

GE Healthcare

**Mac-Lab/CardioLab/  
Centricity Cardiology INW**

Pre-Installation Manual

Software Version 6.9.5

2063076-007E EN



Mac-Lab/CardioLab/Centricity  
Cardiology INW  
Pre-Installation Manual  
2063076-007E EN

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## Publication Information

The information in this manual only applies to Mac-Lab/CardioLab/Centricity Cardiology INW software version 6.9.5. It does not apply to earlier software versions. Due to continuing product innovation, specifications in this manual are subject to change without notice.

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The document number and revision appear on the bottom of each page. The following table outlines the changes applied with each revision.

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A	15 August 2012	Internal release.
B	22 August 2012	Initial public release.
C	21 January 2013	Updated with serviceability improvements.
D	2 April 2013	Updated to distinguish between US and non-US system compliance.
E	26 June 2014	Updated to include information for EIZO monitors. Updated part numbers for RoHS compliance.

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# Chapter 1

## **Introduction**

# Manual Information

## Purpose

This manual covers the following systems: Mac-Lab, CardioLab, ComboLab, SpecialsLab and the Centricity Cardiology INW server. The system ordered may not contain all equipment listed. This manual contains the following information:

- **System Description:** A brief description of typical system configurations.
- **System Requirements:** Lists specific requirements for each system component.
- **Customer Pre-Installation Requirement:** Lists specific requirements client needs to complete on site prior to installation of system.
- **Questionnaire Checklist:** Lists specific actions that need to be completed by client and GE Healthcare personnel prior to installation of system.

## Product References

The name of the product described in this manual is Mac-Lab/CardioLab/ Centricity Cardiology INW system.

## Intended Audience

This manual is intended as a guide and informational resource for professionals planning and properly preparing a location for the installation of a Mac-Lab/CardioLab/Centricity Cardiology INW system.

## Operators

The Mac-Lab/CardioLab operator requires training to become familiar with the capabilities and operations of the Mac-Lab/CardioLab system. The following training options are available:

- Classroom training at GE Healthcare Institute in Milwaukee, WI
- On-site customer training
- Video training via weblink



## System Administrator

- Coordinating the overall Mac-Lab/CardioLab system is the responsibility of the System Administrator. This person has access to additional system supervisory functions, including operational setup parameters, system backup functions, for example.
- The System Administrator is also responsible for monitoring and reporting system hardware and software problems using the procedures described in the Mac-Lab or CardioLab operator manual.
- The Mac-Lab/CardioLab System Administrator should be familiar with the Windows desktop and be fully trained on the Mac-Lab/CardioLab features and configuration settings.

**NOTE:** A System Administrative password is required to perform any of the previous administrative functions.

- The Mac-Lab/CardioLab System Administrator requires training to become familiar with the capabilities and operations of the Mac-Lab/CardioLab system. The following training options are available:
  - ◆ Classroom training at GE Healthcare Institute in Milwaukee, WI
  - ◆ On-site customer training

## Field Service Engineer

Diagnosing and correcting problems with the Mac-Lab/CardioLab system must be done by a trained GE Healthcare Field Service Engineer. Please refer system problems not covered in this manual to GE Healthcare Product Support.

## Indications for Use

### Types Of Systems

The following system names are used:

- **Mac-Lab** is a Hemodynamic Recording System typically used in catheterization laboratories.
- **CardioLab** is an Electrophysiology Recording System built on a common platform with **Mac-Lab**.
- **ComboLab** is a single system that contains the features of both the **Mac-Lab** and the **CardioLab** systems.
- **SpecialsLab** is a system with a subset of the features available on the **Mac-Lab**.

## Mac-Lab System

The Mac-Lab System is intended for acquiring, filtering, digitizing, amplifying, measuring and calculating, displaying, recording and monitoring of clinical data from adult and pediatric patients. The Mac-Lab System is configurable. Clinical data includes: ECG waveforms, heart rate, pulse oximetry (SpO<sub>2</sub>), respiration rate, CO<sub>2</sub> (EtCO<sub>2</sub>), temperature, hemodynamic measures (for example, valve gradients and areas, cardiac output, shunts, Fractional Flow Reserve (FFR), invasive and noninvasive blood pressure). Physiological parameters such as diastolic, systolic, mean pressures, and heart rate are derived from the signal data, displayed and recorded. The data is entered manually or acquired via interfaced devices and/or information systems and may be used for report generation.

Procedural information and optional anatomical and physiological imaging and data devices may be interfaced (for example, X-ray, ultrasound, patient monitors and information systems). The Mac-Lab System can display, store and annotate images previously acquired and stored by other systems. Data may be provided to other systems via multiple formats (for example, HL7, DICOM, Analog outputs). Data may be received from other devices via multiple formats (for example DICOM, Analog inputs).

Optional accessories for hardware and software include research tools to be used exclusively outside of active patient care settings. The purpose of the research tools is to assist researchers or clinicians in developing algorithms.

The Mac-Lab System does not have alarms, does not generate energy delivered to the patient, does not administer drugs and does not perform any life-supporting or life-sustaining functions. The Mac-Lab System is not intended for use on unattended patients, or in situations where diagnostic arrhythmia detection is required.

The Mac-Lab System provides the ability to transmit patient data for storage, analysis and viewing at distributed locations within a clinical facility via network connectivity. The Mac-Lab System also functions as a stand-alone device. The Mac-Lab System is used in a variety of hospital and clinical settings including interventional laboratories (for example, cardiac catheterization and radiology), operating room environments, and pre and post areas all under the direct supervision of licensed healthcare practitioners who are responsible for interpreting the data.

## CardioLab System

The CardioLab System is intended for acquiring, filtering, digitizing, amplifying, measuring and calculating, displaying, recording and monitoring of clinical data from adult and pediatric patients. The CardioLab system is configurable. Clinical data includes: ECG waveforms, intracardiac signals, stimulus data, ablation data, pulse oximetry (SpO<sub>2</sub>), respiration rate, CO<sub>2</sub> (EtCO<sub>2</sub>), temperature, and invasive and noninvasive blood pressure. Physiological parameters such as diastolic, systolic, mean pressures, heart rate, and cycle length are derived from the signal data, displayed and recorded. The data is entered manually or acquired via interfaced devices and/or information systems and may be used for report generation.

Procedural information and optional anatomical and physiological imaging and data devices may be interfaced [for example, X-ray, ultrasound, mapping systems, ablation generators (for example, RF and cryogenic), simulators, patient monitors and information systems]. The CardioLab System can display, store and annotate images previously acquired and stored by other systems. Data may be provided to other systems via multiple formats (for example, HL7, DICOM, Analog outputs). Data may be received from other devices via multiple formats (for example, DICOM, Analog inputs).

Optional accessories for hardware and software include research tools to be used exclusively outside of active patient care settings. The purpose of the research tools is to assist researchers or clinicians in developing algorithms.

Optional accessories for hardware and software includes a waveform simulator to be used exclusively outside patient care settings. The waveform simulator may be used for training, demonstration without a patient attached, and as a troubleshooting tool in the CardioLab System.

The CardioLab System does not have alarms, does not generate energy delivered to the patient, does not administer drugs and does not perform any life-supporting or life-sustaining functions. The CardioLab System is not intended for use on unattended patients, or in situations where diagnostic arrhythmia detection is required.

The CardioLab System provides the ability to transmit patient data for storage, analysis and viewing at distributed locations within a clinical facility via network connectivity. The CardioLab System also functions as a stand-alone device. The CardioLab System is used in a variety of hospital and clinical settings including interventional laboratories (for example, electrophysiology and cardiac catheterization), operating room environments, and pre and post areas all under the direct supervision of licensed healthcare practitioners who are responsible for interpreting the data.

## ComboLab System

The ComboLab System is the combination of both the Mac-Lab and CardioLab Systems. The ComboLab System allows the user to run either the Mac-Lab System or the CardioLab System, although only one system may be used at a time. The ComboLab System executes the same software and runs on the same hardware in the same environments as the Mac-Lab and CardioLab Systems.

## SpecialsLab System

The SpecialsLab System executes the same software and runs on the same hardware in the same environment as the Mac-Lab System. Products designated as a SpecialsLab System support fewer options than the Mac-Lab system.

## Compliance

Non-US Mac-Lab/CardioLab systems comply with the following standards:

- IEC/EN 60601-1 3rd ed Medical Electrical Equipment, Part 1 General Requirements for Basic Safety and Essential Performance
- IEC/EN 60601-1 2nd ed Medical Electrical Equipment, Part 1 General Requirements for Safety
- IEC/EN 60601-1-1 Safety requirements for medical electrical systems
- IEC/EN 60601-1-2 Electromagnetic compatibility - Requirements and tests
- IEC/EN 60601-1-4 Programmable electrical medical systems

**NOTE:** Upgrade systems may not comply with IEC/EN 60601-1 3rd ed.

US-only Mac-Lab/CardioLab systems comply with the following standards:

- IEC/EN 60601-1 2nd ed Medical Electrical Equipment, Part 1 General Requirements for Safety
- IEC/EN 60601-1-1 Safety requirements for medical electrical systems
- IEC/EN 60601-1-2 Electromagnetic compatibility - Requirements and tests
- IEC/EN 60601-1-4 Programmable electrical medical systems

## Classification

This system is classified according to IEC 60601-1 as follows:

	Type of protection against electrical shock	Degree of protection against electrical shock	Degree of protection against harmful ingress of water	Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Mode of Operation
IEB	Class I	N/A	Ordinary	Not Suitable	Continuous
CardioLab II Plus Amplifier: ECG, IBP, IC ECG, Auxiliary	Class I	CF Defib Proof			
PDM Base Station	Class I	N/A	IPX1		
PDM ECG, IBP, SpO <sub>2</sub> , Temp, CO NBP	Class II	CF Defib Proof BF Defib Proof			
TRAM-RAC	Class I	N/A			
TRAM module: ECG, IBP, SpO <sub>2</sub> , Temp, CO NBP	Class II	CF Defib Proof BF Defib Proof	Ordinary		
Capnostat Mainstream CO <sub>2</sub> module	N/A	BF			
CapnoFlex CO <sub>2</sub> module	N/A	BF			
Vivid Remote Trackball	N/A	N/A			

## Conventions

The following conventions are used throughout this manual.

<b>Bold</b>	Indicates keys on the keyboard, text to be entered or hardware items such as buttons or switches on the equipment.
<i>Italics</i>	Indicates software terms that identify menu items, buttons or options in various windows.
<b>[Key1] + [Key2]</b>	Indicates a keyboard operation. A (+) sign between the names of two keys means press and hold the first key while pressing the second key once.  For example, "Press <b>Ctrl + Esc</b> " means to press and hold down the <b>Ctrl</b> key while pressing the <b>Esc</b> key.
<b>Enter</b>	Press the " <b>Enter</b> " or " <b>Return</b> " key on the keyboard. Do not type "enter".

