

# Vanguard 8Ch Tabletop Coil for GE Signa 1.5T HDx Installation and Service Manual

**Manufactured By:**



Sentinelle Medical Inc.

**Distributed By:**



GE Healthcare

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## Damage in Transportation

All packages should be closely examined at time of delivery. If damage is apparent, have notation “**damage in shipment**” written on **all** copies of the freight or express bill **before** delivery is accepted or “signed for” by a General Electric or Sentinelle Medical representative or a hospital receiving agent. 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.

To file a report with GE:

Call 1–800–548–3366 and use option 6.

Fill out a report on <http://edq.health.ge.com/edq/home.jsp>.

Contact your local service coordinator for more information on this process.

To file a report with Sentinelle:

Call 1-866-735-3744 and use option 1.

# ATTENTION!

A GE field engineer or a Sentinelle Medical Field Service Technician **MUST** perform the installation of this coil. Please contact the field engineer from the company which sold the product to arrange for installation.

Attempts to perform installation of this coil without proper system configuration will result in system errors.

<b>ПРЕДУПРЕЖДЕНИЕ</b> E (BG)	<p>Това упътване за работа е налично само на английски език.</p> <ul style="list-style-type: none"> <li>• Ако доставчикът на услугата на клиента изиска друг език, задължение на клиента е да осигури превод.</li> <li>• Не използвайте оборудването, преди да сте се консултирали и разбрали упътването за работа.</li> <li>• Неспазването на това предупреждение може да доведе до нараняване на доставчика на услугата, оператора или пациента в резултат на токов удар, механична или друга опасност.</li> </ul>
<b>警告</b> (ZH-CN)	<p>本维修手册仅提供英文版本。</p> <ul style="list-style-type: none"> <li>• 如果客户的维修服务需要非英文版本，则客户需自行提供翻译服务。</li> <li>• 未仔细阅读和完全理解本维修手册之前，不得进行维修。</li> <li>• 忽略本警告可能对维修服务人员、操作人员或患者造成电击、机械伤害或其他形式的伤害。</li> </ul>
<b>警告</b> (ZH-HK)	<p>本服務手冊僅提供英文版本。</p> <ul style="list-style-type: none"> <li>• 倘若客戶的服務供應商需要英文以外之服務手冊，客戶有責任提供翻譯服務。</li> <li>• 除非已參閱本服務手冊及明白其內容，否則切勿嘗試維修設備。</li> <li>• 不遵從本警告或會令服務供應商、網絡供應商或病人受到觸電、機械性或其他形式的危險。</li> </ul>
<b>警告</b> (ZH-TW)	<p>本維修手冊僅有英文版。</p> <ul style="list-style-type: none"> <li>• 若客戶的維修廠商需要英文版以外的語言，應由客戶自行提供翻譯服務。</li> <li>• 請勿試圖維修本設備，除非 懇請查閱並瞭解本維修手冊。</li> <li>• 若未留意本警告，可能導致維修廠商、操作員或病患因觸電、機械或其他危險而受傷。</li> </ul>
<b>UPOZORENJE</b> (HR)	<p>Ovaj servisni priručnik dostupan je na engleskom jeziku.</p> <ul style="list-style-type: none"> <li>• Ako davatelj usluge klijenta treba neki drugi jezik, klijent je dužan osigurati prijevod.</li> <li>• Ne pokušavajte servisirati opremu ako niste u potpunosti pročitali i razumjeli ovaj servisni priručnik.</li> <li>• Zanimarite li ovo upozorenje, može doći do ozljede davatelja usluge, operatera ili pacijenta uslijed strujnog udara, mehaničkih ili drugih rizika.</li> </ul>
<b>VÝSTRAHA</b> (CS)	<p>Tento provozní návod existuje pouze v anglickém jazyce.</p> <ul style="list-style-type: none"> <li>• V případě, že externí služba zákazníkům potřebuje návod v jiném jazyce, je zajištění překladu do odpovídajícího jazyka úkolem zákazníka.</li> <li>• Nesnažte se o údržbu tohoto zařízení, aniž byste si přečetli tento provozní návod a pochopili jeho obsah.</li> <li>• V případě nedodržování této výstrahy může dojít k poranění pracovníka prodejního servisu, obslužného personálu nebo pacientů vlivem elektrického proudu, respektive vlivem mechanických či jiných rizik.</li> </ul>
<b>ADVARSEL</b> (DA)	<p>Denne servicemanual findes kun på engelsk.</p> <ul style="list-style-type: none"> <li>• Hvis en kundes tekniker har brug for et andet sprog end engelsk, er det kundens ansvar at sørge for oversættelse.</li> <li>• Forsøg ikke at servicere udstyret uden at læse og forstå denne servicemanual.</li> <li>• Manglende overholdelse af denne advarsel kan medføre skade på grund af elektrisk stød, mekanisk eller anden fare for teknikerens, operatøren eller patienten.</li> </ul>
<b>WAARSCHUWING</b> G (NL)	<p>Deze onderhoudshandleiding is enkel in het Engels verkrijgbaar.</p> <ul style="list-style-type: none"> <li>• Als het onderhoudspersoneel een andere taal vereist, dan is de klant verantwoordelijk voor de vertaling ervan.</li> <li>• Probeer de apparatuur niet te onderhouden alvorens deze onderhoudshandleiding werd geraadpleegd en begrepen is.</li> <li>• Indien deze waarschuwing niet wordt opgevolgd, zou het onderhoudspersoneel, de operator of een patiënt gewond kunnen raken als gevolg van een elektrische schok, mechanische of andere gevaren.</li> </ul>
<b>WARNING</b> (EN)	<p>This service manual is available in English only.</p> <ul style="list-style-type: none"> <li>• If a customer's service provider requires a language other than english, it is the customer's responsibility to provide translation services.</li> <li>• Do not attempt to service the equipment unless this service manual has been consulted and is understood.</li> <li>• Failure to heed this warning may result in injury to the service provider, operator or patient from electric shock, mechanical or other hazards.</li> </ul>
<b>HOIATUS</b> (ET)	<p>See teenindusjuhend on saadaval ainult inglise keeles</p> <ul style="list-style-type: none"> <li>• Kui klienditeeninduse osutaja nõuab juhendit inglise keelest erinevas keeles, vastutab klient tõlketeenuse osutamise eest.</li> <li>• Ärge üritage seadmeid teenindada enne eelnevalt käesoleva teenindusjuhendiga tutvumist ja sellest aru saamist.</li> <li>• Käesoleva hoiatuse eiramine võib põhjustada teenuseosutaja, operaatori või patsiendi vigastamist elektrilöögi, mehaanilise või muu ohu tagajärjel.</li> </ul>
<b>VAROITUS</b> (FI)	<p>Tämä huolto-ohje on saatavilla vain englanniksi.</p> <ul style="list-style-type: none"> <li>• Jos asiakkaan huoltohenkilöstö vaatii muuta kuin englanninkielistä materiaalia, tarvittavan käännöksen hankkiminen on asiakkaan vastuulla.</li> <li>• Älä yritä korjata laitteistoa ennen kuin olet varmasti lukenut ja ymmärtänyt tämän huolto-ohjeen.</li> <li>• Mikäli tätä varoitusta ei noudateta, seurauksena voi olla huoltohenkilöstön, laitteiston käyttäjän tai potilaan vahingoittuminen sähköiskun, mekaanisen vian tai muun vaaratilanteen vuoksi.</li> </ul>
<b>ATTENTION</b> (FR)	<p>Ce manuel d'installation et de maintenance est disponible uniquement en anglais.</p> <ul style="list-style-type: none"> <li>• Si le technicien d'un client a besoin de ce manuel dans une langue autre que l'anglais, il incombe au client de le faire traduire.</li> <li>• Ne pas tenter d'intervenir sur les équipements tant que ce manuel d'installation et de maintenance n'a pas été consulté et compris.</li> <li>• Le non-respect de cet avertissement peut entraîner chez le technicien, l'opérateur ou le patient des blessures dues à des dangers électriques, mécaniques ou autres.</li> </ul>

<b>WARNUNG</b> (DE)	<p>Diese Serviceanleitung existiert nur in englischer Sprache.</p> <ul style="list-style-type: none"> <li>• Falls ein fremder Kundendienst eine andere Sprache benötigt, ist es Aufgabe des Kunden für eine entsprechende Übersetzung zu sorgen.</li> <li>• Versuchen Sie nicht diese Anlage zu warten, ohne diese Serviceanleitung gelesen und verstanden zu haben.</li> <li>• Wird diese Warnung nicht beachtet, so kann es zu Verletzungen des Kundendiensttechnikers, des Bedieners oder des Patienten durch Stromschläge, mechanische oder sonstige Gefahren kommen.</li> </ul>
<b>ΠΡΟΕΙΔΟΠΟΙΗΣΗ</b> H (EL)	<p>Το παρόν εγχειρίδιο σέρβις διατίθεται μόνο στα αγγλικά.</p> <ul style="list-style-type: none"> <li>• Εάν ο τεχνικός σέρβις ενός πελάτη απαιτεί το παρόν εγχειρίδιο σε γλώσσα εκτός των αγγλικών, αποτελεί ευθύνη του πελάτη να παρέχει τις υπηρεσίες μετάφρασης.</li> <li>• Μην επιχειρήσετε την εκτέλεση εργασιών σέρβις στον εξοπλισμό αν δεν έχετε συμβουλευτεί και κατανοήσει το παρόν εγχειρίδιο σέρβις.</li> <li>• Αν δεν προσέξετε την προειδοποίηση αυτή, ενδέχεται να προκληθεί τραυματισμός στον τεχνικό σέρβις, στο χειριστή ή στον ασθενή από ηλεκτροπληξία, μηχανικούς ή άλλους κινδύνους.</li> </ul>
<b>FIGYELMEZTETÉS</b> ÉS (HU)	<p>Ezen karbantartási kézikönyv kizárólag angol nyelven érhető el.</p> <ul style="list-style-type: none"> <li>• Ha a vevő szolgáltatója angoltól eltérő nyelvre tart igényt, akkor a vevő felelőssége a fordítás elkészíttetése.</li> <li>• Ne próbálja elkezdni használni a berendezést, amíg a karbantartási kézikönyvben leírtakat nem értelmezték.</li> <li>• Ezen figyelmeztetés figyelmen kívül hagyása a szolgáltató, működtető vagy a beteg áramütés, mechanikai vagy egyéb veszélyhelyzet miatti sérülését eredményezheti.</li> </ul>
<b>ADVÖRUN</b> (IS)	<p>Þessi þjónustuhandbók er aðeins fánleg á ensku.</p> <ul style="list-style-type: none"> <li>• Ef að þjónustuveitandi viðskiptamanns þarfnast annas tungumáls en ensku, er það skylda viðskiptamanns að skaffa tungumálþjónustu.</li> <li>• Reynið ekki að afgreiða tækið nema að þessi þjónustuhandbók hefur verið skoðuð og skilin.</li> <li>• Brot á sinna þessari aðvörun getur leitt til meiðsla á þjónustuveitanda, stjórnanda eða sjúklings frá raflosti, vérlænu eða öðrum áhættum.</li> </ul>
<b>AVVERTENZA</b> (IT)	<p>Il presente manuale di manutenzione è disponibile soltanto in lingua inglese.</p> <ul style="list-style-type: none"> <li>• Se un addetto alla manutenzione richiede il manuale in una lingua diversa, il cliente è tenuto a provvedere direttamente alla traduzione.</li> <li>• Procedere alla manutenzione dell'apparecchiatura solo dopo aver consultato il presente manuale ed averne compreso il contenuto.</li> <li>• Il mancato rispetto della presente avvertenza potrebbe causare lesioni all'addetto alla manutenzione, all'operatore o ai pazienti provocate da scosse elettriche, urti meccanici o altri rischi.</li> </ul>
<b>警告</b> (JA)	<p>このサービスマニュアルには英語版しかありません。</p> <p><input type="checkbox"/> 纏ヒスを担当される業者が英語以外の言語を要求される場合、翻訳作業はその業者の責任で行うものとさせていただきます。</p> <p><input type="checkbox"/> 纏ヒのサービスマニュアルを熟読し理解せずに、装置のサービスを行わないでください。</p> <p><input type="checkbox"/> の警告に従わない場合、サービスを担当される方、操作員あるいは患者 <input type="checkbox"/> さんが、感電や機械的又はその他の危険により負傷する可能性があります。</p>
<b>가</b> (KO)	<p>가</p>
<b>BRĪDINĀJUMS</b> (LV)	<p>Šī apkopes rokasgrāmata ir pieejama tikai angļu valodā.</p> <ul style="list-style-type: none"> <li>• Ja klienta apkopes sniedzējam nepieciešama informācija citā valodā, klienta pienākums ir nodrošināt tulkojumu.</li> <li>• Neveiciet aprikojuma apkopi bez apkopes rokasgrāmatas izlasīšanas un saprašanas.</li> <li>• Šī brīdinājuma neievērošanas rezultātā var rasties elektriskās strāvas trieciena, mehānisku vai citu faktoru izraisītu traumu risks apkopes sniedzējam, operatoram vai pacientam.</li> </ul>
<b>ĮSPĖJIMAS</b> (LT)	<p>Šis eksploatavimo vadovas yra tik anglų kalba.</p> <ul style="list-style-type: none"> <li>• Jei kliento paslaugų tiekėjas reikalauja vadovo kita kalba – ne anglų, suteikti vertimo paslaugas privalo klientas.</li> <li>• Nemėginkite atlikti įrangos techninės priežiūros, jei neperskaitėte ar nesupratote šio eksploatavimo vadovo.</li> <li>• Jei nepaisysite šio įspėjimo, galimi paslaugų tiekėjo, operatoriaus ar paciento sužalojimai dėl elektros šoko, mechaninių ar kitų pavojų.</li> </ul>
<b>ADVARSEL</b> (NO)	<p>Denne servicehåndboken finnes bare på engelsk.</p> <ul style="list-style-type: none"> <li>• Hvis kundens serviceleverandør har bruk for et annet språk, er det kundens ansvar å sørge for oversettelse.</li> <li>• Ikke forsøk å reparere utstyret uten at denne servicehåndboken er lest og forstått.</li> <li>• Manglende hensyn til denne advarselen kan føre til at serviceleverandøren, operatøren eller pasienten skades på grunn av elektrisk støt, mekaniske eller andre farer.</li> </ul>
<b>OSTRZEŻENIE</b> (PL)	<p>Niniejszy podręcznik serwisowy dostępny jest jedynie w języku angielskim.</p> <ul style="list-style-type: none"> <li>• Jeśli serwisant klienta wymaga języka innego niż angielski, zapewnienie usługi tłumaczenia jest obowiązkiem klienta.</li> <li>• Nie próbować serwisować urządzenia bez zapoznania się z niniejszym podręcznikiem serwisowym i zrozumienia go.</li> <li>• Niezastosowanie się do tego ostrzeżenia może doprowadzić do obrażeń serwisanta, operatora lub pacjenta w wyniku porażenia prądem elektrycznym, zagrożenia mechanicznego bądź innego.</li> </ul>
<b>AVISO</b> (PT-BR)	<p>Este manual de assistência técnica encontra-se disponível unicamente em inglês.</p> <ul style="list-style-type: none"> <li>• Se outro serviço de assistência técnica solicitar a tradução deste manual, caberá ao cliente fornecer os serviços de tradução.</li> <li>• Não tente reparar o equipamento sem ter consultado e compreendido este manual de assistência técnica.</li> <li>• A não observância deste aviso pode ocasionar ferimentos no técnico, operador ou paciente decorrentes de choques elétricos, mecânicos ou outros.</li> </ul>

