GE Healthcare

Optima EMS ECG Management System Service Manual

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Publication Information

The information in this manual applies only to Optima EMS ECG Management System Version 1.0. It does not apply to earlier product versions. Due to continuing product innovation, specifications in this manual are subject to change without notice.

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The document part number and revision appear at the bottom of each page. The revision identifies the document's update level. The revision history of this document is summarized in the following table.

Revision	Date	Comments
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В	Nov 11, 2012	Initial Customer Release

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To access Original Equipment Manufacturer (OEM) manuals, go to the device manufacturer's Web site.

Service Manual Language Information

WARNING	This service manual is available in English only.
(EN)	• 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.
ПРЕДУПРЕЖДЕНИЕ	Това упътване за работа е налично само на английски език.
(BG)	 Ако доставчикът на услугата на клиента изиска друг език, задължение на клиента е да осигури превод.
	 Не използвайте оборудването, преди да сте се консултирали и разбрали упътването за работа.
	 Неспазването на това предупреждение може да доведе до нараняване на доставчика на услугата, оператора или пациент в резултат на токов удар или механична или друга опасност.
警告	本维修手册仅提供英文版本。
ZH-CN	● 如果维修服务提供商需要非英文版本,客户需自行提供翻译服务。
	 未详细阅读和完全理解本维修手册之前,不得进行维修。
	● 忽略本警告可能对维修人员,操作员或患者造成触电、机械伤害或其他形式的伤害。
警告	本維修手冊只提供英文版。
(ZH-TW)	 如果客戶的維修人員有英語以外的其他語言版本需求,則由該客戶負責提供翻 譯服務。
	 除非您已詳閱本維修手冊並了解其內容,否則切勿嘗試對本設備進行維修。
	 不重視本警告可能導致維修人員、操作人員或病患因電擊、機械因素或其他因素 而受到傷害。

UPOZORENJE	Ove upute za servisiranje dostupne su samo na engleskom jeziku.
(HR)	 Ukoliko korisnički servis zahtijeva neki drugi jezik, korisnikova je odgovornost osigurati odgovarajući prijevod.
	• Nemojte pokušavati servisirati opremu ukoliko niste konzultirali i razumjeli ove upute.
	 Nepoštivanje ovog upozorenja može rezultirati ozljedama servisnog osoblja, korisnika ili pacijenta prouzročenim električnim udarom te mehaničkim ili nekim drugim opasnostima.
VAROVÁNÍ	Tento provozní návod existuje pouze v anglickém jazyce.
(CS)	 V případě, že externí služba zákazníkům potřebuje návod v jiném jazyce, je zajištění překladu do odpovídajícího jazyka úkolem zákazníka.
	 Nesnažte se o údržbu tohoto zařízení, aniž byste si přečetli tento provozní návod a pochopili jeho obsah.
	 V případě nedodržování této varování může dojít k poranění pracovníka prodejního servisu, obslužného personálu nebo pacientů vlivem elektrického proudu, respektive vlivem mechanických či jiných rizik.
ADVARSEL	Denne servicemanual findes kun på engelsk.
(DA)	• 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 har været konsulteret og er forstået.
	 Manglende overholdelse af denne advarsel kan medføre skade på grund af elektrisk, mekanisk eller anden fare for teknikeren, operatøren eller patienten.
WAARSCHUWING	Deze service manual is alleen in het Engels verkrijgbaar.
(NL)	 Indien het onderhoudspersoneel een andere taal nodig heeft, dan is de klant verantwoordelijk voor de vertaling ervan.
	• Probeer de apparatuur niet te onderhouden voordat deze service manual geraadpleegd en begrepen is.
	 Indien deze waarschuwing niet wordt opgevolgd, zou het onderhoudspersoneel, de gebruiker of een patiënt gewond kunnen raken als gevolg van een elektrische schok, mechanische of andere gevaren.
HOIATUS	Käesolev teenindusjuhend on saadaval ainult inglise keeles.
(ET)	• 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	Tämä huolto-ohje on saatavilla vain englanniksi.
(FI)	• Jos asiakkaan huoltohenkilöstö vaatii muuta kuin englanninkielistä materiaalia, tarvittavan käännöksen hankkiminen on asiakkaan vastuulla.
	 Älä yritä korjata laitteistoa ennen kuin olet varmasti lukenut ja ymmärtänyt tämän huolto-ohjeen.
	 Mikäli tätä varoitusta ei noudateta, seurauksena voi olla huoltohenkilöstön, laitteiston käyttäjän tai potilaan vahingoittuminen sähköiskun, mekaanisen vian tai muun vaaratilanteen vuoksi.

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	Ce manuel technique n'est aisponible qu'en anglais.
(ГК)	 Si un service technique client souhaite obtenir ce manuel dans une autre langue que l'anglais, il devra prendre en charge la traduction et la responsabilité du contenu.
	 Ne pas tenter d'intervenir sur les équipements tant que le manuel technique 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	Diese Serviceanleitung ist nur in englischer Sprache verfügbar.
(DE)	• Falls der Kundendienst eine andere Sprache benötigt, muss er für eine entsprechende Übersetzung sorgen.
	• Keine Wartung durchführen, ohne diese Serviceanleitung gelesen und verstanden zu haben.
	 Bei Zuwiderhandlung kann es zu Verletzungen des Kundendiensttechnikers, des Anwenders oder des Patienten durch Stromschläge, mechanische oder sonstige Gefahren kommen.
ΠΡΟΕΙΔΟΠΟΙΗΣΗ	Το παρόν εγχειρίδιο σέρβις διατίθεται στα αγγλικά μόνο.
(GR)	 Εάν το άτομο παροχής σέρβις ενός πελάτη απαιτεί το παρόν εγχειρίδιο σε γλώσσα εκτός των αγγλικών, αποτελεί ευθύνη του πελάτη να παρέχει υπηρεσίες μετάφρασης.
	 Μην επιχειρήσετε την εκτέλεση εργασιών σέρβις στον εξοπλισμό εκτός εάν έχετε συμβουλευτεί και έχετε κατανοήσει το παρόν εγχειρίδιο σέρβις.
	 Εάν δεν λάβετε υπόψη την προειδοποίηση αυτή, ενδέχεται να προκληθεί τραυματισμός στο άτομο παροχής σέρβις, στο χειριστή ή στον ασθενή από ηλεκτροπληξία, μηχανικούς ή άλλους κινδύνους.
FIGYELMEZTETÉS	Ez a szerviz kézikönyv kizárólag angol nyelven érhető el.
(HU)	 Ha a vevő szerviz ellátója angoltól eltérő nyelvre tart igényt, akkor a vevő felelőssége a fordítás elkészíttetése.
	 Ne próbálja elkezdeni használni a berendezést, amíg a szerviz kézikönyvben leírtakat nem értelmezték és értették meg.
	 Ezen figyelmeztetés figyelmen kívül hagyása a szerviz ellátó, a működtető vagy a páciens áramütés, mechanikai vagy egyéb veszélyhelyzet miatti sérülését eredményezheti.
AÐVÖRUN	Þessi þjónustuhandbók er eingöngu fáanleg á ensku.
(IS)	 Ef að þjónustuveitandi viðskiptamanns þarfnast annars tungumáls en ensku, er það skylda viðskiptamanns að skaffa tungumálaþjónustu.
	• Reynið ekki að afgreiða tækið nema þessi þjónustuhandbók hefur verið skoðuð og skilin.
	 Brot á að sinna þessari aðvörun getur leitt til meiðsla á þjónustuveitanda, stjórnanda eða sjúklingi frá raflosti, vélrænum eða öðrum áhættum.
PERINGATAN	Manual servis ini hanya tersedia dalam bahasa Inggris.
(ID)	• Jika penyedia jasa servis pelanggan memerlukan bahasa lain selain dari Bahasa Inggris, merupakan tanggung jawab dari penyedia jasa servis tersebut untuk menyediakan terjemahannya.
	• Jangan mencoba melakukan servis terhadap perlengkapan kecuali telah membaca dan memahami manual servis ini.
	 Mengabaikan peringatan ini bisa mengakibatkan cedera pada penyedia servis, operator, atau pasien, karena terkena kejut listrik, bahaya mekanis atau bahaya lainnya.