## Illustrations and Names

All illustrations in this manual are provided as examples only. They may not necessarily reflect the setup or the data on your system.

In this manual, all names appearing in examples and illustrations are fictitious. The use of any real person's name is purely coincidental.

## Related Manuals

The following is a list of the related manuals for the Pre-Installation manual.

Part Number	Document
2063076-017	Invasive Workbench Operator's Manual
2063076-001	Mac-Lab/SpecialsLab Operator's Manual
2063076-002	CardioLab Operator's Manual
2063076-003	Centricity Cardiology INW Operator's Manual
2063076-004	Mac-Lab/CardioLab Security Guide
2063076-009	Mac-Lab/CardioLab Software Only Review Workstation Installation Service Manual
2063076-010	Mac-Lab/CardioLab/Centricity Cardiology INW Service Manual
2063076-301	Mac-Lab/SpecialsLab Operator's Manual - US-Only
2063076-302	CardioLab Operator's Manual - US-Only
2063076-303	Centricity Cardiology INW Operator's Manual - US-Only

# Safety Information

Read through the following safety information before putting the system into use. Disregarding information on safety is considered abnormal use.

The terms danger, warning and caution are used throughout this manual to point out hazards and to designate a degree or level of seriousness.

## Definitions



**DANGER:** IMMINENT DEATH OR SERIOUS INJURY

Danger messages indicate an imminently hazardous situation which, if not avoided, will result in death or serious injury.



**WARNING:** POTENTIAL DEATH OR SERIOUS INJURY

Warning messages indicate a potentially hazardous situation which, if not avoided, may result in death or serious injury.



**CAUTION:** POTENTIAL INJURY, EQUIPMENT DAMAGE, OR LOSS OF DATA

Caution messages indicate a potentially hazardous situation which, if not avoided, may result in minor to moderate injury, equipment damage, or loss of data.

**NOTE:** Notes provide additional user information.

## Prescription Device



**CAUTION:** SALE OF DEVICE

U.S. federal law restricts this device to sale by or on the order of a physician.

## General

Hazard as defined as a source of potential injury to a person.



**WARNING: UNSUPERVISED USE**

This device is intended for use under the direct supervision of a licensed healthcare practitioner.



**WARNING:** This system is designed to comply with the applicable IEC/EN 60601-1 series safety standards when connected and powered as specified. Connecting additional devices, parts or accessories that are not recommended by GE Healthcare could lead to a reduced level of safety. Refer to the Service Manual for equipment connection and service information. Contact GE Healthcare if questions arise.



**WARNING:** Before connecting supported interfaced devices to the system, ensure that the devices meet the requirements of the applicable IEC 60601 series safety standards and the system configuration meets the requirements of the IEC 60601-1 medical electrical systems standard.

## Applicable Messages

The following safety information applies to the Mac-Lab, CardioLab, ComboLab, and/or Centricity Cardiology INW Server. Additional safety messages may be found throughout this manual that provide safe operation information.



**DANGER: EXPLOSION HAZARD**

Using this equipment in the presences of flammable gasses (including anesthetics and oxygen) may cause an explosion or fire. Always use this equipment in a well ventilated area away from the presence of potentially flammable gasses.



**WARNING:** Before connecting supported interfaced devices to the system, ensure that the devices meet the requirements of the applicable IEC 60601 series safety standards and that the connected system configuration meets the requirements of the IEC 60601-1-1 medical electrical systems standard.



**WARNING: ANTI-VIRUS SOFTWARE INSTALLATION REQUIRED**

The System is delivered without anti-virus protection. Ensure a validated anti-virus is installed on the system before connecting to any network. Lack of validated virus protection could lead to system instability or failure.



**WARNING: Use caution when cleaning the environment near equipment. Fluid ingress may damage devices or compromise electrical safety.**



**WARNING: AUDIBLE INDICATORS**

The audible indicators are for reference only. The audible indicators are not designed for use as a patient alarm.



**WARNING: ELECTRICAL HAZARD**

Power equipment only as specified. Do not connect equipment to extension cords or multiple socket outlets.



**WARNING: EQUIPMENT FAILURE**

System components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.



**WARNING: FALLING EQUIPMENT**

Monitor suspension systems other than the Mavig GD60 Series have not been validated for remote monitors.



**WARNING: FALLING EQUIPMENT**

Do not place the PDM more than 147 cm (58 in) from the floor when mounting on an IV pole with a base less than 58 cm (23 in) in diameter. This may cause the IV pole to tip over.



**WARNING: NOT A PATIENT MONITOR**

The system is intended to be used as a recording system for catheterization, electrophysiology and related specialty laboratories. A defibrillator or ECG monitor should be attached for patients in need of uninterrupted ECG display. An additional means to display SpO<sub>2</sub> should be attached for patients in need of uninterrupted SpO<sub>2</sub> display. A temporary pacemaker needs to be available for patients in need of uninterrupted delivery of pacing. An additional means to display EtCO<sub>2</sub> should be attached for patients in need of uninterrupted EtCO<sub>2</sub> display.

**WARNING: SHOCK HAZARD**

Do not connect analog input or analog output cables to patient-isolated equipment interfaces. This could compromise patient safety.

**WARNING: SHOCK HAZARD**

To ensure patient safety, all equipment connected to the system must be powered from an isolated power source.

**WARNING: SHOCK HAZARD**

Damaged cables and loose connections present a shock hazard and could cause signal noise or impaired device operation. Ensure all cables are in good condition, protected from potential sources of damage, and securely connected before powering on equipment. Replace damaged cables immediately.

**WARNING: SHOCK HAZARD**

To reduce the risk of electric shock or damage to equipment, the equipment must only be connected to a properly installed power outlet with protective ground contacts.

**WARNING: SHOCK HAZARD**

To reduce the risk of ingress of water into the equipment, do not mount the PDM in a vertical position with the patient cables facing up or down.



**WARNING: SHOCK HAZARD**

Do not power unspecified devices from the system equipment outlets.



**WARNING: SUPERVISED USE REQUIRED**

The system must be used in an attended environment where there is direct visual and audible communication between the physician performing the procedure and the system operators.



**WARNING: SYSTEM INSTABILITY**

Ensure validated anti-virus software is installed on the system. Lack of validated anti-virus software could result in system instability or failure.



**WARNING: SYSTEM INSTABILITY**

Do not install or use unvalidated anti-virus software (including unvalidated versions). Doing so may result in system instability or failure. Use only validated anti-virus software in the appropriate language version.



**WARNING: SYSTEM INSTABILITY**

Ensure validated anti-virus software is installed on the system. Lack of validated anti-virus software could result in system instability or failure.



**WARNING: TRIPPING HAZARD**

Keep cables away from accessible walkways. Failure to do so may present a tripping hazard and could result in cable damage.



**WARNING: UNSUPERVISED USE**

This device is intended for use under the direct supervision of a licensed health care practitioner.

**WARNING: VISUAL INDICATORS MALFUNCTION**

The visual indicators are for reference only. The visual indicators are not designed for use as a patient alarm.

**CAUTION: CABLING**

Route optical cables through conduit in the ceiling or floor to avoid damage to the cables or cable connectors.

**CAUTION: LOSS OF CARDIAC MAPPING FUNCTION**

To help ensure continued functionality of the EPVision application when in use with the CardioLab system, a reliable network connection should be used.

**CAUTION: RESTRICTED SALE**

U.S. federal law restricts this device to sale by or on the order of a physician.

**CAUTION: SYSTEM FAILURE**

To ensure an adequate system power supply, GE Healthcare recommends using a dedicated circuit to power the IEB.

**CAUTION: SYSTEM INSTABILITY**

All networked systems at a location must be on the same version of Mac-Lab/ CardioLab software. Failure to do so may result in slowed performance, data corruption, or system instability.

## Responsibility of the Manufacturer

GE Healthcare is responsible for the effects of safety, reliability and performance only if:

- Assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by GE Healthcare.
- The electrical installation of the relevant room complies with the requirements of the appropriate regulations.
- The equipment is used in accordance with the instructions for use.

## Responsibility of the User

### General

Keep this manual with the equipment at all times. Periodically review this manual for information regarding system operation. If further assistance is required, contact GE Healthcare.

### Anti-Virus Software



**WARNING: SYSTEM INSTABILITY**

**Ensure validated anti-virus software is installed on the system. Lack of validated anti-virus software could result in system instability or failure.**

The following should be noted regarding the use of anti-virus software. Refer to the Mac-Lab/ CardioLab Security Guide (PN 2063076-004) for further information.

- Anti-virus software is not provided with the Mac-Lab/CardioLab system and it is the customer's responsibility to acquire, install and maintain.
- The customer is responsible for updating anti-virus definition files.
- If a virus is found, contact the facility System Administrator and GE Technical Support.
- The anti-virus software used must be one that has been validated by GE Healthcare.
- The language version of the anti-virus software must match the operating system language.

### Product Vulnerability and Security Patches

Customers are responsible to stay informed on the Mac-Lab / CardioLab product vulnerability status and the installation of validated security patches for the Mac-Lab / CardioLab systems. Refer to the Mac-Lab/ CardioLab Security Guide (PN 2063076-004) for further information.



**WARNING: SYSTEM INSTABILITY**

**Do not install or use unvalidated anti-virus software (including unvalidated versions). Doing so may result in system instability or failure. Use only validated anti-virus software in the appropriate language version.**

## Planned Maintenance

It is the responsibility of the user to properly maintain the system equipment. Refer to operator manual and the accompanying service manual for further information.

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 health hazards.

Regular maintenance, irrespective of usage, is essential to ensure that the Mac-Lab/CardioLab system will always be functional when required. In the event that service is needed for the equipment, contact your GE Healthcare service representative.

## Service

Refer equipment servicing to GE Healthcare authorized service personnel only. Any unauthorized attempt to repair equipment under warranty voids that warranty.

Any unauthorized attempt to install third-party software on a system under warranty, voids that warranty.

It is the user's responsibility to report the need for service to GE Healthcare or to one of their authorized agents.