<b>ATENÇÃO</b> (PT-PT)	<p>Este manual de assistência técnica só se encontra disponível em inglês.</p> <ul style="list-style-type: none"> <li>· Se qualquer outro serviço de assistência técnica solicitar este manual noutra idioma, é da responsabilidade do cliente fornecer os serviços de tradução.</li> <li>· Não tente reparar o equipamento sem ter consultado e compreendido este manual de assistência técnica.</li> <li>· O não cumprimento deste aviso pode colocar em perigo a segurança do técnico, do operador ou do paciente devido a choques eléctricos, mecânicos ou outros.</li> </ul>
<b>ATENȚIE</b> (RO)	<p>Acest manual de service este disponibil doar în limba engleză.</p> <ul style="list-style-type: none"> <li>· Dacă un furnizor de servicii pentru clienți necesită o altă limbă decât cea engleză, este de datoria clientului să furnizeze o traducere.</li> <li>· Nu încercați să reparați echipamentul decât ulterior consultării și înțelegerii acestui manual de service.</li> <li>· Ignorarea acestui avertisment ar putea duce la rănirea depanatorului, operatorului sau pacientului în urma pericolelor de electrocutare, mecanice sau de altă natură.</li> </ul>
<b>ОСТОРОЖНО!</b> (RU)	<p>Данное руководство по техническому обслуживанию представлено только на английском языке.</p> <ul style="list-style-type: none"> <li>· Если сервисному персоналу клиента необходимо руководство не на английском, а на каком-то другом языке, клиенту следует самостоятельно обеспечить перевод.</li> <li>· Перед техническим обслуживанием оборудования обязательно обратитесь к данному руководству и поймите изложенные в нем сведения.</li> <li>· Несоблюдение требований данного предупреждения может привести к тому, что специалист по техобслуживанию, оператор или пациент получит удар электрическим током, механическую травму или другое повреждение.</li> </ul>
<b>UPOZORENJE</b> (SR)	<p>Ovo servisno uputstvo je dostupno samo na engleskom jeziku.</p> <ul style="list-style-type: none"> <li>· Ako klijentov serviser zahteva neki drugi jezik, klijent je dužan da obezbedi prevodilačke usluge.</li> <li>· Ne pokušavajte da opravite uređaj ako niste pročitali i razumeli ovo servisno uputstvo.</li> <li>· Zanemarivanje ovog upozorenja može dovesti do povređivanja serviser, rukovaoca ili pacijenta usled strujnog udara ili mehaničkih i drugih opasnosti.</li> </ul>
<b>UPOZORNENIE</b> (SK)	<p>Tento návod na obsluhu je k dispozícii len v angličtine.</p> <ul style="list-style-type: none"> <li>· Ak zákazníkovi poskytovateľ služieb vyžaduje iný jazyk ako angličtinu, poskytnutie prekladateľských služieb je zodpovednosťou zákazníka.</li> <li>· Nepokúšajte sa o obsluhu zariadenia, kým si neprečítate návod na obsluhu a neporozumiete mu.</li> <li>· Zanedbanie tohto upozornenia môže spôsobiť zranenie poskytovateľa služieb, obsluhujúcej osoby alebo pacienta elektrickým prúdom, mechanické alebo iné ohrozenie.</li> </ul>
<b>ATENCION</b> (ES)	<p>Este manual de servicio sólo existe en inglés.</p> <ul style="list-style-type: none"> <li>· Si el encargado de mantenimiento de un cliente necesita un idioma que no sea el inglés, el cliente deberá encargarse de la traducción del manual.</li> <li>· No se deberá dar servicio técnico al equipo, sin haber consultado y comprendido este manual de servicio.</li> <li>· La no observancia del presente aviso puede dar lugar a que el proveedor de servicios, el operador o el paciente sufran lesiones provocadas por causas eléctricas, mecánicas o de otra naturaleza.</li> </ul>
<b>WARNING</b> (SV)	<p>Den här servicehandboken finns bara tillgänglig på engelska.</p> <ul style="list-style-type: none"> <li>· Om en kunds servicetekniker har behov av ett annat språk än engelska, ansvarar kunden för att tillhandahålla översättningstjänster.</li> <li>· Försök inte utföra service på utrustningen om du inte har läst och förstår den här servicehandboken.</li> <li>· Om du inte tar hänsyn till den här varningen kan det resultera i skador på serviceteknikern, operatören eller patienten till följd av elektriska stötar, mekaniska faror eller andra faror.</li> </ul>
<b>OPOZORILO</b> (SL)	<p>Ta servisni priročnik je na voljo samo v angleškem jeziku.</p> <ul style="list-style-type: none"> <li>· Če ponudnik storitve stranke potrebuje priročnik v drugem jeziku, mora stranka zagotoviti prevod.</li> <li>· Ne poskušajte servisirati opreme, če tega priročnika niste v celoti prebrali in razumeli.</li> <li>· Če tega opozorila ne upoštevate, se lahko zaradi električnega udara, mehanskih ali drugih nevarnosti poškoduje ponudnik storitev, operater ali bolnik.</li> </ul>
<b>DİKKAT</b> (TR)	<p>Bu servis kılavuzunun sadece ingilizcesi mevcuttur.</p> <ul style="list-style-type: none"> <li>· Eğer müşteri teknisyeni bu kılavuzu ingilizce dışında bir başka lisandan talep ederse, bunu tercüme ettirmek müşteriye düşer.</li> <li>· Servis kılavuzunu okuyup anlamadan ekipmanlara müdahale etmeyiniz.</li> <li>· Bu uyarıya uyulmaması, elektrik, mekanik veya diğer tehlikelerden dolayı teknisyen, operatör veya hastanın yaralanmasına yol açabilir.</li> </ul>

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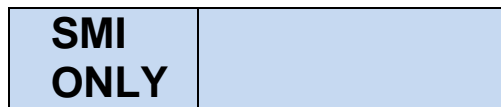
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**Note:**

There are sections in this manual that apply only to Sentinelle Medical (SMI) personnel or GE Healthcare (GEHC) personnel. These sections are noted using the following symbols.



**OR**



GE FE's shall only service systems that were sold by GEHC. Coils sold by GEHC will have a "Distributed by GE Healthcare" label next to the rating plate on the underside of the patient support.

## 1 Purpose

The purpose of this manual is to provide detailed instructions to an SMI Service Technician or a GEHC field engineer for installation, testing, service and maintenance of the Vanguard on compatible 1.5T 8ch GE MRI scanners. The Troubleshooting Table outlines the required steps to methodically assess and correct the reported problem(s).

Information reported from the site contact explaining the problem is paramount and the Service Technician must record the details. The Service Technician must carefully gather and interpret the information received from the site contact, to ensure all details are enclosed to enable the problem to be quickly diagnosed and repaired.

## 2 Compatibility

This device is compatible with GE Signa HDi/HDx/HDxt/Vibrant 8ch 1.5T MRI Scanners with a 60cm bore. Software version of HD16.0\_V02 with Service Pack 1 is required to use the coil; however, software version HD23.0\_V01 with Service Pack 1 or later is recommended for better performance.

## 3 Service Tools Required

The tools defined in this section are all that are required to perform all service procedures in this manual. Many of these tools are included in the standard toolkit.

### 3.1 Primary Tools

Many of these tools are included in the standard toolkit. Equivalent tools may be used. Note that only non-magnetic tools may be used in the magnet room.

Item	GEHC Part #	SMI Part #	Qty	Description
1	5109895-13	-	1	Slot screwdriver medium
2	5109892-6	-	1	Allen Wrench 1/8"
3	5109892-3	-	1	Allen Wrench 5/64"

### 3.2 Consumables

All of these items are included in the standard service toolkit and/or the consumables FRU kit (P/N 4001157-11, GEHC P/N 5408246).

Item	GEHC Part #	SMI Part #	Qty	Description
1	N/A	1-444-29021	1	Loctite Green 290 Wicking, 50mL
2	N/A	1659A2	2	Latch Grab Strike/Catch
3	N/A	20205CN040000	4	4-40 X 1/4 BRS PHMS
4	N/A	20205CN060000	4	6-32 X 1/4 BRS Button Hex Sock Cap Screw
5	N/A	20205FN100004	4	10-32X3/4 BRS Button Hex Socke Cap Screw
6	N/A	S-11712	40	1" White Velcro Line Hook Side
7	N/A	S-11713	40	1" White Velcro Line Loop Side

### 3.3 General Safety Requirements



Follow all required safety and PPE procedures customary for your organization when working on this product.

- Wear safety shoes for foot protection.
- Wear gloves for hand protection.
- Wear safety glasses for eye protection.

### 3.3.1 Occupational Exposure to Infectious Agents

Installing and servicing the Vanguard requires visiting medical facilities which present infection hazards, especially from possible exposure to pathogens found in blood and other potentially infectious bodily materials. Pathogens are microorganisms that can cause disease when transmitted from an infected individual to another individual through blood and certain other body materials. The most common illnesses caused by blood borne pathogens (BBPs) are hepatitis B (HBV), hepatitis C (HCV), and acquired immunodeficiency syndrome (AIDS) from HIV, human immunodeficiency virus. These blood borne pathogens are capable of causing serious illness and death.



**Failure to adhere to these procedures and precautions may result in infection, serious illness and death.**

#### Types of Hazardous Exposure

Hazardous exposures which may occur in medical facilities include:

- Percutaneous inoculations or punctures with blood or body fluid by a sharp instrument or needle.
- Contact with blood or body fluid through a fresh cut (less than 24 hours from occurrence) or mucous membrane contact (e.g., a splash to the eye or mouth, or mouth-to-mouth resuscitation).
- Skin exposure involving large amounts of blood or prolonged contact with blood, especially when the exposed skin is chapped, abraded, or afflicted with dermatitis.

#### Avoiding Exposure

Before beginning work at a medical facility where you may encounter potential infection hazards:

- Ensure that you have had a Hepatitis B vaccination.
- Before beginning to work on equipment, check carefully for signs of blood or body fluids.
- If you notice possible blood or body fluids on the equipment, report it to the responsible facility personnel and have them clean the equipment using their institutional infection control procedures.
- If there is a reasonable expectation of the presence of infectious materials, do not work on the equipment until it is disinfected.
- As a precautionary measure, wear personal protective equipment including gloves, protective eye covering and disposable clothing whenever the potential to be exposed to blood or other potentially infected materials exist.

#### After Exposure

If you contact a potentially infectious blood or body fluid:

- Seek immediate medical assistance.
- Advise your supervisor of the exposure event.

<b>GEHC ONLY</b>	<ul style="list-style-type: none"> <li>· If you have previously refused vaccination to Hepatitis B, GE must offer the vaccination to you at this time at no charge.</li> <li>· As part of the investigation process, contact the GE medical team to assist in identifying the status of source individuals.</li> </ul>
------------------	--

- Document the incident for your employer and the facility where the incident occurred:
  - If feasible, document the name and address of the individual source of the possible infection.
  - Document the time, place, and circumstances of the contact.

## 4 Definitions and Abbreviations

Throughout this document the following terms and abbreviations will be used:

<b>FRU</b>	Field Replaceable Unit
<b>Installation Verification Checklist</b>	SMI-0834 VG TT Installation Verification
<b>Left/Right</b>	Directions relative to the patient lying in prone position
<b>MCQA</b>	Multi Coil Quality Assurance
<b>Patient Support</b>	Mechanical structure supporting the patient
<b>Service Toolkit</b>	SMI-0294 Toolkit utilized by SMI Field Service Technician
<b>SMI</b>	Sentinelle Medical Incorporated
<b>User Manual</b>	SMI-0517 VG TT User Manual

## 5 Performing Service

### 5.1 Precautions

Before entering the MRI Room with the Vanguard system the following activities must be performed:

- Thoroughly inspect the system to ensure loose ferrous/magnetic items are not present anywhere on the system. Loose objects can become airborne and/or travel at high velocity in the presence of the scanner, potentially causing harm to the Patient, Operator or equipment.

<b>SMI ONLY</b>	<ul style="list-style-type: none"> <li>· Do not attempt to make any changes or adjustments to the GE scanner or accessories. If any damage to the GE scanner is observed, report to the customer.</li> <li>· Do not touch metal pins of any connectors. Leave the protective packaging on all connectors until install is complete to prevent electrostatic discharge damage.</li> <li>· Patient data is confidential – be sure not to examine, copy or photograph any printed or electronic matter containing patient names, personal details, medical images or other confidential data to ensure compliance with the Health Insurance Portability and Accountability Act (HIPPA).</li> </ul>
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### 5.2 SMI ONLY Preparing for the Service Call

Prior to performing the service call the following are required:

- Installation should be booked before application training is scheduled to start. Follow up 3 days before the installation date to remind the customer and confirm that the scanner time is booked off and the Vanguard has been delivered to the immediate area of the scanner.
- A copy of the P.O. or work order for the unit to be installed.
- Contact information for the site (usually the charge tech or administrator) and back-up contact person.
- Determine if any nearby sites can be visited during the same trip to perform preventative maintenance.
- Bring a complete service kit, camera (if possible), notebook, service report cards and personal business cards.
- When international travel is required, a signed letter from the service manager or other manager explaining the purpose of the trip, the destination, dates and the employment status of the service technician.
- ID badge, to be kept on person at all times, and passport/visa (as needed).
- Hotel info, customer site address, directions to/from site, airport and hotel.
- If possible, contact the site specific GE Service Personnel to inform them of the pending service call and request information on any recent problems with or service to the scanner (SMI service calls can be generated from recent service to the scanner involving adjustment of mechanical parts or software upgrades and patches). Request they be present to provide the service key (code).

- Ensure that only Sentinelle-authorized service personnel make adjustments or repairs to the system.
- Review Sentinelle service logs for the site for previous service reports and service pending.

### 5.3 Recording the Service Call

Record the results of all activities performed including:

- Any non-conformances that were discovered during unpackaging and installation or service and any remedial action taken.
- Leave a completed service card and inform relevant staff members who are present that service is complete and indicate state of functionality. If the system fails any of the functionality tests in the installation procedure, it must be taken out of service.
- Unless prior arrangements have been made with the Applications Support Specialists, the system will normally be “Out of Service – Pending Applications training” immediately following installation.
- An SMI or affiliate service log must be filled out to officially record the installation.
- If any non-conformances or problems are discovered during installation, it is imperative that these are recorded, reported and entered into the Problem Management / Complaint Database.

Record the rating plate number and serial number when recording the service call.

### 5.4 Departure

- Ensure work area is clean and no tools or garbage are left behind.
- Replace any coils and padding previously on the scanner bed.
- Place all Vanguard components and accessories in a common storage area.

<b>SMI ONLY</b>	<ul style="list-style-type: none"> <li>· Complete a Sentinelle calling card and leave it in a prominent place, preferably at the console.</li> </ul>
-----------------	--

- If possible, inform staff member on site of completion before leaving.
- Ensure doors (especially scanner room door) are locked and lights are off in accordance with the customer site’s requirements.

