

CardioSoft

Service Manual

Version V5.1

2014708-001

Revision D



GE Medical Systems
Information Technologies

gemedicalsystems.com

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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 2014708-001 | | |
|--|------------------|---|
| Revision | Date | Comment |
| A | 08 August 2003 | Initial release of CardioSoft Service Manual. |
| B | 11 October 2003 | ECO 075137 |
| C | 13 April 2004 | ECO 075827 |
| D | 06 December 2004 | ECO 079240 |

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 Medical Systems *Information Technologies* 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 Medical Systems *Information Technologies*.
- 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 Medical Systems *Information Technologies* 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 601 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 ACCESSORY equipment 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.

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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 of 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



ATTENTION: Consult accompanying documents.

In Europe, this symbol means dangerous or high voltage. In the United States, this symbol represents the CAUTION notice.



Type CF defibrillation proved.



Type BF equipment, external defibrillator protected.



Power switch (ON - OFF)



Equipotential



Signal input



Signal output



Fuse



On/Standby



Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical and other specified hazards, only in accordance with UL 2601-1, CAN/CSA C22.2 No. 601.1, IEC 60601-1, and, if required, IEC 60601-2-27, IEC 60601-2-30, IEC 60601-2-34, IEC 60601-1-1.

1.5 Service Information

1.5.1 Service Requirements

Follow the service requirements listed below.

- Refer equipment servicing to GE Medical Systems *Information Technologies*' 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 Medical Systems *Information Technologies* 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 5.x
To run CardioSoft properly the screen resolution must be set to 1024 by 768 pixels with 65536 (64 k) colors.

Note: Only CORINA Models 101 118 31...34 and 37/38 (OEM) are supported by CardioSoft 5.x. When using the new modles, you can also use the new Power Supply SW 172 (or as default the FW 7324/2 Power Supply).

2.1.1.1 Installation in the network

CAUTION: Connect to the network with the delivered Transceiver, do not plug in direct in the network card!

Network Configuration

To communicate with a MUSE server (Version 5.0a) 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/CardioSys/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.

2.1.1.1.1 Network environment: Domain

A Setup Domain User

One of the following criteria must be met:

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

NOTE: Typically, the Domain Administrator must do this step

2. An existing domain user account from the NT/Win2000 domain where the CardioSoft server resides or an existing domain user from an NT/Win2000 domain that has a trust relationship with the NT/Win2000 domain where the CardioSoft server resides is designated as the Network User 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:

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/CardioSys/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/CardioSys/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/CardioSys/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 Add CardioSoft station to NT/Win2000 Domain

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

XP: Control Panel->System->Computer Name
Win2000: Settings->Control Panel->System->Network Identification
->Properties
NT/ME: Settings->Control Panel->Network->Identification

3. Reboot

D Configure Network User on CardioSoft station (not for ME)

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

XP: Control Panel->Administrative Tools->Computer Management
->SystemTools->Local Users and Groups->Groups
->Administrators->Properties

Win2000: Settings->Control Panel->Users and Passwords

NT: Programs->Administrative Tools->User Manager

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

E Running CardioSoft as User~

To run Cardiosoft as User several settings has to be changed.

1. Windows 2000

Log on as Administrator.

Run Cardio.exe at least once that the Registry entries for Btrieve Teehnologies appears in the Registry.

Make the following changes in the registry (use regedt32.exe):

Change security settings for key

HKEY LOCAL MACHINE\Software\Btrieve Technologies
set permissions for Group "Users" to full control.

Change the value for the key

*HKEY LOCAL_MACHINE\Software\Btrieve Technologies\Microkernel
Workstation Engine\Version6.15\Settings\TraceFile*
from C:\WINNT\MKDEWE.TRA to C:\CARDIO

Change the value for the key

*HKEY_LOCAL_MACHINE\Software\Btrieve Technologies\Microkernel
Workstation Engine\Version6.15\Settings\Home Directory*
from C:\WINNT to C:\CARDIO

Change security settings for

| | |
|---------------------|---|
| C:\WINNT | add permission write for Group "Users" |
| C:\WINNT\WTN.INI | add permission full control for Group "Users" |
| C:\WINNT\CA_SYS.INI | add permission full control for Group "Users" |
| C:\WINNT\CARDIO.INI | add permission full control for Group "Users" |

2. Windows XP

Log on as Administrator.

To log on as Administrator press [CTRL] + [ALT] + [DEL] twice to get the log on screen. Run Cardio.exe at least once that the Registry entries for Btrieve Technologies appears in the Registry.

Make the following changes in the registry (use: regedt32.exe):

Change security settings for key

HKEY_LOCAL_MACHINE\Software\Btrieve Technologies
set permissions for Group “Users” to full control.

Change the value for the key

*HKEY_LOCAL_MACHINE\Software\Btrieve Technologies\Microkernel
Workstation Engine\Version6.15\Settings\TraceFile*
from C:\Windows MKDEWE.TRA to C:\CARDIO

Change the value for the key

*HKEY_LOCAL_MACHINE\Software\Btrieve Technologies\Microkernel
Workstation Engine\Version6.15\Settings\Home Directory*
from C:\Windows to C:\CARDIO

Change security settings for files and directories.

*If the explorer does not show the security tab then go to the explorer menue
Tools ⇒ FolderOptions ⇒ View and
uncheck “Display simple folder view in Explores Folder list”.*

| | |
|-------------------------|---|
| C:\Windows | add permission write for Group Users“ |
| C:\Windows \WIN.INI | add pennission full control for Group “Users” |
| C:\Windows \CA_ SYS.INI | add permission full control for Group “Users” |
| C:\Windows \CARDIO.INI | add pennission full control for Group “Users” |
| C:\Cardio | add pennission full control for Group “Users” |

F Merge database (see also diagram, page 2-9)§

1. Login as the designated Network User.

Select the following criteria and perform the according steps:

New CardioSoft-Server:

Local CardioSoft station with existing examinations:

Merge local database to CARD_R0:

Map drive letter to “DB_Merge” (e.g. x:\). 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/CardioSys/CardioSoft has been merged:

Copy merged database to server database:

Map drive letter to “cardio” (e.g. f:\)

Map drive letter to “DB_Merge” (e.g. x:\)

Copy contents of x:\CARD_R0 to f:\
Empty x:\CARD_R0

Existing CardioSoft-Server:

Local CardioSoft station with existing examinations:

Merge local database to CARD_R0:

Map drive letter to “DB_Merge” (e.g. x:\). 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/CardioSys/CardioSoft has been merged:

Merge old server database to CARD_R0:

Map drive letter to “DB_Merge” (e.g. x:\)

Map drive letter to “card_old” (e.g. y:\)

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. f:\)

Copy contents of x:\CARD_R0 to f:\.

Empty x:\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.

G **Install CardioSoft Application Software**

1. Login as Local Administrator.
2. Map the next available drive letter to the “cardio” share 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 setup.exe in directory Disk1 (“e:\Disk1\setup”).
4. At the Choose Destination Location screen, select Browse... and browse to the root folder of the network drive that was just mapped to the CardioSoft server.
5. Verify the “Path” edit box value is the root folder of the mapped network drive, e.g., f:\.
6. 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 2-9)

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/CardioSys/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/CardioSys/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/CardioSys/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.
2. Change the workgroup name to the workgroup name of the CardioSoft server.
XP: Control Panel->System->Computer Name
Win2000: Settings->Control Panel->System->Network Identification

->Properties

NT/ME: Settings->Control Panel->Network->Identification

3. Reboot

D Configure Network User on CardioSoft station (not for Windows ME)

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 administrator group.

XP: Control Panel->Administrative Tools->Computer Management
->SystemTools->Local Users and Groups->Groups
->Administrators->Properties

Win2000: Settings->Control Panel->Users and Passwords

NT: Programs->Administrative Tools->User Manager

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

E Merge database (see also diagram, page 2-9)

1. Login as the new user.

Select the following criteria and perform the according steps:

New CardioSoft-Server:

Local CardioSoft with existing examinations:

Merge local database to CARD_R0:

Map drive letter to "DB_Merge" (e.g. x:\). 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/CardioSys/CardioSoft has been merged:

Copy merged database to server database:

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

Map drive letter to "DB_Merge" (e.g. x:\)

Copy contents of x:\CARD_R0 to f:\

Empty x:\CARD_R0

Existing CardioSoft-Server:

Local CardioSoft with existing examinations:

Merge local database to CARD_R0:

Map drive letter to "DB_Merge" (e.g. x:\). 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/CardioSys/CardioSoft has been merged:

Merge old server database to CARD_R0:

Map drive letter to “DB_Merge” (e.g. x:\)

Map drive letter to “card_old” (e.g. y:\)

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. f:\)

Copy contents of x:\CARD_R0 to f:\.

Empty x:\CARD_R0.

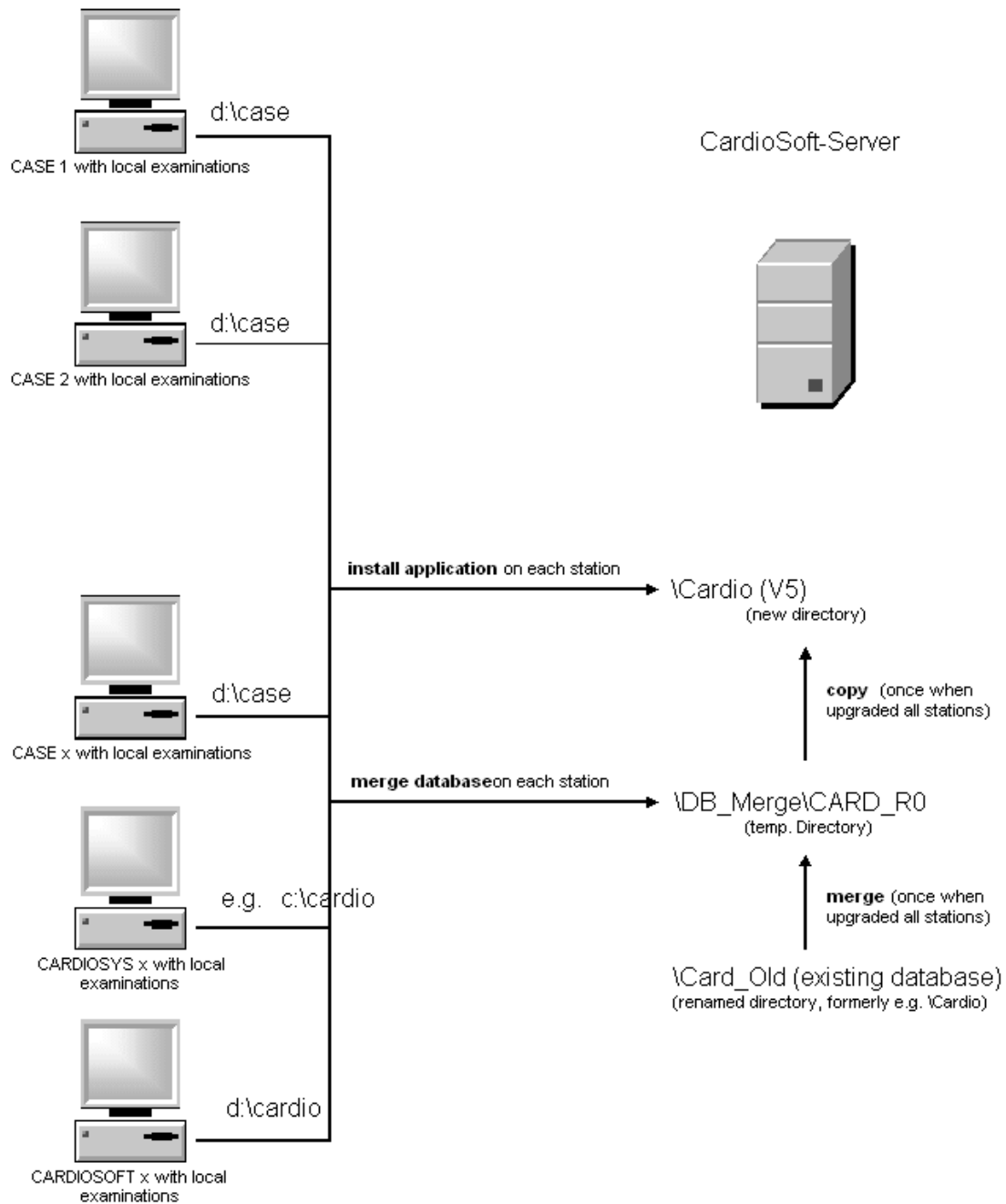
Note: Local users and the configured reports will not be merged automatically by CARD_REP. If you want to take the users and the configured reports from a special station, press the button “Users/Conf.Rep” to copy the files from the local database to the corresponding repair directory.

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 on the CardioSoft server. **Note:** Make sure the “Reconnect at login” box is checked.
3. Begin the installation of the CASE application (appropriate CD-Drive): If the installation does not start automatically (wait some seconds), launch setup.exe in directory Disk1 (“e:\Disk1\setup”).
4. At the Choose Destination Location screen, select Browse... and browse to the root folder of the network drive that was just mapped to the CardioSoft server.
5. Verify the “Path” edit box value is the root folder of the mapped network drive, e.g., f:\.
6. Finish the installation and reboot the system as prompted.

Merging Databases with Card_Rep-Tool



2.1.1.2 Installation of CardioSoft Web on a Web Server

Do following steps to install CardioSoft Web:

1. Installation of Microsoft Information Server
2. Installation of CardioSoft Web
3. Installation on Workstation

Installation of CardioSoft Web on a Windows Server running Internet Information Server (IIS)

It is assumed that Windows Server and IIS (IIS from Windows Server CD) is already installed.

Install CardioSoft Web with the description of topic “Installation of CardioSoft Web”.