## Chapter 2

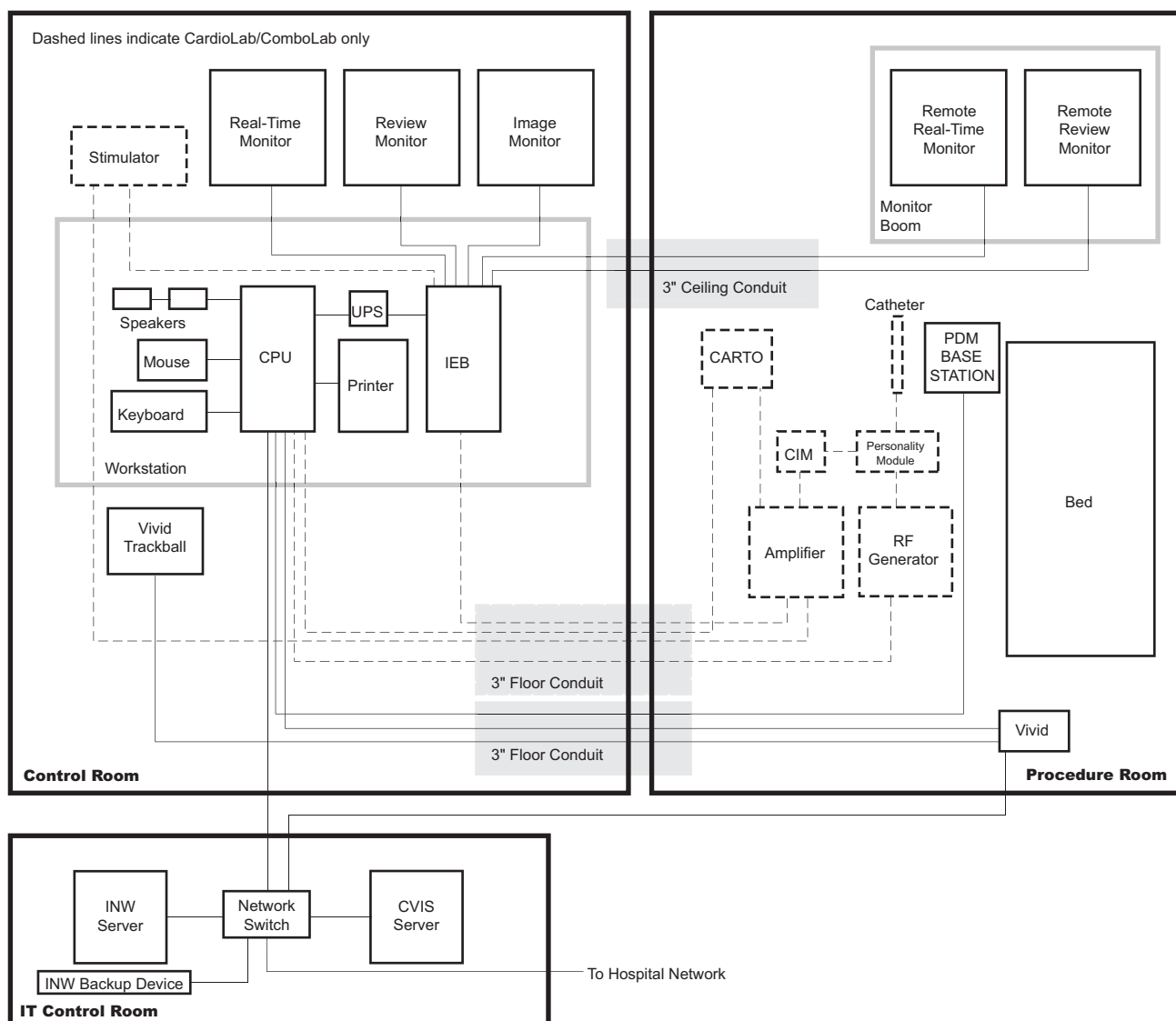
# **System Description**

# Typical System Configuration

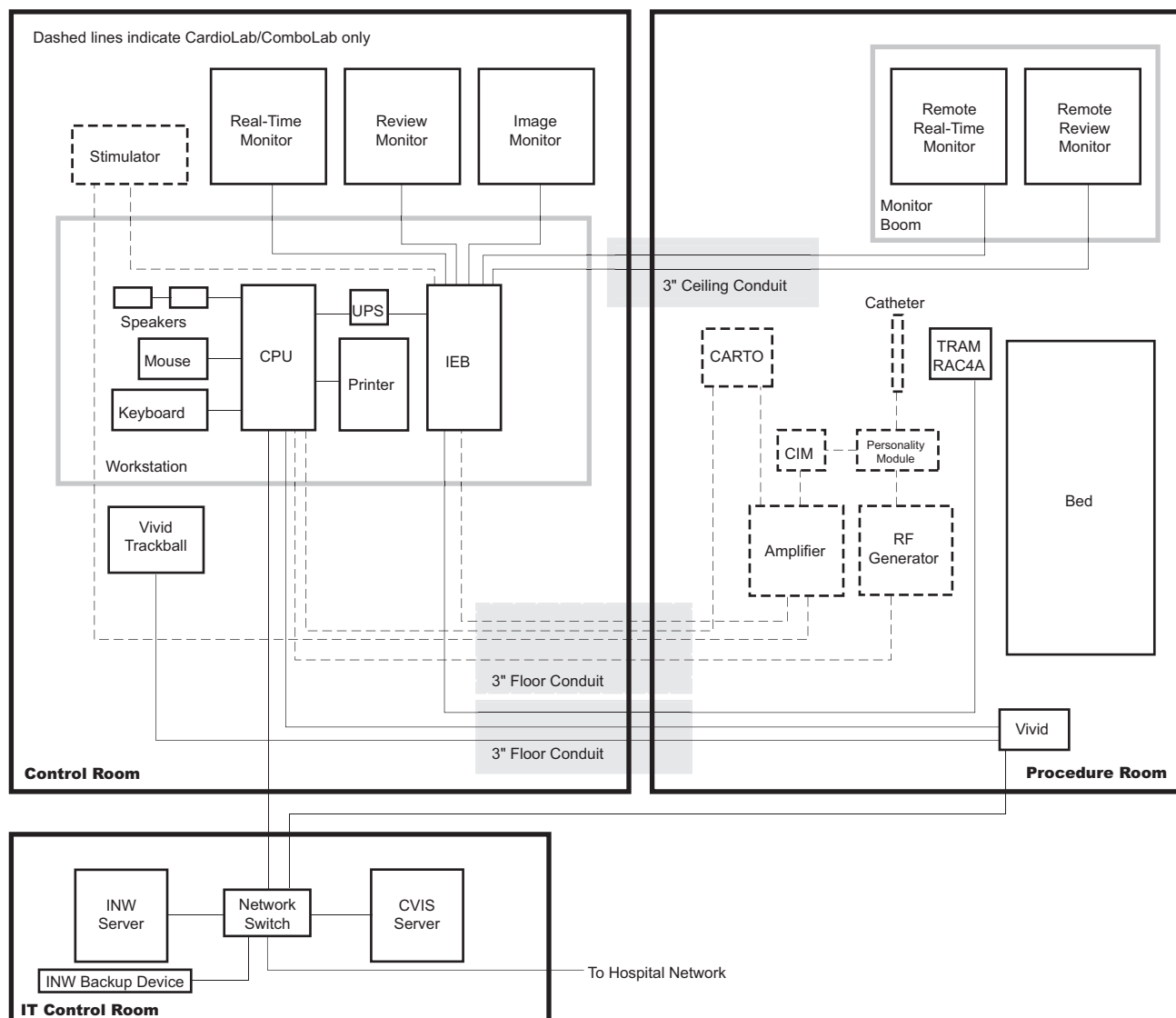
This system may consist of either Mac-Lab (hemodynamic), CardioLab (electrophysiologic), or ComboLab (both systems).

The system may be standalone or connected to a network. Network installations include a Centricity Cardiology INW server. It may be connected to an optional CVIS server.

The block diagrams below show a typical setup. The first diagram shows a PDM as the Cath Amplifier, and the second diagram shows a TRAM-RAC as the Cath Amplifier.







# Acquisition System

## Control Room Components

- **Acquisition Computer:** The Acquisition Computer provides the ability to record the patient's real time waveform data. It uses Windows and has the following drives:
  - ◆ DVD-Drive: used for installation and service of the computer.
  - ◆ SD Drive: used to store backup copies of patient procedure data.
  - ◆ External Blu-ray drive (optional): used to copy procedure data from DVD-RAM media to SD media.
- **Monitors:** Two monitors are standard to display Real-Time and Review windows. An optional third monitor displays images acquired from the X-ray and ultrasound system.
- **Integrated Electronics Box (IEB):** The IEB provides isolated power to system components and distributes video and communication signals to the control and procedure rooms.
- **Uninterrupted Power Supply (UPS):** The UPS provides emergency power to the acquisition computer in the event of a power outage. It will sustain power to the computer for a minimum of 20 seconds. It does not power the monitors during an outage.

**NOTE:** The UPS is external to the IEB and provides uninterrupted power to the HP computer. The monitors and other peripherals will not remain on if power is lost.

- **Printer:** Used to print snapshots, images and reports during or after a procedure.
- **Barcode scanner (optional):** Used to scan in supplies and medication used in a procedure.
- **CARTO Mapping System (optional) - CardioLab or ComboLab systems only:** Provides 3D electroanatomical cardiac maps to the CardioLab.
- **Cardiac Stimulator (optional) - CardioLab or ComboLab systems only:** Provides direct cardiac stimulation to assist the physician during a CardioLab case.
- **Vivid System Remote Trackball (optional):** Provides the ability to control the GE Vivid Ultrasound System from the control room.
- **Desk (optional):** Provides a workspace for control room components.

## Procedure Room Components

- **Monitors:** One remote monitor is standard and is software switchable between Real-Time, Review and Image (if available) windows. A second monitor is optional.
- **Remote Speakers:** Provide output for ECG QRS tone and optional audible indicators in the procedure room.
- **TRAMNet or PDM:** The TRAMNet or PDM acquires invasive pressure and ECG signal data for Mac-Lab systems. It also acquires patient vital data such as respiration rate, noninvasive blood pressure, SpO<sub>2</sub> and temperature for both Mac-Lab and CardioLab systems. The TRAMNet consists of a Remote Acquisition Case (RAC 4A) and a Transport Remote Acquisition Module (TRAM). The PDM is powered by the PDM Base Station unit.
- **CardioLab II Plus Amplifier - CardioLab or ComboLab systems only:** The Amplifier gathers intracardiac and surface ECG data for both the CardioLab and ComboLab systems.
- **Catheter Input Modules - CardioLab or ComboLab systems only:** Used for connecting intracardiac catheters to the CardioLab II Plus Amplifier.
- **RF Filter Box - CardioLab or ComboLab systems only:** Filters RF noise from intracardiac signals acquired by an ablation device.
- **CO<sub>2</sub> Module (optional):** The CO<sub>2</sub> module plugs into the RAC 4A and displays the patient's respiration data on the Mac-Lab or CardioLab System.
- **Remote Operators Terminal (RMOT) (optional):** The RMOT consists of two monitors, a keyboard and a mouse remotely connected to the Acquisition system to provide remote control of the Acquisition computer in the procedure room.
- **Large Display Monitor (LDM) (optional):** The LDM is a large widescreen flat-panel LCD monitor used for simultaneous display of several image sources, including the Acquisition system.
- **Analog Output Box (optional):** Distributes ECG and blood pressure signals from the PDM, TRAM or CardioLab Amplifier to other equipment.
- **CARTO System (Patient Interface Unit) (optional) - CardioLab or ComboLab systems only:** The CARTO PIU gathers data for the CARTO system.
- **Ablation Device (optional) - CardioLab or ComboLab systems only:** An RF ablation device uses radiofrequency energy to destroy abnormal electrical pathways in heart tissue. A Cryoablation device uses a coolant which flows through the catheter to freeze and destroy abnormal electrical pathways in heart tissue.
- **Force Sense Device (optional):** A device which measures the amount of pressure between the tip of an ablation catheter and the tissue with which it is in contact.
- **Vivid System (optional):** A digital imaging GE Ultrasound system.
- **Nurse's Review Workstation (optional):** The Nurse's Workstation is a system used in the procedure room during a study. Provides the operator with the ability to participate in an active study and perform actions such as document administered medications and supplies consumed.