## 6 System Contents

This section outlines the shipping contents of this system and locates the rating plate labels for product identification.

### 6.1 Shipping Contents

The Vanguard components are shipped in three groups; the Patient Support and accessories, RF system and padding kit. All should be verified with included packing list. Refer to page 3 of this manual for the **Damage in Transportation** section if damage is found.

### 6.1.1 Patient Support and Accessories

Item	Box #	GEHC Part #	SMI Part #	Description
1	2 of 2	5408232	4000189-11	Patient Support Assembly
2	2 of 2	5408233	SVC-00330	Contralateral Support
3	2 of 2	5408234	SVC-00331	Catchment
4	2 of 2	5408235	SVC-00319	Shoulder Bridge (Qty 2)
5	2 of 2	5408236	SVC-00318	Headrest Assembly
6	2 of 2	5408240	4000210-51	Compression Slider Left
7	2 of 2	5408241	4000290-51	Compression Slider Right
8	2 of 2	5408239	SVC-00307	Compression Plate (Qty 2)
9	2 of 2	E8811EB	46-25845G1	Kit/Strap (not shown)
10	2 of 2	5408244	4000197-11	Compression Frame Ass'y Right
11	2 of 2	5408245	4000196-11	Compression Frame Ass'y Left
12	2 of 2	5407765-9	SVC-00329	GE Spherical Phantom Positioner (Qty 2, only 1 shown)

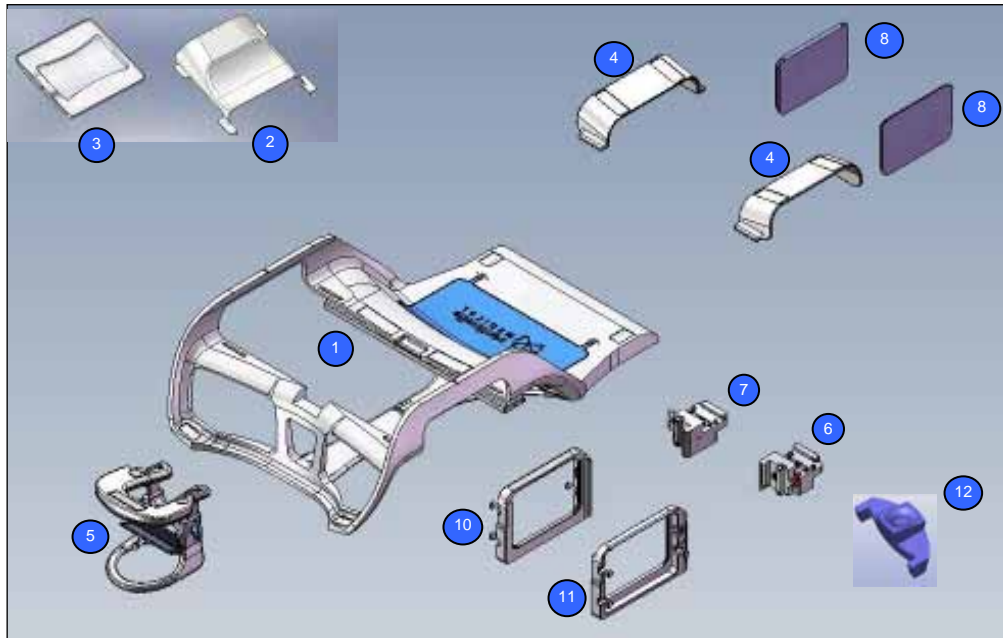


Figure 1

### 6.1.2 RF System

Item	Box #	GEHC Part #	SMI Part #	Description
1	1 of 2	5419349-2	4000205-11	Single Loop Left
2	1 of 2	5419349-3	4000204-11	Single Loop Right
3	1 of 2	5419349-5	4000203-11	8-Ch Lateral Array Left
4	1 of 2	5419349-4	4000202-11	8-Ch Lateral Array Right
5	1 of 2	5419349-6	PRD-01494	Medial Coil
6	1 of 2	5419349-7	PRD-01509	Medial Plug
7	1 of 2	5419349-8	4000209-11	Interface Box 1.5T VGTT

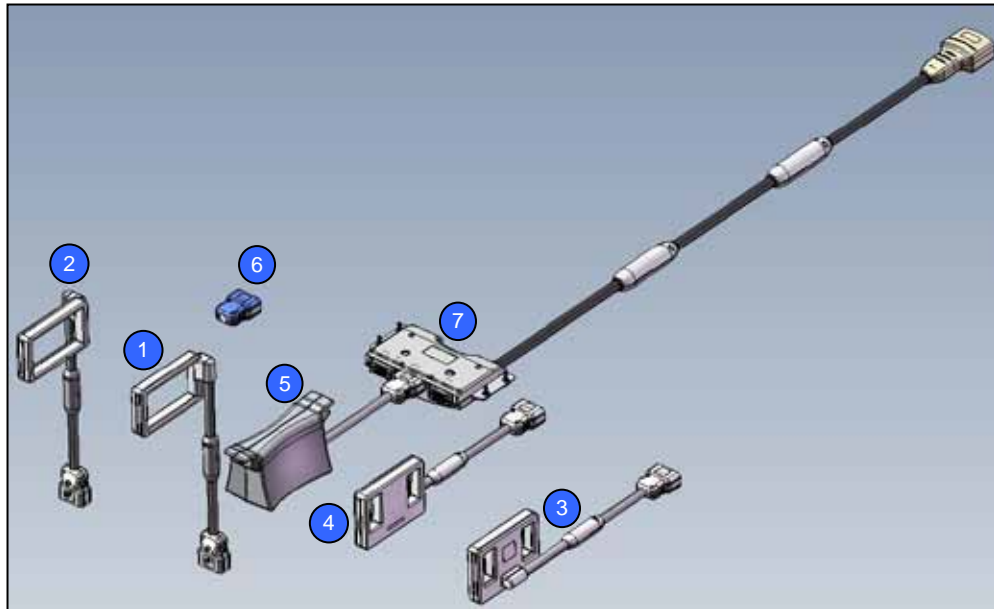


Figure 2

### 6.1.3 Padding Kit

Item	Box #	GEHC Part #	SMI Part #	Description
1	2 of 2	5408291	SVC-00325	Pad Arm Support
2	2 of 2	In 5408290 Kit	SVC-00326	Ramp Pad
3	2 of 2	In 5408290 Kit	SVC-00327	Shoulder Bridge Pad (Qty 2)
4	2 of 2	5408289	SVC-00328	Body Pad
5	2 of 2	5408288	SVC-00309	Wedge Pad
6	2 of 2	5408287	SVC-00308	Headrest Pad
7	2 of 2	In 5408290 Kit	SVC-00322	Medial Pad
8	2 of 2	In 5408290 Kit	SVC-00320	Foot Pad

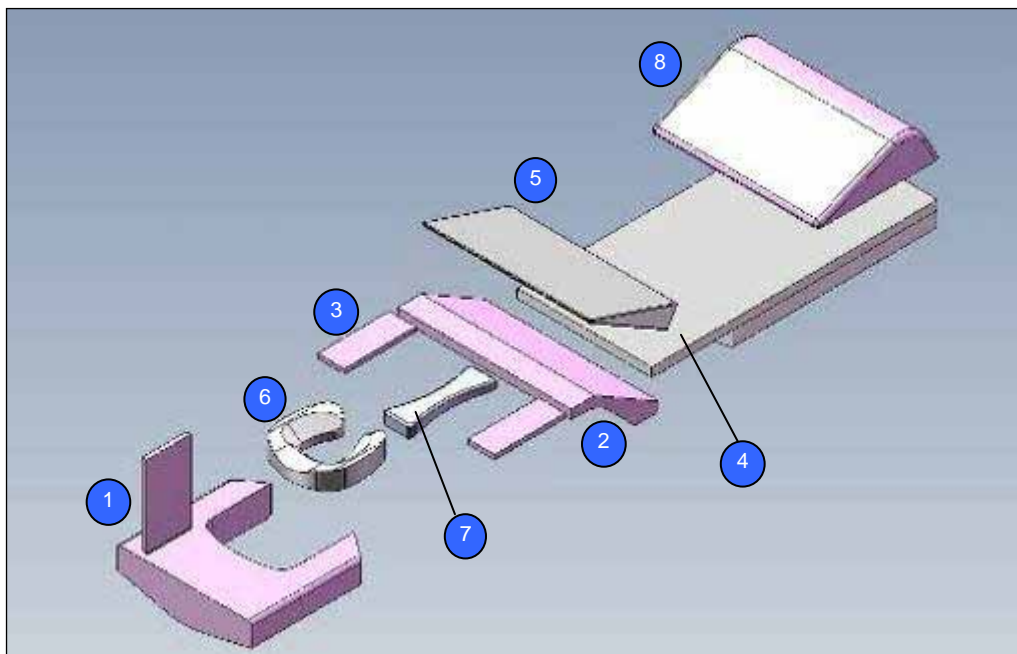


Figure 3

### 6.1.4 Miscellaneous Items

Box #	GEHC Part #	SMI Part #	Description
2 of 2	N/A	SMI-0517	User Manual
2 of 2	N/A	SMI-1222	Service Manual

## 6.2 Product Identification

The GE 1.5T 8Ch HDx system is uniquely identified using the labels below. For clarity, the labels are surrounded by a red box in the figures below. Systems sold and serviced by GEHC will have an additional “Distributed by: GE Healthcare” label next to the rating plate (Figure 4).

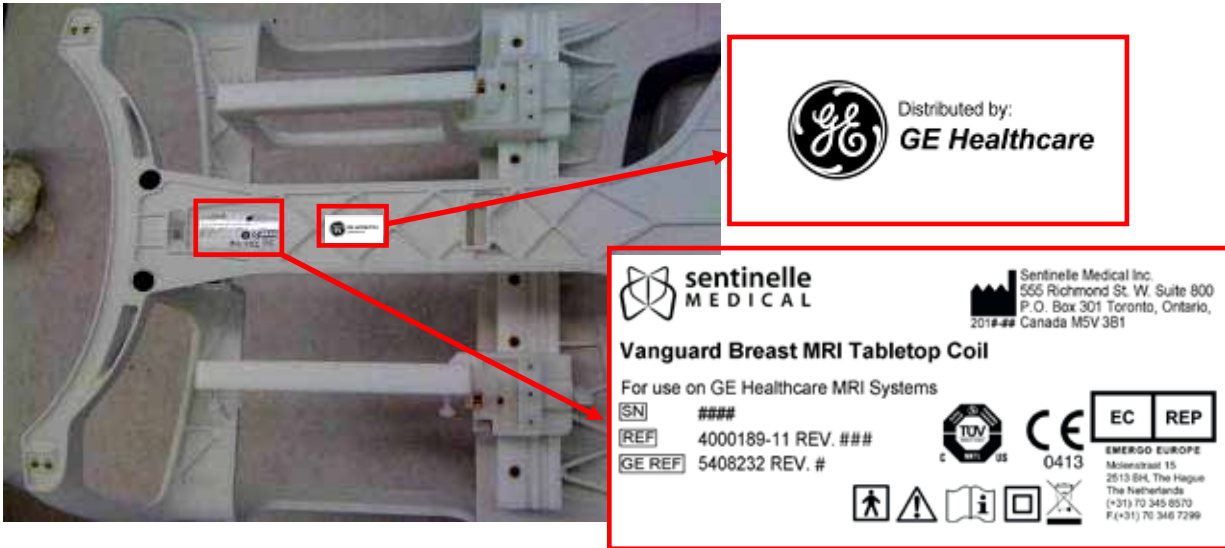


Figure 4: Patient support label



Figure 5: Interface box label



Figure 6: Lateral Single Loop Coil Left Label

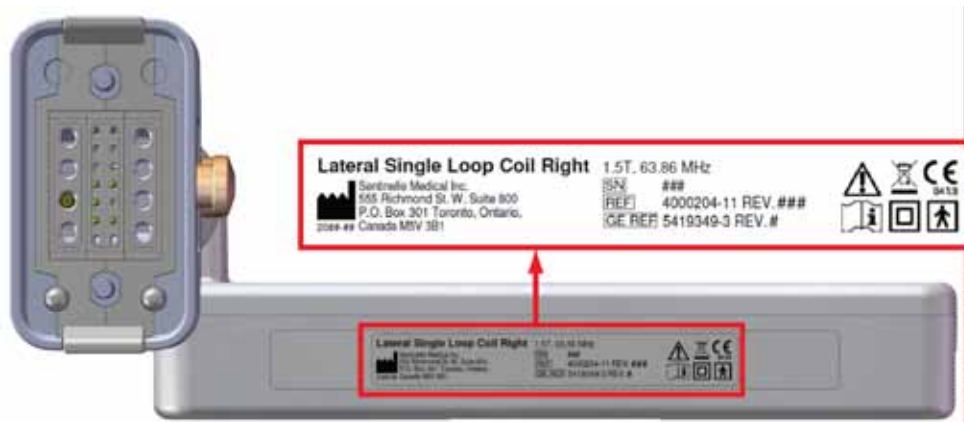


Figure 7: Lateral Single Loop Coil Right Label



Figure 8: Lateral Array Coil Left Label



Figure 9: Lateral Array Coil Right Label



Figure 10: Medial Array Coil Label

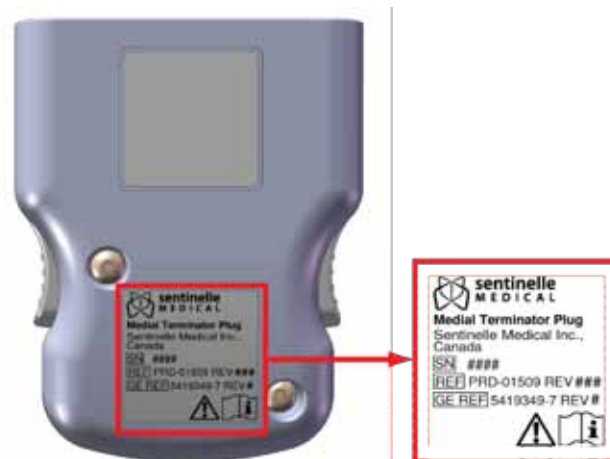


Figure 11: Medial Terminator Plug Label

## 7 Installation Procedure

Required installation time: 30-60 minutes.

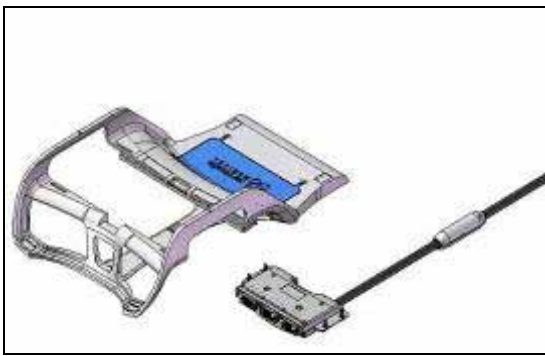
Installation of the Vanguard requires no tools and no mechanical settings to be performed. The accessories must all be connected and assembled and tested to ensure system is functioning correctly with the scanner.