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AVVEKTENZA	i presente manuale al manutenzione e aisponibile soltanto in Inglese.
(11)	• Se un addetto alla manutenzione 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.
	 Il non rispetto 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.
警告	このサービスマニュアルは英語版しかありません。
(AL)	 サービスを担当される業者が英語以外の言語を要求される場合、翻訳作業はその業者の責任で行うものとさせていただきます。
	 このサービスマニュアルを熟読し、十分に理解をした上で装置のサービスを 行ってください。
	 この警告に従わない場合、サービスを担当される方、操作員あるいは患者が、感電 や機械的又はその他の危険により負傷する可能性があります。
경고	본 서비스 지침서는 영어로만 이용하실 수 있습니다.
(KO)	 고객의 서비스 제공자가 영어 이외의 언어를 요구할 경우, 번역 서비스를 제공하는 것 은 고객의 책임입니다.
	 본 서비스 지침서를 참고했고 이해하지 않는 한은 해당 장비를 수리하려고 시도하 지 마십시오.
	 이 경고에 유의하지 않으면 전기 쇼크, 기계상의 혹은 다른 위험으로부터 서비스 제 공자, 운영자 혹은 환자에게 위해를 가할 수 있습니다.
BRĪDINĀJUMS	Šī apkalpotāju rokasgrāmata ir pieejama tikai angļu valodā.
(LV)	 Ja apkalpošanas sniedzējam nepieciešama informācija citā, nevis angļu, valodā, klienta pienākums ir nodrošināt tās tulkošanu.
	Neveiciet aprīkojuma apkopi, neizlasot un nesaprotot apkalpotāju rokasgrāmatu.
	 Šī brīdinājuma neievērošana var radīt elektriskās strāvas trieciena, mehānisku vai citu risku izraisītu traumu apkopes sniedzējam, operatoram vai pacientam.
ĮSPĖJIMAS	Šis eksploatavimo vadovas yra prieinamas tik anglų kalba.
(LT)	 Jei kliento paslaugų tiekėjas reikalauja vadovo kita kalba - ne anglų, numatyti vertimo paslaugas yra kliento atsakomybė.
	 Nemėginkite atlikti įrangos techninės priežiūros, nebent atsižvelgėte į šį eksploatavimo vadovą ir jį supratote.
	 Jei neatkreipsite dėmesio į šį perspėjimą, galimi sužalojimai dėl elektros šoko, mechaninių ar kitų paslaugų tiekėjui, operatoriui ar pacientui.
ADVARSEL	Denne servicehåndboken finnes bare på engelsk.
(NO)	 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	Niniejszy podręcznik serwisowy dostępny jest jedynie w języku angielskim.
(PL)	 Jeśli dostawca usług klienta wymaga języka innego niż angielski, zapewnienie usługi tłumaczenia jest obowiązkiem klienta.
	 Nie należy serwisować wyposażenia bez zapoznania się i zrozumienia niniejszego podręcznika serwisowego.
	 Niezastosowanie się do tego ostrzeżenia może spowodować urazy dostawcy usług, operatora lub pacjenta w wyniku porażenia elektrycznego, zagrożenia mechanicznego bądź innego.
AVISO	Este manual de assistência técnica só se encontra disponível em inglês.
(PT-BR)	 Se o serviço de assistência técnica do cliente não for GE, e precisar de outro idioma, será 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	Este manual técnico só se encontra disponível em inglês.
(PT-PT)	 Se a assistência técnica do cliente 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 técnico.
	 O não cumprimento deste aviso pode provocar lesões ao técnico, ao utilizador ou ao paciente devido a choques eléctricos, mecânicos ou outros.
AVERTISMENT	Acest manual de service este disponibil numai în limba engleză.
(RO)	 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.
ПРЕДУПРЕЖДЕНИЕ	Настоящее руководство по обслуживанию предлагается только на английском языке.
(RU)	 Если сервисному персоналу клиента необходимо руководство не на английском, а на каком-то другом языке, клиенту следует обеспечить перевод самостоятельно.
	 Прежде чем приступать к обслуживанию оборудования, обязательно обратитесь к настоящему руководству и внимательно изучите изложенные в нем сведения.
	 Несоблюдение требований данного предупреждения может привести к тому, что специалисты по обслуживанию, операторы или пациенты получат удар электрическим током, механическую травму или другое повреждение.
UPOZORENJE	Ovo servisno uputstvo je dostupno samo na engleskom jeziku.
(SR)	 Ako klijentov serviser zahteva neki drugi jezik, klijent je dužan da obezbedi prevodilačke usluge.
	Ne pokušavajte da opravite uređaj ako niste pročitali i razumeli ovo servisno uputstvo.
	 Zanemarivanje ovog upozorenja može dovesti do povređivanja servisera, rukovaoca ili pacijenta usled strujnog udara, ili mehaničkih i drugih opasnosti.

VAROVANIE	Tento návod na obsluhu je k dispozícii len v angličtine.
(SK)	 Ak zákazníkov poskytovateľ služieb vyžaduje iný jazyk ako angličtinu, poskytnutie prekladateľských služieb je zodpovednosťou zákazníka.
	 Nepokúšajte sa o obsluhu zariadenia skôr, ako si neprečítate návod na obsluhu a neporozumiete mu.
	 Zanedbanie tohto varovania môže vyústiť do zranenia poskytovateľa služieb, obsluhujúcej osoby alebo pacienta elektrickým prúdom, mechanickým alebo iným nebezpečenstvom.
OPOZORILO	Ta servisni priročnik je na voljo samo v angleškem jeziku.
(SL)	• Če ponudnik storitve stranke potrebuje priročnik v drugem jeziku, mora stranka zagotoviti prevod.
	• Ne poskušajte servisirati opreme, če tega priročnika niste v celoti prebrali in razumeli.
	• Če tega opozorila ne upoštevate, se lahko zaradi električnega udara, mehanskih ali drugih nevarnosti poškoduje ponudnik storitev, operater ali bolnik.
ADVERTENCIA	Este manual de servicio sólo existe en inglés.
(ES)	• Si el encargado de mantenimiento de un cliente necesita un idioma que no sea el inglés, el cliente deberá encargarse de la traducción del manual.
	 No se deberá dar servicio técnico al equipo, sin haber consultado y comprendido este manual de servicio.
	 La no observancia del presente aviso puede dar lugar a que el proveedor de servicios, el operador o el paciente sufran lesiones provocadas por causas eléctricas, mecánicas o de otra naturaleza.
VARNING	Den här servicehandboken finns bara tillgänglig på engelska.
(SV)	 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.
UYARI	Bu servis kılavuzunun sadece İngilizcesi mevcuttur.
(TR)	• Eğer müşteri teknisyeni bu kılavuzu İngilizce dışında bir başka lisandan talep ederse, bunu tercüme ettirmek müşteriye düşer.
	Servis kılavuzunu okuyup anlamadan ekipmanlara müdahale etmeyiniz.
	• Bu uyarıya uyulmaması, elektrik, mekanik veya diğer tehlikelerden dolayı teknisyen, operatör veya hastanın yaralanmasına yol açabilir.

ЗАСТЕРЕЖЕННЯ	Дане керівництво з сервісного обслуговування постачається виключно англійською мовою.
(UK)	 Якщо сервісний інженер потребує керівництво іншою мовою, користувач зобов'язаний забезпечити послуги перекладача.
	 Не намагайтеся здійснювати технічне обслуговування даного обладнання, якщо ви не читали, або не зрозуміли інформацію, надану в керівництві з сервісного обслуговування.
	 Недотримання цього застереження може призвести до травмування сервісного інженера, користувача даного обладнання або пацієнта внаслідок електричного шоку, механічного ушкодження або з інших причин невірного обслуговування обладнання.
C Ả NH BÁO	Tài Liệu Hướng Dẫn Sửa Chữa chỉ có bản tiếng Anh.
(VI)	 Nếu các đơn vị cung cấp dịch vụ cho khách hàng yêu cầu một ngôn ngữ nào khác tiếng Anh, thì khách hàng sẽ có trách nhiệm cung cấp các dịch vụ dịch thuật.
	 Không được sửa chữa thiết bị trừ khi đã tham khảo và hiểu Tài liệu Hướng dẫn Sửa chữa.
	 Không tuân thủ những cảnh báo này có thể dẫn đến các tổn thương cho người thực hiện sửa chữa, người vận hành hay bệnh nhân, do sốc điện, các rủi ro về cơ khí hay các rủi ro khác.

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1

Introduction

This document describes the Optima EMS ECG Management System, also referred to as "the system".

This chapter provides general information required for the proper use of the system and the manual. Familiarize yourself with this information before using the system.

Intended Use

The system is intended to:

- Provide centralize storage and management for electrocardiograph information in a hospital setting;
- Provide the ability to review electrocardiograph records;
- Provide report templates for electrocardiograph report reviewing and editing for physicians;
- Provide the ability to query and generate statistics for ECG data.

Intended User

The system is a software-only product. The user should have experience working on a PC computer.

Contraindications

The following contraindications apply to this system:

- The system does not have diagnostic functionality.
- The system is not intended for real-time patient monitoring.
- The system is not intended for the transfer of time-sensitive data.

System Accuracy

Accuracy of the system is 100% data reproduction, dependent on zoom settings, and the resolution of the display and/or printer you are using.

Regulatory and Safety Information

This section provides information about the safe use and regulatory compliance of this system. Familiarize yourself with this information, and read and understand all instructions before attempting to use this system. The system software is considered medical software. As such, it was designed and manufactured to the appropriate medical regulations and controls.

NOTE:

Disregarding the safety information provided in this manual is considered abnormal use of this system and could result in injury, data loss, or a voided warranty.

Safety Conventions

A **Hazard** is a source of potential injury to a person, property, or the system.

This manual uses the terms DANGER, WARNING, CAUTION, and NOTICE to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with the following definitions and their significance.

Safety Convention	Definition
DANGER	Indicates an imminent hazard, which, if not avoided, will result in death or serious injury.
WARNING	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in moderate or minor injury.
NOTICE	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property or data.

Definitions of Safety Conventions

Safety Hazards

The following messages apply to the system as a whole. Specific messages may also be provided elsewhere in the manual.

NOTICE:

Changing settings without knowing how they affect the system can cause loss of data. Do not change any current settings unless you understand how the change affects the system.

NOTICE:

Installation of software not specified by GE Healthcare may cause damage to the equipment, loss or corruption of data. DO NOT load any software other than that specified by GE Healthcare onto the system.

General Safety Requirements

The device or system is labeled under the original equipment manufacturer's label (for example, UL, CE EU LVD 2006/95/EC) and deemed sufficient by GE Healthcare to be in compliance with EN/IEC 60601-1 (clause 3.201.2 for use of non-medical devices in a medical system), when used according to the device or system's intended use. Hardware supplied by GE Healthcare meets the applicable country requirements for Information Technology Equipment (ITE).

Information Technology Equipment Requirements

The hardware components of the system are not considered medical equipment. They are considered Information Technology Equipment (ITE). The system's individual components comply with the standards for Safety of Information Technology Equipment (for example, UL 60950-1, EN/IEC 60950-1).

If you use the system in a patient's vicinity, it must comply with the standard requirements for medical systems (that is, EN/IEC 60601-1).

- To comply with this standard, you must connect the components and all attached accessories to a medical grade (EN/IEC 60601-1) power source (for example, Medical grade UPS or Isolation Transformer).
- System Inputs/Outputs connected to non-medical equipment must also be isolated for overall system compliance.
- Patient vicinity is defined as a space, within a location intended for the examination and treatment of patients, extending 1.83m (6 ft.) beyond the normal location of the bed, chair, table, treadmill, or other device(s) supporting the patient during examination and treatment, and extending vertically to 2.5m (8 ft. 2.4 in.) above the floor.

In addition, any non-medical electrical equipment that you use with the system (outside the patient vicinity) must comply with applicable safety standards for that equipment (that is, EN/IEC 60950-1).

NOTE:

If the equipment is installed in the U.S.A. using 240V rather than 120V, the source must be a center-tapped, 240V, single-phase circuit.

Responsibility of the Purchaser/Customer

The customer is responsible for providing appropriate desks, chairs, electrical wall outlets, network connections, and analog phone lines, and for locating any of the system components described in this manual in compliance with all local, state, and national codes.