## IT Control Room Components

- **Network Switch:** Provides connection between network components and segments.
- **Centricity Cardiology INW Server:** Provides the ability to review patient data during and after data acquisition and allows for a centralized point of data access.
  - ◆ **Monitor (temporary):** Displays screens during server installation only. Removed after server installation is complete.
  - ◆ **Keyboard (temporary):** Provides an input for commands and text entries during server installation only. Removed after server installation is complete.
- **CVIS Server:** Provides a central location to manage data regarding staff, supplies, inventory, patient scheduling, patient information and statistical reports.
  - ◆ **Monitor (temporary):** Displays screens during server installation only. Removed after server installation is complete.
  - ◆ **Keyboard (temporary):** Provides an input for commands and text entries during server installation only. Removed after server installation is complete.
- **Centricity Cardiology INW Backup Device:** Provides data backup for the Centricity Cardiology INW server.
  - ◆ **Monitor (temporary):** Displays screens during Centricity Cardiology INW Backup Device installation only. Removed after Centricity Cardiology INW Backup Device installation is complete.
  - ◆ **Keyboard (temporary):** Provides an input for commands and text entries during Centricity Cardiology INW Backup Device installation only. Removed after Centricity Cardiology INW Backup Device installation is complete.

# Review Workstations

Mac-Lab/SpecialsLab software can run on hardware provided by GE (GE Client Workstation) or on hardware provided by the hospital (Software Only Review Workstation).

## Nurse's Workstation Components

The Nurse's Workstation is a system used in the procedure room during a study.

- **GE Client Workstation:** Provides the operator with the ability to participate in an active study and perform actions such as document administered medications and supplies consumed.
- **Isolation Transformer:** Provides isolated power for Review Workstation and monitor.
- **Monitor:** Used to display the **Review** window. One monitor is standard.
- **Barcode Scanner (optional):** Used to scan in supplies and medications used in a procedure.

## Remote Review Workstation Components

The Remote Review Workstation is a system installed in the physician's office or an area outside the laboratory.

- **GE Client Workstation:** Used to review previously acquired procedure data and generate reports.
- **Isolation Transformer:** Provides isolated power for Review Workstation and monitor.
- **Monitor:** Used to display the **Review** window. One monitor is standard.
- **Printer (optional):** Used to print snapshots, images and reports after a procedure.

## Pre/Post Review Workstation Components

The Pre/Post Review Workstation is a Review Workstation typically located in a Holding Area for the entry of basic patient demographics, clinical data and patient events prior to, or after, the patient's entry into the Laboratory.

- **GE Client Workstation:** Used before and after the procedure to record patient information.
- **DASH/Solar Monitor:** Connected to the Pre/Post Workstation to acquire patient vitals during pre or post procedure monitoring.

**NOTE:** The Solar and DASH monitors must only be connected to Pre/Post workstations. Do not connect a Solar or DASH monitor to an Acquisition, Nurse's or Remote workstation.

- **Monitor:** Used to display the **Review** window. One monitor is standard.
- **Isolation Transformer:** Provides isolated power for the Pre/Post Workstation and monitor.
- **Mobile Workstand (optional):** Provides portable support for Pre/Post Workstation components.
- **Barcode Scanner (optional):** Used to scan in supplies and medications used in a procedure.

## Software Only Review Workstation

If a Software Only Review Workstation is used with customer provided hardware, all software installation is the responsibility of the customer.



**WARNING:** Before connecting supported interfaced devices to the system, ensure that the devices meet the requirements of the applicable IEC 60601 series safety standards and that the connected system configuration meets the requirements of the IEC 60601-1-1 medical electrical systems standard.

Following are the minimum hardware and software specifications that must be met for current system requirements.

**NOTE:** GE Healthcare is not liable for any hardware or software malfunction, service, or support related to the use of this software only product on hardware not supplied by GE.

**NOTE:** Specifications are subject to change. Please refer to the GE Software Only manual (PN 2063076-009) for current system requirements.

**NOTE:** When used in a patient care area, the hardware must meet IEC60601-1. This can be achieved through the use of a medical grade computer, separate isolation transformer (refer to GE Service Manual (PN 2063076-010) for part number) or other means as determined by appropriate hospital personal.

- Intel Pentium Dual-Core 2.20GHz or greater CPU
- 2 GB RAM or greater
- True Color (32-bit) video adapter
- 1600 x 1200 minimum resolution video adapter and monitor
- Windows XP (SP3) or Windows 7 Professional Edition must be installed on the primary partition on the first hard drive (C: drive)
- Office XP Professional or Office 2007 (Word 2007 and Access 2007 must be installed)
- At least 3 GB free space on the C drive (Client Software)
- At least 5 GB free space on the D drive (Patient data files)
- LAN connection with a minimum network speed of 100Mbps
- One IEEE 802.3 100/1000 BASE-T compatible network interface
- CD-ROM/DVD-ROM Optical Drive
- Standard 104 key Keyboard
- Standard USB mouse

# Supported Peripheral Devices

The following peripheral devices are support for use on Mac-Lab/CardioLab/Centricity Cardiology INW system:

- **DASH:** 3000/4000/5000
- **Solar:** 8000i and 8000M connected with a TRAM
- **TRAM:** 450, 451M, 451N, 851, 851M and 851M
- **PDM**
- **Vivid:** i/q
- **FFR (Mac-Lab only):** Radi PressureWire Aeris and Volcano SmartMap Pressure Instrument
- **Ablation and Force Sense (CardioLab only):**
  - ◆ Atakr II (Model: 4803) RF (Radio frequency) ablation device
  - ◆ EPT-1000 (Model: 800T) RF ablation device
  - ◆ Stockert RF ablation device
  - ◆ IBI 1500T (Software version: v1.25) RF ablation device
  - ◆ HAT 300S RF ablation device
  - ◆ CryoCath (Model: Gen3) cryo-ablation device
  - ◆ JLLCABL-IT RF ablation device
  - ◆ Maestro 3000
  - ◆ Force device availability varies by region, please see your sales representative.
- **Cardiac Stimulator (CardioLab only):** MicroPace EPS 320, Bloom Stimulator
- **Mapping System (CardioLab only):** CARTO XP v10 or CARTO 3
- **X-ray systems:** refer to the product's DICOM conformance statement on the following GE Healthcare website:  
[http://www.gehealthcare.com/usen/interoperability/dicom/products/cvinfosys\\_dicom.html](http://www.gehealthcare.com/usen/interoperability/dicom/products/cvinfosys_dicom.html)

If other devices are used with the Mac-Lab/CardioLab system, the system may not function properly.





## Chapter 3

# System Requirements

## Overview

The customer is responsible for ensuring all systems requirements are maintained at all times. Failure to meet these requirements may result in installation delays or void warranties.

# Network Requirements

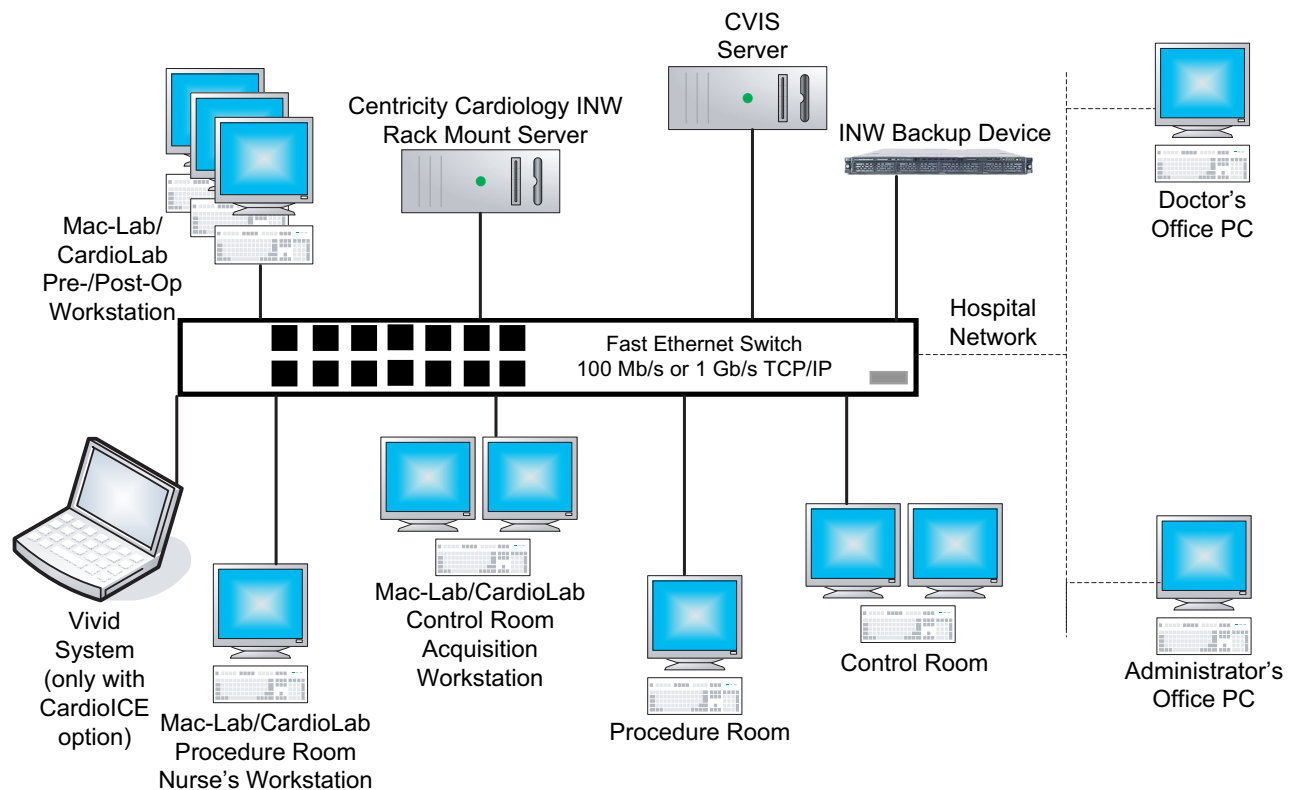
## CardioLab/CARTO/Vivid Router Requirements

