion
- Disinfectant Wipes
- Monster Cable Screen Clean LCD Touch Screen Cleaner (where available) - or a generic touch screen cleaning solution.

Tools and Maintenance Schedule (continued)

Table 10-1: Maintenance Schedule

Cleaning/ Disinfecting Item	Dry, non-abrasive Cleaning Cloth	Disinfecting Wipes	Vacuum	Safety Analyzer/ Volt Meter	Calibrated Tissue Phantom	Frequency
Scanner Head Assembly	X	X				After Each Patient
Scan Station Touch Screen	X					Daily
Scan Station System Cabinet (Console, Articulating Arm, and Tower)	X	X				Weekly
Workstation Monitor and Cabinet	X	X				Weekly
Workstation Vents			X			Yearly
Filter			X			Monthly
Electrical Safety Test (Chassis)				X		Varies by Institution
Electrical Safety Test (Probe)				X		Varies by Institution
Quality Assurance Test with Calibrated Tissue Phantom					X	

Varies. Criteria to Consider:
- Every 3 Months
- After 400 Patients
- After Service Calls
- After the system has been upgraded
- Dropped Probe
- After Power Surge

Invenia ABUS Specific Information

Automated Breast Ultrasound Scan (ABUS) Station

Perform the following to ensure the Invenia ABUS is performing optimally:

- Visual Inspection
- Mechanical Inspection
- Electrical Inspection
- Scanning Inspection

Visual Inspection

To perform a Visual Inspection:

1. Power down the system.
2. Inspect system (Touch Screen, Scanner Assembly, Cables, Power Cord, Workstation); then clean and disinfect surfaces that come into contact with body parts.
   a. Clean the system with a cloth dampened with soap and water.
   b. Use the Transducer's wipes to disinfect the system.

NOTE: *Do not use alcohol to clean or disinfect the transducer.*

3. Inspect the Scanner Assembly for mechanical noise and damage by performing the following checks:
   - Upon Power Up the transducer initializes (moves across the Scanner Assembly from the left to the right and then right to left until stopping in the center of the Scanner Assembly).
   - That the lights on the Scanner Assembly light up when you log in to the Invenia ABUS.

Visual Inspection (continued)

4. Clean and disinfect the Scanner Assembly. Refer to the User Manual for more information
   a. Remove and dispose of the Single Use Stabilization Membrane, if previously used.

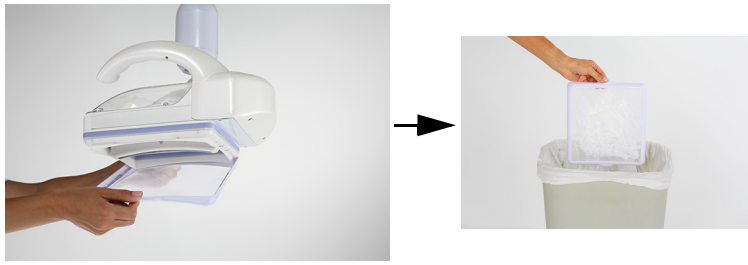


Figure 10-1. Removing and Disposing of the Single Use Stabilization Membrane

CAUTION

Ensure the single-use stabilization membrane is completely removed from the scanner assembly after every use. Visually inspect the underside of the Single Use Stabilization Membrane to insure two (2) small metal plates are present before disposing. If one or more of the small metal plates has come loose from the Single Use Stabilization Membrane, check scanner assembly and remove and dispose of the metal plate(s).

Visual Inspection (continued)

b. Use disinfectant wipes to wipe away lotion from the Scanner Assembly. You can also use a soft, lightly dampened cloth in a mild soap or detergent solution to clean way the residual lotion and other debris from the patient contact areas prior to disinfecting.

Figure 10-2. Remove to Clean Plastic View Window

CAUTION

Be sure to properly seat the Plastic View Window securely after cleaning.

Visual Inspection (continued)

c. Remove and clean the plastic View Window of the Scanner Assembly.

Figure 10-3. Wipe Away Lotion

Visual Inspection (continued)

d. Use transducer disinfectant wipe to clean all portions of the transducer and Scanner Assembly that comes in contact with the patient's breast.

Figure 10-4. Disinfect Transducer Surface

Visual Inspection (continued)

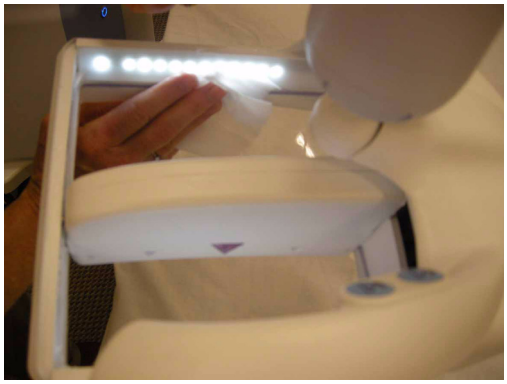


Figure 10-5. Disinfect Scanner Assembly

CAUTION

DO NOT use an alcohol-based solution to clean the transducer.

CAUTION

Inspect Transducer for wear.

CAUTION

DO NOT use disinfectant spray directly on the Invenia ABUS transducer and/or scanner assembly. Unintended overspray of the disinfectant may enter unsealed areas of the Invenia ABUS transducer and scanner assembly mechanism causing harm to the components.

Instead, spray disinfectant spray directly onto a dry cloth, and then use the cloth to wipe the Invenia ABUS transducer and/or scanner assembly.

Visual Inspection (continued)

5. Check the Touch Screen monitor for defects.
6. Check Monitor cables for defects.
7. Check the AC power cord for insulation, overheating, and mechanical connection.
8. Clean the filter on the system, using a vacuum.

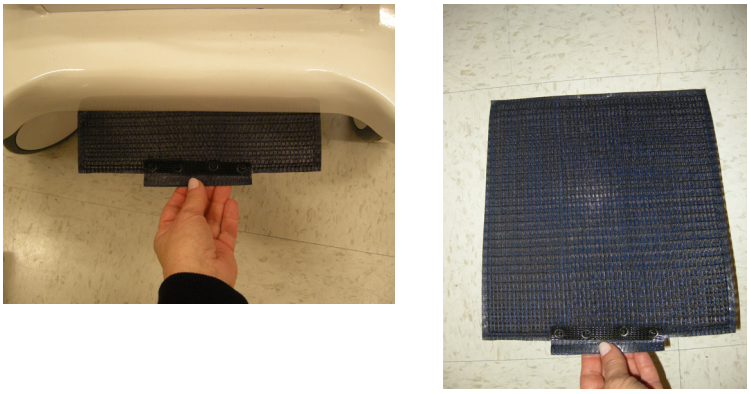


Figure 10-6. Filter Locations

9. Clean the Touch Screen. For maximum performance and clarity, use a Touch Screen cleaning solution to remove fingerprints and smudges on a daily basis.

