GE Healthcare

CardioSoft

Version 6.6

Service Manual

2040396-086

Revision C



NOTE: The information in this manual only applies to the CardioSoft Version 6.6. Due to continuing product innovation, specifications in this manual are subject to change without notice.



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1 Introduction

1.1 Manual Information

1.1.1 Revision History

Each page of the document has the document part number and revision letter at the bottom of the page. The revision letter identifies the document's update level.

The revision history of this document is summarized in the table below.

		Table 1. Revision History PN 2040396-086
Revision	Date	Comment
А	2009-09-15	Initial release of CardioSoft Service Manual V6.6.
В	2010-02-17	Changes on pages 1-5 and 8-1.
С	2011-12-12	Changes on page 1-5.

1.1.2 Manual Purpose

This manual supplies technical information for service representative and technical personnel so they can maintain the equipment to the assembly level. Use it as a guide for maintenance and electrical repairs considered field repairable. Where necessary the manual identifies additional sources of relevant information and or technical assistance.

See the operator manual for the instructions necessary to operate the equipment safely in accordance with its function and intended use.

1.1.3 Intended Audience

This manual is intended for the person who uses, maintains, or troubleshoots this equipment.

1.2 Safety Information

1.2.1 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.
- The country of manufacture appears on the device label.

1.2.2 General

This device is not intended for home use.

Contact GE Healthcare for information before connecting any devices to the equipment that are not recommended in this manual.

Parts and accessories used must meet the requirements of the applicable IEC 60601 series safety standards, and/or the system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard.

Periodically, and whenever the integrity of the device is in doubt, test all functions.

The use of accessories not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the patient vicinity and
- evidence that the safety certification of the accessory has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.

If the installation of the equipment, in the USA, will use 240V rather than 120V, the source must be a center-tapped, 240V, single-phase circuit.

NOTE

The CORINA acquisition module is not for use in the U.S. and Canada.

1.3 Warnings, Cautions, and Notes

The terms danger, warning, and caution are used throughout this manual to point out hazards and to designate a degree or level or seriousness. Familiarize yourself with their definitions and significance.

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

Term	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 minor personal injury or product/property damage.
NOTE	Provides application tips or other useful information to assure that you get the most from your equipment.

1.4 Equipment Symbols



Caution, consult accompanying documents



Consult instructions for use



Type CF signal input, defibrillation-proof



Type BF signal input, defibrillation-proof



Mains power switch (ON - OFF)



On/Standby



Potential equalization pin



Protective earth terminal



Caution! High Voltage!



Signal input



Signal output



Fuse



12 V DC



The number found under this symbol is the date of manufacture in the YYYY-MM format.



Medical Equipment — Classified with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1/CAN/CSA C22.2 No. 601.1, CAN/CSA C22.2 No. 601-2-25, IEC 60601-2-25, IEC 60601-1-1.



Authorized representative in the European Community.



CE marked per the Medical Device Directive 93/42/EEC of the European Union.



Manufacturer's identification



Order number



Serial number



Revision



This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.





China RoHS pollution control label



China RoHS Mobius loop symbol



This symbol indicates that the device was tested and certified according to the Russian safety standards specified by GOST.

Rx Only For use by or on the order of a physician, or persons licensed by U.S. law.

1.5 Service Information

1.5.1 Service Requirements

Follow the service requirements listed below.

- Refer equipment servicing to GE Healthcare'authorized service personnel only.
- Any unauthorized attempt to repair equipment 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.
- 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 equipment will always be functional when required.

For your notes

2 Installation

2.1 Installation of the Software

After Software installation please reboot the system!

2.1.1 Installation of CardioSoft

For CardioSoft start the Setup Program without parameter.

Versions earlier than V 4.2 first have to be upgraded to V 4.2 before installing V 6.x To run CardioSoft properly the screen resolution must be set to 1024 by 768 pixels or 1280 by 1024 pixels with 65536 (64 k) colors.

Note: Only CORINA Models 101 118 31...34 and 37/38 (OEM) are supported by CardioSoft 6.x.

2.1.1.1 Installation in the network

Network Configuration

To communicate with a MUSE server or Remote View Function you have to configure the TCP/IP protocol.

Network Installation of CardioSoft

CAUTION: Before installation close all programs (Case/Cardio) on all stations. If local CASEs/CardioSoft with existing examinations will be networked, perform a data backup before merging the databases as described below. The CardioSoft server itself must not be used as a CardioSoft station.

CAUTION: To guarantee trouble-free access to the database, be sure to install the latest CardioSoft sotware version on all CardioSoft clients/workstations in the network.

2.1.1.1.1 Network environment: Domain

A Setup Domain User

One of the following criteria must be met:

1. A <u>new</u> domain user account must be created (designated as <u>Network User</u>) on the Win2000/2003 domain where the CardioSoft server resides or a Win2000/2003 domain that has a trust relationship with the Win2000/2003 domain where the CardioSoft server resides.

NOTE: Typically, the Domain Administrator must do this step

2. An existing domain user account from the Win2000/2003 domain where the CardioSoft server resides or an existing domain user from a Win2000/2003

domain that has a trust relationship with the Win2000/2003 domain where the CardioSoft server resides is designated as the <u>Network User</u> that will be configured to run the application on the CardioSoft system.

B Configure directory on CardioSoft-Server (see also diagram, page 2-8)

Select one of the following criteria and perform the according steps:

CardioSoft-Server: Network Share

- On the computer designated as the CardioSoft server, create a directory on a local drive volume that meets the minimum space requirements for a CardioSoft database.
- 2. Network Share
 - a. For new installations, share this directory as "GE-cardio".
 - For existing installations, use the existing share. Rename the existing CardioSoft directory "cardio" to "card_old". Create a new directory on a local drive volume that meets the minimum space requirements for a CardioSoft database
- 3. Configure the share permissions such that the designated Network User has "full control" permission.
- 4. If at least one local CASE/CardioSoft with existing examinations will be networked, additionally create a directory on the CardioSoft server for merging the databases later and share the directory as "DB_Merge" with "full control" permission.

See also page 2-8.

NOTE

All further steps have to be performed with each CardioSoft station.

C Add CardioSoft station to Win2000/2003 Domain

- 1. Login as local Administrator.
- Change settings such that the CardioSoft computer joins a Win2000/2003 domain where the CardioSoft server resides, or a Win2000/2003 domain that has a trust relationship with the Win2000/2003 domain where the CardioSoft server resides.

Note: Typically, the Domain Administrator or another user that has been granted the right to add computers to the specified domain must do this step.

<u>Windows XP Professional 32-bit:</u> Control Panel->System->Computer Name <u>Windows Vista Home Premium 32-bit/Business 32-bit:</u> Control Panel->System->Computer Name->Change Settings

3. Reboot

D Configure Network User on CardioSoft station (not for Windows Vista Home Premium)

- 1. Login as Domain Administrator.
- 2. Add the designated Network User to the local Administrator group.

Windows XP Professional 32-bit: Control Panel -> Administrative Tools ->

Computer Management -> SystemTools -> Local Users and Groups -> Groups -> Administrators -> Properties

<u>Windows Vista Business 32-bit:</u>Right-click Computer -> Manage -> Local Users and Groups -> Groups -> Administrators -> Properties

3. Logoff and Login as the designated Network User to create the Network User Profile.

E Merge database (see also diagram, page 2-8)

1. Login as the designated Network User.

Select the following criteria and perform the according steps:

New CardioSoft-Server:

<u>Local CardioSoft station with existing examinations:</u>

Merge local database to CARD_R0:

Map drive letter M: to "DB_Merge" (e.g. M:\). Copy CARD_REP.exe initially to the local program directory. Launch CARD_REP.exe. Change program directory to the local program directory D:\CASE and the repair directory to the mapped DB_Merge drive letter and CARD_R0 directory. Press "Start Repair" button. After the merge press "Program End".

<u>Last system to be networked AND at least one local CASE/CardioSoft has been merged:</u>

Copy merged database to server database:

Map drive letter to "GE-cardio" (e.g. H:\)

Map drive letter to "DB Merge" (e.g. M:\)

Copy contents of M:\CARD R0 to H:\

Empty M:\CARD R0

Existing CardioSoft-Server:

<u>Local CardioSoft station with existing examinations:</u>

Merge local database to CARD R0:

Map drive letter to "DB_Merge" (e.g. M:\). Copy CARD_REP.exe initially to the local program directory. Launch CARD_REP.exe and change the program directory to the local program directory D:\CASE and the repair directory to the mapped DB_Merge drive letter and CARD_R0 directory. Press "Start Repair" button. After the merge press "Program End".

<u>Last system to be networked AND at least one local CASE/CardioSoft has been merged:</u>

Merge old server database to CARD R0:

Map drive letter to "DB Merge" (e.g. M:\)

Map drive letter to "card old" (e.g. H:\)

Launch CARD_REP.exe and change program directory to the old server program directory H:\ and the repair directory to the mapped DB_Merge drive letter and CARD_R0 directory. Press "Start Repair" button. After the merge press "Program End".

Copy merged database to server database:

Map drive letter to "cardio" (e.g. H:\)
Copy contents of M:\CARD_R0 to H:\.
Empty M:\CARD_R0.

NOTE

Local users and the configured reports will not be merged automatically by CARD_REP. If you want to take the users and the configured reports from a special station, press the button "Users/Conf.Rep" to copy the files from the local database to the corresponding repair directory.

For detailed information see **section Database Repair Tool** (chapter 4.6) in this document.

F Install CardioSoft Application Software

- 1. Login as Local Administrator.
- Map the next available drive letter to the "cardio" share (database directory) on the CardioSoft server. Note: Make sure the "Reconnect at login" box is checked.
- 3. Begin the installation of the CardioSoft application (appropriate CD-Drive): If the installation does not start automatically (wait some seconds), launch "[CD-ROM drive]\CASE-CS\setup.exe").
- 4. At the "Choose Program Directory (local)" screen, select the directory for installation of the software (local drive, e.g. C:\CARDIO).
- 5. At the "Choose Database directory (local or network)" screen, select Browse... and browse to the root folder of the network drive that was just mapped to the CardioSoft server.
- 6. Enter the Serial Number and PID from the CD jewel case label.
- 7. Finish the installation and reboot the system as prompted.

2.1.1.1.2 Network environment: Workgroup

The CardioSoft-server is configured as a Workgroup.

A Setup User Account

One of the following criteria must be met:

- 1. A new user account must be created on the CardioSoft server.
- 2. An existing user account on the CardioSoft server will be used.

This user is designated as Network User.

B Configure directory on CardioSoft-Server (see also diagram, page 2-8)

Select one of the following criteria and perform the according steps:

New CardioSoft-Server: Create Network Share

- 1. On the computer designated as the CardioSoft server, create a directory on a local drive volume that meets the minimum space requirements for a CardioSoft database.
- 2. Share this directory as "cardio".

- 3. Configure the share permissions such that the designated Network User has "full control" permission.
- 4. If at least one local CASE/CardioSoft with existing examinations will be networked, additionally create a directory on the CardioSoft server for merging the databases later and share the directory as "DB_Merge" with "full control" permission.

Existing CardioSoft-Server: Configure Network Share

All local CASEs/CardioSoft, that will be networked, are new:

1. Configure the share permissions for the CardioSoft directory such that the designated Network User has "full control" permission.

At least one local CASE/CardioSoft with existing examinations will be networked:

- 1. Rename the existing CardioSoft directory "cardio" to "card_old". Create a new directory on a local drive volume that meets the minimum space requirements for a CardioSoft database.
- 2. Share the new directory as "cardio" and the renamed directory as "card old".
- 3. Configure the share permissions of "cardio" and "card_old" such that the designated Network User has "full control" permission.
- 4. Create a directory on the CardioSoft server for merging the databases later and share this directory as "DB_Merge" with "full control" permission.

NOTE

All further steps have to be performed with each CardioSoft station.

C Configure CardioSoft station as Workgroup

- 1. Login as local Administrator.
- Change the workgroup name to the workgroup name of the CardioSoft server.
 <u>Windows XP Professional 32-bit</u>: Control Panel->System->Computer Name
 <u>Windows Vista Home Premium 32-bit/Business 32-bit</u>: Control Panel->System->Computer Name->Change Settings
- 3. Reboot

D Configure Network User on CardioSoft station (not for Windows Vista Home Premium)

- 1. Login as Local Administrator.
- 2. Create a new local user (same name and password as the designated Network User used on the CardioSoft server) and add this Network User to the local user group.

<u>Windows XP Professional 32-bit:</u> Control Panel -> Administrative Tools -> Computer Management -> SystemTools -> Local Users and Groups -> Groups -> Administrators -> Properties

<u>Windows Vista Business 32-bit:</u>Right-click Computer -> Manage -> Local Users and Groups -> Groups -> Administrators -> Properties

3. Logoff and Login as Network User to create the Profile.

Ε Merge database (see also diagram, page 2-8)

1. Login as the new user.

Select the following criteria and perform the according steps:

New CardioSoft-Server:

<u>Local CardioSoft with existing examinations:</u>

Merge local database to CARD R0:

Map drive letter to "DB Merge" (e.g. M:\). Copy CARD_REP.exe initially to the local program directory. Launch CARD REP.exe. Change program directory to the local program directory D:\CASE and the repair directory to the mapped DB Merge drive letter and CARD R0 directory. Press "Start Repair" button. After the merge press "Program End".

Last system to be networked AND at least one local CASE/CardioSoft has been

Copy merged database to server database:

Map drive letter to "GE-cardio" (e.g. H:\) Map drive letter to "DB Merge" (e.g. M:\) Copy contents of x:\CARD R0 to H:\

Empty M:\CARD R0

Existing CardioSoft-Server:

Local CardioSoft with existing examinations:

Merge local database to CARD R0:

Map drive letter to "DB Merge" (e.g. M:\). Copy CARD REP.exe initially to the local program directory. Launch CARD REP. exe and change the program directory to the local program directory D:\CASE and the repair directory to the mapped DB Merge drive letter and CARD R0 directory. Press "Start Repair" button. After the merge press "Program End".

Last system to be networked AND at least one local CASE/CardioSoft has been merged:

Merge old server database to CARD R0:

Map drive letter to "DB Merge" (e.g. M:\)

Map drive letter to "card old" (e.g. H:\)

Launch CARD REP.exe and change program directory to the old server program directory y:\ and the repair directory to the mapped DB Merge drive letter and CARD R0 directory. Press "Start Repair" button. After the merge press "Program End".

Copy merged database to server database:

Map drive letter to "cardio" (e.g. H:\)

Copy contents of M:\CARD R0 to H:\.

Empty M:\CARD_R0.

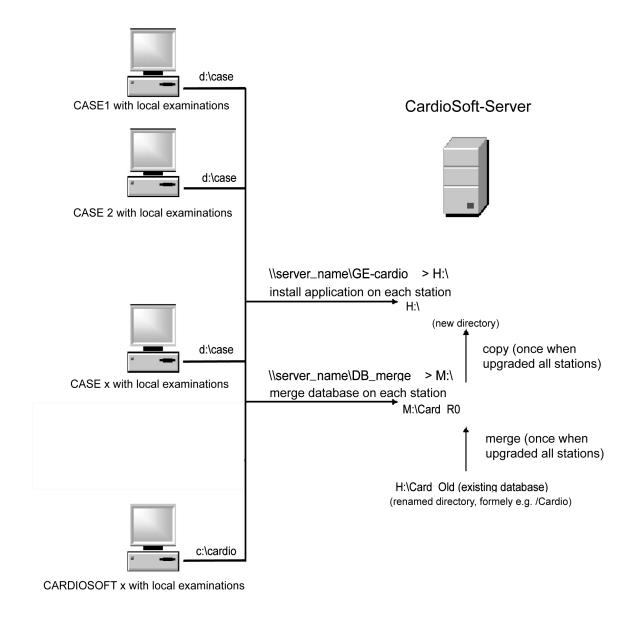
Note: Local users and the configured reports will not be merged automatically by CARD REP. If you want to take the users and the configured reports from a special station, press the button "Users/Conf.Rep" to copy the files from the local database to the corresponding repair directory.

For detailed information see section Database Repair Tool (chapter 4.6) in this document.

F Install CardioSoft Application Software

- 1. Login as Local Administrator.
- 2. Map the next available drive letter to the "cardio" share (database directory) on the CardioSoft server. **Note:** Make sure the "Reconnect at login" box is checked.
- 3. Begin the installation of the CardioSoft application (appropriate CD-Drive): If the installation does not start automatically (wait some seconds), launch "[CD-ROM drive]\CASE-CS\setup.exe").
- 4. At the "Choose Program Directory (local)" screen, select the directory for installation of the software (local drive, e.g. C:\CARDIO).
- 5. At the "Choose Database directory (local or network)" screen, select Browse... and browse to the root folder of the network drive that was just mapped to the CardioSoft server.
- 6. Enter the Serial Number and PID from the CD jewel case label.
- 7. Finish the installation and reboot the system as prompted.

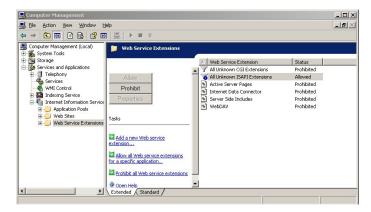
Merging Databases with Card_Rep-Tool



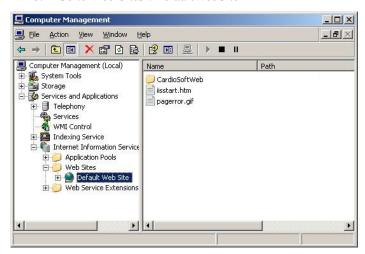
2.1.1.2 Installation/Configuration of CardioSoft Web

Cardiosoft Web must run on the same server as the CardioSoft database file server.

- 1. Verify you have Internet Information service installed and running (Control Panel > Add/Remove programs > Windows components)
- 2. Install the CardioSoft software on the server
- 3. Configure CardioSoft (System Configuration > Country Settings...)
- 4. Install the dongle, parallel or USB, no particular config needed.
- 5. Start CardioSoft:
 - -> verify the dongle is recognized by its "INTERNAL serial number" under the option codes tab.
- 6. Enter the CWEB option code, verify it and close CardioSoft.
- 7. Install CardiosoftWeb software on the server (must be exactly the same version) and reboot.
- 8. Add the directory that contains the iscard.dll (e.g. C:\Inetpub\Scripts\CardioSoftWeb) to the system variable "path".
- 9. Make the following changes in the registry (use: regedt32.exe)
 - a. Security settings
 Go to *HKLM\Software\Btrieve Technologies*Set permissions for Group "Users" to full control.
 - Registry key values:
 Go to HKLM\Software\Btrieve Technologies\
 In \Microkernel Engine\Version 6.15\Microkernel Interface\Settings\
 - ◆ Verify the *Target Engine* value is "0"
 - ◆ In \Microkernel Workstation Engine\Version 6.15\Microkernel Interface\Settings\
 - ♦ Verify the *Requester* value is "0"
 - ◆ Verify the *Local* value is "1"
 - ♦ In \Microkernel Workstation Engine\Version 6.15\Settings\
 - Verify the *TraceFile* value is C:\CARDIO\MKDEWE.TRA
 - ◆ Verify the *Home Directory* value is C:\CARDIO
 - ◆ Verify the *File sharing on local drives* value is "1"
- 10. Internet Information Services (IIS) Manager:
 - a. Under Web Service Extensions ISAPI Extensions adjust "ALLOWED" (See picture)



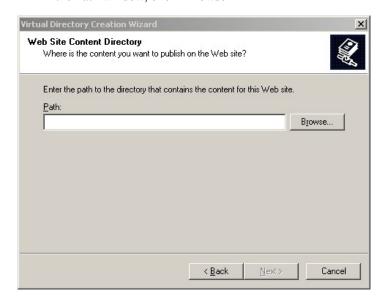
b. Go to Web Sites \ DefaultWebSite



- Right-click "Default Web site", select "NEW" and "Virtual Directory..."
- Name it "Scripts"



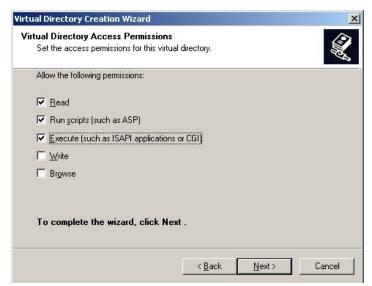
■ In the Path window, click "Browse"



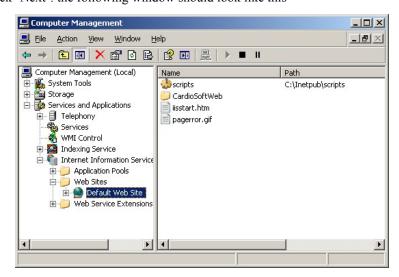
■ Point it to the C:\Inetpub\Scripts folder



■ In the access permissions window, select the "Read", "Run" and "Execute" check boxes



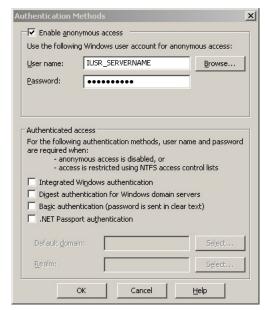
■ Click 'Next': the following window should look like this



- 11. Local Users settings
 - ◆ The local Power Users group must contain the 2 anonymous web users: IUSER & IWAM



- If using a Domain User group, put the 2 anonymous Users into this group.
- ◆ The Group requires permission for full control of the CardioSoft database directory.
- ◆ Leave the directory security options set to "anonymous access". This can be changed later under the responsibility of the hospital's IT department.



- 12. Restart IIS
- 13. Check CardioSoftWeb version: http://SERVER_IP/scripts/CardioSoftWeb/iscard.dll?
- 14. Check access

Homepage URL:

http://SERVER IP/cardiosoftweb/cardiosoftwebhome.htm

Direct URL to patient ID " 123456 ":

http://SERVER_IP/scripts/CardioSoftWeb/iscard.dll?GetExamdirect?Patid=123456

2.1.2 Installation of Communication Server

The Communication Server is a separate PC with up to 4 Modems connected. Resting ECG procedures can be sent from ECG carts supporting A5 or CSI protocol to this Communication Server over a Modem. The Communication Server stores the Resting ECG's in a local network server and this data can be sent to the MUSE. Procedures can be sent from ECG Systems to this Communication Server over Modem.

Note: This PC can only used as Communication Server and cannot used for other purpose.

Prerequisites: PC with minimum requirement see CardioSoft User Manual, Up to 4 serial ports. Up to 4 Modems (CAUTION: all Modems must be from the same type), PC must be integrated in a local network to store the data or send the data to MUSE.

Installation Steps:

- Install CardioSoft on the PC
- 2. Start the CardioSoft Application and view the System Configuration. In the Tab Modem select the Baud Rate and the Modem Type (The Port Setting is not used for the Communication Server). In the Tab MUSE you can configure to send the Resting ECG's to MUSE (The setting "Start Modem connection before transfer" cannot be used). In the Tab General please deactivate the "Enable Password Function".
- 3. For every Modem create a Shortcut to the CardioSoft Application. In the Properties Dialog of the Shortcut view Tab Shortcut. For Modem 1 at COM1 change the content of the field "Target" to "...\cardio.exe cartmodem com1" (for Resting ECG from ECG recorder) or "...\cardio.exe sysmodem com1" (for Resting ECG from ECG System) and rename the shortcut to "CardioSoft Modem 1". Change the other Shortcuts in the same way.
- 4. Connect all Modems and switch on all Modems. Start the first Shortcut. It should be displayed a window with the title "COM1: Data received form ECG System/ECG recorder". If an error message is displayed check the Modem Settings. Press the "End" Button in the window and close the CardioSoft Application. Test every shortcut in the same way.
- 5. Copy all Shortcuts to the Menu Group "Start up" with the Windows Explorer.
- 6. Close all applications and reboot the system.

With every start, up to 4 CardioSoft Applications are started and store the received Resting ECG's. If errors messages are displayed, then check the error like described in Step 4

NOTE

Up to V5.02 the communication server assigned all received examinations, regardless of different patient demographic data. From V5.1 the default behaviour is diffent: examinations that have the same patient ID as stored on the local network server but different demographic data (last name, first name, date of bith), are copied to a list, to allow the customer later a manual assignment of this examinations. The comparison of patient demographic data is done case insentive, possible empty fields don't care. The number of not assigned examinations is displayed. If the "End"-Button of any of the 4 windows is pressed, a dialog to assign manually all received examinations (that have not yet been assigned) comes up automatically.

If it is desired to assign all examinations automatically (as in versions <5.1), even if patient data are different, the entry "PAT_CommSrvTempList=0" in LOC_WIN.INI section [CARDIO] must be inserted. Please note that patient demographic data in the examination is always updated with the patient data of the database (Resting ECGs).

2.1.3 General Entries in INI Files

All INI Files are in the Program Dirctory D:\CASE, C:\Cardio. Procedure Setups will be stored in CARDIO.INI. General settings will be stored in CA_SYS.INI and could be exported to any folder or floppy disc. Special service settings are stored in LOC_WIN.INI. When CardioSoft is started the first time and there is no CA_SYS.INI or no entry in this INI file the default values from the LOC_WIN.INI will be used and copied to the CA_SYS.INI file. After that the values from the CA_SYS.INI file are used.

2.1.4 Entries in LOC_WIN.INI

Entries from the file LOC_WIN.INI described here are mainly those which cannot be changed directly by changing settings in CardioSoft.

Describtion of the CARDIO section in the LOC_WIN.INI File

Font entries, screen settings, HF output ...