### 7.1 Unpack and set-up

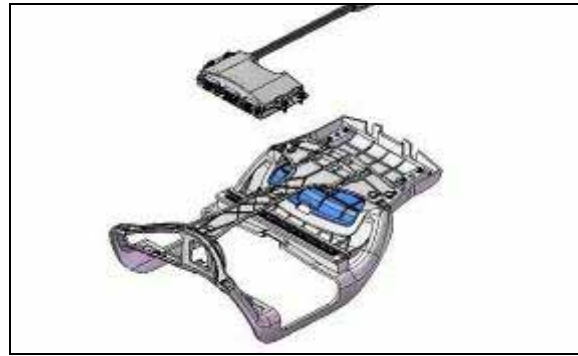
Unpack the Patient Support assembly, padding kit and coil boxes while examining the components for damage. Verify all components and accessories are present including the customer User Manual. Store all components neatly inside the scanner room or as instructed by customer.

### 7.2 Interface Box Installation

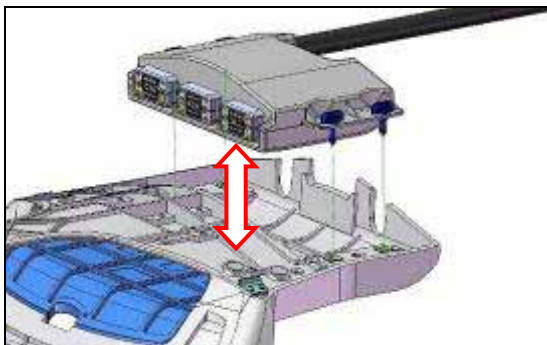
The interface box must be installed on the underside of the Patient Support. Follow the steps below.



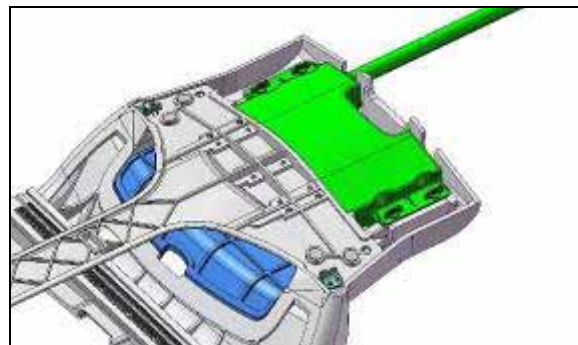
1. Prepare Patient Support and interface box.



2. Position Patient Support to access underside.



3. Align interface box to mounting holes.

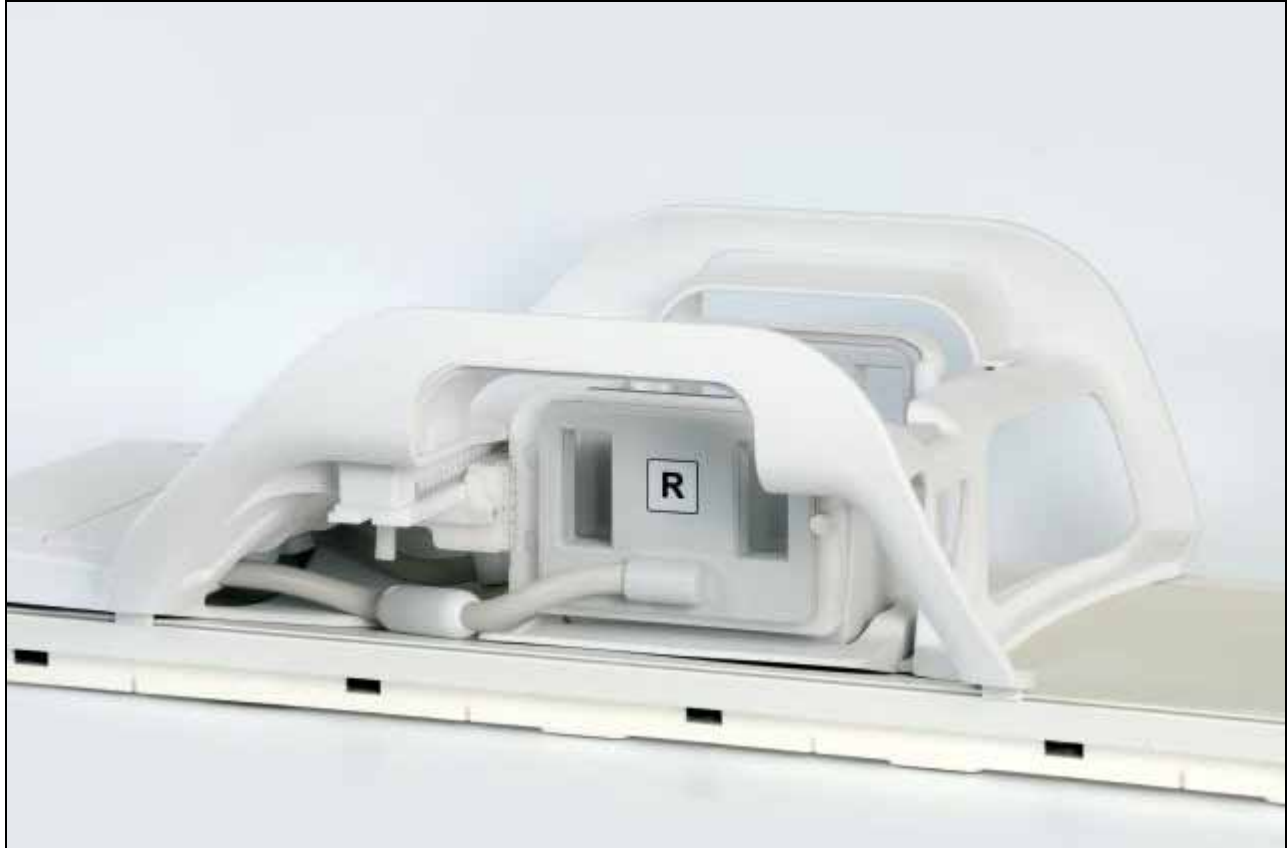


4. Attach interface box to Patient Support with four fasteners.

## 7.3 Vanguard Installation

This section outlines the procedure that must be followed to setup the Patient Support and accessories for use. Verify all parts function correctly and are not damaged.

### 7.3.1 Coil Setup



**Figure 12: Patient Support on GE Signa Table**

The Tabletop should be placed feet first on the GE Signa Table towards the bore so the Tabletop Cable located at the foot end of the patient support can be securely plugged in to the LPCA.

### 7.3.2 General System Function and Components

The Tabletop is a dedicated breast imaging coil and interventional system for 1.5T GE Signa™ MR Scanners.

The Tabletop consists of a patient support with breast immobilization system and an attached 8-channel coil system.

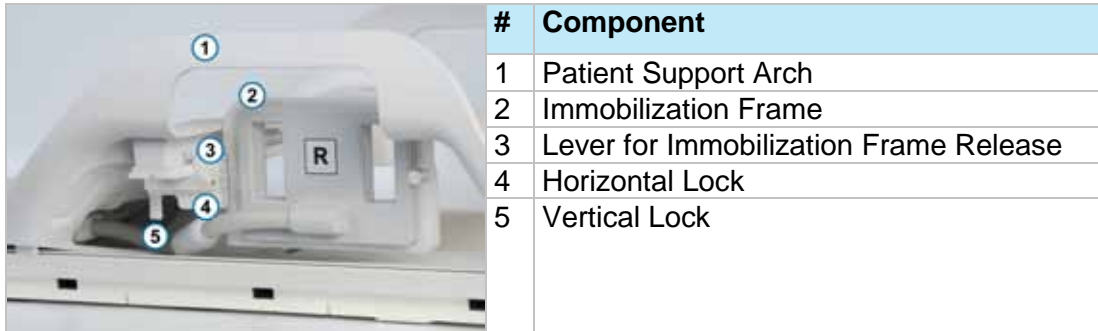
The patient support holds the patient comfortably in a prone position with the breasts lying pendant into the aperture.

The immobilization system can operate in two different imaging modes; clinical and interventional, and consists of immobilization frames in sliders allowing for vertical and horizontal movement of the coils. The Tabletop's unique Variable Coil Geometry enables the coils to be positioned in close proximity to the breast tissue for improved signal-to-noise ratio (SNR).

For clinical imaging, clear immobilization plates are placed in the immobilization frames to help minimize artifacts due to patient motion during scanning. For interventional procedures, these plates are replaced with sterile, single-use disposable biopsy grids which serve to immobilize the breast and provide access windows for biopsy needle guidance.

### 7.3.3 System Components and Function

Figure 13 illustrates the Tabletop’s immobilization system and components.

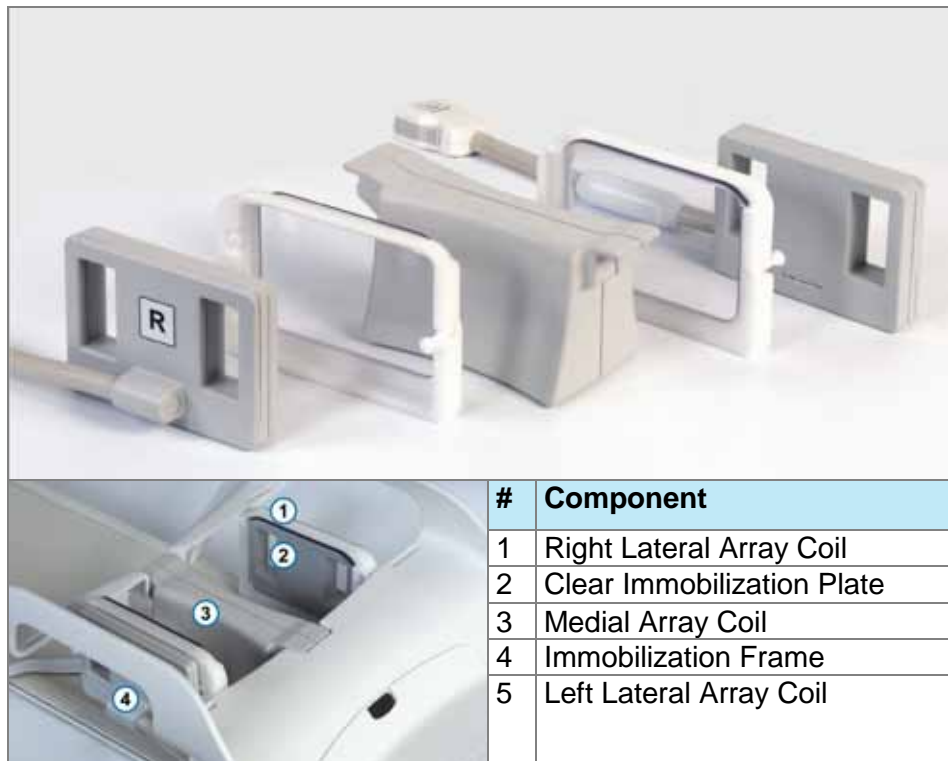


**Figure 13: The Tabletop Immobilization System and Components**

*Note: The connectors on the coils and medial plug are covered with a plastic cap to protect the connector pins from being bent or damaged. You must remove the cover from the connector before you can plug a coil or the medial plug into the interface box. It is recommended that you replace these covers on the connectors when you remove the coils or medial plug to protect them during transportation and storage.*

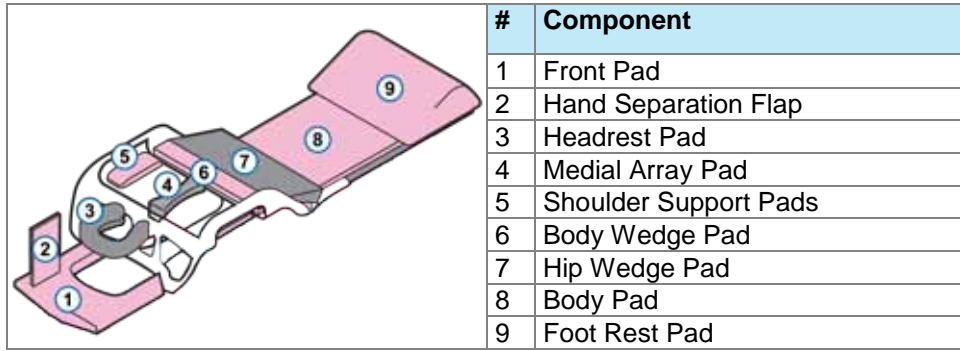
#### 7.3.3.1. System Components for Bilateral Imaging Procedures

The following illustrates the Tabletop’s general set up for bilateral breast imaging, unilateral biopsy and bilateral biopsy procedures.



**Figure 14: Imaging Coils**

Figure 15 illustrates padding set-up on the Tabletop. Padding can be re-arranged for optimal patient comfort.

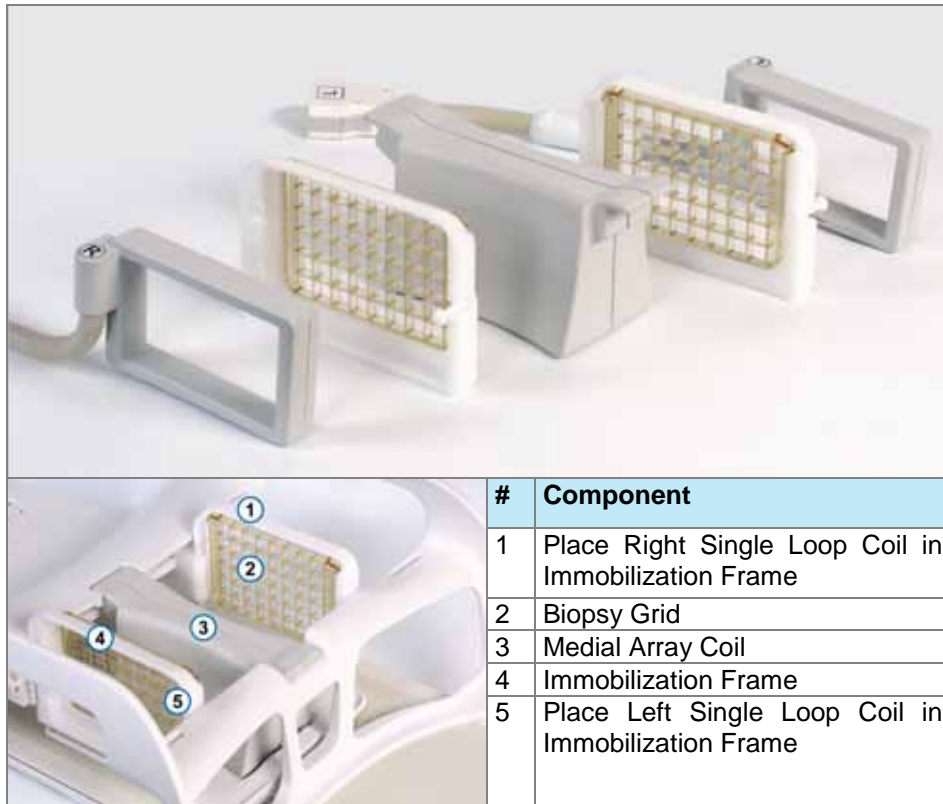


**Figure 15: Full Padding Configuration**

**7.3.3.2. System Components for Bilateral Intervention Procedures**

*Note: Biopsy grids are not included with the GE catalog offering. These products can only be ordered directly from Sentinelle Medical (by calling 1-866-735-3744).*

*Note: This configuration is not available with the 8-channel Imaging-only system*