Mechanical Inspection

To perform a Mechanical Inspection:

1. Inspect system casters for braking ability and integrity.
2. Inspect the Articulating Arm tension. Arm and head should stay in the location where it is moved to. It should not ‘creep.’ If the Scanner head rises or lowers when it is not held, an adjustment can be made to the weight tower.

   Contact GE Service, or qualified and trained Service personnel, to make needed adjustments.
3. Clean the Touch Screen.
   a. Turn off the Touch Screen monitor.
   b. Using the LCD-approved cleaning kit, clean the Touch Screen.
   c. Turn the Touch Screen back on and verify calibration is still accurate.
4. Remove Single Use Stabilization Membrane from Scanner Head to test Single Use Stabilization Membrane Present Sensor.

Electrical Inspection

To perform the Electrical Inspection:

Electrical safety tests

Overview

WARNING

Energy Control and Power Lockout for Invenia ABUS.

When servicing parts of the Invenia ABUS Scan Station where there is exposure to voltage greater than 30 volts:

1. Follow LOCKOUT/TAGOUT procedures.
2. Turn off the Power Mains Switch.
3. Unplug the Invenia ABUS Scan Station.
4. Maintain control of the Invenia ABUS Scan Station power plug.
5. Wait for at least 30 seconds for capacitors to discharge as there are no test points to verify isolation.

Invenia ABUS Scan Station components may be energized.

WARNING

This equipment contains dangerous voltages that are capable of serious injury or death.

If any defects are observed or malfunctions occur, stop operating the equipment and perform the proper action for the patient. Inform a qualified service person and contact a Service Representative for information.

There are no user serviceable components inside the console. Refer all servicing to qualified service personnel only.

Ensure that unauthorized personnel do not tamper with the unit.

The warranty is void if covers have been removed.

Electrical safety tests (continued)

NOTE: For all instructions in the "Electrical safety tests" section in case of using a UPS (uninterruptible power supply) the terms outlet, wall outlet, AC wall outlet and power outlet refer to the AC power outlet of the UPS. In case of further available AC (or DC) power outlets at the same used UPS, these must remain unused i.e. not connected to any other devices.

The following topics and measurements are covered in this subsection:

- 'Safety test overview' on *page 10-14*
- 'Leakage current limits' on *page 10-17*
- 'Grounding continuity' on *page 10-20*
- 'Chassis leakage current test' on *page 10-21*
- 'Probe leakage current test' on *page 10-25*

Safety test overview

WARNING

Energy Control and Power Lockout for Invenia ABUS.

When servicing parts of the Invenia ABUS Scan Station where there is exposure to voltage greater than 30 volts:

1. Follow LOCKOUT/TAGOUT procedures.
2. Turn off the Power Mains Switch.
3. Unplug the Invenia ABUS Scan Station.
4. Maintain control of the Invenia ABUS Scan Station power plug.
5. Wait for at least 30 seconds for capacitors to discharge as there are no test points to verify isolation.

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This equipment contains dangerous voltages that are capable of serious injury or death.

If any defects are observed or malfunctions occur, stop operating the equipment and perform the proper action for the patient. Inform a qualified service person and contact a Service Representative for information.

There are no user serviceable components inside the console. Refer all servicing to qualified service personnel only.

Ensure that unauthorized personnel do not tamper with the unit.

The warranty is void if covers have been removed.

The electrical safety tests in this section are based on NFPA 99 Standard for Health Care Facilities and IEC 62353 Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment. These standards provide guidance on evaluating electrical safety of medical devices which are placed into service and are intended for use in planned maintenance (PM) or testing following service or repair activities. They differ somewhat from the standards that are used for design verification and manufacturing tests (e.g., IEC 60601-1 and UL 60601-1) which require a controlled test environment and can place unnecessary stress on the Invenia ABUS Scan Station.

Electrical safety tests (continued)

These tests may refer to specific safety analyzer equipment as an example. Always refer to the safety analyzer's user manual that will be used to perform the tests.

Prior to initiating any electrical test, the Invenia ABUS Scan Station must be visually inspected. Perform the following visual checks:

- Check for missing or loose enclosure covers that could allow access to internal live parts.
- Examine the mains cord, mains plug and appliance inlet for damaged insulation and adequacy of strain relief and cable clamps.
- Locate and examine transducer. Inspect the cables and strain relief at each end. Inspect the transducer enclosure and lens for cracks, holes and similar defects.

Safety test overview (continued)

Equipment users must ensure that safety inspections are performed whenever damage is suspected and at least every 12 months in accordance with local authorities and facility procedures. Do not use the Ultrasound system or individual probes which fail any portion of the safety test.

W  WARNING

To minimize risk of electric shock, only trained persons are allowed to perform the electrical safety inspections and tests.

C  CAUTION

To avoid electrical shock, the Invenia ABUS Scan Station under test **MUST NOT** be connected to other electrical equipment. Remove all interconnecting cables and wires. The Invenia ABUS Scan Station under test must not be contacted by users or patients while performing these tests.

C  CAUTION

Possible risk of infection. Do not handle soiled or contaminated probes and other components that have been in patient contact. Follow appropriate cleaning and disinfecting procedures before handling the equipment.

Leakage current limits

WARNING

Energy Control and Power Lockout for Invenia ABUS.

When servicing parts of the Invenia ABUS Scan Station where there is exposure to voltage greater than 30 volts:

1. Follow LOCKOUT/TAGOUT procedures.
2. Turn off the Power Mains Switch.
3. Unplug the Invenia ABUS Scan Station.
4. Maintain control of the Invenia ABUS Scan Station power plug.
5. Wait for at least 30 seconds for capacitors to discharge as there are no test points to verify isolation.

Invenia ABUS Scan Station components may be energized.

WARNING

This equipment contains dangerous voltages that are capable of serious injury or death.