[CARDIO]

```
GRA ScreenFont1 = "..."
                             // Default = "MS Sans Serif"
GRA ScreenFont2 = "..."
                              // Default = "Arial"
GRA ScreenFont3 = "..."
                             // Default = "Courier New"
GRA ScreenFont4 = "..."
                              // Default = "Small Fonts"
GRA ScreenFont5 = "..."
                              // Default = "MS Sans Serif"
GRA PrinterFont1 = "..."
                             // Default = "Times New Roman"
GRA PrinterFont2 = "..."
                             // Default = "Arial"
GRA_PrinterFont3 = "..."
                             // Default = "Courier New"
GRA PrinterFont4 = "..."
                             // Default = "Small Fonts"
GRA PrinterFont5 = "..."
                              // Default = "Times New Roman"
```

```
CFG ProdName = GE CardioSoft // Product name for CardioSoft
                    GE MicroLab // Product name for MicroLab
                    GE CASE Client // Product name for CASE Client
CFG CorinaTime = 5
CFG Abcux = 2977
                             // 2978 or entry not available: USA version
                             // 2977: international version
CFG ProgDir = C:\CARDIO // Program Directory
CFG DataDir = C:\CARDIO
                             // Data Directory
CFG SavedDataDir
                             // Path to server database
CFG_DispSwitchDBMsg
                             // 0: disable message when database mode is
                             // changed
                             // Default: 1
CFG OfflineBackup
                             // 1: save tests after sync. with online database in
                             // directory LOCAL_BACKUP
                             // Default: 0
CFG WorkOffline
                             // Setting from user interface
CFG AutoWorkOffline
                             // Setting from user interface
CFG RemoveSpo2Device
                             // 0: make legacy SpO2 devices visible in
                             // configuration
                             // Default: 2
CFG SerialNumber =
CFG UNCNameFor DataDrive=// UNC Name for Data Drive
CAUTION: If the file loc win.ini is inadvertently deleted, only the USA version of
CardioSoft can be started. It is thus advisable to make a backup of the INI files from
time to time.
                             // Device Type is set from the Installation Program
INST DevType=0
                             // 0: CardioSoft (is default if value not present)
```

```
// 1: CardioSoft
                              // 2: MicroLab
                              // 3: CASE
                              // 4: CASE Client
                              // 5: CS
RES ShowQTDispTable=?
                              // Range of values: 0..1 Default: 1
                              // Meaning: Output of the OT data for all leads
                                          in the measurement table
GRA PrinterFontFactor=?
                              // Range of values: 50..500
                                                           Default: 100
                              // Meaning: Font size factor for print fonts
GRA ScreenFactor=?
                              // Range of values: 50..500
                                                           Default: 100
                              // Meaning: Multiplication factor for screen
                                          display fonts
```

```
GRA GridWeight=?
                            // Range of values: 1..9
                                                   Default: 5
                            // Meaning: Grid points in printouts
GRA CharSet=?
                            // Range of values: 0..17 Default: 0
                            // Meaning: Determines the character set
                                       for the CardioSoft fonts.
                                       0: ANSI CHARSET
                                       1: DEFAULT CHARSET
                                       2: SYMBOL CHARSET
                                       3: SHIFTJIS CHARSET
                                          (Recommendation for Japanese)
                                       4: OEM CHARSET
                                       5: BALTIC CHARSET
                                       6: CHINESEBIG5 CHARSET
                                       7: EASTEUROPE CHARSET
                                       8: GB2312 CHARSET
                                       9: GREEK CHARSET
                                      10: HANGUL CHARSET
                                      11: MAC CHARSET
                                      12: RUSSIAN CHARSET
                                      13: SYMBOL CHARSET
                                      14: TURKISH CHARSET
                                      15: JOHAB CHARSET
                                      16: HEBREW CHARSET
                                      17: THAI CHARSET
GRA PropSheetX = 100
                            // Default: 100
                            // Meaning: Scaling factor for the width of
                                       "Property Sheets" like the Setup-Dialog
                            // Default: 100
GRA PropSheetY = 100
                            // Meaning: Scaling factor for the hight of
                                       "Property Sheets" like the Setup-Dialog
GRA ScreenFont Factor=?
                            // Range of values: 50..500 Default:100
                            // Meaning: Multiplication factor for screen
                                       display fonts
GRA_Dlg SizeX = 100
                            // Default: 100
                            // Meaning: Scaling factor for the width of dialogs
GRA Dlg SizeY = 100
                            // Default: 100
                            // Meaning: Scaling factor for the height of dialogs
PRI CancelExe = ?
                            // Range of values 0..1 Default = 1 for P2000 Printer
                            others = 0
PRI GridColorR=?
                            // Range 0..255, default=0 / red value of grid color
                            on printouts
                            // Range 0..255, default=0 / green value of grid color
PRI_GridColorG=?
                            on printouts
PRI_GridColorB=?
                            // Range 0..255, default=0 / blue value of grid color
                            on printouts
```

```
// Controls the comment + history objects to be sent
MUS SendComment=0
                              // to MUSE within the supplements object
                              // Range 0..1, default=1
                              // 0: no objects
                              // 1: comment + history
Some printer drivers have problems with aborting the print job. A seperate program
CancelPr.Exe can be used to improve this behaviour.
GRA DontRemoveGrid = 0
                                       // Range of values 0..1 Default = 1
When CardioSoft is closed before all print layouts are finished, there may be prob-
lems with the grid. Setting this value to 1 causes the grid-font not to be removed
when CardioSoft is closed.
CAMUSB ImpedanceSlape = 115
                                       // Meaning: for Impedance Measurement
CAMUSB_ImpedanceIntercept = 2152 // Meanig: for Impedance Measurement
CAMUSB LeadFailBias = 1
                                       // Range of values 0..1 Default: 1
                                       // Meaning: Enable lead Fail Detection
Some printer drivers have problems managing the printout area, so that the last line
may be missing, for example. Where printing should start can be set as follows:
PRI FrameLeft=?
                                       // left-hand margin in 1/10 mm
PRI FrameTop=?
                                       // top margin in 1/10 mm
                              // Range of values 0..1 Default: 0
Mai MoveMainWindow=?
                              // Meaning: 1. The main window can be moved by
                              clicking on the title bar in the initial screen
                              // Meaning 0: The main window can not be moved
Mai ResizeMainWindow=?
                              //Range of values 0...1 Default: 0
                              Specifies if the main window can be resized to
                              minimum 800x600 pixels
Mai MainWindowPosition=left,top,width,height
                              // Position and size of the CardioSoft main window
                              (in pixels)
                              Example:
                              Mai MainWindowPosition:1024,0,1024,768 moves
                              the main window to the 2nd screen of a dual screen
                              system
                              Note: Be sure to enter valid values. Otherwise you
                              may not see the CardioSoft screen.
MUS LosslessCompression=? // Range of values 0...1 Default: 1
                              Specifies that the 10 second ECG is sent to MUSE
                              with our wihtout compression
FDA InfoText=?
                              // Range of values 0...1 Default = 1 for CardioSoft in
                              English and Spanish
                              Specifies if the following text is shown on the Initial
                              Screen or not:
                              CAUTION: U.S. Federal law restricts this device
```

to sale by or on the order of a physician

RES GlobalValuesReadOnly=?//Range of values 0...1 Default: 0

Specifies if Measurement Results in Resting ECG / Post Text Review / Test Summary can be modified

or not.

DSP_ClipCurves=? //Range of values 0...1 Default: 1

Specifies if the ECG curves are printed within the

designated frame.

EMR ErrDir=<error folder>

The folder for error logging for the EMR Interface can be set individually for each client (System Configuration, EMR tab). If no value is specified, the default value is used:

<Program folder>/emr errors, i.e. D:\CASE\emr errors or C:\CARDIO\emr errors

EMR MOde=1

If this entry does not yet exist, EMR mode is automatically enabled (=1) when starting CardioSoft, if the file emr.ini in c:\winnt\ with entry "LogicianInstallPathTo" in section "[Installation]" is available (which is automatically done with the Installation of the EMR system). Note that additionally the option XEMR is needed to run the EMR interface.

CFG EnableEMR=0

The EMR mode can be switched off temporarily on the service screen. This is to have access to all functions for service purposes without the need to change EMR_MODE in LOC_WIN.INI manually. (So the entry EMR_Mode is not changed in this case).

PAT CheckDemogr=?

// Range of values 0...2 Default:1

//Meaning: If CardioSoft is launched by an external information system via HL7, BDT, or GDT, this entry defines the reaction, if the incoming patient ID is identical with the local database, but the patient demographic data (one of first name, last name or date of birth) are different.

- 0: No user interaction; If the incoming data field is not blank, the data is taken from the information system, else from the local database.
- 1: A side-by-side dialog comes up to select the patient demographic data to be used for the local database.
- 2: An error message comes up which must be confirmed. A new test cannot be performed.

PAT RequirePatID=0

// Range of values: 0...1: Default: 1
Meaning: When CardioSoft is launched by an EMR (HL7, BDT, GDT), an existing Patient ID is mandatory and an error message comes up if no Patient ID was provided by the EMR.

If set to zero, no error message occurs if no Patient ID is provided by the EMR. The patient record as

well as the test is stored without Patient ID.

CFG TEMP PATH PDF=d:\temp// Default: ""

Meaning: Folder used when creating a synchronous temporary PDF output (for DICOM encapsulated PDF).

The default value uses the "TMP"- or "TEMP"-path variable as folder.

[CARDIO]

CFG EXT LOCATION SOURCE=0// Range of values: 0...2; Default: 1

CardioSoft Source for Ergospirometry location used by LF8 (field "Ward"):

0: Not used

1: Room field

2: Location name configured in MUSE tab

2.1.5 Entries in CARDIO.INI

CARDIO.INI stores the user dependent settings. In this chapter only those settings are described which cannot be changed directly by the CardioSoft application.

[REST_ECG]
PostTestPage=0

Controls the default tab appearing in Post Test Review of the resting ECG examination: default: 0

0 = Test Summary 1 = ECG Traces 2 = Medians 3 = Arrhythmia Review 4 = Vector Loops 5 = Full Disclosure

Color customization for Ambulatory Blood Pressure printouts [LBD RECORD]

Remark: Header and footer are configured in the Printer Setup.

Format of the following items: R value (Red), G value (Green), B value (Blue) Range: 0...255

Color of BP lines "Day" phase (affects Standard Page report format #1): LBD_PriColLineDay=100,200,300 (Default: 0,255,0)

Color of BP lines "Night" phase (affects Standard Page report format #1): LBD_PriColLineNight=100,200,300 (Default: 0, 0,128)

Color of Pulse Pressure lines "Day" phase (affects Standard Page report format #2): LBD PriColLinePPDay=100,200,300 (Default:0,0,0)

Color of Pulse Pressure lines "Night" phase (affects Standard Page report format #2):

LBD PriColLinePPNight=100,200,300 (Default:0,0,0)

Color of area "Day" phase (affects Standard Page report format #2, Tabular Summary report, Histogram in Phases report)

LBD_PriColFlatDay=100,200,300 (Default: 255,245, 0)

Color of area "Night" phase (affects Standard Page report format #2, Tabular Summary report, Histogram in Phases report):

LBD PriColFlatNight=100,200,300 (Default: 166,202,240)

Color of Histogram (affects Statistic Summary report)

LBD_PriColFlatSum=100,200,300 (Default: 255,128, 0)

Color of upper limit area (affects Standard Page report format #3):

LBD PriColFlatUpperLim=100,200,300 (Default: 255, 0, 0)

Color of lower limit area (affects Standard Page report format #3):

LBD_PriColFlatLowerLim=100,200,300 (Default: 0, 255, 0)

2.1.6 Entries in SETUP_CM.INI

This file is located in the program directory.

Option to set the sorting sequence of the alphanumerical key as required. Example: sort patients in reverse order; max. 255 characters permitted

[DATABASE]

SortTable = ``ZzYyXxWwVvUuTtSsRrQqPpOoNnMmLlKkJjIiHhGgFfEeDdCcB-bAa"

This entry only comes into effect when made before calling up CardioSoft for the first time. The sorting sequence is stored in the database during its creation. If a change in the sorting sequence is to be made at some later time, the entire database has to be deleted.

[GENERAL]

CFG TEST ATTACHMENTS=1 (Default: 0)

This item is automatically set to 1, when at least one workstation provides test attachments (e.g. Ergospirometry with LF8 reports). This is needed to control test attachment specific configuration items (e.g. for the Export dialog).

2.1.7 Entries in CardioSoft.INI

[Installation]

CardioSoft.ini is created by the EMR system and used by both, EMR and Cardio-Soft. It is stored in the folder <EMR install path>/CardioSoft. The following entries are used:

CARDIOPATH=<filepath>

Specifies the full pathname of the CardioSoft executable (is filled and used by EMR):

READDIR=<dir path>

CardioSoft output directory for car-files (Folder is automatically set by the EMR system and used by EMR and CardioSoft; It can be changed in CardioSoft, System Configuration, EMR tab, "Write to" folder):

WRITEDIR=<dir path>

CardioSoft input directory for emr-files (Folder is automatically set by the EMR system and used by EMR and CardioSoft; It can be changed in CardioSoft, System Configuration, EMR tab, "Read from" folder):

TESTMODE=<value>

If value is TRUE then the CPO EMR will run in test mode. Test mode causes the HL7 files to be written with MSH-11 set to D (Debug) rather than the normal P (Production). Patient demographic data of simulated patient is used for all tests. Test mode should only be enabled for testing and should not be used in a production environment.

FILEHANDLING=<value>

Specifies what should be done with files read or written (only used by EMR). The value must be one of the following: 1. DELETE (default: car-files are deleted, emr-files are always deleted by CardioSoft). 2. MOVE (car-files and emr-files are saved to <readdir>/save and <writtedir>/save)

2.1.8 Entries in HL7.INI

[GENERAL]

HL7.INI is used by Cardiosoft to setup the interface to the EMR system. The file is stored on the Cardiosoft server, so the items are valid for all clients. The following items are set by using the EMR tab in CardioSoft (System Configuration) by the user:

GEN OutboundDir=c:\temp\inbound

This is for the upload of existing patient and test records to the EMR database

GEN TCPIP=0

Enable/Disable TCP/IP for the upload of existing patient and test records to the EMR database

GEN HostName=DTSServer

Hostname of DTS server (or IP address)

GEN PortNrOut=34000

TCP/IP OUT port

GEN Header=\011

Header for HL7 Low Level protocol

GEN Trailer=\028\013

Trailer for HL7 Low Level protocol

The following settings can be entered manually in section [GENERAL] in HL7.INI (they are used with their default values)

GEN ReqAckFromResponder=1

HL7 is used in Acknowledge mode (only with TCP/IP; default value is 0):

GEN AckTimeout=1000

Timeout after an expected Acknowledge Message (only in Acknowledge mode) from the Responder in ms (default value is 2000ms, value is valid from 500 to 5000ms)

GEN MaxSentMess=1

Total number of messages sent (default value is 2: original message and 1 repetition after error; value is valid from 1 to 5)

GEN EndOfSegmWithCRLF=0

HL7 segments end with CR/LF (default is 1, that means all segments end with CR and LF; 0 means only CR)

2.1.9 Directory structure and notes on CardioSoft files

Upon installation, CardioSoft creates a subdirectory (default: \CARDIO) where all files required for execution of the program are copied.

After the CardioSoft application has been started once, the following directories have been created. **Database** Directories (CardioSoft Default: C:\CARIO):

AVER Late Potential Examinations
CAS CASE8000 Examinations

DATABASE Btrieve File (e.g. database engine)

EMECG Emergency Examinations
EMRLINK HL7 files (links for EMR)

ERGOECG Stress tests

EXTPROG Reports from external programs
HOLTERRBP Ambulatory blood pressure files

NARRATIV Configured reports

ONL500 Full disclosure files for research (500Hz)
ONL2000 Full disclosure files for research (2000Hz)
ONLINE Full disclosure files for procedure types

RESTECG Resting ECG files

RHK Not in use
SETUP User settings
SOUND Test attachments

SPIR Spirometry Examinations

TAPE Not in use

After the CardioSoft application has been started once, following directories have been created. Program Directories (CardioSoft Default: C:\CARIO):

ATTACH Temp directory for test attachments (e.g. ergospirometry)

ConnSrv (Connectivity Server data directory, if installed)

DIAGS Thermal writer diagnostic software

DICOMLOG DICOM log and cache files
DOC User manuals and help files

emr errors EMR log files

LOCAL_DB Database directory for offline mode
LOG CASE / CardioSoft event log files

PatientEducation Patient education files

RESTORE Restore folder due no network problems

WRITER Thermal writer Windows driver

The data base files containing the patient data and the references (file names) from the examinations are located in the directory \DATABASE. BTRIEVE is used as a data base. The examination data from operating modes resting ECG, spirometry, emergency and ergometry are stored in the directories \RESTECG, \SPIR,

\EMECG, \ERGOECG, respectively. In all examinations online ECGs are stored In \ONLINE. Configurations are stored in the \SETUP directory.

Windows:

CASEsplashscreen.bmp

CaseStartup.bmp

CaseStartup_1152x864.bpm CaseStartup_1280x1024.bpm

Windows\<Fonts Folder>:

GEInspBd.TTF GEInspBI.TTF

Windows\inf:

Camusb.inf MmsAcq_pci.inf MmsUsbWriter.inf

Windows\System:

cor_vxd.vxd
hel grid.ttf

Windows\System32:

CASE8000.cpl Hel_grid.ttf Mfc42.dll

MSFLXGRD.OCX msvcp60.dll

Msvcrt.dll

Windows\System32\ drivers:

camusb.sys
COR_SYS.sys

Windows\System32\drivers\Case:

AcqKeypad.sys btn_blk.sys CardioMsg.dll mmsacq_isa.sys mmsacq_pci.sys mmscom_isa.sys mmscom_pci.sys mmsusb.sys

mtpd.sys

pgsusbsw.bix

PgsUsbWriter.sys

PgsUsbWriterLoader.sys

thermal_printer_fpga.bin

UsbWriter.sys

801284a.bin

acq boot.bin

acq_brd.abf

acq_prog.abf

am114.m

bootldr.abf

ee_mgr.abf

eeboot.abf

main.abf

modldr.abf

Windows\System32\drivers\Case\inf:

 $Bimini_NT.inf$

Case.inf

MmsAcq_isa.inf

MmsAcq_pci.inf

MmsAcqKeypad.inf

MmsBtn isa.inf

 $MmsCom_isa.inf$

MmsCom_pci.inf

MmsUsb.inf

MmsUsbWriter.inf

Mtpd.inf

 $P2000_NT.inf$

 $P2000_XP.inf$

PgsUsbWriter.inf

PgsUsbWriterLoader.inf

Radisys_NT.inf

 $Radisys_XP.inf$

Chinese_GB2312.itf

Cyprwrtr.dld

EastEurope.itf

Japanese.itf

Korean.itf

Latin1.itf

Russian.itf

Turkish.itf

Usbwrtr.dld

Windows\System32\drivers\spool\drivers\w32x86: camusb.sys

COR SYS.sys

File name nomenclature of the examination procedure

The file name comprises the ID letter for the examination procedure (C: Ergometry, R: Resting ECG, S: spirometry, N: STAT (emergency) ECG, A: late potential analysis, B: ambulatory blood pressure measurement, H: Holter ECG, U: ultrasound, T: stress echocardiography, Y: X-ray, K: cardiac catheterization, X: external programs, Z: Right-Heart-Catheterization), the identification letter for the compression (C: compressed, U: uncompressed), the internal patient ID (6-digit with leading zeros) and the internal examination ID (3-digit with leading zeros), giving additional file data.

File in windows inf directory: camusb.inf

INI files

An initialization file CARDIO.INI is created in the program directory, where the program settings are stored. These settings can be allocated with an identifier and stored in the help functions under Settings in the \SETUP directory, thus making them available to all users of a network (load help functions under Settings). Up to 10 settings can be stored. The file names are SETUP0.INI to SETUP9.INI. Stress test driver settings are stored in file PA5V0.DAT to PA5V9.DAT. Entries in the initialization files SYSTEM.INI and LOC_WIN.INI are described in the corresponding sections of this Service Maunual.

An initialization file CA_SYS.INI is created in the program directory, where the system settings are stored.

Stress test driver (ergometer, treadmill) settings are stored in the file ERG_PROT_V5AN.DAT in the program directory. If the profiles are modified or recreated, this file should be saved. It has been known for this file to have been deleted during new installations. It can also prove useful to assign the file with the attribute READONLY. This prevents overwriting or deletion. However, this attribute must be removed again before making any new changes in the profile. It is more advisable, however, to make a backup of the file as it cannot then be lost, even in the event of a hard disk error.

The initialization file HL7.INI is used for the EMR Interface created in the database directory. It is valid for all clients. For entries, see the corresponding section of this manual.

This initialization file CardioSoft.INI is created by the EMR system and is also used by CardioSoft.

2.1.10 System Configuration/Service screen

The service screen is accessed in the General Settings via the "For Service" key. The password is **helserv or case8k**. This contains the logbook listing the errors arising during the run period since the last program start. One can delete the logbook or save it for future reference under a different file name.

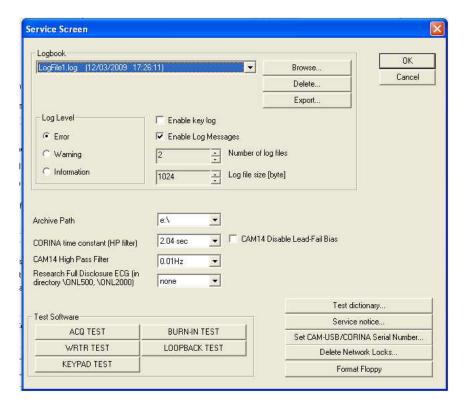


Figure 2-1:

Service Screen Description

- Logbook: Displays internal logbook entries with time stamp
- Active: Activates the entries in the internal logbook. Can only be deactivated until next program start
- Delete...: Deletes all entries in internal logbook.
- Save as...: Saves all entries of the internal logbook to a text file.
- OK or Cancel: Close the Service Screen
- Archive Path: Select on a CASE System the path to the archive A: (floppy drive) or E: (CDROM drive). This Archive Path is only displayed if the password case8k was entered.
- CORINA time constant (HP filter): Time Constant for CORINA ECG Acquisition Module. Should be not changed, if not requested from Customer.
- CAM14 High Pass Filter: High Pass Filter for CAM14 ECG Acquisition Module. Should be not changed, if not requested from Customer.
- Research Full Disclosure ECG (in directory \ONL500, \ONL2000): Please always select "non". If you select other than "none" the hard disk will be filled up very fast, because for every Full Disclosure ECG a Full Disclosure ECG with 500 Samples per second or 2000 Samples per second will be stored.

- CAM14 Disable Lead-Fail Bias: Disable Lead-Fail Bias for CAM14 ECG Acquisition Module.
- ACQ TEST: Test of the CASE ECG Acquisition Module
- WRTR TEST: Test of the Thermal Writer
- KEYPAD TEST: Test of the CASE function keyboard
- BURN-IN TEST: Burn-In Test for CASE
- LOOPBACK TEST: Loop back test for CASE Serial ports
- Test dictionary...: Compares the Text Strings of the selected language with the actual selected language of the system configuration.
- Service notice...: Service Person can write notice to a file.
- Set CAM-USB/CORINA Serial Number...: Set the CAM-USB or the CORINA Serial number of a CAM-USB or CORINA from Service with Serial Number 0.
- Delete Network Locks...: All other stations of the network using this server must be stopped before this Network Locks should be deleted.
- Save Log Files: Save the Log Files what have been activated from Engineering and send this Log Files please to Engineering.
- Format Floppy: Formats a Floppy Disk.

2.1.11 Data transfer to/from MUSE

Store Examinations for MUSE

Prerequisites: Network with correct installed TCP/IP specifications, or Modem and RAS with installed TCP/IP, assuming FTP or a shared directory will be used.

Each CardioSoft <u>has to use</u> its unique Cart number as well as the correct location number for generating an unique filename!

Tests on CardioSoft can be transferred to MUSE database for general accessibility Three possibilities are implemented in CardioSoft:

- a) Save Examinations on Floppy and carry it to MUSE
- b) Send Examinations to MUSE using FTP via LAN or RAS
- Store Examinations on a shared directory located on MUSE via LAN or RAS

The usual way for **MUSE 5.x** is FTP:

- 1. Specify the FTP account informations on CardioSoft -> System Configuration -> MUSE by enabling "Data transfer via FTP"
- 2. Type in the FTP Server (normally the same as the Web Server)
 Use Username and Password if this information is required for the FTP Server.

For **MUSE 4.x** the prefered method will be the shared directory:

- Specify the account informations on CardioSoft ->
 System Configuration -> MUSE by enabling "Data transfer via shared directory".
- 2. Type in the correct shared directory.
 Use Username and Password if these informations is required for accessing this shared directory.

Example: Use an existing mapped network drive (f.e. "F:\" as a synonym for \\SvrName\SharePointName) already established from file manage reconnected at logon time (not available if using a modem!), or use the UNC Format in a valid form like "\\SvrName\SharePointName".

If no DNS/WINS is installed on the domain server (f.e. you're using RAS) write "\\123.456.789.255\SharePointName" (all samples without quotes!), where 123.456.789.255 is the physical IP address of the Server.

Transfering examinations to MUSE using FTP or shared directory, the connection to the server can be established via local modem.

Enable "Start modem connection before transfering data" to use these RAS functionality.