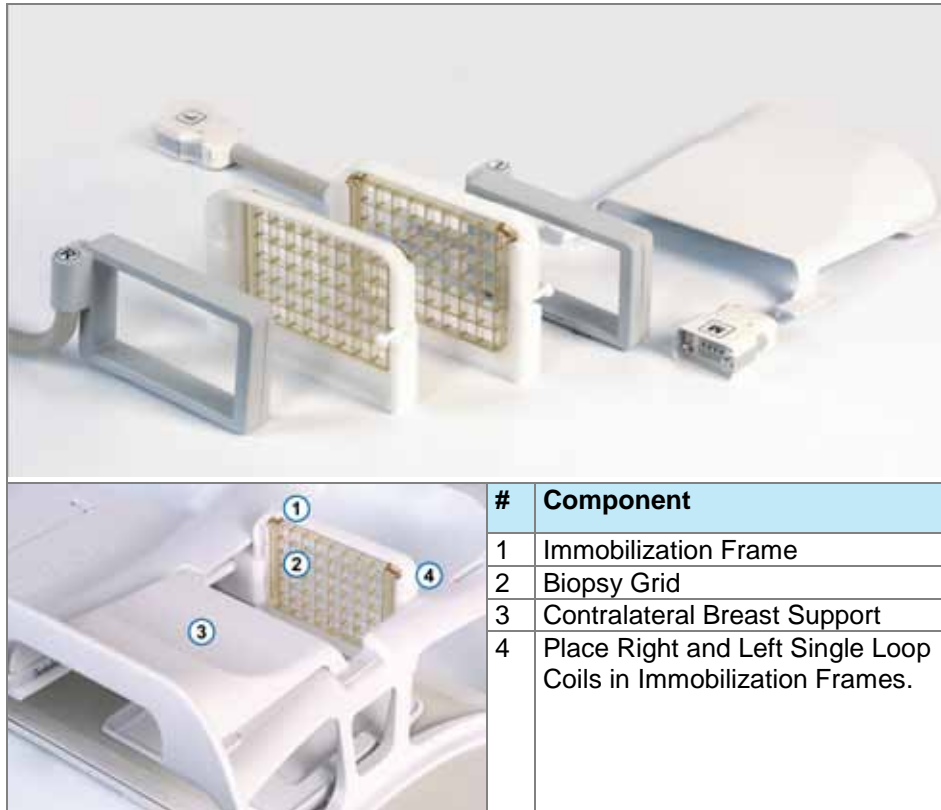


**Figure 16: Bilateral Intervention Setup and Components**

**7.3.3.3. System Components for Unilateral Intervention Procedures**

*Note: Biopsy grids are not included with the GE catalog offering. These products can only be ordered directly from Sentinelle Medical (by calling 1-866-735-3744).*

*Note: This configuration is not available with the 8-channel Imaging-only system*



**Figure 17: Unilateral Interventional Setup Components**

### 7.3.4 Contralateral Breast Support

The contralateral breast support is used to hold the contralateral breast away to improve medial access when performing unilateral interventional procedures. The design of the breast support puts the patient in a slightly oblique position to allow the breast of interest to fall further into the open aperture for increased posterior access to the breast during intervention.

### 7.3.5 Catchment Tray

For Unilateral and Bilateral Interventional procedures the catchment tray must be in place. This is a safety mechanism ensuring the MR guided needle device can safely be directed into the breast tissue.



**Figure 18: Inserting the Catchment Tray**

### 7.3.6 Vanguard Cable



**CAUTION**

Plug in the Vanguard cable (Figure 19). Do not scan if the cable is unplugged or if there is an MR system warning. The Vanguard cable **must** be covered at all times during operation with the body pad (Figure 20).



**Figure 19: Vanguard Cable**



**Figure 20: Covering the Vanguard Cable with the Body Pad**

## 7.4 QA Scanning

Perform a QA scan of the phantoms to ensure all coils are working to specification. The QA scan must be completed for 8ch and 4ch configurations of the Vanguard.

There are two types of QA tests: tests for use with spherical phantoms (see section 7.4.1), and tests for use with rectangular phantoms (see section 7.4.2). Use the appropriate tests for the phantoms at your site.

*Note: QA scan test results should be determined using the procedures appropriate to the phantoms at your site outlined below and entered into the Quality Assurance SNR Section in the **Installation Verification Checklist** which can be found in the Appendix.*

### 7.4.1 QA Scanning Using Spherical Phantoms

Sentinel Medical recommends that the coils be checked for imaging integrity on a regular basis, by performing the Multi-Coil Quality Assurance (MCQA) procedure. The phantoms used for the QA scan are part of GE's System Phantom Set. The instructions below only apply to the Sentinel Vanguard system.

*Note: If bubbles are apparent in the phantom, tap the outside of the phantom until these bubbles disappear.*

#### 7.4.1.1. Tools Required

The following tools are required to complete the MCQA procedures.

Description	GEHC Part #	SMI Part #	Qty
10cm Silicon Oil Spherical Phantom	2360034	-	2
Phantom positioner	5407765-9	SVC-00329	2

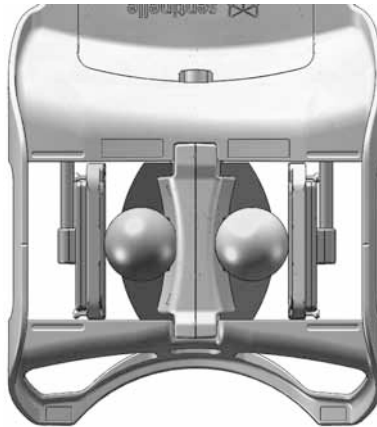
#### 7.4.1.2. Test 1: 8-channel Bilateral Breast SNR Verification Using Spherical Phantoms

1. Install Vanguard tabletop on MR scanner table.
2. Install the 8-channel coil set (for bilateral imaging) and connect the cables (refer to Figure 21). Plug the Vanguard system cable into the connector port.
3. Locate phantom positioners on either side of the medial coil as shown in Figure 21.



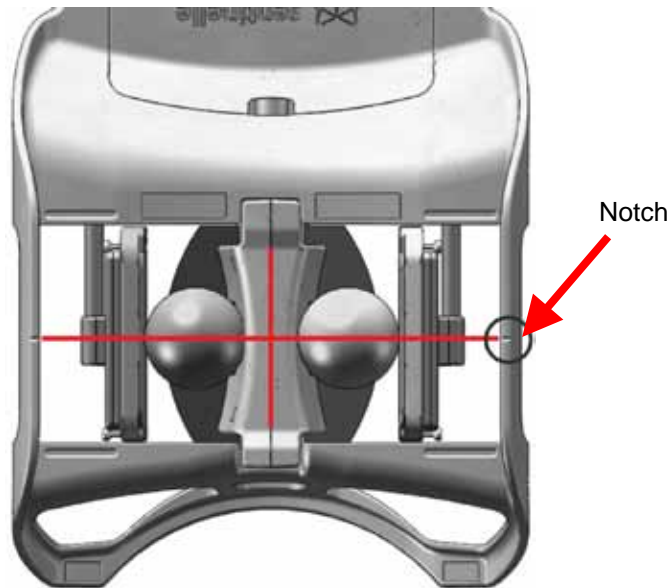
**Figure 21: 8-Channel - Phantom Positioner Setup**

4. Add spherical GE phantoms and adjust lateral coils so that lateral coils lightly touch the phantoms as shown in Figure 22.



**Figure 22: 8-Channel - Phantom Setup**

5. Landmark using the notch on the edge of the patient support as shown in Figure 23.



**Figure 23: 8-Channel - Landmark Phantoms**

- Do not start a new patient; open the Tools box, and start MR Service Desktop. Select the top tab marked 'Image Quality.' In the side menu, select 'Multi-Coil QA Tool', then 'Click here to start this tool.' The program shown in Figure 24 will start:

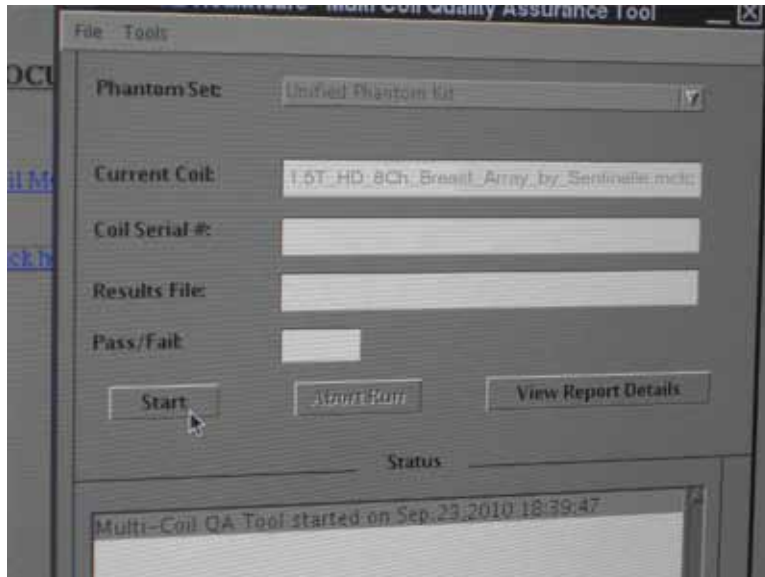


Figure 24: Screen Capture – MCQA Tool Start

- Click 'Start', and answer 'Yes' to the dialog box that opens. The MCQA program will run for approximately 5 minutes, and test each channel of the system independently. When the program finishes, the screen capture shown in Figure 25 will display.

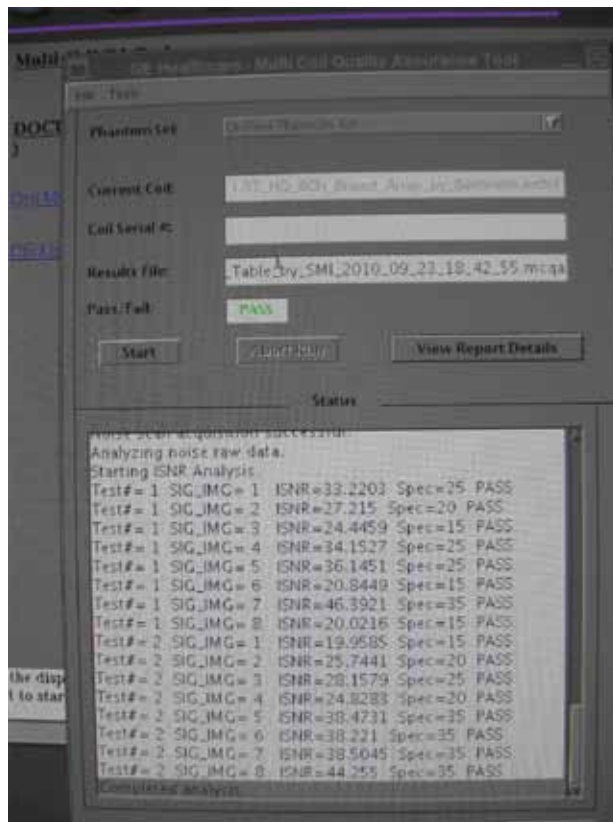


Figure 25: Screen Capture – MCQA Tool Finish

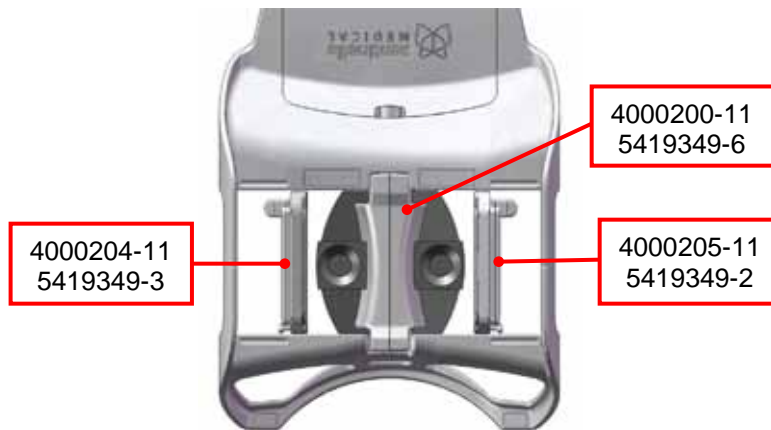
8. The MCQA program will display a PASS/FAIL indicator for each image (SIG\_IMG in Figure 25) which corresponds to a particular channel on one of the coils tested. If you receive a FAIL indication, check that all coils are connected properly and rerun the test. If the test fails the second time refer to the following table. Additional information related to the specific channels used in each imaging configuration is available in section 8.1 *Imaging Troubleshooting*.

<b>MCQA Test Image</b>	<b>Associated Coil</b>	<b>GEHC P/N</b>	<b>SMI P/N</b>
Test#=1 SIG_IMG=1	Left Lateral Array	5419349-5	4000203-11
Test#=1 SIG_IMG=2	Left Lateral Array	5419349-5	4000203-11
Test#=1 SIG_IMG=3	Left Lateral Array	5419349-5	4000203-11
Test#=1 SIG_IMG=4	Medial Array	5419349-6	4000200-11
Test#=1 SIG_IMG=5	Medial Array	5419349-6	4000200-11
Test#=1 SIG_IMG=6	Right Lateral Array	5419349-4	4000202-11
Test#=1 SIG_IMG=7	Right Lateral Array	5419349-4	4000202-11
Test#=1 SIG_IMG=8	Right Lateral Array	5419349-4	4000202-11

9. Record the results in the Installation Verification Checklist in Appendix A.

**7.4.1.3. Test 2: 4-channel Bilateral Breast SNR Verification Using Spherical Phantoms**

1. Install Vanguard tabletop on MR scanner table.
2. Install and connect the three coil cables of the 4-channel coil set (refer to Figure 26) to the Vanguard table and plug in the Vanguard system cable into the P-port receptacle.
3. Locate phantom positioners on either side of the medial coil as shown in Figure 26.



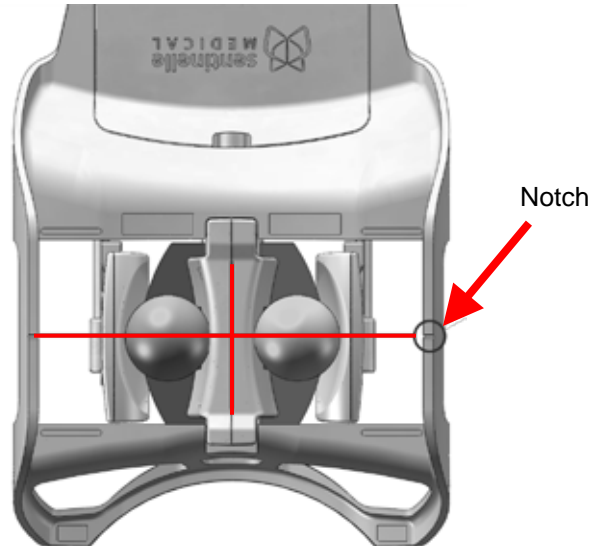
**Figure 26: 4-Channel - Phantom Positioner Setup**

4. Add spherical GE phantoms and adjust lateral coils so that lateral coils lightly touch the phantoms as shown in Figure 27.