Set the location of the CardioSoft Database through the following entry in the section [Cardio] of the file win.ini.

```
CFG_ProgDir=<DriveLetter>:\<path>      ( c:\cardio)
or
CFG_ProgDir=\\<machine>\<share>\<path>(\\mhd\Csys42\CardioSoft)
```

Use Microsoft Management Console (MMC) to configure the CardioSoft Web Site.

To run CardioSoft Web on the **Default Web Site** allowing anonymous access, set up a virtual directory “scripts” to the path InetPub\scripts under Default Web Site. (Use MMC).

To run CardioSoft Web on a **separate Web Site**, set up a new web site. Under this new web site set up a virtual directory named scripts. Set the local path for this directory to \InetPub\scripts.

Setting access and authentication control for the web site:
Select the web site properties. Select tab directory security.
Edit authentication methods. Check Allow Anonymous Access to allow all users to establish a web (HTTP) connection to this web site.
Check Basic Authentication to limit access to the web site. During the basic authentication process the user has to enter a valid Windows account user name and password.
Setup Windows user account using the User Manager.

To identify a web site on a server hosting several web sites, either the IP address, Port or Host Header Name must be unique.
A host header name is an additional name for the same IP address. The host header name is transmitted to the IIS in the request header.

CardioSoft and CardioSoft Web uses Btrieve for Windows MicroKernel engine W32MKDE.EXE (standalone workstation implementation).
If there is an Installation of Btrieve for Windows (Server Edition) on the Windows Server the MicroKernel engine NTMKDE.EXE is used to access the database files. This causes problems if the database is on a remote machine not running a server engine. In this case the MicroKernel is not able to access the remote files. To solve this problem set the target engine to workstation using the BTI Database Setup Utility.

Installation of CardioSoft Web

1. Install CardioSoft on the PC. Install the Hardlock. Start CardioSoft. Enter the "CWEB" Software Option Code in System Configuration Tab "Option Code". Set in System Configuration Tab "Country Settings" the language field, Time Format field, Date Format field and ST Level field. CardioSoft Web uses the database in which CardioSoft is installed (see field "CFG_ProgDir" in section "[CARDIO]" in file WIN.INI).

Example: If you start CardioSoft and "Btrieve Error 20" is displayed, please change the following registry entries:

Entry "HKEY_LOCAL_MACHINE\SOFTWARE\Btrieve Technologies\Microkernel Engine\Version 6.15\Microkernel Interface\Settings\Target Engine" set to 0 value.

Entry "HKEY_LOCAL_MACHINE\SOFTWARE\Btrieve Technologies\Microkernel Workstation Engine\Version 6.15\Microkernel Interface\Settings\Local" set to 1 value.

Entry "HKEY_LOCAL_MACHINE\SOFTWARE\Btrieve Technologies\Microkernel Workstation Engine\Version 6.15\Microkernel Interface\Settings\Requester" set to 1 value.

Entry "HKEY_LOCAL_MACHINE\SOFTWARE\Btrieve Technologies\Microkernel Workstation Engine\Version 6.15\Settings\File Sharing On Local Drives" set to 1 value.

2. Install CardioSoft Web in the created directory "\InetPub" and go to topic "Installation on the Workstation".

Installation on the Workstation

1. Check that Internet Explorer V 6.0 or higher is installed.
2. Client Workstation Settings: Check the Proxy Settings of the Internet Explorer (Control Panel -> Internet Options -> Connections -> LAN Settings). If "Use Proxy Server" is activated then press "Advanced..." button and enter at Field "Do not use proxy server for addressing beginning with" the Computer Name of the Web Server. If "Use Proxy Server" is activated then activate "Bypass proxy server for local addresses".
3. Start on Client Workstation the Internet Explorer and enter the www address "<Computer Name>/CardioSoftWeb/CardioSoftWebHome.htm".

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 send from MicroSmart/MAC 500, CardioSmart/MAC 1000, MAC1100/1200 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:

1. 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 al received examinations, regardless of different patient demographic data. From V5.1 the default behaviour is different: examinations that have the same patient ID as stored on the local network server but different demographic data (last name, first name, date of birth), 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 insensitive, 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 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 Windows-Directory. Procedure Setups will be stored in CARDIO.INI. General settings will be stored in CA_SYS.INI and could be exported to floppy disc. Special service settings are stored in 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 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 WIN.INI

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

Description of the CARDIO section in the WIN.INI File

Font entries, full screen, 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 marquette CardioSoft // Product name for CardioSoft
               GE marquette MicroLab // Product name for MicroLab
```

```
CFG_CorinaTime = 5
```

```
CFG_Abcux = 2977 // 2978 or entry not available: USA version
               // 2977: international version
```

CAUTION: If the file 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.

```
INST_DevType=0 // Device Type is set from the Installation Program
               // 0: CardioSoft (is default if value not present)
               // 1: CardioSoft
               // 2: MicroLab
               // 3: CASE
```

```
RES_ShowQTDispTable=? // Range of values: 0..1 Default: 1
                      // Meaning: Output of the QT 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

GRA_PropSheetY = 100 // Default: 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

Some printer drivers have problems with aborting the print job. A separte program CancelPr.Exe can be used to improve this behaviour.

GRA_DontRemoveGrid = 0 // Range of values 0..1 Default = 0

When CardioSys is closed before all print layouts are finished, there may be problems with the grid. Setting this value to 1 causes the grid-font not to be removed when CardioSys is closed.

CAMUSB_ImpedanceSlape = 115 // Meaning: for Impedance Measurement

CAMUSB_ImpedanceIntercppt = 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

[CARDIO] // Range of values 0..1 Default : 0

Mai_MoveMainWindow=0

// Meaning: 1. The main window can be moved by clicking on the title bar in the initial screen

0: The main window can not be moved

2.1.5 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 = "ZzYyXxWwVvUuTtSsRrQqPpOoNnMmLlKkJjIiHhGgFfEeDdCcBbAa"

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.

2.1.6 Directory structure and notes on CardioSoft files

When installing CardioSoft it creates a subdirectory (default: \CARDIO), into which the files required for execution are copied. When calling up CardioSoft for the first time several subdirectories are then created in this directory for the examination data, speech entries and the configuration data. After calling up CardioSoft the directory structure is as follows:

| | | |
|--------------|------------|---|
| ...— CARDIO— | — DATABASE | Databases for Patient Examination Data |
| | — RESTECG | Resting ECG Reports |
| | — SPIR | Spirograms |
| | — EMECG | Emergency ECG Reports (not supported since CardioSoft V 5.0) |
| | — ERGOECG | Ergometry ECG Reports (not supported since CardioSoft V 5.0) |
| | — SOUND | Sound Files from all Examin. |
| | — ONLINE | Online ECG from all Examin. |

| | | |
|-------------|-----------|--|
| ...—CARDIO— | —DATABASE | Databases for Patient Examination Data |
| | —SETUP | Configurations |
| | —TAPE | Dictaphone Data |
| | —AVER | Late Potential Reports |
| | —DOC | User manual and Help Files |
| | —CAS | Ergometry Reports |
| | —NARRATIV | Configured report templates |
| | —ONL500 | not used |
| | —ONL2000 | not used |
| | —RHK | Right-Heart-Catheterization |
| | —HOLTERBP | Long-Term Blood Pressure Reports |
| | —EXTPROG | Reports from all External Progs. |
| | —DIAGS | Thermal Writer Diagnostic Software |
| | —HELP | Help files |
| | —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, spoken comments in \SOUND. Dictated files are stored in \TAPE. Configurations are stored in the \SETUP directory.

Files in Windows system32 directory:

CardioSoft requires the following files from the Windows system32 directory:

mfc42.dll, msvert.dll
Visual C++ class library Functions

Hel_grid.ttf
Special Font

Msflxgrd.OCX
Flex Grid Tools for Stress Test Table

Files in Windows system32\drivers directory:

CardioSoft requires the following files from the Windows system32/drivers directory:

Cor_sys.sys
PATIENT MODULE driver

mmsusb.sys, mtpd.sys
Thermal Printer driver

Cor_W98.sys
PATIENT MODULE driver for Windows 98

Camusb.sys
CAM-USB Driver

Files in Windows system directory:

CardioSoft requires the following files from the Windows system directory for Windows 98.

hardlock.vxd
Hardlock Functions

cor_vxd.vxd
PATIENT MODULE driver for Windows 95

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 Windows 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 WIN.INI are described in the corresponding sections of this Service Manual.

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

Stress test driver (ergometer, treadmill) settings are stored in the file ERG_PROT_V5AN.DAT in the Windows 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.

2.1.7 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.

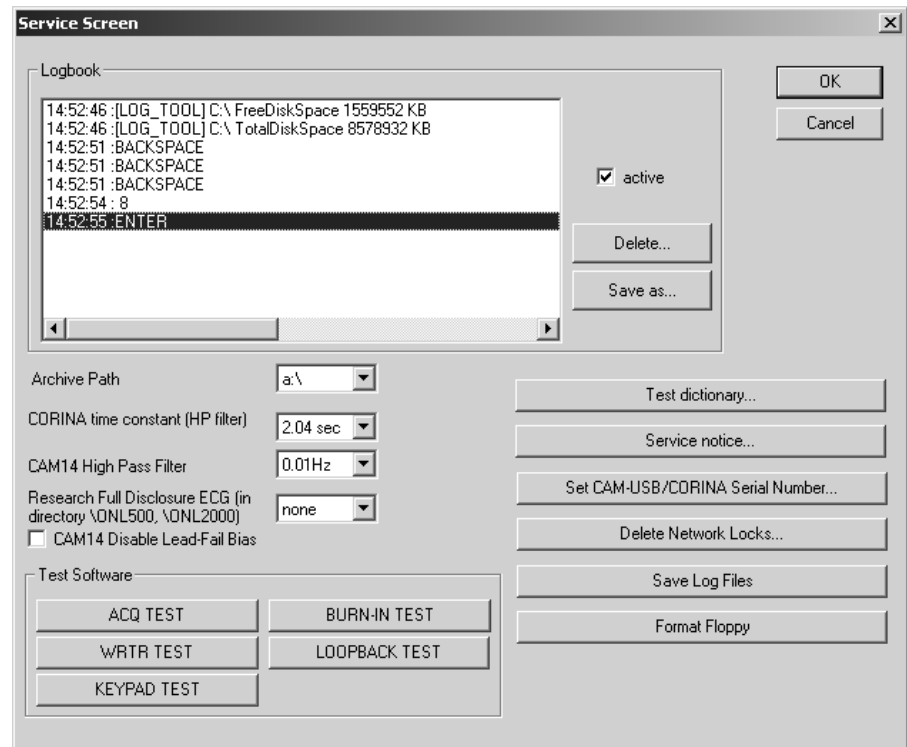


Figure 2-1:

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.

2.1.8 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 has to use 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
- c) 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 preferred method will be the shared directory:

1. 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 manager 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.

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

Enable "Start modem connection before transferring 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.

Transferring 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 Properties ->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 transferring 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.

1. 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 (IEExplorer)

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

Prerequisites: IEExplorer 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 depends 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 IEExplorer are working not before next restart of the Operating System!

2.1.9 Metabolic Interface

2.1.9.1 Communication over serial port

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

| | |
|-----|----------------------|
| 'E' | echo on |
| 'T' | start treadmill |
| 'O' | stop treadmill |
| 'H' | stage hold |
| 'R' | request measurements |
| 'W' | start pretest |
| 'S' | start exercise |
| 'M' | start recovery |

The stress test module writes the stress test data if it receives the command 'R' (request measurements) to a serial port. The default settings for serial port are

| | |
|-----------|------|
| parity | no |
| data bits | 8 |
| stop bits | 1 |
| baudrate | 1200 |
| handshake | no |

The settings for the serial port can be changed with the following entries in the 'CARDIO.INI'.

| | |
|------------------|--|
| 'SpiroParity' | 0 = no parity, 1 = even parity, 2 = odd parity |
| 'SpiroDataBits' | 0 = 7 data bits, 1 = 8 data bits |
| 'SpiroStopBits' | 0 = 1 stop bit, 1 = 2 stop bits |
| 'SpiroBaudrate' | 0 = 300 baud, 1 = 600 baud, 2 = 1200 baud, 3 = 2400baud, 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 |

Example entries in the file 'CARDIO.INI' in the Windows directory to change the default settings to even parity, 7 data bits, 2 stop bits, 9600 baud, XonXoff:

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

CASE8000 sends every 5 seconds the following string to the serial port.

[recoxxx34xMxxxx0x%xxx60xxxx4x-999x-999x-999xx-19xxxx1xx-12x]4CCR
where a space is shown as an 'x'.

| Part of string | Meaning | Note |
|----------------|--------------------------|-------|
| [| Beginning | |
| reco | Stage 'Recovery' | 5, 10 |
| xxx34 | Speed * 10 | 5, 8 |
| xM | Speed designator | 1 |
| xxxx0 | Grade * 10 | 5 |
| x% | Grade designator | 2 |
| xxx60 | Heart Rate | 5 |
| xxxx4 | Ectopic Beats per Minute | 3, 6 |
| x-999 | BP Measurement NBR | 6, 9 |
| x-999 | Systolic BP | 4, 6 |
| x-999 | Diastolic BP | 4, 6 |
| xx-19 | ST Level [mm]*10 | 6 |
| xxxx1 | ST Slope [mV/s]*10 | 6 |
| xx-12 | ST Integral uV | 6, 9 |
| x] | Ending | |
| 4C | Checksum | 7 |
| CR | Carriage return | |

Notes:

1. Could be 'K' for KPH. Kilometers per hour. If so, SPEED is KPH.
Could be 'P' for KPM. Kilopondmeters. If so, SPEED is KPM from Ergo.
Could be 'W' for WATTS. Watts. From Ergo.
2. Could be 'D' for DEGREES. If so, GRADE is DEGREES.
3. This is ECTOPIC COUNT for the minute previous.
4. mmHg
5. If unavailable, pass 0.
6. If unavailable, pass -999.
7. Rightmost 2 ASCII characters of checksum. Checksum includes [, all spaces,]
Alpha characters must be Upper Case.
8. If Ergometer Watts or KPM, SPEED value is not *10.
9. Not supported in the current version (value = -999)
10. The stage names are fixed as the following table shows:

| Phase | Stagenumber | Stagename in the shared file (4 characters) |
|----------|-------------|--|
| Pre-Test | 1 | base |
| Pre-Test | 2 | warm |
| ... | ... | warm |
| Exercise | 1 | ramp |
| ... | ... | ramp |
| Recovery | 1 | reco |
| ... | ... | reco |

2.1.9.2 Communication over shared file

If this option is set test data is written every 5 seconds to a shared file with the name 'ERGOSPIR.DAT'. The default directory for the file is 'C:\TEMP'. It is possible to change the directory of the shared file with a entry in the file 'WIN.INI' in the Windows directory. The name of the entry must be 'SpiroDirectory' in the section [CAS_RECORD].