Note: You have to configure the modem, RAS, phonebook, etc. in a separate step.

Modem/RAS Installation

Prerequisites: RAS access on MUSE-Server for required account.

Transfering Data from/to MUSE can be done via LAN or modem.

- 1. Select taskbar -> Start -> Settings -> Control Panel.
- 2. Doubleclick on "Modem" and follow the questions on the displayed dialogs. Take attention in "Properties" -> "Call preferences" and disable "Wait for dial tone before dialing" if modem is linked in an Inhouse telephon compount.
- 3. Select taskbar -> Start -> Settings -> Control Panel.
- 4. Doubleclick on "Network"
- 5. Select Tab "Services", add "Remote Access Service" and confirm by "OK"
- 6. Choose "TCP/IP" protocol in Properites ->Network
- 7. Select taskbar ->Start ->Programs ->Accessories ->Dial-Up Networking Describe your connectivity to the MUSE server modem.
- 8. Behind Advanced... -> change properties -> Tab "Server" select the correct type of server, protocol TCP/IP and the properties for this protocol

So far it's possible to establish a RAS connection for receiving patient and order information from MUSE, or for transfering examinations to MUSE.

(In advance you should confirm the configuration of RAS/Modem before you start a transfer in CardioSoft. Use explorer.exe or winfile.exe after establishing a connection to a PC via RAS, and try to down-/upload some files)

Example: The most problems occur with Dial-Up Networking ->Advanced... >change properties ->Tab "Entries" ->Configuration... ->Modem compression and in combination with ->Tab "Server" ->Software compression, as well as with "LCP-Extensions for PPP" and in Tab "Security" with the correct encryption/certification by using Service Packs before Version 3. The switches are dependent strongly on modem characteristics (on both sides) and on configuration of the integrated network with which you linked on it.

- 9. Connecting Internet Browser to MUSE via modem:
 - 1. Select taskbar -> Start -> Settings -> Control Panel.
 - 2. doubleclick on "Internet".
 - 3. Open tab "Connection".

- 4. Activate "Connect via modem".
- 5. Confirm by "OK"

Patient database reading from MUSE

Prerequisites: Network with correct installed TCP/IP specifications

If you are using the MUSE database for selecting patients instead of the local database, you need an account on the MUSE server.

- Specify the Web account informations on CardioSoft ->
 System Configuration -> MUSE by enabling "Request MUSE data".
- 2. Type in Web Server, the Username and the Password
- 3. Select the correct MUSE site number.

Example: For the MUSE servername specification you can use either the Internet name convention "http:\\www.myMuseSvr....", or the Intranet name convention "myMuseSvr", as well as a valid TCP/IP address in form of "123.456.789.255" (all samples without quotes!).

Configuration of Internet-Browser (IExplorer)

Reading stored examinations from MUSE database, CardioSoft requires an Internet Browser. Install IExplorer V6.0. Older versions as V4.01 (SP 2) of IE have some difficulties in working with MUSE.

Prerequisites: IExplorer V4.01 SP 2 or above MUSE version 5.x or above Acrobat Reader V4.0 or above

- 1. Select taskbar -> Start -> Settings -> Control Panel.
- 2. doubleclick on "Internet".
- 3. Open tab "Connection".
- 4. Deactivate "Access via proxy server", but this depents on the configuration of the proxy server in your LAN. (if you have to use a proxy server, look furthermore in "Advanced Settings").
- 5. Activate "Connect to Internet via LAN" if connection is caused by LAN, otherwise activate "Connect via modem".
- 6. Confirm by "OK"

Example: Some changes of MS IExplorer are working not before next restart of the Operating System!

2.1.12 Metabolic Interface

The system can communicate with the data acquisition device over the workstation's serial port or it can record test data to a shared file on the network.

This section describes:

- the available communication commands
- the serial port settings
- the structure of the serial data string
- the structure of the test data file
- general settings

2.1.12.1 Communication Commands

To enable the serial port communication, select the "Metabolic Cart" checkbox in System Configuration -> Devices and select the appropriate COM port.

The stress test module can process the following commands from the serial port:

echo on
start treadmill
stop treadmill
stage hold
request measurements
start pretest
start exercise
start recovery

2.1.12.2 Serial Port Settings

The default settings for serial port are

no
8
1
1200
no

You can modify the settings for the serial port by modifying the following values in the [CAS_RECORD] section of the file

 $<\!\!installation\ program\ folder \!\!>\!\! \backslash CARDIO.INI.$

Field	Values
SpiroParity	0 = no parity 1 = even parity 2 = odd parity
SpiroDataBits	0 = 7 data bits 1 = 8 data bits

Field	Values
SpiroStopBits	0 = 1 stop bit 1 = 2 stop bits
SpiroBaudrate	0 = 300 baud 1 = 600 baud 2 = 1200 baud 3 = 2400 baud 4 = 4800 baud 5 = 9600 baud 6 = 19200 baud 7 = 38400 baud 8 = 56000 baud 9 = 128000 baud
SpiroHandShake	0 = no handshake 1 = XonXoff 2 = hardware handshake 3 = hardware handshake and interpretation of CR and NULL

For example, to configure the serial port for even parity, 7 data bits, 2 stop bits, 9600 baud, and XonXoff, *cardio.ini* would look like this:

```
[CAS_RECORD]
SpiroParity = 1
SpiroDataBits = 0
SpiroStopBits = 1
SpiroBaudrate = 5
SpiroHandShake = 1
```

2.1.12.3 Data String Structure

If the system receives the "R" command (request measurements), the following data string is sent:

```
[AAAA_BBBB_C_DDDD_E_FFFF_GGGG_HHHH_IIII_JJJJ_KKKK_LLLL_M MMM_]NNPP where a space is shown as an '_'.
```

AAAA - Combined Phase and Stage name

```
"base" - Pretest phase, stage 1
"warm"- Pretest phase, stage 2 or higher
"ramp" - Exercise phase, all stages
"reco" - Recovery phase, all stages
```

BBBB - Value for load parameter 1 (value 0 if unavailable)

C - Designator for load parameter 1

```
M - Treadmill Speed in [0.1 mph]
K - Treadmill Speed in [0.1 km/h]
W - Ergometer Load in [W]
```

DDDD - Value for load parameter 2 (value 0 if unavailable)

- E Designator for load parameter 2
 - % Treadmill Grade in [0.1 percent]
 - U Ergometer revolutions in [/min] = [rpm]
- FFFF Heart rate in [/min] = [bpm] (value 0 if unavailable)
- GGGG Ventricular Ectopic beats per minute (VE/min)
- HHHH BP Measurement NBR (always -999 since not used)
- IIII Systolic BP in [mmHg] (-999 if unavailable)
- JJJJ Diastolic BP in [mmHg] (-999 if unavailable)
- KKKK ST Level for most significant ECG lead in [0.01 mV] = [0.1 mm] (-999 if unavailable)
- LLLL ST Slope for most significant ECG lead in [0.1 mV/s] (-999 if unavailable)

Remarks concerning the "most significant ECG lead":

- ◆ The most significant ECG lead is the lead with the largest ST-depression.
- ◆ The leads aVR, aVL and V1 are excluded.
- ◆ If no ST segment depression is found, lead V5 is defined as the most significant lead.

MMMM - ST Integral for most significant ECG lead in [µVs] (-999 if anavailable)

NN - Rightmost 2 ASCII characters of checksum expressed hexadecimal in upper case

The checksum is the sum of the numeric values of all characters from "[" to "]" inclusive. (Example: Numeric value of character 'A' is 65).

PP - Fixed string "CR" for Carriage return

2.1.12.4 Shared File Settings

The shared file otuput is enabled by the field "SpiroOptionWriteToFile". If enabled, the system will write the stress test data to a shared file named *ergospir.dat*. By default, the file is stored in *c:\temp*. You can change that setting by modifying the following fields in the [*CAS_RECORD*] section of the file

<installation program folder>\LOC_WIN.INI.

Field	Values			
SpiroOptionWriteToFile	0 = Do not write to file 1 = Write to file			
SpiroDirectory	Valid directory path			

For example, if you want the shared file *ergospir.dat* to be written to a directory called *spirapp\data* located on the c:\ drive, the entry in *LOC_WIN.INI* would look like this:

[CAS_RECORD]
SpiroOptionWriteToFile = 1
SpiroDirectory = C:\SPIROAPP\DATA

2.1.12.5 Data File Structure

If the shared file output is enabled, the system will write the following data string to the shared file every five seconds or immediately after phase or stage has changed.

AAAA - Combined Phase and Stage name

```
"Chck" - Lead check phase, before start of Pretest
```

"Base" - Pretest phase, stage 1

"Warm"- Pretest phase, stage 2 or higher

"Exer" - Exercise phase, all stages

"Reco" - Recovery phase, all stages

"Stop" - Stress test was finished

BBBB - Value for load parameter 1 (value 0 if unavailable)

C - Designator for load parameter 1

M - Treadmill Speed in [0.1 mph]

K - Treadmill Speed in [0.1 km/h]

W - Ergometer Load in [W]

DDDD - Value for load parameter 2 (value 0 if unavailable)

E - Designator for load parameter 2

% - Treadmill Grade in [0.1 percent]

U - Ergometer revolutions in [/min] = [rpm]

FFFF - Heart rate in [/min] = [bpm] (value 0 if unavailable)

GGGG - Ventricular Ectopic beats per minute (VE/min)

HHHH - BP Measurement NBR (always -999 since not used)

IIII - Systolic BP in [mmHg] (-999 if unavailable)

JJJJ - Diastolic BP in [mmHg] (-999 if unavailable)

KKKK - ST Level for most significant ECG lead in [0.01 mV] = [0.1 mm] (-999 if unavailable)

LLLL - ST Slope for most significant ECG lead in [0.1 mV/s] (-999 if unavailable)

Remarks concerning the "most significant ECG lead":

- ◆ The most significant ECG lead is the lead with the largest ST-depression.
- ◆ The leads aVR, aVL and V1 are excluded.
- ◆ If no ST segment depression is found, lead V5 is defined as the most significant lead.

MMMM - ST Integral for most significant ECG lead in $[\mu Vs]$ (always -999 since not used)

NN - Rightmost 2 ASCII characters of checksum expressed hexadecimal in upper case

The checksum is the sum of the numeric values of all characters from "[" to "]" inclusive. (Example: Numeric value of character 'A' is 65).

PP - Fix string "CR" for Carriage return

Example

Format:	[AAAA_	BBBB	_C	_DDDD	_E_	FFFF	GGGG	_нннн_	IIII	_JJJJ	KKKK_	LLLL	_MMMM]NNPP
Bicycle:	[Exer	25	M	0	U	84	5	-999	120	80	-2	0	-999] 4ACR
Treadmill:	[Exer	40	K	120	용	85	5	-999	-999	-999	7	7	-999]83CR
		Mea	ning								Bicy	cle		Trea	dmill
AAAA		Coml	oined	Ph	ase ar	nd (Stage	name		E	Exercis	e phas	se l	Exercis	se phase
BBBB	С	Load	parar	net	er 1 -	Va	alue an	d Des	ignatoı		Loa	id: 25	W S	Speed:	4.0 km/h
DDDD	E	Load	parar	net	er 2 -	Va	alue an	d Des	ignato	Rev	olution	s: 0 /m	nin (Grade:	12.0 %
FFFF		Heart rate								84 /n	nin		85 /min		
GGGG		VE/min									5		5		
НННН		BP Measurement NBR - not used -999 -999													
IIII		Systolic BP in mmHg 120 mmHg -99							-999						
JJJJ		Diastolic BP in mmHg 80 mmHg -999							-999						
KKKK		ST Level for most significant ECG lead								-0.02 r	nV		0.07 mV		
LLLL		ST Slope for most significant ECG lead						0	.00 m\	//s	C).70 mV/s			
MMMM		ST Integral for most significant ECG lead							-9	99		-999			
NN		Checksum								4A		83			
PP	P Fix string "CR"							(CR		CR				

2.1.12.6 General Settings

For serial output and for shared file output:

The availability of the blood pressure values can be controlled by the following entries in the file *<installation program folder>\LOC WIN.INI*:

ExerciseBpGreyoutTime:?

Range: 5..360, default = 60, unit = seconds

The BP values will be greyed out after this period of time

SpiroNegateGreyedBp=?

Range: 0..2, default 1

BP values older than defined with entry

'ExerciseBpGreyoutTime' will be converted as

follows:

0: old BP value will be positive

1: old BP value will be invalid (-999)

2. old BP value will be negative

2.1.13 Configuration of "Complete Patient Information"

When patient demographic data are provided externally, the "Complete Patient Information-Dialog" allows the user to complete missing patient demographic data, depending on the procedure type and the selected configuration.



The "Complete Patient Information-Dialog" can be used in the following **scenarios**:

- (1) CardioSoft is launched by an EMR (HL7, BDT, GDT) to perform a new test.
- (2) CardioSoft performs a new test via an order list (MUSE, DICOM)
- (3) CardioSoft performs a new test via the MUSE patient list.

The following items <u>can individually be enabled or disabled per procedure type</u>: Last name, first name, date of birth, weight, weight, gender, ethnic, pacemaker.

Sequence must be separated by a comma:

Last name, first name, date of birth, height, weight, gender, ethnic, pacemaker Example: PAT ComplDemogrSPI=1,0,1,1,0,1,0,0

Configuration for External tests:

PAT_ComplDemogrUNKNOWN=

Default for scenario (1): All items disabled

Default for scenario (2) and (3): Enable Last name, date of birth

Configuration for Exercise test:

PAT ComplDemogrCAS=

Default for scenario (1): All items disabled

Default for scenario (2) and (3): Enable Last name, date of birth, gender

Configuration for Spirometry:

PAT_ComplDemogrSPI=

Default for scenario (1): All items disabled

Default for scenario (2) and (3): Enable Last name, date of birth, height, gender

Configuration for Ambulatory Blood Pressure:

PAT ComplDemogrABP=

Default for scenario (1): All items disabled

Default for scenario (2) and (3): Enable Last name, date of birth

Configuration for HOLTER ECG:

PAT_ComplDemogrLEG=

Default for scenario (1): All items disabled

Default for scenario (2) and (3): Enable Last name, date of birth enabled

Configuration for Resting ECG:

PAT_ComplDemogrRES=

Default for scenario (1):All items disabled

Default for scenario (2) and (3): Enable Last name, date of birth, gender

Configuration for Ergospirometry:

PAT ComplDemogrESP=

Default for scenario (1): All items disabled

Default for scenario (2) and (3): Enable Last name, first name, date of birth, height, weight, gender

There are different 3 modes using this dialog:

(1) Mode 1

Activation of the dialog:

The dialog comes up if at least one item is enabled.

Display of the dialog:

Enabled items are displayed always.

Disabled items are greyed out.

PAT_ComplDemogrIfEmptyFields=0 (default value for scenario (1))

(2) Mode 2

Activation of the dialog:

The dialog comes up if at least one item is enabled that is empty.

Display of the dialog:

Enabled items are displayed always, whether or not they are empty. Display a hint to indicate which of all enabled items that he has to complete because they are empty.

Disabled items are greyed out.

PAT ComplDemogrIfEmptyFields=1

(3) Mode 3

Activation of the dialog:

The dialog comes up if at least one item is enabled that is empty.

Display of the dialog:

All empty items are displayed, whether or not they were enabled. Display a hint to indicate which of the empty items he has to complete because they were enabled.

All items that already have values are greyed out.

PAT_ComplDemogrIfEmptyFields=2 (default value for scenario (2) and (3))

2.2 Installation of the hardlock modules (Parallel/serial & USB type)

If CardioSoft is running without PATIENT MODULE, some of the options are locked with a hardlock. There are three hardlock modules available: One is the hardlock with 'DB 25 connectors. This hardlock can be connected to the parallel or the serial interface. Another USB hardlock can be connected to the USB port. When using this USB hardlock the hardlock has to be plugged into one free USB port of the PC. If a USB server hardlock module is connected to a USB port of a server, up to 250 CardioSoft without patient modules are enabled. An FLXX option activation key is required for this functionality. When using the parallel/serial hardlock, then using an environment variable the program can be informed where to look for the hardlock. In the default setting a search for the hardlock is made at the interfaces LPT1 and LPT2 only. In addition, using these environment variables, certain PC configurations, which could lead to problems, can be indicated.

Port Identification	Meaning:
p = parallel	normal parallel port
s = serial	normal serial port
e = ECP	parallel port in ECP mode
n = NEC (Japan)	As the Japanese NEC models have a different port configuration, a special operation can be activated with this parameter. A separate NEC API is thus no longer necessary.
C = Compaq Contura Dockingbase	The dockingbase multiplexer (to toggle between the parallel port and Ethernet adapter) is reset on the parallel port to scan for the hardlock.
I = IBM PS/2	The specification for IBM PS/2 rectifies an error in reprogramming the ports for certain video drivers under Windows (hardlock is no longer found after Windows has been started). This effect can now only be activated via the specification of the environment variables.

Example:

in the file autoexec.bat

SET HL SEARCH=378p, 2f8s

The hardlock is searched for at the parallel interface at address 0x378 and the serial interface at address 0x2f8.

If PATIENT MODULE is connected to LPT1, the hardlock at LPT2 may not be identified. In this case use

SET HL_SEARCH=278p

to inform hardlock API that the search for LPT2 should commence. The ports are generally located at the following addresses:

COM1 3F8 COM2 2F8

COM3	3E8
COM4	2E8
LPT 1	378
LPT 2	278

Define the protocol used for accessing the HL Server.

Set HL SERACH = IXP

IPX	HL server searched for via IPX or SPX			
OP	HL server searched for via TCP/IP			
NetBios	HL server searched for via NetBios			

IP is searched first by default.

(Optimize search via TCP/IP protocol.)

Set HLS_IPADRR = <server name>

For detailed information about installation of the server dongle, please refer to the Installation Guide.

For more hardlock details and how to use Alladin DiagnostiX, please refer to the Hardlock's User Manual (see on CD, folder Hardlock Server).

2.3 MARS PC Application Configuration

If using MARS PC as the Holter ECG program, go to System Configuration >Devices > Path to Holter ECG Program. Browse to the following path, where "drive:\" is the driver letter whre MARS is installed: Drive:\gem-sit\op\MarsNT\bin\superapp.exe

2.4 Configuring a CASE/CardioSoft System with the EMR Application

NOTE

The term "CASE/CardioSoft" is used generically to denote whichever system is being configured, CASE or CardioSoft.

The CASE/CardioSoft system can be configured with the EMR application in the following configurations:

New CASE/CardioSoft System to EMR	Existing CASE/CardioSoft System to EMR
1. Go through "Before You Begin" checklist.	1. Go through "Before You Begin" checklist.
Install Logician 5.6.3 or higher on each CASE / CardioSoft client. See "Configuring a CASE/CardioSoft System with the EMR Application" on page 2-41.	Install Logician 5.6.3 or higher on each CASE / CardioSoft client. See "Configuring a CASE/CardioSoft System with the EMR Application" on page 2-41.
3. Install the CASE/CardioSoft interface kit. See "CASE/CardioSoft Interface Kit" on page 2-41.	Install the CASE/CardioSoft interface kit. See "CASE/CardioSoft Interface Kit" on page 2-41.
Import the CardioSoft clinical kit to the EMR application. Follow the instructions in the CASE/CardioSoft - EMR Integration Release Notes.	Import the CardioSoft clinical kit to the EMR application. Follow the instructions in the CASE/CardioSoft - EMR Integration Release Notes.
 Configure the CASE/CardioSoft EMR settings. See "Configure CASE/CardioSoft EMR Settings" on page 2-41. 	5. Configure the CASE/CardioSoft EMR settings. See "Configure CASE/CardioSoft EMR Settings" on page 2-41.
	Migrate Historical CASE/CardioSoft Data. This is a four-part process.
	Refer to the instructions in the CASE/CardioSoft - EMR Integration Release Notes to: — Configure the Cross Reference File — CreateLinkLogic Relationships, and — Configure the LinkLogic Document Relationship.
	Refer to "Migrate Data" on page 2-43 of this document to Migrate CASE/CardioSoft Data.

Before You Begin

Before using these instructions to configure the CASE/CardioSoft to EMR interface, go through this checklist.

CASE/CardioSoft System Installed

The CASE/CardioSoft system must be installed and operational prior to beginning to configure the CASE/CardioSoft to EMR interface.

■ Use the procedures described in the CASE Service Manual for configuring the CASE system.

- Use the installation procedures described in the CardioSoft Installation Guide for configuring the CardioSoft system.
- The CASE/CardioSoft database must reside in a shared location, accessible to all users.

NOTE

GE recommends installing the CASE/CardioSoft database on a separate server from the EMR application. If you install it on the same server, GE recommends that it is on a separate, dedicated hard drive to ensure that file sizes do not hinder performance.

EMR Option Enabled on CASE/CardioSoft

The following requirements must be met for the EMR Option to be enabled on the CASE/CardioSoft system:

- The CASE/CardioSoft option code for the EMR application must be entered in the *System Configuration* >> *Option Codes* tab PRIOR to configuring the EMR application on the CASE/CardioSoft system.
- The EMR option must be enabled in the *System Configuration* >> *General*. Click *For Service Only* (service password: **helserv**) to display the *Service Screen*. Click *Enable EMR-Mode*.

Permissions for the EMR Application Web Site

You will need a User ID and password to access the EMR application's support web site. Ask your EMR application manager for this information.

Instructions — CASE/CardioSoft – EMR Integration Release Notes

You will need the CASE/CardioSoft EMR Integration Release Notes for EMR-specific instructions for configuring the EMR application. The release notes can be found on the EMR support web site (http://support.medicalogic.com/).

EMR Application Installed

The EMR application must be installed and operational prior to beginning to configure the CASE/CardioSoft to EMR interface. For information on installing the EMR application, go to http://support.medicalogic.com/, select your version of the product, and then look under Installation Checklists.

Administrator Privileges

You will need administrator privileges to both the CASE/CardioSoft system and to the EMR application to complete this configuration. If you do not have administrator privileges, contact your system administrator.

Default Provider Name

The customer site administrator must designate the default provider for use before migrating historical data from the CASE/CardioSoft system to the EMR application.

2.4.1 Configuring a CASE/CardioSoft System with the EMR Application

- 1. Set up the CASE/CardioSoft V6 in a networked environment.

 Make sure that the XEMR option code for interfacing to the EMR application is available (in the CASE/CardioSoft system, click *System Configuration*, then the *Option Code* tab).
- 2. Install Logician 5.6.3 or higher on each CASE/CardioSoft client.

2.4.2 Install the Centricity EMR Application

2.4.2.1 CASE/CardioSoft Interface Kit

Install the CASE/CardioSoft Interface Kit. This is available for download/installation on the EMR application support website (http://support.medicalogic.com/).

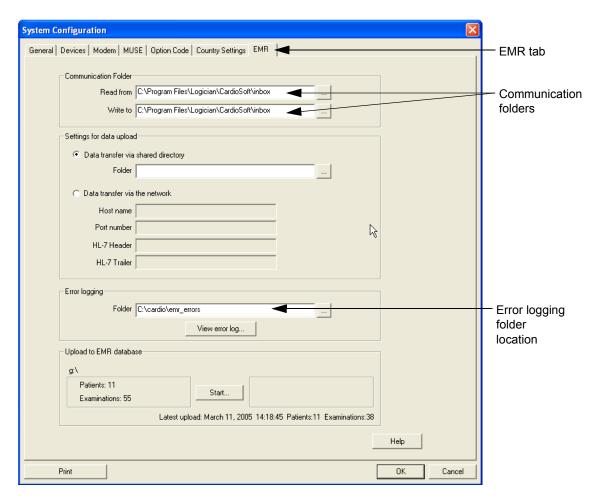
2.4.2.2 Import Clinical Kits

Follow the instructions in the CASE/CardioSoft - EMR Integration Release Notes to import the CardioSoft clinical kit.

2.4.2.3 Configure CASE/CardioSoft EMR Settings

After importing the CASE/CardioSoft clinicial kit into the EMR application, verify on the CASE/CardioSoft system that the EMR settings are configured correctly.

- 1. Launch the CASE/CardioSoft application.
- 2. Click System Configuration. The System Configuration window displays.



3. Verify that the *EMR* tab now is available onscreen.

CASE/CardioSoft System Configuration Setup Tab

NOTE

The Communication Folder locations were determined automatically after the EMR application was installed, using information from the file <EMR ApplicationInstallFolder>/ CardioSoft/CardioSoft.ini.

4. The folder for error logging is automatically generated. Verify that the folder location is accurate (i.e., for CardioSoft c:\cardio\emr_errors, or for CASE: d:\case\emr_errors).

2.4.3 Migrate Historical CardioSoft Data

If you have been using CASE/CardioSoft prior to integrating with the EMR application, you'll want to migrate your existing CASE/CardioSoft data. This migration transfers **all** of the data. You cannot selectively migrate only certain records. There are four steps to this migration:

- 1. Configure the Cross Reference File.
- 2. Create LinkLogic Relationships.
- 3. Configure the LinkLogic Document Relationship.

4. Migrate Data.

Follow the detailed instructions in the CASE/CardioSoft - EMR Integration Release Notes to configure the cross reference file, create LinkLogic relationships, and to configure the LinkLogic document relationship (steps 1-3 above). Refer to "Migrate Data" below to migrate historical data from the CASE/CardioSoft system to the EMR application.