If any defects are observed or malfunctions occur, stop operating the equipment and perform the proper action for the patient. Inform a qualified service person and contact a Service Representative for information.

There are no user serviceable components inside the console. Refer all servicing to qualified service personnel only.

Ensure that unauthorized personnel do not tamper with the unit.

The warranty is void if covers have been removed.

The following acceptance limits and test conditions are summarized from NFPA 99 and IEC 62353 and in some cases are lower than that specified by the standards.

In accordance with these standards, fault conditions like Reverse Polarity of the supply mains and Open Neutral are no longer required for field evaluation of leakage current. Because the main source of leakage current is the mains supply, there are different acceptance limits depending on the configuration of the mains (100-130, 220-240, or 230-240).

CAUTION

Compare all safety-test results with safety-test results of previously performed safety tests (e.g. last year etc). In case of unexplainable abrupt changes of safety-test results consult experienced authorized service personnel or GE for further analysis.

Leakage current limits (continued)

Table 10-2: Leakage current limits for Invenia ABUS Scan Station operation on 100-130 Volt mains (US/Canada/Japan)

Leakage Current Test	System Power	Grounding/ PE Conductor	Limit mA
Chassis/Enclosure Leakage	On and Off	Open	0.3
Type BF Applied Parts	On (transmit)	Closed Open	0.1 0.5
Type BF Applied Parts (sink leakage, mains voltage on applied part)	On and Off	Closed	5

NOTE: Open Grounding is also known as "Lift Ground".

Table 10-3: Leakage current limits for Invenia ABUS Scan Station operation on 220-240 Volt mains

Leakage Current Test	System Power	Grounding/ PE Conductor	Limit mA
Chassis/Enclosure Leakage	On	Open and Closed	0.5
Type BF Applied Parts	On (transmit)	Closed Open	0.1 0.5
Type BF Applied Parts (sink leakage, mains voltage on applied part)	On and Off	Closed	5

Leakage current limits (continued)

Table 10-4: ISO and Mains Applied Limits*

Probe Type	Measurement
BF	5.0 mA

*ISO and Mains Applied refers to the sink leakage test where mains (supply) voltage is applied to the part to determine the amount of current that will pass (or sink) to ground if a patient is in contact with mains voltage.

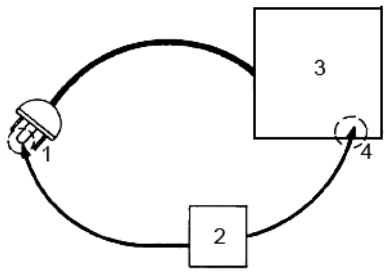
Table 10-5: Equipment Type and Test Definitions

Applied Parts (AP)	Parts or accessories that contact the patient to perform their function. For ultrasound equipment, this includes transducers and ECG leads.	
Type BF	Body Floating or non-conductive ultrasound probes which are marked with the 'man in box' BF symbol. this includes all transducers.	
Sink Leakage	The current resulting from the application of mains voltage to the applied part. This test is required for Type BF applied parts.	

Grounding continuity

DANGER ELECTRIC SHOCK HAZARD. THE PATIENT MUST NOT BE CONTACTED TO THE EQUIPMENT DURING THIS TEST.

Measure the resistance from the third pin of the attachment plug to the exposed metal parts of the case. The ground wire resistance should be less than **300** milliohms.



1. GROUND PIN
2. OHMMETER
3. Invenia ABUS
4. CASTER/WHEEL LOCK NUT

Figure 10-7. Ground continuity test

Chassis leakage current test

DANGER ELECTRIC SHOCK HAZARD. WHEN THE METER'S GROUND SWITCH IS OPEN, DON'T TOUCH THE Invenia ABUS Scan Station!.

CAUTION Equipment damage possibility. **NEVER switch the Polarity and the status of Neutral when the Invenia ABUS** Scan Station **is powered ON (booted up).** Be sure to turn the Invenia ABUS Scan Station power OFF before switching them using the POLARITY switch and/or the NEUTRAL switch. Otherwise, the Invenia ABUS Scan Station may be damaged.

Definition

This test, also known as Enclosure Leakage current test, measures the current that would flow through a grounded person who touches the accessible conductive parts of the equipment during normal and fault conditions.

The test verifies the isolation of the power line from the chassis.

The testing meter is connected to parts of the equipment, easily contacted by the user or patient.

Measurements should be made under the test specifications as found in:

- Table 10-2 *on page 10-18*

  or
- Table 10-3 *on page 10-18*

  as applicable.

Record the highest reading.

Invenia ABUS Scan Station procedure

The test verifies the isolation of the power line from the chassis.

The testing meter is connected from accessible metal parts of the case to ground.

*NOTE: The system is **not** booted up (powered off with Power Mains Switch On).*

1. Connect Safety analyzer to wall AC power outlet.
2. Plug the equipment under test power cable into the receptacle on the panel of the meter.
3. Unscrew the ball joint screw just enough turns to allow ground clip to make contact with out removing the screw.
4. Connect the meter to the Ball Joint Screw using the cable provided with the meter.

Figure 10-8. Ball Joint Screw Ground Clip Location

Invenia ABUS Scan Station procedure (continued)

5. Select the Chassis or Enclosure leakage function on the meter.

NOTE: For more information, refer to the safety analyzer's user manual.

6. Push the open ground switch and record the leakage current using table 10.5 or 10.6.

NOTE: For more information, refer to the safety analyzer's user manual that will be used to perform the tests."

The maximum allowable limit for chassis source leakage is shown in:

- Table 10-2 *on page 10-18*, or Table 10-3 *on page 10-18*

Data sheet for enclosure/chassis leakage current

Table 10-6 *on page 10-24* or Table 10-7 *on page 10-33* shows a typical format for recording the enclosure/chassis leakage current.

NOTE: Values in italics font are given as examples only.

Record all data in the Electrical safety tests log.