For the 3-way interface between CardioLab/CARTO/Vivid i/q, it is the customer's responsibility to supply a router that meets the following specifications:

- The router shall provide a minimum of 4 ports: 3 incoming and 1 outgoing connection to support CARTO and Vivid network connectivity.
- It is recommended that the router be configured to use DHCP to get its WAN IP Address. In the event that the hospital does not support DHCP all relevant network settings shall be provided to GE Field Service (IP, Subnet, DNS, Gateway and so on).
- The router should not be configured to act as a DHCP server. IP Addresses for the Vivid and CARTO systems will be configured manually to use static IP Addresses.
- The router shall be configured to allow for incoming ping requests for troubleshooting and diagnostic purposes.
- The router should support a minimum speed of 100Mbps not to exceed 1000Mbps.
- The router must be configured to allow for NTP, Windows File Sharing and DICOM communications.
- The router must support Network Address Translation (NAT) and Port Address Translation (PAT).
- The router should not support wireless network connections.

**NOTE:** The router configuration settings must be made accessible to GE Field Service. If authentication is required for the configuration, this information must be made available to GE Field Service.

## Typical Setup



A typical network setup consists of multiple Acquisition systems and Review Workstations with a Centricity Cardiology INW server and a CVIS server and the Vivid system (which is only included with the CardiolCE option).

### ■ Centricity Cardiology INW Server

- ◆ Acquisition systems and Review Workstation access to patient studies
- ◆ Network repository for patient studies
- ◆ The INW Server Backup Device option (if purchased) in Member Server environments can have a DHCP address on the Backup Device. The Backup Device requires a DHCP reserved IP address.

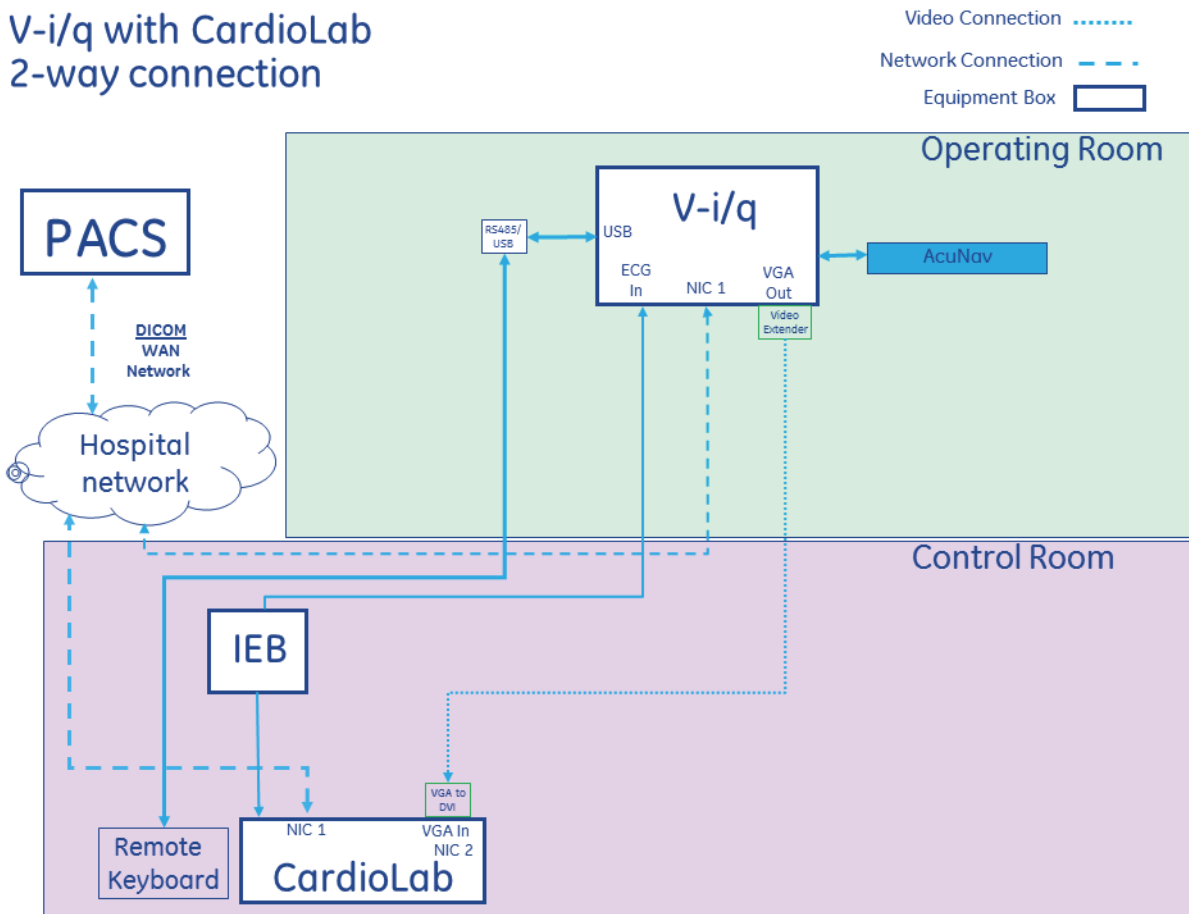
### ■ CVIS Server

- ◆ Central list management for staff, supplies, and so on
- ◆ Patient scheduling
- ◆ Patient information
- ◆ Inventory Management
- ◆ Statistical Reports

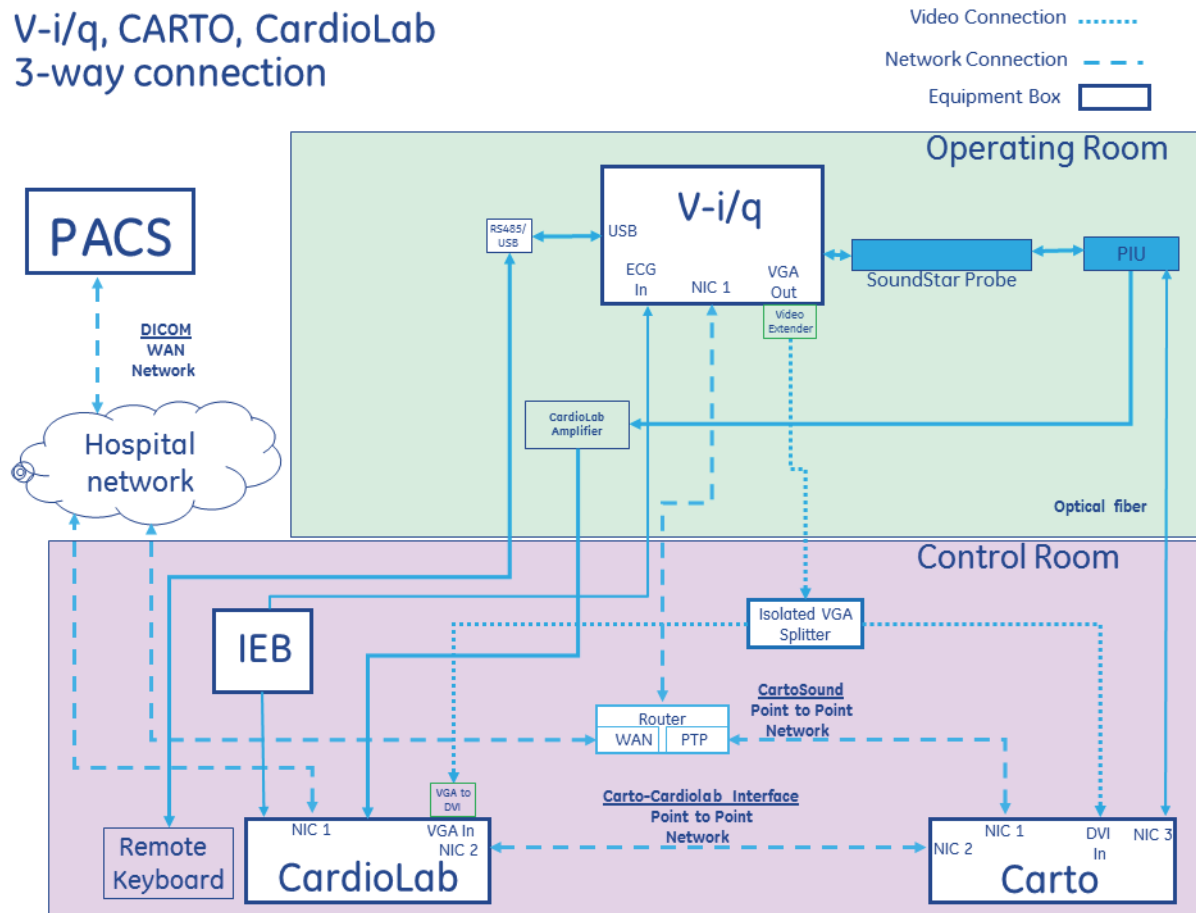
Refer to the Mac-Lab/CardioLab Security Guide (PN 2063076-004) for additional information.

## Interface Setup

### V-i/q with CardioLab 2-way connection



## V-i/q, CARTO, CardioLab 3-way connection



# Security Information

Validated configurations consist of product scenario implementations that are tested against GE product failure and sample cases run to simulate a real environment while conducting testing. GE provides service and support based on validated configurations only and bears responsibility for GE products only.

## Non-Validated Software Applications

This section details the policy for non-validated software applications applied to the following products:

- Mac-Lab Hemodynamic Systems
- CardioLab Electrophysiology Systems
- ComboLab Hemodynamic and Electrophysiology Systems
- SpecialsLab Systems
- Centricity Cardiology INW Server

## Policy

Our policy is that we do not recommend installations of any other third party software applications (that is, not mentioned above) on the products above as they could affect performance, warranty and serviceability. Examples of such might include other Anti-Virus programs, print servers, interface engines, anti-spyware, anti-adware, viruses, malware, and so on. GE does not support the use or installation of these non-validated applications or tools. If such programs are installed the customer bears the risk of the product not functioning properly and any risks that are introduced for patient safety. GE will not guarantee support for an environment that is different than a validated implementation. In cases where this is found and technical assistance is requested, GE will provide support, by first eliminating the third party software on the product and bringing it back to a known and validated configuration. If it is found that the third party software is the cause of product failure, any costs associated with this will be the responsibility of the hospital.