Example entry in the file 'WIN.INI' in the Windows directory to change the directory for the shared file 'ERGOSPIR.DAT':

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

The following string is written to the shared file every 5 seconds and immediately after phase or stage has changed.

[recoxxx34xMxxxx0x%xxx60xxxx4x-999x-999x-999xx-19xxxx1xx-12x]4CCR
where a space is shown as an 'x'.

| Part of string | Meaning | Notes |
|----------------|--------------------------|--------------|
| [| Beginning | |
| reco | Stage 'Recovery' | 5, 10, 11 |
| xxx34 | Speed * 10 | 3.4 5, 8 |
| xM | Speed designator | MPH 1 |
| xxxx0 | Grade * 10 | 0.0 5 |
| x% | Grade designator | % 2 |
| xxx60 | Heart Rate | 60 BPM 5 |
| xxxx4 | Ectopic Beats per Minute | 4 3, 6 |
| x-999 | BP Measurement NBR | -999 6, 9 |
| x-999 | Systolic BP | -999 4, 6 |
| x-999 | Diastolic BP | -999 4, 6 |
| xx-19 | ST Level [mm] * 10 | -1.9 6 |
| xxxx1 | ST Slope [mV/s] * 10 | 0.1 6 |
| xx-12 | ST Integral uV | -12 6, 9 |
| x] | Ending | |
| 4C | Checksum | 7 |
| CR | Carriage return | |

Notes:

- Could be 'K' for KPH. Kilometers per hour. If so, SPEED is KPH.
Could be 'P' for KPM. Kilopondmeters. If so, SPEED is KPM from Ergo.
Could be 'W' for WATTS. Watts. From Ergo.
- Could be 'D' dor DEGREES. If so, GRADE is DEGREES.
- This is ECTOPIC COUNT for the minute previous.
- mmHg
- If unavailable, pass 0.
- If unavailable, pass -999.
- Rightmost 2 ASCII characters of checksum. Checksum includes [, all spaces,] Alpha characters must be Upper Case.
- If Ergometer Watts or KPM, SPEED value is not *10.
- Not supported in the current version (value = -999)

10. The stage names are fixed as the following table shows:

| Phase | Stagenumber | Stagename in the shared file (4 characters) |
|-------------------|--------------------|--|
| before Test-Start | | chck |
| Pre-Test | 1 | base |
| Pre-Test | 2 | warm |
| ... | ... | warm |
| Exercise | 1 | exer |
| ... | ... | exer |
| Recovery | 1 | reco |
| ... | ... | reco |
| Test finished | | stop |

If a phase or stage change occurs, the complete string is written immediately.

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

If CardioSoft is running without PATIENT MODULE, some of the options are locked with a hardlock. There are two hardlocks available: One is the hardlock with 'DB 25 connectors. This hardlock can be connected to the parallel or the serial interface. And a newer USB hardlock to be connected to USB port. When using this USB hardlock the hardlock has to be plugged into one free USB port of the PC and it will work. 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 |

Under Windows ME, when using the hardlock the file hardlock.vxd must be located in the \system directory. It is copied there during the installation of CardioSoft

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 where MARS is installed: Drive:\gem-sit\op\MarsNT\bin\superapp.exe

For your notes

3 Aquisition Modules for CardioSoft

3.1 CAM-USB

CAM-USB is a 15-leads 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).

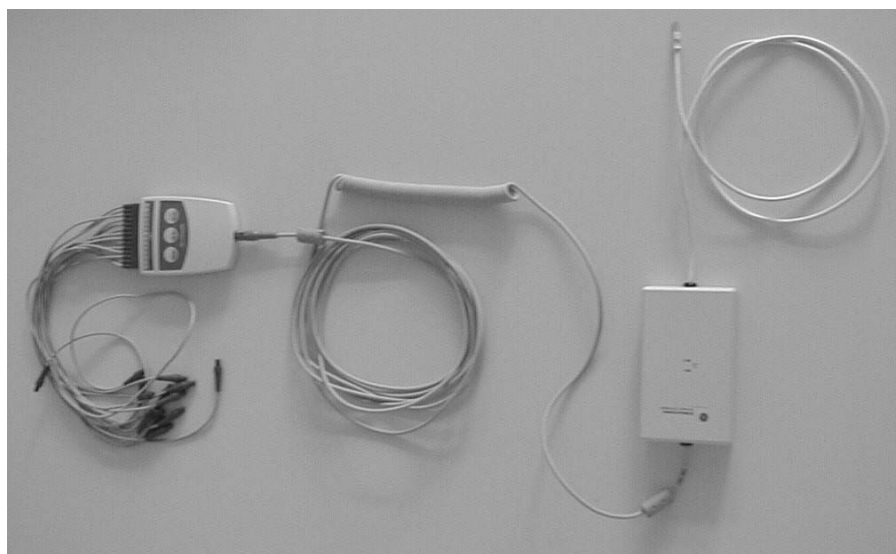


Figure 3-1:

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 (1.5 m).
- 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 V5.x are working with

- a) **Windows ME**
Recommended PC: min. 1.6 GHz, min. 128 MB SDRAM, min. 20 GB HDD
- b) **Windows 2000 (SP2 or higher)**
Recommended PC: min. 1.6 GHz, min. 128 MB SDRAM, min. 20 GB HDD
- c) **Windows XP Professional (SP1 or higher)**
Recommended PC: min. 1.6 GHz, min. 128 MB SDRAM, min. 20 GB HDD

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).

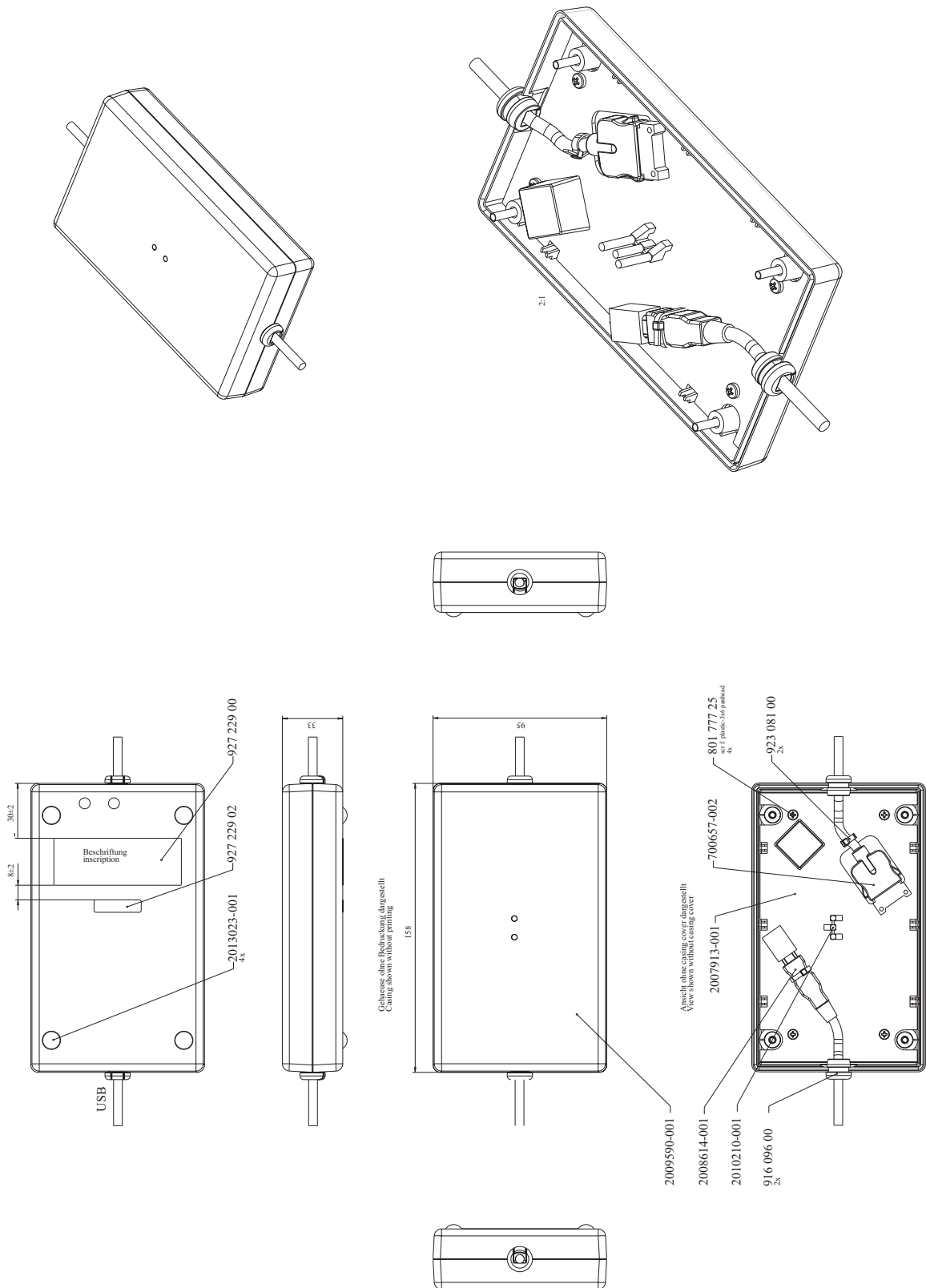
Meaning of the system status LED's / beeper signals

| Buzzer | LED(B) (green) | LED(A) (yellow) | Function |
|--------|-------------------|--------------------|---|
| OFF | OFF | OFF | Device not powered |
| OFF | ON | ON | Device powered, not ready (after startup) |
| OFF | ON | OFF | Device powered, normal operation |
| OFF | ON | Blinking | No CAM-14 module connected |
| ON | ON | ON | No USB communication, i.e PC system Application crash, or/and no CAM-14 module detected due to CAM-14 module error |

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, chapter 8).

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



3.2 CORINA

3.2.1 Context

CORINA is an ECG recorder for the system CardioSys and CardioSoft. CORINA stands for **C**ORD **I**NTEGRATED **A**MPLIFIER and is an interface between patient and personal computer. There are four CORINA models.

3.2.2 Supported Operating Systems and System performance

CORINA and CardioSoft V5.x are working with

- a) **Windows ME**
Recommended PC: min. 1.6 GHz, min. 128 MB SDRAM, min. 20 GB HDD
- b) **Windows 2000 (SP2 or higher)**
Recommended PC: min. 1.6 GHz, min. 128 MB SDRAM, min. 20 GB HDD
- c) **Windows XP Professional (SP1 or higher)**
Recommended PC: min. 1.6 GHz, min. 128 MB SDRAM, min. 20 GB HDD

3.2.3 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.

3.2.4 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:

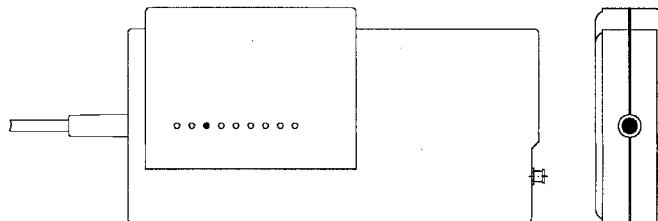


Figure 3-3:

3.2.5 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.

3.2.6 Model 4 CORINA with suction pump and Analog Output

Like Model 3 with additional suction pump.

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

Note: Only CORINA Models 101 118 31...34 and 37/38 (OEM) are supported by CardioSoft V5.x. When using the new modles, you can also use the new Power Supply SW 172 (or as default the FW 7324/2 Power Supply).

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)

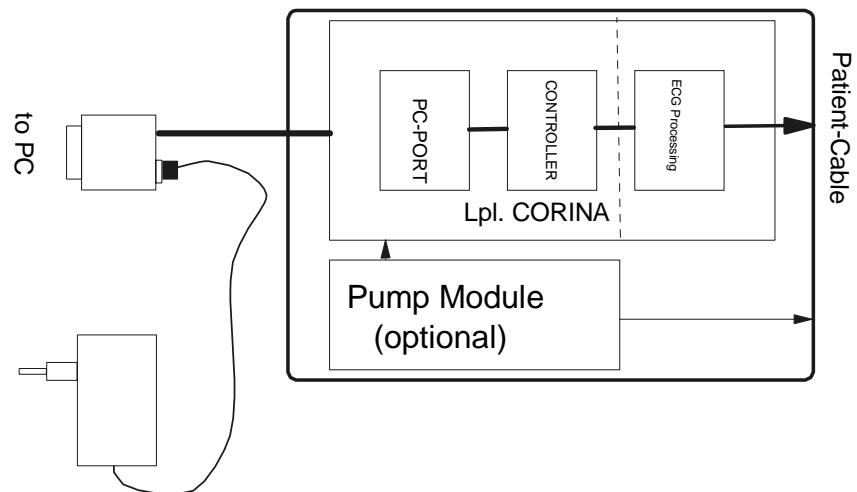


Figure 3-4:

3.3 Introduction

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

3.3.1 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 (4 types, 2 with and 2 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.