Product and Packaging Information

This section identifies the labels, indicates their locations on the product and its packaging, and describes the symbols used. See "Symbol Descriptions" on page 16 for detailed descriptions of the symbols used on these labels.

Software Label Locations

The following illustration and table describe the label on your CD or DVD.

NOTE:

The Serial Number is located on the jewel case of your CD or DVD.



Descriptions of CD/DVD Label

Item	Description
1	Product Name
2	Software Model
3	Copyright Notice
4	Software Version
5	Serial Number
6	Part Number
7	Revision
8	Date of Manufacture

Symbol Descriptions

The following table describes symbols or icons that may be on the device or its packaging. Not all of the symbols defined in the table apply to your device or its packaging.

Symbols are used to convey warnings, cautions, prohibitions, mandatory actions, or information. Any symbol on your device or packaging with markings in color indicates there may be a danger, warning, or mandatory action. Any symbol on your device or packaging that is in black and white provides additional information or may indicate a caution. Familiarity with these symbols assists in the use and disposal of the equipment.

For equipment symbols not shown, refer to the original equipment manufacturer (OEM) manuals.

Symbol	Description
REF	Catalog or Orderable Part Number Indicates the manufacturer's catalog or part number.
SN	Serial Number Indicates the manufacturer's serial number.
LOT	Batch Code or Lot Number Indicates the manufacturer's batch code or lot number.
$\sim \sim$	Date of Manufacture (Year-Month) Indicates the original manufacture date for this device.
	Manufacturer Indicates the name and address for the manufacturer of this device. It may also include the date it was manufactured.
EC REP	Authorized Representative in the European Community Indicates the name and address of the authorized representative in the European Community for this device.
12SL MARQUETTE	12SL Indicates the device uses the Marquette™ 12SL ECG Analysis Program to analyze and interpret ECG readings.
	Consult Instructions for Use Consult the operating instructions.
\bigotimes	No User– or Field-serviceable Parts Do not open or disassemble the device for any reason.
	Class II Equipment Identifies equipment that meets the safety requirements specified for class II equipment by IEC 60601–1. This device was designed so that it does not require a safety connection to electrical earth (US ground). No single failure results in dangerous voltage becoming exposed and causing an electric shock. This is achieved without relying on an earthed metal casing.

Symbol	Description
	Defibrillation-proof Type BF Applied Part Identifies a defibrillation-proof type BF applied part on medical equipment that complies with IEC 60601–1. This device meets the requirements for protection against electric shock for an earth-free (floating) applied part (one intended for contact with patients).
	Defibrillation-proof Type CF Applied Part Identifies a defibrillation-proof type CF applied part on medical equipment that complies with IEC 60601–1. This device meets the requirements for protection against electric shock for an earth-free (floating) applied part (one intended for contact with patients) for cardiac application.
IPxy	IP Code (Ingress Protection Rating) Classifies and rates the degree of protection provided against the intrusion of solid objects (such as body parts like hands and fingers, dust, accidental contact), and fluids. The first numeral (x) represents the degree of protection against the ingress of solid objects. The second numeral (y) represents the degree of protection against the ingress of liquids. For products with an IPxy rating, refer to the <i>Classification of Medical</i> <i>Device</i> in this chapter for a description of that rating. Not all products have an IPxy rating.
	CAUTION: SAFETY GROUND PRECAUTION Pulling on the cable can cause the cord to deteriorate resulting in electrical problems. Remove the power cord from the mains source by grasping the plua_DO NOT pull on the cable
\triangle	CAUTION: CONSULT ACCOMPANYING DOCUMENTS There may be specific warnings or precautions associated with the device that are not otherwise found on the label. Consult the accompanying documentation for more information about safely using this device.
<u>A</u>	CAUTION: ELECTRIC SHOCK Indicates the presence of hazardous energy circuits or electric shock hazards. To reduce the risk of electric shock hazards, do not open this enclosure. Refer servicing to qualified personnel.
	CAUTION: HOT SURFACE Indicates that the marked item may be hot. Take appropriate precautions before touching the item.

Symbol	Description
(((•)))	Non-ionizing Electromagnetic Radiation Indicates that the equipment emits elevated, potentially hazardous, levels of non-ionizing radiation (electromagnetic energy) for diagnosis or treatment.
	Protective Earth (ground) Identifies the terminal of a protective earth (ground) electrode or any terminal that is intended for connection to an external conductor for protection against electric shock in case of a fault.
	Follow Instructions For Use Read and understand the operator's manual before using the device or product. As a mandatory action sign, this symbol is identified by a blue background and white symbol.
	WARNING: ENVIRONMENTAL OR HEALTH HAZARD Incinerating the device or product could present a risk to the environment or human health.
	Do not incinerate this device or product. As a general prohibition sign, this symbol is identified by a white background, red circular band and slash, and a black symbol.
	WARNING: HAND CRUSHING HAZARD This device contains moving parts that could crush the user's hand. Keep hands clear of the device while it is in operation. Disconnect power before reaching into or servicing the device.
	As a warning sign, this symbol is identified by a yellow background, black triangular band, and a black symbol.
	WARNING: PINCH POINT This device contains moving parts that could pinch body parts. Keep hands clear of the device while it is in operation. Disconnect the power before reaching into or servicing the device.
	As a general prohibition sign, this symbol is identified by a white background, red circular band and slash, and a black symbol.
	WARNING: PERSONAL INJURY DO NOT REACH IN Reaching into the equipment can cause personal injury. Do not place hands into any openings.
	As a general prohibition sign, this symbol is identified by a white background, red circular band and slash, and a black symbol.

Symbol	Description
	 WARNING: BODILY INJURY Indicates the presence of mechanical parts that can result in pinching, crushing, or other bodily injury. To avoid risk of bodily injury, keep away from moving parts. Disconnect power before reaching into area or servicing. As a warning sign, this symbol is identified by a yellow background, black triangular band, and a black symbol.
	 WARNING: BODILY INJURY Indicates the presence of a sharp edge or object that can cause cuts or other bodily injury. To prevent cuts or other bodily injury, do not contact sharp edge of object. As a warning sign, this symbol is identified by a yellow background, black
	 triangular band, and a black symbol. WARNING: BODILY INJURY Indicates the presence of a potential tip-over hazard that can result in bodily injury. To avoid risk of bodily injury, follow all instructions for maintaining the stability of the equipment during transport, installation, and maintenance. As a warning sign, this symbol is identified by a yellow background, black triangular band, and a black symbol.
X	Upper Temperature Limit Indicates the maximum temperature for transportation and handling of this package. The limit is indicated next to the upper horizontal line.
X	Temperature Limits Indicates the upper and lower temperature limits for the transportation and handling of this package. They are indicated next to the upper and lower horizontal lines.
	Can Be Recycled Indicates you may recycle this material or device. Recycle or dispose of in accordance with local, state, or country laws.
X	Waste Electrical and Electronic Equipment (WEEE) Indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste but collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Symbol	Description
	Contains <heavy chemical="" metal="" symbol=""></heavy> Indicates this equipment contains heavy metal and must not be disposed of as unsorted municipal waste but collected separately. The example shows Lithium Ion.
(a)	 Environmental Friendly Use Period (EFUP) Per Chinese standard SJ/T11363–2006, indicates the number of years from the date of manufacture during which you can use the product before any restricted substances are likely to leak, causing a possible environmental or health hazard. NOTE: If the device contains less than the maximum concentration of restricted substances, the symbol contains a lowercase <i>e</i>. This is also referred to as China RoHS.
	Innan BoHS
G F WW, XX, YY, ZZ	Indicates the device or product meets the regulations limit or ban for specific substances in new electronic and electric equipment in Japan. The Green Mark (with the G) indicates the product is within the tolerances of hazardous chemicals. The Content Mark (with the R and letters below) indicates which hazardous substance(s) was used during the manufacturing of the electrical or electronic equipment that exceeds maximum tolerances.
Ĭ	Fragile Indicates the contents are fragile. Handle with care.
<u>11</u>	This Way Up Indicates the correct upright position of the package.
☆■	Do Not Stack Indicates that you should not stack the container or place a load on the container.
	Keep Dry Indicates that you need to keep the container away from rain and other sources of moisture.
<u>ش</u>	Humidity Limits Indicates upper and lower humidity limits for the transportation and handling of this package. They are indicated next to the upper and lower horizontal lines.

Symbol	Description
6.6	Atmospheric Limits Indicates the upper and lower barometric pressure limitations for the transportation and handling of this package. They are indicated next to the upper and lower horizontal lines.
Rx Only	Rx Only US Federal law restricts this device to sale by or on the order of a physician.

The following table describes certification symbols that may be used on your device or its packaging. The inclusion of a symbol in this table **does not** indicate that your product was certified by that symbols governing body and is listed for reference only. To identify which organizations have certified your device, refer to the labeling on your device or its packaging.

Certification Symbols

Certification Symbol	Description
(UL)	UL Mark Indicates compliance with applicable Underwriters Laboratories requirements.
LISTED	UL Listed Mark Indicates compliance with international or regional standards for Underwriters Laboratories safety requirements.
	UL Listed, Canada/US Indicates compliance with international or regional standards for Underwriters Laboratories safety requirements in Canada and the United States.
	UL Classification Mark Indicates this medical equipment is UL Classified with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 NO. 601.1, and IEC 60601-2-25.
CUL US	UL Classification Mark, Canada/US Indicates this medical equipment is UL Classified with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 NO. 601.1, and IEC 60601-2-25 for the US and Canada.
CE	CE Mark Indicates the device or product conforms with applicable EU (European Union) directives.
	PCT (GOST-R) Mark Indicates the device or product conforms with applicable Russian Gosstandard technical and safety standards.

Certification Symbols (cont'd.)

Certification Symbol	Description
	NRTL Certification Indicates the device or product has met the National Recognized Testing Laboratories certification. The NRTL certification attainted is added to the mark of the applicable testing laboratory. The example displays the NRTL certification with the MET Laboratories mark.
(Ľ)	China Metrology Certification Indicates the device or product complies with applicable China Metrology Certification requirements.
F©	FCC Approval (US only) Indicates the device or product complies with Federal Communications Commission Rule Part 18 Subpart B (Section 18.203) – General information regarding applications and authorizations for industrial, scientific, and medical (ISM) equipment.
TÜVRheisland US TÜVRheisland US	TÜV Rheinland Indicates the device or product complies with applicable technical and safety requirements following testing by Technischer Überwachungs-Verein, (Technical Inspections Organization).
	CCC (China) Indicates the device or product conforms with applicable China requirements.