2.4.3.1 Migrate Data

To migrate the CASE/CardioSoft data, complete the following steps:

- 1. In the CASE/CardioSoft application, click System Configuration.
- 2. Select the *EMR* tab.
- 3. In the *Data Transfer Via Shared Directory* field, click the ellipsis and select the network LinkLogic installation of the ...Data\In folder.
- 4. Click OK.
- 5. Click Start.

A demographics file (.hd) and its related ImageLink files (.ht) are created for every patient in the CASE/CardioSoft database. These files are picked up by LinkLogic and included in the patent's chart.

2.5 DICOM Interface Configuration

2.5.1 Terminology

IHE: Integrating the Healthcare Enterprise

DICOM: Digital Imaging and Communication in Medicine

SCP: DICOM Service Class Provider
SCU: DICOM Service Class User
PPS: Performed Procedure Step
DSS: Department System Scheduler

MWL: Modality Work List
AE title: Application entity title

2.5.2 General

The DICOM Interface is enabled with the option key DICM.

A valid DICM option key provides the DICOM tab in the System Configuration which allows you to configure the DICOM Interface.

The service password is needed to access the screen (see "System Configuration/ Service screen" on page 2-26).

There are some items that affect the workflow/ User Interface of the system (e.g. work list configuration, archiving).

Those items should be reviewed with the clinical staff before using the systems.

The default setup is the setup recommended by the IHE Stress test profile.

2.5.3 **Setup**

To complete a standard IHE configuration the following steps are needed:

DICOM tab access

■ Go to the *System Configuration*, select the *DICOM* tab and enter the service password.

Perform local setup

On the *DICOM* tab, perform the following local setup (mandatory for each workstation):

NOTE

All data entered in this section is automatically stored in the local file CA_SYS.INI (section [DICOM]), located where the CARDIO application is installed.

■ Enter the AE title for this workstation in the SCU AE title field.

Perform server-based setup

On the DICOM tab, perform the following server-based DICOM setup (done once, possible at any workstation if you have a CASE/CardioSoft network).

NOTE

All data entered in this section is automatically stored in the server-based file DICOM.INI, located where the database is installed.

■ Enter the network configuration for DSS/Order Filler and PPS Manager (may be identical to the Order Filler) using the button "Network Configuration" in the section "Worklist".

AE title, host name and port number of the remote host are required to complete this configuration.

Click both "Verify remote host" buttons to check the configuration (verification service, using ECHO Messages).

■ Enter the network configuration for the Image Archive and Image Manager (may be identical to the Image Archive) using the button "Network Configuration" in the section "Image Archiving".

AE title, host name and port number of the remote host are required to complete this configuration.

Click both "Verify remote host" buttons to check the configuration (verification service, using ECHO Messages).

The SCU port is used to receive storage commitment responses. Click the

button "Verify SCU port" to check the configuration (verification service, using ECHO messages).

 Configure the extended character set for the DICOM Interface depending on the language used: add the item CHARACTER_SET to "Special DICOM setup items without UI").

Check the DICOM setup

- Click the "Check connection" button and verify that no error occurs.
- In case of errors, click "View error log..." and check the listed error message.
- Confirm the dialog.

Verify Order List button

Click "New test" and verify that the "Order List" button is enabled in the patient list dialog.

Verify the protocol code mapping

The CARDIO application receives protocol schema and codes from the DSS/ Order Filler and maps them to the internally used procedure types Exercise test, Resting ECG, Spirometry, Ambulatory Blood Pressure or Ergospirometry.

The protocol code mapping is responsible for starting the correct procedures out of the DICOM work list.

Therefore it is is crucial that the received and the used protocol schema and codes match

To verify this, create at least one order per desired procedure type in the DSS/ Order Filler system.

Then bring up the Order List via patient list dialog.

Select each of the orders and verify that the "Start procedure" button is always active.

If this button is disabled for one of the orders, the corresponding protocol code mapping has to be modified.

The CARDIO application has implemented several sets of predefined protocol schema/codes (see chapter "Default protocol schema/codes").

Either the DSS/ Order Filler adapts it's used protocol schema/codes to this predefined schema/codes or the protocol code mapping has to be modified within this system (see chapter "Protocol Code Mapping").

2.5.4 Special DICOM setup items without UI

File DICOM.INI in database folder, section [DICOM]:

Character set for the DICOM Interface:
 The following extended character sets are supported:
 CHARACTER SET=0 (Default 0; range: 0 to 4)

- 0: ISO IR 6 (ASCII)
- 1: ISO IR 100 (ISO 8859-1: Latin 1: Western European languages)
- 2: ISO IR 101 (ISO 8859-2: Latin 2: Central/Eastern European languages)
- 3: ISO_IR 144 (ISO 8859-5: Cyrillic: Russian)
- 4: ISO IR 148 (ISO 8859-9: Latin 5: Turkish)
- Use the selected ECG Report formats of the Exercise test setup for ECG Waveform Images (only valid if the "General ECG Waveform SOP Class" is disabled and 12-leads are selected in the Exercise test setup):

IA_USE_SELECTED_ECG_REPORT_FORMATS=1 (Default: 0, use always 1x10s format)

■ Timeout value for reading DICOM messages.

READ MESSAGE TIMEOUT=10 (Default: 5 seconds; Range: 1 to 100s)

■ Transfer syntax for DICOM File Export.

FILE TRANSFER SYNTAX=1 (Default: 0; range 0 to 3)

- 0: Explicit Little Endian
- 1: Implicit Little Endian
- 2: Explicit Big Endian
- 3: Implicit Big Endian
- ECHO_INTERVAL for sending ECHO-RQ during "Verify remote host" action. ECHO_INTERVAL_MS=1000 (Default: 2000; Range: 500 to 10000 ms)
- ECHO Retry Number for sending ECHO_RQ during "Verify remote host" action.

ECHO RETRY=5 (Default: 3; Range 1 to 20000)

2.5.5 Protocol Code Mapping

2.5.5.1 General

DICOM Protocol Codes are grouped in so called schemas.

There is a predefined DICOM protocol schema ("SRT") for Exercise test that CASE/CardioSoft uses as default data.

However, the DSS/Order filler may use other schemas and protocol codes.

In this case you can add or adjust schemas and protocol codes.

CASE/CardioSoft has also implemented it's own schema per procedure type that could be used by the DSS/Order filler.

The DICOM interface provides the Protocol Code Mapping in both directions:

Scheduled test (Incoming Protocol Codes)

Using the DICOM worklist, the received (scheduled) DICOM Protocol Schema/Code is mapped to the

- CASE/CardioSoft Procedure Type (e.g. Exercise test, Resting ECG...) and to the
- CASE/CardioSoft Protocol Code I and II for detailed information

(e.g. for Exercise test: Use of treadmill or ergometer. Use of protocol, e.g. BRUCE, WHO...).

If CASE/CardioSoft cannot find a corresponding procedure type, the "Start examination" button in the DICOM worklist is disabled.

Performed test (Outgoing Protocol Codes)

The DICOM Protocol Schema/Code sent out (Performed Protocol Schema/Code) is built by using the performed

- CASE/CardioSoft Procedure Type (Exercise test, Resting ECG...) and the
- CASE/CardioSoft protocol code I and II for detailed information (e.g. for Exercise test: Treadmill or Ergometer. Exercise test protocol, e.g. BRUCE, WHO...).

The DICOM Performed Protocol Code may be different than the DICOM Scheduled Protocol Code (but identical schema), because the user could have changed it.

Example:

The user startes a scheduled order, that initiates an Exercise test with a Treadmill and the BRUCE protocol.

Before going to the pre-test phase, the user switches to the NAUGHTON protocol.

So the DICOM Performed Protocol Code reflects what was executed in reality.

It is essential to have the correct Protocol Code Mapping in both directions.

2.5.5.2 Method of Protocol Code mapping

The DICOM Protocol Code Mapping is achieved by sections and entries in the file <Installation database folder>\DICOM.INI.

Changing or appending additional schemas for the mapping can only be done by manually changing the data in this file using an editor (e.g. Notepad).

Changes always affect all workstations and clients in the CASE/CardioSoft network.

The DICOM Protocol Schema/ Code applies to the DICOM tag 0040, 0008 (Scheduled Protocol Code Sequence) and 0040, 0260 (Performed Protocol Code Sequence).

2.5.5.3 Syntax of the Protocol Code mapping per schema:

Example: SRT NO 0=STRESS,P2-7131C,1,BALKE

Four parameters are used per protocol code in a schema section.

The used delimiter is ",".

- CASE/CardioSoft Procedure Types: "STRESS" (Exercise test); "ABP" (Ambulatory Blood Pressure); "SPI" (Spirometry); "ECG" (Resting ECG); "ESPIRO" (Ergospirometry)
- 2. DICOM Performed Protocol Code: Depends on the used scheme. If a predefined DICOM schema is used, the protocol codes are well defined. If a user defined scheme used, it depends on the system's requirements.
- 3. CASE/CardioSoft Protocol Code I (Value): Depends on CASE/CardioSoft Procedure Type
 - For Exercise test/ Ergospirometry: 0 is Bicycle Ergometer, 1 is Treadmill For all other procedure types this is not yet used (= zero).
- 4. CASE/CardioSoft Protocol Code II (String): Depends on CASE/CardioSoft Procedure Type

For Exercise test/ Ergospirometry: Protocol name that must match the Exercise test protocol names listed in the Exercise test configuration (e.g. "BRUCE"). For all other procedure types this is not yet used.

2.5.5.4 Adding a new Protocol Schema

Example for adding a new Protocol Schema including new Protocol Codes required by the DSS/Order Filler:

- Determine the procedure type for which you want to add a new schema and use the corresponding test type identifier, e.g.
 Procedure type is Exercise test --- corresponding procedure type identifier is "STRESS".
- 2. Append the new schema for unscheduled tests in section [PROTOCOL_SCHEMES], using the item with the corresponding procedure type identifier, e.g.

New schema is "ABCD":

STRESS PROT SCHEME UNSCHED=SRT,99IHE,CSO STRESS,ABCD

3. Use the new schema as default protocol schema for the determined procedure type in section [PROTOCOL_SCHEMES], if the performed protocol code could not be mapped to a DICOM protocol code, e.g.

```
STRESS_PROT_SCHEME_USED_IF_UNKNOWN=ABCD
```

4. Determine DICOM default protocol codes for this schema, if the performed protocol code could not be mapped to a DICOM protocol code, e.g.

"ABCD_ERG_UNKNOWN", if CASE/CardioSoft Protocol Code I is 0 (Ergometer)

or

- "ABCD_TRM_UNKOWN", if CASE/CardioSoft Protocol Code I is 1 (Treadmill)
- 5. Use the new DICOM Protocol Codes as required by the DSS/Order Filler for this procedure type, e.g.
 - "ABCD_WHO" for Ergometer with WHO-Protocol.
 "ABCD_BRUCE" for Treadmill with BRCUE-Protocol.
 Number of new DICOM Protocol Codes is 2.
- 6. Add the new schema as a new section, using the syntax as described, e.g.

```
[ABCD]
ABCD_UNKNOWN_0_PROT_CODE=ABCD_ERG_UNKNOWN
ABCD_UNKNOWN_1_PROT_CODE=ABCD_TRM_UNKNOWN
ABCD_NO=2
ABCD_NO_0=STRESS,ABCD_WHO,0,WHO
ABCD_NO_1=STRESS,ABCD_BRUCE,1,BRUCE
```

2.5.5.5 Default protocol schema and codes used in DICOM.INI

```
[PROTOCOL_SCHEMES]
```

; List of protocol schemas per procedure type for the unscheduled case, max. 10 schemas allowed,

; delimiter is ","

STRESS_PROT_SCHEME_UNSCHED=SRT,99IHE,CSO_STRESS ESPIRO_PROT_SCHEME_UNSCHED=SRT,99IHE,CSO_ESPIRO ECG_PROT_SCHEME_UNSCHED=CSO_ECG ABP_PROT_SCHEME_UNSCHED=CSO_ABP

; Default performed protocol schema used, if the performed protocol code could not be

; mapped to a DICOM protocol code

SPI PROT SCHEME UNSCHED=CSO SPI

STRESS_PROT_SCHEME_USED_IF_UNKNOWN=CSO_STRESS ESPIRO_PROT_SCHEME_USED_IF_UNKNOWN=CSO_ESPIRO ECG_PROT_SCHEME_USED_IF_UNKNOWN=CSO_ECG ABP_PROT_SCHEME_USED_IF_UNKNOWN=CSO_ABP SPI_PROT_SCHEME_USED_IF_UNKNOWN=CSO_SPI [SRT]

; DICOM protocol scheme SRT for procedure type Exercise test

; list of defined protocol codes; first item must specify the number of protocol codes in this schema.

SRT NO=9

SRT NO 0=STRESS,P2-7131C,1,BALKE

SRT_NO_1=STRESS,P2-7131A,1,BRUCE

SRT_NO_2=STRESS,P2-7131D,1,ELLESTAD

SRT NO 3=STRESS,P2-7131B,1,MODBRUCE

SRT NO 4=STRESS,P2-713A1,1,MODNAUGHTON

SRT NO 5=STRESS,P2-713A0,1,NAUGHTON

SRT NO 6=STRESS,P2-7131F,1,PEPPER

SRT NO 7=STRESS,P2-7131E,1,RAMP

SRT_NO_8=STRESS,P2-31102,0,WHO

[99IHE]

; DICOM protocol scheme 99IHE for procedure type Exercise test

; list of defined protocol codes; first item must specify the number of protocol codes in this schema.

99IHE NO=4

99IHE NO 0=STRESS,PHARMSTRESS,1,MODBRUCE

99IHE_NO_1=STRESS,PERSANTINE,1,PERSANTINE

99IHE NO 2=STRESS,ADENOSINE,1,ADENOSINE

99IHE_NO_3=STRESS,DOBUTAMINE,1,DOBUTAMINE

[CSO STRESS]

; User defined protocol scheme for procedure type Exercise test

; outgoing default protocol codes for this scheme

CSO_STRESS_UNKNOWN_0_PROT_CODE=CSO_ERG_UNKNOWN

CSO STRESS UNKNOWN 1 PROT CODE=CSO TRM UNKNOWN

; list of defined protocol codes; first item must specify the number of protocol codes in this schema.

CSO STRESS NO=21

CSO_STRESS_NO_0=STRESS,CSO_WHO,0,WHO

CSO STRESS NO 1=STRESS,CSO WHO50,0,WHO50

CSO_STRESS_NO_2=STRESS,CSO_WHO75,0,WHO75

CSO_STRESS_NO_3=STRESS,CSO_HOLLMANN,0,HOLLMANN

CSO STRESS NO 4=STRESS,CSO BAL,0,BAL

CSO STRESS NO 5=STRESS,CSO STD.FRANCE,0,STD.FRANCE

CSO STRESS NO 6=STRESS,CSO MODWHO,0,MODWHO

CSO_STRESS_NO_7=STRESS,CSO_CONCONI,0,CONCONI

CSO_STRESS_NO_8=STRESS,CSO_BRUCE,1,BRUCE

CSO_STRESS_NO_9=STRESS,CSO_MODBRUCE,1,MODBRUCE

CSO STRESS NO 10=STRESS,CSO NAUGHTON,1,NAUGHTON

CSO STRESS NO 11=STRESS,CSO ELLESTAD,1,ELLESTAD

CSO STRESS NO 12=STRESS,CSO MODBALKE,1,MODBALKE

CSO STRESS NO 13=STRESS,CSO USAFSAM,1,USAFSAM

CSO_STRESS_NO_14=STRESS,CSO_SLOWUSAFSAM,1,SLOWUSAFSAM

CSO_STRESS_NO_15=STRESS,CSO_CORNELL,1,CORNELL

CSO STRESS NO 16=STRESS,CSO BALKE,1,BALKE

 $CSO_STRESS_NO_17 = STRESS, CSO_MODBALKEWARE, 1, MODBALKEWARE$ WARE

CSO STRESS NO 18=STRESS,CSO ADENOSINE,1,ADENOSINE

CSO STRESS NO 19=STRESS,CSO DOBUTAMINE,1,DOBUTAMINE

CSO_STRESS_NO_20=STRESS,CSO_PERSANTINE,1,PERSANTINE

[CSO_ESPIRO]

; User defined protocol scheme for procedure type Ergospirometry test

; outgoing default protocol codes for this scheme

CSO_ESPIRO_UNKNOWN_0_PROT_CODE=CSO_ERG_UNKNOWN

CSO ESPIRO UNKNOWN 1 PROT CODE=CSO TRM UNKNOWN

; list of defined protocol codes; first item must specify the number of protocol codes in this schema.

CSO ESPIRO NO=21

CSO ESPIRO NO 0=ESPIRO,CSO E WHO,0,WHO

CSO ESPIRO NO 1=ESPIRO,CSO E WHO50,0,WHO50

CSO ESPIRO NO 2=ESPIRO,CSO E WHO75,0,WHO75

CSO ESPIRO NO 3=ESPIRO,CSO E HOLLMANN,0,HOLLMANN

CSO ESPIRO NO 4=ESPIRO,CSO E BAL,0,BAL

CSO ESPIRO NO 5=ESPIRO,CSO E STD.FRANCE,0,STD.FRANCE

CSO ESPIRO NO 6=ESPIRO,CSO E MODWHO,0,MODWHO

CSO ESPIRO NO 7=ESPIRO,CSO E CONCONI,0,CONCONI

CSO_ESPIRO_NO_8=ESPIRO,CSO_E_BRUCE,1,BRUCE

CSO_ESPIRO_NO_9=ESPIRO,CSO_E_MODBRUCE,1,MODBRUCE

CSO_ESPIRO_NO_10=ESPIRO,CSO_E_NAUGHTON,1,NAUGHTON

CSO ESPIRO NO 11=ESPIRO,CSO E ELLESTAD,1,ELLESTAD

CSO_ESPIRO_NO_12=ESPIRO,CSO_E_MODBALKE,1,MODBALKE

CSO ESPIRO NO 13=ESPIRO,CSO E USAFSAM,1,USAFSAM

CSO ESPIRO NO 14=ESPIRO,CSO E SLOWUSAFSAM,1,SLOWUSAFSAM

CSO ESPIRO NO 15=ESPIRO,CSO E CORNELL,1,CORNELL

CSO ESPIRO NO 16=ESPIRO,CSO E BALKE,1,BALKE

 $CSO_ESPIRO_NO_17 = ESPIRO, CSO_E_MODBALKEWARE, 1, MODBALKEWARE$ WARE

CSO ESPIRO NO 18=ESPIRO,CSO E ADENOSINE,1,ADENOSINE

CSO_ESPIRO_NO_19=ESPIRO,CSO_E_DOBUTAMINE,1,DOBUTAMINE

CSO ESPIRO NO 20=ESPIRO,CSO E PERSANTINE,1,PERSANTINE

[CSO ECG]

; User defined protocol scheme for procedure type Resting ECG

; outgoing default protocol codes for this schema

CSO_ECG_UNKNOWN_0_PROT_CODE=CSO_ECG_UNKNOWN

; list of defined protocol codes; first item must specify the number of protocol codes in this schema.

CSO ECG NO=1

CSO ECG NO 0=ECG,CSO ECG,0,Resting ECG

[CSO ABP]

; User defined protocol scheme procedure procedure type Ambulatory Blood Pressure

; outgoing default protocol codes for this schema

CSO_ABP_UNKNOWN_0_PROT_CODE=CSO_ABP_UNKNOWN

; list of defined protocol codes; first item must specify the number of protocol codes in this schema.

CSO ABP NO=1

CSO_ABP_NO_0=ABP,CSO_ABP,0,ABP-Test

[CSO SPI]

; User defined protocol scheme for procedure type Spirometry

; outgoing default protocol codes for this schema

CSO_SPI_UNKNOWN_0_PROT_CODE=CSO_SPI_UNKNOWN

; list of defined protocol codes; first item must specify the number of protocol codes in this schema.

CSO_SPI_NO=1

CSO_SPI_NO_0=SPI,CSO_SPI,0,Spirometry-Test

;The user can add other protocol schemas or change existing protocol schemas as needed, but the required syntax must be followed.

2.5.6 Description of dialogs

2.5.6.1 DICOM tab

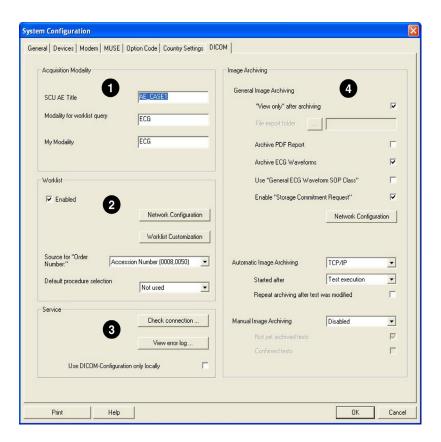


Figure 1

- 1. **Acquisition modality** (configuration affects this workstation)
 - a. SCU AE-title (Unique ID for this workstation, mandatory)
 - b. Modality for the worklist query (Default: Orders for modality "ECG")
 - c. Own Modality (Default: "ECG")
- Worklist (configuration affects all workstations in the CASE/CardioSoft network)
 - a. DICOM Work list function (Default: Enabled)
 If the Work list function is disabled, the system does not connect to the DSS/Order Filler and the PPS Manager at all.
 Only the Image Archiving is done, if it is enabled.
 - b. Network Configuration See description Figure 2
 - c. Worklist CustomizationSee description Figure 4
 - d. DICOM Source for the Order number (part of the test information):

- Accession number (0008,0050)
- Requested Procedure ID (0040,1001)
- Scheduled Procedure Step ID (0040,0009)
- Not used (blank)
- e. Default procedure type for starting the test if the scheduled protocol code did not match:
 - Exercise test
 - Resting ECG
 - Spirometry
 - ABP
 - Ergospirometry
 - Not used

3. **Service** support

a. Check the DICOM-Interface according to the DICOM configuration setup: The following checks are implemented:

•DICOM library (Merge3-COM) initialization

- "Open Association" and "Close Association" action to the DSS/Order filler is performed, if the work list is enabled; the Service List [DMWL_Service_List] in file MERGECOM.APP is used for association negotiation.
- "Open Association" and "Close Association" action to the PPS
 Manager is performed, if the work list is enabled; the Service List
 [MPPS_Service_List] in file MERGECOM.APP is used for association
 negotiation.
- "Open Association" and "Close Association" action to the Image
 Archive is performed, if one of the TCP/IP functions for image
 archiving is enabled and the ECG Waveform object is enabled and the
 "General ECG Waveform Object SOP Class" is disabled; the Service
 List [IA_Service_List_12LECG] in file MERGECOM.APP is used for
 association negotiation.
- "Open Association" and "Close Association" action to the Image Archive is performed, if one of the TCP/IP functions for image archiving is enabled and the ECG Waveform object is enabled and the "General ECG Waveform Object SOP Class" is enabled; the Service List [IA_Service_List_GenECG] in file MERGECOM.APP is used for association negotiation.
- "Open Association" and "Close Association" action to the Image
 Archive is performed, if one of the TCP/IP functions for image
 archiving is enabled and the PDF Report object is enabled; the Service
 List [IA_Service_List_EncPDF] in file MERGECOM.APP is used for
 association negotiation.
- "Open Association" and "Close Association" action to the Image
 Manager is performed, if one of the TCP/IP functions for image
 archiving is enabled and the "Storage Commitment Request" is
 enabled; the Service List [IM_Service_List] in file MERGECOM.APP
 is used for association negotiation.

The results are logged in the file

"<Installation ProgramFolder>\DICOMLOG\DicomLog.txt".

b. View error log

The DICOM-Interface logs its events using 3 files:

- <Installation Program folder>\DICOMLOG\DicomLog.txt (viewed automatically by using this button; includes the most DICOM-Interface events)
- <Installation Program folder>\DICOMLOG\DicomLogThread.txt (can only be manually displayed; includes events logged by the DICOM Listener Thread)
- <Installation Program folder>\Merge.log (this comes from the DICOM MergeCOM-3 library (is not considered here).

The DICOM-Interface uses 2 levels of event logging.

The default event logging level is level 0, which is used for errors.

Changing the level to level 1 has the following effect:

- Adds more informations (that are not necessarily errors) to the log files
- Lists the DICOM messages of one transaction as files in the DICOM LOG folder

To change the event logging level, use the Notepad to edit the file CA_SYS.INI in program folder, section [DICOM], entry DICOM LOG LEVEL=1.

- c. Local usage of the DICOM setup:
 - Use the server-based DICOM setup (default). In a CASE/CardioSoft network all workstations use one server-based DICOM setup.
 - Use local DICOM setup. In a CASE/CardioSoft network you can switch the server-based DICOM setup of this workstation to a local setup that affects only this workstation.
- 4. **Image Archiving** (configuration affects all workstations in the CASE/CardioSoft network)
 - a. Set the test to "Read only" in the database after a successful image archiving (when the test was set to "Archived (DCM)" in the test list).

NOTE

Archiving occurs at different times, see 4i

- b. File export folder configuration for automatic or manual image archiving via file export (UNC is supported)
- c. Image archiving includes the PDF report of the test (report format is as configured for the print report in the modality)
- d. Image archiving includes the following raw ECG Waveforms of the Exercise test:
 - The first 12SL ECG strip in pretest phase (as "Resting ECG"), if available.
 - The last ECG strip in pretest phase (as "Baseline ECG"), if available.
 - The last ECG strip per stage in exercise phase (as "Exercise ECG"), if available.
 - The last ECG strip in recovery phase (as "Post Exercise ECG"), if available.
- e. Use the "General ECG Waveform SOP Class" for archiving ECG Waveforms (instead of "12-Lead ECG Waveform SOP Class"): There may be two scenarios to enable this item:

- The Image Archive cannot process/view the DICOM 12-lead ECG Waveform object.
- The Exercise test is performed with 3-, 6- or 15 leads.
- f. Enable "Storage Commitment transaction"

Some Image Managers may not have the ability to process the "Storage Commitment transaction". In this case uncheck this item.