3.4 Hardware Structure

3.4.1 Physicomechanical 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)

3.4.1.1 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:

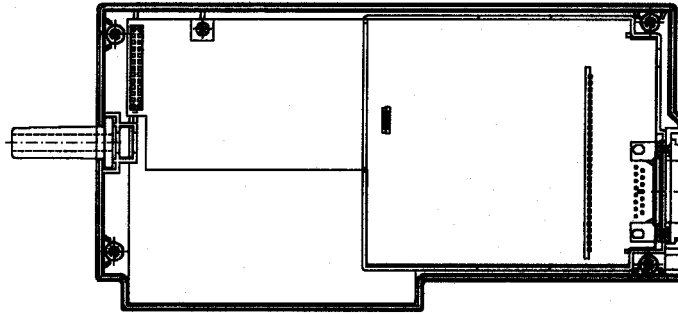


Figure 3-5:

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

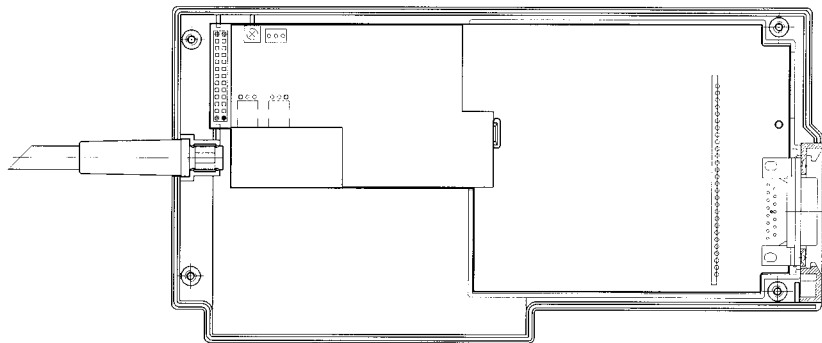


Figure 3-6:

3.4.1.2 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):

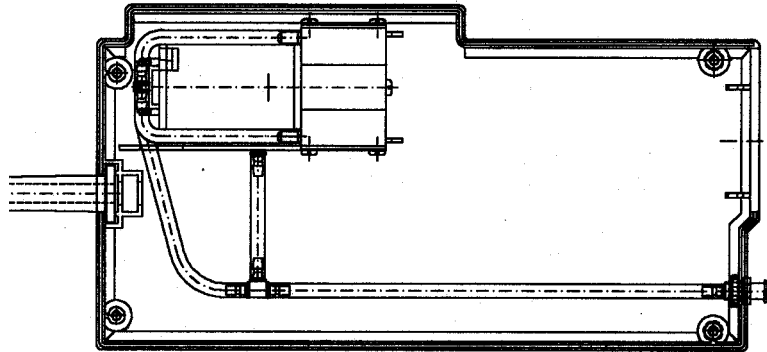


Figure 3-7:

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

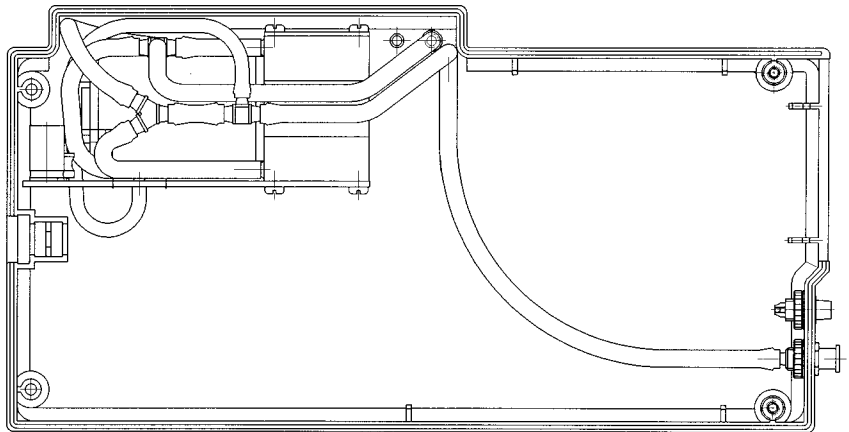


Figure 3-8:

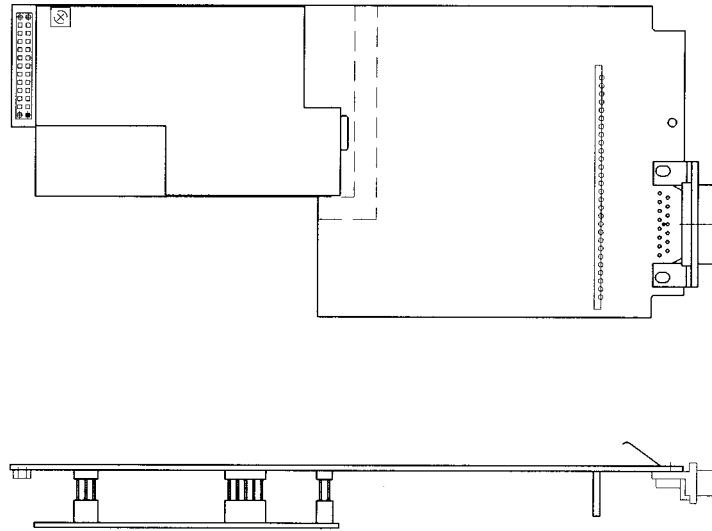


Figure 3-9:

3.4.1.3 PCB CORINA

There are 5 PCB versions:

- a) 2x Standard b) 2x for Analog Out c) Standalone
- 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 and 101 118 41...42 provides a newer communication protocol 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...36 and 101 118 43...44 provides a newer communication protocol to the PC and will not work inside other (older) CORINA variants.

- c) The CORINA PCB model for the CORINA standalone is almost exactly the same as model b). The PCB CORINA TRIGGER is also plugged in here and the internal analog lead as well as, optionally, the pump power supply connected.

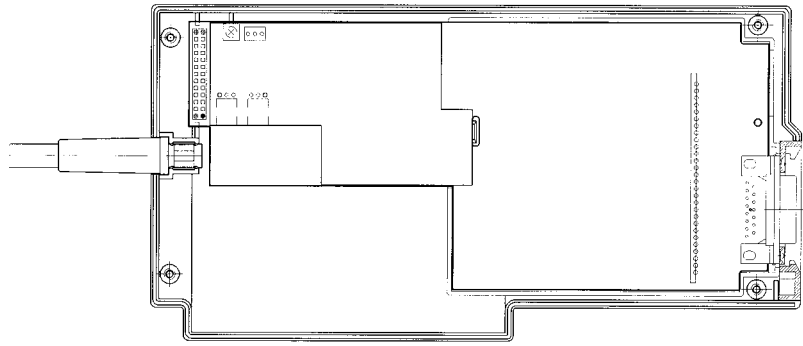


Figure 3-10:

3.4.1.4 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 socket terminal strip. This is then plugged directly onto the PCB.

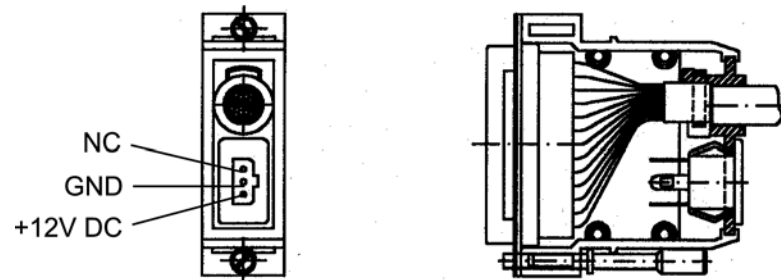


Figure 3-11:

3.4.1.5 Pump Module:

The pump module comprises the following components:

- pump
- PCB
- tubing connection

Pump (old tubing system)

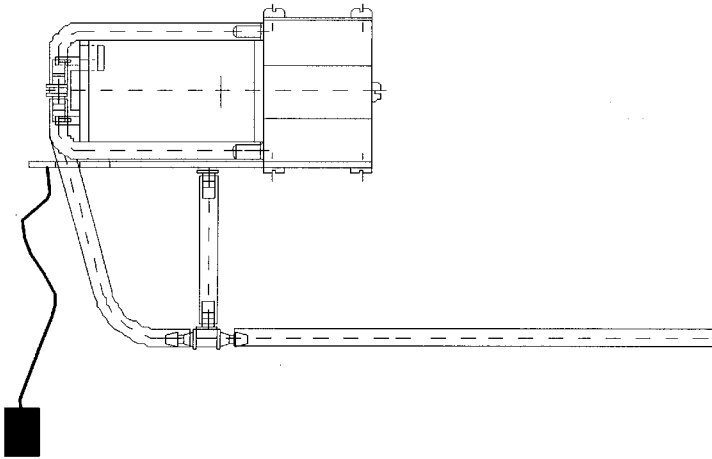


Figure 3-12:

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 pump power supply wires must be covered by a heat-shrinkable tube!

Pump (new tubing system)

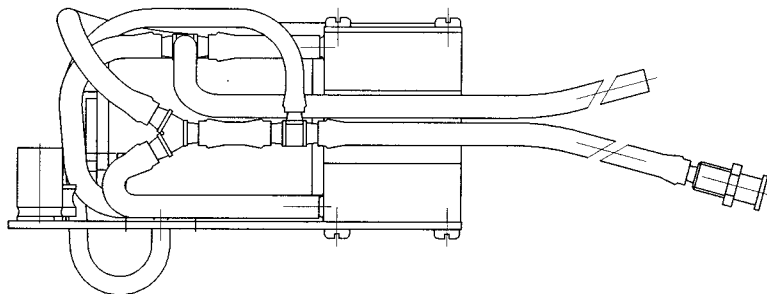


Figure 3-13:

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).

3.4.1.6 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)

3.4.1.7 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.

3.4.1.8 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.

3.4.2 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).

3.4.2.1 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].

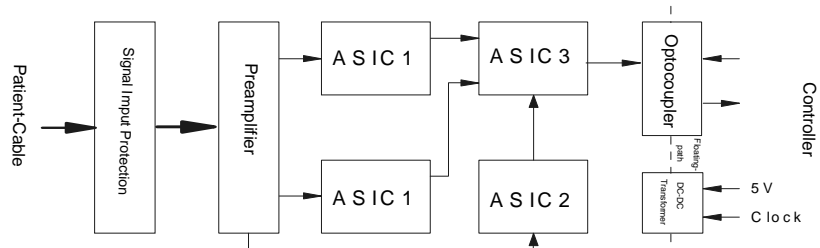


Figure 3-14:

3.4.2.2 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 transducer on PCB CORINA TRIGGER (optional)

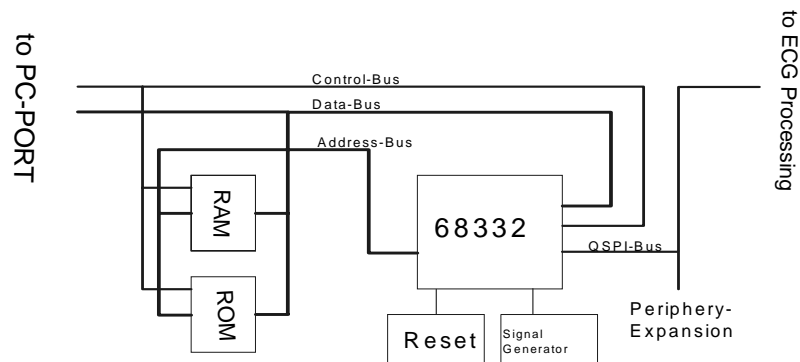


Figure 3-15:

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.

3.4.2.3 PC PORT:

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

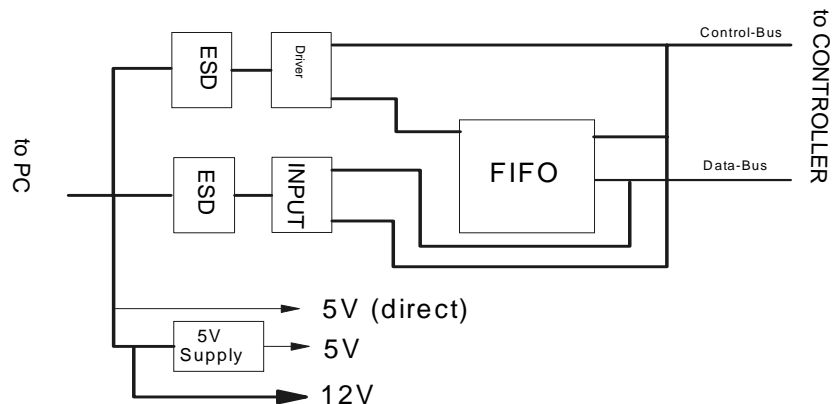


Figure 3-16:

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.

3.4.2.4 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.

Functionality:

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.

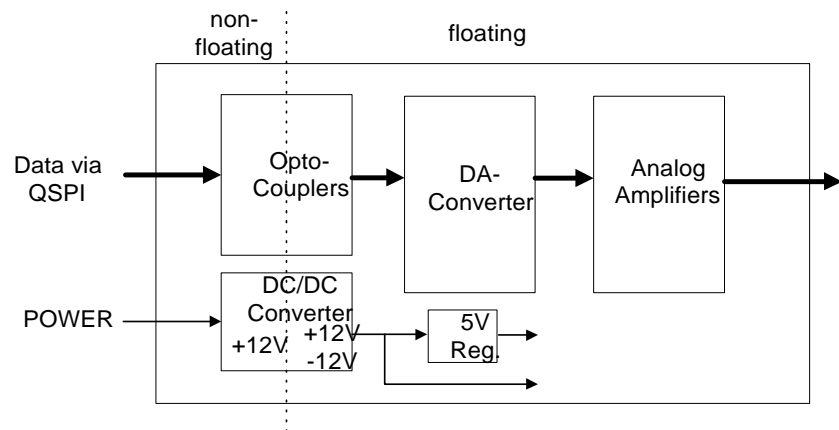


Figure 3-17:

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 be connected to the input of the peripheral.