Table 10-6: Typical data format for recording enclosure/chassis leakage (Fluke 175)

Unit under test_____ **Date of test:**_____			
Test Conditions			**Measurement/Test Point Location**
Power On/Off S1	**Polarity S2**	**Grounding/PE S3**	**System**
Off	normal	open	
Off	reverse	open	
on	normal	open	
on	reverse	open	

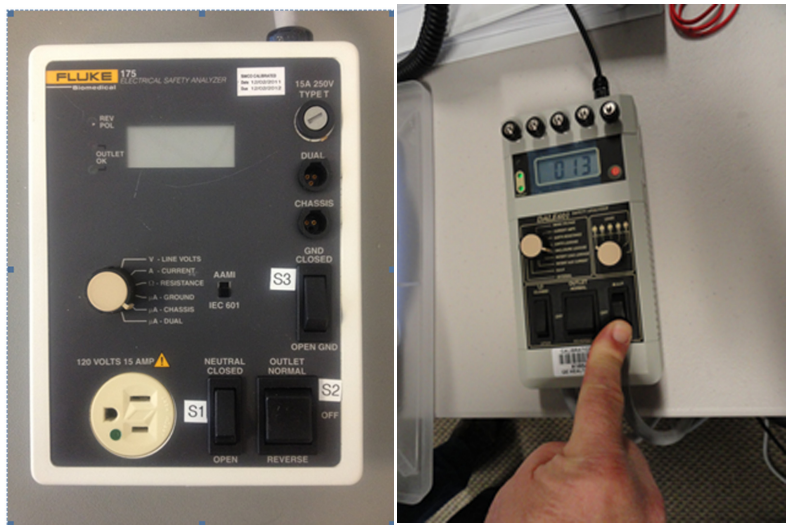


Figure 10-9. Fluke Meter (left) and Dale Meter (right)

NOTE: The meters depicted are for reference only.

Probe leakage current test

Definition

This test measures the current that would flow to ground from any of the probes through a patient who is being scanned and becomes grounded by touching some other grounded surface.

Invenia ABUS procedure on probe leakage current

The most common method of measuring probe leakage is to partly immerse the probe into a saline bath while the probe is connected to the Invenia ABUS Scan Station and RF active. This method measures the actual leakage current resulting while the RF drive is active to the transducer RF drive.

This test is also known as Patient Auxiliary Current.

1. Turn the Invenia ABUS **OFF**:
2. Connect Safety analyzer to wall AC power outlet.
3. Set the Safety analyzer's function switch to “Chassis” or “Enclosure Leakage” (depending on the meter).
4. Set meter switches to:
   - L2 - Closed (Dale meter) or Neutral (Fluke meter)
   - Outlet - Normal
5. Plug the Invenia ABUS’s power cord into the test meter.
6. Plug the Chassis Ground Probe clip (saline probe clip) into the test meter's “CHASSIS” connector.

Invenia ABUS procedure on probe leakage current (continued)

7. Prepare the transducer for testing:
   a. Obtain a plastic tray (at least 11”x15”x1”).
   b. Obtain a sponge (at least 7”x3”x1”).
   c. Saturate the sponge with saline solution.

NOTE: *The Saline solution can be a mixture of water and salt. The salt adds free ions to the water, making it conductive. Normal saline solution is 0.9% salt and 99.1% water. If ready-mixed saline solution is not available, a mixture of 1 quart or 1 liter water with 9 or more grams of table salt, mixed thoroughly, will substitute.*

   d. Place the sponge in the plastic tray.
   e. Clip the saline probe clip to the sponge.

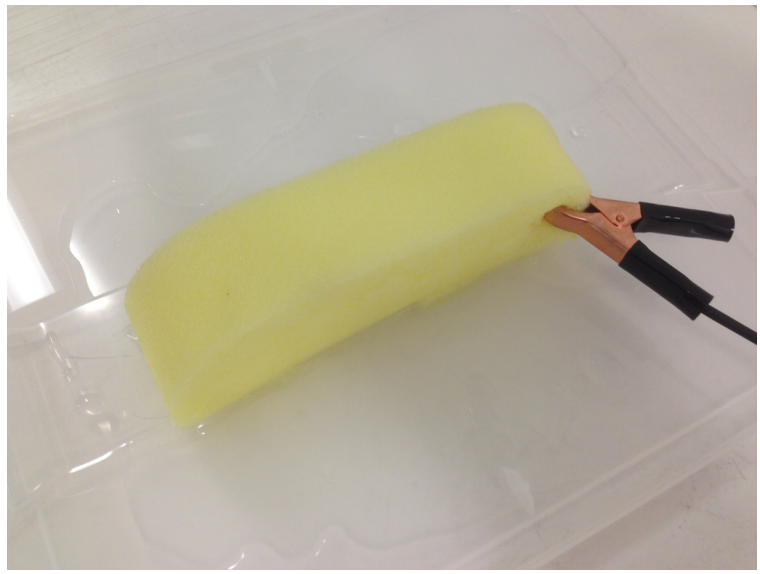


Figure 10-10. Clip Sponge

Invenia ABUS procedure on probe leakage current (continued)

8. Power ON the Invenia ABUS.
   a. After the Invenia ABUS unit has completed the boot process, create an exam by entering Patient ID, Last Name, and First Name. Energize the probe with RF power by clicking on the “Image” tab. DO NOT start the exam.
   b. Press down on the Scanner Assembly such that the probe has good contact against the saturated sponge.
   c. Immerse the Ultrasound Probe’s probe face (imaging area of the probe) onto the saline-saturated sponge.

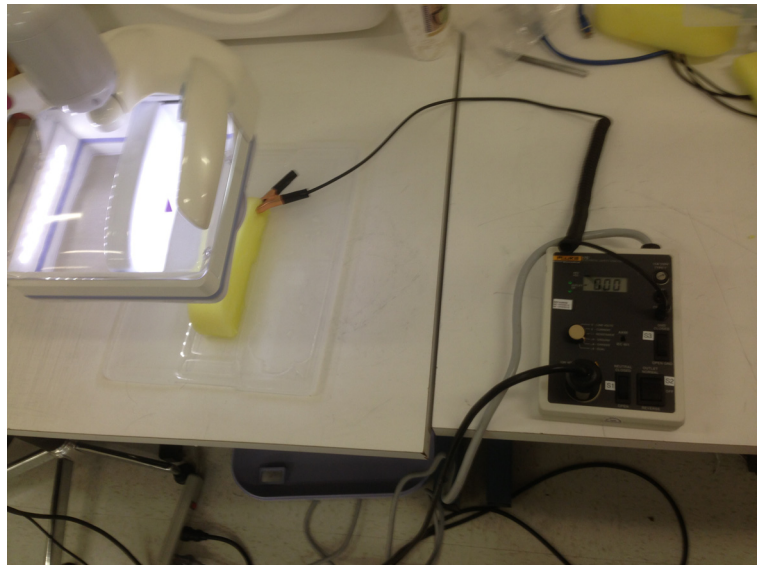


Figure 10-11. Immersing the Probe in the Saline Bath

Invenia ABUS procedure on probe leakage current (continued)