Training

This manual is intended as a supplement to, not a substitute for, thorough product training. If you have not received training on the use of the system, you should request training assistance from GE Healthcare.

To see available training, go to the GE Healthcare training Web site (<u>http://www.gehealthcare.com/usen/education/index.html</u>). Select *Education>Product Education-Technical>Diagnostic Cardiology*.

For more self-paced course offerings, tools, and reference guides you may find useful, please visit the GE Healthcare Education Store at www.gehealthcare.com/educationstore.

Equipment Identification

Every GE Healthcare product has a product label that identifies the product name, part number, manufacturing information, and unique serial number. This information is required when contacting GE Healthcare for support.

Product Label

The product label is laid out in the following format. Depending on the product, the label may vary slightly in format, but it contains the same information.

Op	tima E	MS
	V1.0	-
Manufacturer : Co., Ltd. Address: No.19 National Hi-tecl P.R.China Tel: (0510)8522 Fax: (0510)8522 Date of MFG: Volume: 310×24 Net Weight: 2KG Gross Weight: 3 Quantity: 1/1 P.N. 2061284-(S/N XXXXXX-)	GE Medical Sys , Changjiang Ro h Development 5888 6688 42×55 (mm) 3 KG 001 • XX	tems (China) ad Wuxi Zone Jiangsu, 2

Item	Description
1	Product description
2	Manufacturer name and address
3	Product part number
4	Product serial number
5	Product bar code

Serial Number Format

Each device has a serial number that uniquely identifies it and provides important information. You need the product code and the entire serial number before servicing

or requesting support for your product. The serial number format is shown in the following illustration:



Serial Number Format

Item	Name	Description
1	Product Code	Three-letter code that uniquely identifies the product line. See "Product Codes" on page 25 for more information.
2	Year Manufactured	Two-digit code identifying the year the device was manufactured. Values range from 00 to 99 For example: 00 = 2000, 04 = 2004, 05 = 2005 (and so on).
3	Fiscal Week Manufactured	Two-digit code identifying the week the device was manufactured. Values range from 01 to 52. GE Healthcare's fiscal weeks correspond to the calendar week. For example, 01 = first week in January.
4	Product Sequence	Four-digit number identifying the order in which this device was manufactured. Values range from 000 to 9999.
5	Manufacturing Site	One-letter code identifying the site where the device was manufactured. For example, F = Milwaukee, N = Freiburg, P = Bangalore
6	Miscellaneous Characteristic	For example, $P =$ device is a prototype, $R =$ device was refurbished, $U =$ device was upgraded to meet the specifications of another product code, $A =$ device is in production.

Product Codes

The product code identifies specific system platforms.

You can identify the product code using the serial number listed on the product label located in one of the following places:

- On the product label attached to the device.
- On the product label provided with the application CD.

For software application systems, you can view the serial number by launching the system application and clicking *Help* > *About*.

For information on launching the application, refer to the service or operator's manual for this system.

Service Information

This section provides information pertaining to the maintenance and servicing of the system. Familiarize yourself with this information before requesting service from GE Healthcare or its authorized representatives.

Service Requirements

Failure on the part of the responsible individual, hospital, or institution using this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible safety hazards.

Regular maintenance, irrespective of usage, is essential to ensure that the components of this system are always functional when required.

Customer-supplied Hardware

Customers who purchase their own equipment are responsible for any repair or maintenance, and for completing equipment checkout after any repair or maintenance.

Security Updates

A list of viruses that pose a significant threat to GE Healthcare customers' system security is posted on the GE Healthcare Product Security web site.

As new vulnerabilities and potential security issues arise, GE Healthcare makes every effort to quickly identify and notify customers of approved fixes. Time is required for GE Healthcare to identify the vulnerability, test the fix, and run a validation test on the system for safety and functionality. Only after this rigorous process does GE Healthcare release the official patch. While we recognize the urgency to correct these problems, we must ensure that the integrity of the system is not compromised.

After security patches are validated for specific GE Healthcare systems, the information is added to the Product Security website . You can download the patch directly from the website of the software manufacturer (Microsoft, and so forth) and apply it to your GE Healthcare system. To check on the latest information regarding validated security patches:

1. Browse to the GE Healthcare Product Security website: <u>http://</u> prodsecdb.gehealthcare.com

The Single Sign On (SSO) window opens.

2. Enter your SSO number and password and click *Log In*.

If you do not have an SSO number, click the *Sign Up* link to obtain one.

3. Use the features on the GE Healthcare *Product Security Database* Web site to identify security patches that you can apply to your system.

Additional Assistance

GE Healthcare maintains a trained staff of application and technical experts to answer questions and respond to issues and problems that may arise during the installation, maintenance, and use of this system.

Contact your local GE Healthcare representative to request additional assistance.

Manual Information

This section provides information for the correct use of this manual.

Keep this manual with the equipment at all times and periodically review it. You should request training assistance from GE Healthcare, if needed.

Intended Audience

This manual is intended for an operator of the system. The operator requires training to become familiar with the capabilities and operations of the system.

- Read and understand all instructions in the manual before attempting to use the product.
- Request training from GE Medical System *Information Technologies*, Inc. (GE Healthcare) if needed.

Additional manuals may be ordered by contacting GE Healthcare.

Manual Purpose

This manual contains the instructions necessary to operate the system safely and in accordance with its function and intended use.

Document Conventions

This manual uses the following conventions.

Typographical Conventions

Convention	Description
Bold Text	Indicates keys on the keyboard, text to enter, or hardware items such as buttons or switches on the equipment.
Italicized-Bold Text	Indicates software terms that identify menu items, buttons or options in various windows.
CTRL+ESC	Indicates a keyboard operation. A plus (+) sign between the names of two keys indicates that while holding the first key, you should press and release the second key. For example, Press CTRL+ESC means to press and hold the CTRL key and then press and release the ESC key.
<space></space>	Indicates that you must press the spacebar. When instructions are given for typing a precise text string with one or more spaces, the point where you must press the spacebar is indicated as <space></space> . This ensures that the correct number of spaces is inserted in the correct positions within the literal text string. The purpose of the < > brackets is to distinguish the command from the literal text within the string.

Convention	Description	
Enter	Indicates that you must press the Enter or Return key on the keyboard. Do not type Enter .	
>	The greater than symbol, or right angle bracket, is a concise method to indicate a sequence of menu selections.	
	For example, the statement "From the main menu, select System > Setu Options to open the Option Activation window" replaces the following:	
	1. From the main menu, select System to open the System menu.	
	2. From the System menu, select Setup to open the Setup menu.	
	3. From the Setup menu, select Options to open the Option Activation window.	

Illustrations

All illustrations in the manual are provided as examples only. Depending on system configuration, screens in the manual may differ from the screens on your system.

All patient names and data are fictitious. Any similarity to actual persons is coincidental.

Notes

Notes provide application tips or additional information that, while useful, are not essential to the correct operation of the system. They are called out from the body text through a flag word and indentation, as follows:

NOTE:

The tip or additional information is indented below the **NOTE** flag word.

Related Documents

The following documents provide additional information that may be helpful in the installation, configuration, maintenance, and use of this system.

Documents Related to the Optima EMS Service Manual

Part Number	Document Title
2061274-002	Optima ECG Management System Operator's Manual

2

Product Overview

This chapter provides a general description of the product, its connectivity to other devices and interfaces, and a description of available options.

General Operation

The Optima EMS System is a single software product that is used to:

- Manage the registration and storage of ECG information, create an edition, and audit the patient's examination report.
- Connect with the ECG device through RS232 or a network connection, to review the ECG data from the ECG device and display it in the PC monitor for the doctor's diagnosis, and support the comparison with historical examination records.
- Implement the internal share of medical information and improve the doctors' working efficiency.
- This system is available for multiple, concurrent end users on a single system.

Data Acquisition

The user can acquire data into the Optima EMS database via different interfaces from different sources. Following is a summary of the different interfaces.

CSI

Optima EMS can acquire data from Carts via a serial cable connection, an 802.11b/g wireless connection, or a LAN connection.

NOTE:

CSI is a proprietary protocol running on top of Serial Line Internet Protocol (SLIP).

• DCP

Optima EMS can acquire data from Carts via an 802.11b/g wireless connection or a LAN connection

NOTE:

DCP is a proprietary protocol running on top of HTTP protocol.

• Direct Media Acquisition

Optima EMS can acquire data stored in a removable storage by a Cart, such as a floppy disk (on older Carts) or a Secure Digital (SD) card.

• General Acquisition

Optima EMS can acquire data from either a local folder or a shared folder. This is the only way that Stress and Holter data can be acquired.

• XML Import

Optima EMS can acquire data from third-party devices through a standard XML data format. The user can convert third-party data into this format through third-party data converters.

Newly acquired data is listed in the task list, where a user can view, and edit the report. New tasks are automatically routed to a certain user according to the Task Assignment configuration. Confirmed tasks are exported to EMS according to System Configuration. The following Data Types table lists the different data types that can be stored in Optima EMS, along with the acquisition device and typical record size.

Data Type	Acquisition Device	Typical Record Size
Resting ECG — 12 Lead (500 Hz)	Electrocardiograph	10 KB — 20 KB
Stress	CASE 12/15/16	50 KB — 400 KB
Stress	CASE 8000/CASE	750 KB — 3 MB
Holter	MARS	1 MB – 2.5 MB

Data Types

Device Interfaces

The Optima EMS system can interface with the following systems and devices:

- MAC Carts
- MARS
- CASE/CardioSoft Stress Systems
- Compatible third-party Converters

MAC Carts

ECG data acquired at the MAC carts can be sent to the Optima EMS system for long-term storage. Depending on the type of cart and the options installed, you can send data one of several ways:

- Remove the diskette or secure digital (SD) card from the cart and import it through an Optima EMS client.
- CSI direct (direct serial connection)
- CSI network (wireless/LAN)
- DCP network
- Shared folder

Carts, which support Order Download, can retrieve orders from Optima EMS. You must purchase Order Download as a cart option. The Optima EMS system runs a thread for Order Download for each site. Carts must indicate the site ID, from which the orders are downloaded. If the site ID does not match with the thread, no order is returned.