At GE Healthcare we understand the uniqueness of our customers and pride ourselves in the personalized solutions we provide to help you in your quest to care for patients. We hope this section will help you to better understand our policy on non-validated software applications and we hope you can work with us as we proceed in further developing our products for your future benefit.

## Validated Third Party Software

Currently validated and allowed third party software such as Enterprise Back-up, Archival, Anti-virus and other applications to run on the same computer are:

### Enterprise Backup Software

Mac-Lab/CardioLab/ComboLab	IT (Version 6.9.5)
Symantec Backup Exec	2010 R3
CA ARCserve Backup for Windows	r16
IBM Tivoli Storage Manager Client	v6.3.0
EMC NetWorker	v7.6 SP3

### Validated Anti-Virus Software



#### **WARNING: SYSTEM INSTABILITY**

**Ensure validated anti-virus software is installed on the system. Lack of validated anti-virus software could result in system instability or failure.**

The Mac-Lab/CardioLab 6.9.5 system has been validated to run with the software listed below. Except where noted, the software below supports English, French, German, Italian, Spanish, Swedish, Chinese, and Japanese:

Supported Anti-Virus Software	Supported Anti-Virus Software Version
CA Total Defense	r12
McAfee VirusScan Enterprise	8.8
McAfee ePolicy Orchestrator with McAfee VirusScan Enterprise 8.8	v4.6 (Does not support Italian and Swedish)
Symantec EndPoint Protection	12.1
Trend Micro OfficeScan Client/Server Edition	10.6

The Antivirus Server software can be installed at a hospital domain level and the Centricity Cardiology INW server can be a client for the Antivirus software.



## Previously Validated Anti-Virus Software

The Mac-Lab/CardioLab system has previously been validated to run with the software listed below. It is recommended that systems run with one of the currently validated Anti-Virus software packages to avoid any unforeseen issues. Please refer to [Validated Anti-Virus Software on page 3-8](#).

Supported Anti-Virus Software	Supported Anti-Virus Software Version
CA eTrust AntiVirus Enterprise (for a single Acquisition, Review, or Server)	r8.1.655
McAfee VirusScan (with McAfee ePolicy Orchestrator v4.5, Patch 1)	8.7i, Patch 3
McAfee ViruScan Enterprise	8.7i, Patch 3
Symantec EndPoint Protection (for Acquisition, Review or Server)	11.0.6
Trend Micro OfficeScan Client/Server Edition (for Acquisition, Review or Server)	10.0 + SP1

## 3rd Party: PedCath

Language	PedCath Version
English	v7.7.2
French	v7.5.5
Swedish/German (see note)	v7.6.5
Italian	v7.5.5
Spanish	v7.5.5
Japanese	v7.4.3J
Chinese (see note)	v7.4.3J

**NOTE:** Chinese systems will use the Japanese version of PedCath. Swedish and German systems will use the English version of PedCath.

## System Requirements for Reviewing 5.x Studies

In order to review studies created at v5.x, a separate system must be provided in order to install a utility to convert those studies to the newest version of SQL Server. Once the studies are converted they can then be reviewed on a v6.9.5 system. The following are the requirements for the system to be used to convert the v5.x studies.

- Windows XP (SP3) or Windows 7 Professional Edition must be installed on the system.
- Do not install the 5.x to 6.9 Study Converter utility on a system where the Mac-Lab/CardioLab application is installed.
- Do not install the 5.x Study Converter utility on a system where a later version than Microsoft SQL Server 2005 (any Edition) is installed.
- C Drive Partition: The partition wherein the Operating System is installed should have at least 1 GB of free disk space.
- Processor: The processor must be an Intel Pentium Dual-Core 2.20 GHz or greater.
- DVD-ROM/CD-ROM Drive: The system must have a DVD-ROM/CD-ROM Drive.
- Memory: The system must have at least 2 GB or greater of RAM installed.

# Environmental Requirements

## Atmospheric Conditions

	Temperature	Relative Humidity	Pressure	Maximum Altitude
Operating	15°C – 30°C 59°F – 86°F	30% to 70%	700 hPA to 1060 hPA	3000 m 9842.49 ft
Non-Operating	-10°C – 50°C 14°F – 122°F	10% to 85%	700 hPA to 1060 hPA	N/A

## Ventilation

A well ventilated or air-conditioned work area is required to avoid overheating of components.

The work area should be as dust free as possible to reduce buildup on internal system components which can reduce heat flow.

When planning placement of components, ensure sufficient clearance (2-3 feet) is provided around air vents to ensure adequate air flow. Never block or restrict air vents and blowers.

# Physical Dimensions

Review this table to ensure the system purchased will fit in the intended location.

Component	Width (in/cm)	Depth (in/cm)	Height (in/cm)	Weight (lb/kg)
Workstation Desk – 47"	47/119	30/76	29.5/74.9	265/120
Workstation Desk – 65"	65/165	30/76	29.5/74.9	340/154
Mobile Workstand	32/81.2	27/68.5	62/157.5	80/36.3
Accessory Cart – 27"	27/68.5	28/71	30/76.2	300/136
Computer – HP Z600	6.5/16.5	17.5/44.5	17.3/44	37/17
Review Workstation	6/15.2	16/40.6	14/35.5	20/9.1
IEB	11/28	21/53	24.5/62	75/34
Isolation Transformer	10.5/26.7	6.5/16.5	3.5/8.89	13/6
NEC 20" LCD Monitor (with stand)	17.3/43.9	9.5/24.1	16.5 - 22.6 / 41.9 - 57.4	20.6/9.3
EIZO 21" Monitor (with stand)	18.3/46.5	8/20.3	17.8 - 21.1 / 45.3 - 53.5	18.8/8.5
HP Laser Jet Printer	16/40.6	17.9/45.5	12.7/32.3	50/22.67
PDM BASE STATION	11.3/28.6	13.0/33.1	3.3/8.4	5.5/2.5
PDM	5.75/14.77	10.1/25.7	3.1/7.9	2.4/1.1
TRAM-RAC	5.7/14.5	15.1/38.4	9.0/22.9	7.9/3.5
CardioLab II Plus Amplifier - 32/64 Channels	14/36	14/36	9.5/24	22/10
CardioLab II Plus Amplifier - 96/128 Channels	14/36	14/36	14/36	25/11
Centricity Cardiology INW Server (G6)	19.03/48.34	27.53/69.93	6.88/17.48	77/34.93
Centricity Cardiology INW Server (G8)	19.0/48.26	28.83/73.22	8.58/21.8	67/30.4
Centricity Cardiology INW Backup Device	17.64/44.80	26.85/68.20	1.7/4.32	37/16.78
Vivid GE Ultrasound System	14.2/36.07	12.4/31.5	2.3/5.9	11/5

# Shipping Dimensions

**NOTE:** Dimensions and weights are approximate. Shipping containers may change without notice.

Component	Width (in/cm)	Depth (in/cm)	Height (in/cm)	Weight (lb/kg)
Accessory Cart - 27"	27/68.58	28/71	30/76.2	300/136
Workstation Desk - 47"	50/127	32/81	35/89	285/130
Workstation Desk - 65"	68/172	32/81	35/89	360/164
Mobile Workstand	32/81	27/68.58	49/124.4	129/58.5
HP Computer	12/30	22/56	24/61	37/17
Review Workstation	20/51	18.5/47	13.5/34.3	27/12.2
Centricity Cardiology INW Server (G8)	23.8/60.5	39.0/99.1	18.6/47.2	97/44.0
Centricity Cardiology INW Backup Device	23.31/59.2	38.56/97.9	8.88/22.5	51/23
Vivid GE Ultrasound System	39/99.06	39/99.06	20/50.8	132/60

# Special Component Requirements

## Mounting

### EIZO Remote Monitors

If the monitors are to be mounted on a Mavig GD60 Series Monitor Suspension, contact an Innova product Field Engineer.



**WARNING: FALLING EQUIPMENT**

**Monitor suspension systems other than the Mavig GD60 Series have not been validated for remote monitors.**

The following must be considered when selecting monitor location within the room:

- **Monitor Mounting Hardware:** (Mavig GD60 Series only) Use mounting kit (PN 2081124-001)
- **Monitor size:**
  - ◆ Dimensions: 18.3 x 14.2 x 2.5 in./46.5 x 36.1 x 6.4 cm
  - ◆ Weight: 12.2 lbs/5.5 kg

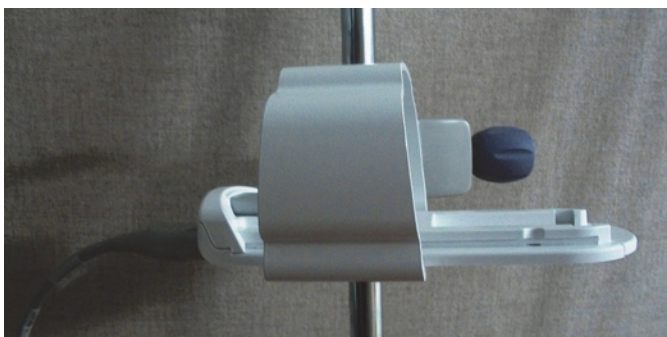
### PDM Base Station

The PDM Base Station can be mounted to a stand where the PDM is also docked.

**NOTE:** The green light on the front of the PDM Base Station is quite bright. It is suggested that the PDM Base Station is installed facing away from the physician, toward the foot or the far side of the bed.



The PDM Base Station may also rest with its feet on the floor, connected to the PDM by a longer cable. In this setup, the PDM dock is attached to the pole/rail clamp, which clamps onto a bed rail or pole. The pole/rail clamp is attached and detached by adjusting the clamp knob. Ensure the knob is fully tightened when clamping to bed rails and poles.





**WARNING: TRIPPING HAZARD**

Keep cables away from accessible walkways. Failure to do so may present a tripping hazard and could result in cable damage.



**WARNING: FALLING EQUIPMENT**

Do not place the PDM more than 147 cm (58 in) from the floor when mounting on an IV pole with a base less than 58 cm (23 in) in diameter. This may cause the IV pole to tip over.



**WARNING: SHOCK HAZARD**

To reduce the risk of ingress of water into the equipment, do not mount the PDM in a vertical position with the patient cables facing up or down.

## TRAM-RAC

The TRAM-RAC can be mounted as follows:

- **Floor Mount:** Designated location to mount bracket.
- **Bed Rail:**
  - ◆ Weight of TRAM-RAC
  - ◆ Location on bed rail

## Vivid

The Vivid is mounted to the bed rail. The weight of Vivid and mounting location on bed rail must be considered.