Suitable low-pass configuration:

Revision D

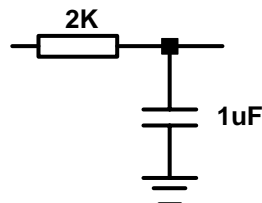


Figure 3-18:

3.4.3 Internal Interfaces

3.4.3.1 Mechanical Interfaces

Tubing connection of the pump module:

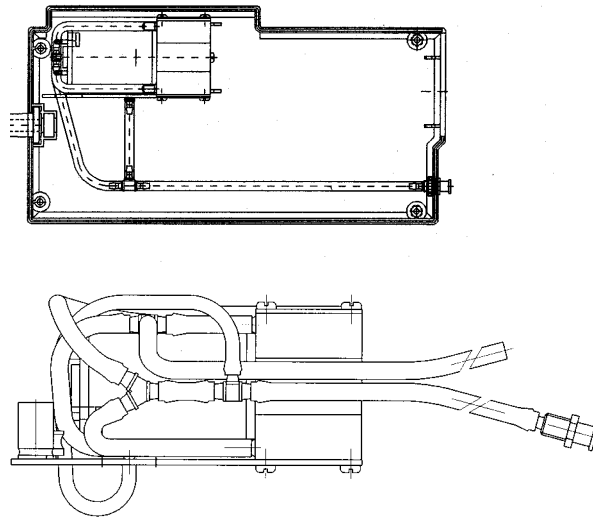


Figure 3-19:

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

3.4.3.2 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:

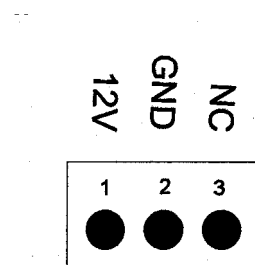


Figure 3-20:

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.

3.4.4 Interfaces to Peripherals

3.4.4.1 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

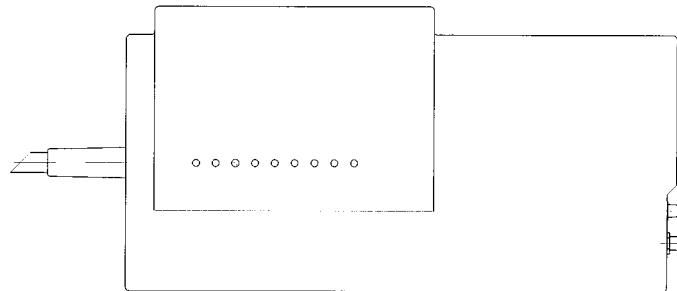


Figure 3-21:

3.4.4.2 Electrical Interfaces

CORINA has two external interfaces. These are:

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

3.4.4.2.1 Interface to PC:

Data interface:

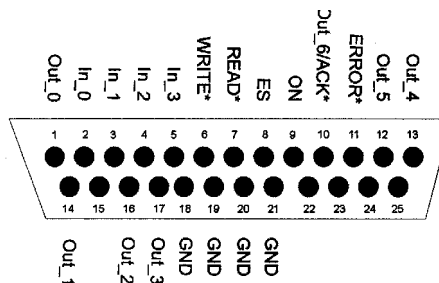


Figure 3-22:

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 and 101 118 41...44 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 |

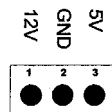
Power source interface:

Figure 3-23:

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

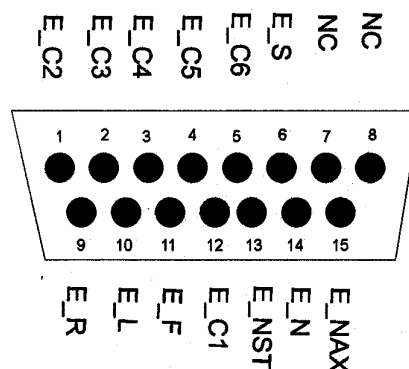
3.4.4.2.2 ECG Input:

Figure 3-24:

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 |

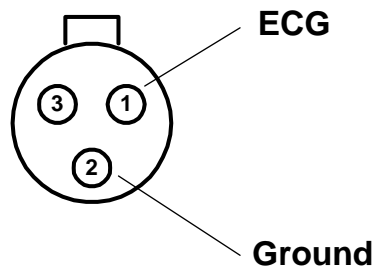
3.4.4.2.3 Analog Out

Figure 3-25:

Pin assignment of this socket: Pin 1 = Analog Out, Pin 2 = ground, Pin3 = reserved.

3.5 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 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 have 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: I see red lines on remote screen

Solution:

Set the TCP/IP Protocol Parameter MaxMTU to the value 512 of the sending PC
(important of the sending PC)

For Windows 4.0:

With the Registry Editor please locate the following key:

“HKEY_LOCAL_MACHINE\SYSTEM\CurrentControlSet\Services\<Adapter
Name>\Parameters\Tcpip”

Where <Adapter Name> refers to the subkey for a network adapter that TCP/IP is
bound to.

Please enter the key “MTU” with the Type “REG_DWORD” with the value 512.
After the change please reboot the System.

For Windows ME/98:

With the Registry Editor please locate the following key:

“HKEY_LOCAL_MACHINE\SYSTEM\CurrentControlSet\Ser-
vices\Class\netTrans\000n”

Where 000n refers to the network adapter that TCP/IP is bound to.

Please enter the key “MaxMTU” with the Type “String” with the value “512”
(Important: use Type “String” and enter the string “512”).
After the change please reboot the System.

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 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 heart rate of 130)

Question: The modem I use is not in the modem list and brings up an error message 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 menu will not fit within the screen

Solution:

Select "SMALL FONTS" within the display configuration window.

Question: The buttons on the screen have a grey shadow when using CardioSoft on a Windows 2000 based system

Solution:

Select the scheme "Windows Classic" under "Appearance" in 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 CardioSoft 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: Instruction how to use the ECG record interval and blood pressure interval

Solution:

CardioSoft and CardioSoft up to version 4.14 need a special way to program the ECG record intervals and blood pressure intervals.
The list of interval times are completely independent from the list of stage times.
That means every interval time entry is processed one time.

When the time is over the next time entry is processed until all time entries are processed. After that there are no more ECG reports.

So a time entry does not belong to the stage and is not repeated until the stage is over.

For example you have four stages, every stage lasts three minutes and you want to set the ECG record interval time to one minute for every stage.

Then you need twelve ECG record interval time entries with one minute.

That looks like:

| Stage | Time | ECG Rec.Int. |
|-------|-------|--------------|
| 03:00 | 01:00 | \ |
| 03:00 | 01:00 | Stage 1 |
| 03:00 | 01:00 | / |
| 03:00 | 01:00 | \ |
| | 01:00 | Stage 2 |
| | 01:00 | / |
| | 01:00 | \ |
| | 01:00 | Stage 3 |
| | 01:00 | / |
| | 01:00 | \ |
| | 01:00 | Stage 4 |
| | 01:00 | / |

CardioSoft/CardioSoft since version 4.2 and CASE-8000 use the interval time entries stage-dependent, so a time entry belongs to its stage and will be repeated until the stage is over.

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

Solution:

Customer buys “Adobe Acrobat V4.0/V5.x”. Adobe Acrobat installs a printer driver which can generate PDF files. This 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: The Windows 2000 network display a BTRV error message when a registered user tries to invoked CardioSoft.

Solution:

In the Windows 2000 network, register the user and grant ALL rights. In Windows 2000, the selection of users with limited rights is the default setting.

Question: [11007] Error starting print job on Windows 2000 PC?

Solution:

This Error Message is generated, if the print job can not be started.

Reasons for this error message:

1. No printer is defined as Default Printer

or

2. The user does not have all rights. The user in Windows 2000 must be not created as belonging to the restricted user group (default for new users in Windows 2000).

The user must belong to the administrator group with full rights.

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 V5.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" tab
4. Set field "Graphic-> True Type Font" to value "Download as Softfont" on the "Advanced" tab

Problem: When transferring data from MAC 1200, the same patient record is created twice.

Solution:

The function of CardioSys/Soft to automatically assign an incoming resting ECG from a MAC 1200 to a patient record does not pose any problems.

If the patient with the patient ID from MAC 1200 already exists in CardioSys/Soft, the resting ECG will automatically be assigned to this patient.

If the patient with the patient ID from MAC 1200 does not exist in the CardioSys/Soft database, the patient record will be generated and the resting ECG will be assigned to the new patient record.

A second patient record with the name displayed in capital letters is generated only when a resting ECG with the same acquisition date and time is transferred a second time.

This second resting ECG is assigned to the second patient record and can thus be deleted.

Make sure that you do not unnecessarily transfer resting ECGs more than once.

If a new resting ECG is transferred after the resting ECG sent a second time, the new one will be assigned to the first patient record.

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 NT 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, if the value displayed there may be higher than in CardioSoft.

Question: Access to DEMO CardioSoft Web?**Answer:**

<http://194.45.46.68>

Login with webuser1 and password webuser1.

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 Cardiosys 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 Cardiosys client as the Administrator (local), add the user “?Domäne?\cardiouser” to the local user group of main users. Repeat this configuration at each CardioSys client.

If multiple users use the CardioSys 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 CardioSys/Soft 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 expiratorisches Volumen in 1 Sekunde |
| PEF [liters/second] | Peak expiratory flow | Max. expiratorischer Flow |
| MEF75 [liters/second] | Max. expired flow at 75% FEVC remaining | Forcierter max. expiratorischer Flow bei 75% Restvolumen FEVC |

| Parameter Designation | | |
|-----------------------|---|--|
| MEF50 [liters/second] | Max. expired flow at 50% FEVC remaining | Forcierter max. expiratorischer Flow bei 50% Restvolumen FEVC |
| MEF25 [liters/second] | Max. expired flow at 25% FEVC remaining | Forcierter max. expiratorischer 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 inspiratorisches 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 |
| 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 ventilation of air expired for one minute (indirect, derived from FEV1) | Maximales expiratorisches Ventilationsvolumen pro Minute (indirekt, abgeleitet von FEV1) |

Question:

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

Answer:

1. $FEV1/IVC \geq 70\%$ and $IVC_{ref}/IVC \geq 70\%$
-> No Respiratory Problem
2. $FEV1/IVC < 70\%$ and $IVC_{ref}/IVC < 70\%$
-> Combined Respiratory Problem
3. $FEV1/IVC < 70\%$ and $IVC_{ref}/IVC \geq 70\%$
-> Obstruction
4. $FEV1/IVC \geq 70\%$ and $IVC_{ref}/IVC < 70\%$
-> Restriction

Question:

After installation of CardioSoft V5.x on a notebook with Windows 2000, why is the “Standby” shut-down selection no longer available?

Solution:

Two drivers of CardioSoft V5.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.

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: **NT 4.0, slowly printing with HP6P, HP2100M, HP4050M (only CardioSoft)**

Solution: Please replace the original printer driver with “HP Laserlet 5M” from the Windows Workstation CD ROM.

Symptom: **Windows ME/98 (only CardioSoft) EPL-5700 do not work properly**

Solution: Replace the original printer driver with the “EPL-5500”
(Problem: no landscape printout possible under Windows 98 with original printer driver)

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 wants to work with this software.
- b) Open Printer properties menu and change the printer scheduling to "Print direct .."
- c) Do the following entries to the 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 menu.

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 cause 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: **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 Windows 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 sufficient 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 connected PATIENT MODULE to the system**

CardioSoft normally checks all LPT ports to detect the PATIENT MODULE 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 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 from 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 to be 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 dialing is not supported from ELSA 33.6 TQV Modem

Solution: Select Tone Dialing.

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 compromising 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 "WIN.INI" file.

Symptom: OS Message appears: „Adobe Acrobat 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 privileges to install the software.
2. Insert the CardioSoft CD in the CD ROM drive. If the CD drive does an automatic 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.

4.4 System diagnosis with Windows 2000 / ME / XP

Windows 98/ME: Use the tab “System Information” under the Tab
“Start - Programs - Accessories - Tools”

Other Windows: 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 / 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.

The screenshot shows the 'Service Tool for Corina and CAM-USB V5.0' window. It features a GE Medical Systems logo in the top right. The main area contains several input fields and buttons. On the left, there are three fields: 'Acquisition System serial number' with value '0', 'Acquisition System software revision' with value 'V5.1', and 'Acquisition System found on port' with value 'usb'. Below these are four more fields: 'Vendor ID' (0x05D0), 'Product ID' (0x000B), 'Device ID' (0x0001), and 'CAM USB hardware revision' (0). At the bottom left, a 'Status' section shows 'Connection' as 'CONNECTED' and an empty 'Error Code' field. On the right side, there are two buttons: 'Read Acquisition System Information' and 'Enter Serial Number Programming Mode'. A 'Close' button is located at the bottom right.

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.