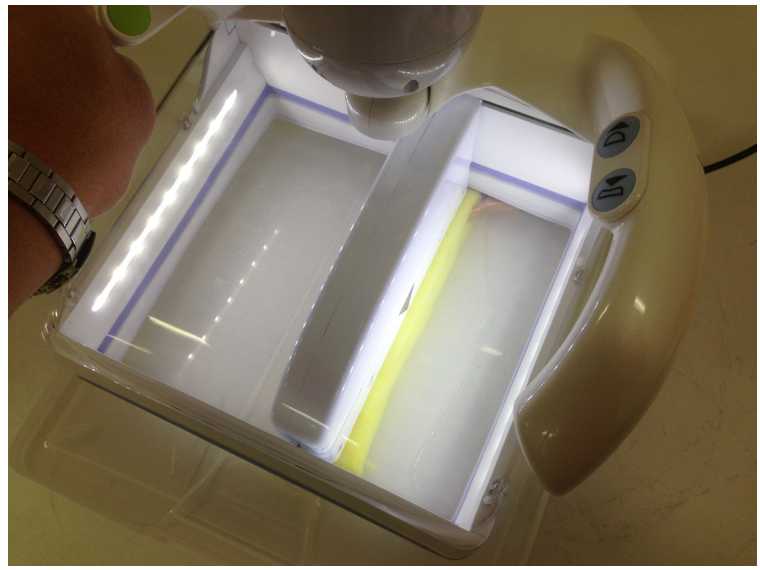


Figure 10-12. Immersing the Probe in the Saline Bath

d. Record leakage values.
e. End the exam on the Invenia ABUS system.
f. Log off the Invenia ABUS system.

9. Turn the Invenia ABUS **OFF**:
10. Repeat above steps with reverse polarity.
11. Set meter to:
    - L2 - Closed (Dale meter) or Neutral (Fluke meter)
    - Outlet - Reverse

Invenia ABUS procedure on probe leakage current (continued)

12. The test passes when all readings measure less than the stated limits. See Table 10-2 *on page 10-18*, or Table 10-3 *on page 10-18*

    Keep a record of the results with other hard copies of maintenance data.

Reference Materials

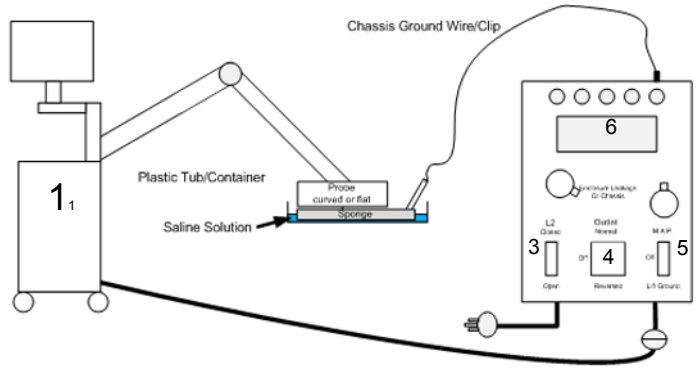


Figure 10-13. Dale Meter

1. Scan Station
2. Tester
3. Neutral Switch or L2
4. Outlet Switch
5. Ground Switch
6. Meter Readout
7. Saline-Saturated Sponge
8. Probe
9. Electrical Clip

Reference Materials (continued)

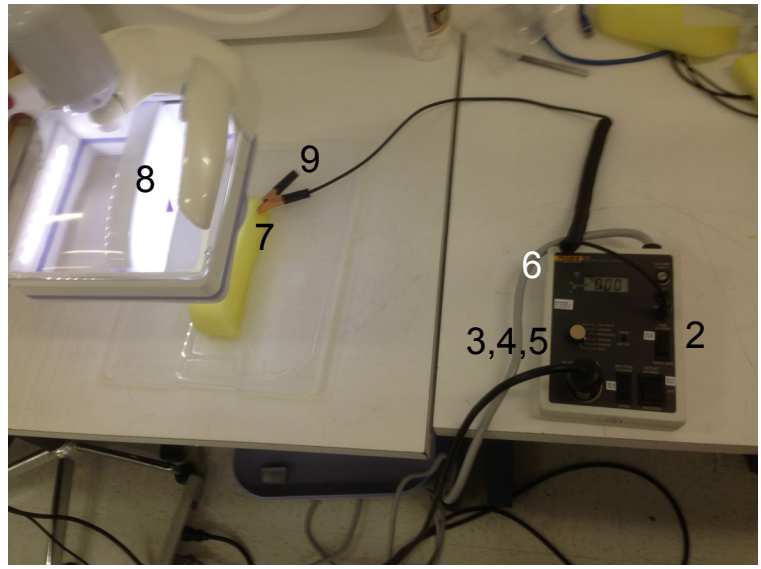


Figure 10-14. Set up for Probe Leakage Current

NOTE: Follow manufacturer's recommendations for handling saline solution. Refer to their Material Safety Data Sheet (MSDS) for more information.

Invenia ABUS procedure on probe leakage current (continued)