# Electrical Power

Component	Voltage (V)	Frequency (Hz)	Current (A)	Power Cord Length (Ft)
IEB	100/120/230	50/60	15/15/7	8
CardioLab II Plus Amplifier – 32 and 64 channel	100 – 230	50/60	0.5 – 0.25	6
CardioLab II Plus Amplifier – 96 and 128 channel	100 – 230	50/60	0.75 – 0.38	6
PDM Base Station	100 – 240	50/60	0.5 – 0.3	6
TRAM-RAC	100 – 230	50/60	1 – 0.5	10
Isolation Transformer	115/230	50/60	5.3/2.7	6
Centricity Cardiology INW Server (G6)	100 – 230	50/60	5.5 – 2.3	6
Centricity Cardiology INW Server (G8)	100 – 240	50/60	7.1 – 3.5	6
Centricity Cardiology INW Backup Device	100 – 230	50/60	10 – 5.5	10



## **WARNING: ELECTRICAL HAZARD**

Power equipment only as specified. Do not connect equipment to extension cords or multiple socket outlets.



## **CAUTION: SYSTEM FAILURE**

To ensure an adequate system power supply, GE Healthcare recommends using a dedicated circuit to power the IEB.

# Electromagnetic Compatibility Requirements

## Introduction

Changes or modifications to this system not expressly approved by GE Healthcare can cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulation regarding EMC and must be installed and put into service according to the EMC information stated in this document.

**WARNING: EQUIPMENT FAILURE**

**System components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.**

## Guidance and Manufacturer's Declaration - Electromagnetic Emissions


The Mac-Lab / CardioLab System is intended for use in the electromagnetic environment specified below. The customer or the user of the Mac-Lab / CardioLab System should assure that it is used in such an environment.

Emissions Tests	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The Mac-Lab / CardioLab System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	The Mac-Lab / CardioLab System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

## Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Mac-Lab / CardioLab System is intended for use in the electromagnetic environment specified below. The customer or the user of the Mac-Lab / CardioLab System should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines (signal lines exempt from testing, length is less than 3 m)	± 2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% 100-120Vac <5% 200-240Vac (>95% dip) for 0.5 cycle  40% 100-120Vac 40% 200-240Vac (>60% dip) for 5 cycles  70% 100-120Vac 70% 200-240Vac (>30% dip) for 25 cycles  <5% 100-120Vac <5% 200-240Vac (>95% dip) for 5 seconds	<5% 100-120Vac <5% 200-240Vac (>95% dip) for 0.5 cycle  40% 100-120Vac 40% 200-240Vac (>60% dip) for 5 cycles  70% 100-120Vac 70% 200-240Vac (>30% dip) for 25 cycles  <5% 100-120Vac <5% 200-240Vac (>95% dip) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Mac-Lab / CardioLab System requires continued operation during power mains interruptions, it is recommended that the Mac-Lab / CardioLab System be powered from an Uninterruptable power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>Conducted RF emissions IEC 61000-4-6</p> <p>Radiated RF emissions IEC 61000-4-3</p>	<p>3 Vrms 150kHz to 80 MHz with 2 Hz modulation</p> <p>3V/m80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Mac-Lab / CardioLab System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance (d)</p> <p><math>d = 1.2 P</math></p> <p><math>d = 1.2 P</math></p> <p><math>d = 2.3 P</math></p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m).Field Strengths from fixed RF transmitters, as determined by a electromagnetic site survey<sup>1</sup>, should be less than the compliance level in each frequency range<sup>2</sup>. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p><b>NOTE:</b> At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects and people.</p>			

<sup>1</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Mac-Lab / CardioLab System is used exceeds the applicable RF compliance level above the Mac-Lab / CardioLab System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Mac-Lab / CardioLab System.

<sup>2</sup> Over the frequency range 150 kHz to 80 MHz. Field strengths should be less than 3 V/m

## Recommended Separation Distances

The Mac-Lab/CardioLab system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Mac-Lab/CardioLab system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Mac-Lab/CardioLab system as recommended below, according to the maximum output power of the communications equipment.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Mac-Lab/CardioLab system			
Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p><b>NOTE:</b> At 80 MHz and 800 MHz, separation distance for the higher frequency range applies.</p> <p>These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects and people.</p>			

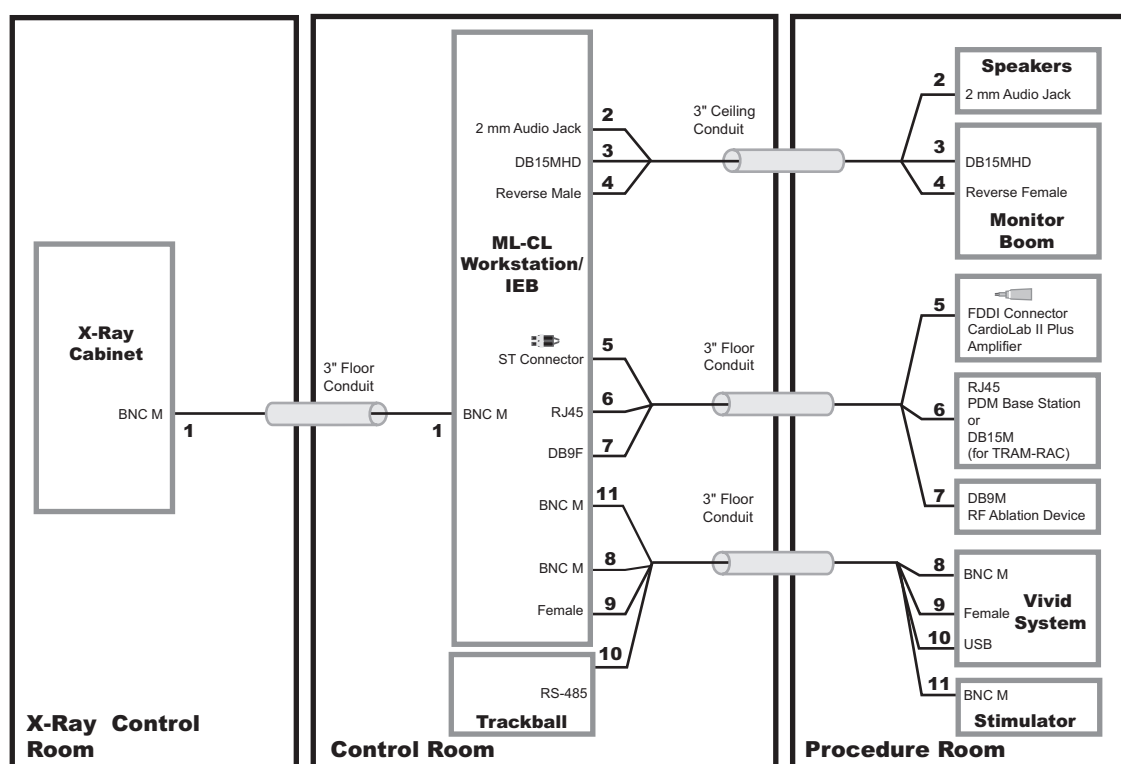
# Cable Routing

Some cables may need to be run through conduit. A 3" conduit in the ceiling and floor is recommended. The installer needs to route two fiber optic cables when installing the system.

The customer is responsible for the placement and installation of all cables (and is therefore also responsible for compliance with all federal, state, and local safety and building codes).

A GE Field Service representative is available to provide assistance during the first day of the system installation.

Refer to the following cable diagram for layout of cables included in the Mac-Lab SpecialsLab Pre-Install Cable Kit (PN 2063780-005) or CardioLab ComboLab Pre-Install Cable Kit (PN 2063780-006).



Number	Part Number	Qty	Connections	Length	Conduit Location
1	2003411-002*	1	BNC Cable. Communications between Mac-Lab/CardioLab system and X-Ray: HP (BNC M) to X-Ray Imaging (BNC M)	50'/15.24m	Floor
2	2011108-003*	1	Audio Cable: HP to Remote Speakers	100'/30.48m	Ceiling
3	2003442-003*	2	Video Cable: IEB (DB15MHD) to Remote Monitors (DB15MHD)	100'/30.48m	Ceiling
4	403689-010*	2	Power Cable: IEB (Reverse IEC Male) to Remote Monitors (Reverse IEC Female)	100'/30.48m	Ceiling
5	2003434-001*	2	Data Cable: Acquisition System (ST) to Amplifier <b>NOTE:</b> Cable is fragile, run two, one for spare.	75'/22.86m	Floor
6	418335-008*	1	<b>If the site will have a PDM:</b> Data between Mac-Lab/CardioLab system to PDM BASE STATION: HP (RJ45) to PDM BASE STATION (RJ45).	100'/30.48m	Floor
	417335-004*	1	<b>If the site will have a TRAM-RAC:</b> Data between Mac-Lab/CardioLab system to TRAM: IEB (DB15M) to TRAM (DB15M)	100'/30.48m	Floor
7	2018835-001	1	RF Ablation Device Interface	50'/15.24m  2m/6.56' 6'/1.828m	Floor
	2003408-002	1	50-foot serial cable		
	2042981-001	1	Optical Isolator		
	2035570-001	1	Serial Cable for CryoCath Interface		
	2042214-001	1	Serial Cable for RF Ablation Interface		
8	2031919-001	1	ECG between Vivid and CardioLab (BNC)	100'/30.48m	Floor
9	2032340-002	1	VGA Cable	100'/30.48m	Floor
10	2031215-001	1	USB to RS-485 Remote Trackball Cable	100'/30.48m	Floor
11	2003410-001*	2	Communications: IEB (BNC) to Analog In (BNC) & IEB (BNC) to Stimulator for Analog Out (BNC)  Note: Cable placement is dependent on device placement	30'/9.14m	Floor
N/A	2037660-001	1	MUX Control Cable for MicroPace (MP3090)	15m/49.21'	Floor
	2049323-001	1	Stim Extension for MicroPace (MP3070-13)	13m/42.65'	Floor
	2049324-001	1	Stim Extension for MicroPace (MP3070-17)	17m/55.77'	Floor
<p>* Cables included in one of the following kits, depending on the system type and the Cath Amplifier:</p> <p>Mac-Lab/SpecialsLab v6.9.5 PDM Pre-Install Cable Kit (2063780-005)  CardioLab/ComboLab v6.9.5 PDM Pre-Install Cable Kit (2063780-006)  Mac-Lab/SpecialsLab v6.9.5 TRAM Pre-Install Cable Kit (2063780-003)  CardioLab/ComboLab v6.9.5 TRAM Pre-Install Cable Kit (2063780-004)</p>					





## Chapter 4

# **Customer Pre-Installation Requirements**

# Overview

The following steps must be performed prior to installation. Contact local GE Field Service representative with any questions regarding these requirements. Refer to CVIS server documentation for pre-install actions related to that product.