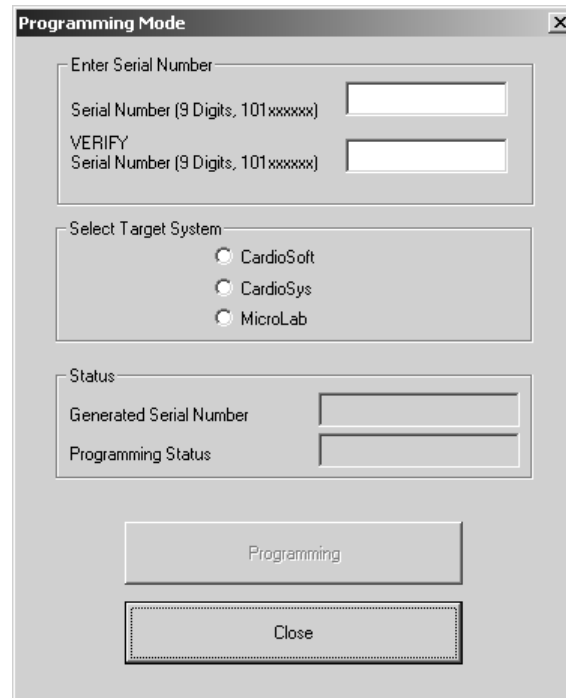


Figure 4-2:

4.6 Database-Repair for CASE / CardioSys / Card_Rep V5.x

4.6.1 General

- The repair-tool can be used for all **CASE**-Versions to V5.x and for **CardioSys/ CardioSoft** from version V4.1 to V5.x.
- There is no installation-program. The program file CARD_REPEXE must be manually copied into a directory on the hard disk where CASE/CardioSys is installed, because some DLLs used from CASE/CardioSys are needed.
- The user interface is in English or German language.
- It is possible to repair the database, because CASE/CardioSys stores the patient-data in the header of the examination-files. So with each examination-file that can be successfully read and if necessary decompressed, an according entry can be made in the files PATIENT.BTR and EXAMINA.BTR
- It is possible to repair the database for the following modalities supported from Version 5
Exercise Test, Resting ECG, Ambulatory Blood Pressure, Spirometry, Archived Patient Records. The modalities from CardioSys prior V5, like *Exercise Test, Late Potentials, STAT ECG, Right-Heart Cath.* are supported also.
- It is **not** possible to repair the entries made from “*External Programs*”, because there is no patient-information stored in these examination-files.

- It is **not** possible to repair the following entries, because the according 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 same as the password of *the current day* used for CASE/CardioSys
- CARD_REP doesn't make any modifications with the original data from a CASE/CardioSys 0 database. Instead of this, the repaired data is stored in a temporary directory.
So the person who repairs the database is responsible how to continue working with the repaired data.
- After the repair is finished a protocol can be printed.

4.6.2 Directory / Filestructure

4.6.2.1 Case/CardioSys directory-structure

| Directory/File | Description |
|----------------|--|
| CARDIO | Program-directory |
| DATABASE | Database-directory |
| Patient.Btr | Btrieve-file: Patients |
| Examina.Btr | Btrieve-file: Examinations |
| Users.Btr | Btrieve-file: Users |
| Station.Btr | Btrieve-file: Network-Stations, not used in V5 |
| Network.Btr | Btrieve-file: Network-Locking, temporary files |
| RESTECG | Resting ECG - directory |
| R*.* | Examinations-files |
| ERGOECG | Exercise Test - directory |
| E*.* | Examinations-files from CardioSys until V4.2 |
| AVER | Late Potentials-directory |
| AC*.* | Examinations-files |
| SPIR | Spirometry - directory |
| SC*.* | Examinations-files |
| EMECG | STAT ECG - directory |
| N*.* | Examinations-files |
| RHK | Right-Heart Cath - directory |
| Z*.* | Examinations-files |
| HOLTERBP | Ambulatory Blood Pressure - directory |
| BC*.* | Examinations-files |
| CAS | Case8000 - directory |
| C*.* | Examinations-files |
| 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 |

4.6.2.2 Repair directory-structure

The repair directories have fix names from Card_R0 to Card_R9, where any write-able disk-drive can be selected.

4.6.3 User Interface

- Select the directories where Case/CardioSys 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.
- Special Settings for handling the patient-data.
This is what to do when the patient data which is stored in the examination file is different from the data stored in the database. This may happen when the patient-data is modified after an examination was made.
 1. Control the Patient data with a dialogue
 2. Use always the Patient data from the examination-file
 3. Retain always 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
This is what to do when the key which is generated out of the examination-file is already available in the database. This may happen when examination are merged from different directories and there are several entries for one patient from the same date and time.(year, month, day, hour, minute and second). This is quite unique!
 1. Ignore examination: The examination-file will not be copied to the repair directory
 2. Generate new key and store the examination:
The second of the recording-time will be incremented and a new try is made with this modified key.
This possibility should be used with care, because when Card_Rep is used with the same examination-files more than once, also more than one entry will be found in the database.

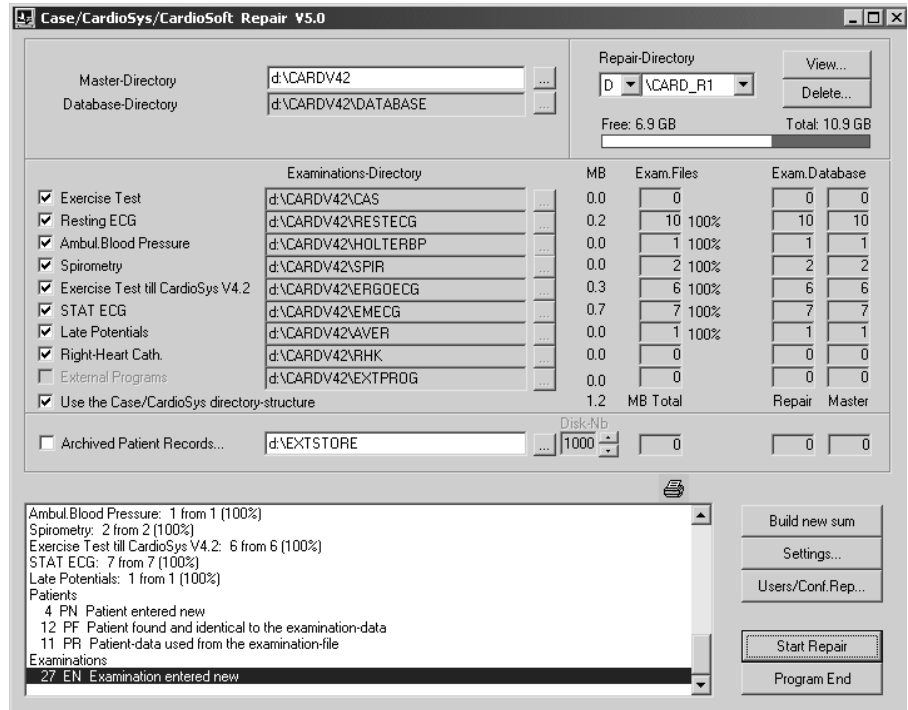


Figure 4-3:

4.6.4 After Repair...

With the *View*-Button it is possible to have a look at the entries made in PATIENT.BTR and EXAMINA.BTR

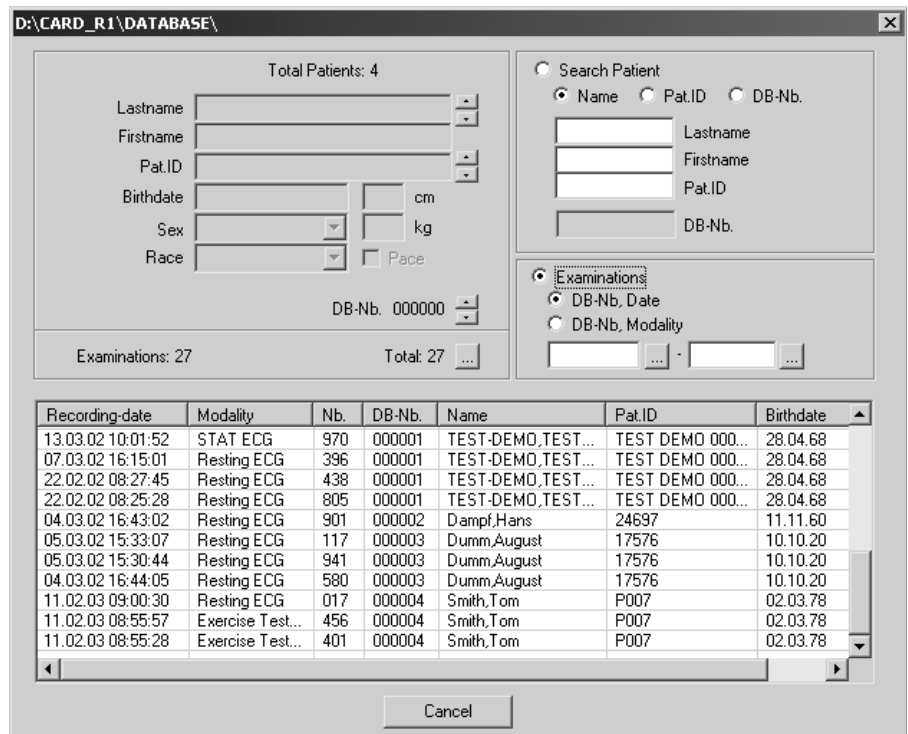


Figure 4-4:

To continue working with the repaired database there are the following possibilities:

1. Install CASE/CardioSys on 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.

4.6.5 Specials

4.6.5.1 Merging data

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

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

Continue with the work described in the chapter 1.4 (After Repair...).

4.6.5.2 External stored examinations

It is possible to regenerate the database entries for the external stored examinations. The only restriction is, that the device must be writeable where the examinations are stored, because the repair-procedure makes it necessary that the header of each examination-file has to be changed and file has to be renamed.
So before the repair is started, it is advisable to make a backup from the directory of the external stored examinations. This would be helpful when the system crashes while all the files are renamed.

4.6.5.3 Examinations with Online-ECG

When using a directory-structure not according to CASE/CardioSys conventions, there may be problems with examinations which have an Online-ECG.

That's why Card_Rep assumes that the Online-Files are stored in the directory ..\ONLINE, which is parallel to examinations. So when Card_Rep doesn't find such a directory, no Online-File will be available for that examinations.

The modalities which may have Online-Files 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 according online-files are stored in *d:\online*.

4.6.5.4 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, empty 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: Patientenummer ist null |
| EE | Allgemeiner Fehler |

4.6.5.5 Patient-Filter

It is possible to set a filter for the patient's lastname. So only patients/examinations according this filter are stored in the new database. The filter-specification can also include wildcards (* ?) for example

| | |
|-------|--|
| Me* | selects patients beginning with Me followed by any other combination of characters |
| Me??? | selects patients beginning with Me followed by exact 3 other characters. |
| Meier | selects patients with the lastname Meier . |
| *xyz* | selects patients containing the substring xyz |

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

The filter can be set on the dialog "Settings".

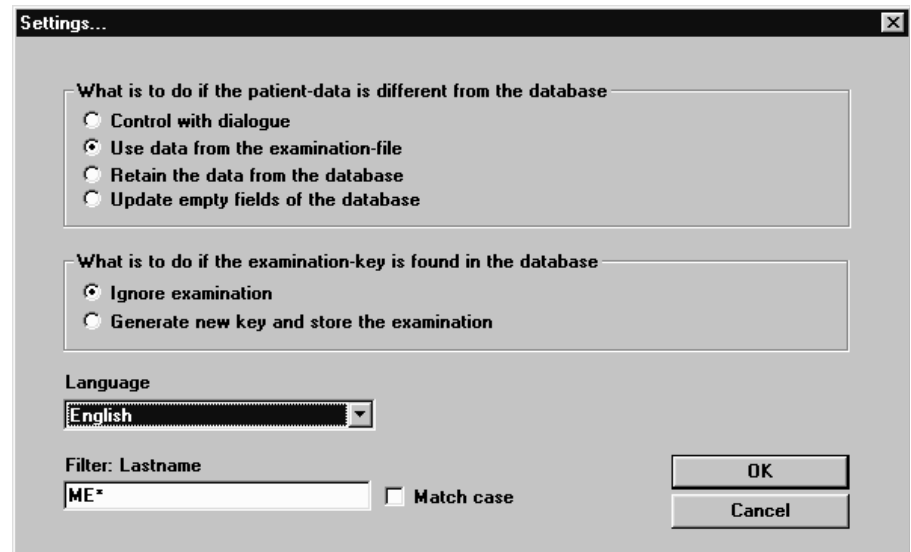


Figure 4-5:

4.7 Remote Servicing

"Remote Servicing" could be realized by using Symantec's "PCAnywhere 10.5 HOST ONLY" Software.

CAUTION: Disconnect the patient from the system during remote servicing or when the modem is connected.

This chapter describes the general configuration of this software by example of a modem configuration.

Install the PCAnywhere 10.5 HOST ONLY Software (typical installation) and skip any registration screens.. Select "Reboot".

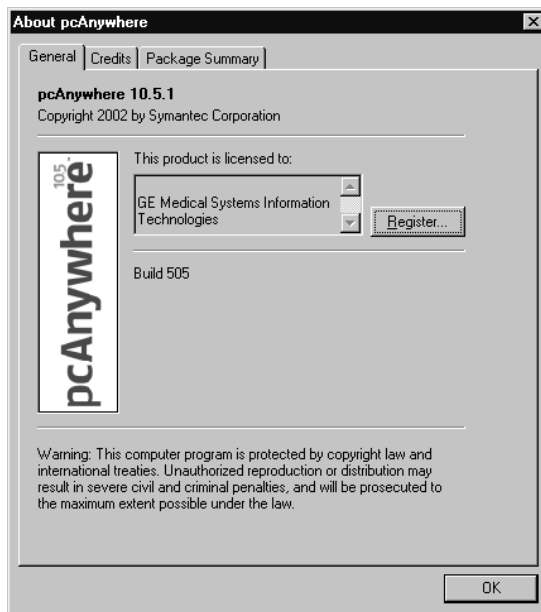
Install then the PCAnywhere Update to 10.5.1.