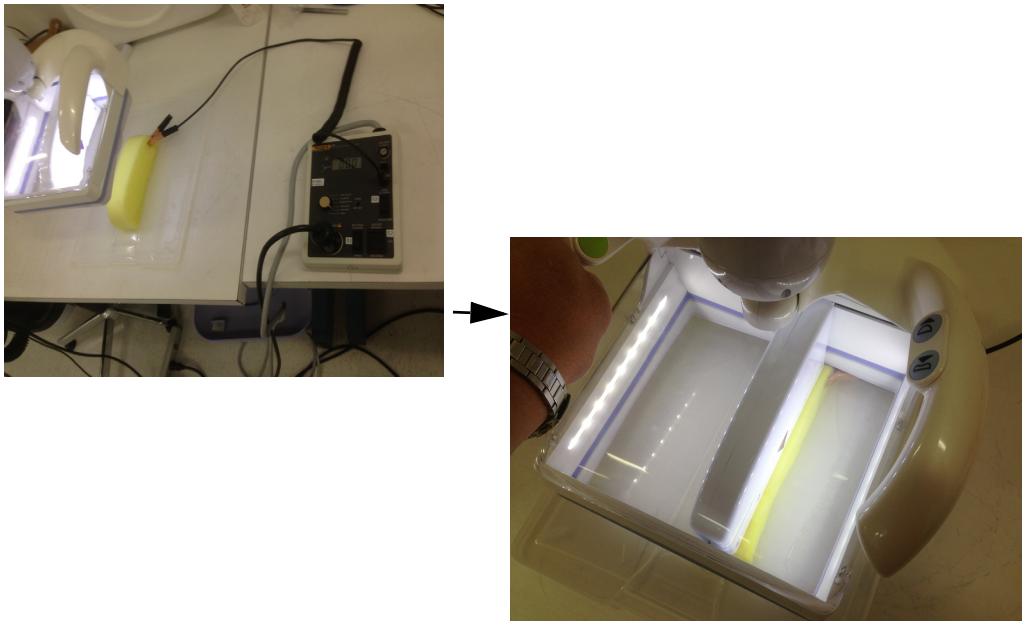


Figure 10-15. Immersing Transducer in Saline

Invenia ABUS procedure on probe leakage current (continued)

DANGER TO AVOID PROBE DAMAGE AND POSSIBLE ELECTRIC SHOCK, DO NOT IMMERSE PROBES INTO ANY LIQUID BEYOND THE LEVEL INDICATED IN THE USER'S MANUAL. **DO NOT TOUCH THE PROBE, CONDUCTIVE LIQUID OR ANY PART OF THE UNIT UNDER TEST WHILE DOING THE TEST**.

Follow the test conditions and test limits described in:

- Table 10-2 *on page 10-18*

  or

- Table 10-3 *on page 10-18*

  as applicable for every probe.

Keep a record of the results with other hard copies of maintenance data using Table 10-6 *on page 10-24*.

CAUTION Equipment damage possibility. Never switch the Polarity or the status of the Neutral when the Invenia ABUS Scan Station is powered on. Power off the Invenia ABUS Scan Station, allow the stored energy to bleed down, and turn the Power Mains Switch off BEFORE switching the POLARITY switch and/or the NEUTRAL switch on the leakage meter to avoid possible power supply damage.

NOTE: Values in italics font are given as examples only.

Table 10-7: Probe Leakage Test

	Power on/ off L2	Polarity/ Outlet	Ground/ MAP	Reading	Pass/Fail Less than 0.5 mA
Probe Leakage Test	On	Normal	Open		
Probe Leakage Test	On	Reversed	Open		
	Power on/off L2	Polarity/Outlet	Ground/MAP	Reading	Pass/Fail Less than 0.5 mA
Probe Leakage Test	On	Normal	Closed		
Probe Leakage Test	On	Reversed	Closed		

Mains on applied part

NOTE: Mains Applied refers to the sink leakage test where mains (supply) voltage is applied to the part to determine the amount of current that will pass (or sink) to ground if a patient contacted mains voltage.

Mains on applied part is one of the described leakage current tests applicable for probes (Ref: IEC60601-1). This is to be performed with the probe disconnected from the Invenia ABUS Scan Station. Apply mains voltage over the insulation barrier. (Between protective earth on the probe connector, and an electrical clip in contact with the saline-saturated sponge. The patient-applied part of the probe is in contact with the saline-saturated sponge.) Measure current flowing in the circuit. = leakage current.

As a minimum, tests according to IEC60601-1 must be performed once a year.

The test passes when the reading measure less than the values in:

- Table 10-2 *on page 10-18*.

When there's too much leakage current …

Chassis Fails

Check the ground on the power cord and plug for continuity. Ensure the ground is not broken, frayed, or intermittent. Replace any defective part.

Where applicable, tighten all grounds. Ensure star washers are under all ground studs.

Inspect wiring for bad crimps, poor connections, or damage.

Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.

NOTE: No outlet tester can detect the condition where the white neutral wire and the green grounding wire are reversed. If later tests indicate high leakage currents, this should be suspected as a possible cause and the outlet wiring should be visually inspected.

Still Fails

If all else fails, begin isolation by removing the probes, external peripherals, then the on board ones, one at a time while monitoring the leakage current measurement.

Where applicable, in the case of using a UPS (uninterruptible power supply), perform the tests in the “Electrical Safety tests” section without using the UPS (i.e. directly connect the Invenia ABUS Scan Station to the AC wall outlet). If this leads to a pass result, the specific UPS must no longer be used.

New Unit

If the leakage current measurement tests fail on a new Invenia ABUS Scan Station and if situation can not be corrected, submit a Safety Failure Report to document the Invenia ABUS Scan Station problem. Remove Invenia ABUS Scan Station from operation.

Scanning Inspection

To complete the Scanning Inspection:

1. Verify correct system date and time in Setup Menu.
2. Set the system to the manual Work Item Input on the Worklist Configuration page via “Default Select Page.” Then enter patient information with “Quality Check” as the patient name. Verify functionality.
3. Using a phantom, perform a scan. After each scan is complete touch the monitor to set the Nipple Marker.

   The scanner should be able to resolve targets as close to each other as 0.5mm. The penetration depth depends on the phantom (or more precisely the attenuation of the phantom) and with this particular phantom is beyond 5cm. Since we do not image beyond 5cm there would be no way for the service person to measure it.

NOTE: *Phantoms may require maintenance and periodic calibrations. Ensure this is performed per manufacturer instructions.*

Phantom Specifications:

- Small parts phantom
- Lateral and axial resolution are 0.5 +- 0.1mm.
- Penetration depth > 5cm.
- Gray scale resolution better than 3dB. Phantom has a target (or targets) that look like circles that result in 3dB higher intensity than the background material. If you can see the target then the resolution is 3dB or better if you cannot then it is worse than 3dB.

NOTE: *Please refer to more information on the phantom in the Quality Assurance section later in this chapter.*

Scanning Inspection (continued)

4. Select the Medial Scan View. The Image Orientation on the Touch Screen rotates 180 degrees. Rotate the Scanner Assembly to match the image orientation on the Touch Screen (Item 3 in the image below).