- g. Network configuration (see section "Network Configuration Image Manager, Image Archive" on page 2-58)
- h. Function of automatic image archiving

The following functions are available for the automatic image archiving:

- Perform the automatic archiving via TCP/IP (default; uses the Image Archive SCP configuration and the Image Manager SCP configuration, see 4g)
- Perform the automatic archiving via File Export. The destination folder of 4b is used. The file name is used as configured in the Export setup dialog (see User Manual, System Configuration)
- Disable the automatic archiving
- i. Start automatic image archiving
 - Initiate the archiving of a test automatically after Test Execution
 - Initiate the archiving of a test automatically after Test Confirmation
- j. Repeat automatic image archiving after a test modification.

A test modification after archiving it is only possible, if the test was not yet set to "Read Only" (see 4a).

k. Function of manual image archiving

Manual image archiving is not intended for the normal workflow. It is accessible through a button in the test list, if it was enabled here. One or more tests can be selected and be archived manually. The following functions are available for the manual image archiving:

- Perform the manual archiving via TCP/IP (uses the Image Archive SCP configuration and the Image Manager SCP configuration, see 4g)
- Perform the manual archiving via File Export (uses the destination folder of 4b and the filename as configured in the Export setup dialog, see User Manual, System Configuration)
- Disable the manual archiving (default)
- 1. Use not yet archived tests for manual image archiving

Archive all tests or only tests, that were not yet archived.

m. Use reviewed (confirmed) tests for manual image archiving Archive all tests or only tests, that were reviewed before.

2.5.6.2 Network configuration - DSS/Order Filler, PPS Manager

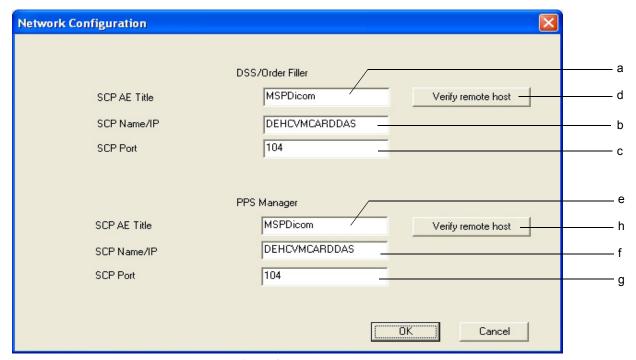


Figure 2

The following data are stored server-based (unless local storage was explicitly set in the configuration) accessible for all CASE/CardioSoft Workstations and Clients (file DICOM.INI in Database folder):

- a DSS/Order filler SCP AE Title
- b DSS/Order filler SCP IP/Host name
- c DSS/Order filler SCP Port number
- d DSS/Order filler verify remote host
- e PPS Manager SCP AE Title
- f PPS Manager SCP IP/Host name
- g PPS Manager SCP Port number
- h PPS Manager verify remote host

2.5.6.3 Network Configuration - Image Manager, Image Archive

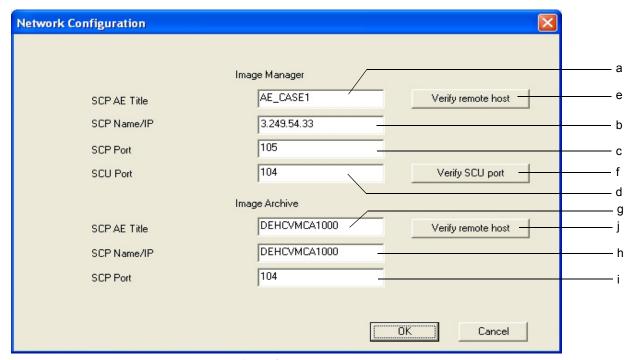


Figure 3

The following data are stored server-based (unless local storage was explicitly set in the configuration) accessible for all CASE/CardioSoft Workstations and Clients (file DICOM.INI in Database folder):

- a Image Manager SCP AE Title
- b Image Manager SCP IP/Host name
- c Image Manager SCP Port number
- d Image Manager SCU Port number (for Storage commitment responses)
- e Image Manager verify remote host
- f Image Manager verify reception on SCU port
- g Image Archive SCP AE Title
- h Image Archive SCP IP/Host name
- i Image Archive SCP Port number
- j Image Archive verify remote host

2.5.6.4 Worklist customization

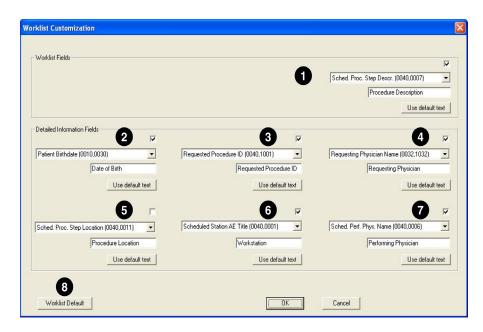


Figure 4

The worklist customization dialog allows to customize the following fields in the DICOM worklist:

- 1. Worklist fields (correspond to the last column in the DICOM worklist)
- 2...7.Six detailed information fields (correspond to the fields in the detailed information section of the DICOM worklist)

They are made up of identical elements

- a. Check box: allows you to enable or disable the corresponding field in the DICOM worklist.
- b. Drop-down list: available DICOM data object to select
- c. Text box for entry of the DICOM data object prompt
- d. *Use default text* button to restore the default text prompt for the selected DICOM data object
- 8. *Worklist Default* button to reset all fields of the DICOM worklist to their default values.

3 Acquisition Modules for CardioSoft

3.1 CAM-USB

CAM-USB is a 15-lead ecg acquisition device with USB interface. It consists of two main parts, the CAM-14 acquisition module and the CAM-USB Interface box. Only additionally lead wires and electrode grabbers are needed to complete the system hardware for the CAM-USB (see Figure 3-1).

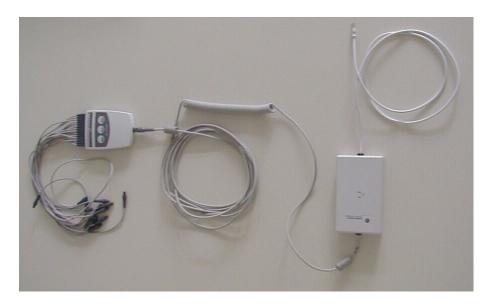


Figure 3-1:

Supported PC and Operating Restrictions

The CAM-USB system is allowed to be connected to the USB port of any PC certified according IEC950.

- The PC must not be within the patient care area in accordance with IEC 60601-1.
- The CAM-USB system may only be connected directly to a PC USB PORT. It is not allowed to use any USB-HUB or cable extension between PC and the CAM-USB system
- Because the CAM-USB device is powered directly from the USB bus, care must be taken with the connection of other bus-powered USB devices to assure full USB single port operating power (+5V DC, 500 mA) for the CAM-USB system.

Supported Operating Systems and System Performance

CAM-USB and CardioSoft V6.x are working with

a) Windows XP Professional 32-bit (SP2 or SP3)
 Recommended PC (P4 class): 1.6 GHz min., 512 MB SDRAM min., 20 GB
 HDD min

b) Windows Vista Home Premium 32-bit (SP1 or SP2)
OR

Windows Vista Business 32-bit (SP1 or SP2))

Recommended PC (P4 class): 2GHz min., 1 GB SDRAM, 20 GB HDD min.

CAM-14 Acquisition Module

(P/N: 901142 - 005, 901142 - 008)

Functions

15-lead acquisition module, already used with CASE8000, CASE and MAC5000

Interface

Serial digital communication interface with 1 MHz clock

CAM-USB Interface

(P/N: 2009000 - 001)

Functions

The CAM-USB INTERFACE implements the function of the protocol converter between the PC-USB communication port and the patient data acquisition module CAM-14. It is used to isolate the PC-System from the Patient environment with a 4kV medical floating isolation. It also generates the operating voltage for the CAM-14 module. (see Figure 3-2)

Interfaces

USB Interface: PC Communications Bus (12 MHz full-speed device,

bus powered)

CAM-14 Interface: Serial two wire protocol with 1 MHz serial clock.



Figure 3-2:

Indicators

The CAM-USB Interface has two LED's (LED A, yellow and LED B, green) to display the actual CAM-USB interface status. Additional there is a buzzer to allow any acoustically signalling and the QRS beep (if enabled within the CardioSoft software).

Meaning of the system status LEDs

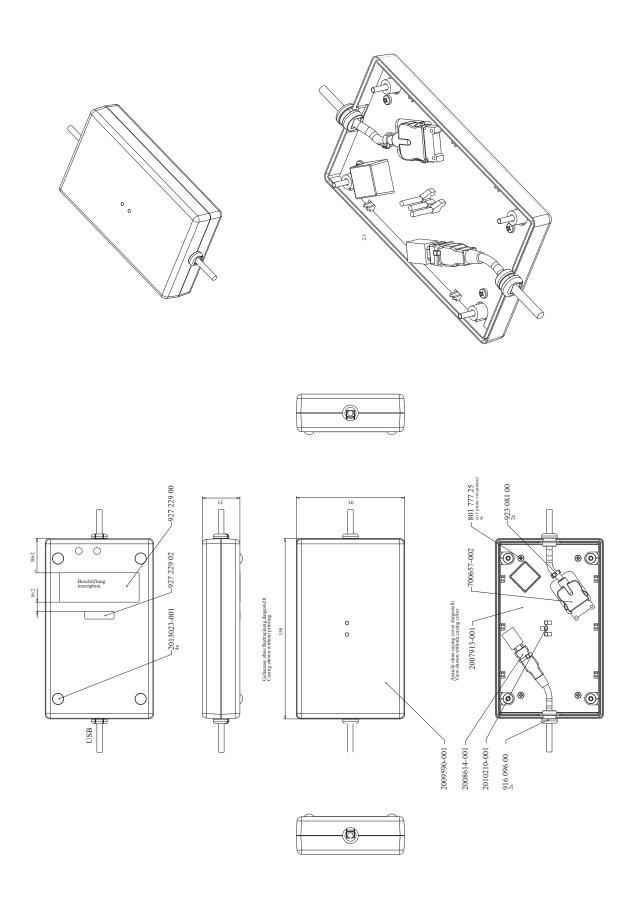
green LED	yellow LED	system status
ON	OFF	ECG signal transmission in pro-
		gress
ON	ON	ready to send ECG signals
		(e.g., no communication with
		CAM-14)
OFF	OFF	no power
ON	blinking	communication with CAM-14 in-
		terrupted
		(e.g., CAM-14 not connected)

When a communication problem between the CAM-USB Interface Box and the PC occurs, the box will emit a continuous tone and both LEDs will be illuminated.

CAM-USB Interface defects handling

According to the actual service strategy, there will be no repair of the CAM-USB Interface. In the case of defect, the complete box (with mounted cables) will be exchanged. Only the two cables could be exchanged (see Spare Parts, chaper 8).

Reprogram the serial number after box exchange, see herefore chapter 4.5 Reprogramming Serial Number.



3.2 CAM-USB A/T & CAM-USB A/T KISS

CAM-USB A/T is a 15-lead ecg acquisition device with USB interface and Analog-/Digital Trigger Outputs (A/T) . It consists of three main parts, the CAM-14 acquisition module, the CAM-USB A/T Interface box and an external medical power supply.

CAM-USB A/T KISS is a 15-lead ecg acquisition device with USB interface, Analog-/Digital Trigger Outputs (A/T) and an integrated suction pump. It consists of three main parts, the CAM-14 acquisition module, the CAM-USB A/T KISS Interface box and an external power supply.

Only additional lead wires and electrode grabbers are needed to complete the system

Hardware for the CAM-USB A/T or CAM-USB A/T KISS (see Figure 3-3).

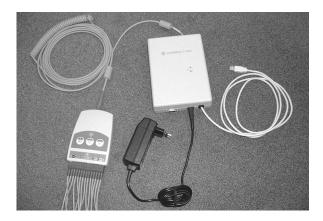


Figure 3-3:

Supported PC and Operating Restrictions

The CAM-USB A/T or CAM-USB A/T KISS system are allowed to be connected to the USB port of any PC certified according IEC950.

The PC must not be within the patient care area in accordance with IEC 60601-1-1.

The CAM-USB system may only be connected directly to a PC's USB PORT. It is not allowed to use any USB-HUB or cable extension between PC and the CAM-USB A/T or CAM-USB A/T KISS system.

Due to electrical safety of patient, only the included wall-pluggable medical power supply is allowed to be used with the devices.

Supported Operating Systems and System performance

CAM-USB A/T (P/N: 2009500-001), CAM-USB A/T KISS (P/N:2009500-009) are working with CardioSoft V6.5 software or higher and with:

a) Windows XP Professional 32-bit (SP2 or SP3)
Recommended PC: 1.6 GHz min., 512 MB SDRAM min., 20 GB HDD min.

b) Windows Vista Home Premium 32-bit (SP1)

OR

Windows Vista Business 32-bit (SP1)

Recommended PC (P4 class): 2 GHz min., 1 GB SDRAM, 20 GB HDD min.

CAM-14 Acquisition Module

(P/N: 901142 - 005, 901142 - 008)

Functions

15-lead acquisition module

Interface

Serial digital communication interface with 1 MHz clock

CAM-USB A/T Interface and CAM-USB A/T KISS Interface

(P/N: 2009500 - 001 and 2009500-009)

Functions

The CAM-USB A/T or CAM-USB A/T KISS Interface serves as protocol converter to connect the CAM-14 acquisition module to the USB port of an standard IEC60950 PC. The externally powered (by an IEC60601-1 power supply) device contains the USB cable as well as the CAM14 cable. Additionally four analog outputs and one digital output are supported by the device. The CAM-USB A/T KISS variant also includes a suction pump to supply the external KISS MULTILEAD electrode suction system. For the product safety there is a 1.5kV insulation between CPU core and CAM-14 acq. Module and an 1.5 kV insulation between CPU core and the Analog/Trigger outputs.

Interfaces

- 1. USB Interface: PC Communications Bus (12 MHz, full-speed device)
- 2. Power Input: 12VDC, max. 2A
- **3. CAM-14 Interface:** Serial two wire protocol with 1 MHz serial clock.
- 4. Analog-/Trigger Outputs:

9-Pin Sub-D connector, Output pin-no. are identical to CASE. All output signals are short circuit protected.

- 1. +15VDC@50mAmax
- 2. CH1OUT, Analog Output; Range: -5V...+10V@RL>= 2kOhm
- 3. Digital Trigger Output with TTL-Level @ RL>=2kOhm
- 4. CH2OUT, Analog Output; Range: -5V...+10V@RL>= 2kOhm
- 5. *GND*
- 6. CH3OUT, Analog Output; Range: -5V...+10V @RL>= 2kOhm
- 7. NO
- 8. CH4OUT, Analog Output; Range: -5V...+10V @RL>= 2kOhm
- 9. NC

CH GND

(CH = connector housing)

5. Suction System Air Inlet (only in CAM-USB A/T KISS, P/N: 2009500-009)

Indicators

The CAM-USB A/T Interface and the CAM-USB A/T KISS Interface have two LED's (LED A, green and LED B, yellow) to display the actual interface status. Additional there is a buzzer to allow any acoustically signaling and the QRS beep (if enabled within the CardioSoft software).

Meaning of the system status LEDs

green LED	yellow LED	system status
ON	OFF	ECG signal transmission in progress
ON	ON	ready to send ECG signals (e.g., no communication with CAM-14)
OFF	OFF	no power
ON	blinking	communication with CAM-14 interrupted (e.g., CAM-14 not connected)

When a communication problem between the CAM-USB Interface Box and the PC occurs, the box will emit a continuous tone and both LEDs will be illuminated.

CAM-USB A/T Interface and CAM-USB A/T KISS Interface defects handling

According to the actual service strategy, there will be a possible exchange of the

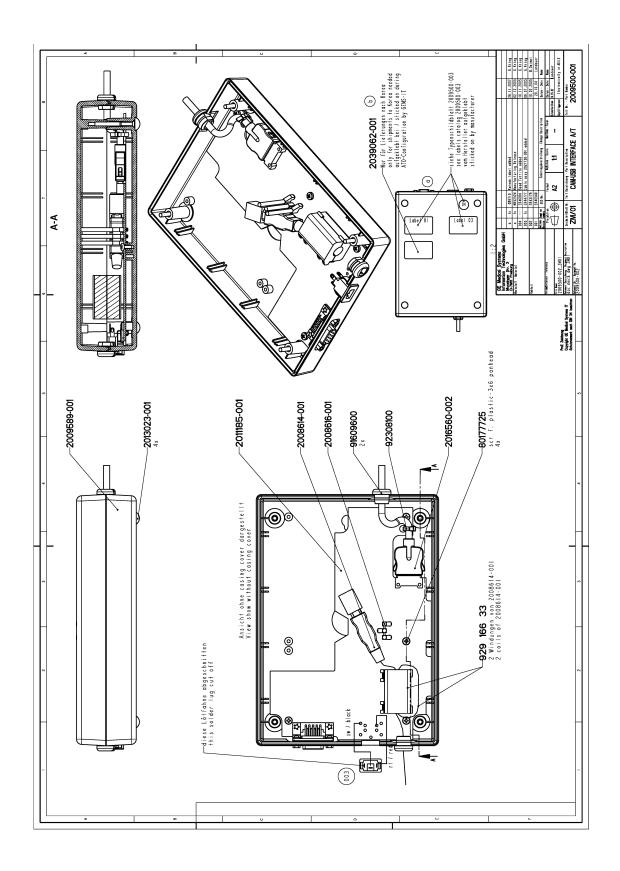
Complete Box

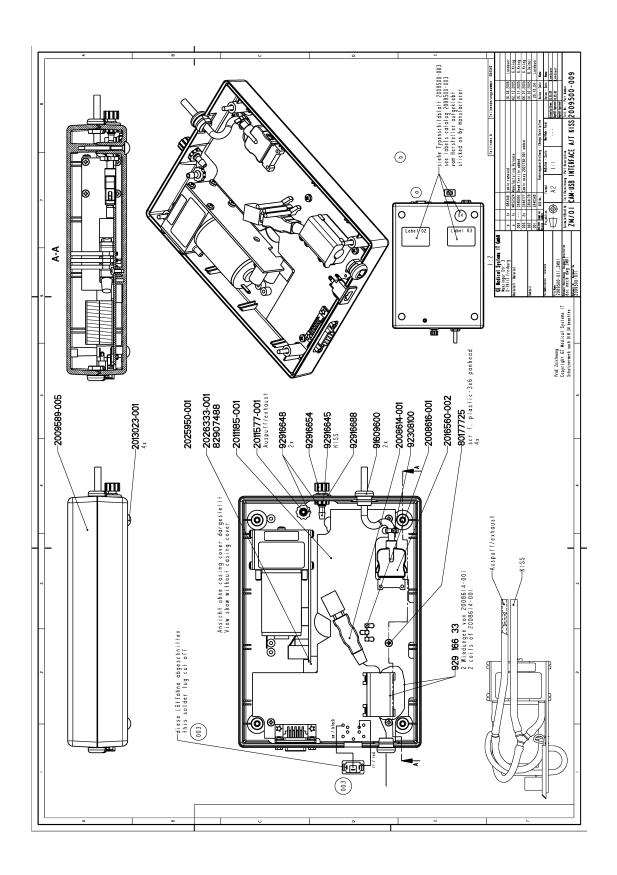
or

- 2. PWA
- 3. Housing
- 4. USB-Cable
- 5. Cable to CAM-14
- 6. Power Supply
- 7. Suction Pump (2009500-009 only)

(see Spare Parts, chaper 8)

Reprogram the serial number after PWA or box exchange, see herefore chapter 4.5 Reprogramming of Serial Number.





3.3 CORINA

NOTE

The CORINA acquisition module is not for use in the U.S. and Canada.

3.3.1 Context

CORINA is an ECG recorder for CardioSoft. CORINA stands for **CORD** INTE-GRATED **AMPLIFIER** and is an interface between patient and personal computer. There are four CORINA models.

3.3.2 Supported Operating Systems and System performance

CORINA and CardioSoft V6.x are working with

Windows XP Professional 32-bit (SP2 or SP3)

Recommended PC: min. 1.6 GHz, min. 512MB SDRAM, min. 20 GB HDD

3.3.3 Model 1 CORINA

Comprises the following components:

Compact plastic casing with interfaces for patient cable and connection cable to PC. All the electronics are integrated inside the casing. This includes ECG preprocessor, controller to buffer data, data converter and transfer to PC. The electronics has its own power supply.

3.3.4 Model 2 CORINA with Suction Pump

Is designed for use with the Electrode Application System. The casing also houses the suction pump with the additional electronics required.

Casing design CORINA models 1 + 2:

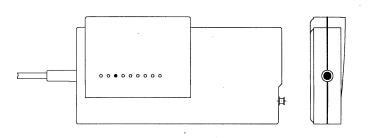


Figure 3-4:

3.3.5 Model 3 CORINA with Analog Output

As Model 1 plus additional analog ECG output. This output enables CORINA & CardioSoft models prior to release 3.0 output of lead II. The output signal of the analog output in the stress test mode is configurable.

3.3.6 Model 4 CORINA with suction pump and Analog Output

Like Model 3 with additional suction pump.

3.3.7 Replacement of CORINA Model 1...4 through newer CORINA Variants (101 118 31...34) with enhanced communication interface to PC

Note: Only CORINA Models 101 118 31...34 and 37/38 (OEM) are supported by CardioSoft V5.x or V6.x.

Note: Redesign of PCBs and PWAs due to EMC 2nd Edition:

- 101 118 31 ... 34: Starting with rev. G. New PWA and PC cable.
- 101 118 37, 38: Starting with rev. H. New PWA and PC cable.

CORINA Block Circuit Diagram

Block circuit diagram of CORINA models 1 + 2, in models 3 + 4 there is an additional functional block (= PCB CORINA TRIGGER) to generate the analog signal)

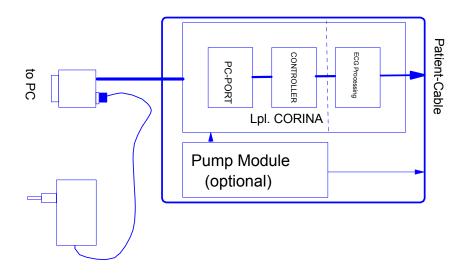


Figure 3-5:

3.4 Introduction

The "Hardware Design Description" describes the structure of the hardware implemented, internal interfaces and those for connection of peripherals.

3.4.1 Repair Procedure

A number is stored in the CORINA which allows the accurate assignment of user and software options.

Repairs conducted by:

Availability of AT PCBs CORINA (6 types, 3 with and 3 without the possibility of plugging in the PCB CORINA TRIGGER).
 To reprogram the serial number please see chapter 4.5 Reprogramming Serial Number.

This tool enables the authorized service technician to program the replaced CORINA PCB with the customer-specific serial number. The AT PCB is programmed. This number only allows the PCB to be modified by overwriting. Replacement works with the AT PCB only. The AT PCB can be programmed once only.

3.5 Hardware Structure

3.5.1 Mechanical Structure

CORINA comprises 4 (optionally 8) mechanical functional units.

These are:

- casing
- floating screening
- PCB CORINA (5 types: a) 2x standard, b) 2x for Analog Out, c) standalone)
- cable to PC
- pump module for Electrode Application System (optional)
- PCB CORINA TRIGGER (optional)
- insulating foil for PCB Analog Out (optional)
- internal wiring Analog Out (optional)

3.5.1.1 Casing:

The casing comprises the following components.

- lower case shell
- upper case shell
- locking device

The pump module (optional) is affixed to the lower section of the casing. The PCB and the floating screening are attached to the upper section. The locking device is screwed to the PCB and serves to secure the Marquette HELLIGE patient cable.

Upper case shell with integrated PCB:

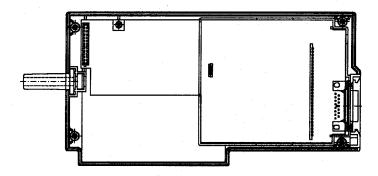


Figure 3-6:

Upper case shell with integrated PCB, incl. PCB CORINA TRIGGER:

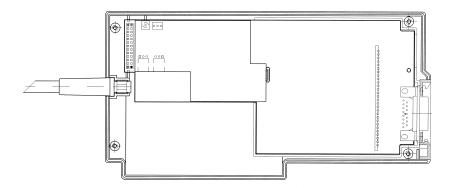


Figure 3-7:

3.5.1.2 Floating screening:

The floating screening comprises a plastic shell with a floating shield cemented in place. The plastic shell is secured with the locking device and by clipping it in onto the PCB. On the one hand, the floating screening protects the highly sensitive electronics from interference while on the other hand, the plastic shell ensures a defined safe gap to the metal plating of the casing.