After successful installation of the update, please start the PCAnywhere HOST 10.5 application and configure the program as described within the next pictures; skip any registration screens:

PcAnywhere HOST Initialization



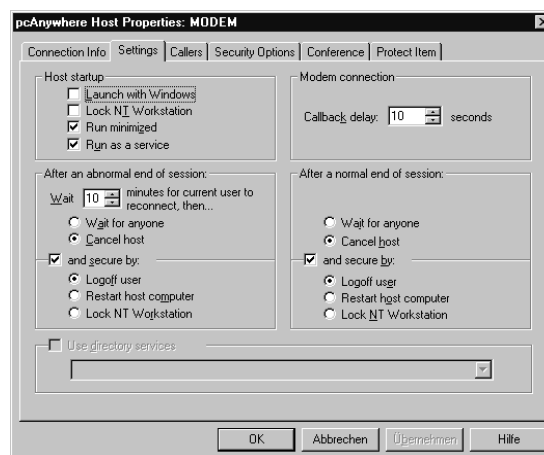
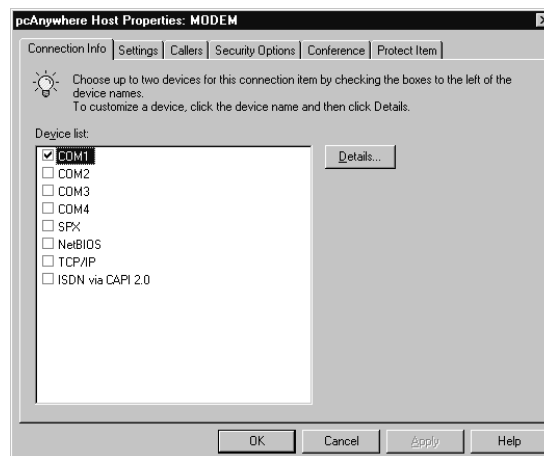
PC Anywhere Startup Screen



Use the tab “about” and check the software version 10.5.1

MODEM Properties:

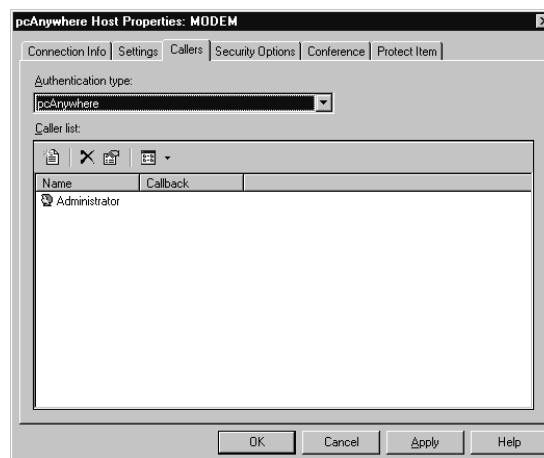
Within the startup screen select “MODEM” and press right mouse button. Then select “PROPERTIES”



Change “Wait 10 minutes for current user to reconnect” then “Cancel host” and secure by selecting “logoff user”

After a normal end of Session “Cancel host” and secure by selecting “logoff user”

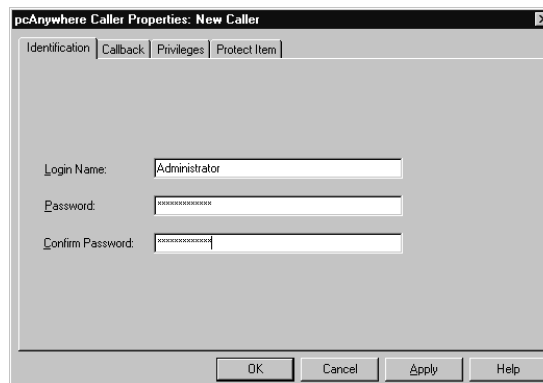
Press “Apply”



Add new caller:
Press button 'New item' to create a new caller. See also pictures of MODEM Properties -> Caller Properties below

MODEM Properties

→ Callers Properties:



pcAnywhere Caller Properties: New Caller

Identification | Callback | Privileges | Protect Item

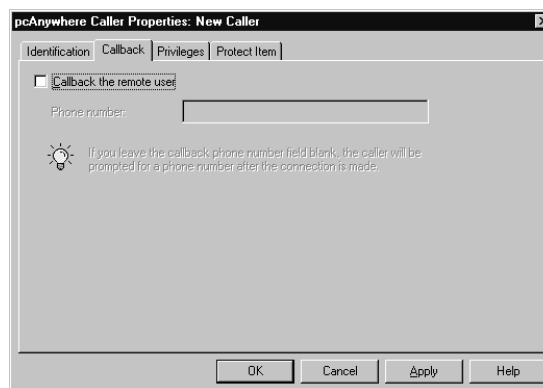
Login Name: Administrator

Password: [masked]

Confirm Password: [masked]

OK Cancel Apply Help

Login Name: *Administrator*
Password: *Administrator*



pcAnywhere Caller Properties: New Caller

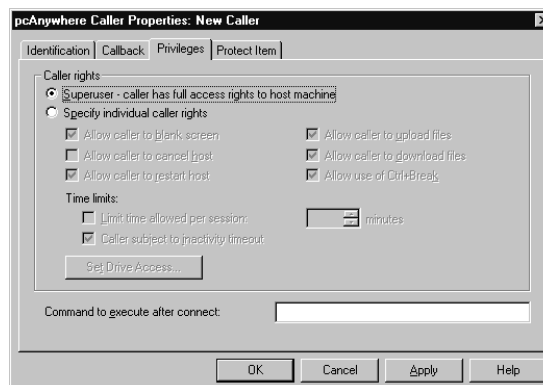
Identification | Callback | Privileges | Protect Item

☐ Callback the remote user

Phone number: [text box]

If you leave the callback phone number field blank, the caller will be prompted for a phone number after the connection is made.

OK Cancel Apply Help



pcAnywhere Caller Properties: New Caller

Identification | Callback | Privileges | Protect Item

Caller rights:

☒ Superuser - caller has full access rights to host machine

☐ Specify individual caller rights

- ☒ Allow caller to blank screen
- ☒ Allow caller to upload files
- ☒ Allow caller to cancel host
- ☒ Allow caller to download files
- ☒ Allow caller to restart host
- ☒ Allow use of Ctrl+Break

Time limits:

☐ Limit time allowed per session: [text box] minutes

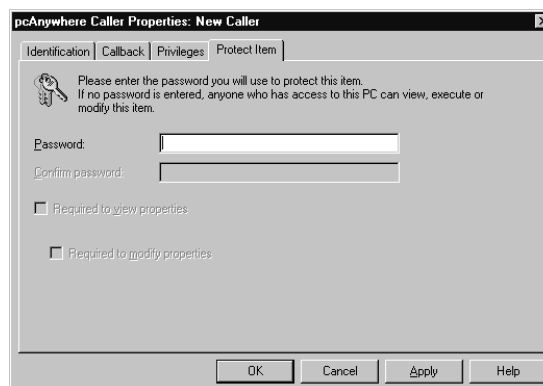
☒ Caller subject to inactivity timeout

Get Drive Access...

Command to execute after connect: [text box]

OK Cancel Apply Help

Caller rights:
Superuser – caller has full access rights to the host machine



pcAnywhere Caller Properties: New Caller

Identification | Callback | Privileges | Protect Item

Please enter the password you will use to protect this item. If no password is entered, anyone who has access to this PC can view, execute or modify this item.

Password: [text box]

Confirm password: [text box]

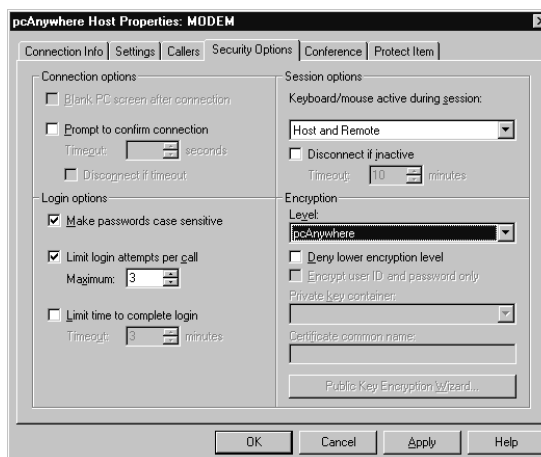
☐ Required to view properties

☐ Required to modify properties

OK Cancel Apply Help

Press “OK”

Back to the MODEM Properties:



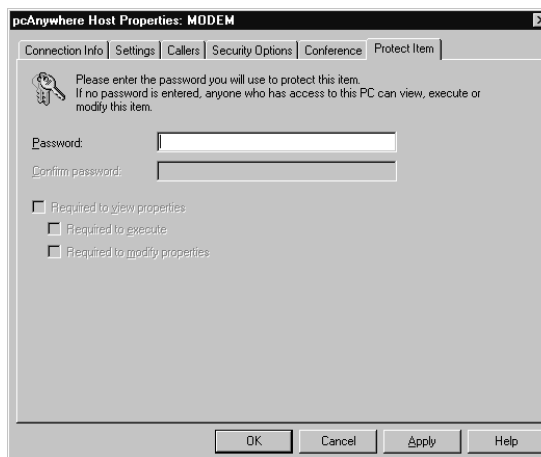
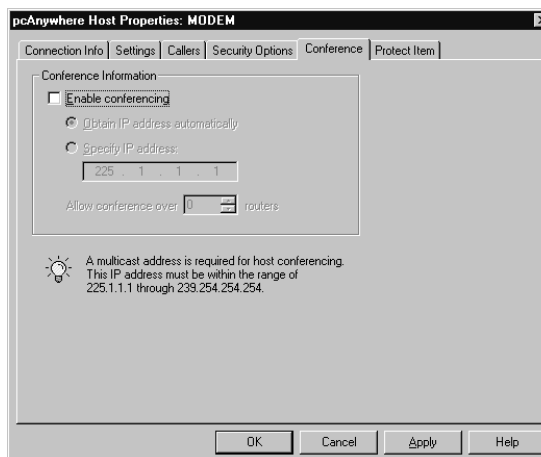
Changes to default:

Make passwords case sensitive

Encryption Level:
pcAnywhere

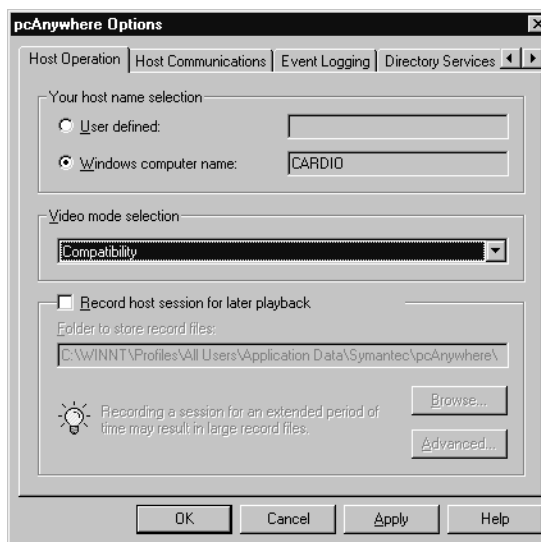
Disable “Limit time to complete login”

Press “Apply”



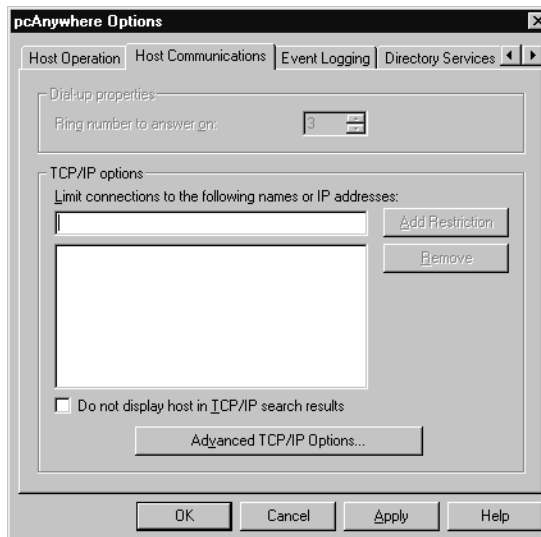
Press “OK”

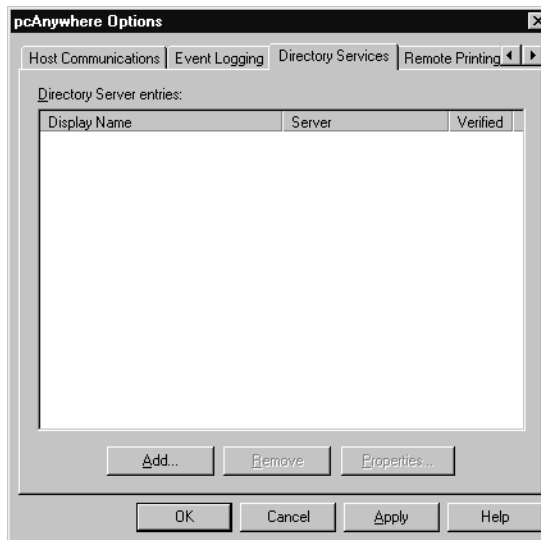
pcAnywhere TOOLS OPTIONS:



Change “Video mode selection” to “Compatibility”

Press “Apply”





Press "OK"

1. Administrator privileges are necessary to use the remote service feature.
2. Contact your nearest Remote Service Center and arrange a time and date for remote servicing.
3. At the agreed time start the *Symantec pcAnywhere* program and click *Modem*.
4. After servicing/installation of software upgrades, the Remote Service program shuts automatically down and the system user is logged off.

5 Supported Operating Systems

CardioSoft:

- Windows ME
- Windows 2000 → min. Service Pack 2
- Windows XP → min. Service Pack 1

For your notes

6 Care and Maintenance

6.1 General introduction

The suggested Safety Analysis Tests refer to the international standard IEC 601-1. The tests are generally performed with Safety Testers, on most of them, the measuring circuits according IEC 601 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 601.
- 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 601-1-1 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.