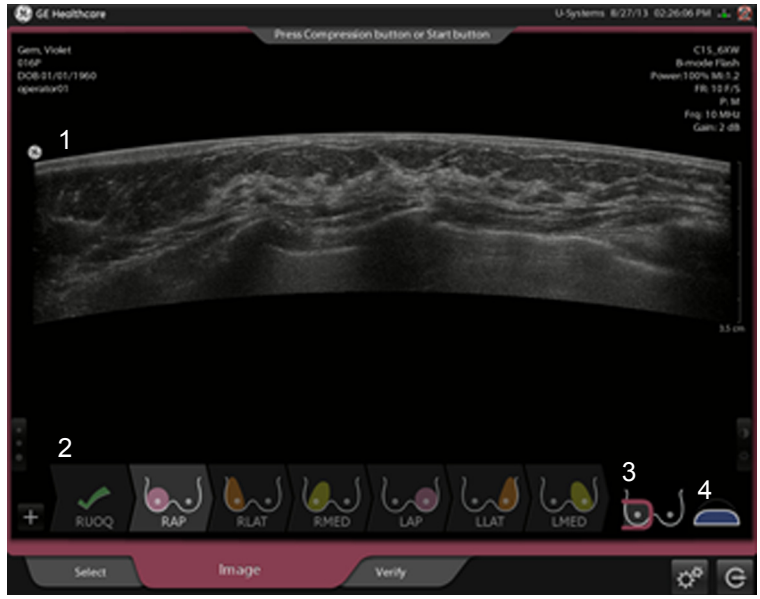


Figure 10-16. Imaging Screen

NOTE: Confirm Scan Orientation changes according to the scan view selected (refer to the Invenia ABUS Scan Station Basic User Manual for more information).

5. Start another scan and verify the ability to abort a scan by pressing the Red Abort button on the Scanner Head Assembly left-handle.
6. Verify that the system re-initializes after the system has aborted the scan after having pressed the Abort button and touched the screen.
7. Record and confirm Scan Station and Workstation Network Configuration and Customer settings.

Scanning Inspection (continued)

8. Record and confirm Scan Station, Workstation, and Probe Name/Model/Serial Numbers.
9. Check InSite.
10. Confirm DICOM services.
11. Confirm Invenia ABUS Scan Station and Workstation connectivity.
12. Confirm PACS operation, including Q/R process.
    a. Send the image to the PACS by reviewing/signing the report. Be sure the Workstation is set for Auto Export.
    b. Confirm that the study is on the PACS.
    c. Delete the image from the Workstation via the Study Browser.
    d. Query the PACS from the Workstation via the Study Browser.
    e. Retrieve the study from the PACS back to the Workstation via the Image Browser.
13. Perform Functional Checks (refer to Chapter 4 for more information).
14. Evaluate Customer Probe Care Maintenance, Cleaning, and Disinfection.
15. Confirm Labelling is present.
16. Perform physical inspection of Workstation (clean monitor, check power cord, etc.).

Workstation

You need to perform the following:

- Visual Inspection
- Save Workstation Presets
- Save the Presets on the Workstation, if applicable

Visual Inspection

To perform the Visual Inspection:

1. Clean and dust monitor, keyboard and mouse.
2. Check and clean airflow vents and power supply vent. Vacuum, if needed
3. Verify cabling on Monitor.
4. Power on the Workstation and verify normal boot.
5. Select setup and verify date and time match the scan station.
6. Inspect monitor for any display issues.
7. Verify “Phantom Test” scan did transfer to the Workstation. Inspect scan for image quality. (Missing elements, penetration -- Refer to the Workstation Basic User Manual, Chapter 8, “Invenia ABUS Review Software Image Quality Assessment” section, for more information).
8. Measure vertical and horizontal distance accuracy and lateral resolution Pass/Fail.
9. Copy the image and save to a jumpdrive or save to a folder on the Workstation.
10. Verify normal mouse movements and speed.

Quality Assurance

Introduction

A good Quality Assurance Evaluation program consists of periodic systematic checks that provide the user with adequate confidence that their diagnostic Invenia ABUS Scan Station will produce consistently high quality images and quantitative information.

Therefore, it is in the best interests of every ultrasound user to routinely monitor equipment performance.

Contact GE Service to perform the Image Quality Check.

Quality assurance evaluation program responsibilities for image quality check:

Table 10-8: Required Personnel

Flat Phantom	Curved Phantom
GE authorized personnel or trained customer personnel	GE authorized personnel

Introduction (continued)

The frequency of Quality Assurance evaluations should be based on user's specific needs and clinical practice.

Periodic monitoring is essential in order to detect the performance changes that occur through normal aging of system components. Routine equipment evaluations may also reduce the duration of exams, number of repeat exams, and maintenance time required.

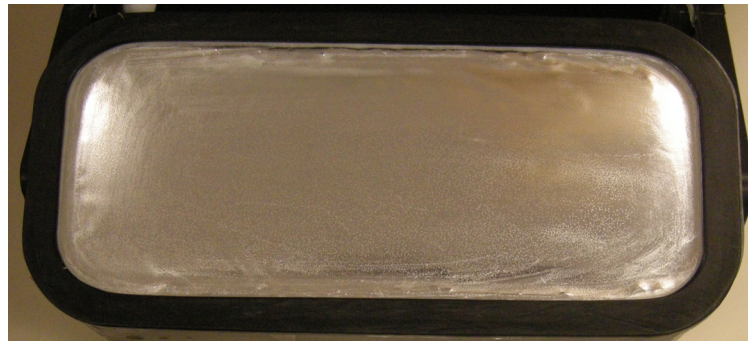


Figure 10-17. Sample Phantom

Typical Tests to Perform

Quality assurance measurements provide results relating to system performance. Typically these are:

- Axial Measurement Accuracy
- Lateral Measurement Accuracy
- Axial and Lateral Resolution
- Penetration
- Functional & Contrast Resolution
- Gray Scale.

With these tests, a performance baseline can be set at installation with the phantom in your department. Future test results can be compared to the baseline in order to maintain a record of system performance trends.

NOTE: Also plan to run these tests if there has been a service event that impacts the image quality, such as a probe replacement or system board replacement.

The phantom shown is shown as a representative example of a phantom. You can select from any number of phantoms available on the market.

Frequency of tests

Quality assurance tests are used to determine whether a scanner is providing the same level of performance from day to day.

The frequency of testing varies with the amount of system usage and modes to be tested. It is recommended that the user perform quality assurance tests at least every three months or every 400 patient studies. Tests should also be performed when a question about system performance exists.

Image quality should also be tested immediately after the following events:

- Service calls
- System upgrades/modifications
- Power surge, etc.