Lower case shell with integrated pump module (old tubing system):

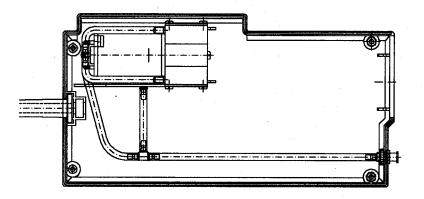


Figure 3-8:

Lower case shell with integrated pump module (new tubing system):

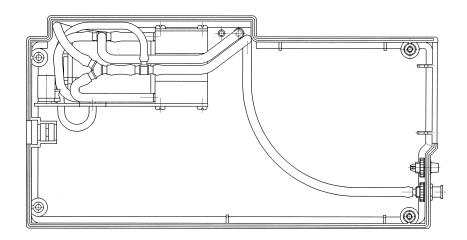


Figure 3-9:

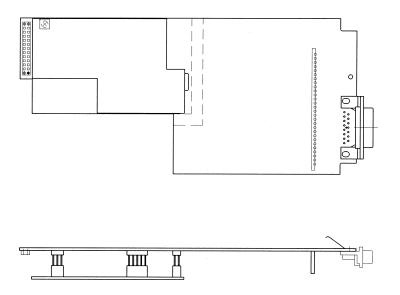


Figure 3-10:

3.5.1.3 PCB CORINA

There are 4 PCB versions:

- a) 2x Standard b) 2x for Analog Out
- a) 2x Standard PCB:

The entire electronics as well as all interfaces are located on the PCB. The patient input socket is fixed permanently to the PCB. The lead to the PC and the power supply cable to the pump are plugged in. The operational readiness display (LED green) is also located on the PCB. When operative the light is transmitted to the outside of the casing via an optical fiber. The newer PCB version, used in CORINA 101 118 31...32 provides a newer communication protocoll to the PC and will not work inside other (older) CORINA variants.

b) 2x CORINA PCB model for CORINA TRIGGER (Analog Out)

It has longer male multipoint connectors than the standard PCB model. The PCB CORINA TRIGGER is plugged into this and the internal analog lead as well as, optionally, the suction pump connected.

The newer PCB version, used in CORINA 101 118 33, 34 and 101 118 37, 38 provides a newer communication protocoll to the PC and will not work inside other (older) CORINA variants.

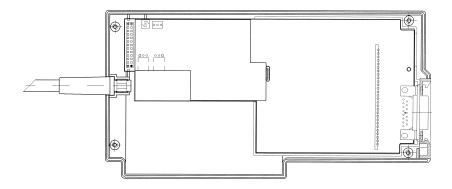


Figure 3-11:

3.5.1.4 Cable to PC

The connection cable to the PC has a 25-pin plug on the PC side. The plug casing also houses a 3-pin socket. A plug-in power supply, supplying CORINA with power, is then connected to this socket. On the CORINA side" is a 26-pin or 20-pin (EMC redesign) socket terminal strip. This is then plugged directly onto the PCB.

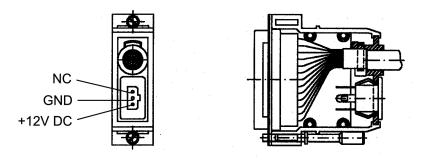


Figure 3-12:

3.5.1.5 Pump Module

The pump module comprises the following components:

- pump
- PCB
- tubing connection

Pump (old tubing system)

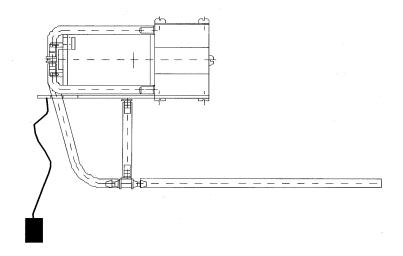


Figure 3-13:

Pump:

When using the PCB Analog Out the power line to the suction pump (optional) is not plugged into the PCB CORINA, but the PCB CORINA TRIGGER.

CAUTION: When used together with the PCB CORINA TRIGGER, the braided pumppower supply wires must be covered by a heat-shrinkable tube!

Pump (new tubing system)

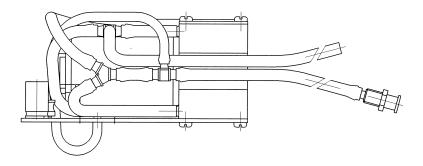


Figure 3-14:

PCB:

The PCB is screwed onto the pump casing. The electronics for pressure regulation is located on the PCB. The 12-V power cable is soldered to the PCB.

Tubing connection:

The air tubing is preassembled and only needs connecting to the nozzle (on the casing).

3.5.1.6 PCB CORINA TRIGGER

There is a floating, analog ECG output based on an optional plug-in card. It provides a 1V/1mV signal (unedited signal, without filter and ADS, pacing pulse is blanked out)at the analog output. The PCB CORINA TRIGGER only needs plugging in. It remains firmly attached without requiring any additional fixation. The standard signal to be output is a lead II signal. For CORINA and CardioSoft Version 3.0 and later versions the output signal can be configured in the stress test mode.

Peripherals can be connected via a 3-pin output socket. Pin assignment of this socket: Pin 1 = Analog Out, Pin 2 = ground, Pin 3 = reserved (also refer to Section 3.4.2.3)

3.5.1.7 Insulation Foil for PCB CORINA TRIGGER

The insulation foil serves to effect floating isolation of the analog section of the PCB CORINA TRIGGER with reference to the casing and (optionally) to the pump.

3.5.1.8 Internal Wiring of the Analog Output

The connection from the analog output of the PCB CORINA TRIGGER to the 3-pin output socket on the casing is effected using a lead covered by a heat-shrinkable tube. For EMV purposes there are two wide-band interference suppression coils inside this tube. Using this tube effects high-voltage-resistant isolation between the analog output signal and ground and patient floating part.

3.5.2 Electrical and electronic structure

The entire CORINA electronics is divided up into three functional units and located on a PCB. These are ECG CONDITIONING, CONTROLLER and PC PORT. (In addition, optionally, Analog Out electronics on the plug-in PCB CORINA TRIGGER).

3.5.2.1 ECG Processing

- acquisition and analog-digital conversion of the ECG signals via up to 11 electrodes
- preprocessing and intermediate storage of the data
- data transfer via a serial interface
- additional functions are: pace identification, checking and testing functions, configuration of the inputs, N negative-feedback loop, measurement of d.c. voltage and blocking function

Transfer of data between the functional unit ECG Processor and CONTROLLER is via a QSPI interface. The exact specifications are described in the document [ASIC Interface].

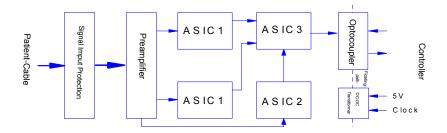


Figure 3-15:

3.5.2.2 CONTROLLER

- all CORINA control functions
- initialization of hardware
- data communication from and to the functional unit ECG Processor
- data communication from and to the functional unit PC PORT
- output of ECG data to DA transductor on PCB CORINA TRIGGER (optional)

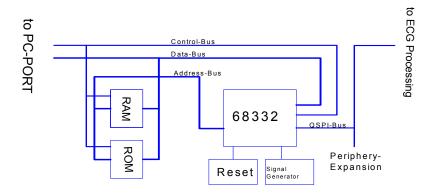


Figure 3-16:

CORINA is controlled by the Controller 68332. This controller already has all the important functions required to control CORINA.

These are:

- CPU (68000 family plus 68020 commands plus commands for controller applications)
- 2 serial interfaces (SCI, QSPI)
- on-chip memory (for faster applications)
- maximum of 12 programmable chip selects
- interrupt manager
- intelligent 16-bit timer
- clock generator

Memory:

A 128 kByte FLASH (128 K x 8 PEROM), which can be programmed directly with the 5-V operating voltage supply, is used as a program memory store. This permits the subsequent loading of software updates using the PC. The data memory comprises the ON-The interrupt requests IEKG_and IPCPW_ are both stored by using FLIPFLOPS, since the interrupt inputs IRQ1 to IRQ6 are only level gated. In contrast to the others, IRQ7 is edge gated and can thus be actuated directly. Resets are generated by a MICROPROCESSOR SUPERVISORY CIRCUIT. A floating section is used to connect the functional unit ECG Processor to the QSPI interface of the 68332. This is a full duplex interface with data input MISO (Master-In Slave-Out), data output MOSI (Master-Out Slave-In) and serial clock SCK. A maximum of 4 devices can be connected to this interface. To achieve this, the PCB is equipped with a connector onto which this bus can be switched in. Using this connector thus allows the connection of a maximum of 3 further peripherals (e.g., experimental input). One of the peripherals is the PCB CORINA TRIGGER (optional).

A signal transmitter gives an acoustic status message. This signal transmitter enables signalling of errors, for example.

3.5.2.3 PC PORT

- CORINA power supply
- ESD protection
- data communication to and from PC

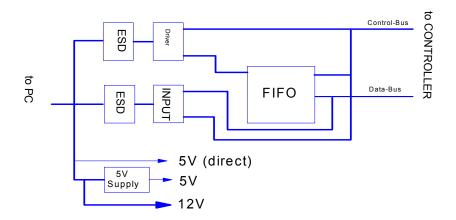


Figure 3-17:

All cables leading to and from the PC are provided with ESD protection.

A DC/DC transducer is used to generate the 5 V. This transducer generates the 5-V power voltage from the 12 V received from the plug-in power supply. The DC/DC transducer can be switched on and off by the PC via the control cable. There is a connector on the PC to connect the 12 V. The pump module can then be connected to this connector.

Data communication between PC and CORINA is via a FIFO. This enables the PC to pick up ECG data at any time. The FIFO has a memory depth of 8 K / 32K X 9 bits, 7/4 bits being used (of these, 6/3 bits for ECG data and 1 bit for synchronization).

All output leads are led through a driver chip.

3.5.2.4 Optional Analog Out Electronics

The PCB CORINA TRIGGER provides the user with a floating analog ECG output signal for connection to ultrasound units. Pacing pulses are blanked out.

Funtionality:

Using QSPI (serial data transfer) the ECG data are transmitted via a medically floating segment to a D/A transducer (10 bits) located on the PCB CORINA TRIGGER. The analog output signal is subsequently standardized, amplified and made available to the user. The signal is short-circuit-proof, unfiltered and does not have ADS bed-side processing.

CAUTION: To enable QRS complex triggering when using PACE, the pacing pulses are removed from the ECG signal.

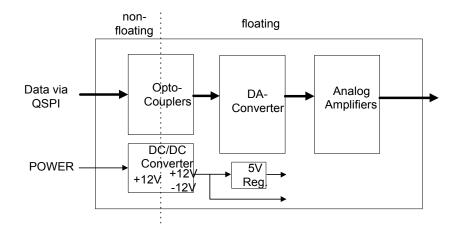


Figure 3-18:

CAUTION: When connecting up an ultrasound unit it is important to ensure that the instrument connected has an input LPF of < 400 Hz. If this is not the case, an external (passive) low pass should connected to the input of the peripheral.

Suitable low-pass configuration: Revision C

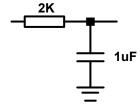


Figure 3-19:

3.5.3 Internal Interfaces

3.5.3.1 Mechanical Interfaces

Tubing connection of the pump module:

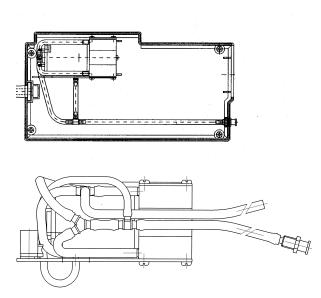


Figure 3-20:

The pump module air tubing is preassembled and only needs connecting to the nozzle (on the casing).

3.5.3.2 Electrical Interfaces

CORINA has three internal interfaces. These are:

- interface to pump module
- debugging interface
- interface for further peripherals (PCB Analog Out):

Interface to pump module:

Description of interface:

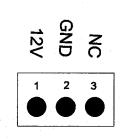


Figure 3-21:

The pump module interface is in the form of a 3-pin male multipoint connector. The pump module requires only a 12-V power supply.

3.5.4 Interfaces to Peripherals

3.5.4.1 Mechanical Interfaces

CORINA has three mechanical interfaces. These are:

- power cable to PC
- connection socket for patient cable
- nozzle for air tubing
- optional: Analog Out connector

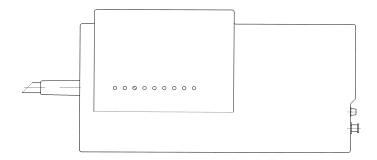


Figure 3-22:

3.5.4.2 Electrical Interfaces

CORINA has two external interfaces. These are:

- interface to PC
- ECG input
- optional: Analog Out

3.5.4.2.1 Interface to PC:

Data interface:

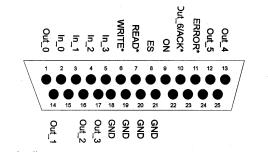


Figure 3-23:

Description of interface:

OUT(0-5) data to PC

OUT6/ACK data bit to PC and data acceptance confirmation this interface

lead fulfils two functions

READ MODE -> data line D6 (data from CORINA -> PC)
WRITE MODE -> ACK* (data from PC -> CORINA)

For outputs OUT(0), OUT(1) and OUT(3) it is important to observe that these are output inverted by CORINA since, initially, the PC inverts these inputs. In newer CORINA versions (101 118 31...38) a new cable to PC is used, where only OUT (2, 4, 5) are used to transmit data to the PC.

ERROR* indicates "full or empty FIFO"

IN(0-3) data from PC

ES selection whether ERROR* should indicate "full or empty

FIFO"

ES = LOW -> CORINA indicates "empt" FIFO ES = HIGH -> CORINA indicates "full" FIFO

READ* transmit data to PC
WRITE* read data from PC
ON switch on CORINA

ON = LOW -> CORINA is switched off ON = HIGH -> CORINA is switched on

Power source interface:



Figure 3-24:

As of 05/1997 this interface no longer delivers a 5-V signal.

3.5.4.2.2 ECG Input:

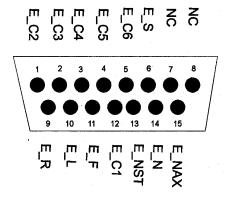


Figure 3-25:

Description of interface:

E_R	electrode input right arm
E_L	electrode input left arm
E_F	electrode input left foot
E_N	electrode input right foot
E_C1	electrode input chest electrode C1 (Wilson)
E_C2	electrode input chest electrode C2 (Wilson)
E_C3	electrode input chest electrode C3 (Wilson)
E_C4	electrode input chest electrode C4 (Wilson)
E_C5	electrode input chest electrode C5 (Wilson)
E_C6	electrode input chest electrode C6 (Wilson)
E_NAX	electrode input chest electrode NAX (Nehb)
E_NST	electrode input chest electrode NST (Nehb)
E_S	shielding

3.5.4.2.3 Analog Out

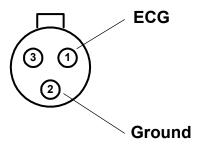


Figure 3-26:

Pin assignment of this socket: Pin 1 = Analog Out, Pin 2 = ground, Pin 3 = reserved.

3.6 Troubleshooting Help Functions

After startup, CORINA performs an internal self-test. The test results are filed in FIFO memory. If an error is detected, an alarm signal also sounds three times in succession.

Meaning of the error messages:

Self-Test Results (BYTE)	Program Display Value	Meaning
00000000	0	no error
00000001	1	error in internal RAM of 68332
00000010	2	error in vector list
00000100	4	error in RAM memory
00001000	8	system software CRC check error
00010000	10	custom software CRC check error
00100000	20	QSPI check error

When several errors occur together, the relevant bit in each case is set.

Example:

System and custom software CRC check error.

Self-Test Results (BYTE)	Program Display Value	Meaning
00011000	24	System and custom software CRC check error

For your notes

4 Troubleshooting Tips

4.1 Frequently Asked Questions

Question: Error Message "Acquisition module not connected" occurs repeatedly with CAM-USB Interface:

Solution:

Disable power save mode for laptops.

Windows XP:

Because Windows XP has no icon of flag in the Windows taskbar, a vendor-specific applet has to be installed:

- Turn off SpeedStep in the Bios and WinXP: go to the power applet in the control panel and select "Always on option" to disable SpeedStep
- If attempt fails, please contact your laptop vendor in order to get the applet for disabling Intel SpeedStep Technology or AMD power non.

Set Power Scheme to Always On:

- Start Control Panel with Start -> (Settings) -> Control Panel
- In Control Panel click Power Options
- Choose the Power Schemes tab, choose Always On
- Choose Never for Turn off monitor/Turn off hard disks/System standby

Check minimum requirements (Service Pack 2 or 3 / 512 MB RAM)

- Start Control Panel with Start -> (Settings) -> Control Panel -> System
- In Control Panel check Computer on the General tab

Windows Vista:

- Start Control Panel
- In Control Panel click **Power Options**
- Choose High Performance
- Click Change Plan Setings below the High Performance radio button
- Choose Change advanced power settings
- Choose Sleep
- Set Allow hybrid sleep to OFF

Optionally, you can also change the values for **Hard drive** and **Display**.

Question: Error Messages with CAM-USB Interface

[7983] Exercise test option not found

[6400] Note: The "Record" function is available only in conjunction with the

"Resting ECG, Standard" option!

Generally: Option not found

Solution:

Look for the serial number (System Configuration, Option Code).

If the serial number is "0", leave CardioSoft, disconnect the USB connector, wait 5 sec before reconnecting them and start CardioSoft.

Look again for the serial number. The CAM-USB Interface has to be plugged in before starting CardioSoft.

Question: No curves with CAM-USB Interface

Solution:

Please disconnect the USB connector and wait min. 5 sec before reconnecting them.

Question: PATIENT MODULE is not detected at the LPT port:

Solution:

Set LPT Mode in BIOS to "NORMAL MODE" (not to "ECP" or "EPP" Mode) If this will not help, please use Multi I/O card from GEMS IT Service (PN: 2000148-001)

There is be a new PATIENT MODULE generation with better communication capabilities (PATIENT MODULE V3.1) available. Because of the enhanced communication features, this new

PATIENT MODULE only will work with newer CardioSoft versions greater/equal V4.14.

PATIENT MODULE V3.0 and older work only with PCI card VSCOM210. PATIENT MODULE V3.1 and higher work with all XT compatible or 16550 compatible PCI cards.

Question: I got the error message -115 when installing CardioSoft

Solution:

The file that was displayed within the error message is write protected or the actual User do not have the rights to write to the destination directory. Change the readonly attribute for the file or the User's policies.

Question: When I start CardioSoft, I get a data base error Solution:

Copy new "REORG.BAT" file from CardioSoft V4.1x directory to "DATABASE" directory and start a reorganisation of the data base.

Question: When I open an examination I get a Decompression Error:

Solution:

Use Check and repair hard disk using SCANDISK or CHKDSK. Then restore the system by using the last BACKUP file.

Question: PCW130 value will not be displayed in the stress test measurement summary

Solution:

PCW 130 is not for use in combination with treadmill stress tests. The stress test must be done, weight of the patient is existing and a heart rate of 130 was reached. (ECG equipment must have the capability for a hart rate of 130)

Question: The modem I use is not in the modem list and brings up an error mesage at initialisation

Solution:

Chose modem type "User defined" and delete "\X1" out of the field "Initialisation". After doing this the error message will disappear.

Configure modems type "MultiTech" only with 14400 baud and 19.2K baud. Use the newer MultiTech 56K with the modified modem type "User defined".

Question: Patient selection menue will not fit within the screen

Solution:

Select "SMALL FONTS" within the display configuration window.

Question: Heart Rate removed after transfered from MAC 1200 to CardioSoft

Solution:

The Heart Rate is calculated from the RR duration. To get the Heart Rate in Cardio-Soft you must have the Measurement Software Option on the MAC 1200 then the RR duration and the Heart Rate can be calculated.

Question: Small differences in the measurement values after transferd from MAC 1200 to CardioSoft

Solution:

The protocol which is used to transfer the data doesn't use the same amplitude unit for the measurement values from MAC 1200. These values have to be converted when the data is received in CardioSoft and the results may not be exactly the same values.

Question: Integration of CardioSoft in an archiving system of the customer

Solution:

Customer buys any tool which is able to create PDF files (e.g. Adobe Acrobat Distiller). The generated PDF files can be send to the archiving system of the customer and the archiving system can view this files with the PDF reader. PDF files can be printed with high quality on a Laser Printer. This PDF files are better than Export screen shoots as JPG files.

Question: Proxy Settings from the Internet Explorer influence the FTP file transfer to MUSE

Solution:

If a Proxy Server name is configured, than must be the intranet MUSE FTP Server Name excluded from the Proxy Server.

Problem: On some occasions, the program does not calculate the target load.

Solution:

To calculate the target load, the program needs to know the patient's gender, date of birth, height, and weight.

In the following situations, the program is not able to calculate the target load: age < 15 years or age > 84 years or height < 50 cm or height > 250 cm or weight < 20 kg or weight > 200 kg or body surface area (men) < 1.6 m² or body surface (women) < 1.2 m²

Problem:

If a PDF report with ECG grid is generated with Adobe Acrobat in CardioSoft, the figure 2 is displayed instead of the ECG grid.

Solution:

- 1. Display Acrobat Distiller from Adobe Acrobat V6.x: Start Menu -> Settings -> Printers
- 2. Double-click on Acrobat Distiller and select the menu: Printer -> Document Defaults...
- 3. Deactivate field "Do not send fonts to Distiller" on the "Adobe PDF Settings"
- 4. Set field "Graphic-> True Type Font" to value "Download as Softfont" on the "Advanced" tab

If these steps do not resolve the problem, change the grid style in "System Configuration/Printer" by deselecting the "Dotted lines" check box. Now the grid uses solid lines and the grid color can be individually adjusted.

Problem: The MUSE Web Server works, but an error message appears when the CardioSoft patient list is invoked.

Solution:

A MUSE Web user account must be created under Windows and assigned to the MUSE group. The user account must also be created in MUSE.

Question: Is the Japanese version of MAC 1200 capable of transferring resting ECGs to CardioSoft V4.2 or above, using the A5 protocol?

Yes, if Japanese Windows Operation System is used.

Problem: Metabolic Carts display a higher heart rate than CardioSoft?

Solution:

During exercise tests, the heart rate is calculated for the 30-second tabular data. The heart rate is averaged over 30 seconds at 5-second intervals and entered in the table. The max. heart rate is derived from the tabular data. The heart rate is sent to the metabolic cart at 5-second intervals, it the value displayed there may be higher than in CardioSoft.

Problem: If in exercise tests with the EC1200 the stage time for the PRETEST phase is set to 0 minutes, the error message "No communication with ergometer/treadmill" appears in about every second exercise test after initiation of the modality and before the patient start pedalling. This problem only occurs with CardioSoft V4.2 (not with V4.14).

Solution:

Change the PRETEST phase of the protocol from 0 minutes to 99 minutes and select "Phase >>" when the patient start pedalling. With this method, the connection will not be interrupted.

Problem: Patient assignment problems of CardioSoft in conjunction with MASTERSCOPE V4.52?

Solution:

Mr. Eirich knew about the patient assignment problem of CardioSoft V4.14 and Masterscope V 4.52.

The problem has been resolved with CardioSoft V4.2.

Mr. Eirich only released CardioSoft V4.2 in conjunction with V4.52 and higher.

The functionality of transferring patient data from the medical reimbursement program to the JAEGER Masterscope program via CardioSoft is not implemented in V4.14 or V4.2, this functionality is implemented in CardioSoft V5.x.

Network installation using cardiouser as the domain user does not work.

What can be done?

For CardioSoft to run in the Windows2000 environment, the registered user must be a member of the local group of main users. This applies to both local users and domain users. The user must have the right to access the Cardio installation directory and the Temp directory. We assume you have verified the latter requirement. So the user rights are probably the root cause of the problem.

Log on to the CardioSoft client as the Administrator (local), add the user "?Domäne?\cardiouser" to the local user group of main users. Repeat this configuration at each CardioSoft client.

If multiple users use the CardioSoft clients, it is recommended to create a special user group for them on the domain controller and to add this user group to the local user group of main users.

To do so, expand the entry "Local users and groups" in the computer administration and click the "Groups" folder. In the window at right click "Main User". A dialog opens showing all members of the group. Clicking the "Add" button opens a second dialog "Select user or group". Select the domain from the combo box at the top. From the list box below, select the user or the group and confirm with Add. Exit with OK.

Running CardioSoft Web on Windows 2000 Domain Controller

For CardioSoft Web to run on Windows 2000 domain controllers, users IUSR_<Computer Name> and IWAM_<ComputerName> must be assigned to the group "Server Operators" after installation.

To do so open the dialog "Active Directory Users and Computers" via Control Panel, Administrative Tools. In the dialog at left, select the Domain, under Domain, on the folder "Builtin" and open the Property Dialog for the "Server Operators". Select the Members tab a add the users IUSR_<Computer Name> and IWAM_<ComputerName>.

Question: What is the meaning of the spirometry test parameters (LF501)?

SpiroSoft parameters see users manual.