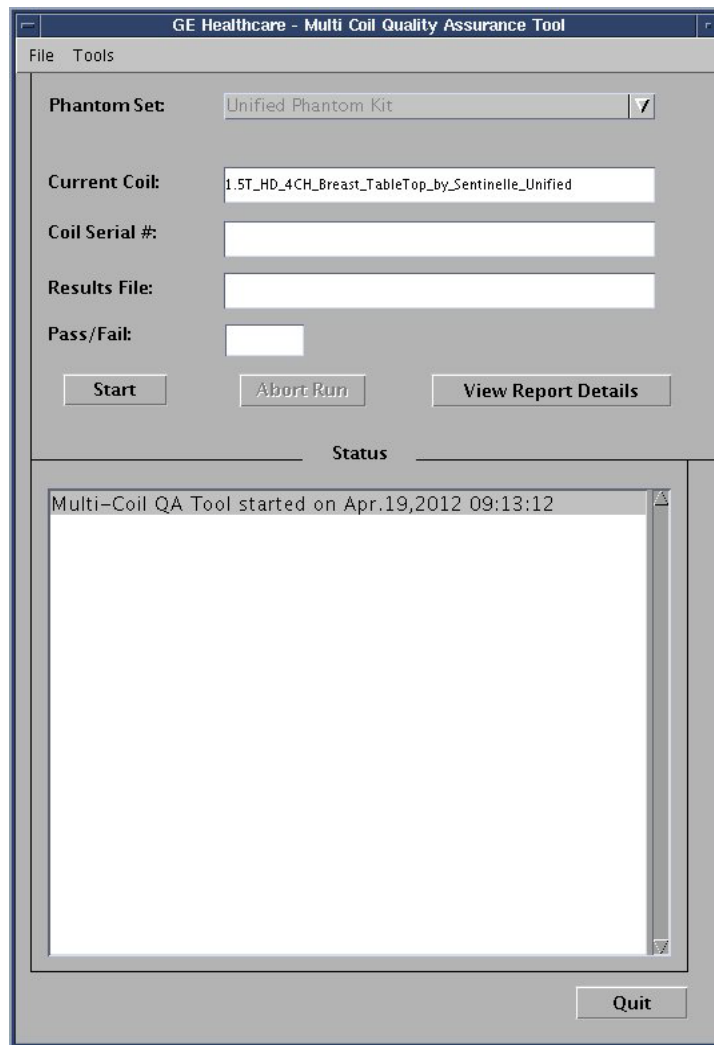
**Figure 27: 4-Channel - Phantom Setup**

5. Landmark using the notch on the edge of the patient support as shown in Figure 28.



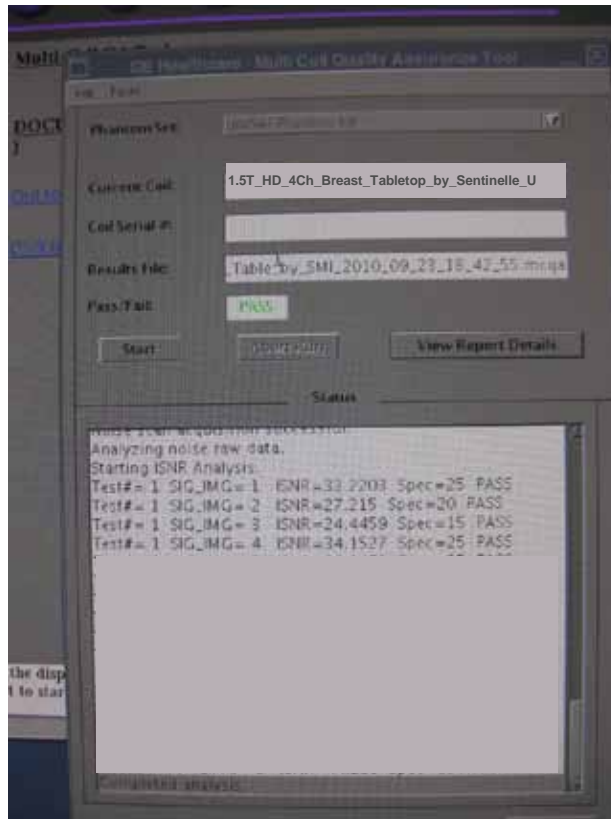
**Figure 28: 4-Channel - Landmark Phantoms**

6. Do not start a new patient; open the Tools box, and start MR Service Desktop. Select the top tab marked 'Image Quality.' In the side menu, select 'Multi-Coil QA Tool', then 'Click here to start this tool.' The program shown in Figure 29 will start.



**Figure 29: Screen Capture – MCQA Tool Start**

7. Click 'Start', and answer 'Yes' to the dialog box that opens. The MCQA program will run for approximately 5 minutes, and test each channel of the system independently. When the program finishes, the screen capture shown in Figure 30 will display.



**Figure 30: Screen Capture – MCQA Tool Finish**

8. The MCQA program will display a PASS/FAIL indicator for each image (SIG\_IMG in Figure 30) which corresponds to a particular channel on one of the coils tested. If you receive a FAIL indication, check that all coils are connected properly and rerun the test. If the test fails the second time refer to the following table. Additional information related to the specific channels used in each imaging configuration is available in section 8.1 Imaging Troubleshooting.

<b>MCQA Test Image</b>	<b>Associated Coil</b>	<b>GEHC P/N</b>	<b>SMI P/N</b>
Test#=1 SIG_IMG=1	Left Single Loop	5419349-2	4000205-11
Test#=1 SIG_IMG=2	Medial Array	5419349-6	4000200-11
Test#=1 SIG_IMG=3	Medial Array	5419349-6	4000200-11
Test#=1 SIG_IMG=4	Right Single Loop	5419349-3	4000204-11

9. Record the results in the Installation Verification Checklist in Appendix A.

**7.4.1.4. Troubleshooting Tips**

1. Ensure that no patient has been started before beginning the MCQA procedure.
2. Landmark the coils before starting the MCQA tool.
3. Only use the spherical GE phantoms (GE Model 2360034), and the Sentinelle phantom positioners.
4. Ensure that all coils are touching the phantoms.

**7.4.2 QA Scanning Using Rectangular Phantoms**

Sentinelle Medical recommends that the coils be checked for imaging integrity on a regular basis, by performing the Quality Assurance (QA) procedure. The QA procedure involves a phantom scan, a visual inspection of the QA images and a calculation of the signal-to-noise ratio. The rectangular phantoms used for this QA scan are provided by Sentinelle Medical. Only use these phantoms when performing the QA scans described below on the Vanguard.

*Note: If bubbles are apparent in the phantom, tap the outside of the phantom until these bubbles disappear.*

**7.4.2.1. Tools Required**

The following tools are required to complete the QA procedures described below.

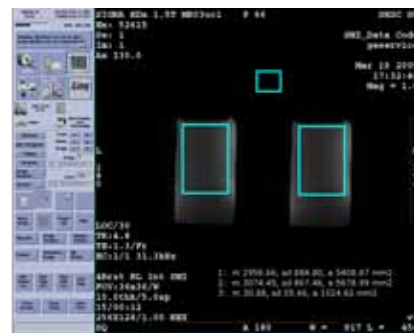
Description	GEHC Part #	SMI Part #	Qty
Rectangular Imaging Phantom	-	4000467-51	2

**7.4.2.2. 8-Channel Bilateral Breast SNR Verification with Rectangular Phantoms**

1. Set up coils for a routine bilateral breast exam using the 8-channel setup as described in section 7.3.3.1. For optimal results, position both lateral coils at the same height. Align the tops of the lateral coils approximately one inch higher than the top of the medial coil.
2. Slide an imaging phantom between the medial and each lateral coil. Position both phantoms so they are just touching the Medial Array Coil. Lock the horizontal lock. Advance the patient support into the bore.



**Figure 31 Positioning Phantoms in Holder**



**Figure 32 Placing ROIs Over Signal in Phantom**

3. At the MR console, prescribe the following scan.

**Patient Information:**

**Patient ID:** "geservice"  
**Patient Name:** SMI\_ <Date> (for example SMI\_26FEB10)  
**Patient Weight:** "180lbs"

**Coil Configuration:**

Select **currently connected**  
**8ch Bilat HD Breast Array by Sentinelle**  
**8 BrstBL SMI**

**Description: 8Ch SNR  
Imaging Parameters:**

<b>Scan Plane:</b>	"Coronal"
<b>Field of View:</b>	"32 cm"
<b>Pulse Sequence:</b>	"SE (Spin Echo)"
<b>TR:</b>	"450 ms"
<b>TE:</b>	"14 ms"
<b>Start Location:</b>	"S0.0"
<b>End Location:</b>	"I0.0"
<b># Slices:</b>	"1"
<b>Slice Thickness:</b>	"5 mm"
<b>Spacing:</b>	"0"
<b>NEX:</b>	"1"
<b>Matrix Size:</b>	"256x256"
<b>BW:</b>	"15.63 kHz"

- Click **Save Prescription** when done, select the Q/A exam then click the small arrow below scan.
- Select **Research > Download > Modify CVs**.
- Type "saveinter" as the CV name, and "1" as the value. Click **Accept**, then click on the small arrow next to **Scan > Research > Download**, then scan.
- Display all images in the series, page through images 1 through 16, and verify that some signal is being received from all channels. Note that channels placed far away from the slice may have low signal.
- Display the last image in the series using the image viewer found in the browser.
- Click and hold the **Measure** button and select the rectangle option.
- Draw three rectangular regions of interest (ROIs) as shown in Figure 32. Note that the ROIs over the phantoms should encompass at least 90% of the signal producing area and the ROI above and between the phantoms should be approximately 1100 mm<sup>2</sup>.
- Make a note of the signal mean values for the left and right ROIs and the standard deviation for the ROI in the region outside of both phantom signals in the image.
- Calculate the Signal-to-Noise Ratio (SNR) using the following equation:

$$SNR = \frac{(\text{Left Signal Mean} + \text{Right Signal Mean}) / 2}{\text{Noise Standard Deviation}}$$

- Record the result in the Installation Verification Checklist in Appendix A.

**7.4.2.3. 4-Channel Bilateral Breast SNR Verification with Rectangular Phantoms**

*NOTE: This procedure is not required if the site has an 8-channel imaging-only system.*

- Set up coils for a routine bilateral breast biopsy procedure using the 4-channel setup as described in section 7.3.3.2. For optimal results, position both single loop coils at the same height. Align the tops of the single loop coils approximately one inch higher than the top of the medial coil.
- Slide an imaging phantom between the medial and each single loop coil. Position both phantoms so they are just touching the medial array coil. Lock the horizontal lock. Advance the patient support into the bore.
- Follow steps 3 to 13 of section 7.4.2.1 above to calculate and record the Signal-to-Noise Ratio (SNR) for the 4-channel coil configuration.

### 7.4.2.4. 2-Channel Unilateral Breast SNR Verification with Rectangular Phantoms

*NOTE: This procedure is not required if the site has an 8-channel imaging-only system.*

1. Remove the medial array coil and slide both single loop coils to one side of the patient support. Position the medial single loop coil just past the medial line on the patient support and lock the horizontal lock on that slider.
2. Slide an imaging phantom between the single loop coils. Adjust the lateral single loop coil so that it just touches phantom, and the phantom just touches the medial single loop coil. Lock the horizontal lock on the lateral single loop coil. Advance the patient support into the bore.
3. Follow steps 3 to 9 of section 7.4.2.1 above.
4. Draw two rectangular ROIs: one over the phantom and one in the noise area away from the phantom. Note that the ROI over the phantom should encompass at least 90% of the signal producing area and the ROI away from the phantom should be approximately 1100 mm<sup>2</sup>.
5. Calculate the Signal-to-Noise Ratio (SNR) using the following equation:

$$\text{SNR} = \frac{\text{Signal Mean of Signal ROI}}{\text{Noise Standard Deviation}}$$

6. Record the result in the Installation Verification Checklist in Appendix A.

## 7.5 Coil Files

On GE Signa scanners with software version 16.0\_V02 service pack 1 or later, the coil config files required to operate the Vanguard are pre-installed on the scanner. The first time each coil configuration is connected a message will appear prompting user to add coil files. Upon accepting this option the particular coil configuration can be used.

<b>SMI ONLY</b>	Scanners with 12 and older revision software will require manual installation of the coil config files to operate the Vanguard. The coil files are installed by the <b>SMI Coil Config File Instructions</b> .
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### 7.5.1 Coil Configuration File Names

The following coil configuration files are available:

- 8Brst BL TT SMI
- 8Brst Lt TT SMI
- 8Brst Rt TT SMI
- 4Brst BLI TT SMI
- 2Brst Int TT SMI

## 7.6 Final Verification Checklist

Final verification of install is an important series of functional and visual checks which are undertaken to ensure that the installation procedure was executed correctly.

<b>SMI ONLY</b>	Complete the Installation Verification Checklist (Appendix A) and submit to SMI Service department.
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<b>GEHC ONLY</b>	Complete the Installation Verification Checklist (Appendix A) and store on site.
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## 7.7 System Storage

When installation is complete, store the system as directed by the customer or inside the scanner room in an area where it will not pose a hazard or impede access to any part of the room. The storage environment should be **1.5m x 1m x 1m** or **60in x 40in x 40in** and must meet the criteria listed in the table below. The weight of the system is 9kg or 20lb.

	Minimum	Maximum
Ambient Temperature (°C)	-30	+65
Relative Humidity (non-condensing)	10%	95%
Atmospheric Pressure	500 hPa	1060 hPa

## 8 Troubleshooting

GE FE's shall only service systems that were sold by GEHC. Coils sold by GEHC will have a "Distributed by GE Healthcare" label next to the rating plate on the underside of the patient support.

If the Vanguard is not functioning correctly, steps must be taken to troubleshoot the problem by analysing the symptoms displayed and identifying the cause.

The two classifications of problems which may occur are *imaging* or *mechanical*.

### 8.1 Imaging Troubleshooting

Imaging problems may occur due to damage or malfunction of any component of the RF system, or incorrect use of the system as a whole. Imaging problems can be addressed by analysing and modifying the protocols utilised on the scanner or replacing damaged RF components. Initially consult the following table to troubleshoot any imaging problems.

Problem	Possible Solution(s)
<p>You are unable to pre-scan or are scanning and receiving no signal.</p>	<ul style="list-style-type: none"> <li>· Verify that you have selected the correct coil configuration. Refer to 8.3 <i>Coil Configurations</i> to verify the proper coils have been selected.</li> <li>· Verify that the coils are:                             <ul style="list-style-type: none"> <li>○ Properly attached to the immobilization frames.</li> <li>○ Properly connected to the signal lines.</li> <li>○ Correspond to the coil configuration.</li> </ul> </li> <li>· Verify that the landmark is correct</li> <li>· Verify that the Tabletop cable is properly connected to the MRI.</li> <li>· Verify that the scan locations and any FOV offsets are correct</li> </ul> <p><b>Note:</b> <i>When selecting two separate 2D imaging volumes, the scan may select the middle slice of the entire set of slices for prescan. Ensure the middle slice is covering an appropriate volume of interest.</i></p> <p><i>If a scan still cannot be performed, remove all of the coils, terminate all of the signal lines, and attempt to scan using the body coil and the identical imaging sequence and parameters. If there is still no signal received, the problem is probably with the MRI system. Please contact your service representative.</i></p>
<p>Signal quality obtained in the quality assessment check is not acceptable or clinical imaging scan quality is not acceptable.</p>	<ul style="list-style-type: none"> <li>· Ensure the protocol used in the periodic quality assessment check is identical to initial baseline scan.</li> <li>· Verify that all coils are properly selected.</li> <li>· Verify that coils are in proper positions.</li> <li>· Verify that there are no loops in the cables.</li> <li>· Verify that the imaging area is free from ferromagnetic and foreign objects.</li> <li>· Verify that the center frequency is within the adjustment range of your system.</li> <li>· Ensure electrical contacts on the coils and the MRI connectors are clean and free from obstruction. If they are not clean, they can be cleaned with a cotton swab and isopropyl alcohol.</li> </ul>
<p>A dark region appears in the image.</p>	<ul style="list-style-type: none"> <li>· Verify there are no ferromagnetic or foreign objects within the imaging volume.</li> </ul>

If the problem can not be corrected, inspect the housings, cables and connectors of all RF components for damage. If an RF component is replaced, complete the *QA Scanning* according to Section 7.4.