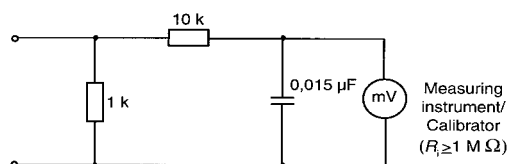


Figure 6-1:

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 foil (10 x 20 cm) wrapped around the CAM-USB 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 mA | 500 μ A |
| | 300 μ A (U.L. requirements) |

Electrical Diagram for Enclosure Leakage Current Test

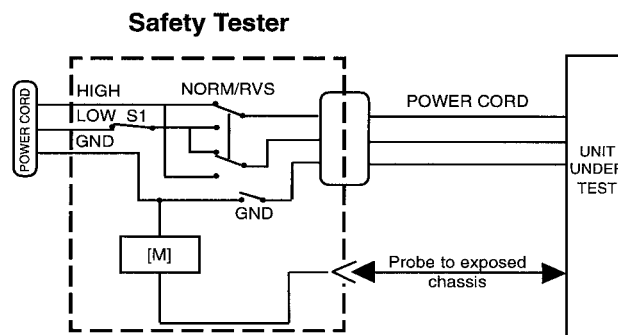


Figure 6-2:

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 mA

Electrical Diagram for Patient Leakage Current Test

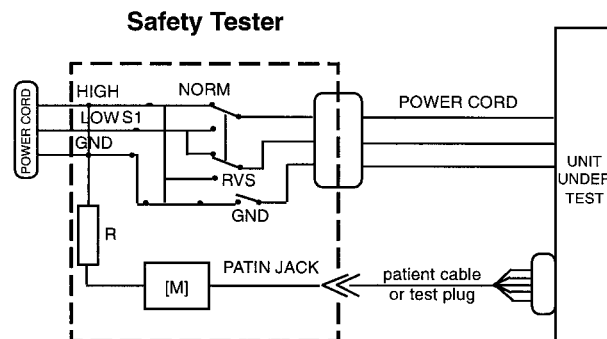


Figure 6-3:

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 (1,5m / 5ft.) if there are not in the condition with IEC 601-1!

All units there are connected to the CardioSoft system (PC / VGA Monitor / Printer / ...) has to be tested as follow.

Connect all power cords from the units sepatartly 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 3500 μ A

Electrical Diagram for Enclosure Leakage Current Test

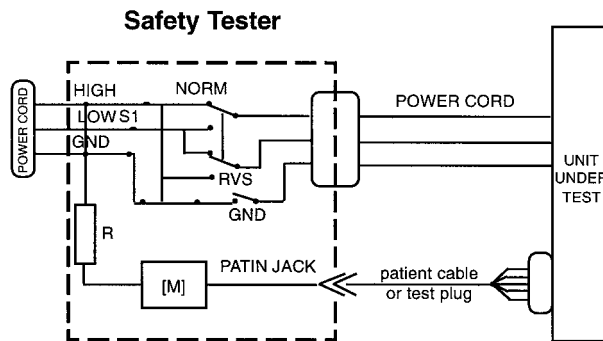


Figure 6-4:

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 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 μ V/LSB @ 500 Hz |
| Noise | < 15 μ V 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 Electro-cardiograph“ |
| Common mode rejection | Measured: 100 dB, calculated: > 140 dB (123 dB with AC filter disabled) |
| Input impedance | > 10 M Ω @ 10 Hz, defibrillator protected |
| Pace detect | Orthogonal LA, LL, and V6; 750 μ V @ 50 μ s, Software corrected |

Table B-2. Physical

| Item | CAM-USB | CAM-14 |
|---------------------|----------|-------------|
| Height | 33 mm | 27 mm |
| Width | 155 mm | 125 mm |
| Depth | 95 mm | 95 mm |
| Weight | 525 g | 181 g |
| Interfaces included | USB V1.1 | Proprietary |

Table B-3. Safety

| Item | Description |
|---|---|
| Certification | <ul style="list-style-type: none"> ■ 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 | <ul style="list-style-type: none"> ■ Use only parts and accessories manufactured or recommended by GE. ■ Follow manufacturer's 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 μ A |
| Degree of protection against electrical shock | Type BF defibrillation protection for the patient cable (acquisition module) |
| Maintenance frequency | <ul style="list-style-type: none"> ■ 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 - Power Requirements

| Item | Description |
|---|---|
| Operating conditions Temperature Humidity Pressure | +10 to +40° C (+50 to 104° F) 30 to 90% RH non-condensing 700 to 1060 hPa |
| Storage/Transport conditions Temperature Humidity Pressure | -30 to +60° C 10 to 90% RH non-condensing 500 to 1060 hPa |

7.2 Description of Conformity of CAM-USB to IEC 60601-1-2, Second Edition

CAM-USB means CAM-USB-Interface Box and CAM-14 Aquisition Module

Changes or modification to this system not expressly approved by GE Medical Systems 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. The equipment is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| RF emissions CISPR11 | Class B | |
| Harmonic Emissions IEC 61000-3-2 | not applicable | |
| Voltage fluctuations/Flicker emissions IEC 61000-3-3 | not applicable | |

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The CAM-USB 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 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% U_t (>95% dip in U_t) for 0.5 cycles 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for 5 s | <5% U_t (>95% dip in U_t) for 0.5 cycles 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for 5 s | Mains power should be that of a typical commercial or hospital environment. If the user of the CAM-USB requires continued operation during power mains interruptions, it is recommended that the CAM-USB 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:

U_t is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CAM-USB 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 is used in such an environment.

| Immunity Test | IEC 60601- test level | Compliance level | Electromagnetic environment – guidance |
|---|---|---|---|
| <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p> | <p>$3 V_{rms}$ 150 kHz to 80 MHz</p> <p>$3 V/m$ 80 MHz to 2,5 GHz</p> | <p>$3 V_{rms}$</p> <p>$3 V/m$</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the CAM-USB, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1, 17 \sqrt{P}$ $d = 1, 17 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2, 33 \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>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.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| <p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p> <p>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 is used exceeds the applicable RF compliance level above, the CAM-USB 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.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> | | | |

Recommended Separation Distances

The table below provides the recommended separation distances (in meters) between portable and mobile RF communication equipment and the CAM-USB.

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

| Rated Maximum Output Power of Transmitter in Watts | Separation Distance in Meters (m) According to Frequency of Transmitter | | |
|--|---|--|---|
| | 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 Medical Systems 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 μ V
- 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 μ V 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 mA, in single-fault condition (e.g. patient in contact with line voltage) < 20 mA
- 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

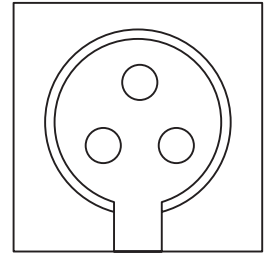
Important: ECG signal output to synchronize ultrasound units (not for diagnostic purposes!)

- lead II standard (configurable with CardioSoft/CardioSys 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, $U_{\max} = \pm 10$ V
- offset accuracy over the entire range < 300 mV (typically, full deflection)
- accuracy over the entire range (typically) < 3%
- RL min 2k Ω
- delay < 10 ms
- pacing pulse filtered out
- unedited 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 FW 7324/2 supplied with the system

The newer PCB version, used in CORINA 101 118 31...36 and 101 118 41...44 you can choose between the FW 7324/2 power supply or the new SW 172 widerange power supply. The default is the FW 7324/2 power supply.

- 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 |
| with pump | 900 g |

7.3.6 Grounding

Grounding of intermediate circuit for interference elimination (to potential equalization system or water pipe)

7.4 Description of Conformity of CORINA to IEC 60601-1-2, Second Edition

Changes or modification to this system not expressly approved by GE Medical Systems 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 establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic Emissions IEC 61000-3-2 | not applicable | |
| Voltage fluctuations/Flicker emissions IEC 61000-3-3 | not applicable | |

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 | $<5\%$ U_t ($>95\%$ dip in U_t) for 0.5 cycles 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles $<5\%$ U_t ($>95\%$ dip in U_t) for 5 s | $<5\%$ U_t ($>95\%$ dip in U_t) for 0.5 cycles 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles $<5\%$ U_t ($>95\%$ dip in U_t) 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:

U_t is the AC mains voltage prior to application of the test level

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 |
|---|---|--|---|
| <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p> | <p>$3 V_{rms}$ 150 kHz to 80 MHz</p> <p>$3 V/m$ 80 MHz to 2,5 GHz</p> | <p>$10 V_{rms}$</p> <p>$3 V/m$</p> | <p>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.</p> <p>Recommended separation distance:</p> $d = 0,35 \sqrt{P}$ $d = 1,17 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,33 \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>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.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| <p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p> <p>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.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.</p> | | | |

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.

| Rated Maximum Output Power of Transmitter in Watts | Separation Distance in Meters (m) According to Frequency of Transmitter | | |
|--|---|---|--|
| | 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 Medical Systems 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.

To order parts, contact Service Parts at the address or telephone number on the, “How to Reach Us...,” page provided at the beginning of this manual.

| Software | |
|-------------|------------------------------|
| Part Number | Item |
| 2006301-011 | Software CD CardioSoft V5.15 |

| Hardware | |
|-------------|-------------------|
| Part Number | Item |
| 2009000-001 | CAM-USB Interface |
| 2001762-007 | System Tonoport V |
| 2014845-001 | System Spirosoft |

| CAM-14 Modules | | |
|----------------|-------------------|---------------|
| Part Number | Item | |
| 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 |
| 700657-002 | Cable coild assy Host AM114 |

8.2 CORINA

| Power Supply | |
|--------------|--|
| Part Number | Item |
| 91920251 | Power Supply Cable 12V |
| 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... 44 only for CORINA up to Rev. F |
| 2024996-001 | CABLE ASSY INTCON CORINA TO PC for CORINA 10111831..38 Rev. G |
| 91541779 | PANEL PLUG |
| 91541780 | PLUG HOUSING |

| Pump | |
|-------------|-----------------------------------|
| Part Number | Item |
| 30344291 | Pump 12 V (Standard) |
| 30344485 | Pump for Corina with Analogoutput |

| CORINA10111831...32 (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 |
| 2024804-004 | Exchange PCB CORINA for CORINA Rev. G |

| CORINA 10111833...38 (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 |
| 2024807-005 | Exchange PCB CORINA ANALOG OUT for CORINA Rev. G |

This table defines the valid configurations of CORINA with CardioSoft V3.04, V4.2, V5.02, V5.11 and V5.15

| Component | | Part No. | (Prod.) | Reference | Compatible(Service) | in Device Variation |
|------------------------------|-----------------------|-----------------|-------------|-----------|-----------------------|----------------------------|
| CORINA | PCB CORINA | | 388 028 39 | K, K1 | E , F , G , H , I , J | 01 ... 05 |
| | Ersatzteil-Nr. | Spare Part No. | - | | | 21; 22 |
| | Austausch Nr. | Replacement No. | 389 003 98 | | | |
| | PCB CORINA | | 388 032 09 | G, G1 | C , D , E , F | 11 ... 14; 17; 18 |
| | Ersatzteil-Nr. | Spare Part No. | - | | | 23; 24 |
| | Austausch Nr. | Replacement No. | 389 004 17 | | | |
| | PCB CORINA | | 2002899-001 | B, B1 | A | 31; 32; 41; 42 |
| | Ersatzteil-Nr. | Spare Part No. | - | | | |
| | Austausch Nr. | Replacement No. | 2002980-001 | | | |
| | PCB CORINA | | 2003219-001 | B, B1 | A | 33; 34; 37; 38 |
| | Austausch Nr. | Replacement No. | 2002981-001 | | | 43; 44 |
| | PCB CORINA | | 388 032 35 | G | B , C , D , E , F | 15 ... 16 |
| | Austausch Nr. | Replacement No. | 389 004 29 | | | |
| | PCB CORINA | | 2024804-001 | A | | 31; 32 |
| | Austausch Nr. | Replacement No. | 2024804-004 | | | |
| | PCB CORINA ANALOG OUT | | 2024807-001 | A | | 33; 34; 37; 38 |
| | Austausch Nr. | Replacement No. | 2024807-005 | | | |
| CardioSoft V3.04 | | | 250 339 13 | | | 01; 02; 05; 11; 12; |
| CardioSoft V3.04 US Version | | | 250 375 11 | | | 17; 18 |
| Software CD CSOFT V4.2 | | | 2006301-001 | | | 01; 02; 05; 11; 12; |
| | | | | | | 31 ... 34 |
| Software CD CSOFT V4.2 US | | | 2006305-001 | | | 17; 18; 37; 38 |
| Software CD CARDIOSOFT V5.02 | | | 2006301-005 | C | | 31 ... 34; 37; 38 |
| Software CD CARDIOSOFT V5.11 | | | 2006301-008 | B | | 31 ... 34; 37; 38 |
| Software CD CARDIOSOFT V5.15 | | | 2006301-011 | A | | 31 ... 34; 37; 38 |
| Lpl. CORINA Trigger | PCB CORINA Trigger | | 388 032 02 | B | A2 | 11 ... 18; 23; 24 |
| | Ersatzteil-Nr. | Spare Part No. | - | | | 33 ... 38; 43; 44 |
| | Austausch Nr. | Replacement No. | 389 004 18 | | | |
| Pumpenmodul: | | | 303 442 91 | | | 2; 4; 22; 32; 42 |
| Pumpenmodul: | | | 303 444 85 | | | 12; 14; 16; 18; 24 |
| | | | | | | 34; 38; 44 |
| Lpl. Pumpe | PCB Pumpe | | 388 029 18 | D | B , C | 2; 4; 12; 14; 16; 18; |
| | Ersatzteil-Nr. | Spare Part No. | - | | | 22; 24; 32; 34; 38; 42; 44 |
| | Austausch Nr. | Replacement No. | - | | | |



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