Answer:

Designation of Spirometry Test Parameters CardioSoft \geq V5.x of LF501

Parameter Designation		
IVC [liters]	Inspiratory vital capacity (relaxed)	Inspiratorische Vitalkapazität
EVC [liters]	Expiratory vital capacity (relaxed)	Exspiratorische Vitalkapazität
FEVC [liters]	Forced expiratory vital capacity	Forcierte Exspiratorische Vitalkapazität
FEV1 [liters]	Volume of air exhaled during the 1st second of FEVC	Forciertes exspiratorisches Volumen in 1 Sekunde
PEF [liters/second]	Peak expiratory flow	Max. exspiratorischer Flow
MEF75 [liters/second]	Max. expired flow at 75% FEVC remaining	Forcierter max. exspiratorischer Flow bei 75% Restvolumen FEVC
MEF50 [liters/second]	Max. expired flow at 50% FEVC remaining	Forcierter max. exspiratorischer Flow bei 50% Restvolumen FEVC
MEF25 [liters/second]	Max. expired flow at 25% FEVC remaining	Forcierter max. exspiratorischer Flow bei 25% Restvolumen FEVC
MMF [liters/second]	Max. mid-expiratory flow (forced) between 25 and 75% of FEVC	Mittlerer Flow bei 25-75% FEVC
FIVC [liters]	Forced inspiratory vital capacity	Forcierte inspiratorische Vitalkapazität
FIV1 [liters]	Volume of air inhaled during the 1st second of FIVC	Forciertes inspirato- risches Volumen nach 1 s
PIF [liters/second]	Peak inspiratory flow	Max. inspiratorischer Flow
MIF75 [liters/second]	Max. inspired flow at 75% of inhaled FIVC	Forcierter max. inspirator. Flow bei 75% der inhalierten FIVC

Parameter Designation		
MIF50 [liters/second]	Max. inspired flow at 50% of inhaled FIVC	Forcierter max. inspirator. Flow bei 50% der inhalierten FIVC
MIF25 [liters/second]	Max. inspired flow at 25% of inhaled FIVC	Forcierter max. inspirator. Flow bei 25% der inhalierten FIVC
MVV [liters/second]	Maximal voluntary ven- tilation of air expired for one minute (indirect, derived from FEV1)	Maximales exspiratorisches Ventilations- Volumen pro Minute (indirekt, abgeleitet von FEV1)

Question:

What are the rules for the MILLER spirometry interpretation (LF501)?

Answer:

- 1. FEV1/IVC \geq 70% and IVCref/IVC \geq 70%
 - -> No Respiratory Problem
- 2. FEV1/IVC < 70% and IVCref/IVC < 70%
 - -> Combined Respiratory Problem
- 3. FEV1/IVC < 70% and IVCref/IVC $\ge 70\%$
 - -> Obstruction
- 4. FEV1/IVC \geq 70% and IVCref/IVC < 70%
 - -> Restriction

Question:

After installation of CardioSoft V6.x on a notebook with Windows 2000, why is the "Standby" shut-down selection no longer available?

Solution:

Two drivers of CardioSoft V6.x do not support power management and this removes the standby selection.

These two drivers must be disabled inorder to retain the standby selection.

Start Control Panel with Start -> Settings -> Control Panel.

Start Administrative Tools.

Start Computer Management.

Select Device Manager from the System Tools.

Select "Show hidden devices" from the View menu.

Select "Non-Plug and Play Drivers".

Double-click on "COR SYS" driver.

Select Tab "Driver" and change Startup Type to "disable".

Double-click on "Hardlock" driver.

Select Tab "Driver" and change Startup Type to "disable".

After reboot of the notebook, the Standby selection is available.

Question:

InSite ExC - No remote access to server

Solution:

Check if the remote servicing software "PC Anywhere" is installed on your PC. If yes, please remove.

4.2 Printer Debugging

Symptom: Windows 2000 some characters overlap the following character

Select "Start" > "Settings" > "printers" and select your Standard printer.

Solution: Select menu "File" the entry "Properties". Select "General" Tab and press button "Printing Preferences" and than press button "Advanced". In the displayed list is in the topic "Document Options" the Entry "Print Optimizations". This "Print Optimizations" must be disabled.

Symptom: **Printout incomplete**

Solution: The printer probably has insufficient memory.

Symptom: EPSON EPL-5700 does not work at the Novell server

Solution: The speed of the parallel interface in the configuration of the Epson EPL-5700 must be set on LOW.

Symptom: Laser Printer prints numbers instead of grid

Solution: There are four solutions for this issue

- a) If you work within a network installation, make sure that CardioSoft is installed on every client that want's to work with this software.
- b) Open Printer properties menue and change the printer scheduling to "Print direct .."
- c) Do the following entries to the LOC_WIN.INI, section [CARDIO]: GRA_DontRemoveGrid=1
- d) Control Panel: "Regional Options"/"General"/"Language settings for the system". The support for the following languages has to be deactivated: Arabic, Hebrew, Indic, Korean, Thai, Vietnamese. After changing these settings the system must be reboot.

Symptom: While printing a Resting ECG on an EPL5500 printer, the lettering is printed over the sheet margins

Solution: Disable the "Advanced Printing Features" under "Advanced Options" in the printer configuration menue.

Symptom: Paper out message from a laser printer is displayed delayed

Solution: You can reduce the Transmission Retry Timeout. This will decrease the delay of the displayed Paper out message, but it could case a timeout message during print of pages with noisy ECG curves.

Reduce the Transmission Retry Timeout in Windows Printer Settings

(Tab "Port", button "Configure Port...".)

4.3 General Troubleshooting

Symptom: **P2000 thermal writer printout or remote screen communication is** interrupted

Solution: Optimize the performance

Windows XP

Set Windows Effects:

- Start Control Panel with Start -> (Settings) -> Control Panel
- In Control Panel click Systems
- Choose the **Advanced** tab
- In Performance click Settings
- In the Visual Effects tab, choose Custom
- Select the following check boxes:
 - Animate windows when minimizing and maximizing
 - Smooth edges of screen fonts
 - Use common tasks in folder
 - Use drop shadows for icon labels on the desktop
 - Use visual styles on windows and buttons

Symptom: Stress test driver settings lost

Stress test profiles were changed or newly created and are no longer there

Solution: The file ERG_PROT_V5AN.DAT (ERG_PROT_ANSI.DAT old name before V4.2) in the program directory was inadvertently deleted or overwritten. A backup of this file should be made after changing profiles so that it can be restored even after a hard disk error (restore file into Windows directory).

Symptom: Defective data sets in the database

Errors occur during patient selection, but not when selecting examination options.

Solution: Contact technical support for a reorganisation tool, which may repair the error in the data base.

By activating the REORG procedure you can reorganize defective BTRIEVE files from CardioSoft. This repair procedure may become necessary when the data become damaged for some reason or another (e.g. after a power failure). To carry out the repair procedure successfully, CardioSoft must first of all be terminated. There must be sufficent memory space on your hard disk.

As a general rule, the following applies:

memory space required = twice as much free memory space as the sum of all CardioSoft files with the suffix "BTR"

The original CardioSoft files are still available in the form of "OLD" files after reorganization and should only be deleted when the reorganization has been completed successfully.

If the reorganization is unsuccessful, the only option remaining is to retrieve the latest backup data or contact technical support for the Database Repair Tool (CARD_REP).

Symptom: There are problems with my printer, since I connnected PATIENT MODULE to the system

CardioSoft normally checks all LPT ports to detect the PATIENT MOD-ULE acquisition box. If the connected printer has problems with this access and you have CardioSoft V4.14 or greater, there is a possibility to fix this problem.

Solution: Open LOC_WIN.INI and write in section [CARDIO]

WCO_CorinaLptPort=x where x is the number of the LPT Port,

PATIENT MODULE is connected to. If you define PortNo. 0, the detection for PATIENT MODULE will be disabled. This could be necessary on View and Edit stations, if there are problems with the printer after starting CardioSoft.

Symptom: Error when reading examinations, examinations get lost

Error messages when calling up examinations from the archive or examinations no longer there.

Solution: There are two causes which may lead to the loss of data on hard disks.

One is a read error on the disk, the second is the destructive influence of some viruses. Indications of a defective hard disk sometimes exhibit themselves as reading errors in certain sectors. The number of defective sectors increases with time. Such a hard disk must be replaced.

Symptom: Patient locked, although only called up from one work station

A patient in the network is locked, although they are only called up from one work station. This error occurs only occurs when the program crashes or after switching off the PC without having terminated CardioSoft beforehand.

Solution: Delete the file network.btr and station.btr in the subdirectory \database of the CardioSoft directory. Please be sure that CardioSoft is not running form any workstation.

Symptom: Monitoring stress tests

Attempt to monitor a stress test from two stations at the same time.

Solution: None! A stress test currently being performed can be monitored from one station only at any one time.

Symptom: Swapping out examinations

Almost simultaneous swap-out at several stations; examinations are destroyed.

Solution: None! Refer to Device Manual.

Symptom: Transferring examinations to data media

When an examination is transferred to another data medium, naming a subdirectory with an umlaut (ä,ö,ü...), the examination cannot be retrieved.

Solution: Create subdirectories without umlauts.

It is not possible to transfer more than 512 examinations into the root directory of a data medium as DOS is only able to manage a maximum of 512 files on this medium. If more examinations are the to transferred, a subdirectory must be created. The number of files there is practically unlimited.

Symptom: Blood pressure display cut off

In the operating modes late potentials and ergometry the blood pressure display can be cut off, especially when the diastolic value is a 3-figure number (only in the case of monitors > 17" and VGA or 800 x 600 resolution)

Solution: Select higher resolution (800 x 600 or 1024 x 768 or 1280 x 1024).

Symptom: No connection to ergometer

Stress test performed in German with EC 1200 and BD2 (BOSO), was correct. Language option French selected and start: no command sent to ergometer. Command comes only after calling up stress test a second time.

Solution: After switching to a new language option terminate the program and restart

Symptom: No connection to ergometer Ergoline 900

Solution: Use of Version "752" or "M345" with OEM 4 Buttons or Version "236"/ "436" in Program 10 with original 25 Button Ergoline.

Symptom: No RAS connection with ELSA Modem

Pulse dailing is not supported from ELSA 33.6 TQV Modem

Solution: Select Tone Dailing.

Symptom: Modem RAS connection is not started

In MUSE Settings of System Configuration of CardioSoft is activated "Start Modem connection before transfer", but the connection is not started. Please do not start manually the Modem RAS connection, when you configure that the application should start the connection.

Solution: Terminate the manually started Modem RAS connection.

Symptom: Not enough memory space when compromizing examination

When compressing examination and using a Hard Disk >4.3GB the following message will occur that less than 15% of storage medium is free.

Solution: Set the percentage of storage medium in CardioSoft

Tab "System Configuration", Button "Database" to 1 % or Disable Check of free disk space with Entry "LOG_DisableFreeCheck=1" in section "[CARDIO]" in the "LOC_WIN.INI" file.

Symptom: OS Message appears: "Adobe Acrobar Reader is not installed"

Solution: When the message appears, please install the Acrobat Reader V5.1 from the CardioSoft CD.

- 1. You must have system administrator priviliges to install the software.
- 2. Insert the CardioSoft CD in the CD ROM drive. If the CD drive does an automaitcally start up, close the CardioSoft Installation Screen.
 - Select Start > Run.
 - In the command line type X:\Disk\Setup Acrobat (X=CD ROM drive letter, e.g. "E" or "D").
 - Click OK.
- 3. Follow the displayed prompts.

Symptom: Cannot start CARDIO.exe a second time within a short period of time.

This problem may occur in a network environment, when more than one CardioSoft client is active. After closing the CardioSoft application, the CardioSoft window disappears at once, but the process CARDIO.exe may still be running for about 20 to 30 seconds. During this time span it is not possible to start CARDIO.exe again.

Solution: Make the following entry in the registry

HKEY_LOCAL_MASCHINE\Software\Btrieve Technologies\Microker-

nel Workstation Engine\Version 6.15\Settings

Delete TMP Files = 0

Symptom: "Paper Jam" error message occurs

Solution: If the P2000 is turned off after the PC boots, the error message "Paper Jam" will be shown. The only way to clear a "Paper Jam" error is by opening and closing the writer door (with power ON).

Prevention:Do not turn off the P2000 after the PC boots.

Symptom: "Lock Up" after Post Test printing to P2000 on Windows XP

Solution: During printing, an error occurs which prevents printing to P2000. A message will appear. Right-click the message and delete the print job.

Symptom: Application seems to lock up at Test End in Exercise Test.

If the database is damaged and the user initiates to store the test, there is a BTRV error message. But this error message may appear behind the acquisition window. The problem is that the user will not see the message box and for him it seems that the system locked up.

Solution: Press one of the keys ALT, ESC, RETURN. This will bring the error message into the foreground

Symptom: Application seems to lock up while printing a Post Test Report on the thermal printer

Solution: Delete the print jobs from the Marquette Thermal printer: Settings / Control Panel / Printer

4.4 System Diagnosis with Windows XP / Vista

Use the tab "Event Viewer" or "Windows Diagnostics" under Tab "Start - Programs - Administrative Tools"

4.5 Reprogramming Serial Number

Go to Service Screen and call Set CAM-USB, A/T, A/T KISS / Corina Serial Number.

The following Screen comes up. Read Acquisition System Information. Only when the Acquisition System serial number is "0" the Serial Number Programming Mode can be entered.

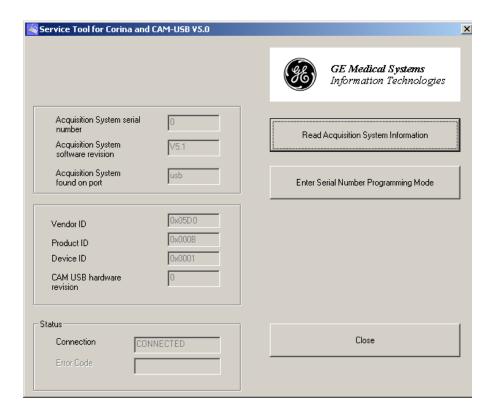


Figure 4-1:

Enter the serial number. The Serial number always starts with 101 and has 9 Digits.. Select the Target System. When the Serial number is entered correct the button Programming is enabled. Press it to program the serial number.

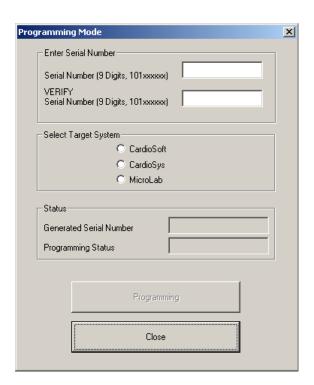


Figure 4-2:

4.6 Database Repair for CASE / CardioSoft / Card_Rep V6.x

4.6.1 General

- The Repair Tool can be used for all CASE, CardioSoft and CS versions up toV6.6. In this section the term CASE/CardioSoft will be used to cover these 4 products.
- There is no installation program. The program file CARD_REP.EXE must be manually copied into the directory where CASE/CardioSoft is installed (Program Directory). There is a choice between English or German user interface language.
- The database can be repaired, because CASE/CardioSoft stores the patient data in the header of the examination files. So with each examination file that can be successfully read from the disk, the appropriate entry can be made in the files PATIENT.BTR and EXAMINA.BTR
- The Repair Tool supports the following modalities.

 Exercise Test, Resting ECG, Ambulatory Blood Pressure, Spirometry, Archived Patient Records. The modalities from CardioSoft prior to V5, like Exercise Test, Late Potentials, STAT ECG, Right-Heart Cath. are supported also.

 Ergospirometry tests are a subset of Exercise Tests and will also be repaired.
- The Repair Tool also supports to repair the entries made from "External Programs" acquired with systems version 6.5 and later.
- It is **not** possible to repair the following entries, because the corresponding data is not stored in the examination file: Device/Cart number, Flag if the examination was sent to MUSE.
- Starting the repair is protected with a password. The valid password is the same as the password of the current day used for CASE/CardioSoft
- CARD_REP does not modify the original data from a CASE/CardioSoft database. The repaired data is stored in a temporary directory instead.
 Therefore, the person who repairs the database is responsible for determining how to continue working with the repaired data.
- After the repair is finished a protocol can be printed.

4.6.2 Directory / File Structure

4.6.2.1 CASE/CardioSoft directory structure

Desciption
Program-directory
Database-directory
Btrieve-file: Patients
Btrieve-file: Examinations
Btrieve-file: Users
Btrieve-file: Network-Stations, not used from V5 on
Btrieve-file: Network-Locking, temporary file

RESTECG R*.*	Rest ECG - directory Examinations-files
ERGOECG E*.*	Exercise Test - directory Examinations-files from CardioSoft until V4.2
AVER AC*.*	Late Potentials-directory Examinations-files
SPIR SC*.*	Spirometry - directory Examinations-files
EMECG N*.*	STAT ECG - directory Examinations-files
RHK Z*.*	Right-Heart Cath - directory Examinations-files
HOLTERBP BC*.*	Ambulatory Blood Pressure - directory Examinations-files
CAS C*.*	CASE - directory Exercise Tests
EXTPROG *.*	Directory: Results from external programs Result-files
SOUND *.*	Directory: Sound-Files from all modalities Sound-Files
ONLINE *.*	Directory: Online-Files from all modalities Online-Files
NARRATIV *:*	Directory: Configured Reports Configured Reports from all modalities

Repair workflow

Each examination is stored in a different file. This file contains the complete data testa and also the patient-demographics. To have a fast access to the patients examination, there are 2 index files. These files are the patient database (PATIENT.BTR) and the examination-database (EXAMINA.BTR). The repair works as follows:

- 1. Generate a new temporary patient database / examination database
- 2. Find first examination
 - a. Extract the patient-demographics out of the examination file
 - b. Make a new entry or update the Patient-Database
 - c. Make a new entry in the Examination-Database
 - d. Copy the examination file from the original directory to the temp. directory,
 - e. Rename the examination file according to the new internal patient-index
 - f. Find next examination
- 3. Repeat until all examination files are scanned

When the repair is done the complete data (index files + examation files) is available in the temporary directory. The result of the repair is that the index files are generate new, but the content of the examination files remain unchanged.

Example of the file structure

Examination Files

RC000001.300

P1717171	Miller	Resting	01/10/2004 - 10.14	Test-Data
CU000001.444				
P1717171	Miller	Stress	01/10/2004 - 11.26	Test-Data
CU000002.300				
P6765655	Lewis	Stress	01/10/2004 - 8.11	Test-Data
CU000003.777				
P1111111	Brown	Stress	01/10/2004 - 12.34	Test-Data

PATIENT.BTR

Patient ID	Patient Name	Patient Index
P1717171	Miller	1
P6765655	Lewis	2
P1111111	Brown	3
P2222222	Smith	4

EXAMINA.BTR

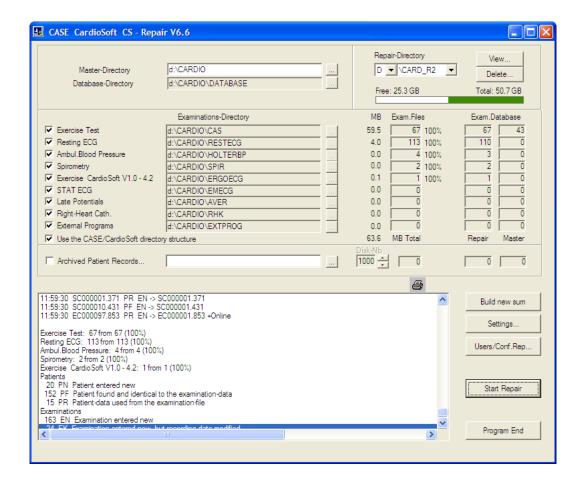
Patient Index	Modality	Recording Date
1	Resting	01/10/2004 - 10.14
1	Stress	01/10/2004 - 11.26
2	Stress	01/11/2004 - 8.11
3	Stress	01/10/2004 - 12.34

4.6.2.2 Repair directory structure

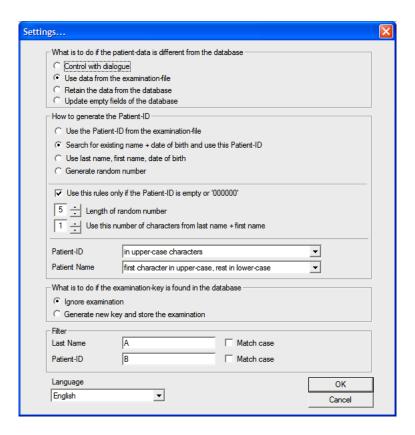
The repair directories have fix names Card_R0 ... Card_R9. Any writeable disk drive can be selected.

4.6.3 User Interface

- Select the directories where CASE/CardioSoft is installed (Program Directory).
 This is important because CARD_REP generates the directories of all modalities depending on this directory.
- Select the disk drive and the directory where all the repaired data is stored.
 Make sure that there is enough disk space.



4.6.4 Settings



Special Settings for handling the patient data

Follow these steps if the patient data stored in the examination file is different from the data stored in the database. This can occur when the patient data was modified after an examination was acquired.

- 1. Check the Patient data with a dialogue
- 2. Always use the patient data from the examination file
- 3. Always retain the patient data found in the database
- 4. Update empty fields of the database with valid entries from the examination file

Special Settings for handling the examination data

Follow these steps if the key generated on the basis of the examination file already exists in the database. This can occur when examinations from different directories are merged and several entries for one patient with the same date and time (year, month, day, hour, minute and second) are found. In reality, this will probably never occur!

- Ignore examination: The examination file will not be copied to the repair directory
- Generate new key and store the examination:
 The second of the recording time will be incremented and a new attempt is made with this modified key.

Exercise great care when using this possibility for the following reason: when Card_Rep is used more than once with the same examination files, more than one entry will consequently be found in the database.

Building the Patient ID

This setting may be helpful for tests coming from ECG devices like MAC1200, 1600, 5000, 5500 where the user did not enter a Patient ID and CASE/CardioSoft assigned all the tests to the Patient with ID 000000.

It is also possible to rebuild the whole Patient ID system by using random numbers or by using some characters from the patient's Last Name, First Name and the Date of birth.

Patient Filter

It is possible to set a filter for the patient's Last Name and Patient ID, so only patients / examinations matching this filter shall be stored in the new database. The filter specification can also include wildcards (*?). Examples:

Filter "Last Name":

Me* selects patients beginning with Me followed by any other combination

of characters

Me??? selects patients beginning with Me followed by exactly 3 other char-

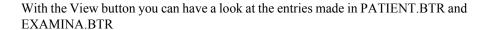
acters.

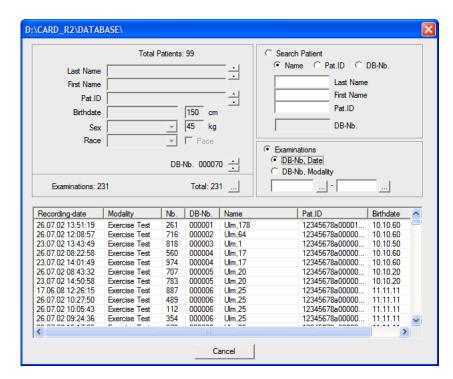
Meier selects patients with the Last Name Meier.

xyz selects patients containing the substring xyz

The specification for searching can also be extended by the property "Match case".

4.6.5 After Repair...





You can continue working with the repaired database by choosing one of the following options:

- Install CASE/CardioSoft in the temporary repair directory (c:\CARD_R0)
 Copy the file Users.Btr and the Configured Reports from the master directory to the temporary directory. (Button: Users/Conf.Rep...)
 Delete the master directory and rename the temporary directory to the master directory
- 2. Delete the content of the master directories DATABASE*.BTR RESTECG*.* ERGOECG*.* AVER*.* SPIR*.* EMECG*.* RHK*.* HOLTERBP*.* CAS*.* SOUND*.* ONLINE*.* and copy these from the temporary repair directories.
 - Copy the files Examina.Btr and Patient.Btr from the temporary database directory to the master database directory.

4.6.6 Specialities

4.6.6.1 Merging data

With Card_Rep it is also possible to merge the patient and examination data stored in different directories into one database:

- 1. Decide which database to use as the base and copy the whole directory into a repair directory (c:\Card_Rep0, ... c:\Card_Rep9)
- 2. Select the directories of the examination files to be merged.
- 3. Start Repair: the selected examinations will be merged to the repair directory.

Continue with the work described in "After Repair..." on page 4-22.

4.6.6.2 Examinations stored on external media

It is possible to regenerate the database entries for the examinations stored on external media.

However, the device where the examinations are stored must be writeable, because during the repair procedure the header of each examination file will be changed and the file will be renamed.

So before the repair is started, it is advisable to back up the directory of the externally stored examinations. This would also be helpful if the system crashes while all the files are renamed.

4.6.6.3 Examinations with full disclosure ECG

When using a directory structure not complying with the CASE/CardioSoft conventions, there may be problems with examinations that include a full disclosure ECG.

That is why Card_Rep assumes that the full disclosure files are stored in the directory ..\ONLINE which exists in parallel with the examinations. So when Card_Rep does not find such a directory, no full disclosure file will be available for these examinations.

Modalities for which full disclosure ECGs may exist are *Exercise Test, STAT ECG, Right-Heart Cath*.

Example: If you want to repair Exercise Tests, where the examinations are stored in the directory *d:\exercise*, make sure that the corresponding full disclosure files are stored in *d:\online*

4.6.6.4 Repair message codes

The following codes are used to indicate the status of the actual examination to be repaired.

English	
PN	Patient entered new
PF	Patient found and identical to the examination-data
PD	Patient found and different to the examination-data, not updated
PE	general error
PU	Patient-data different, updated by the user
PM	Patient-data different, emty fields supplemented
PR	Patient-data used from the examination-file
EN	Examination entered new
EK	Examination entered new, but recording-date modified
EF	duplicate examination-key, examination ignored
E0	Error: internal patient-number is zero
EE	general error
German	
PN	Patient neu eingetragen
PF	Patient gefunden und identisch
PD	Patient gefunden, aber unterschiedlich, kein Update
PE	Allgemeiner Fehler
PU	Patientendaten unterschiedlich, Update durch Benutzer
PM	Patientendaten unterschiedlich, leere Fehler ergänzt
PR	Patientendaten aus dem Untersuchungsfile übernommen
EN	Untersuchung neu eingetragen
EK	Untersuchung neu eingetragen aber Aufnahmedatum modifiziert
EF	doppelter Untersuchungsschlüssel, Untersuchung ignoriert
E0	Fehler: Patientennummer ist null
EE	Allgemeiner Fehler

4.6.6.5 Hidden functions

The following functions are implemented by settings in Card_Rep.ini, section [Settings] and cannot be activitated from the User Interface.