## 8.2 Mechanical Troubleshooting

Mechanical problems can be addressed by identifying and replacing damaged or worn components or FRUs. *Section 11 Replacement Procedures* provides guidance for components that are not replaceable by the user.

## 8.3 Coil Configurations

<b>Imaging Configuration</b>	<b>Connect to Left Cable Plug</b>	<b>Connect to Middle Receptacle</b>	<b>Connect to Right Cable Plug</b>	<b>Configuration to Select on Scanner</b>	<b>Channels Used by Coils</b>
8ch Bilateral	Lateral Array Coil Left	Medial Array Coil	Lateral Array Coil Right	Breast SMI	Left: 6 – 8 Medial: 4 – 5 Right: 1 – 3
4ch Left Breast Unilateral	Lateral Array Coil Left	Medial Array Coil	Lateral Array Coil Right	LtBreast SMI	Left: 6 – 8 Medial: 4 – 5 Right: Inactive
4ch Right Breast Unilateral	Lateral Array Coil Left	Medial Array Coil	Lateral Array Coil Right	RtBreast SMI	Left: Inactive Medial: 4 – 5 Right: 1 – 3
4ch Interventional Bilateral	Single Loop Coil Left	Medial Array Coil	Single Loop Coil Right	4Brst Int SMI	Left: 6 Medial: 4 – 5 Right: 3
2ch Unilateral Breast	Lateral Single Loop Coil Left	Medial Plug	Lateral Single Loop Coil Right	2Brst Int SMI	Left: 6 Medial: Inactive Right: 3

## 9 FRU List with GE Part Numbers

FRUs are parts or assemblies that can be replaced if damaged. The following tables list all FRUs that are available for ordering from Sentinelle or GEHC.

### 9.1 Patient Support FRUs

<b>GEHC Part #</b>	<b>Sentinelle Part #</b>	<b>Part Description</b>	<b>Section #</b>
5408232	SVC-00442	Patient Support Assembly	6.1.1
5408233	SVC-00330	Contralateral Support	6.1.1
5408234	SVC-00331	Catchment	6.1.1
5408235	SVC-00319	Shoulder Bridge	6.1.1
5408236	SVC-00318	Headrest Assembly	6.1.1
5408237	SVC-00337	Headrest Mirror Assembly	-
5408240	SVC-00383	Compression Slider Left	6.1.1
5408241	SVC-00384	Compression Slider Right	6.1.1
5408239	SVC-00307	Compression Plate	6.1.1
5408244	SVC-00385	Compression Frame Ass'y Right	6.1.1
5408245	SVC-00386	Compression Frame Ass'y Left	6.1.1
5408251	SVC-00347	Compression Rail	10.1, 11.1
5408250	SVC-00346	Table Alignment Tab	10.1, 11.2
5408248	SVC-00344	Patient Support Cover	10.1, 11.4
Contained in 5408246	1659A2	Patient Support Cover Catch	10.1, 11.5
5407765-9	SVC-00329	GE Spherical Phantom Positioner	6.1.1

### 9.2 RF System FRUs

<b>GEHC Part #</b>	<b>Sentinelle Part #</b>	<b>Part Description</b>	<b>Section #</b>
5419349-2	SVC-00444	Single Loop Left	6.1.2
5419349-3	SVC-00445	Single Loop Right	6.1.2
5419349-5	SVC-00448	8-Ch Lateral Array Left	6.1.2
5419349-4	SVC-00447	8-Ch Lateral Array Right	6.1.2
5419349-6	SVC-00450	Medial Coil	6.1.2
5419349-7	SVC-00451	Medial Plug	6.1.2
5419349-8	SVC-00452	Interface Box 1.5T VGTT	6.1.2, 11.3

### 9.3 Padding Kit FRUs

<b>GEHC ONLY</b>	Pads and straps are designed as customer consumable components. They are not intended to be covered by any GE service contract. If pads and straps are replaced they should be billed to the customer.
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<b>GEHC Part #</b>	<b>Sentinelle Part #</b>	<b>Part Description</b>	<b>Section #</b>
5408291	SVC-00325	Pad Arm Support	6.1.3
5408289	SVC-00328	Body Pad	6.1.3
5408288	SVC-00309	Wedge Pad	6.1.3
5408287	SVC-00308	Headrest Pad	6.1.3
5408290	4001152-51	Padding Kit Table	-
Contained in 5408290 Kit	SVC-00322	Medial Pad	6.1.3
Contained in 5408290 Kit	SVC-00320	Foot Pad	6.1.3
Contained in 5408290 Kit	SVC-00326	Ramp Pad	6.1.3
Contained in 5408290 Kit	SVC-00327	Shoulder Bridge Pad	6.1.3
E8811EB	46-25845G1	Kit/Strap	6.1.3

## 10 FRU and Fastener Locations

### 10.1 Patient Support FRUs

Item	GEHC FRU #	SMI FRU #	FRU Description	Fasteners	
				Type	Qty
(A)	5408248	SVC-00344	Patient Support Cover	-	-
(B)	Contained within 4001157-11 Tabletop Spare Parts Kit	1659A2	Patient Support Cover Catch	(2) PHMS Slot 4-40x0.25L Brass	8
(C)	-	-	Not a FRU – removal required for Patient Support Cover replacement	(1) BHCS 6-32x0.25L Brass	8
(D)	5408251	SVC-00347	Compression Rail	(3) BHCS 10-32x0.75L	8
(E)	5408250	SVC-00346	Table Alignment Tab	(1) BHCS 6-32x0.25L Brass	8
(F)	5408232	SVC-00442	Patient Support Assembly	-	-

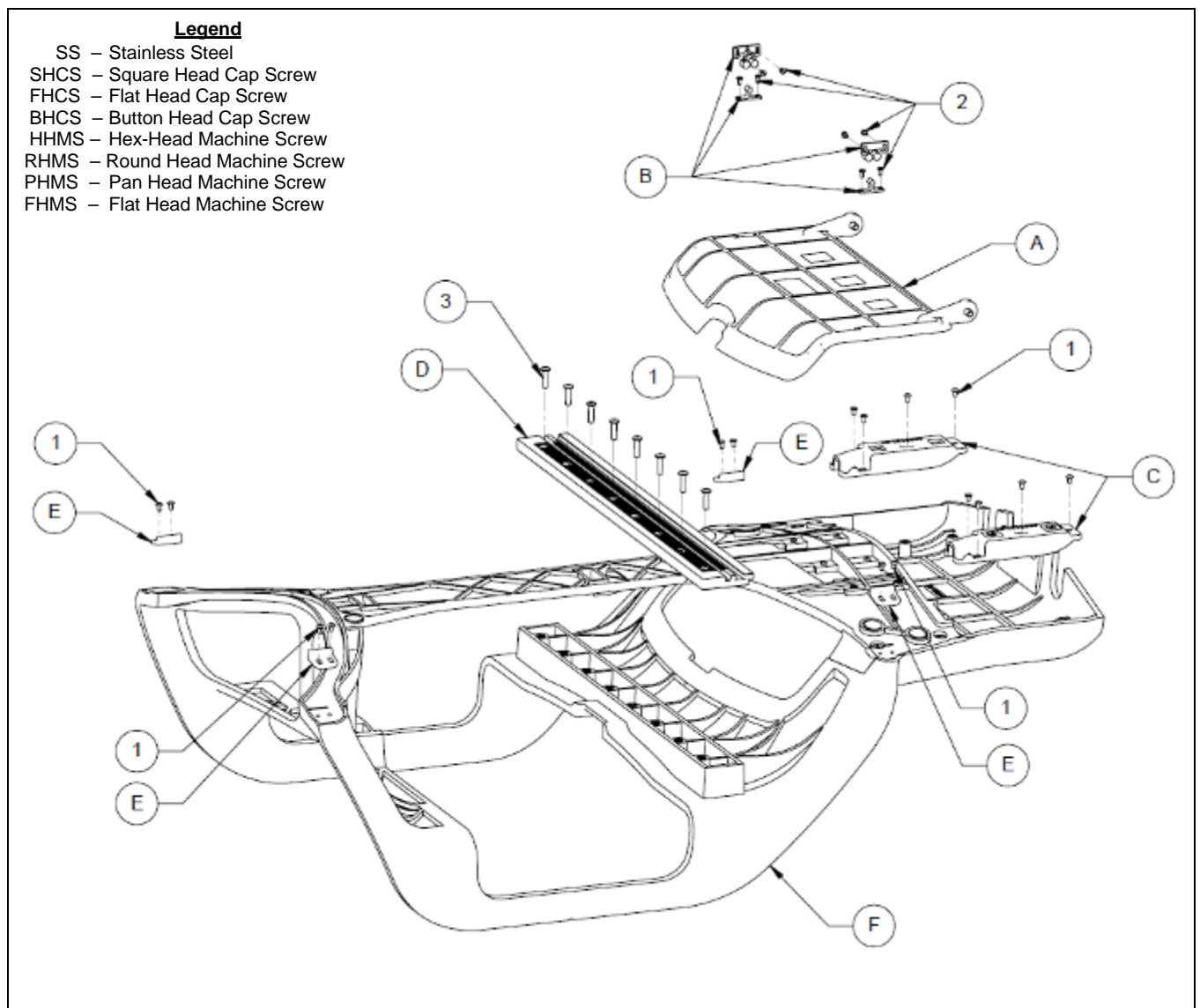


Figure 33

## 11 Replacement Procedures



If any BBPs are present, stop work and notify customer that the Vanguard must be cleaned prior to performing service.

Most components are direct replacements requiring no tools or training to perform. Replacement procedures are defined for components that should be cleaned, replaced or repaired by the field service technician and require testing after replacement.

### 11.1 Compression Rail

**SMI Part #:** SVC-00347

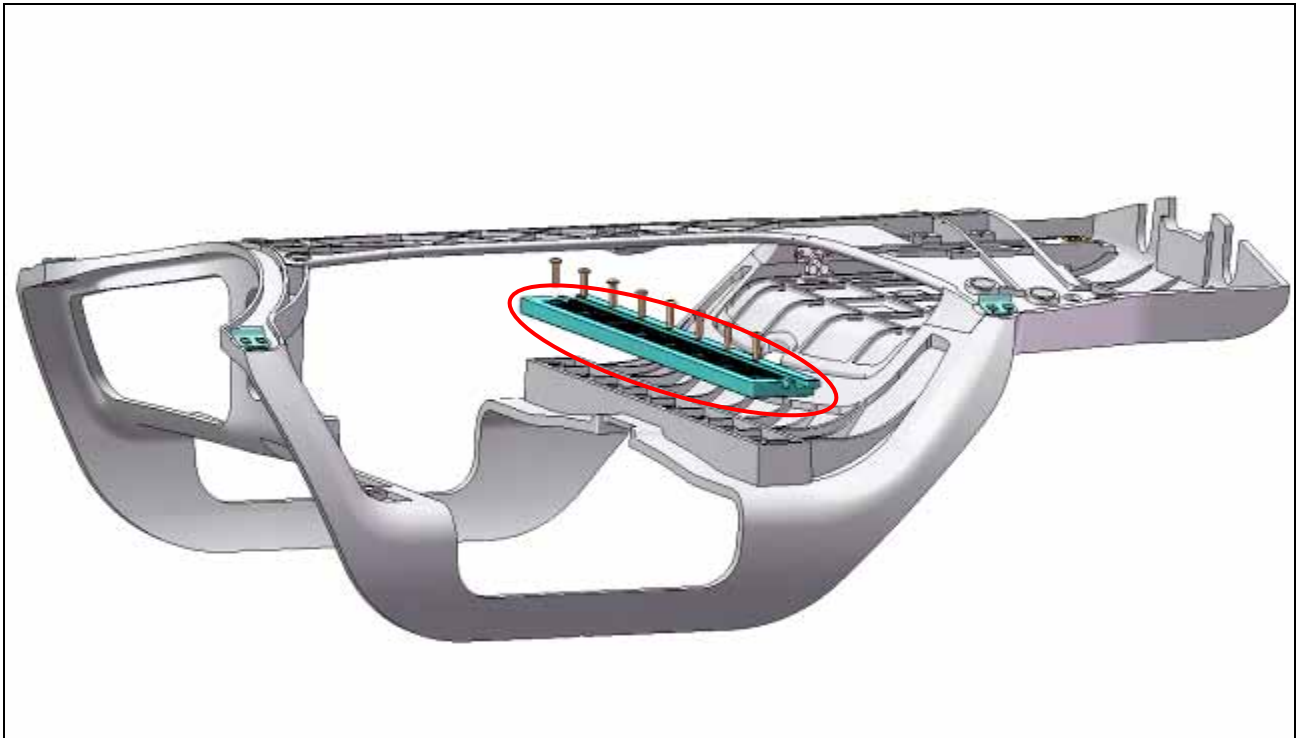
**GEHC Part #:** 5408251

**Time required:** 20 minutes

**Tools required:** 1/8" Allen wrench

**Personnel required:** 1

1. Place Patient Support upside down on a soft/protected surface to access Compression Rail.
2. Take note of orientation of Compression Rail for correct replacement.
3. With a 1/8" Allen wrench, remove 8 screws which fasten Compression Rail.
4. Replace Compression Rail and replace 8 screws.



**Figure 34**

#### **Finalization Steps**

- i. Test function of sliders on Compression Rail by sliding and locking them on several positions along the length of the Compression Rail.