The following table provides the methods available for transferring data from the Cart to the Optima EMS system. Many of the methods listed in the following table require

the purchase and activation of an option on the Cart. Refer to your GE Healthcare sales representative for more information.

ECG Cart	CSI Network		CSI Direct	Dickotto	SD Card	Order
	Wireless	LAN		DISKelle	SD Culu	Download
MAC 600			×		×	
MAC 800	×	×	×		×	×
MAC 1200			×			
MAC 1600		×	×		×	
MAC 3500	×	X ¹	×		×	
MAC 5000	×		×	×		×
MAC 5500	×	×	×		×	×
¹ This option is available on the MAC 3500 only outside of North America.						

ECG Cart Interfaces to Optima

MARS

You can configure the MARS Holter systems to store saved PDF reports to the Optima EMS system for long-term storage. *Full Disclosure* is not sent to the Optima EMS system. To accomplish the data transfer, the Optima EMS system connects to a shared folder on the MARS system over the network and copies the files to the Optima EMS server for processing. The Optima EMS system requires the *Holter Data Type* option. UNIX-based MARS systems require the *Enterprise Network Card* option. The Optima EMS system needs full access to the MARS shared folder.

CASE/CardioSoft Stress Systems

You can configure the CASE/CardioSoft Stress systems to store saved PDF reports to the Optima EMS system for long-term storage. CASE/CardioSoft systems require a network option to send data to the Optima EMS system. The CASE/CardioSoft system copies the files to a shared folder on the Optima EMS system, and then the Optima EMS system picks up the files locally for processing. You must enable the *Stress Data Type* option on the Optima EMS system.

NOTE:

The Optima EMS system needs full access to the CASE folder.

HL7 Interface

The system supports HL7 interfaces to accept ADT and Order messages from Hospital Information System (HIS). You must enable the appropriate HIS options (ADT, Orders) in the system.

HL7 Inbound

Use the following procedure to enable the appropriate HIS option (ADT, orders) in the Optima EMS system:

1. Click **System Configuration** > **Site Configuration**.

Use the following table to set your configurations.

Setting	Value
Allow HL7 ADT	Checked
Allow HL7 Order	Checked

- 2. In the left panel, click the *HL7 Service Entry* tab.
 - Each site should use an HL7 service entry singleton. This means that each site has its own mapped service entry.
 - Ensure that the port is not occupied by other programs or software. The port is different for each site.
- 3. In the right panel, click *Start* to start the *Service Entry*.
- 4. Confirm that the *Service Entry* status is *Running*.

You can change the configuration of the service entry (such as the port, remove service entry, and so forth).

5. Restart the *Service Entry* service after changing its configuration.

After the configurations are complete, the Optima EMS system accepts **HL7 ADT** and **Order** messages from HIS.

HIS/EMR Outbound

The Optima EMS system supports export billing and test report information to a shared folder for HIS or the EMR system. The HL7 outbound message does not communicate between the Optima EMS system and HIS/EMR in real-time. After you enable the appropriate HIS option (HIS output) in the Optima EMS system, it exports billing and test reports automatically when the test is confirmed.

Connect HIS/EMR to the shared folder on the Optima EMS system over the network.

Use the following procedure to engage the Optima EMS system for HIS outbound:

1. Select **System configuration** > **Site Configuration**.

Configure the settings as described in the following table:

Setting	Value
Allow HIS Outbound	Checked
HIS Name	Not empty

Report Template	Default
	This template is the test report format to export to HIS.
Shared Folder	Set this to be accessed by the HIS/EMR system.
	The shared folder is on the Optima EMS server. The default path is:
	"C:\Program Files\GE HealthCare\ OptimaEMSService\ECG Data\MACIT outBound" + HIS Name

After you are finished configuring the *HIS Outbound* settings, the Optima EMS system exports the billing and test report to the shared folder automatically when a user confirms the test.

Optional Features

To view a list of installed options on the system, click *Help* > *Options...* to view the *Options List* screen.



The following table lists available options for the Optima EMS system.

Purchased Option	Description	
Advanced ECG Report Designer	Provides ECG report template for ECG report print.	
User Management	Includes:	
	role management	
	user management	
ECG Statistics and Report Module	Includes:	
	 Statistics report template for database query. 	
	• Statistics report view, export, and print.	
ECG 12SL Measurements Matrix Module	Provides ECG 12SL measurement data value.	
Stress Module	Provides the ability to acquire Stress data from GE Healthcare devices for diagnosis.	
Holter Module	Provides the ability to acquire Holter data from GE Healthcare devices for diagnosis.	
HIS HL7 Communication	Provides the ability to obtain information from HIS through HL7.	
Webservice HIS Integration	Provides the ability to obtain information from HIS through non HL7.	
Bi-directional Commutation with GE ECG Carts	Provides online order download for testing.	
Advanced Measurement Tool Module	Provides ECG waveform measurement tool for diagnosis.	
12SL Statement Library Module	Provides:	
	 Marquette 12SL Analysis Program statements for diagnosis. 	
	 User-defined 12SL statements for diagnosis. 	

System Features Options

Specifications

This section provides the hardware and software specifications for the Optima EMS system.

Hardware Specifications

The Optima EMS system has the following hardware specifications.

Optima EMS System Server

Hardware	Specifications
Processor	Xeon processor 2-core 2.8GHz

Optima EMS System Server (cont'd.)

RAM	4GB RAM,
Hard disk	Four 500GB hard disk
Networking	Gigabit Ethernet
Minimum disk space for installation	1GB

Optima EMS System Client Workstation

Hardware	Specifications
Processor	Intel Pentium 4 2.4GHz processor
Memory	1GB
Hard drive	80GB
Minimum disk space for installation	1GB
Networking	Fast Ethernet

Optima EMS System Acquisition Workstation

Hardware	Specifications
Processor	Intel Pentium 4 2.4GHz processor
Memory	1GB
Hard drive	80GB
Minimum disk space for installation	1GB
Networking	Fast Ethernet

Software Specifications

The Optima EMS system has the following software specifications.

Server

System	Software
Operating System	Microsoft Windows 2003 Server or later version.
Database	Microsoft SQL Server 2008 R2

Client

System	Software
Client Workstation	Microsoft Windows XP Professional
Acquisition Workstation	Microsoft Windows XP Professional

Optima EMS Drive Contents and Supporting Folders

By default Optima EMS server/client is installed on the C drive. The user can change the drive during installation.

The user can install the Optima EMS server, client, and database on one PC, or separate PCs.

On the Optima EMS server, the installation program creates a shared folder for data acquisition called **Optima EMS ECG data**. On the Optima EMS client, if it acts as a data acquisition host, it requires a shared folder called **Optima EMS ECG data client**.

Optima EMS Services

The Optima EMS server runs as a Windows service named **Optima EMS Service**. Its startup type is set as **automatic** so the service starts automatically after the server is started.

Required Network Ports

The following port information is provided for the Optima EMS system as a guideline to help you understand the system's networking requirements and to assist in situations where you may need to consider either software or hardware firewall configurations. Not all systems use each connection. The following ports are default values and, in some cases, can be changed.

There are three types of TCP ports in the Optima EMS system. All of them are configurable.

- Optima EMS Server hosts a WCF service. By default the port is **8999**. The user can configure it in the file **OptimaEMSService.exe.config**.
- If a device transmits the data via DCP, you should configure the DCP server and port in *Device* configuration.
- The HL7 inbound service communicates on another port. Configure this port in *HL7 Service Entry* configuration.
System Administration

This chapter provides procedures for administrative functions you may need to do on the Optima EMS system.

Remote Databases

This section provides additional considerations to ensure system installation and operation on a remote database. Remote database means that the SQL instance running the system databases is located on a separate server. In a simple system configuration, the system application, the SQL, and system databases are all installed on the same server.

SQL Ports

If the Optima EMS system is using a remote Optima EMS database, the Optima EMS server requires access to the Optima EMS databases. This requires the following ports be open to the SQL server.

• SQL Listening Port

The listening port listens for incoming connections. In the Optima EMS system, these incoming connections originate at the Optima EMS server. SQL assigns TCP port 1433 as the listening port when the default instance of SQL is used. If the customer wants added security, they can change this port. When using a named instance of SQL, SQL assigns a dynamic port, which the database administrator (DBA) can change to a known fixed port.

• SQL Monitor Server

The monitor server service uses UDP port 1434, which allows administrators and users to check the status of the SQL databases. Like the listening port described previously, the customer can assign this port a different port number for increased security.

If the Optima EMS server is having problems communicating with the database, and the Optima EMS service accounts have **Super Admin** privileges, contact the local DBA and verify that the correct ports are open.

SQL Remote Connections

When installed on a separate database, the Optima EMS system requires that the SQL remote connections are enabled as follows. Contact the local IT department or DBA for additional assistance for the SQL Remote connections.

- 1. On the SQL server, go to **Start** > **Microsoft SQL Server 2005** > **Configuration Tools** > **SQL Server Surface Area Configuration**.
- 2. Click Surface Area Configuration for Services and Connections.
- 3. Under the SQL instance where the Optima EMS databases are being installed, select *Remote Connections*.
- 4. Verify that the *Local and remote connections > Using both TCP/IP and Name Pipes* check box is selected.

If it is not selected, select the check box and apply the change.

5. Exit the SQL Server 2005 Surface Area Configurator.

NOTE:

In addition to the *Remote Connections* configuration, you must start the *SQL Server Browser* service.

Installing/Uninstalling/Upgrade

This section describes the process for installing, uninstalling, and upgrading the Optima EMS system.

Installing the Optima EMS System

Listed below are the basic steps required to install a new Optima EMS system server and client.

Installing the System Server

GEHC support team will help you to install the system server.

NOTE:

When processing the installation, you can click **Back** at any time if you want to modify your previous entries. You can click **Cancel** when you want to abort the installation.

- 1. Insert the installation CD into the computer.
- 2. Open *My Computer*.