PatNameFormat1

PatNameFormat1=1

- If the length of the patient name is 2 characters: A point shall be inserted after characters
- If the length of the patient name is 3 characters and the second character is a '.'
- A point shall be set at the second and fourth position.
- Example: AN --> A.N. U,G --> U.G.

NOTE

This was implemented due a request from a customer who wanted to get his special Patient ID format uniform.

PatIdFormat1

C syntax like format string used to format numeric Patient IDs,

Range: max. 20 characters.

Default: empty

Example: PatIdFormat1="%06d"

Result: the PID has 6 characters with leading zeros

PID	New PID
457	000457
63	000063

Example: PatIdFormat1="1%06d" and NumPatIdLength=6

Result: adds one Million to the PID

PID	New PID
457	1000457
63	1000063

Example: PatIdFormat1="%d"

Result: Leading zeros shall be trimmed

PID	New PID
00457	457
63000	63000
002200	2200

PatIdFormat3

PatIdFormat3=1

Uses acquisition date and file extension to generate the Patient ID, if the items Patient ID, Last Name, First Name coming from the the examination file are empty and the acquisition date is valid.

PatIdFormat3=2

Generates a random Patient ID, if the items Patient ID, Last Name, First Name coming from the the examination file are empty and the acquisition date is valid.

Length see chapter settings

4.7 Wireless LAN

Symptom: BTRV error upon launching Cardiosoft

Explanation: Probably the connection to the network drive is disconnected when Cardio.exe is started. As a result, CardioSoft has no access to the database. Possible cause: While the system boots, WLAN is still in the initialization phase when the network drive is mapped.

Solution: Open Microsoft Explorer, click on the mapped network drive and the drive will be mapped.

Symptom: Starting CardioSoft and loading/saving examinations takes too much time when using a wireless network

Solution: Disable Power Save Mode for LAN, Wireless LAN, USB Controller

- Start Control Panel with Start -> (Settings) -> Control Panel
- In Control Panel click Systems
- Choose the **Hardware** tab
- For Device Manager select **Device Manager**
- In Device Manager expand Network adapters
- Double-click on LAN Controller
- If the **Power Management** tab is available, click on it The following check boxes should not be selected:
 - Allow the computer to turn off this device to save power
 - Allow this device to bring the computer out of standby
- In Device Manager expand Network adapters
- Double-click on Wireless WLAN Card
- In the **Property** window of the **Advanced** tab, **Disable Power Save Mode**
- In Device Manager expand Universal Serial Bus controllers
- Double-click on every USB Root Hub
- If the **Power Management** tab is available, click on it The following check boxes should not be selected:
 - Allow the computer to turn off this device to save power
 - Allow this device to bring the computer out of standby
- Reboot the PC.

4.8 Remote Servicing

NOTE

Refer to the CardioSoft Software Installation and Upgrade Guide.

For your notes

5 Supported Operating Systems

CardioSoft:

- Windows XP Professional 32-bit, Service Pack 2 & Service Pack 3
- Windows Vista Home Premium 32-bit, Service Pack 1
- Windows Vista Business 32-bit, Service Pack 1

For your notes

6 Care and Maintenance

6.1 General introduction

This test is designed to verify that the equipment and its electrical connections comply with domestic standards and are safe to use. For international electrical safety tests, refer to the internal standards agencies of the appropriate country.

GE Healthcare recommends these tests be performed:

Once every 12 months thereafter as part of a regular maintenance plan. Whenever internal assemblies are serviced.

The suggested Safety Analysis Tests refer to the international standard IEC 60601-1. The tests are generally performed with Safety Testers, on most of them, the measuring circuits according IEC 60601 are already implemented.

The following is a general description of the tests to be performed. For the handling of your Safety Tester follow the user manual.

The tests may be performed under normal ambient conditions of temperature, humidity and pressure and with line voltage.

The leakage currents correspond to 110 % of rated voltage for the tested unit. Most Safety Testers take this into account, otherwise the measured values have to be calculated.

6.1.1 Recommended Test Equipment

- Safety Tester for measurements according to IEC 60601.
- Testing connector according to the following description.

6.1.2 Leakage Current Measurement

To perform the suggested measurements, the unit under test has to be separated from any interconnection to a system. If the unit is part of a system, extended tests according to IEC 60601-1-1 have to be performed. The following diagram shows the Measuring Circuit [M] required for leakage current. The reading in mV corresponds to mA (leakage current). The Safety Testers generally work with this Measuring Circuit [M] and the displayed values are already converted to leakage current.

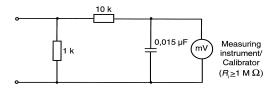


Figure 6-1:

6.1.2.1 Enclosure Leakage Current Test

This test is performed to measure leakage current from chassis to ground during normal conditions (N.C.) and single fault conditions (S.F.C.).

In all cases, the leakage current is measured from any exposed conductive parts to ground, the unit under test has to be switched on and off.

Connect the unit under test to your Safety Tester and measure with the probe to

a) CAM-USB, A/T, A/T KISS:

a foil (10 x 20 cm) wrapped around the CAM-USB, A/T, A/T KISS Interface Box

b) CORINA: the parallelport connector housing from CORINA

- During normal conditions (N.C.), referring to the electrical diagram, measurements have to be done under the following conditions:
 - Polarity switch NORM and RVS

* GND switch n/a * S1 closed

- During single fault conditions (S.F.C.), referring to the electrical diagram, the measurements have to be done under the following conditions:
 - * Polarity switch NORM and RVS

* GND switch n/a * S1 open

Test has failed if the measured values are greater than:

N.C. S.F.C 100 μA 500 μA

300 µA (U.L. requirements)

Electrical Diagram for Enclosure Leakage Current Test

Safety Tester | High | NORM/RVS | POWER CORD | UNIT UNDER TEST | | GND | GND | Probe to exposed | Chassis | Probe to exposed | Probe t

Figure 6-2:

6.1.2.2 Patient Leakage Current Test

This test performs a leakage current test under single fault conditions (S.F.C.) depending on domestic power outlet with 115 or 230 V AC as source into the floating inputs.

In all cases, the leakage current is measured from input jack of unit under test to ground.

Connect the unit under test to your Safety Tester.

- Referring to the electrical diagram, measurements have to be done under the following conditions:
 - * Polarity switch NORM and RVS
 - * GND switch GND closed
 - * S1 closed

Test has failed if the measured values are greater than 50 μ A.

Electrical Diagram for Patient Leakage Current Test

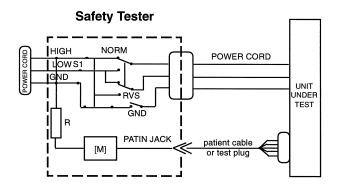


Figure 6-3:

For protection of the test person, the following values of resistor R may be used:

Typ CF 100 kOhm (220 to 240 V)

6.1.2.3 Enclosure Leakage Current Test (System)

CAUTION

Do not operate devices (PC / VGA Monitor / Printer / ...) in the vicinity of the patient (as defined in IEC 60601-1-1), if they do not fulfil the requirements of IEC 60601-1!

All units connected to the CardioSoft system (PC / VGA Monitor / Printer / ...) have to be tested as follow.

Connect all power cords from the units separately for test to your Safety Tester.

 During single fault conditions (S.F.C.), referring to the electrical diagram, the measurements have to be done under the following conditions:

Polarity switch NORM and RVS

* GND switch GND open * S1 closed S.F.C 500 µA

Electrical Diagram for Enclosure Leakage Current Test

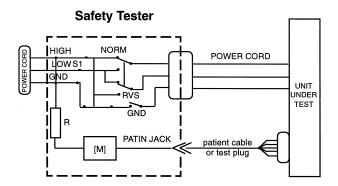


Figure 6-4:

6.1.2.4 Protective Earth Resistance Test

The power cord is to be included in the protective earth resistance test. This test determines whether the device has a power ground fault.

- The protective earth resistance from power connector to any protective earth connected exposed conductive part is measured.
- Specs. of test circuit: AC current source 50 Hz/60 Hz of at least 10 A up to 25 A with limited output voltage of 6 V.
- If resistance is greater than 100 mOhm, the unit fails this test.

7 Specifications

7.1 Technical Specifications for CAM-USB, CAM-USB A/T, CAM-USB A/T KISS and CAM-14

Table B-1. Performance Specifications - Data Acquisition		
Item	Description	
Technology	Active, "Type BF" floating isolated powered 14 channel acquisition module with built-in lead-fail detection and lead prep impedance measurement	
Sampling rate	Over-sampling @ 4000 Hz, 12 leads	
Dynamic range	320 mV, ±10 mV signal superimposed on ±150 mV DC offset	
Resolution	4.88 μV/LSB @ 500 Hz	
Noise	< 15 µV peak-to-peak noise over 0.1 to 150 Hz (-3 dB) bandwidth	
Frequency response	-3dB, display and writer	
High pass filter	0.01 Hz (or 0.05 Hz, special use) with DC offset control measured with enhanced measurement methods 0.1 Hz measured according to YY 1139-2000 "Single and Multichannel Electrocardiograph"	
Common mode rejection	Measured: 100 dB, calculated: > 140 dB (123 dB with AC filter disabled)	
Input impedance	$> 10 \text{ M}\Omega$ @ 10 Hz, defibrillator protected	
Pace detect	Orthogonal LA, LL, and V6; 750 μV @ 50 μs, Software corrected	

Table B-2. Physical				
Item	CAM-USB	CAM-USB A/T	CAM-USB A/T KISS	CAM-14
Height	33 mm	45 mm	45 mm	27 mm
Width	155 mm	187 mm	187 mm	125 mm
Depth	95 mm	138 mm	138 mm	95 mm
Weight	525 g	703 g	913 g	180 g
Interfaces included	USB V1.1	USB V1.1	USB V1.1	Proprietary

Table B-3. Safety		
Item	Description	
Certification	 UL 2601-1 classified UL classified for CAN/CSA C22.2 No. 601.1 CE marking for Council Directive 93/42/EEC concerning Medical Devices Meets applicable AAMI EC-11 requirements 	
Type of protection against electrical shock	Class 2	
Degree of protection against ingress of liquids	Ordinary	
Handling of disposable supplies and other consumables	 Use only parts and accessories manufactured or recommended by GE Healthcare. Follow manufacturerfs instructions for use for disposable/consumable product. Follow local environmental guidelines concerning the disposal of hazardous materials. 	
Patient mode of operation	Continuous	
Patient leakage current	<10 μΑ	
Degree of protection against electrical shock	Type BF defibrillation protection for the patient cable (acquisition module)	
Maintenance frequency	 Recommended user daily visual inspection and cleaning. Recommended six-month routine maintenance checks and test procedures performed by qualified technical personnel. 	

Table B-4. Environmental		
Item	Description	
Operating conditions Temperature Humidity Pressure	+10 to + 40° C (+50 to 104° F) 25 to 95% RH non-condensing 700 to 1060 hPa	
Storage/Transport conditions Temperature Humidity Pressure	-30 to +70° C 10 to 95% RH non-condensing 500 to 1060 hPa	

Table B-5. Power Requirements		
Item	Description	
CAM-USB	+5 V DC, max. 500 mA, USB-powered	
CAM-USB A/T	+12 V DC, max. 1 A by external power supply	
CAM-USB A/T KISS	+12 V DC, max. 2 A by external power supply	

7.2 Electromagnetic Compatibility of CAM-USB, CAM-USB A/T and CAM-USB A/T KISS

CAM-USB means CAM-14 aquisition module and CAM-USB interface box

CAM-USB A/T means CAM-14 acquisition module, CAM-USB A/T interface box and power supply AM-USB A/T KISS means CAM-14 acquisition module, CAM-USB A/T KISS interface box and power supply

Changes or modification to this system not expressly approved by GE Healthcare could cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulation regarding EMC and needs to be installed and put into service according to the EMC information stated as follows.

WARNING

Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

WARNING

The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR11	Group 1	The equipment 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 CISPR11	Class B	The equipment is suitable for use in all
Harmonic Emissions IEC 61000-3-2	not applicable	establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings
Voltage fluctuations/Flicker emissions IEC 61000-3-3	not applicable	used for domestic purposes.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The CAM-USB / CAM-USB A/T / CAM-USB A/T KISS is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the CAM-USB / CAM-USB A/T / CAM-USB A/T KISS 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	± 2 kV for power supply lines ±1 kV for input/output lines	not applicable ±1 kV for input/output lines	Mains power should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	not applicable not applicable	Mains power 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% Ut (>95% dip in Ut) for 0.5 cycles 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 s	<5% Ut (>95% dip in Ut) for 0.5 cycles 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 s	Mains power should be that of a typical commercial or hospital environment. If the user of the CAM-USB / CAM-USB A/T / CAM-USB A/T KISS requires continued operation during power mains interruptions, it is recommended that the CAM-USB / CAM-USB A/T / CAM-USB A/T KISS be powered from an uninterruptible 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 characteristics of a typical location in a typical commercial or hospital environment.

NOTE:

Ut is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CAM-USB / CAM-USB A/T / CAM-USB A/T KISS is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to assure that the CAM-USB / CAM-USB A/T / CAM-USB A/T KISS is used in such an environment.

Immunity Test	IEC 60601- test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V _{ms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V _{rms} 3 V/m	Electromagnetic environment — guidance Portable and mobile RF communications equipment should be used no closer to any part of the CAM-USB / CAM-USB A/T / CAM-USB A/T KISS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1, 17\sqrt{P}$ $d = 1, 17\sqrt{P}$ $d = 1, 17\sqrt{P}$ 80 MHz to 800 MHz $d = 2, 33\sqrt{P}$ 800 MHz to 2,5 GHz where \mathbf{P} is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and \mathbf{d} is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.
			Interference may occur in the vicinity of equipment marked with the following symbol: (((•)))

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- a 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 CAM-USB / CAM-USB A/T / CAM-USB A/T KISS is used exceeds the applicable RF compliance level above, the CAM-USB / CAM-USB A/T / CAM-USB A/T KISS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CAM-USB / CAM-USB A/T / CAM-USB A/T KISS.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

The table below provides the recommended separation distances (in meters) between portable and mobile RF communication equipment and the CAM-USB / CAM-USB A/T / CAM-USB A/T KISS.

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

	Separation Distance in Meters (m) According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter in Watts	150 kHz to 80 MHz $d = 1,17\sqrt{P}$	80 MHz to 800 MHz $d = 1, 17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2, 33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			

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.

NOTE:

These guidelines may not apply in all instances. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Compliant Cables and Accessories

WARNING

The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

The table below lists cables, transducers, and other applicable accessories with which GE Healthcare claims EMC compliance.

NOTE:

Any supplied accessories that do not affect EMC compliance are not included.

Part No	Description
420101-001	14 leadwire set

7.3 Technical Specifications CORINA

7.3.1 ECG Signal Processing

Continuous acquisition of the ECG signal, formation of lead II which is transmitted to signal output [symbol]

- lower cut-off frequency (-3-dB limits) 0.08 Hz
- upper cut-off frequency (-3-dB limits) 150 Hz
- resolution, referred to the input, 20 μV
- gain x 1000
- non-linear distortion better than specified in IEC and AHA recommendations
- noise of signal transmission path below values specified in IEC and AHA recommendations: <2.5 μV rms
- common-mode rejection better than specified in IEC and AHA recommendations
- electrode connections for R, F, N
- input impedance for differential signals between any two electrode connections > 50 M Ω at 10 Hz
- dynamic range for differential signals between any two electrode connections for AC voltage ±10 mV, for superimposed DC voltage (polarization voltage) ±600 mV
- patient leakage current (rms values) according to IEC, class CF: in normal condition < 10 μA, in single-fault condition (e.g. patient in contact with line voltage) < 50 μA
- suppression of pacer pulses, detection via F electrode
- non-destructive range for lead-electrode connections and the neutral electrode connection referred to chassis (either polarity, e.g. defibrillation) 1500 V

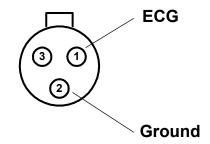
7.3.2 Analog Output Data

Important: ECG signal output to synchronize ultrasound units (output signal not suitable for ECG analysis or therapeutic purposes!)

- lead II standard (configurable with CardioSoft V 3.0 and later)
- ECG lead selectable (from CORINA & CardioSoft Version V3.0)
- floating output (± 1500 V referred to ground / chassis)
- 1-V output signal per 1-mV input signal, Umax = \pm 10 V
- DC offset over the entire range < 300 mV (typically, full deflection)
- amplitude accuracy over the entire range (typically) < 3%
- RL min 2kOhm
- delay < 10 ms
- pacing pulse filtered out
- raw signal, unfiltered, no ADS
- short-circuit-proof

7.3.3 Signal Output

Insulated ECG signal output, 1 V (floating output)



pin assignment

1 = signal output

2 = zero

3 = not assigned

 output voltage +10 V +5% minimum load 2 kOhms max. output current 5 mA delay input/output <10 ms

7.3.4 Power Supply

From plug-in power supply unit type SW 172 supplied with the system

- design in compliance with protection class II
- rated voltage range 230 to 240 V AC / 100...250 V (SW 172)
- operating voltage range 207 to 264 V, 50 Hz / 90 V to 265 V, 50 60 Hz (SW 172)
- rated current 0.22 A
- power consumption, typically w/o. pump 6 W, with pump 9 W, 15 W max.
- with Analog Out, typically, w/o. pump 7,5 W, with pump 16,5 W max.

7.3.5 Environment

Operation

- ambient temperature between +10 and +40 °C
- rel. humidity between 30 and 75%
- atmospheric pressure between 700 and 1060 hPa

Storage and Transport

- ambient temperature between -30 and +60 °C
- rel. humidity between 10 and 90 %
- atmospheric pressure between 500 and 1060 hPa

Dimensions and Weight

_	length	400 mm
_	depth	200 mm
_	height	48 mm

weight w/o. pump 700 g

900 g with pump

7.3.6 Grounding

Grounding of intermediate circuit for interference elimination (to potential equalization system or water pipe)

Electromagnetic Compatibility of CORINA 7.4

Changes or modification to this system not expressly approved by GE Healthcare could cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulation regarding EMC and needs to be installed and put into service according to the EMC information stated as follows.

WARNING

Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

WARNING

The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

Guidance and Manufacturer's Declaration -**Electromagnetic Emissions**

Emissions Test	Compliance	Electromagnetic Environment – Guidance	
RF emissions CISPR11	Group 1	The equipment 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 CISPR11	Class B	The equipment is suitable for use in all	
Harmonic Emissions IEC 61000-3-2	not applicable	establishments including domestic establishments and those directly connected to the public low- voltage power supply network that supplies buildings	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	not applicable	used for domestic purposes.	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The CORINA is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the CORINA 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	± 2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power supply lines not applicable	Mains power should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power 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% Ut (>95% dip in Ut) for 0.5 cycles 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 s	<5% Ut (>95% dip in Ut) for 0.5 cycles 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 s	Mains power should be that of a typical commercial or hospital environment. If the user of the CORINA requires continued operation during power mains interruptions, it is recommended that the CORINA be powered from an uninterruptible 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 characteristics of a typical location in a typical commercial or hospital environment.

NOTE:

Ut is the AC mains voltage prior to application of the test leve

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CORINA is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to assure that the CORINA is used in such an environment.

Immunity Test	IEC 60601- test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the CORINA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V _{ms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	10 V _{rms}	Recommended separation distance: $d=0,35\sqrt{P}$ $d=1,17\sqrt{P} 80 \text{ MHz to } 800 \text{ MHz}$ $d=2,33\sqrt{P} 800 \text{ MHz to } 2,5 \text{ GHz}$ where $\textbf{\textit{P}}$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $\textbf{\textit{d}}$ is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- a 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 CORINA is used exceeds the applicable RF compliance level above, the CORINA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CORINA.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended Separation Distances

The table below provides the recommended separation distances (in meters) between portable and mobile RF communication equipment and the CORINA.

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

	Separation Distance in Meters (m) According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter in Watts	150 kHz to 80 MHz $d = 0, 35\sqrt{P}$	80 MHz to 800 MHz $d = 1, 17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2, 33\sqrt{P}$
0.01	0.035	0.12	0.23
0.1	0.11	0.37	0.74
1	0.35	1.17	2.33
10	1.1	3.7	7.37
100	3.5	11.7	23.3
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			

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.

NOTE:

These guidelines may not apply in all instances. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Compliant Cables and Accessories

WARNING

The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

The table below lists cables, transducers, and other applicable accessories with which GE Healthcare claims EMC compliance.

NOTE:

Any supplied accessories that do not affect EMC compliance are not included.

Part No	Description
223 418 XX	Patient trunk cable, 10-lead
384 018 08 / 09	Set of 10 leadwires

8 Spare Parts

8.1 CAM-USB

Introduction

The parts lists and assembly drawings in this chapter supply enough detail for you to order parts for the assemblies considered field serviceable.

If you require additional information, schematic diagrams, or troubleshooting assistance, contact Technical Support.

Hardware		
Part Number	Item	
2009000-001	CAM-USB Interface	

CAM-14 Modules		
Part Number	Ite	em
901142-005	KIT CAM 14 Stress	AHA W/O cable
901142-008	KIT CAM 14 Stress	IEC W/O cable

Spare Parts		
Part Number	Item	
2008614-003	FRU CABLE USB TYPE A TO B 2M	
2016560-005	FRU CABLE ASSY HOST CASE	
801280-001	CAM-14 V1 PWA (obsolete)	
2028778-001	CAM-14 V2 PWA	
900995-002	CAM-14 V2 Assembly	

8.2 CAM-USB A/T

Hardware		
Part Number	Item	
2009500-001	CAM-USB Interface A/T	
2024264-001	PWR SPLY SW 30W 12VDC/2.5A MEDICAL	

Spare Parts		
Part Number	Item	
2011185-001	PCB INTFC CAMUSB EXT	
2008614-003	FRU CABLE USB TYPE A TO B 2M	
2016560-005	FRU CABLE ASSY HOST CASE	
2009589-001	CASING PLASTIC CAM-USB A/T W/O LABELS	

8.3 CAM-USB A/T KISS

Hardware		
Part Number Item		
2009500-009	CAM-USB INTERFACE A/T KISS	
2024264-001	PWR SPLY SW 30W 12VDC/2.5A MEDICAL	

Spare Parts	
Part Number	Item
2011185-001	PCB INTFC CAMUSB EXT
2008614-003	FRU CABLE USB TYPE A TO B 2M
2016560-005	FRU CABLE ASSY HOST CASE
2009589-005	CASING PLASTIC CAM-USB A/T KISS W/O LABELS
2025950-001	ASSY KISS PUMP CAM-USB INTERFACE A/T

8.4 CORINA

NOTE

The CORINA acquisition module is not for use in the U.S. and Canada.

Power Supply	
Part Number	Item
2000300-001	Power Supply 12V - Table Version with International Main Power Input Connector

Housing	
Part Number	Item
43252221	Lower Shell
43252261	Upper Shell
90227200	Shield and insulation tube
43252231	Connection Panel Patient Input
43252223	Fiber optic
92916645	Luer connection kit (female)
92916648	Nut
92916654	Filler cap

PC-Connection cable	
Part Number	Item
2001934-001 or 2009877-001	Connection Cable to PC for CORINA 10111831 38 only for CORINA up to Rev. F
2024996-001	CABLE ASSY INTCON CORINA TO PC for CORINA 1011183138 Rev. G and higher
91541779	PANEL PLUG
91541780	PLUG HOUSING

Pump	
Part Number	Item
30344291	Pump 12 V (Standard)
30344485	Pump for Corina with Analog output

CORINA1011183132 (only for CardioSoft Version starting from V4.14)	
Part Number	Item
2002899-001	PCB CORINA only for CORINA up to Rev. F
2002980-001	Exchange PCB CORINA only for CORINA up to Rev. F
2024804-001	PCB CORINA for CORINA Rev. G and higher
2024804-004	Exchange PCB CORINA for CORINA Rev. G and higher

CORINA 1011183338 (only for CardioSoft Version starting from V4.14)	
Part Number	Item
2002899-002	PCB Corina Analog Output only for CORINA up to Rev. F
2002981-001	Exchange PCB Corina Analog Output only for CORINA up to Rev. F
2024807-001	PCB CORINA ANALOG OUT for CORINA Rev. G and higher
2024807-005	Exchange PCB CORINA ANALOG OUT for CORINA Rev. G and higher

8.5 KISS Module

Dongle	
Part Number	Item
2042109-500	KISS Multilead

8.6 Dongle CardioSoft Client and Web Server

Dongle	
Part Number	Item
2021721-002	Dongle USB Client
2026115-002	Dongle USB Server
45110401	Print Port Dongle

8.7 CardioSoft CDs

Software	
Part Number	Item
2006301-025	CD CardioSoft V6.6
2042486-001	CD CASE/CardioSoft/CS InSite ExC V1.0
2043133-001	CD Adobe Reader V8/International

8.8 TONOPORT V/EasyOne-CS

Hardware	
Part Number	Item
2001762-100	System Tonoport V / ABP Measurement
2030430-100	EasyOne-CS / Spirometer

8.9 Cables

Cables	
Part Number	Item
700609-002	Treadmill Cable

For your notes





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