Phantoms

Quality Assurance Evaluations may be done with phantoms and test objects that are applicable to the parameters being evaluated or to the user's clinical practice.

Typical phantoms are composed of material that acoustically mimic human tissue. Pins, anechoic and echogenic targets are physically positioned to provide information for a variety of tests.

A sample phantom is shown in the illustration below as a representative example of a phantom.

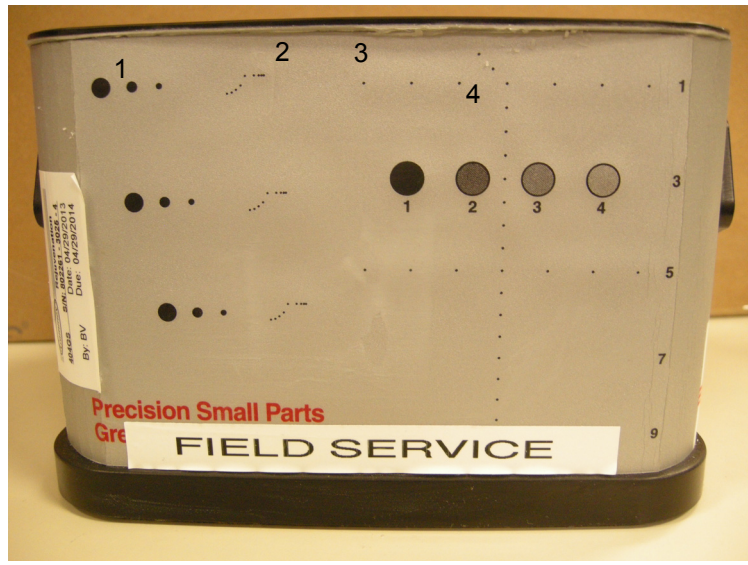


Figure 10-18. Example of Curved Phantom

1. Vertical-Horizontal Line Targets
2. Axial-Lateral Resolution Array
3. Anechoic Target Structures
4. Gray Scale Target Structures

Phantoms (continued)

Sample of Using a Flat Phantom Scan Examples

Figure 10-19. Apply Lotion Liberally and Position Transducer

WARNING

Take care when pressing on the phantom **NOT** to press on the edges of the phantom with the probe.

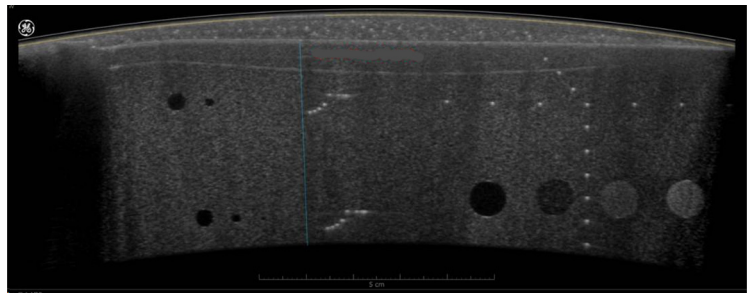


Figure 10-20. Representative Phantom Image

Phantoms (continued)

Baselines

An absolute necessity for a quality assurance program is establishing baselines for each test or check. Baselines are established after the system has been verified to be working properly at installation or after a repair. If a probe or major assembly is replaced, new baselines should be generated.

Baselines can be made by adjusting system parameters to prescribed levels or to the best possible image. The key factor to remember is reproducibility. The same conditions must be reproduced for each periodic check.

All system parameters not displayed on the monitor should be recorded for the permanent record.

Periodic Checks

Periodic checks should be performed in accordance with your facility's quality assurance requirements. For the data to be valid, periodic checks should mimic the baseline setup, power level, and display depth.

The resulting image, when scanning the phantom exactly as before, should be recorded and compared to the baseline. When a matching image is obtained, it can be assumed that the system performance has not degraded from the baseline.

If a significant difference between the baseline and periodic check is noted, double check the system setup and repeat the test. If the difference between the baseline and periodic check persists, contact a local Service Representative.

Failing to reproduce the control settings as in the baselines will introduce errors in the data and potentially invalidate the results.

Phantoms (continued)

Results

Lack of standardization among test instruments, the wide range of acceptance criteria, and incomplete knowledge regarding the significance of certain performance parameters prohibit the establishment of absolute performance criteria for these tests.

Quality Assurance Evaluation results should be compared to previously-recorded results.

Performance trends can then be detected. Unacceptable performance or diminishing trends should be identified for maintenance or repair before a malfunction or inappropriate diagnosis occurs.

The user should determine the best method for recording and archiving the baseline and periodic checks. In most cases the choice is hard copy.

It is important to maintain good consistent records for inspections that may arise, as well as to detect system performance trends.

System Setup

The user should tailor the tests to their particular needs. A representative example should be adequate in judging system performance trends.

Use a gray scale phantom as the scan object for the tests. Commercial phantoms are supplied with its own operator manual. Be familiar with proper phantom operating procedures prior to use for quality assurance evaluations.

Phantoms (continued)

Test Procedures

The following are recommended Quality Assurance tests. A brief description of the test, the benefit it provides and steps to accomplish the test are supplied.

The importance of recording scan parameters and consistent record keeping cannot be stressed enough. Reproducibility to monitor system trends is the key to quality assurance evaluations.

Because of the large size of the transducer, the transducer will make contact with the casing of many phantoms.

If undue pressure is applied on the scanner, the transducer may be damaged where it makes contact with the hard edges of the phantom.

To avoid damage to the transducer while scanning a phantom, do not apply any downward force using the system's Compression Assist function.

Gently press the scanner on the phantom, holding it with two hands, maintaining it level with the surface of the phantom. Use large amounts of lotion to bridge the gap between the flat surface of the phantom and the curved surface of the transducer.

Using a phantom, perform a scan. After each scan is complete touch the monitor to set the Nipple Marker.

- The scanner should be able to resolve targets as close to each other as 0.5mm. The penetration depth depends on the phantom (or more precisely the attenuation of the phantom). Phantoms with attenuation 0.5dB MHz^{-1} cm^{-1}.

  Phantom Specifications:

  - Small parts tissue-mimicking phantom
  - Lateral and axial resolution targets of 0.5 +/- 0.1mm
  - Attenuation of 0.5dB MHz^{-1} cm^{-1}
  - At least 8 cm depth
  - +/- 6dB gray level targets
  - Speed of sound=1540m/sec

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