The following window opens:

2 My Computer	
File Edit View Favorites Tools	: Help
0 144 - 0 - 3 Psed	😢 Folders 🛄 - 🚺 文件美嗣步
Address 🖳 My Computer	
System Tasks 🙁	Hard Disk Drives
Verw system information Add or remove programs Change a setting	System (C:) Cata (D:) Devices with Removable Storage
Other Places (*) Phy Network Places Phy Documents (*) Control Panel	OptimaEMS Other
Details (2) My Computer System Folder	Control Partel

 Open OptimaEMS > Optima EMS V1.0 > Optima EMS > Optima EMS Service to open the Installation Language Selection window.

The system defaults to set the installation language as the operating system's language. You can use the drop-down menu to select Chinese or English if needed.

Optimal	EMSService - InstallShield V		x
	Select the language for the inst	allation from the cł	noices below.
	English (United States)		_
		OK	Cancel

 Click Yes to open the Welcome window and click Next to continue. The License Agreement window opens.

cense Agreement	
Please read the following license agreement carefully.	
SOFTWARE LICENSE AGREEMENT AND LIMITED SOFTWARE	
Please carefully read the following terms and conditions before inst GE Healthcare Software ("Software"). By installing or using the So Healthcare product, You indicate your acceptance of these terms do not agree with the terms and conditions, do not install or operate return it to GE Healthcare.	alling or operating the ftware in your GE and conditions. If You e the Software and
The Software has been provided to You for use on a specific GE H Software is provided under the terms of this Agreement and is licen Your rights to use the Software are subject to the terms and condit	Healthcare product. The ised to You, not sold. ions contained within
I accept the terms of the license agreement	Print
C I do not accept the terms of the license agreement	
ealthCare	
	1

- 5. Do one of the following actions:
 - If you choose "I accept the terms of the license agreement", you can click **Next** to continue with the installation. The **Customer Information** Window opens.
 - If you choose "I do not accept the terms of the license agreement", the **Next** button is disabled and you can click **Cancel** to exit the installation.
 - If you want to print out the terms of the license agreement, click *Print*.

6. On the **Customer Information** window:

Please enter y	rmation our information.	
User Name:		
GE		
<u>C</u> ompany Nam	ie:	
General Elect	ric	
	lication for	
Install this app		1/2/2016
Install this app	 Anyone who uses this computer (al 	l users)
Install this app	 Anyone who uses this computer (all Only for me (GE) 	l users)
Install this app	 Anyone who uses this computer (al Only for me (GE) 	l users)

- a. Enter your **User Name** and **Company Name**.
- b. Choose the range of users.

Install this application for:

- Anyone who uses this computer (all users).
- Only for me (GE)
- 7. Click *Next* to continue the installation, and open the *Database Server Settings* window.

8. Enter the Server Name, LoginID and Password.

OptimaEMS Server			×
DataBase Server Settings Please Enter the DataBase Server Inform	nation		
<u>S</u> erver Name:			
ļ.			
Login ID:			
sa			
Password:			

GE HealthCare			
	< <u>B</u> ack	<u>N</u> ext >	Cancel

- 9. Click *Next* to open the *Site Information* window.
- 10. Enter your *Site Name*, your computer *IP Address*, and *Serial Number*.

ptimaEMS Server						1
Site Information						
Please Enter the Site Information	n					
Site Name:						
1						
IP Address:						
3.	35		24	×	89)
Carial Number						
1						
E HealthCare						
		1	Back Í	Novis	_	Cancel
				Mext /		Cancel

11. Click *Next* to go to the *Choose Destination Location* window.

12. Click **Browse** to choose the location where you want to install the Optima EMS System Server on your current computer.

timaEMS Server			
Choose Destination Location Select folder where setup will install files.			Z
Setup will install OptimaEMSService in the follow	wing folder.		
To install to this folder, click Next. To install to a another folder.	a different folder, cli	ck Browse and :	select
Destination Folder			
C:\\GE HealthCare\OptimaEMSService		B	iowse
HealthCare			
		100	
	< Back	Next>	Cancel

13. Click *Next* to open the *Ready to Install the Program* window, and click *Install* to start the installation.

OptimaEMS Server	×
Ready to Install the Program The wizard is ready to begin installation.	
Click Install to begin the installation.	
If you want to review or change any of your the wizard.	installation settings, click Back. Click Cancel to exit
GE HealthCare	< <u>B</u> ack Install Cancel

Wait until the progress bar is finished. Then the system automatically opens the *InstallShield Wizard Complete* window.

14. Click *Finish* to complete Optima EMS System Server installation.



Installing the System Client

GE Healthcare support team will help you to install the system Client.

NOTE:

When processing the installation, you can click **Back** at any time if you want to modify your previous entries. You can click **Cancel** when you want to abort the installation.

- 1. Insert the installation CD into the computer.
- 2. Open *My Computer*.

The following window opens:

Hy Computer	
File Edit View Favorites Took	s Help
0 144 - 0 - 1 P Sead	n 🕑 Folders 🛄 • 🎉 文件美能步
Address 🖳 My Computer	
System Tasks	Hard Disk Drives
Vere system information Add or remove programs Change a setting	System (C:) Cuta (D:) Devices with Removable Storage
Other Places (*) Pry Network Places Pry Documents (*) Control Panel	CptimaEMS Other
Det als (2) My Computer System Folder	Control Panel

 Open OptimaEMS > Optima EMS V1.0 > Optima EMS > Optima EMS Client to open Installation Language Selection window.

The system defaults to set the installation language as the operating system's language. You can use the drop-down menu to select Chinese or English if needed.

EMSClient - InstallShield Wiz	ard	×
Select the language for the inst	allation from the cł	noices below.
English (United States)		_
	ΟΚ	Cancel
	EMSClient - InstallShield Wiz Select the language for the inst English (United States)	EMSClient - InstallShield Wizard Select the language for the installation from the ch English (United States)

 Click Yes to open the Welcome window and click Next to continue. The License Agreement window opens.

icense Agreement		And and A
Please read the following license agreement of	carefully.	
License		<u>^</u>
		•
C Laccept the terms of the license agreeme	nt	 Print
 I accept the terms of the license agreeme I do not accept the terms of the license agreeme 	nt greement	
 I accept the terms of the license agreeme I do not accept the terms of the license againshield 	nt greement	

- 5. Do one of the following actions:
 - If you choose "I accept the terms of the license agreement", you can click **Next** to continue with the installation. The **Customer Information** Window opens.
 - If you choose "I do not accept the terms of the license agreement", the *Next* button is disabled and you can click *Cancel* to exit the installation.
 - If you want to print out the terms of the license agreement, click **Print**.
- 6. On the *Customer Information* window, enter your *User Name* and *Company Name*.
- 7. Choose the range of users.

Install this application for:

- Anyone who uses this computer (all users).
- Only for me (GE)

ustomer Info	rmation			and the
Please enter y	our information.			
User Name:				
GE				
Company Nam	ie:			
General Elect	ric			
Install this app	lication for:			
	Anyone who uses	s this computer (all us	ers)	
	C Only for me (GE)			
llShield				

8. Click *Next* to open the *Server Configuration* window.

Use the following table to complete the *Server Configuration* window.

IP address Port Number	These 2 fields have default values, you do not need to change them normally because the Optima EMS System Client Installation program can automatically get the IP address and port number of the Server.
Test	This is a connection test button, which can verify the correctness of IP address and port number. With correct IP address and port number, the test will show Connect to the Server Successfully .

erver Configuration Server IP address and port number	configuration.		
Input server IP address and port m	umber please.		
IP address: 3.35.89.76			
Port number: 8999			
		Test	
JIC kield			
aliometu	_		

9. Click *Next* to open the *Ready to Install the Program* window, and click *Install* to start the installation.

Optima EMS - InstallShield Wizard		×
Ready to Install the Program The wizard is ready to begin installation.		EZ.
Click Install to begin the installation.		
If you want to review or change any of your ins the wizard.	tallation settings, click Back. Click Ca	ancel to exit
InstallShield	< Back Install	Cancel

Wait until the progress bar is finished. Then the system automatically opens the *InstallShield Wizard Complete* window.

10. Click *Finish* to complete the Optima EMS System Client installation.



Install the ClickOnce Optima EMS Application

The Optima EMS system client and server is installed on the same server. The Optima EMS system client is only Optima application publish program. The end user (physicians) can install Optima EMS application through web browser.

1. Open *Internet Explorer*.

NOTE:

Internet Explorer Version 8 is recommended.



2. Type the Optima EMS Application Publish address: <u>http://"your server IP</u> address"/OptimaEMS/publish.htm in the **Address** bar of **Internet Explorer**.

The **Publish** page opens.

OptimaEMS -	Windows Internet Explorer	
`€ ~ [@) http://3.35.26.154/OptimaEM5/publish.htm 🔄 🐓 🗙 🔎 百度一下,你就知道	P
le Edit Vie	ew Favorites Tools Help	
Favorites	Ø OptimaEMS	- 0
		_
Gene	ral Electric Healthcare	
Ontin	nal Elosalis filosistica e	
ohen	паень	
Name:	OptimaEMS	
Version:	1.0.0.0	
Publisher:	General Electric Healthcare	
The followin	ng prerequisites are required:	
• Micro	osoft .NET Framework 4 (x86 and x64) <u>Download</u>	
• Visua	al C++ 2010 Runtime Libraries (x86) <u>Download</u>	
• Visua	al C++ 2005 Runtime Libraries (x86) <u>Download</u>	
If these cor Otherwise,	mponents are already installed, you can install the application now. click the link above to download and install the prerequisites.	
Install		
Install		
Install	ClickOnce and .NET Framework Resources	

3. Click *Download* to download and the *Prerequisites* displayed on the *Publish* page.

The following prerequisites are required:

- Microsoft .NET Framework 4 (×86 and ×64)
- Visual C++ 2010 Runtime Libraries (×86)
- Visual C++ 2005 Runtime Libraries (×86)
- 4. If all prerequisites are installed, click *Install*.
- 5. The *Security Warning* window opens.

oplication Install - Security Warning		x
Publisher cannot be verified. Are you sure you want to install this application?		Solution
Name:		
OptimaEMS		
OptimaEMS From (Hover over the string below to see the C:\Inetpub\www.root\OptimaEMS	full domain):	
OptimaEMS From (Hover over the string below to see the C:\Inetpub\www.root\OptimaEMS Publisher: Unknown Publisher	full domain):	

6. Click *Install* to start running the installation, and the *Installing OptimaEMS* window opens.

(21%) In	stalling	OptimaEM5	
Installi This the i	ng Optii may take installatio	maEMS e several minutes. You can use your computer to do other tasks during n.	
	Name:	OptimaEMS	
	From:	C:\Inetpub\wwwroot\OptimaEMS	
	Downlo	ading: 5.91 MB of 28.0 MB	
		[Cancel

7. When the installation is finished, a shortcut icon is displayed on the desktop.

Uninstalling the Optima EMS System

This section describes how to uninstall the Optima EMS System Server and Client.