## 11.2 Table Alignment Tab

**SMI Part #:** SVC-00346

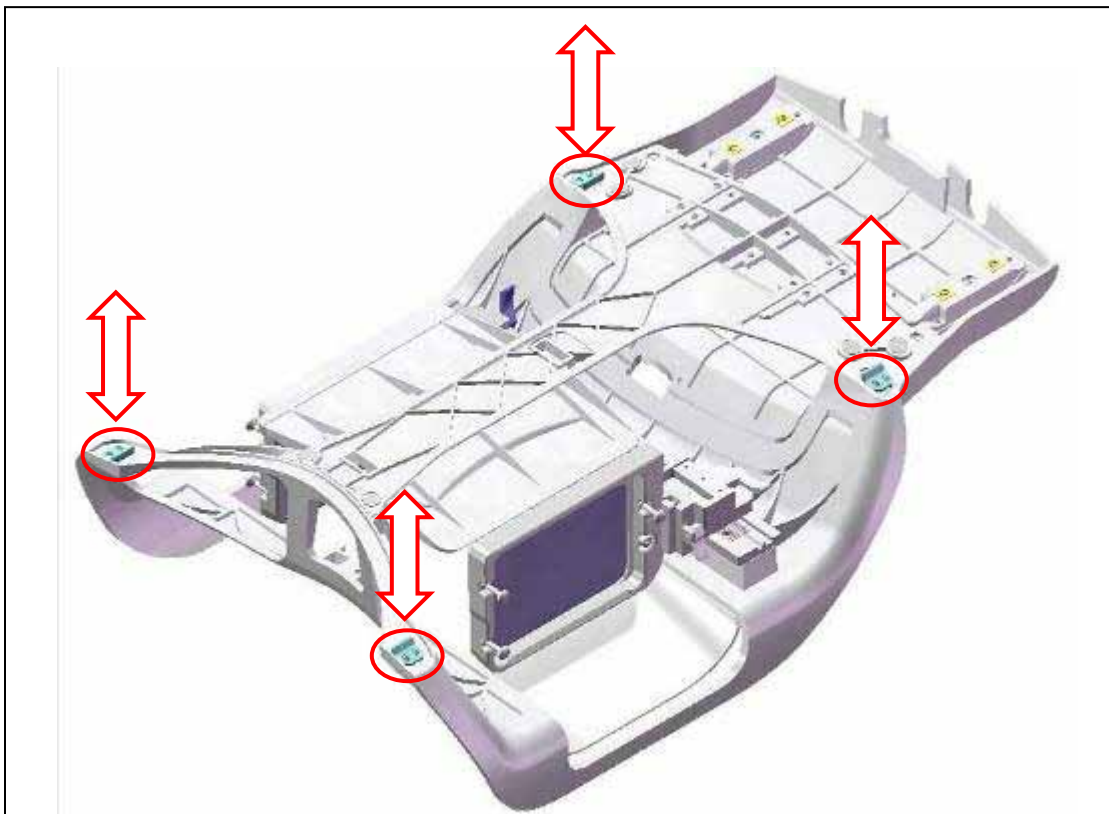
**GEHC Part #:** 5408250

**Time required:** 20 minutes

**Tools required:** 5/64" Allen wrench

**Personnel required:** 1

1. Place Patient Support upside down on a soft/protected surface to access Table Alignment Tab(s).
2. Note position of alignment tab by marking a reference line with a delible writing utensil on the Patient Support.
3. Unscrew and remove the two round head cap screws on alignment tab(s) and remove alignment tab.
4. Place new alignment tab on patient support carefully aligning it to reference line marked in step 2.
5. Tighten round head screws while ensuring tab does not shift.



**Figure 35**

### Finalization Steps

- i. Place Patient Support on GE table and ensure that it fits flatly on scanner bed and remains stationary.

### 11.3 Interface Box 1.5T VGTT

**SMI Part #:** 4000209-11

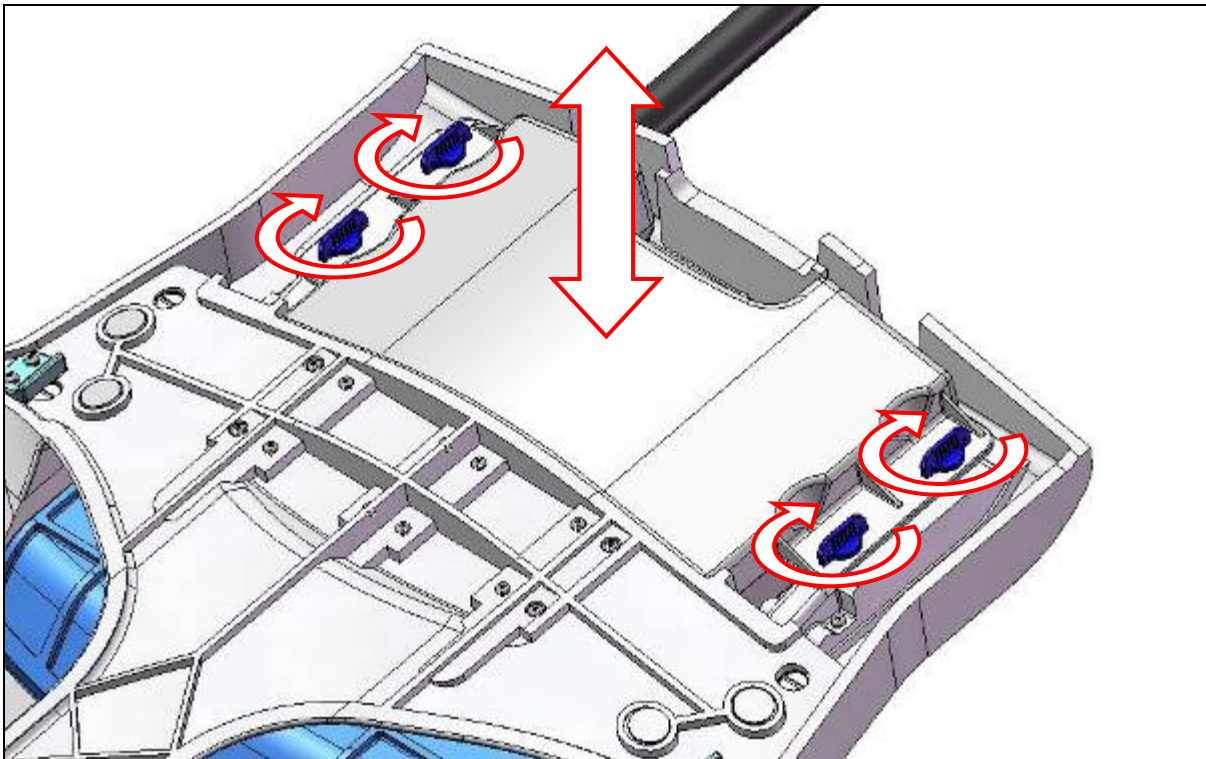
**GEHC Part #:** 5419349-8

**Time required:** 10 minutes

**Tools required:** none

**Personnel required:** 1

1. Place Patient Support upside down on a soft/protected surface to access Interface Box.
2. Turn each fastener  $\frac{1}{4}$  turn to loosen.
3. Remove Interface Box.
4. Mount replacement interface box and turn each fastener  $\frac{1}{4}$  turn to tighten.



**Figure 36**

#### **Finalization Steps**

- i. Perform QA test in 7.4 QA *Scanning* section and record results for service report.

## 11.4 Patient Support Cover

**SMI Part #:** SVC-00344

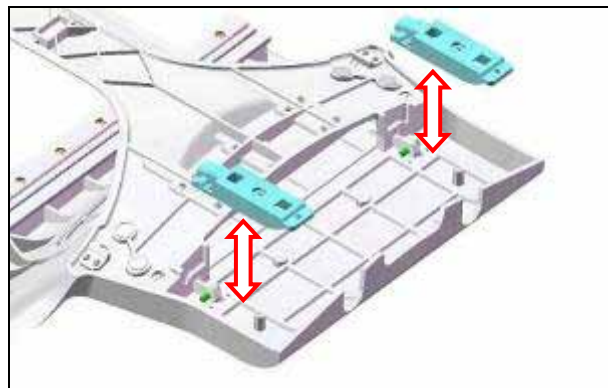
**GEHC Part #:** 5408248

**Time required:** 20 minutes

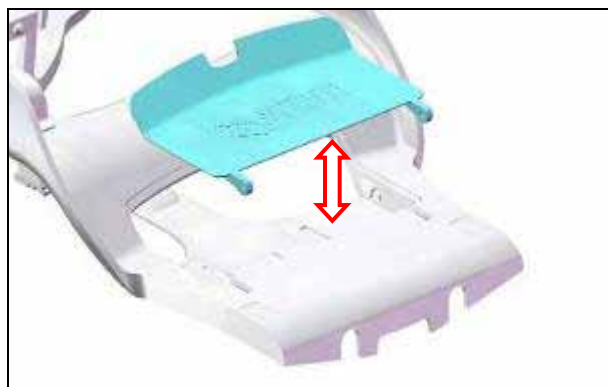
**Tools required:** 5/64" Allen Wrench  
Slot Screwdriver

**Personnel required:** 1

1. Place Patient Support upside down on a soft/protected surface.
2. Remove Interface Box as detailed in section 11.3 *Interface Box*.
3. Remove the striker from the underside the Patient Support Cover by unfastening two mounting screws. Retain the striker and screws for reinstallation on the new Patient Support Cover.
4. Remove four screws which fasten each cover mounting bracket using a 5/64" Allen wrench.
5. Slide pins (shown in green) out of mounting holes in cover.
6. Remove damaged Patient Support Cover and replace with new Patient Support Cover.
7. Insert hinge pins.
8. Re-attach mounting brackets.
9. Replace the striker by fastening with the two screws.
10. Replace Interface Box.



**Figure 37**



**Figure 38**

### Finalization Steps

- i. Test function of new Patient Support Cover by opening and closing it.
- ii. Ensure no interference, misalignment or noises are evident.

## 11.5 Patient Support Cover Catch

**SMI Part #:** 1659A2

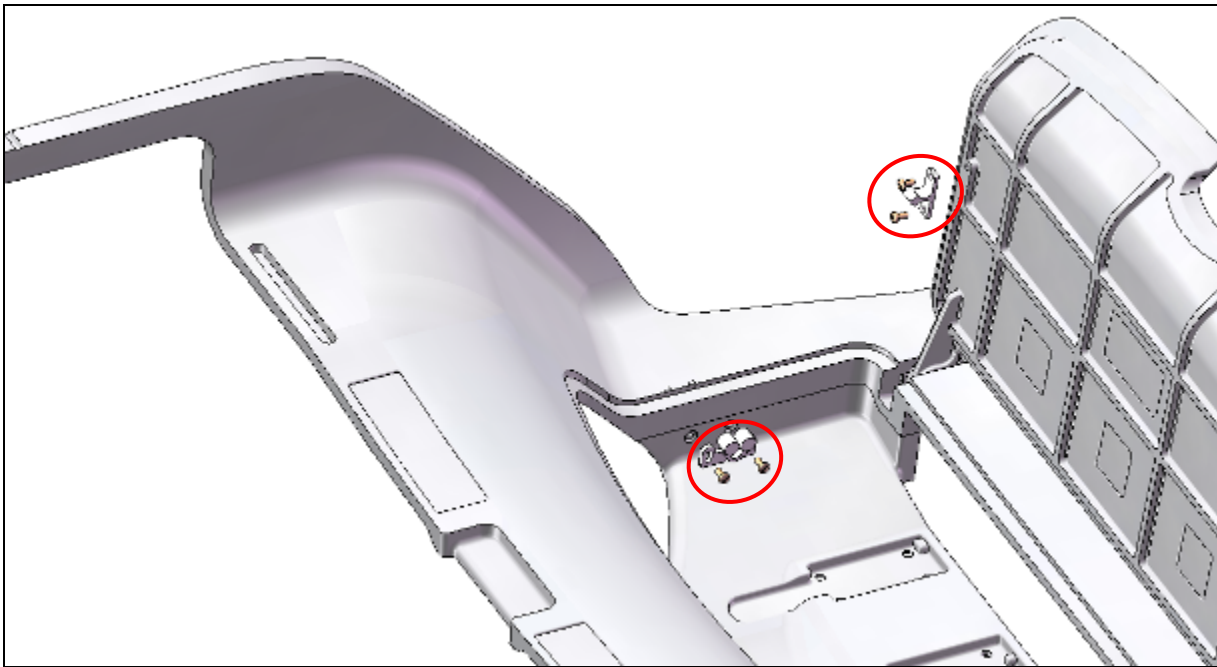
**GEHC Part #:** Contained in 5408246

**Time required:** 20 minutes

**Tools required:** Slot Screwdriver

**Personnel required:** 1

1. Open the Patient Support Cover.
2. Remove the striker from the underside the Patient Support Cover by unfastening two mounting screws.
3. Remove the rotary catch from the Patient Support by unfastening two mounting screws.
4. Remove the rotary catch and striker and replace with a new rotary catch and striker.
5. Partially fasten the rotary catch to the Patient Support with two screws.
6. Fasten the striker to the underside the Patient Support Cover with two screws.
7. With the cover closed, position and hold in place the catch assembly. Open the cover and tighten the screws.



**Figure 39**

### **Finalization Steps**

- i. Test function of new Patient Support Cover Catches by opening and closing the Patient Support Cover.
- ii. Ensure no interference, misalignment or noises are evident.
- iii. Inspect the rotary catches for any scratching or roughness which would indicate striker misalignment.

# Appendix A

## Vanguard Tabletop for GE 1.5T 8Ch HDx Installation Verification Checklist

Install Date:	D _ D _ M _ M _ M _ 20 Y _ Y _	Location:	CITY, STATE / PROVINCE , _ _ _
Customer Name:			
Vanguard Serial #:		Configuration:	_ Channel
Scanner:	_ T GE Signa	Software Rev:	1 _ . _ _ _ _ _ _

After completion of install, the following items must be checked to verify function of the Vanguard on a GE Signa 1.5T MRI scanner:

### Installation

- .. All components unpackaged, inspected and free of blemishes or damage.
- .. Patient support fits flatly on scanner bed and remains stationary.
- .. Patient support is centered and does not contact bore or any other surface.
- .. System is clean and free of fingerprints or debris.
- .. All coils snap in and hold firmly in the compression frames.
- .. Compression sliders slide smoothly and locks (2) work without excessive force.
- .. All padding is present, free of rips or damage and installed as per reference card.

### SNR/QA Verification

#### For QA Scans using Spherical Phantoms

- .. 8ch BL MCQA Result: Pass / Fail (Circle Result)
- .. 4ch BL MCQA Result: Pass / Fail (Circle Result)
- .. SNR protocol is saved on scanner console.
- .. SNR results for all configurations are recorded in the user manual.

#### For QA Scans using Rectangular Phantoms

- .. 8ch BL SNR: \_ \_ \_ (>403), 8 channels functioning (input XXX if not applicable)
- .. 4ch BL SNR: \_ \_ \_ (>333), 4 channels functioning
- .. 2ch UL SNR: \_ \_ \_ (>280), 2 channels functioning

<b>SMI ONLY</b>	<ul style="list-style-type: none"> <li>.. Any results not in specification reported immediately to SMI Service – 1-866-735-3744.</li> <li>.. For any failing results, DICOM data saved to USB/DVD storage.</li> </ul>
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### Pre-Departure

- .. All parts and accessories are present and shortages reported immediately.
- .. Accessories are neatly grouped for storage and/or as directed by customer.

<b>SMI ONLY</b>	<ul style="list-style-type: none"> <li>.. Fill out calling card and leave it in a visible location.</li> <li>.. Any items not checked must be reported immediately by phone to SMI Service Department.</li> <li>.. After completing this checklist, provide a signed copy to the SMI Service Department.</li> </ul>
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<b>GEHC ONLY</b>	<ul style="list-style-type: none"> <li>.. After completing this checklist, store a signed copy on site.</li> </ul>
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All items checked confirms Vanguard installation successfully completed.

Name:	Position: D _ M _ M _ Y _	Company:
Signed:	Date: _ _ _ _ 20 _ _	
Notes:		