1. Review this manual as well as the Mac-Lab/CardioLab Security Guide (PN: 2063076-004) for product specifications, performance data, and network specifications.
2. Ensure all construction requirements are complete prior to the start of installation.
3. Schedule down time in each lab for the installation. Typically, a full installation takes 8 hours per lab.
4. Ensure the following people are available during the installation, in case there are any questions or problems:
  - Project Manager
  - Cardiology Manager
  - Bio-Medical Representative
  - Facilities Manager
  - System Administrator
  - IT Representative (to add systems to domain, if required)

# Physical Requirements

## Control and Procedure Rooms

1. For each device ordered, ensure there is enough space in the room and the device will fit through all doors from the shipping dock to the room (you may have to designate a staging area to unpack larger items). Refer to [Shipping Dimensions on page 3-13](#) and [Physical Dimensions on page 3-12](#).
2. Determine placement of all mounted devices and ensure mounting brackets or stands are correctly installed. (Devices that may require mounting are: Remote Monitors, the Vivid Ultrasound system, the PDM and PDM BASE STATION, and the TRAM-RAC 4A). Mounting specifications are available on request.



### **WARNING: FALLING EQUIPMENT**

**Monitor suspension systems other than the Mavig GD60 Series have not been validated for remote monitors.**

3. Ensure wall power outlets are available for all devices that require wall power outlets. Verify for proper voltage and grounding. Refer to [Electrical Power on page 3-17](#) for devices requiring wall power and for power cord lengths.
4. Verify all conduit is in place for cable runs between the control room, procedure room, and any other remote location. Minimum, 3 in. (8 cm) conduit is required. Refer to [Cable Routing on page 3-22](#) for an illustration.
5. Verify network connections are available for all networked devices.
6. Verify temperature and humidity for all rooms is within the specifications listed for each device. Refer to [Environmental Requirements on page 3-11](#).
7. Ensure all other furniture and chairs required are available at installation.
8. At delivery, the customer is responsible for:
  - Receiving the equipment and indicating on the shipping documents any external physical damage.
  - Storing the equipment in a safe location until the system is installed.
  - Moving the equipment from the receiving or storage location to the installation location.
  - Disposal of any pallets or packing materials.

## Networking

Contact the local GE Field Service representative with any questions regarding network interface, capacity, or other requirements.

1. Verify the network uses static IP addresses.

**NOTE:** Static IP addresses are also required for the interface with Innova EP Vision to properly communicate.

2. Verify the system will be on a routable segment of the network.
3. Order and install any required network hardware (wall plates, wiring, switches, and cabling).

**NOTE:** At least a 100 Mbps switch is required for all network communication. Ensure the switch and all necessary cabling are installed.

4. At installation time, the IS/IT Representative will need to be available for the Centricity Cardiology INW server portion of the installation.

- Prepare the setup domain trusts.
- Create the GE Healthcare Global security groups and add Hospital users as needed to those groups.

**NOTE:** If electronic signature will be used, user accounts must be set up first. Refer to Mac-Lab/ SpecialsLab Operator's manual (PN 2063076-001 non-US or PN 2063076-301 US-only) or CardioLab Operator's manual (PN 2063076-002 non-US or PN 2063076-302 US-only) for additional information.

5. Ensure Enterprise Archive and Enterprise Backup software and procedures are in place.

**NOTE:** The customer assumes full responsibility for data integrity during archive and backup procedures.

6. Ensure that anti-virus software is available to be installed and has been validated to run with Mac-Lab/CardioLab. Refer to the Mac-Lab/CardioLab Security Guide for list of validated anti-virus software.



### **WARNING: SYSTEM INSTABILITY**

**Ensure validated anti-virus software is installed on the system. Lack of validated anti-virus software could result in system instability or failure.**

## Policy Import on Microsoft Server 2003 Hospital Domain Controller

The Mac-Lab/CardioLab v6.9 Member Server policies were created in Microsoft Server 2008 R2. Microsoft Server 2008 R2 uses Group Policy Management Console (GPMC) version 2 which creates policies that can not be imported by operating systems which use GPMC version 1 such as Microsoft Server 2003 and Windows XP.

If the Domain Controller hosting the v6.9 Member Server policies is Microsoft Server 2003, another computer with the following Operating Systems must import the v6.9 policies:

- Microsoft Windows 7
- Microsoft Server 2008 R2
- Microsoft Vista
- Microsoft Server 2008

The computer must have GPMC version 2 installed and be located within the same domain as the Member Server Domain Controller. The hospital domain network administrator is responsible for the v6.9 Member Server policy import.

## Bio-Med or Facilities Department Responsibilities

- Has GE provided video and power to the boom from the Mac-Lab/CardioLab location? Refer to conduit and cabling diagrams.
- Have the Fiber Optic/PDM BASE STATION/TRAM-RAC cables been run from the Mac-Lab/CardioLab location to the x-ray table?
- Have arrangements been made to balance the booms if replacing a CRT with a lightweight flat screen display?
- Have all safety precautions been set for flammable gases?
- Is there enough room on the table rail for the Vivid System mount? The table mount requires a minimum of 15 in. (38.1cm) of width.

## Cath Lab Director Responsibilities

- Who will attend Mac-Lab/CardioLab training in Milwaukee?  
Student will return with default Macros and Reports CD necessary to complete the Mac-Lab/CardioLab installation.
- Invasive pressure cables must be ordered from the hospital's transducer supplier.
- After hours installation is an additional charge. If the hospital requires after hours installation, please address this with your GE Sales Representative.

## Electrician Responsibilities

- If a rack is provided by GE; has the power been run for the provided rack?  
The requirement is NEMA L5-30R (30 Amp Receptacle).
- Is there power available in the Control Room for the IEB?
- Is there power available in the Procedure Room for the CardioLab II Plus Amplifier?
- Is there power available in the Procedure Room for the PDM Base Station or TRAM-RAC?
- Is there power available in the Nurse's Workstation area for the Isolation Transformer?

Refer to the [Electrical Power on page 3-17](#) for specific power information.

## Chapter 5

# Questionnaire Checklist

## IT Department Responsibilities

☐ Is server going to be housed in a GE or IT rack?

☐ Is the server rack going to be located on-site or at another location?

**NOTE:** The Centricity Cardiology INW server requires 5 U of rack space.

☐ Is there sufficient rack space available for servers?

☐ If a rack was not purchased from GE, is there power available for the server?

**NOTE:** The Centricity Cardiology INW server has dual power supplies.

☐ Are the required network cable drops in place?

- Centricity Cardiology INW: requires 2 network drops
- CardioLab: require 1 network drop
- Mac-Lab: require 1 network drop
- Review Workstations: require 1 network drop
- Vivid: require 1 network drop

☐ Are the network drops Properly configured?

- The Network Interface Card (NIC) on each Mac-Lab/CardioLab Acquisition system, Review Workstation, and Centricity Cardiology INW server is connected to a port on a network switch. For all of these systems to communicate optimally with each other and with other networked systems, it is essential that each Mac-Lab/CardioLab system's NIC and the port on the network switch to which it is connected are configured correctly.
- The preferred configuration is to have both the Mac-Lab/CardioLab system's NIC and the port on the network switch configured for Auto. This allows both the NIC and the switch to automatically negotiate the best communication settings.
- If it is not possible for the port on the network switch to be configured for Auto, then 1000/Full or 100/Full will also work as long as the Mac-Lab/CardioLab system's NIC is configured the same way.
- Each Mac-Lab/CardioLab system's NIC must be configured the same way as the port on the network switch to which it is connected. If the NIC and network port are not configured the same way (for example, one is set to "Auto" while the other is set to "100/Full"), the Mac-Lab/CardioLab systems may have network problems, which can cause sporadic dropped connections or lockups while sending or receiving data. Make sure each network switch is configured to match the connected Mac-Lab/CardioLab system's NIC.



- ☐ Have you determined remote support (InSite ExC)?
  - InSite ExC is recommended for remote support. Please contact the GE project manager to make arrangements for InSite ExC. Ensure the following conditions are met for InSite ExC:
    - A configurable router that supports 3DES encryption.
    - Network firewall software is installed.
    - Static IPs.
  - Allow outbound Internet access for InSite ExC using Web Services Standard protocol (HTTPS Port 443).
  - If a Hospital proxy server is used for web access, the IP address of this server as well as any authentication information will need to be made available.
  
- ☐ Has the network configuration been determined?
  - INW: no trust
  - INW: one-way trust
  - INW: 2 one-way trust
  - No INW, workgroup
  - If a trust is agreed upon, have the domain groups been created: **MLCLADMGRP**, **MLCLEMERGENCYGRP**, **MLCLUSERGRP**
  - For Centricity DMS, has the Domain **MuseAdmin** account been created with the recommended password. Refer to Appendix A of Mac-Lab/CardioLab Security Guide (PN: 2063076-004).
  
- ☐ Have the IP addresses been determined and are they available?
  - INW requires 1 IP address
  - Subnet, Gateway, DNS, Wins
  - Each Mac-Lab/CardioLab requires 1 IP address
  - Subnet, Gateway, DNS, Wins
  - Each Review Workstation requires 1 IP address
  - Vivid System requires 1 IP address
  
- ☐ If the DICOM Viewer option was ordered, will you be accessing PACS or image archive?
  - AE Title, Ports, IP addresses for PACS
  - Image Archive
  
- ☐ If the CardioICE option was purchased, will you be storing ultrasound images to the PACS or Image Archive?
  - AE Title, Ports, IP addresses
  - Is PACS/Image Archive able to support the ultrasound modality?

- ☐ This item applies only if your site already has Mac-Lab/CardioLab systems that are going to be upgraded. It does not apply for a new Mac-Lab/CardioLab installation. If the PedCath software is installed in the Mac-Lab/CardioLab environment, it is your responsibility to create a backup of any shared PedCath database and then to restore that database after the upgrade is complete. It is also your responsibility to re-install the PedCath software as needed after the upgrade is complete.





GE Medical Systems  
*Information Technologies, Inc.*  
8200 West Tower Avenue  
Milwaukee, WI 53223 USA  
Tel: + 1 414 355 5000  
1 800 558 7044 (US Only)  
Fax: + 1 414 355 3790

#### **Asia Headquarters**

GE Medical Systems  
*Information Technologies Asia; GE (China) Co., Ltd.*  
No. 1 Huatuo Road,  
Zhangjiang Hi-tech Park Pudong  
Shanghai, People's Republic of China 201203  
Tel: + 86 21 3877 7888  
Fax: + 86 21 3877 7402

[www.gehealthcare.com](http://www.gehealthcare.com)