Uninstall the Optima EMS System Server

Use the following procedure to uninstall the Optima EMS System Server.

1. Open the Add or Remove Programs window by clicking Start > Control Panel > Add or Remove Programs.

	8	
Currently installed programs: 🔲 Show updates Sort	by: Name	
	Size	28.12M
授 OptimaEMSService	Size	243.00M
Click here for support information.	Used	rarely
To change this program or remove it from your computer, click Change or Remove.	Change	Remove
侵 PC Info	Size	1.25ME
S PDF-Viewer	Size	27.80ME
B PKZip 50		
🔀 PKZip Shared Components 5.0		
13 PSIG Screen Saver		
ouickTime	Size	73.04ME
RICOH Media Driver ver.2.11.01.02	Size	2.56ME

2. Select **OptimaEMSService** and click **Remove**.

The Uninstall Confirmation window opens

OptimaEM5Service	- InstallShield Wi	zard	×
Do you want to com	pletely remove the s	elected application and a	II of its features?
	Tes		

- 3. Click **Yes** to confirm that you want to uninstall **OptimaEMSService**.
- Wait until the Uninstall Complete window opens.
 Click Finish to complete the Server uninstallation.

OptimaEMSService - InstallSh	ield Wizard
	Uninstall Complete InstallShield Wizard has finished uninstalling OptimaEMSService.
	K Back Finish Cancel

Uninstall the Optima EMS System Client

Use the following procedure to uninstall the Optima EMS System Client.

1. Open the Add or Remove Programs window by clicking Start > Control Panel > Add or Remove Programs.

Add or Ren	nove Programs		
5	Currently installed programs: 🔲 Show updates Sor	t by: Name	
<u>hange</u> or	NB. Moder	Size	.561918
Programs	🥂 NVIDIA PhysX	Size	73.21MB
<i>1</i>			
10 M	OptimaEMSClient	Size	28.12MB
Add <u>N</u> ew Yrograms	Click here for support information.	Used	<u>rarely</u>
6	To change this program or remove it from your computer, click Change or Remove.	Change	Remove
d/Remove	得 PC Info	Size	1.25MB
<u>V</u> indows mponents	S PDF-Viewer	Size	27.80MB
~	段 PKZip 50		
	B PKZip Shared Components 5.0		1
t Pr <u>o</u> gram	B PSIG Screen Saver		
Defaults	🚭 QuickTime	Size	73.04MB

2. Select **OptimaEMSClient** and click **Remove**.

The Uninstall Confirmation window opens.

stallShield Wiza	ard	×
etely remove the s	elected application and a	all of its features?
Yes	No	
	stallShield Wize stely remove the s Yes	stallShield Wizard stely remove the selected application and a Yes No

- 3. Click **Yes** to confirm that you want to uninstall **OptimaEMSClient**.
- Wait until the Uninstall Complete window opens.
 Click Finish to complete the Client uninstallation.

OptimaEMSService - InstallSh	ield Wizard
	Uninstall Complete InstallShield Wizard has finished uninstalling OptimaEMSService.
	< Back Finish Cancel

Uninstall the ClickOnce Optima EMS Application

Use the following procedure to uninstall the ClickOnce Optima EMS Application.

1. Open the Add or Remove Programs window by clicking Start > Control Panel > Add or Remove Programs.

dd or Rem	nove Programs		
5	Currently installed programs: 🛛 🗖 Show updates	Sort by: Name	•
ange or	12. Mader	Size	.56IVIB
ograms	🚳 NVIDIA PhysX	Size	73.21MB
id <u>N</u> ew ograms	DetimaEMS <u>Click here for support information.</u> To change this program or remove it from your comput Change/Remove.	er, clickChang	e/Remove
-	PC Info	Size	1.25MB
(Remove	S PDF-Viewer	Size	27.80MB
indows	믢 PKZip 50		
ponencs	🖟 PKZip Shared Components 5.0		
	😼 PSIG Screen Saver		
Program	🍘 QuickTime	Size	73.04MB
rogram			

2. Select **OptimaEMS** and click **Remove**.

The OptimaEMS Maintenance window opens.



3. Click **OK** to uninstall the ClickOnce Optima EMS application.

Upgrading the Optima EMS System

When an end user runs the Optima EMS application, it detects if a version is already installed. If an older version is installed, the Optima EMS application updates the system to the new version automatically.

System Administration



Maintenance

A regular equipment maintenance program helps prevent unnecessary equipment and power failures and also reduces possible health hazards. This chapter contains instructions for the following recommended maintenance:

- Cleaning the equipment's accessories
- Visual inspection of equipment
- Exterior cleaning of equipment
- Conducting repair and replacement checkout procedures.

Maintenance Guidelines

GE Healthcare recommends that you perform the tests described in this chapter:

- Every year as part of routine maintenance.
- Whenever internal assemblies are serviced.
- Whenever you repair or replace equipment.
- As prescribed in the OEM documentation that comes with the equipment.

NOTE:

Unless you have an Equipment Maintenance Contract, GE Healthcare does not assume responsibility for performing the recommended maintenance procedures. The sole responsibility rests with the individual or institution using the equipment. GE Healthcare service personnel may, at their discretion, follow any or all of the procedures as a guide during visits to the equipment site.

Items requiring maintenance include:

- Optima EMS server(s)
- Optima EMS Client
- Monitors
- DVD-RW or CD-RW Drive
- Printer

OEM Maintenance

For information on maintenance of Original Equipment Manufacturer (OEM) components, please reference the appropriate OEM manuals for the recommended

maintenance of their product. For links to the OEM manuals, refer to the Optima EMS System Hardware Manual.

For technical support, contact your local GE Healthcare technical support team.

Functional Checkout Procedures

Whenever a system is serviced, you must perform checkout procedures to comply with FDA guidelines to ensure that the system is safe and functioning properly. The specific procedures depend on the service performed.

Follow the checkout procedure appropriate for the repair you performed.

NOTE:

For customer-supplied hardware, the customer is responsible for troubleshooting, FRU replacement, and checkouts, as they relate to hardware repairs on the system servers.

Non-FRU Repairs

System functional checks are required for non-FRU repairs and typically involve system setup and configurations that you can perform remotely or onsite. If you perform them remotely, the remote support engineer can confirm them through remote access, or verify them with the customer contact. For additional instructions, refer to the Operator's manual for your system.

Printing

Use the following procedures to verify that the printing functions are working correctly.

Preview Print Checkout

- 1. Double-click a confirmed order on the order list to open diagnosis editor.
- 2. Select preview print mode from the drop-down menu.
- 3. Click *Print* to open preview print dialog.
- 4. Select printer and report template, and click **OK**.
- 5. Verify that the ECG record printed out through selected printer and report template.

Direct Print Checkout

- 1. Double-click a confirmed order on the order list to open diagnosis editor.
- 2. Select direct print mode from the drop-down menu.
- 3. Click **Print**.
- 4. Verify that the ECG record printed out through default printer and report template.

Editing/Confirming

Use the following procedures to verify that the editing and confirming functions are working correctly.

Edit Record Checkout

- 1. Accept a processing order in **Order List**.
- 2. Double-click an accepted order to waveform viewer edit and save the record.
- 3. Re-open the record to verify the changes were saved.

Confirm Record Checkout

- 1. Accepts a processing order in **Order List**.
- 2. Double-click accepted order to waveform viewer edit and confirm the record.
- 3. Re-open the record to verify the changes were saved.

Verify the record is confirmed in **Order List**.

Report Distribution Checkout

Use the following procedures to verify that the report distribution function is working correctly.

- 1. Create a report template in *Report Designer* window.
- 2. Set the print mode as *preview print* in *Client Configuration*.
- 3. Enter waveform viewer by double-click a confirmed order in Order List.
- 4. Print a report with the selected report template.

Device Setup

Use the following procedures to verify that the devices are set up correctly.

- 1. Transmit a record from a source device.
- 2. Verify that the record is displayed in the application.

User Setup

Use the following procedures to verify that the user is set up correctly.

- 1. Have a newly created user start the application.
- 2. Have the user log on and confirm application access based on roles/privileges given during setup.

Carts Transmission/Acquisition

Use the following procedures to verify that the Carts transmissions and acquisitions functions are working correctly.

Wireless Transmission

- 1. Configure the communication method on a Cart.
- 2. Configure the ECG device in the Optima EMS system, and make sure the configure is the same as the Cart.

A shared folder is associated with the device.

3. From the Cart, transmit the ECG file through wireless.

The Optima EMS system detects and parses the file so the user can complete an analysis.

4. Check that the *PID/Name* of the ECG transmitted from the cart was acquired in the Optima EMS system.

LAN Transmission Checkout

- 1. Configure the communication method on a Cart.
- 2. Configure the ECG device in the Optima EMS system, and make sure the configure is the same as the Cart.

A shared folder is associated with the device.

3. From the Cart, transmit the ECG file through LAN.

The Optima EMS system detects and parses the file so the user can complete an analysis.

4. Check that the *PID/Name* of the ECG transmitted from the cart was acquired in the Optima EMS system.

Removable Media Acquisition

- 1. Insert the media into the client.
- 2. Download the initialized orders to the media.
- 3. Insert the media to Cart, acquire the ECG record and send it to media on Cart.
- 4. Insert the media to the client again, and select the test from media back to the Optima EMS system.

The Optima EMS system detects and parses the file so the user can complete an analysis.

5. Check that the *PID/Name* of the ECG transmitted from the cart was acquired in Optima EMS system.

MARS Transmission

Use the following procedure to transmit a Holter report to the Optima EMS system.

- Configure the Holter device in the Optima EMS system. A shared folder is associated with the device.
- 2. From a MARS workstation, export the Holter report to a PDF file.
- 3. Copy the PDF file to the shared folder configured in step 1.

The Optima EMS system detects and parses the file so the user can complete an analysis.

CASE/CardioSoft Transmission

Use the following procedure to transmit a Stress report to the Optima EMS system.

1. Configure the Stress device in the Optima EMS system.

A shared folder is associated with the device.

- 2. From a CASE/CardioSoft workstation, export the Stress report to a PDF file.
- 3. Copy the PDF file to the shared folder configured in step 1.

The Optima EMS system detects and parses the file so the user can complete an analysis.

Database Search

Use the following procedures to verify that the database search function is working correctly.

Manual Search Checkout

- 1. Go to the **Database Search** function of the application.
- 2. Create a search.
- 3. Choose criteria and run the search.
- 4. Verify that the search results match the selected criteria.

Automatic Search Checkout

- 1. Go to the **Database Search** function of the application.
- 2. Create a search.
- 3. Save the criteria.
- 4. Schedule the search.
- 5. Verify that the search runs when scheduled and expected results are generated. The Optima EMS system runs all scheduled searches only once per day.

Remote Support

Use the following procedures to verify that the you can access the system for remote support.

- 1. Log on to the customer's system using the remote connection configured for that system (InSite ExC).
- 2. Confirm that you can access the customer's desktop via the remote connection.
- 3. Confirm that you can upload and download files to the customer's system.

XML Import

Use the following procedures to verify that the system can import XML data correctly.

1. Configure the non-GE device in the Optima EMS system.

A shared folder is associated with the device.

2. Copy XML data files from the manufacturer's device to the shared folder configured in Step 1.

The Optima EMS system detects and parses the file so the user can complete an analysis.

3. Check that the *PID/Name* of the ECG transmitted from the cart was acquired in Optima EMS system.

Backup

Use the following procedures to verify that the backup procedures work correctly.

- 1. Use **SQL Server Management Studio** to run a manual Optima EMS backup.
- 2. Confirm that the backup was successful.

Login

Use the following procedures to verify that the Optima EMS Authentication procedures work correctly.

Optima EMS Authentication

- 1. Have the user log on to the Optima EMS system using Optima EMS Authentication.
- 2. Verify the user is able to successfully log on to the Optima EMS system.

Via Citrix Using Optima EMS Authentication

- 1. Have the user log on to the Optima EMS system using Optima EMS Authentication.
- 2. Verify the user is able to successfully log on to the Optima EMS system.

Discarding/Recovering/Deleting Data

Use the following procedures to verify that the user can discard a test.

Discarding Data

- 1. Put a .doc file to device folder on the Optima EMS system.
- 2. Verify that the discard log exists in the log file of the Optima EMS system.

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Optima EMS System Backup and Recovery

Introduction

A backup and recovery plan is crucial to prevent data loss and to minimize service interruption in the event of system failure or disaster. This chapter describes the backup and recovery options for the Optima EMS system.

Backup and Recovery of the Database

There are two ways to back up the Optima EMS database: manually or using SQL Server tools.

Backing Up and Recovering the Database Manually

The following procedures describe how to backup and recover the database manually.

- 1. Stop the **SQL Server**.
 - a. Click the *Start* button in the bottom left corner.
 - b. In the *Start* menu select *Run...*.
 - c. In the popup window text box, enter *services.msc*.
 - d. Find the *SQL Server* service and click the *Stop Service* button on the toolbar.
- 2. In the SQL Server installation folder, find the *MacIt.mdf* and *MacIt_log.ldf* files.
 - By default, the folder is located in **C:\Program Files|Microsoft SQL** Server\MSSQL.1\MSSAL\DATA.
- 3. Copy the two files to a backup folder, for example **D:\DbBackup**.
- 4. In the *Services* window, click the *Start Service* button on the toolbar to restart the *SQL Server* service.
- 5. To restore the file (for example, the data file is corrupted), stop the **SQL Service**.
- 6. Copy the *MacIt.mdf* and *MacIt_log.ldf* files back to the SQL Server installation folder.
- 7. Restart the service.

Backing Up and Recovering the Database Using SQL Server Tools

The following procedures describe how to backup and recover the database using the SQL Server tools.

- 1. In the SQL Server 2005/2008 Management Studio, click Database.
- 2. Right-click the *macit* database.
- 3. In the **Context** menu, select **Tasks** > **Backup...**.
- 4. In the popup window, accept the default settings and click **Add** to select the path and name for the backup file.
- 5. Click **OK** to complete the backup procedure.
- 6. To restore the database files right-click the *macit* database.
- 7. In the Context menu, select Tasks > Restore > Database....
- 8. In the popup window, in *source and location* select *from device* and click *OK*.
- 9. In the new popup window, select *File* as the backup media and click *Add*.
- 10. Select the backup file generated in step 4.
- 11. Click **OK** to restore the database

Additional Information

When configuring or performing the system backups, you may need to shut down the system, restart the system, or initialize a new backup tape. The instructions for performing these additional tasks are provided in the following sections.

System Shutdown and Restart Procedure

During the Optima EMS backup and recovery process, it may become necessary to shut down and restart the system. This section provides instructions for safely shutting down and restarting the system:

NOTICE:

DATA LOSS OR CORRUPTION: Shutting down or restarting the Optima EMS system any way other than that specified in this manual could result in data loss or corruption.

Follow the instructions provided in this manual to shut down and restart the Optima EMS system.

1. Notify users that you are about to shut down the Optima EMS system so they can save their changes before the system is shut down.

This prevents any changes being made to open tests from being lost when the system is shut down. Records that are open when the user is disconnected remain locked but can be unlocked by a user with the proper permissions under *Status* > *Locked Data List*.

2. From the Windows desktop on the Optima EMS server, select **Start** > **Shut Down**.

- 3. Select either of the following options:
 - Restart

This option powers down and immediately restarts the computer.

• Shut down

This option powers down the computer until you manually restart it.

The Optima EMS services launch automatically when the server restarts and are available immediately to Optima EMS clients. If the system has an HL7 interface, the inbound messages queue on the HL7 server until the Optima EMS server is restarted.

- 4. After the File server is restarted, verify that all of the Optima EMS-related services have started and that you can run the Optima EMS application on the server.
- 5. Verify that clients are able to attach when running the Optima EMS application.

Initializing a New Tape

When using an AIT tape for the first time, you must initialize it to receive data. Use the following procedure to initialize a new tape:

- 1. Insert a new tape into the tape drive.
- 2. Right-click on *My Computer* and select *Manage*.
- 3. Expand *Removable Storage* and select *Media*.

The tape should be listed on the right. If it is new, it displays in the *Media Pool* column as **\Unrecognized\8mm AIT 1**.

- 4. Highlight the new tape in the list.
- 5. On the menu, click *Action* > *Free*.

The following message opens:

onfirm	Make Free	
<u>.</u>	This operation will destroy the data on the media and move it to a Free media pool. Are you sure you want to move the selected medium to the free pool?	
	<u>Yes</u> <u>N</u> o	

6. Click **Yes**.

Another message opens asking you to confirm that you want to make it free.

- 7. Click Yes.
- Label the tape externally. For a nightly tape, label it <Day> Backup, where Day is replaced by the appropriate day of the week. For the weekly tape, label it Weekly C: Backup. For the monthly tape, label it Monthly Backup.

Optima EMS System Backup and Recovery



Product Specification

This section provides the hardware and software specifications for the Optima EMS system.

Storage Environmental Requirements

The Optima EMS system has the following environmental requirements.

Label

Storage Requirement	Specification
Humidity	< 65%
Temperature	-30°C to + 60°C

DVD

Storage Requirement	Specification
Transport/Storage Temperature	-30°C to +60°C
Transport/Storage Relative Humidity	10% to 95% (non-condensing)
Transport/Storage Pressure	500 hPa to 1060 hPa

Functional Limitations

The Optima EMS system has the following functional limitations.

Password

Field	Maximum Input
Password	16 characters

Site Basic Information

Field	Maximum Input
Site Number	16 characters
Site Name	32 characters
Short Title of the Site	16 characters
Site Description	128 characters

Site Basic Information (cont'd.)

Telephone number	20 characters
Host Name	20 characters
Port Number	32 integers

Department Basic Information

Field	Maximum Input
Department Name	16 characters
Department Description	128 characters

Role Basic Information

Field	Maximum Input
Role Name	32 characters
Role Description	64 characters

User Basic Information

Field	Maximum Input
User Login Name	16 characters
User Name	16 characters
Password	16 characters
Confirm Password	16 characters
User Description	128 characters
Office Phone Number	20 characters
E-mail Address	128 characters
Fax Number	32 characters
Cellphone Number	11 characters

Diagnosis Information

Field	Maximum Input
Diagnosis	512 characters

Patient Information

Field	Maximum Input
Patient ID	32 characters
Patient Name	20 characters
Age	8 characters
Phone Number	32 characters
Address	128 characters

Hardware Specifications

The Optima EMS system has the following hardware specifications.

System Server

Hardware	Minimum Requirements
Processor	Xeon processor 2-core 2.8GHz
RAM	4GB
Hard Disk	500GB
Ethernet	Gigabit
Disk space for installation	1GB

System Client Workstation

Hardware	Minimum Requirements
Processor	Intel Pentium 4 2.4GHz
Memory	1GB
Hard Disk	80GB
Ethernet	Fast
Disk space for installation	1GB

System Acquisition Workstation

Hardware	Minimum Requirements
Processor	Intel Pentium 4 2.4GHz
Memory	1GB
Hard Disk	80GB
Ethernet	Fast
Disk space for installation	1GB

Software Specifications

The Optima EMS system has the following software specifications.

System Server

System	Software
Operating System	Microsoft Windows 2003 Server or later version
Database	Microsoft SQL Server 2008 R2

Client

System	Software
System Client Workstation	Microsoft Windows XP Professional
System Acquisition Workstation	Microsoft Windows 7 Professional, 32–bit Operation System
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